FEDERAL ENVIRONMENTAL PESTICIDE CONTROL ACT OF 1971

HEARINGS

BEFORE THE

SUBCOMMITTEE ON THE ENVIRONMENT

OF THE

COMMITTEE ON COMMERCE

UNITED STATES SENATE

NINETY-SECOND CONGRESS

SECOND SESSION

ON

H.R. 10729

TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AND FOR OTHER PURPOSES

JUNE 15 AND 19, 1972

Serial No. 92–80

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FEDERAL ENVIRONMENTAL PESTICIDE CONTROL ACT OF 1971

THURSDAY, JUNE 15, 1972

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON THE ENVIRONMENT,
Washington, D.C.

The subcommittee met at 9:40 a.m. in room 1318, New Senate Office Building, Hon. Philip A. Hart (chairman of the subcommittee) presiding.

Present: Senator Hart.

OPENING STATEMENT BY SENATOR HART

Senator HART. The committee will be in order. I apologize for being late, but the moral of the story is that you should not go to the office before you come to a hearing.

On the 7th of this month, our Senate Committee on Agriculture reported H.R. 10729, the Federal Environmental Pesticide Control Act, and it was passed by the House.

Then this bill was referred to the Committee on Commerce. Our hearing this morning will begin an examination by the Subcommittee on the Environment of the bill reported by the Agriculture Committee for the purpose to see if any further changes are needed.

As passed by the House, the proposed legislation contained several weaknesses that Senator Nelson and I hope to remedy by amendments we have introduced.

I am glad that the Agriculture Committee adopted some of the amendments and made some other constructive changes of their own. But a number of the amendments suggested to the committee were not adopted. Our purpose this morning is to seek testimony on these proposals.

(The bill as reported by the Committee on Agriculture and Forestry and agency comments follow:)

Staff members assigned to these hearings: Leonard Bickwit, Jr. and Lee Tyner.

92D CONGRESS
2D SESSION

H. R. 10729

[Report No. 92–838]

IN THE SENATE OF THE UNITED STATES

NOVEMBER 19, 1971

Read twice and referred to the Committee on Agriculture and Forestry

JUNE 7, 1972

Reported by Mr. ALLEN, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

JUNE 7, 1972

Referred to the Committee on Commerce

AN ACT

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Environmental Pesticide Control Act of 1972".

AMENDMENTS TO FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SEC. 2. The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 et seq.) is amended to read as follows:

"SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

"(a) SHORT TITLE.—This Act may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act'.

"(b) TABLE OF CONTENTS.—

"*SEC. 2. DEFINITIONS.*

"*For purposes of this Act—*

"*(a) ACTIVE INGREDIENT.—The term 'active ingredient' means—*

"*(1) in the case of a pesticide other than a plant regulator, defoliant, or desiccant, an ingredient which will prevent, destroy, repel, or mitigate any pest;*

"*(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;*

retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

"(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant; and

"(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue.

"(b) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Environmental Protection Agency.

"(c) ADULTERATED.—The term 'adulterated' applies to any pesticide if:

"(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

"(2) any substance has been substituted wholly or in part for the pesticide; or

"(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

"(d) ANIMAL.—The term 'animal' means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

"(e) CERTIFIED APPLICATOR, ETC.—

"(1) CERTIFIED APPLICATOR.—The term 'certi-

"(2) PRIVATE APPLICATOR.—The term 'private applicator' means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

"(3) COMMERCIAL APPLICATOR.—The term 'commercial applicator' means a certified applicator (whether or not he is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

"(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

"(f) DEFOLIANT.—The term 'defoliant' means any sub-

applicator is not physically present at the time and place the pesticide is applied.

"(f) DEFOLIANT.—The term 'defoliant' means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

"(g) DESICCANT.—The term 'desiccant' means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

"(h) DEVICE.—The term 'device' means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other micro-organism on or in living man or other living animals; but not including equipment used for the application of pesticides when sold separately therefrom).

"(i) DISTRICT COURT.—The term 'district court' means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

"(j) ENVIRONMENT.—The term 'environment' includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

animals and those on or in processed food, beverages, or pharmaceuticals.

"(l) IMMINENT HAZARD.—The term 'imminent hazard' means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in substantial adverse effects on the environment or will involve hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 91–135.

"(m) INERT INGREDIENT.—The term 'inert ingredient' means an ingredient which is not active.

"(n) INGREDIENT STATEMENT.—The term 'ingredient statement' means a statement which contains—

"(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

"(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

"(o) INSECT.—The term 'insect' means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and

merous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

"(p) LABEL AND LABELING.—

"(1) LABEL.—The term 'label' means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

"(2) LABELING.—The term 'labeling' means all labels and all other written, printed, or graphic matter—

"(A) accompanying the pesticide or device at any time; or

"(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health, Education, and Welfare, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

"(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 24(c)(3);

"(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

"(D) its label does not bear the registration number assigned under section 7 to each establishment in which it was produced;

"(E) any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

"(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of this Act, are adequate to protect health and the environment;

"(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of this Act, are adequate to protect health and the environment;

"(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment; or

"(H) when used in accordance with the requirements imposed under this Act or commonly recognized practice, it nevertheless causes unreasonable adverse effects on the environment. In the case of a plant regulator, defoliant, or desiccant used in accordance with its labeling, physical or physiological effects on plants or parts thereof shall not be deemed to be injury when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

"(2) A pesticide is misbranded if—

"(A) the label does not bear an ingredient statement on that part of the immediate container (and

"(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

"(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

"(B) the labeling does not contain a statement of the use classification under which the product is registered;

"(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

"(i) the name and address of the producer, registrant, or person for whom produced;

"(ii) the name, brand, or trademark under which the pesticide is sold;

"(iii) the net weight or measure of the content: Provided, That the Administrator may permit reasonable variations; and

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"(i) the name and address of the producer, registrant, or person for whom produced;

"(ii) the name, brand, or trademark under which the pesticide is sold;

"(iii) the net weight or measure of the content: Provided, That the Administrator may permit reasonable variations; and

"(iv) when required by regulation of the Administrator to effectuate the purposes of this Act, the registration number assigned to the pesticide under this Act, and the use classification; and

"(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this Act—

"(i) the skull and crossbones;

"(ii) the word 'poison' prominently in red on a background of distinctly contrasting color; and

"(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

"(r) NEMATODE.—The term 'nematode' means invertebrate animals of the phylum nemathelminthes and class

"(t) PEST.—The term 'pest' means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 24(c)(1).

"(u) PESTICIDE.—The term 'pesticide' means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

"(v) PLANT REGULATOR.—The term 'plant regulator' means any substance or mixture of substances, intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term 'plant regulator' shall not be required to include at all any of such of those nutriment mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest

tended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term 'plant regulator' shall not be required to include at all any of such of those nutriment mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

"(w) PRODUCER AND PRODUCE.—The term 'producer' means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device. The term 'produce' means to manufacture, prepare, compound, propagate, or process any pesticide or device.

"(x) PROTECT HEALTH AND THE ENVIRONMENT.—The terms 'protect health and environment' and 'protection of health and the environment' mean protection against unreasonable adverse effects on the environment.

"(y) REGISTRANT.—The term 'registrant' means a person who has registered any pesticide pursuant to the provisions of this Act.

"(z) REGISTRATION.—The term 'registration' includes reregistration.

"(aa) STATE.—The term 'State' means a State, the District of Columbia, the Commonwealth of Puerto Rico, the

environment' means any injury to man or any substantial adverse effects on environmental values, taking into account the public interest, including benefits from the use of the pesticide.

"(cc) WEED.—The term 'weed' means any plant which grows where not wanted.

"(dd) ESTABLISHMENT.—The term 'establishment' means any place where a pesticide or device is produced, or held, for distribution or sale.

"SEC. 3. REGISTRATION OF PESTICIDES.

"(a) REQUIREMENT.—Except as otherwise provided by this Act, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator.

"(b) EXEMPTIONS.—A pesticide which is not registered with the Administrator may be transferred if—

"(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

"(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

"(c) PROCEDURE FOR REGISTRATION.—

establishment or for use as a constituent part of another pesticide produced at the second establishment; or

"(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

"(c) PROCEDURE FOR REGISTRATION.—

"(1) STATEMENT REQUIRED.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

"(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

"(B) the name of the pesticide;

"(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

"(D) if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based: Provided, That the Administrator shall require inclusion of all such test data not in his possession as he may need to make the determination provided for by paragraph (5): Provided further, That data submitted in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration

kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information he shall permit sufficient time for applicants to obtain such additional information. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

"(3) TIME FOR ACTING WITH RESPECT TO APPLICATION.—The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of his determination that it does not comply with the provisions of the Act in accordance with paragraph (6).

"(4) NOTICE OF APPLICATION.—The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30

CATION.—The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of his determination that it does not comply with the provisions of the Act in accordance with paragraph (6).

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"(5) APPROVAL OF REGISTRATION.—The Administrator shall register a pesticide if he determines that, when considered with any restrictions imposed under subsection (d)—

"(A) its composition is such as to warrant the proposed claims for it;

"(B) its labeling and other material required to be submitted comply with the requirements of this Act; and

tor refuses to register a pesticide, he shall notify the applicant of his decision and of his reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6.

"(d) CLASSIFICATION OF PESTICIDES.—

"(1) CLASSIFICATION FOR GENERAL USE, RESTRICTED USE, OR BOTH.—

"(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use, provided that if the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, he shall classify it for both general use and restricted use. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses: Provided, however, That the Administrator may re-

"(1) CLASSIFICATION FOR GENERAL USE, RESTRICTED USE, OR BOTH.—

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"(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a commonly recognized practice, will not cause unreasonable

cide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

"(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause substantial adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

"(2) CHANGE IN CLASSIFICATION.—If the Administrator determines that a change in the classification of

cide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

"(2) CHANGE IN CLASSIFICATION.—If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonble adverse effects on the environment, he shall notify the registrant of such pesticide of such determination at least 30 days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 6(b).

"(e) PRODUCTS WITH SAME FORMULATION AND

vided, That as long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act.

"(3) AUTHORITY TO CONSULT OTHER FEDERAL AGENCIES.—In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

"SEC. 4. USE OF RESTRICTED USE PESTICIDES; CERTIFIED APPLICATORS.

"(a) CERTIFICATION PROCEDURE.—

"(1) FEDERAL CERTIFICATION.—Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification.

"(2) STATE CERTIFICATION.—If any State, at any time, desires to certify applicators of pesticides, the Governor of such State shall submit a State plan for such purpose. The Administrator shall approve the plan sub-

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"(2) STATE CERTIFICATION.—If any State, at any time, desires to certify applicators of pesticides, the Governor of such State shall submit a State plan for such purpose. The Administrator shall approve the plan submitted by any State, or any modification thereof, if such plan in his judgment—

"(A) designates a State agency as the agency responsible for administering the plan throughout the State;

"(B) contains satisfactory assurances that such agency has or will have the legal authority and qualified personnel necessary to carry out the plan;

"(C) gives satisfactory assurances that the State

hearing before so doing. If the Administrator approves a plan submitted under this paragraph, then such State shall certify applicators of pesticides with respect to such State. Whenever the Administrator determines that a State is not administering the certification program in accordance with the plan approved under this section, he shall so notify the State and provide for a hearing at the request of the State, and, if appropriate corrective action is not taken within a reasonable time, not to exceed ninety days, the Administrator shall withdraw approval of such plan.

"SEC. 5. EXPERIMENTAL USE PERMITS.

"(a) ISSUANCE.—Any person may apply to the Administrator for an experimental use permit for a pesticide. The Administrator may issue an experimental use permit if he determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide under section 3. An application for an experimental use permit may be filed at the time of or before or after an application for registration is filed.

"(b) TEMPORARY TOLERANCE LEVEL.—If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, he may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit.

"(c) USE UNDER PERMIT.—Use of a pesticide under

within a reasonable time, not to exceed ninety days, the Administrator shall withdraw approval of such plan.

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"(c) USE UNDER PERMIT.—Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the permit.

"(d) STUDIES.—When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously

"SEC. 6. ADMINISTRATIVE REVIEW; SUSPENSION.

"(a) CANCELLATION AFTER FIVE YEARS.—

"(1) PROCEDURE.—The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five-year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect: Provided, That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this Act and will not have substantial adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.

"(2) INFORMATION.—If at any time after the registration of a pesticide the registrant has additional

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currence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect: Provided, That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.

"(2) INFORMATION.—If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.

"(b) CANCELLATION AND CHANGE IN CLASSIFICATION.—If it does not appear to the Administrator that a pesticide or its labeling or other material required to be submitted

"(c) SUSPENSION.—

"(1) ORDER.—If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, he may, by order, suspend the registration of the pesticide immediately. No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide.

"Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of 'imminent hazard'. The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Agency on the question of whether an imminent hazard exists.

"(2) EXPEDITE HEARING.—If no request for a hearing is submitted to the Agency within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless

registration of the pesticide immediately. No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide.

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"(2) EXPEDITE HEARING.—If no request for a hearing is submitted to the Agency within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Agency agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of title 5 of the United States Code, except that the presiding officer need not be a certified hearing examiner. The pre-

withstanding the fact that any related cancellation proceedings have not been completed. Petitions to review orders on the issue of suspenion shall be advanced on the docket of the courts of appeals. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending hearing before the Administrator. This action may be maintained simultaneously with any administrative review proceeding under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

"(d) PUBLIC HEARINGS AND SCIENTIFIC REVIEW.—In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the

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"(d) PUBLIC HEARINGS AND SCIENTIFIC REVIEW.—In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue

review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this Act. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before him and issue an order either revoking his notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

"(e) JUDICIAL REVIEW.—Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 15.

"SEC. 7. REGISTRATION OF ESTABLISHMENTS.

"(a) REQUIREMENT.—No person shall produce any pesticide subject to this Act in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

"(b) REGISTRATION.—Whenever the Administrator re-

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"SEC. 8. BOOKS AND RECORDS.

"(a) REQUIREMENT.—The Administrator may prescribe regulations requiring producers to maintain such records with respect to their operations and the pesticides and devices produced as he determines are necessary for the effective enforcement of this Act. No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

"(b) INSPECTION.—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to

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shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

"(b) WARRANTS.—For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

"(1) entry for the purpose of this section;

"(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide), or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information re-

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the Administrator determines that such action will be sufficient to effectuate the purposes of this Act.

"(2) NOTICE NOT REQUIRED.—The notice of contemplated proceedings and opportunity to present views set forth in this subsection are not prerequisites to the institution of any proceeding by the Attorney General.

"(3) WARNING NOTICES.—Nothing in this Act shall be construed as requiring the Administrator to institute proceedings for prosecution of minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

"SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

"(a) IN GENERAL.—In submitting data required by this Act, the applicant may (1) clearly mark any portions thereof which in his opinion are trade secrets or commercial or financial information, and (2) submit such market material separately from other material required to be submitted under this Act.

"(b) DISCLOSURE.—Notwithstanding any other provision of this Act, the Administrator shall not make public information which contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary

the Administrator determines that such action will be sufficient to effectuate the purposes of this Act.

"(2) NOTICE NOT REQUIRED.—The notice of contemplated proceedings and opportunity to present views set forth in this subsection are not prerequisites to the institution of any proceeding by the Attorney General.

"(3) WARNING NOTICES.—Nothing in this Act shall be construed as requiring the Administrator to institute proceedings for prosecution of minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

"SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

"(a) IN GENERAL.—Copies of any written communication, document, report, or other information pertaining to the functions of the Administrator under this Act received by the Administrator from any person or sent by the Administrator to any person shall be made available to the public upon identifiable request, and at reasonable cost if required by the Freedom of Information Act or if not so required, subject to such conditions as the Administrator determines by regulation will not unreasonably interfere with the administration of this Act, unless such information may not be publicly released under the terms of subsection (b) or (c) of

"(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3;

"(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 3;

"(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 24(c)(5);

"(E) any pesticide which is adulterated or misbranded; or

"(F) any device which is misbranded.

"(2) It shall be unlawful for any person—

"(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this Act;

"(B) to refuse to keep any records required pursuant to section 8, or to refuse to allow the inspection of any records or establishment pursuant to section 8 or 9, or to refuse to allow an officer or employee of the Environmental Protection Agency

ations with respect to the data earlier received, that the pesticide does not meet the requirements of section 3(c)(5) and within said 30 day period notifies the applicant for registration of his determination and of his reasons (including the factual basis therefor) pursuant to section 3(c)(6). The reasons and factual basis shall include a statement of the new evidence or new evaluations which have prompted his determination.

After the notice to the applicant of his decision to register has been sent in writing and received by the applicant and published in the Federal Register, the Administrator shall make available to the public all data except that which is not subject to disclosure under subsection (c). The Administrator shall, by regulation, designate those minor registration actions, such as renewals or minor additions to present label uses, which shall become effective immediately without a 30-day waiting period on notification to the applicant.

"(c) DISCLOSURE.—

"(1) The Administrator or any officer or employee of the Environmental Protection Agency or any committee referred to in subsection (d) of section 6 of this Act shall not disclose any information which constitutes a trade secret, any financial information which is privileged or confidential, or any commercial information the disclosure of which may give a competitor a

giving the classification of the product assigned to it under section 3;

"(F) to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 3(d) and any regulations thereunder;

"(G) to use any registered pesticide in a manner inconsistent with its labeling;

"(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

"(I) to violate any order issued under section 13;

"(J) to violate any suspension order issued under section 6;

"(K) to violate any cancellation of registration of a pesticide under section 6, except as provided by section 6(a)(1);

"(L) who is a producer to violate any of the provisions of section 7;

"(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 7, any records

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the owner of such data as to who received it and any person receiving such data shall be liable for its disclosure.

"(2) Nothing contained in this section shall be deemed to require the release of any information described by subsection (b) of section 552 of title 5, United States Code, or which is otherwise protected by law from disclosure to the public.

"(d) DISPUTES.—If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (c)(1), he shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until 30 days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection under subsection (c)(1).

"SEC. 11. STANDARDS APPLICABLE TO PESTICIDE APPLICATORS.

"(a) IN GENERAL.—No regulations prescribed by the Administrator for carrying out the provisions of this Act shall require any private applicator to maintain any records or file any reports or other documents.

porting, delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

"(3) any public official while engaged in the performance of his official duties;

"(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

"(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

"SEC. 13. STOP SALE, USE, REMOVAL AND SEIZURE.

"(a) STOP SALE, ETC., ORDERS.—Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this Act, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide

"(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 25(c)(5);

"(E) any pesticide which is adulterated or misbranded; or

"(F) any device which is misbranded.

"(2) It shall be unlawful for any person—

"(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this Act;

"(B) to refuse to keep any records required pursuant to section 8, or to refuse to allow the inspection of any records or establishment pursuant to section 8 or 9, or to refuse to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to section 9;

"(C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which guaranty shall contain, in addition to his own name and address, the name and address of the person

the representations made in connection with its registration;

"(2) in the case of a device, it is misbranded; or

"(3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this Act and as directed by the labeling, it nevertheless causes substantial adverse effects on the environment. In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

"(c) DISPOSITION AFTER CONDEMNATION.—If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this Act or the laws of the jurisdiction in which it is sold: Provided, That upon payment of the costs of the condemnation proceedings and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions

experimental use permit contrary to the provisions of such permit;

"(I) to violate any order issued under section 13;

"(J) to violate any suspension order issued under section 6;

"(K) to violate any cancellation of registration of a pesticide under section 6, except as provided by section 6(a)(1);

"(L) who is a producer to violate any of the provisions of section 7;

"(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 7, any records required to be maintained pursuant to section 8, any report filed under this Act, or any information marked as confidential and submitted to the Administrator under any provision of this Act;

"(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this Act;

"(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this Act;

a civil penalty by the Administrator of not more than $1,000 for each offense.

"(3) HEARING.—No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged. In determining the amount of the penalty the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation.

"(4) REFERENCES TO ATTORNEY GENERAL.—In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

"(b) CRIMINAL PENALTIES.—

"(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than $25,000, or imprisoned for not more than one year, or both.

device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

"(3) any public official while engaged in the performance of his official duties;

"(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

"(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

"SEC. 13. STOP SALE, USE, REMOVAL AND SEIZURE

"(a) STOP SALE, ETC., ORDERS.—Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this Act, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the

Agency discretion by law are judicially reviewable in the districts courts.

"(b) REVIEW BY COURT OF APPEALS.—In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in

"(2) in the case of a device, it is misbranded; or

"(3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this Act and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment. In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

"(c) DISPOSITION AFTER CONDEMNATION.—If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this Act or the laws of the jurisdiction in which it is sold: Provided, That upon payment of the costs of the condemnation proceedings and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation

notice of cancellation of a registration of a pesticide to the governments of other countries and to appropriate international agencies.

"(c) IMPORTATION OF PESTICIDES AND DEVICES.—The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon his request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this Act, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: Provided, That the Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for

unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged. In determining the amount of the penalty the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation.

"(4) REFERENCES TO ATTORNEY GENERAL.—In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

"(b) CRIMINAL PENALTIES.—

"(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than $25,000, or imprisoned for not more than one year, or both.

"(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this Act shall

procedures and regulations for the disposal or storage of packages and containers of pesticides and for disposal or storage of excess amounts of such pesticides, and accept at convenient locations for safe disposal a pesticide the registration of which is canceled under section 6(c) if requested by the owner of the pesticide.

"(b) ADVICE TO SECRETARY OF TRANSPORTATION.—The Administrator shall provide advice and assistance to the Secretary of Transportation with respect to his functions relating to the transportation of hazardous materials under the Department of Transportation Act (49 U.S.C. 1657), the Transportation of Explosives Act (18 U.S.C. 831–835), the Federal Aviation Act of 1958 (49 U.S.C. 1421–1430, 1472 H), and the Hazardous Cargo Act (46 U.S.C. 170, 375, 416).

"SEC. 19. RESEARCH AND MONITORING.

"(a) RESEARCH.—The Administrator shall undertake research, including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this Act, and he shall give priority to research to develop biologically integrated alternatives for pest control. The Administrator shall also take care to insure that such research does not duplicate research being undertaken by any other Federal agency.

"(b) NATIONAL MONITORING PLAN.—The Administrator shall formulate and periodically revise, in cooperation

actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, op-

Environmental Protection Agency as the Administrator may designate for the purpose.

"(b) COOPERATION.—The Administrator shall cooperate with the Department of Agriculture, any other Federal agency, and any appropriate agency of any State or any political subdivision thereof, in carrying out the provisions of this Act, and in securing uniformity of regulations.

"SEC. 22. STATE COOPERATION, AID, AND TRAINING.

"(a) COOPERATIVE AGREEMENTS.—The Administrator is authorized to enter into cooperative agreements with States—

"(1) to delegate to any State the authority to cooperate in the enforcement of the Act through the use of its personnel or facilities, to train personnel of the State to cooperate in the enforcement of this Act, and to assist States in implementing cooperative enforcement programs through grants-in-aid; and

"(2) to assist State agencies in developing and administering State programs for training and certification of applicators consistent with the standards which he prescribes.

"(b) CONTRACTS FOR TRAINING.—In addition, the Administrator is authorized to enter into contracts with Federal or State agencies for the purpose of encouraging the training of certified applicators.

to the amount in controversy, over suits brought under this section.

"(b) No civil action may be commenced under this section prior to 60 days after the plaintiff has given notice of such action to the Administrator. Notice shall be given in such manner as the Administrator shall prescribe by regulation.

"(c) In any action under this section, the Attorney General, if not a party, may intervene as a matter of right.

"(d) Nothing in this section shall restrict any right which any person (or class of persons) may have under any other statute or under common law to seek enforcement of any regulation or order or to seek any other relief.

"(e) For purposes of this section, the term 'person' means an individual, corporation, partnership, association, State, municipality, or political subdivision of a State or any agency of the Federal Government.

"SEC. 17. IMPORTS AND EXPORTS.

"(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—Notwithstanding any other provision of this Act, no pesticide or device shall be deemed in violation of this Act when intended solely for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser, except that (1) producers of such pesticides and devices shall be subject to section 8 of this

Such regulations shall take into account the difference in concept and usage between various classes of pesticides.

"(b) EXEMPTION OF PESTICIDES.—The Administrator may exempt from the requirements of this Act by regulation any pesticide which he determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act.

"(c) OTHER AUTHORITY.—The Administrator, after notice and opportunity for hearing, is authorized—

"(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;

"(2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;

"(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91-601)) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated

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teristics and shall differentiate among uses of such pesticides and/or geographical areas to which the export of such pesticides is likely to result in adverse effects on the environment of the United States. After the effective date of such regulations, any person who exports any pesticide with knowledge or reason to know that it will be used for a use or in a geographical area covered by such regulations shall submit to the Administrator a statement which complies with paragraphs (A), (B), (D), and (E) of section 3(c)(1) and which includes a description of the uses and directions for use for such pesticide of which such person is aware or has reason to be aware and may petition for a certificate approving export of that product. The Administrator shall have 30 days to grant or deny the petition and any denial shall be appealable under the terms of section 6.

"(c) CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS.—Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies.

"(d) IMPORTATION OF PESTICIDES AND DEVICES.—The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to

to be appropriated for any fiscal year ending after June 30, 1975, shall be the sums hereafter provided by law. The expenses of the Federal Government in carrying out the provisions of this Act shall be paid solely out of funds so appropriated, and no fee other than reasonable fees for registration of pesticides under section 3 shall be required to be paid to the Federal Government in connection with any activity under this Act."

AMENDMENTS TO OTHER ACTS

SEC. 3. The following Acts are amended by striking out the terms "economic poisons" and "an economic poison" wherever they appear and inserting in lieu thereof "pesticides" and "a pesticide" respectively:

(1) The Federal Hazardous Substances Act, as amended (15 U.S.C. 1261 et seq.);

(2) The Poison Prevention Packaging Act, as amended (15 U.S.C. 1471 et seq.); and

(3) The Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

EFFECTIVE DATES OF PROVISIONS OF ACT

SEC. 4. (a) Except as otherwise provided in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, and as otherwise provided by this section, the amendments made by this Act shall take effect at the close of the date of the enactment of this Act, provided if regu-

by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

"(e) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

"(f) REGULATIONS.—The Secretary of the Treasury, in consultation with the Administrator, shall prescribe regulations for the enforcement of subsection (d) of this section.

"(g) QUALITY CONTROL SCREENING OF IMPORTED AGRICULTURAL COMMODITIES.—

"(1) In order to more effectively carry out the provisions of the Federal Food, Drug, and Cosmetic Act to protect consumers in the United States from the dangers of pesticide residues in or on imported agricultural commodities, the Secretary of Health, Education, and Welfare and the Secretary of Agriculture shall initiate and carry out an intensive quality control screening system to detect and quantify pesticide residues in and on imported agricultural commodities for which they are respectively responsible for sampling or otherwise monitoring. Such system shall include, but shall not be limited to, screening at ports of entry into the United States.

use only by a certified applicator shall not be effective until four years from the date of enactment of this Act.

(4) A period of four years from date of enactment shall be provided for certification of applicators.

(A) One year after the enactment of this Act the Administrator shall have prescribed the standards for the certification of applicators.

(B) Within three years after the enactment of this Act each State desiring to certify applicators shall submit a State plan to the Administrator for the purpose provided by section 4(b).

(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.

(5) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.

(d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days

enactment of this Act the Secretary of Health, Education, and Welfare and the Secretary of Agriculture shall jointly promulgate regulations prescribing the intensive quality control screening system to be carried out under this subsection to detect the levels of pesticide residues in or on imported agricultural commodities.

"SEC. 18. EXEMPTION OF FEDERAL AGENCIES.

"The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that such exemption would be consistent with the purposes of this Act and would be in the public interest.

"SEC. 19. DISPOSAL AND TRANSPORTATION.

"(a) PROCEDURES.—The Administrator shall, after consultation with other interested Federal agencies, establish procedures and regulations for the disposal or storage of packages and containers of pesticides and for disposal or storage of excess amounts of such pesticides, and accept at convenient locations for safe disposal a pesticide the registration of which is canceled under section 6(c) if requested by the owner of the pesticide.

"(b) ADVICE TO SECRETARY OF TRANSPORTATION.—The Administrator shall provide advice and assistance to the Secretary of Transportation with respect to his functions relating to the transportation of hazardous materials

under the Department of Transportation Act (49 U.S.C. 1657), the Transportation of Explosives Act (18 U.S.C. 831–835), the Federal Aviation Act of 1958 (49 U.S.C. 1421–1430, 1472 H), and the Hazardous Cargo Act (46 U.S.C. 170, 375, 416).

"SEC. 20. RESEARCH AND MONITORING.

"(a) RESEARCH.—The Administrator shall undertake research, including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this Act, and he shall give priority to research to develop biologically integrated alternatives for pest control. The Administrator shall also take care to insure that such research does not duplicate research being undertaken by any other Federal agency.

"(b) NATIONAL MONITORING PLAN.—The Administrator shall formulate and periodically revise, in cooperation with other Federal, State, or local agencies, a national plan for monitoring pesticides.

"(c) MONITORING.—The Administrator shall undertake such monitoring activities, including but not limited to monitoring in air, soil, water, man, plants, and animals, as may be necessary for the implementation of this Act and of the national pesticide monitoring plan. Such activities shall be carried out in cooperation with other Federal, State, and local agencies.

"SEC. 21. SOLICITATION OF COMMENTS.

"(a) The Administrator, before publishing regulations under this Act, shall solicit the views of the Secretary of Agriculture.

"(b) In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this Act, the Administrator may, at his discretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as he deems proper.

"SEC. 22. DELEGATION AND COOPERATION.

"(a) DELEGATION.—All authority vested in the Administrator by virtue of the provisions of this Act may with like force and effect be executed by such employees of the Environmental Protection Agency as the Administrator may designate for the purpose.

"(b) COOPERATION.—The Administrator shall cooperate with the Department of Agriculture, any other Federal agency, and any appropriate agency of any State or any political subdivision thereof, in carrying out the provisions of this Act, and in securing uniformity of regulations.

"SEC. 23. STATE COOPERATION, AID, AND TRAINING.

"(a) COOPERATIVE AGREEMENTS.—The Administra-

tor is authorized to enter into cooperative agreements with States—

"(1) to delegate to any State the authority to cooperate in the enforcement of the Act through the use of its personnel or facilities, to train personnel of the State to cooperate in the enforcement of this Act, and to assist States in implementing cooperative enforcement programs through grants-in-aid; and

"(2) to assist State agencies in developing and administering State programs for training and certification of applicators consistent with the standards which he prescribes.

"(b) CONTRACTS FOR TRAINING.—In addition, the Administrator is authorized to enter into contracts with Federal or State agencies for the purpose of encouraging the training of certified applicators.

"(c) The Administrator may utilize the services of the Cooperative State Extension Services for informing farmers of accepted uses and other regulations made pursuant to this Act.

"SEC. 24. AUTHORITY OF STATES.

"(a) A State may regulate the sale or use of any pesticide or device in the State but only if and to the extent the regulation does not permit any sale or use prohibited by this Act;

"(b) Such State shall not impose or continue in effect any requirements for labeling and packaging in addition to or different from those required pursuant to this Act; and

"(c) A State may provide registration for pesticides formulated for distribution and use within that State to meet special local needs if that State is certified by the Administrator as capable of exercising adequate controls to assure that such registration will be in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize distribution and use only within such State and shall not be effective for more than 90 days if disapproved by the Administrator within that period.

"SEC. 25. AUTHORITY OF ADMINISTRATOR.

"(a) REGULATIONS.—The Administrator is authorized to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides.

"(b) EXEMPTION OF PESTICIDES.—The Administrator may exempt from the requirements of this Act by regulation any pesticide which he determines either (1) to be adequately regulated by another Federal agency, or (2) to be

of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act.

"(c) OTHER AUTHORITY.—The Administrator, after notice and opportunity for hearing, is authorized—

"(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;

"(2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;

"(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91-601)) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this Act;

"(4) to specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) or section 7 of this Act upon his determination that appli-

cation of such provision is necessary to effectuate the purposes of this Act;

"(5) to prescribe regulations requiring any pesticide to be colored or discolored if he determines that such requirement is feasible and is necessary for the protection of health and the environment; and

"(6) to determine and establish suitable names to be used in the ingredient statement.

"SEC. 26. SEVERABILITY.

"If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this Act which can be given effect without regard to the invalid provision or application, and to this end the provisions of this Act are severable.

"SEC. 27. AUTHORIZATION FOR APPROPRIATIONS.

"There is authorized to be appropriated to carry out the provisions of this Act not to exceed $40,000,000 for the fiscal year ending June 30, 1973, not to exceed $52,000,000 for the fiscal year ending June 30, 1974, and not to exceed $64,000,000 for the fiscal year ending June 30, 1975. The amounts authorized to be appropriated for any fiscal year ending after June 30, 1975, shall be the sums hereafter provided by law. The expenses of the Federal Government in carrying out the provisions of this Act shall be paid solely out of funds

so appropriated, and no fee other than reasonable fees for registration of pesticides under section 3 shall be required to be paid to the Federal Government in connection with any activity under this Act."

AMENDMENTS TO OTHER ACTS

SEC. 3. The following Acts are amended by striking out the terms "economic poisons" and "an economic poison" wherever they appear and inserting in lieu thereof "pesticides" and "a pesticide" respectively:

(1) The Federal Hazardous Substances Act, as amended (15 U.S.C. 1261 et seq.);

(2) The Poison Prevention Packaging Act, as amended (15 U.S.C. 1471 et seq.); and

(3) The Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

EFFECTIVE DATES OF PROVISIONS OF ACT

SEC. 4. (a) Except as otherwise provided in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, and as otherwise provided by this section, the amendments made by this Act shall take effect at the close of the date of the enactment of this Act, provided if regulations are necessary for the implementation of any provision that becomes effective on the date of enactment, such regulations shall be promulgated and shall become effective within 90 days from the date of enactment of this Act.

(b) The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act and the regulations thereunder as such existed prior to the enactment of this Act shall remain in effect until superseded by the amendments made by this Act and regulations thereunder: Provided, That all provisions made by these amendments and all regulations thereunder shall be effective within four years after the enactment of this Act.

(c)(1) Two years after the enactment of this Act the Administrator shall have promulgated regulations providing for the registration and classification of pesticides under the provisions of this Act and thereafter shall register all new applications under such provisions.

(2) After two years but within four years after the enactment of this Act the Administrator shall register and reclassify pesticides registered under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act prior to the effective date of the regulations promulgated under subsection (c)(1).

(3) Any requirements that a pesticide be registered for use only by a certified applicator shall not be effective until four years from the date of enactment of this Act.

(4) A period of four years from date of enactment shall be provided for certification of applicators.

(A) One year after the enactment of this Act the

Administrator shall have prescribed the standards for the certification of applicators.

(B) Within three years after the enactment of this Act each State desiring to certify applicators shall submit a State plan to the Administrator for the purpose provided by section 4(b).

(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.

(5) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.

(d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days after the Administrator has published effective regulations in the Federal Register and taken such other action as may be necessary to permit compliance with the provisions under which the penalty is to be imposed.

(e) For purposes of determining any criminal or civil

penalty or liability to any third person in respect of any act or omission occurring before the expiration of the periods referred to in this section, the Federal Insecticide, Fungicide, and Rodenticide Act shall be treated as continuing in effect as if this Act had not been enacted.

Passed the House of Representatives November 9, 1971.

Attest: W. PAT JENNINGS,
Clerk.

Passed the Senate with an amendment September 26, 1972.

Attest: FRANCIS R. VALEO,
Secretary.

THE GENERAL COUNSEL OF THE TREASURY,
Washington, D.C., June 27, 1972.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: The proposed "Federal Environmental Pesticide Control Act of 1971", H.R. 10729, has recently come to our attention. Since enactment of the bill would necessitate some action by this Department, we would like to offer our views on it.

The bill would amend the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 *et seq.*), by expanding the comprehensive program for the control and use of pesticides, including Federal and State cooperation.

Section 2(aa) defines the term "State" as "a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa." This would extend the coverage of the Act to a geographical area greater than that comprising the Customs territory of the United States (the States, the District of Columbia and the Commonwealth of Puerto Rico). Therefore, we recommend that subsection 16(c) be amended to define "State" for the purposes of that subsection to include the States, the District of Columbia, and the Commonwealth of Puerto Rico.

Section 16(c), like the existing law (7 U.S.C. 135h), provides that the Secretary of the Treasury shall notify the Administrator of the Environmental Protection Agency of the arrival of pesticides and devices, and deliver samples to the Administrator, upon his request. Because acute dermal or inhalation toxicity of many of those substances may be hazardous to the persons handling them, we would expect to make regulations under the authority of section 16(e) to insure the safety of Customs officers taking samples.

Section 16(c) would also provide that the Secretary of the Treasury may deliver a pesticide or device in violation of the provisions of the Act to the consignee pending examination and decision, on execution of a bond for the full amount of the invoice value plus duty. On refusal to return the pesticide or device to the custody of the Secretary of the Treasury, when demanded, the consignee shall forfeit the full amount of the bond. As worded, this provision would allow for no reduction of the claim for liquidated damages, such as presently provided for in section 1623(c), Tariff Act of 1930, under which the Secretary of the Treasury may cancel any charge against a bond upon payment of a lesser amount.

As primary administrative and enforcement responsibility properly is to be exercised under the bill by the Administrator, Environmental Protection Agency, it is suggested that section 16(e) be changed to read:

"(e) Regulations.—The Administrator shall prescribe regulations for the enforcement of this section, and the Secretary of the Treasury, in consultation with the Administrator, shall prescribe conforming regulations for Customs enforecment and sampling procedures at ports of entry."

Since the Bureau of Customs does not have the expertise to determine if a pesticide or device complies with the requirements of the Environmental Protection Agency, you may wish to consider inclusion of a provision similar to the following:

"Every person importing a pesticide or device into the United States shall furnish Customs at the port of entry a certificate of compliance in the form prescribed by the Administrator, certifying that such pesticide or device conforms to all Federal requirements prescribed under this Act, or that nonconforming articles will be brought into compliance under procedures prescribed in regulations of the Administrator."

The Department defers to the Environmental Protection Agency, which has primary administrative and enforcment responsibilities, on the merits of the bill. The Department does not anticipate any unusual difficulties in carrying out at ports of entry its supporting enforceent responsibilities.

The Department has been advised by the Office of Management and Budget that there is no objection from the standpoint of the Administration's program to the submission of this report to your Committee.

Sincerely yours,

SAMUEL R. PIERCE, Jr.,
General Counsel.

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Senator HART. Our first witness, and we welcome her, is Mrs. Valerie Kantor of Migrant Legal Action, and also Mr. A. V. Krebs, Agribusiness Accountability Project, who is accompanied by Mr. Jerry Berman, legal counsel.

STATEMENT OF A. V. KREBS, AGRIBUSINESS ACCOUNTABILITY PROJECT, WASHINGTON, D.C.; ACCOMPANIED BY VALERIE KANTOR, MIGRANT LEGAL ACTION, WASHINGTON, D.C.; AND JERRY BERMAN, LEGAL COUNSEL

Mr. KREBS. Mr. Chairman, the Agribusiness Accountability Project appreciates the opportunity to present testimony today on legislation concerning the amending of the Federal Environmental Pesticide Control Act of 1972.

My name is A. V. Krebs, corporate research associate for the Agribusiness Accountability Project. With me today is Jerry Berman, legal counsel to the Project. The Agribusiness Accountability Project is an independent, nonpartisan, nonprofit organization funded by the field foundation and sponsored by the Center for Community Change and the Project on Corporate Responsibility.

Created in 1970, it is based here in Washington, D.C., and is engaged in public interest research, advocacy and education on the issues of corporate involvement in rural America.

Mr. Chairman, once again the physical well-being and lives of the thousands of men, women, and children who grow and harvest the crops of the world's most abundant Nation are being deliberately ignored by laws which will affect them most intimately.

Nowhere in the Federal Environmental Pesticide Control Act of 1972 do we find any mention of the farmworker.

And to say, as one person who has worked extensively on this act told our project, that it is designed to provide for the protection of man and his environment and therefore, by inference, the farmworker, is being both naive and ignorant to the inhuman way American farmworkers have historically been treated by so-called protective Federal legislation.

Is it no wonder they have become cynical and bitter when it comes to promises by our leaders in the White House and Congress of "equal justice under law?"

But, Mr. Chairman, what the AAP finds most appalling in the legislative history of the act is the unfeeling and negligent manner in which the Environmental Protection Agency has conducted itself in supposedly assisting the House and Senate in drafting this act.

The Agency's complete and deliberate silence before the Congress of the United States when it came to recommendations and provisions which would substantially protect the health of farmworkers in an economic-poisoned environment is a scandal of national import.

How can we expect lawmakers to pass legislation which will benefit all our people if publicly established divisions of the Government like EPA go willfully about suppressing vital information?

Disregarding their own studies which have shown both the short- and long-term harmful effects on farmworkers from economic poisons, even when the label recommendations are explicitly followed; ignoring the need for even more stringent controls on the application and

increasing use of these poisons; shunting the necessity for rigid standards covering human experimentation involving economic poisons; and denying the fact that they need laws, not merely recommendations, to administer this act, EPA has acted shamefully, jeopardizing the health of America's some 2.6 million farmworkers.

Throughout the country EPA has today some 15 offices of the community studies pesticides project. Their objective is "to collect and evaluate information aimed at finding whether and how exposure to pesticides, as experienced in an occupation or in the environment, is affecting the health of Americans."

Each year these offices file a report with the division of pesticide community studies in Chamblee, Ga. Our project after reviewing the 1970 and 1971 California reports, which we obtained independently of EPA, sought similar reports from the other States.

We were told by letter, however, that the division was unable to send copies of these reports to us. We did receive a selected reading list of papers available through EPA, many of which were obviously drawn from these past yearly reports.

It is from the California reports and these individual papers that we have learned how the EPA has so utterly failed in its responsibilities in presenting the necessary information which would enable this Congress to enact a "pesticide control" bill worthy of its title.

Let us take one of the key terms of the bill and see how it is defined. We refer to "substantial adverse effects on the environment." Section 2(bb) says:

> The term "substantial adverse effects on the environment" means any injury to man or any substantial adverse effects on environmental values, taking into account the public interest, including benefits from the use of pesticide.

The key word here, as we interpret it, is "substantial," but nowhere is substantial defined in the act. It is left for the EPA and the administrator to give it meaning. While Mr. Ruckelshaus might define that word one way, his successor might choose to give it a different interpretation. We are a Nation that is supposed to be guided by laws, not men. The act itself should make clear the definition of "substantial."

The EPA's handling of a case in California makes it imperative that a precise definition of the word "substantial" be made part of this act.

Before Sentator James Allen's Subcommittee on Agriculture and General Research [1] the AAP presented testimony concerning a shocking story of how two major U.S. chemical companies performed economic poison experiments in 1970 in California using farmworkers as "human guinea pigs."

I would like to say, however, in light of the recommendations made by the California Department of Public Health in emergency regulations passed by the State of California Department of Agriculture, EPA turned its back on these recommendations and followed what the chemical companies maintained were the substantial safe reentry times, ignoring, as I say, their own reports.

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[1] See p. 317 on hearings before the U.S. Senate, Subcommittee on Agricultural Research and General Legislation of the Committee on Agriculture and Forestry, pt. II, Mar. 7 and 8, 1972.

After several cases of farmworkers poisonings had been reported in California citrus orchards in 1970, that State's Department of Agriculture imposed an emergency 30-day reentry ban on the two pesticides, ethion and Guthion, suspected of causing the poisonings.

Subsequently the two companies performed tests, which we described in our testimony before Senator Allen, in an effort to prove their labels recommending "zero days" reentry for ethion and "7 days" reentry time for Guthion were safe. The companies claimed after completing their tests that no worker's health was impaired.

An analysis, however, of these tests by the Community Studies on Pesticides Division of the California Public Health Department showed that workers participating in these experiments had their plasma and red blood cells cholinesterase levels "depressed by absolute amounts or proportions and which by accepted medical standards represented a potential hazard to their health" and that "they should have been removed immediately from the fields."

This complete analysis was sent to Chamblee, Ga., in December 1970. On February 11, 1971, the day following AAP's public disclosure of these tests, the California Department of Agriculture held hearings on why the emergency 30-day worker reentry ban for citrus should not be made permanent.

On May 14, 1971, the Department issued an order adopting and repealing regulations of the California Department of Agriculture pertaining to economic poisons and injurious materials. In setting down worker safety time intervals for a variety of different economic poisons that are used in citrus, grapes, peaches, and nectarines, the order specified 30-day reentry intervals for ethion and Guthion when applied to citrus. The order noted that the regulations "become effective on June 15, 1971."

In issuing their periodic "summary of registered agricultural pesticide chemical uses" the EPA subsequently choose to ignore California's order. Their latest summary for ethion, first issued on May 31, 1969, recommends "no time limitations" when used in citrus.

The Guthion summary has been updated by the EPA—from an old U.S. Department of Agriculture summary. It is dated January 21, 1972, a full year after the community studies report and 7 months after the California regulation went into effect. This updated regulation for citrus, however, still states, "a single application per year may be applied up to within 7 days of picking."

In both cases EPA elected to dismiss the expert medical evidence provided under contract by one of its own divisions and follow what the chemical industry had defined as a "substantial" safe worker reentry period.

You can see here, Mr. Chairman, why the AAP is concerned that the word "substantial" be defined by law and not arbitrarily be left up to the EPA.

Another point. The manner in which the California tests were conducted we feel should have motivated the EPA to recommend that carefully prescribed guidelines for human experimentation where economic poisons are used be set down by law.

When the AAP and the migrant legal action program petitioned the EPA in February 1971, for an emergency suspension of registration of all economic poisons for use in experiments and tests involving human subjects, John R. Quarles, Jr., Assistant Administrator for

Standards and Enforcement and General Counsel, replied that there was nothing in the Federal Insecticide, Fungicide and Rodenticide Act, calling for "human data or human experiments" to support the registration of an economic poison and that therefore there was no such registrations to suspend.

Contrast that reply with the remarks made by Dr. Raymond E. Johnson formerly of the EPA's Pesticide Office, after the AAP's disclosures appeared in the press. He said that to his knowledge "there are no restrictions that I know of" to prevent such experimentation, except those of decency and morality. "It's a serious thing. It's extremely difficult to solve this problem, because regardless of the use of restrictions we are still unable to regulate human behavior."

Dr. Johnson went on to say that his office had "seen this problem shaping up" since the summer of 1970. "We are generally familiar with the problems of reentry of people in fields recently treated with organic phosphate chemicals."

While the EPA may be full of vocal concern, the fact of the matter is that when it came to formulating this Control Act they made no objection to the wording of section 5(b) dealing with temporary tolerance levels in the issuing of experimental use permits.

This section reads:

> If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue *on or in food or feed*, he may establish a temporary tolerance level for the residue of the pesticide before issuing the experimental use permit. [Emphasis added.]

In agreeing to this terribly sloppy language EPA paid no heed to its own studies which have shown that "the exposure to dangerous pesticide residues of a professional farm worker is much more prolonged and intense than could possibly be matched by a consumer. The more skilled and dedicated the farm worker the greater the peril."

Also as far back as 1965 Wayland J. Hayes, Jr., of the Toxicology Section, Technology Branch, Comunicable Disease Center of the Public Health Service urged that certain prescribed laws be established governing the testing of economic poisons involving human subjects.

There is another area where the EPA failed to provide the full measure of its expertise toward the strengthening of this act. I refer to section 11(a) which states that "no regulations prescribed by the Administrator for carrying out the provisions of this act shall require any private applicator to maintain any records or file any reports or other documents."

In May 1971, Dr. Donald S. Kwalick, director of the New Jersey State Health Department's Community Study on Pesticides, in a study supported by the U.S. Department of Health, Education, and Welfare, the Public Health Service, and the Food and Drug Administration, and under contract to the EPA, declared:

> Organophosphates have caused over 60 percent (in New Jersey) ... of the reported pesticide poisonings. Since 1967 the number of organophosphate poisonings has greatly exceeded poisoning from other pesticides. With the decreased use of persistent pesticides (such as DDT) there will be a corresponding increase in the use of less persistent compounds such as carbamates and organophosphates.
>
> Although less persistent, the organophosphates include some of the most dangerous chemicals known to man. An increased number of poisonings with possible fatal outcomes can be expected with the anticipated rise in organophosphates usage unless there is stringent control on the purchase and use of these substances, and unless there is intensive education of the public and many occupational-exposed individuals.

Certainly a vital component of the "stringent control on the purchase and use of these substances" called for by Dr. Kwlick are well-kept and accurate records concerning the types and amounts of economic poisons used on farms and ranches.

If such records are not available how is a doctor to know when faced with a case of economic poisoning how to treat a worker, or to what degree he has been exposed, or to what poison he has been exposed?

It is interesting to note that the only farmworkers today which have the protection that this section of the act should provide are those covered by contracts containing such disclosure clauses and which were negotiated by the National Farm Workers Union under the leadership of Cesar Chavez. And we might point out here that the same forces which have played such a major role in shaping this act which treats farmworkers so shamefully—and I am speaking here of agribusiness—are now also seeking throughout the country to deny the farmworker the right to bargain collectively for such protective measures in their job contracts.

The loophole that the act presently provides was made abundantly clear during court proceedings in California 4 years ago when the National Farm Workers Union was seeking the right to inspect the county agricultural commissioner's books concerning application information which had been closed to them.

It was the commercial applicators who pointed out in court that such disclosure might lead some of their number into hiding certain of their activities by turning that portion of the business they wanted to keep secret over to a "private applicator" who was not required to maintain any records. Section 11(a) of the present act would only encourage this type of behavior and EPA should have recognized that fact and stressed to the Congress the need to strike section 11(a) from the law.

Instead EPA is allowing the chemical industry to hide behind the skirts of the trade secrets god rather than recognizing, in the words of Dr. Robert Van den Bosch, prominent University of California entomologist, that pest control as it is now practiced "is essentially not an ecological matter it is largely a matter of merchandising. In essence, we are using the wrong kinds of material in the wrong places at wrong times in excessive amounts and engendering problems which increases the use of these materials, adds to the pollution problem, adds to the cost of agricultural pest control, and adds to what you might describe as the concern of the general public."

Finally, Mr. Chairman, there is the matter of safe worker reentry times. Under current label setting procedures whether the chemical manufacturer establishes a safe worker reentry time for a given economic poison as part of the registration process is left to the discretion of the EPA Administrator.

On February 2, 1972, the Community Studies on Pesticides Division of the California State Department of Public Health under contract to the EPA submitted a lengthy report detailing the serious health hazards to farmworkers from organophosphates pesticides.

Yet having this report in its possession, the EPA in testimony before Senator James Allen's Subcommittee on Agriculture and General Research on March 7, 1972, made no mention, nor reference to this vital and informative California study.

California, compared to the other 49 States, has not only the strongest pesticide safety regulations but, to date, has done the most extensive research in pesticides and their effects on farmworker. For these reasons alone the above-mentioned report is a most significant document.

Important points made in detail in the California report to the EPA included:

(1) "* * * when a researcher finds that the cholinesterase level of a particular occupational group is significantly lower than that of a control group, if society is serious about its commitment to occupational health and safety, equal protection under law, and other professed social values, then it is incumbent upon someone to take steps necessary to eliminate those occupationally-induced differences.

"In the present instance, this would mean that more attention must be given to the question of organophosphate residues on the foliage of such crops as grapes and citrus. 'Safe waiting periods' between application of pesticides and re-entry of workers should be re-examined, across the board, not from the standpoint of protecting consumers of the ultimate products, nor from the standpoint merely of protecting workers against acutely toxic levels of exposures, but from the standpoint of protecting workers against low, cumulative exposure levels."

Dr. Thomas Milby, Project Director, underscored this point in his written testimony to Senator Allen's committee. We recommended that this committee study Dr. Milby's testimony:[1]

He said:

> Our research leads us to suspect, furthermore, that there is probably an even more common form of "adverse effect"—one which is even slower to develop and even subtler in its manifestations. The individual may not feel nauseated, dizzy, etc.; he may not lose any time from work at all. But he may have a little more difficulty getting to sleep at night. His appetite may be a little less hearty than it was. And there may be a gradual impairment of this hand-eye coordination and other neuromuscular functions, so that he is able to pick ten percent fewer oranges or peaches, say, than formerly. The affected individual may not notice the difference at all; or if he notices, will most likely shrug and ascribe it to "getting older."
>
> Impairment of neuromuscular function is not measurable through cholinesterase tests . . . but we in California are working on new methods for directly measuring these kinds of pesticide "poisoning."
>
> In my opinion, these are perhaps the most important "adverse effects on the environment" of pesticides. They may be unspectacular; they do not make headlines. But I suspect they are very widespread among farm workers and working farmers.

Other points in the California studies include:

(2) Every piece of evidence examined to date "without exception," points in the same direction: that cholinesterase levels among agricultural workers are lower than those of a matched control group. "It seems clear that this difference must be due to some factor in the environment of the farmworker population, and that this factor is most probably anti-cholinesterase pesticide residues."

(3) Farmworkers are generally unaware of the dangers inherent in their jobs due to pesticides, the nature and extent of how pesticides affect their physical and mental health, and of the medical care and compensation available to them resulting from pesticide "injuries.".

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[1] See p. 397 on hearings before the U.S. Senate Subcommittee on Agricultural Research and General Legislation of the Committee on Agriculture and Forestry, pt. II, Mar. 7 and 8, 1972.

(4) Acute symptoms as an indicator of pesticide poisoning constitute an effect so advanced they must be rejected for ethical reasons.

(5) Organophosphates as a class are least amenable to removal by soap and water wash after dermal exposure. Washing at times greater than 1 hour post application either has little or no effect on removing some pesticides and actually increases the extent of absorption after the use of certain other organophosphates.

(6) "Epidemics" of organophosphates poisoning which have broken out periodically among farmworkers occur even when all current regulations governing the use of the pesticide have been followed scrupulously.

(7) In all the cases of testing for safe worker re-entry times, controlled experimentation has pointed toward the necessity for longer rather than shorter re-entry periods.

(8) Although probably half or more of the grape growers in the southern San Joaquin Valley still apply their pesticides in from 100 to 300 gallons of water per acre, there is a strong trend toward concentrate spraying, that is, applications of approximately the same amount of active ingredient but applied in from 25 to 30 gallons of water, per acre. These concentrates result in less loss from plant surfaces in "runoff" and result in increased residues.

(9) Present testing methods for safe worker re-entry times by corporations, like Chemagro Corp., and Niagara Chemical Co., and universities, like University of California, are dangerous and pose a genuine peril to the health of the participating subjects.

All these points, Mr. Chairman, are relevant to the main question of safe worker re-entry times, yet nowhere do we see the slightest mention of the subject by EPA. If they had been doing their job as they should be doing it, EPA would have demanded that safe worker re-entry times be one of the essential criteria contained in section 3(c) for registering economic poisons.

Other studies done for the EPA which we would like to make part of the committee's records, underscore this point.

Dr. Keith R. Long, project director of the Iowa Community Pesticides Study, in a report done under contract for the EPA, best summarizes the situation:

> People must somehow be made to realize that pesticides are poisons and should be used in response to a specific problem and not for convenience.

There seems to us, Mr. Chairman, to have been a deliberate effort by the EPA and the chemical industry throughout the legislative history of this act to ignore experts like Dr. Long and others and make conditions just as comfortable and just as easy for manufacturers of economic poisons as possible.

You will notice that throughout our testimony we have used the term "economic poisons" because that simply is what they are. The term, however, has been expunged from this act and in its place appears the euphemism "pesticides"; a neat public relations coup by the chemical industry.

Indeed Dr. Philip C. Minter, formerly in the public information office of the Pesticide Program of the U.S. Public Health Service,

writing in a 1967 issue of the trade publication Agricultural Chemicals suggests:

> One of the reasons for the present adverse state of public opinion about pesticides has been default on the part of the pesticide chemicals industry . . . Failure to recognize the need for public relations (by the chemical manufacturers) has not only resulted in the present status of public opinion toward pesticides, but it has also resulted in a large number of government regulations being imposed on the use of chemical pesticides. Many of these government regulations . . . are quite impractical and make the task of industry a lot more difficult than it would have been if these regulations had never been imposed.

This article titled "Pesticides and Public Relations" is available today through the EPA's Chamblee, Ga. office.

Does EPA honestly subscribe to Dr. Minter's apologist views that the whole controversy regarding economic poisons is due to bad public relations by the manufacturers? If it doesn't then it should immediately and completely disassociate itself from these views.

In conclusion, Mr. Chairman, the AAP feels there still is an opportunity for the drafting of a strong piece of pesticide control legislation by the Congress providing, of course, that agencies like EPA will come forth with factual and unbiased information which shows that they value the life and health of farmworkers at least, if not more so, as the air we breathe, the water we drink, and the food we eat.

Thank you.

Senator HART. Mr. Krebs, if Mrs. Kantor does not object, before having her testimony let me raise a couple of questions based on your statement.

Your statement is a disturbing one. You say that there were tests that two companies did involving ethion and Guthion, and these were done in 1970.

Then an analysis of these tests by the California Public Health Department showed that the workers participating in the experiments had blood enzyme levels, "depressed by absolute amounts in a proportion which by accepted medical standards represented a potential hazard to their health."

They should have been removed immediately from the fields. Then you say that complete analyses were sent to the Georgia office of EPA in December 1970.

I believe that the University of California conducted further tests on these same two pesticides. I am sure you are familiar with those university tests. Could you, for our record, briefly suggest what they show?

Mr. KREBS. Mr. Chairman, concerning those tests, we understand that common medical criteria says that a 20 percent or more depression in cholinesterase levels in plasma and red blood cells constitutes a threat to the health of the farmworker.

Now, in the two companies' tests, the Public Health Department said that there was a significant number who suffered such depressions. We have the exact number in our testimony presented to Senator Allen.

Regarding the University of California tests, it has to be remembered that there are a variety of different ways of measuring how you arrive at this 20 percent, and even the people in the profession have not agreed upon a one tried and true way. At present there are a variety

of ways they measure it. But even in the University of California tests, the percentages were way over 20 percent, no matter what method you used.

As a matter of fact, one of the most accepted methods or probably one of the truest methods, in our view, is to take the worker's exposure level when he comes back into the field and measure that against a control group that is completely away from the pesticides. When we do that with the University of California tests, we find 21 out of the 23 test subjects were registering depressions like 57 percent, 52 percent, 39 percent and 36 percent.

You know, those are very dramatic increases. As the California report points out, those people should have been removed immediately from the field, but they were not.

Senator HART. For a layman, tell me what happens to a person, whether a farmworker or anyone else, when that 20-percent drop in the level occurred.

Mr. KREBS. Once again, from what we have learned from different studies, organophosphates cause a short circuit of the nervous system, and while we know what happens in the acute stages, you get nausea, and you get sweating, and you have difficulty in breathing and everything, studies are still going on as to the long term effects.

This is the thing that Dr. Milby goes into, the fact that the worker may be losing a little sleep each night, or he may not be eating as much, or his hand-eye coordination may not be as good as it was.

In many cases he himself does not realize it. As Dr. Milby says, he may ascribe it to getting older. He is not conscious of the fact because it has been part of his life, part of his day-to-day working conditions.

Senator HART. If I follow you, then, EPA had evidence of adverse effects sometime late in 1970, and then the University of California test that you now describe confirmed the earlier tests that had been performed on the ethion and Guthion properties. That is a correct statement?

Mr. KREBS. The company tests were included in the 1970 report. The University of California tests were included in the 1971 report, but EPA had both of these reports before they testified before Senator Allen.

Mr. BERMAN. Senator Hart, one or two other points should be made. The reports that EPA has before them establish two things: One, that no one was really following safe testing methods in terms of testing the dangers of pesticides on farmworkers, neither the chemical companies nor the University of California, and they were at the same time establishing that the depression in these values were a potential danger and of possible long-term adverse effects on farmworkers. Not everything was, you know, based on the outbreak of serious poisoning. Yet many are concerned and expressing that to EPA in studies conducted all the way across the country, and EPA had expressed a concern by contracting for the studies. Yet when we get a chance to look at new legislation and build in the professions and the kinds of concerns and problems and deal with some of the problems which EPA has in these studies, EPA says nothing about the studies in their testimony, and endorses the bill. So we have this kind of weak bill which comes out, one that does not deal with the farmworkers, and leaves them without protection.

It is the same story over and over again, and we consider it gross irresponsibility and we don't think that Congress could really deal with this legislation and deal with the farmworkers problem without this information before them, and instead they are sitting piled up somewhere in EPA's offices.

That is, I think, the kind of theme and information that is contained in our testimony.

Senator HART. Contained in that story, it seems to me is the basis that would indicate that substantial questions as to safety have been developed in the files of the agency, and under the agency's own rule, when there is substantial question as to the safety, cancellation proceedings can be initiated by EPA. Is that not correct?

Mr. KREBS. That is true, Mr. Chairman. When EPA had the opportunity to do this with the results of the company tests, as we point out in our testimony, even when they issued their own summaries of how pesticides should be used, they ignored the results that they got out of the tests, they ignored California's 30-day ban that it imposed on these particular pesticides and went ahead and continued to follow the labels recommendations on zero days and one label and 7 days on the other, and that regulation still continues today, in EPA's own guidelines for the application of these pesticides.

So we think it needs to be stated in law, because if it is left up to the Administrator, the same thing is going to happen.

Senator HART. I would react this way: No matter what the law in its language provides in the future, it would seem to me that under existing language, under their own regulations, EPA is on notice with respect to potential danger in two products, and while I don't know what the result of it is, I would hope that the agency will initiate the cancellation proceedings and will make a final determination whether we write more language into some other bill or not.

There is now, in fact, a clear indication, with respect to these two products, a substantial question as to safety.

Mr. KREBS. There is nothing, however, Mr. Chairman, in the bill now that requires, except by the wish of the Administrator, reentry time regulations on pesticides as part of the registration process.

Senator HART. But they can be set. Either we can do it, if we think we have the knowledge, and we assign ourselves knowledge sometimes that we don't have, or they can.

You say that the agency has ignored and disregarded its own study, which has shown both the short- and long-term harmful effects on farmworkers of economic poison, even when there was a precise and correct use so far as the label instructions were concerned, and you cite those two products.

Are there studies which have demonstrated substantial lists of farmworkers in the use of the other pesticides, not just these two, even when the label instructions have been followed precisely?

Mr. KREBS. Yes, Mr. Chairman. Probably one of the most dramatic cases was in 1963, with parathion, which is one of the substitutes now being recommended for DDT.

After its use, workers went back into the field 33 days after application, and there was a mass outbreak of poisonings, where the regulations stated 2 weeks as a safe time for reentry.

In subsequent studies, California indicated that sunlight was changing this product into a much more deadly chemical, and that was what was poisoning the workers. So there have been other studies.

Senator HART. You say that is a substitute, a suggested substitute for DDT?

Mr. KREBS. In the Washington Post story this morning, it has been suggested that methyl parathion might be used as a substitute for DDT.

Senator HART. You are cautioning that the suggested substitute itself has a serious hazard in it?

Mr. BERMAN. The chemical companies are saying, "We are going to have to increasingly move with the DDT ban," and by the way we have supported that ban, but there is going to be a push toward the extensive use and increased use of the kinds of pesticides we are talking about here today. The chemical companies are going to be coming into EPA and having meetings to discuss the problems, and the companies are saying "we want registration, because we need the chemicals out there," and we are saying there are other questions that are being raised, questions about human life, questions of the environment. We are going to be caught in a rush and this bill is going to have to deal with this, and I think it is not in a position to deal with it at this time.

Mr. KREBS. Mr. Chairman, I think the real question, that would be legitimate to raise now is, as one of the California reports states, and I'm paraphrasing their statement, we are going to have to, the American consumer, is going to have to make the ultimate decision of whether he wants blemishes on his fruits and vegetables, or perennially sick farmworkers, whether he wants damage by thrips on his orangerinds or dead farmworkers.

Those are the decisions that are going to have to be made. We are talking about organophosphates, and we are dealing with some of the most dangerous chemicals known to man. We don't feel at the present time that there has been given that much cooperation—that that much consideration has been given—to the farmworker.

Because while DDT has harmful effects to the general population, and that is one fact, when you use organophosphates you are using toxic chemicals and you are creating intense residues which are dangerous to the farmworker.

It may not be that dangerous to the consumers, but it is dangerous to the farmworkers, because they are not just dealing with the one orange or the one peach you are eating. They are dealing with all the foliage and the air and the whole business on an 8- to 10-hour-a-day basis

Mr. BERMAN. Let me underscore that. We talk about the consumer and the ultimate, you know, food bin and we have a whole consumer movement, but there is at the first end the farmworker. I think the relative risk, of danger in terms of pesticide poisoning to the farmer versus the consumer, is underscored by the example which is given in the California study which is in EPA's possession.

It says that it seems a "reasonable estimate that a consumer would have to eat several hundred pounds of peaches or oranges per day to

match the pesticide body burden of the fruitpicker who brushes against thousands of leaves and inhales thousands of times in the course of each day's employment."

There are 2.6 million farmworkers in this country. We know the statistics. Every year we talk about statistics. Their average life expectancy is 49 years. Their infant mortality rate is 5 or 6 times the national average, even higher by some calculations than among children in North and South Vietnam.

There are 240,000 children working in the fields in this country and exposed to pesticides with long-term damage, as we are just beginning to find out. We are finding it out from the agency which has the primary responsibility to disclose this and bring these issues before Congress and the people.

Senator HART. You can make certain book that the consumers will elect to have unblemished fruit to eat unless they become aware that the price of unblemished fruit may be dead farmworkers.

That is in the nature of what we call the communications problem, I think, but that does not absolve either Congress or the EPA, which are on notice.

But to look to the public, the consumer to rise up is something we can anticipate only after enormous educational efforts, just as I hope sooner or later they wake up to the fact that the family that does not have a handgun on the premises is safer than the one that does.

Congress should do something about both of those, because we do have a responsibility.

May I apoligize for sort of reaching out and bringing in handguns? We are going to have to interrupt this hearing because the Judiciary Committee is picking up handguns. The underlying theme to your statement is that the farmworkers' health has been inadequately protected under existing law, and likewise would receive inadequate protection under the bill on which we are now holding hearings.

But in your judgment, is there any question as to the authority of the EPA to protect workers through labeling of pesticides under the current pesticides?

Mrs. KANTOR. If I might point out to you, when the Senate Agriculture Committee was considering the bill, there were several amendments which go directly to the issues we are talking about today. The issuance of experimental use, the labeling that would protect workers, and we are concerned not only about the farmworkers, but about all workers who are exposed over long periods of time to the concentrated dosages of pesticides, and that is at every phase of the game.

Farmers are just as exposed as other farmworkers, and while the farmworkers of the interest we represent, we feel that the amendments that have been proposed by you, Senator Nelson and Senator Stevenson would go to these issues, and I think would provide the mandatory consideration that is now lacking in the Agriculture Committee version of the bill.

Senator HART. Do you have any doubts with respect to the pending legislation if these further amendments are not adopted?

Mrs. KANTOR. Yes. I think the committee report assumes that the definition would include all farmworkers. I think in view of Mr. Krebs' testimony, and those of us who have worked with farmworkers in the past, we know that farmworkers are not usually included in a definition of "all men."

They are treated as human guinea pigs. I don't think that we can rest on that assurance without having language in the bill that they were intended to be protected.

Senator HART. Thank you very much. May I ask that we interrupt for the purposes of welcoming Senator Nelson?

I know you have a schedule problem, Senator, and why don't you proceed and we can then pick up the panel?

STATEMENT OF HON. GAYLORD M. NELSON, U.S. SENATOR FROM WISCONSIN

Senator NELSON. I don't want to interrupt the witnesses.

Senator HART. I think we are at a point where there really is not an interruption, we have concluded the testimony of Mr. Krebs and have not yet begun with Mrs. Kantor.

Senator NELSON. Thank you, Mr. Chairman.

I appreciate the opportunity to appear today to discuss several particular aspects of the proposed Federal Environmental Pesticide Control Act. When the scientists began raising questions about the environmental damage and human health hazards proposed by the unrestrained use of pesticides over a decade ago, it was a lonely position for anyone in or out of Congress advocating study of the problem.

I recall at the time anyone proposing controls was banned as some kind of a "nut." Like the warnings of Rachel Carson in her 1962 book "The Silent Spring," the concerns of those of us in Congress over the indiscriminate use of toxic and dangerous chemicals in pest control were dismissed out of hand with the argument that you cannot halt the march of progress. Furthermore, the possible dangers were not proven, it was said.

The French writer, Jacques Ellul, has stated that there is a "technological imperative" which is the dominating force of our age:

> Everything which is technique is necessarily used as soon as it is available, without distinction of good or evil. This is the principal law of our age.

Such a law is not inevitable. Technical possibility can and must be incorporated with human and ethical judgments in making decisions about proceeding from laboratory possibility to society-wide application.

The application of human considerations in the decisionmaking processes surrounding the application of new technology is often labeled "technology assessment." As one of this country's leading science writers has pointed out, "technology assessment" is only "a specialized type of commonsense applied at a high level. Just as the average man is expected to contemplate the probable consequences of his acts in everyday life, so decisionmakers should attempt to evaluate the consequences of technological advance."

Mr. Chairman, in the report of the full Commerce Committee which accompanied S. 1478, the Toxic Substances Control Act of 1972 developed in this subcommittee, it was stated:

> As man continues to develop and produce chemicals at an increasing rate, the risk of producing a chemical which will cause serious environmental or health problems also increases. It is the object of this legislation to provide knowledge of those problems before the substance is introduced into the environment, rather than at some later date as is all too frequently the case now.

I would like to say, Mr. Chairman, that we resolved this question—or at least substantially resolved it—respecting prescription drugs by establishing standards which require animal tests, human tests, and toxicity tests. These tests are presumably adequate to demonstrate the effect of the particular compound on the target organism as well as any possible side effects.

The parallel is similar, if not identical, between prescription drugs and the introduction of pesticides into the environment. As we introduce pesticides and herbicides into the environment we are affecting all living creatures that live in that environment, with consequences that have not been studied and cannot be predicted. It has been well known for quite sometime that DDT has serious effects on birds, on marine creatures, and possibly on human beings. Though we have had more than a decade of experience with DDT, finally yesterday Mr. Ruckelshaus set a deadline of December of this year for eliminating the use of DDT in this country except for a few limited crops and for public health purposes.

On May 30, 1972, the Senate cast an assent, in a 79 to 0 vote, with this subcommittee's position that adequate information must be accumulated and evaluated about the potential dangers of new chemicals before they are introduceed into the marketplace.

If it is agreed that this standard of technological assessment, or commonsense applied at a higher level, is now in order to develop the controls necessary to safely introduce new chemicals into our environment, how much more important is it to exercise a higher degree of care and control over those chemicals already pervasive in commerce and which have shown themselves to be extremely dangerous?

On March 7, 1972, Senator Hart and I introduced a package of 11 amendments to the House-approved version of H.R. 10729. The essential features of two of the amendments dealing with indemnities and with the criteria for general and restricted use were accepted by the Agriculture Committee.

It is important that any bill to reform pesticide regulation, which is reported to the full Senate, contain provisions for informed public decisionmaking on pesticides before the public health, the environment, or the commerce of this Nation are threatened or actually injured.

I am confident that H.R. 10729 and the remainder of the amendments which Senator Hart and I have introduced will receive thorough consideration and appropriate attention in this committee.

Particular attention is deserved by several of these amendments. Amendment No. 1012 would expressly provide that the social costs and social benefits will be considered in registering a pesticide. Amendment No. 1003 and amendment No. 1011 would allow citizens to have access to information at an appropriate time to participate in the administrative process, while also giving the public the right to participate in the enforcement proceedings.

Amendment No. 1007 seeks to insure a degree of impartiality in the makeup of any advisory committee of the National Acedamy of Sciences to which a scientific question may be referred. And amendment No. 1004 is important in that it would prevent needless duplication of test data and the restriction of competition in the pesticides market.

All of these features deserve inclusion in any bill which professes to modernize and reform Federal pesticides regulations.

Instead of setting up mechanisms to search for the hard information and proof about pesticides, we have chosen to wait for evidence to force itself upon our consciences. And that is what we have done. We have been content to wait. And we have sat by and watched as each tragic step has unfolded.

Unfortunately, the dangers of highly toxic pesticides must still be proven in literal human terms. Only then is action taken to institute the appropriate preventive informational and control techniques.

It appears now that another such tragic incident is presently being documented in Iraq where an insidious epidemic of mercury poisoning has occurred. According to Dr. Thomas Clarkson and other University of Rochester scientists studying mercury toxicity under a June 1971 grant from the National Science Foundation in cooperation with the Food and Drug Administration, Iraq is suffering a severe outbreak of mercury poisoning, and the full effects of this episode may not be realized for generations.

I might say that in our investigation of this situation, and in discussing it with those who have been there accumulating information, this mercury poisoning catastrophe in Iraq is far greater than the tragedy in Minamata, Japan, where many people were poisoned and many more died.

The incident in Japan was several years ago, as you know, but just recently a substantial article was run on it in Life magazine.

The first cases of mercury poisoning were recorded by Iraqi officials on December 27, 1971, when 50 cases were officially recognized. By January, Iraqi officials in the Ministry of Health were recording 400 hospital admissions each day. All of the official cases occurred outside the urban areas of this country of 10 million people and involved peasant farm families, who had taken mercury-treated grains and utilized them to make bread instead of sowing them as seed.

Although official diplomatic relations between the United States and Iraq are severed, an invitation was extended in January of this year by scientists at the University of Bahgdad to Dr. Clarkson and the team of University of Rochester scientists working on mercury poisoning.

With the understanding, support, and essential cooperation of the National Science Foundation, Dr. Clarkson assembled the necessary men and equipment and affirmatively responded to the formal request for his assistance in February of this year.

The official Iraqi figures for this outbreak record 450 deaths and 6,000 hospital admissions.

However, it is felt that these figures could be multiplied by 10, which would bring you up to 60,000 mercury poisonings in that country and up to 4,000 deaths. Unofficial sources now report that 60,000 peasants may have ingested enough mercury to exhibit signs of damage. Actual deaths may eventually approach 1,000.

Mercury poisonings have occurred in the past several years at several points throughout the world, most notably in Minamata, Japan, in the State of New Mexico, and twice before in Iraq in 1956 and in 1960 when 350 people were severely poisoned and 36 deaths recorded.

But never before have the outbreaks been so large. In Minamata, Japan, where the largest known previous mercury poisoning occurred, 181 victims have been officially designated as sick and they have 52 listed deaths in the 20-year history of that disaster.

So you can see the comparative dimensions of these two tragedies.

Mercury poisoning is irreversible and produces brain and nerve damage that can result in death, blindness, and loss of control of muscle function. As the Minamata incident has revealed, the results may be delayed and may not show up in a victim for months, or even years.

The more devastating effect of mercury poisoning, however, comes not from the neurological damage and destruction of brain cells, but from the teratogenic effects—birth defects suffered by the growing fetus while it is still in a mother's womb.

Even more insidious in its impact, since the damage may not surface for three, four, or five generations, is the effect of mercury upon chromosomal material. This is a change in the genetic code which can produce structural damage to any system, or any part of the body in some future generation.

The June 2, 1972 issue of Life magazine graphically showed the pathetic result of teratogenic damage to a fetus in a Minamata mother's womb. Life also reports in the same article that otherwise healthy women in Minamata are fearful of producing deformed children some 20 years after the first signs of mercury poisoning appeared.

Even if extrapolations on the number of Iraqi's who have been exposed sufficiently to the mercury poisoning to suffer damage cannot be definitively proven at this point, the number of official cases of deaths and hospital admissions, and a comparison with the Minamata experience, should raise great concern for the possible secondary and longer range results to children born of exposed mothers. The possibility of genetic damage must be considered.

In a country where the unofficial birth rate is 40 per thousand population each year, and where there is the ability of mothers to pass on a significant level of mercury to children through mother's milk, this concern must be taken seriously. The damage to present and future children may far outweigh the immediate effects on adults and be the basis for a major public health problem in Iraq for years to come.

In addition to the devastating effects of the poison on the country's human population, there has been an incalculable impact upon Iraq's aquatic, bird, and rodent population ecosystem. The relationship between the cats and birds that ate the rodents and the bugs that ate the grain that fed the population has been disrupted.

This tragedy is the result of improper use of wheat and barley seeds which were imported by the Iraqi Government late in 1971, and, at the Government's direction, coated with an alkyl mercury fungicide.

The exact origin of the grain involved in the Iraqi outbreak is not definitely clear. Treated grain came to Iraq in late September and October of last year in a shipment of 14,000 tons of barley and 63,000 tons of wheat, and in another shipment of 14,000 tons of wheat. While the barley is known to be of U.S. origin, there is some dispute as to whether the wheat was Canadian, American, or Mexican grown and in which country it was treated with the alkyl mercury fungicide.

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The barley and 63,000 tons of wheat were part of a trade between the Iraq Government and Cargill, Inc., of Minneapolis, Minn., or one of its international subsidiaries and trading corporations, such as the Tradex Corp. A Cargill representative was reported to be on the docks when the shipments arrived. The other shipment of 14,000 tons of wheat came from other sources and is thought to have been involved in a dispute at the border which delayed its entry into Iraq.

I emphasize that the Iraqi Government requested that the grain be treated with the fungicide. The grain was dyed red, and the language explaining the dangers was in either Spanish or English, neither of which languages the Iraqi peasants read. Many of them are illiterate in their own language.

So far, no one has indicated that the alkyl mercury fungicides used to coat the grain were of other than U.S. origin.

With the grain arriving in Iraq late in the summer after a devastating drought affecting crop harvest, it is believed that distribution to the farmers occurred too late for total use in planting. However, the large bird kills in the northern part of the country would indicate that some was used in sowing.

Most of the treated barley seed is believed to have been fed to the peasants' sheep and cattle. When the animals appeared to show no immediate effects, the peasants are thought to have begun to convert the remaining treated wheat in their possession into flour, and thus into homemade bread which is the staple of their diet.

With the bread came the approximately 6.7 parts per million of highly toxic alkyl mercury fungicide that coated the wheat seeds. With an average ingestion of three loaves of bread per day and with each loaf containing about 1.2 milligrams of mercury, each exposed individual would be ingesting about 3.6 milligrams each day of mercury.

The Swedish and Japanese literature on the subject indicate the appearance of the first symptoms of mercury poisoning when the body burden reaches the 30 milligram level. Other scientists look for the first signs of damage at the 100 milligram level.

Using both thresholds, it can be seen that with an average ingestion of three loaves of contaminated bread per day, it would not take an unusually long period of ingestion to build up a body burden of mercury sufficient to produce symptoms of serious damage.

With the peak of the admissions occurring in January, ingestion of contaminated bread could have occurred over a 6-month period from October 1971 to March of this year with the peak consumption occurring at the end of 1971.

If the flour eaten in Iraq had contained six parts per million of mercury, 1,000 tons of wheat would be sufficient to poison 60,000 people. Of the 80,000 tons of treated wheat known to have been sent to Iraq, the Government has confiscated and recovered 5,000 tons. When it is possible to seriously poison 60,000 Iraqis with 1,000 tons of wheat treated with alkyl mercury fungicides, and there are 75,000 tons of treated wheat which are still unaccounted for, there is cause for substantial concern. Whatever assistance may be the most appropriate cannot be denied in this situation.

It is understood that the World Health Organization and the team of scientists from the University of Rochester will continue to offer their expertise and assistance in a cooperative effort with the Iraqi Government and Iraqi scientists.

In addition to the National Science Foundation support for Dr. Clarkson's assistance to the Iraqis, the Dow Chemical Co. has also indicated its willingness to cooperate with the efforts of the University of Rochester team when it returns to Iraq.

The July 5, 1971, issue of Chemical and Engineering News reported that Dow has been providing Dr. Clarkson with sulfhydryl resin on an experimental laboratory basis. As described in this article and in an earlier article in the April 26, 1971, issue of the same magazine, this cooperative effort between the Dow Chemical Co. and the University of Rochester scientist was to test whether these resins, or various modifications of them, may be effective in binding methylmercury that has been ingested, and in increasing the rate at which mercury is excreted from the body by preventing reabsorption in the digestive tract.

I might say the scientists, as is the nature of the discipline, have been careful in the claims made for this resin. However, in the handful of cases in which the resin was used in Iraq, a dramatic drop of the mercury content of the bodies of the individuals on which it was used was noted.

The resin captures the mercury in the digestive tract and it is then excreted from the body. So the scientists feel they may have a dramatic solution for mercury poisoning if the resin is given in adequate quantities and early enough.

If these resins could successfully act as a chemical magnet, which we believe they do, and accelerate the natural elimination of this poisonous heavy metal from the human body, an important breakthrough for helping moderate the gruesome effects of mercury poisoning would be achieved.

It would also immediately bring into mind the question as to whether this principle could be made applicable to other toxic heavy metals such as lead and cadmium.

So far the work on this sulfhydryl resin, so-called 17–B, had proceeded only on an experimental basis in the laboratory with tests on mice. When doctors from Iraq familiar with this study used experimental quantities of 17–B with Iraqi patients suffering dangerously high mercury blood levels, positive results were observed. The body content of methyl mercury was lowered without apparent side effects.

This is particularly important in the cases of new mothers, since mercury is carried in the mother's milk, and the newborn baby can ingest enough mercury to cause serious harm.

The possibilities of utilization of 17–B in the Iraqi situation are of great interest. It is not a cure for mercury poisoning and will not reverse any symptoms of damage that already has occurred. Symptoms and damage from methyl mercury poisoning are thought to be a function of the quantity of mercury in the body and the length of time it takes naturally to eliminate the mercury.

Efforts to accelerate the rate of excretion of mercury from the body and lower the total mercury level may be important in preventing extreme symptoms or damage. In the case of children affected in the womb or through breastfeeding, the use of a substance which accelerated the flushing of mercury from the body could be extremely important.

And I think the scientists believe that it is.

With the possible humanitarian aspects of resin 17–B well in mind, Dow has indicated that they will increase their output of the material and provide Dr. Clarkson with a donation of 100 pounds of resin for use in Iraq. While future production, costs, availability, and nontoxicity of 17–B itself remain speculative at this moment, it is my understanding that Dow has expressed their willingness to continue to cooperate in appropriate activities to moderate the effects of this incident if they are required in Iraq.

The use of organic mercury compounds as fungicides was discovered in 1914 by European chemists. Large-scale production began in the 1930's with worldwide use of organomercurials. All manner of agricultural applications became widespread after 1940. By 1968, world consumption of organic mercury compounds for agricultural use had reached 4,724,977 pounds.

Of the three major classes of organic mercury compounds, the most deadly formulations are the alkyl compounds, methyl and ethyl mercury, with methyl mercury known to be particularly a dangerous chemical since the last century. In his book, Diseases of Occupations, the English physician, Dr. Donald Hunter, states:

> Work published in 1940 made it clear that ethyl and methyl mercury compounds are so dangerous that they should never be manufactured again. The warning remains unheeded and the grim record of deaths occurring in many countries is a sad monument to the greed and stupidity of men.

After the Minamata poisonings began to appear in April 1953, scientific attention to the dangers of mercury compounds in the world environment began to increase. Sweden started testing for mercury in animals and the environment in the early 1960's. After a national conference in Stockholm in 1965 convinced authorities of the serious threat to the environment posed by methyl mercury used for agricultural purposes, the Swedish Government restricted the use of methyl mercury in agriculture. As of February 1, 1966, Sweden refused to approve the use of any alkyl-mercury compounds for agricultural purposes.

In the United States, however, mercury used for agricultural pesticides continued, and in 1967, 283,632 pounds of mercury were used in the manufacture of pesticides for agriculture. This was the second highest amount used for such purposes in the 10-year period—1959 to 1970.

It was not until disaster struck home in Alamogordo, N. Mex., that action on alkyl mercurials in the United States occurred. In December 1969, some 3 to 4 months after mercury fungicide treated grain clearly labeled as poisonous and dyed red had been fed to hogs, three children in a New Mexico family who had consumed the tainted pork were permanently injured by mercury poisoning.

The story of the New Mexico mercury poisoning was carried on NBC's Nightly News on February 17, 1970. On February 18, 1970, the Department of Agriculture notified the manufacturer of the fungicide used to coat the New Mexico seed that its mercury fungicide registration was suspended.

On March 9, 1970, the Pesticides Regulation Division of USDA issued PR Notice 70–7, which suspended registration for all alkyl mercury compounds used in seed treatment.

In PR Notice 70–7, the USDA stated:

> Recently information has become available to show that ingestion of alkyl mercury compounds cause irreversible injury to the control nervous system.

Because suspension of registration applied only to alkyl mercury used in seed treatment, because there were no recalls of alkyl mercury fungicides already produced and on the shelf, because the order only made shipment in interstate commerce illegal, because the order could be challenged in court before it became effective in the domestic marketplace, and because the order would not cover the export of alkyl mercurials used for seed treatment, the USDA action was only a beginning step in controlling the use of organic mercury pesticides in the United States.

Two years after PR notice 70–7 the Administrator of the Environmental Protection Agency announced in PR notice 72–5 on March 22, 1972:

> I am persuaded that all pesticides uses of mercury should be ended, and certain uses halted immediately since they create an imminent hazard in the environment.

In a statement which gave recognition to the dangers to health and the environment which all uses of mercury compounds pose, Mr. Ruckelshaus announced the suspension of registration for all alkyl mercury products and for mercury products used in rice treatment, laundries, and marine paints. In addition, administrative proceedings were begun to halt the use of mercury in other forms.

This is certainly an important additional step in limiting the use of mercury pesticides in the United States. It is subject to legal challenge.

It does not halt the export of any of these products.

In the Pesticides Review, 1971, released by the Department of Agriculture in March of this year, the total usage of mercury in pesticide manufacture in the United States declined slightly between 1969 and 1970, the last year for which figures are given.

Although mercury used in the United States to produce agricultural pesticides declined by about one-third in this period, the export of U.S.-manufactured fungicides actually increased in poundage and dollar value between 1969 and 1970, and the USDA report shows that exports of organic fungicides, in particular, remained about the same.

In the 4th edition of his Diseases of Occupations, Dr. Donald Hunter states:

> The farmer should be warned that mercurial dressings are poisonous, and should obtain seed which has already been dressed in an enclosed apparatus . . . Every available means must be used to educate people not to use dressed seed wheat for making bread. All dressed seed grain should be distributed immediately before the sowing season and clearly labelled that it is to be used for this purpose only. In countries where peasant populations are illiterate this precaution will usually fail. It has been suggested (Jalili and Abbasi, 1961) that a dye of substance with an unpleasant taste be added to the fungicidal dust to make it almost impossible to use the dressed grain as food.

Hunter's statement reads like a script of the Iraqi alkyl mercury poisoning.

The Iraqi farmers are illiterate.

Their literacy would not apparently have made much difference since the labels on the bags of treated seed were either written in English or Spanish, according to different sources.

The grain also arrived either after or at the end of the growing season.

The skull and crossbones symbol apparently had no deterrent effect upon the peasants other than to cause them to try some of it on their animals.

When the cattle and sheep did not immediately react adversely, the peasants washed off the red dye, and thinking they had thus eliminated any danger, turned the grain into bread.

I recite this incident in some detail, Mr. Chairman, because it is applicable to amendment No. 1013 cosponsored by the chairman and pending before the committee. While I would prefer to take stronger action on the export of these pesticides which have been restricted or banned for use in the United States, the minimal requirements that should be included within this bill should be the features of amendment No. 1013.

This catastrophe has occurred in a foreign country. However, the incident is a reflection and an exported extension of our present policy and attitudes governing the manufacture and control of persistent, dangerous pesticides.

Our Nation's policy on pesticides has not sought to promote and protect our national interests through the advance development and continuous assessment of information about the impact of these dangerous chemicals. Instead, we have been content to add tragic postscripts well after the decisions about use in our environment have been made.

We have used our energies to carefully notate the growing number of incidents of misuse.

As we view this pesticides record, with the understanding that the ledger cannot be closed for at least several generations, it should be abundantly clear that our pesticide use and control policy has been an environmental, agricultural, economic, and public health failure.

If we are to change our attitudes about the appropriate use of pesticides in the United States, our previous record may make it presumptuous to force this change of policy upon any foreign country. But surely we should articulate and communicate the reasoning for our change of attitude to the international community.

If we are going to continue in the business of worldwide marketing of pesticides, we should expressly make available every piece of information which has determined our decisions on the manufacture, use, or restriction of any pesticide in this country.

As I previously stated, stronger action on the export of pesticides which have been restricted or banned for use in the United States is needed. The minimal requirement that should be included within this bill should be the features of amendment No. 1013.

Pesticides produced in this country solely for export are not required to comply with the standards for domestic products under this amendment, but test data would have to be provided to the Environmental Protection Agency before they are exported.

Furthermore, the availability of such test data shall be expressly communicated to any foreign government to which such pesticide may

be exported and these governments shall be expressly provided information about all labeling requirements and orders of suspension, notices of cancellation, or change in classification.

This amendment would be measurably strengthened if, as in the House-passed section 17 on imports and exports, the furnishing of information, test data, and notices to foreign governments would also go to appropriate international agencies.

This language, I believe, would certainly cover any office or arm of the United Nations which may be created as a result of the current U.N. Conference on the Environment in Stockholm to offer technical assistance and worldwide environmental monitoring of the extent, need, and use of pesticides, as well as existing international scientific organizations.

This would be a simple addition. The additional requirement that the appropriate international agency be supplied with this information, would assure that there would be two sources of information available to foreign governments who import pesticides into their countries from the United States.

This modification in amendment No. 1013 could be accomplished by having subsection 17(b) read:

> Notices furnished to foreign governments.—The Administrator shall furnish to the governments of the foreign nations to which any pesticide may be exported and to appropriate international agencies (1) a notice of the availability of the statement required under section 3(c)(1), (2) all labels approved under section 3 and (3) all orders of suspension and all notices of cancellation or change in classification issued pursuant to section 6.

This furnishing of information about the products which we sell in international commerce is an integral part of our obligation for environmental cooperation. It is a minimal requirement considering the dangers which improper use of these pesticides may pose. A small added administrative burden for EPA is not justification for forsaking international responsibility. For those nations which do not have the technical skills to exercise appropriate controls over the use of persistent toxic pesticides, the international scientific community and anybody that is likely to emerge from the Stockholm Conference should be of important assistance.

I would hope that the committee would strengthen that amendment and adopt it as part of this bill. This dramatic case in Iraq demonstrates the urgent necessity for this type of information and warning.

Thank you, Mr. Chairman.

Senator HART. Thank you, Senator. As you have over the years, you have again today expressed in very compelling language both the failure of the Government—but I assume it is a failure that is shared—to respond in time even though we have been on notice of danger.

And you have made some specific suggestions about some of these amendments that you and I put in. I agree with you that at a minimum we ought to include an obligation on EPA to advise international organizations, not just the foreign governments.

But we perceive some suggestions that would go further than that, that ought to be even more severe with respect to pesticides manufactured here for export.

Now, one suggestion is that any pesticide that is banned in the United States ought not be exported unless the country receiving it has specifically told EPA that they wanted it, that they know the limitations and hazards that have persuaded us to prohibit its use here, but notwithstanding that they want it.

Do you, given the experience in Iraq, believe that going as far as that last suggestion; namely, no export unless the country to which it would go says, "We know the danger and we want it," do you think that leaves us open to the charge of being overly paternalistic?

Senator NELSON. No. I think that a waiver requirement may be the best way to handle the question of informed consent, so to speak. Governments are run the way they are all over the world, one agency may very well receive all the notices of changes and information on classification, or cancellations of registration or what have you, while another arm of the government may be purchasing the product and be quite unaware of the information at hand.

So the requirement of a specific waiver may very well be one way to handle it. Of course, that would be a relatively simple matter in any government-to-government transaction. I don't know that in the case of a private corporation transaction in the western world some place the situation would be the same, or whether you need to add something to that or not, but I would approve that kind of a requirement.

On the other hand, I am wondering how strong to make it. We have got the case now with DDT in which it is to be limited to three agricultural uses in this country, sweet potatoes in storage, onions and something else. The argument for these exceptions is that there is not an alternative for it.

But this action on DDT would very dramatically reduce its use in agriculture in this country. For disease vectors in a public health situation where there is not an alternative pesticide, of course, DDT could still be used.

Now the World Health Organization has had a lot of spokesmen from a lot of areas making silly statements about DDT. WHO has attacked those who wanted to restrict DDT, because it is widely used to control disease bearing insects in all kinds of countries around the world.

In those cases, I would hope that it would be at least applied in a scientifically controlled fashion rather than in the irrational way we have applied our pesticides. Spraying DDT out of an airplane and a lot of other forms of application have had no relationship whatsoever with respect to controlling the target organism.

With respect to DDT as a disease vector control, I would suppose that a foreign government would say that there is a health hazard and we therefore want to use it. Maybe we wouldn't even apply a waiver requirement in the DDT case because we are accepting health hazards ourselves on DDT.

But if you do bar use here in this country, then a different situation exists. I don't understand the mercury fungicide case at all, except that the Iraqi officials requested that the grain be mercury treated, and that they did it despite the fact that they had two previous poisonings in Iraq. So they would have gotten the mercury fungicide under the amendment you suggest. But I would think that any amount of

information on pesticides and some requirement that they be informed and recognize what they are doing with any imported pesticide would be good.

This amendment is not a difficult requirement. It is not a tough administrative thing to notify the countries in the world and notify the U.N.

Senator HART. I think I am inclined to go with you that we should beef up the export control to the very maximum possible within the reach of 51 votes.

I don't want you to leave until I read something from your statement. It will appear in the record, but in his book, "The Diseases of Occupation," the English physician, Donald Hunter, states in a work published in 1940:

> Work published shows that either mercury compounds are so dangerous that they should never be manufactured again. The warning remains unheeded and the grim record occurring in many countries is a sad monument to the greed and stupidity of men.

Now in two sentences this Dr. Hunter describes, I think, all of it. You and I and the rest of us in this room, I suspect were not aware in 1940 that this was clear, but many in positions of responsibility surely were, and it is now 32 years later and the greed and stupidity level has not been reduced appreciably, and it is a crime that it takes the equivalent of a thalidomide disaster to compel us to do that which reason makes clear should be done long before that kind of emotional shocker come along.

Senator NELSON. I did not emphasize that because I thought the chairman would take judicial notice of the greed and stupidity of men.

Senator HART. We ought to remind ourselves periodically that we are subject to both of those weaknesses.

Senator NELSON. This bill, especially with the amendments we have proposed, is a very dramatic step forward. What is not widely recognized unless one follows this sort of thing is that the educators on the use of the pesticides in this country are the producers of the product, and they have a selfish self-interest in excessive use of their chemicals.

They have educated the Agricultural Departments of our Federal Government, and the agricultural departments of our State governments. They have educated the entomologists in the universities and they have educated the farmers and the farm agents. Almost all the information on these pesticides comes from those who wish to promote their use.

This bill, for the first time, would institute some controls and require prior submissions of evidence of any side effects and the environmental effects. It will take a step which should have been taken a long time ago in controlling the introduction into the marketplace of pesticides and in controlling their use once they are introduced into the marketplace.

Thank you, Mr. Chairman.

Senator HART. Thank you again, Senator. If your schedule permits, we would like you to stay with us.

Senator NELSON. I have another meeting. Thank you.

Senator HART. Mrs. Kantor, the Judiciary Committee to which I made reference earlier, which was going to try to respond to another

piece of legislation, has not been able to get a quorum. As a consequence, I have no time problem here, and we will welcome hearing you. I will order your statement printed in the record in full. If you want to footnote anything, or add to it, you may do so.

Mrs. KANTOR. I just want to add three additional points to the testimony Mr. Krebs gave. I am sitting here promoting the self-interests of farmworkers. But I want to emphasize that even though we are here on behalf of organizations that do represent farmworkers, I think the real dangers are most serious to anyone exposed daily, over contined periods of time, to very concentrated doses of these poisons.

That includes workers, farmers, and applicators at every stage of the game. The three points that I really think need to be made, commenting on the version of the bill as reported out by the Committee on Agriculture, are, first, the Agriculture Committee's complete failure to really seriously consider the worker protection amendments that were proposed in March before that committee.

They seem to very cavalierly dismiss these by saying, "Well, of course, men are included in environment." I think in view of the testimony here and in view of three volumes of hearing testimony that Senator Mondale compiled in 1969, that documented tragedies of quite large proportions of pesticides poisoning of farmworkers in over 30 States. That was in 1969 and we know now that EPA has had considerable additional information within its possession since 1969. Perhaps if EPA had shared this information with the Agriculture Committee at the time it was deliberating on this bill the Agriculture Committee might have been more prone to including these important amendments in that bill.

Perhaps it was because EPA never even mentioned the subject of danger to humans at the exposure stage, as opposed to the ultimate consumer stage, that the Agriculture Committee did not takes these seriously. I feel the main shortcoming of the bill as reported by the Agriculture Committee to you is that too much is left to the sole discretion of the Administrator of the EPA.

I think with the addition of your amendment, and Senator Nelson's and Senator Stevenson's proposals included within the language of the bill, that that would provide sufficient legislative history and an indication of the committee's concern that there are very serious dangers that must be dealt with not only at the handling and usage stages, but which must be considered in classifying whether a pesticide is for restricted or general use. In addition, the dangers to human beings would have to be considered as factors in the experimental use permits which Mr. Krebs spoke of, and in testing on farmworkers directly, as is usually done under an experimental use permit.

These dangers have to be written into the law or we will be faced with more difficulties. In view of the present and past record of the EPA, I, for one, am not willing to sit back and abandon our efforts and leave the welfare of farmworkers to the sole discretion of the director of EPA.

Instead, I think he has to have a law that mandates requirements in the whole process of whether pesticides are registered.

Senator HART. It is true, isn't it, that the EPA does now require testing on the effects of the pesticides, the effects that they may have on farmworkers when application is made?

Mrs. KANTOR. I am not exactly certain of the present state. I do know that under the Senate Agriculture Committee version and as passed by the House, it is within the discretion of the Administrator of EPA whether to require that these test data are submitted to EPA. While it is required that the manufacturer conform to these tests, although he does no have to have tests performed specifically on workers, section 3(c)(1)(d) that I mention in my written statement, in the registration process the manufacturing company need not furnish test data unless specifically requested by the Administrator.

Senator HART. And one of those Nelson-Hart amendments does require that.

Mrs. KANTOR. That is correct.

Senator HART. Do you in addition to your specific support for the Stevenson amendments, support the other amendments that are pending?

Mrs. KANTOR. Yes, in fact, I consider the Hart-Nelson amendments really to be the priority ones that are essential to have any effective control of pesticides. In my opinion, it is more of a promotion of pesticides bill unless you include those amendments. It is simply that I am here on behalf of farmworkers and I feel they are too often neglected. Fortunately we have spokesmen like you to impose controls on producers and manufacturers, but most definitely I consider them essential.

Senator HART. Mr. Berman, was there something you wanted to add?

Mr. BERMAN. No; I think that was one of the points that Senator Nelson dealt with, that we are dealing with farmworkers in Iraq, and they are the people who are growing food, and if we have to wait for that kind of situation to occur in this country in order to get strong legislation, then I think we are in very serious trouble.

Senator HART. I hope we won't have to wait for that.

Thank you very much.

Mrs. KANTOR. Thank you.

(The statement follows:)

STATEMENT OF VALERIE KANTOR, MIGRANT LEGAL ACTION PROGRAM

The Migrant Legal Action Program, and the farmworkers it represents, are grateful for the opportunity to again urge Congress to enact provisions for the protection of farmworkers and others from the dangerous and deadly effects of pesticide poisoning.

The Migrant Legal Action Program is a federally funded, non-profit corporation organized to work for charitable and educational purposes, for the special benefit of poor and distressed migrant and seasonal farmworkers. We testified before the Senate Agricultural Research and General Legislation Subcommittee in March when it was considering H.R. 10729,, as did several other farmworker representatives having firsthand knowledge of the dangers of pesticides to field workers. At that time we included in the record some of the most recent studies that had been done by private doctors on pesticides and farm labor families.

Not included in the hearing record of the Agriculture Committee were the public studies that were subsequently discovered to be in the possession of the Environmental Protection Agency, which would have further documented the problem, as well as the need for very carefully considered legislation on this topic. Perhaps if the Agriculture Committee had had the benefit of EPA's knowledge from these studies, more serious consideration would have been given to the amendments proposed regarding farmers, farmworkers and others who come into direct contact with the economic poisons or their residues.

However, EPA was silent on the issue of dangers to man, and the Committee on Agriculture dismissed the recommended amendments without even a mention of farmworkers or field workers at any point in the bill as reported out of the Agricultural Committee or in the report accompanying that bill.

The report at page 14 cavalierly states: "The bill provides complete safeguards to protect farmers and others coming into contact with pesticides or residues."

The various amendments offered were rejected by the Committee's rationale that "by specifically mentioning particular areas protected by the general provisions, there might be some suggestion that the general provisions should be construed to cover less than actually intended," citing the definition of "environment" in Section 2(j) as including *all men*, whether or not they come into contact with pesticides or pesticide residues.

It is obvious to anyone who has dealt in farmworker issues that farmworkers are usually not included within a definition of "all men" any more than they were considered by the Committee on Agriculture who omitted any mention of them in their bill or report; or any more than the chemical companies consider farmworkers as human guinea pigs when they conduct experimental tests on them in California and elsewhere.

On the same basis, if it appears so certain that the labelling and classification of pesticides under the Committee bill will protect farmworkers, farmers, and others coming into contact with pesticides or residues, why then did the Committee include at page 82, line 22, in discussing classification for restricted use: "Injury to the applicator" to amplify "substantial adverse effects on the environment."

The third amendment offered by Senator Stevenson to this bill proposes the inclusion of the following language after applicator, "farmer, farmworker, or other person who may come into contact with the pesticide or pesticide residues."

How does the Committee justify the inclusion of one special interest group, "the applicators," without including specifically those who are in the field at the time it is being applied or those who come into the field after the pesticide is applied, or those who are in an adjacent or neighboring field at the time of application? There can be no moral or legal rationale for failing to include farmer and farmworker injuries in the determination for classifying a pesticide for restricted or general use.

At this time, I urge the Commerce Committee to remedy this gross inequity by including the suggested Stevenson language at this point, or making it abundantly clear in the definitions or legislative report accompanying the bill, that all those who come into contact with the poison at any stage of operation—and we should not limit ourselves solely to the interests of farmworkers, even though they have been abused more than any other workers by the use of pesticides—but it should be made clear that the Committee is concerned with the dangers to humans at all stages of exposure to these poisons.

This would start with proper labelling in any facility whether for the manufacture, formulation, mixing or application of a pesticide and continue through the monitoring stage of any work environment where employees are engaged in the manufacture, formulation, application, or exposure to these pesticides.

The EPA has dealt with establishing tolerance levels for various pesticides based on the dangers of non-washable residues to the ultimate consumers of food products. However, the EPA has not *publicly* concerned itself with the tolerance levels for these various poisons on people who are exposed to them in great concentrated quantities over a sustained, prolonged period of time.

While we can look in years ahead to put pressure on the Occupational Safety and Health Administration for enforcing regulations [that are yet to be developed] concerning field reentry times and the whole gamut of occupational exposure in the work or field environment, FIFRA or the Federal Environmental Pesticide Control Act, is the only vehicle for regulating the manufacture, production, registration, and use of pesticides.

I cannot stress too vehemently the absolute necessity for considering the dangers and results that these poisons pose to those who come into contact with them on a daily basis. And this consideration must play a determining factor in the registration criteria and in the classification process, as well as in the strictures regarding labelling and usage.

We are unable to explain the disregard of these amendments by the Agriculture Committee, and we are not satisfied that we should abandon our efforts to call this to the attention of Congress.

I have in front of me the Table of Contents from three days of hearings held in 1969 by the Subcommittee on Migratory Labor. These hearings were concerned exclusively with Pesticides and the Farmworker, and the report totals over 800 pages of testimony, with specific examples of pesticide poisonings to farmworkers in Texas, Washington state, Minnesota, Florida, South Carolina, Colorado, Mississippi, South Dakota, Maryland, Connecticut, Arizona, Tennessee, Ohio, North Carolina, Massachusetts, New Jersey, Alabama, Pennsylvania, Vermont, Nebraska, and California, among others.

Since the time of those hearings further atrocities and more lives have been lost—not only through accidents—but for the most part through unregulated, direct exposure to these poisons.

In view of this public record, together with the revelations contained in the documents in the possession of the EPA, this Committee should be extremely cautions in its deliberations on this measure.

To me, the most serious shortcoming of the entire bill is the amount of regulation and determination that is left entirely to the sole discretion and interpretation of the Administrator of EPA.

"In the Registration process, the manufacturing company need not furnish test data UNLESS requested by the Administrator;" § 3(c)(1)(D), p. 78, lines 11–12).

"The Administrator has complete discretion to determine whether a pesticide is to be classified for general or restricted use or both; or if a classification of a pesticide should be changed or restricted in any way;" (§ 3(d)(1) and (2)).

I urge this Committee to insist on adequate protections for those who are exposed directly to the dangers of these poisons, along the lines indicated by the Stevenson and Hart-Nelson proposals, because it is our opinion that the dangers are too great to relegate to a passing inclusion within the definition of "environment" and too serious to leave to the complete discretion of the administrator of the EPA.

Senator HART. Next, we will hear from individuals who themselves represent organizations that long have been involved in the environmental protection effort, and we have suggested that they come up together and join at the table here. For the Sierra Club, Mr. William Futrell, who is a member of the board; and for the Environmental Defense Fund, Mr. William Butler; for The Health Research Group, Ms. Anita Johnson; for the National Audubon Society, Ms. Cynthia Wilson; and for the National Wildlife Federation, Mr. Joel Pickelner.

Let me order printed in the record all the statements given.

You may proceed, Mr. Futrell.

STATEMENTS OF WILLIAM FUTRELL, MEMBER, BOARD OF DIRECTORS, SIERRA CLUB; WILLIAM BUTLER, ENVIRONMENTAL DEFENSE FUND; ANITA JOHNSON, HEALTH RESEARCH GROUP; CYNTHIA WILSON, NATIONAL AUDUBON SOCIETY; AND JOEL PICKELNER, THE NATIONAL WILDLIFE FEDERATION

Mr. FUTRELL. Thank you, Mr. Chairman. Presently, I am Associate professor of the School of Law of the University of Alabama, teaching courses in environmental legislation and law. The Sierra Club appreciates the fact that the Senate Commerce Committee is giving attention to this legislation.

This particular proposal has had a long and arduous history starting with the hearings on H.R. 4152, and Senate 745 at the beginning of 1971.

Those bills held out the hope that the promise of the Mrak Commission report, would be enacted into law and that we would indeed see in 1972 the passage of effective pesticide regulations. The bill

that came out of the House of Representatives was disappointing. It was the subject of debate on the floor of the House and a rather close vote resulted on various amendments offered there.

During the last months, the Senate Agriculture Committee has given its attention to the bill and now the fact that the Commerce Committee is giving its attention to this matter is particularly gratifying in that representatives from this committee will attend the joint conference on a final reconciliation of the House bill and what we hope will be the stronger Senate bill.

We had the opportunity to appear before Senator Allen's Subcommittee on Agricultural Research. Our remarks there focused on the provisions of the House bill, concerning judicial review and the indemnities provisions. The Senate Committee on Forestry and Agriculture has corrected these difficulties with the House bill.

These Senate changes are important and should be defended in the conference. The judicial review provision had used a new standard called "party at interest."

This term was unclear and suggested that only a party to the agency hearing, such as the pesticide manufacturer, might seek judicial review. At best, the language was suggestive of litigation and would have had to have been defined in costly court action by environmental groups.

We are pleased that the Senate Agriculture Committee struck this term and substituted instead the tested term from the present Federal Insecticide Fungicide Rodenticide Act, "party adversely affected," which has been interpreted by a series of cases.

An important way in which this bill can be strengthened is to add a provision allowing citizens suits. The Michigan Environmental Protection Act of 1970 and the Clean Air Act of 1970 are examples of citizens suit legislation. I do not have to describe to you the effect of the Michigan statute nor, after the recent hearing on S. 1032, describe the citizens suits.

The need for the citizens suit remedy is even greater after the Supreme Court's recent unfortunate decision in the *Mineral King* case. Certainly, the predictions that had been made to the effect that Michigan courts would be clogged with a huge backlog of citizens suits making them unavailable for any other type of business has not come to pass.

The opportunity for a citizen to get a hearing on those matters which concern him and threaten his health and environment should be a certainty. The availability of a court of law to hear the controversy should be one of his rights. As a lawyer and law professor, I believe that access to the courts is one of the most effective means for people to participate directly in environmental decisions. It may be the only way to do so effectively.

We hear much of the fact that the courts will be clogged with these types of cases if a citizen's suit provision is enacted. The contrary is the case. The burden of environmental litigation is heavy, both in monetary expense and in the disruption of the lives of those who bring the lawsuits.

I know this from the personal experience of my friends who have been plaintiffs in environmental litigation.

Next Monday the Tennessee-Tombigbee lawsuit against the Corps of Engineers will go to trail in Aberdeen, Miss. The individuals who brought this suit have suffered; at least one has had his job terminated, and all have received an inordinate amount of public and private abuse because of their association with the lawsuit. The lead plaintiff's cause has been taken up by the grievance committee of the American Association of University Professors, but those in the community know the burden that the plaintiffs in this lawsuit have undertaken to redress the environmental grievance.

I recently met with the citizens group which is bringing a lawsuit to stop the building of an interstate highway through Overton Park in Memphis, Tenn. Theirs is a story of a several year long struggle to raise funds, of official indifference and hostility, and of dogged perseverance. The experience of people such as these bears out the observation of the court in the *Scenic Hudson Preservation Conference* case that "the experience with public actions confirms the view that the expense and vexation of legal proceedings is not lightly undertaken."

Standing was not an issue in either the *Tennessee-Tombigbee* or the *Overton Park* cases. Both involved specific pieces of real estate and local persons served as plaintiffs, and because of these local connections, the environment had champions who undertook the legal battle.

The possibility of widespread environmental degradation is just as likely from pesticide abuse as from the misplacing of a highway or a large canal. Highways are tangible projects with a specific locus. The victims of pesticide programs have no specific geographical locus. Yet there are thousands of Americans who are deeply concerned over such questionable pesticide programs as the recent Gypsy Moth and fire ant eradication projects. Provisions for citizens suits are particularly appropriate in the pesticide regulation field. Without a citizen suit provision, a reluctant court might be hesitant to uphold a local citizen's right to challenge a multi-State massive campaign for the aerial spreading of poisons.

Citizen initiatives in the courts have already made great contributions in the pesticide regulation field. Without environmental lawsuits, it is doubtful if the agencies involved would ever have undertaken the examination of the role of DDT which is still continuing under court order.

If ever environmentalists needed access to the courts they need it in the pesticide regulation field. A special case can be made for legislation enabling citizens suits in the pesticide regulation field just as was done in the air pollution field.

Chemicals broadcast in the environment are as pervasive and as ambient as particulate matter in polluted air. The field of pesticide pollution needs the same strong tool provided for air pollution control—the citizens suit.

If you talk to lawyers who try air pollution suits, like Mat Walker in San Francisco, they will tell you that the citizen's suit as a backdrop, as the remedy in the arsenal remaining behind the local attorney, who tries these citizen air pollution suits, is a very real tool and is a stimulus to the district attorney and to the State attorney doing his duty in this field.

For these reasons we fully endorse the Hart-Nelson amendment No. 1011, which would add a citizen suit provision to H.R. 10729.

In closing, Senator Hart, we would again like to state the Sierra Club's support of the other amendments which you and Senator Nelson have introduced to make H.R. 10729 an instrument for environmental protection. We are grateful to you for the leadership you have given on this issue.

I have read the statements of Miss Johnson and Mr. Butler, Miss Wilson and Mr. Pickelner regarding the prior disclosure of test data and mandatory disclosure of data, the exclusivity of test data, the hearing structure, the advisory committee procedure, and the other provisions of the Hart-Nelson amendments, and I concur in the remarks they will make.

Senator HART. Thank you, Professor. Every time one has a chance, I think the point should be made. True enough, any suggestion of a citizen's suit, whether a broad, across-the-board one, or a section in a specific consumer protection law, always elicits the cry, "You will badger the industry to death, you will jam up the courts."

And "It only takes $2 to file a lawsuit."

Mr. FUTRELL. More than that, $20 or $30, and a lot of grief.

Senator HART. The commission across the board in the Environmental Protection Act to which you made reference has been on the books now for close to 2 years. Heaven knows it was widely advertised, and there have been about 35 actions filed. That is about two lawsuits a month, and as far as I am aware, none has been regarded as frivolous.

In cases thus far disposed of, the courts have indicated competence to evaluate the competing claims.

Mr. BUTLER. Mr. Chairman, and members of the committee, my name is William A. Butler. I am Washington counsel of the Environmental Defense Fund (EDF). EDF is a nonprofit, public-benefit corporation which may be described as a legal action arm of members of the scientific community who are concerned with environmental degradation.

I wish to thank you for holding these hearings and for inviting an EDF representative here today to testify on the bill entitled "The Federal Environmental Pesticide Control Act of 1972."

The scientists associated with EDF have been interested in the impact of pesticides on the environment, human health, and upon the effectiveness and economics of agricultural production for many years. For example it has been our organization's and my personal privilege to represent not only EDF, but many of the groups here represented this morning, in the marathon DDT cancellation proceedings which reached a successful culmination yesterday after approximately 5 years of citizen volunteer effort.

Through the experience gained during the lengthy court and administrative proceedings involving cancellation of DDT, as well as similar litigation involving other environmental damaging pesticides, I think that the Environmental Defense Fund has gained much practical experience from which to evaluate the strength and weaknesses of the proposed bill being discussed today.

Much of the proposed new bill is a substantial improvement over the statute it has displaced. However, there are several deficiencies in the current version of the bill which will greatly reduce the degree

with which it fulfills the goal of rectifying omissions and weaknesses of the present version of the Federal Insecticide, Fungicide, and Rodenticide Act.

In short, in its present version, the bill is not nearly so effective as it could be. Its short comings, will in the long run, adversely affect the public, EPA, and the pesticide industry alike.

I am submitting to the committee, with your permission, sir, a detailed analysis of our views of the deficiencies of this version of the bill. These comments are too detailed, lengthy, and specific to be presented here today in their entirety.

I hope, however, that they will be of some benefit to you and the committee's staff assessing proposed changes in the bill.

At this time, I would like merely to summarize the most important general criticisms we have of the bill in its current version. Given the shortness of time, I will also restrict our comments by prearrangement with other members of this panel to those portions of the bill which deal with the scientific advisory committee, the structure of the suspension, and cancellation hearings, and with the provisions for judicial review.

In summary, our comments on these three areas of the bill are as follows:

(1) ADVISORY COMMITTEE

Both the House and Senate Agricultural Committees revisions of the present law in regard to advisory committees are generally wise. However, as was inferred by the proposed amendment offered by you, sir, and Senator Nelson, for H.R. 10729, there is need to be more specific about the mechanisms by which advisory committees are appointed, or constituted, as well as about what witnesses they hear.

In the past, advisory committees on DDT, 2–4–5–T, aldrindieldrin, and mirex, have not been representative of the scientific community as a whole, nor have been the lists of witnesses that they heard.

It may well be that this is properly a matter for regulation by the EPA, but general phrasing in the act that the advisory committee personnel should represent a balanced segment of the scientific community involved, and that they should hear evidence from a representative cross-sample of interested parties would be beneficial.

The species then could be left to regulation.

The current time provided for the report of the advisory committee is probably too short. In the present version, it is 60 days. The present law provides for an extension of time which inevitably has been requested by the members of the committee, all of whom have, of course, additional professional duties than merely serving on an advisory committee.

In order to do a scientifically adequate job, there should be at least a provision for some extension of time at the discretion of the Administrator.

(2) STRUCTURE OF EPA'S SUSPENSION AND CANCELLATION HEARINGS

The most glaring omission in the present version of the bill, as reported out by the Senate Agricultural Committee, concerning the structure of the suspension hearings, is that citizen action groups such as ours would be excluded from suspension hearings, and permitted only to participate by filing written views.

Allegedly, the purpose of this omission is to reduce potential delay. However, citizens environmental groups who very likely initially brought the petition for suspension would be all in favor of expediting the hearings and there is no reason why their participation, particularly if consolidation is required by the hearing examiner, should delay the proceedings.

Past experience has shown that participation of third party citizen environmental groups need not delay such administrative proceedings, and can add a great deal to the scientific knowledge which is brought to bear on important decisions of the hearing examiner.

(3) PROVISIONS FOR JUDICIAL REVIEW

The version of the bill reported out by the Senate Agriculture Committee provides for review of failures to suspend or cancel a pesticide in the district court. In contrast, where there has been an administrative hearing, all judicial review is to be in court of appeals.

This constitutes a change from present law, which requires appears of all final orders, whether the result of an administrative hearing, or the failure to hold same, to take place in the court of appeals.

Practical experience has shown that the court of appeals is infinitely preferable to the district court for such appeals, and therefore any change in the present law to require any final order to be petitioned to the district court could only lead to interminable delays and is therefore undesirable.

It has been very important to the Environmental Defense Fund and its clients in the DDT litigation, for example, to get prompt review in the court of appeals of the failures first of the Department of Agriculture, and then of the EPA, to suspend or cancel DDT. Had EDF been required to go to the district court for this review, where the dockets are much more crowded, the decision won yesterday might have been either greatly delayed or never come at all.

It is significant that the EPA itself agrees with this view, and recommends that all appeals for final orders under this act should continue to go to the court of appeals. I here quote from EPA's April 17, 1972, submission to Senator Allen making comments on the proposed amendments to H.R. 10729 sponsored by Senators Hart and Nelson.

> We (EPA) favor all review in the courts of appeals because district court proceedings are time-consuming. District court review, moreover, tends to create some confusion. Instead of coping with legal constructions reached by eleven circuits, and speedily resolved in the Supreme Court, we must administer a statute under the supervision of some one hundred district courts.
>
> It is inevitable that the courts, in reviewing decisions to suspend or orders refusing not to cancel or suspend, will flesh out the substantive standards of the act. Indeed a district court in finding a refusal to cancel is arbitrary will announce the outer boundaries of legal criteria that the Administrator must apply at the hearing.
>
> That hearing record will then be reviewed in a circuit court, perhaps a circuit that does not supervise the district court that ordered cancellation. It would not be long before the annotated reports on this legislation are equal in length and complexity to those following the ICC's legislation.
>
> The last point of our (EPA) amendment is to return to the courts of appeals the task of reviewing those decisions not to cancel taken because the Administrator finds that there is no "new substantial question of safety." The decision not to

cancel is taken based on a compiled documentary record which includes the registration file, scientific documents which are exhibits and a published order with findings.

Written petitions and comments are made part of a formal docket. This is, we believe, a sufficient record for review by a circuit court.

The Environmental Defense Fund concurs in these views of the Environmental Protection Agency, and on the basis of experience, suggest that all judicial review be held in the courts of appeals.

With the improvements we have suggested today in H.R. 10729, as well as those which we will cover in greater detail in our submission to the committee, we believe the American public will be greatly aided by a strengthened regulatory procedure which will not only prevent harmful economic poisons from ever reaching the market, but which will prevent the pesticide industry from incurring the heavy economic losses involved in registering a pesticide only to have it subsequently suspended or cancelled.

Further, the public, as represented by citizens environmental groups like those sitting before you today, will have a say in the ultimate determination of the important questions facing the society regarding pesticides, human health, and the environment, instead of leaving these decisions entirely up to the pesticide industry and the regulatory agencies.

Thank you.

I might also say I have read the statements of the other members of the panel and agree with their comments.

Senator HART. We will welcome the detailed analysis that you will provide.

(The analysis follows:)

SUPPLEMENTARY COMMENTS BY WILLIAM A. BUTLER ON BEHALF OF THE ENVIRONMENTAL DEFENSE FUND

The following are the supplementary comments of the Environmental Defense Fund (EDF) submitted in reference to HR 10729:

The Environmental Defense Fund wishes to draw to the Committee's attention the following points which were not adequately covered in the comments offered June 15 by interested persons appearing before the committee, and which in our opinion are not fully covered in the proposed amendments to this Bill offered by Senators Hart and Nelson.

1. The Environmental Defense Fund opposes Section 23(c) permitting state registration of pesticides for specific local needs for limited but extendable time periods.

EDF feels that this provision is unnecessary, will be difficult to enforce, and may well provide a huge and unnecessary loophole in the regulatory provisions of this act.

2. Concerning Section 10 of the Bill, dealing with disclosure of information, EDF feels that the Environmental Protection Agency (EPA) should be permitted to determine in the first instance what constitutes a trade secret as is currently provided in EPA's regulations, and not be bound by the views of the pesticide manufacturers submitting the data, as currently is provided in the Bill. Ultimately the determination of the Environmental Protection Agency can be challenged in the courts, but in the first instance, EPA should be permitted within the carefully circumscribed confines of its regulations to make this determination. (The current version of the Bill, as interpreted by the Senate Agriculture Committee on page 10 of its report, at subparagraph 8, expresses a desire to "leave the determination of what is a trade secret to the courts (rather than the Administrator)." If court action is required for every Freedom of Information Act request to EPA, the purposes of that Act will be effectively thwarted.

3. EDF feels that the question of human safety is inadequately covered in the bill as presently drafted and supports the original amendment number 3 offered by Senator Stevenson. This amendment would provide in the sections dealing with classifications for restricted use that not only "applicators" but also "farmers, farm workers, or other persons who may come into contact with the pesticide or pesticide residues," should be specifically protected. There is value in this instance of making explicit what probably is already implicit, *i.e.*, that hazard to farm workers from pesticides is a subject of major concern in classifying and registering a pesticide.

4. As part of Section 3's discussion of the control of pesticide use, EDF feels that EPA should be left with the option to create a permit system for particularly dangerous pesticides not sufficiently hazardous either to suspend or to cancel outright. If not a permit system, EPA should be given the express authority to require the actual physical presence of a certified applicator during the application of a pesticide which EPA determines to be particularly hazardous.

Further, there should be a specific requirement in Section 3 that where the same pesticide is registered for both restricted and general use, that separate packaging as well as separate labeling should be required.

5. The time limits of Section 4, within which the provisions of this Bill are to become effective provide far too much time to elapse before the Act becomes law.

6. Section 14(a)(3) provides for an automatic violation hearing held where an alleged violator resides. This should be changed to require a hearing only if requested by either party. The Bill or committee report should make clear that it is contemplated that violation hearings will be the exception rather than the rule, that other means of defense against charges of violation (such as correspondence by the accused's attorney) will be relied upon in most instances, and that if there is a hearing, it should take place at a place of mutual convenience. To require that in each instance of a violation an adversary hearing be held where the alleged violator resides would be practically so onerous as in fact to cripple any effective enforcement of this Act.

7. In the discussion of Section 6(c) dealing with hearings, it is provided that "other interested persons with the concurrence of the registrants" may "contest the denial, cancellation, or suspension of registration, or a change in classification, where the registrant fails to do so." It is unclear from the wording whether the registrants approval is also required to protest a *failure* to deny, cancel or suspend. It should be made clear that this approval is *not* required since the party contesting the *failure* to deny, cancel or suspend would always have interests adverse to the registrant, and therefore would be unlikely to get from the registrant permission to contest an EPA decision favorable to the registrant.

Further, it should be specifically stated in the law that these "interested persons" must meet the standing requirements currently governing court actions.

8. Section 20(a) states that EPA should be required to solicit the views of the United States Department of Agriculture before it publishes any regulations. This provision should be made more specific by requiring that EPA solicit Agriculture's views prior only to the publication of *final* regulations on matters covered by *this* statute. There is no reason why EPA need solicit USDA's views prior to the publication of draft regulations.

9. Provisions of Section 24(b) calling for the exemption of pesticides regulated by another federal agency are entirely superfluous and present a potential loophole which should be closed by elimination of this provision. Because DDT or Mirex, for example, are now restricted to USDA use does not mean these economic poisons should be exempt from the provisions of the Act.

10. The reference in Section 2 to arsenic should also be eliminated since there is no reason specifically to single out this one economic poison for comment, except for the fact that arsenic is currently under review by EPA, its uses may be banned, and pesticide manufacturers currently making use of arsenic would like to argue that in recent legislation Congress focused specific attention upon arsenic, this implicitly supporting its continued use. For this very reason, specific reference to arsenic is unnecessary and should be eliminated.

II. The Environmental Defense Fund wishes specifically to associate itself with the following comments concerning this Bill as reported out by the Senate Agriculture Committee, and as referenced to a greater or lesser degree in comments of others before the Committee on Commerce on June 15, or in the proposed amendment by Senators Hart and Nelson.

1. The provisions in Section 6 concerning the appointment of the advisory committee are vague as to who does the appointing, qualifications of persons to be appointed, and to whom the advisory committee ultimately reports. Specifics of appointment should be spelled out in legislation to a greater extent than currently.

Further, there should be an option left for the Administrator to extend the amount of time within which his advisory committee may report. Many of the questions involved may require lengthy study. Each of the four advisory committees appointed to date has asked for an extension of time in which to file its report.

2. Provisions of Section 6 regarding suspension hearings do not provide for the personal participation of counsel for the environmentalists who may well have brought the initial suspension petition. This omission should be rectified. Those calling for suspension are unlikely to delay the suspension hearing they have requested.

3. Provisions of Section 15(a) for judicial review currently state that appeals after suspension or cancellation hearings should be in the Court of Appeals, whereas appeals from EPA's failure to hold suspension or cancellation hearings should be in the district court. Such a distinction is unwise. The provisions of the current law should be retained, *i.e.*, that all appeals from a final order of the Environmental Protection Agency should be filed in the Court of Appeals, as is the case with other final orders of administrative agencies. The only reason given by the Senate Agriculture Committee for district court appeals is that allegedly failure to hold a suspension or cancellation hearing does not create a reviewable record. EDF's litigation in the D.C. Circuit Court of Appeals regarding failure to suspend DDT and Aldrin/Dieldrin shows this is not true. There will be an adequate record in either case for review in the Court of Appeals. The case law on DDT, as well as Aldrin/Dieldrin supports the position that petition of EPA's decision not to hold suspension and cancellation hearings can be heard by the Court of Appeals.

4. There should be added to the Bill provisions of the nature of amendment number 1013 of Senators Hart and Nelson requiring specific notification to foreign governments receiving pesticides exported from the U.S. regarding any relevant and current cancellation or suspension notices outsetanding here involving the pesticides in question. Further, additional information should be as a matter of course provided to foreign governments concerning potential hazards of pesticides being sold them by U.S. concerns.

5. The provisions of Section 17 calling for possible federal and state agency exemptions from the provisions of this bill are entirely superfluous and open large loopholes which should not be permitted to exist. In several instances involving the U.S. Department of Agriculture, for example, alleged overuse of pesticides has been the focal point of litigation. The State of Florida has been criticized in the past for permitting intrastate uses of Azodrin resulting in bird kills, as another example. There is no reason why federal and state agencies should be exempt from the strictures of the proposed Act. (This argument is particularly compelling in the case of state agencies: the provision for exemption of state agencies was added by the Senate Agriculture Committee for reasons nowhere explained in its report.)

6. The provision of Section 23 prohibiting political subdivisions of states from adopting stricter regulations than the state or federal government should be dropped. There is no reason why counties or other political subdivisions of a state cannot decide that they wish not to have a particular pesticide used within their boundaries. Massive state spraying for gpysy moths in the Northeast is an example of an instance in which many local communities, and quite properly, have opted out or banned pesticides being so used. Any amendment, however, should not permit political subdivisions of states to be more liberal in their treatment of pesticides than the relevant state or federal law.

7. Section 14 should provide for increased maximum penalties for violations of the Act by private pesticide applicators. In an age of corporate farmers, a court should be given the opportunity to assess a fine adequate to deter repeated violation of the Act.

8. A citizens suit provision such as that of Senators Hart and Nelson's amendment number 1011 should be added to the Bill. It could be very similar to that included in the Toxic Substances Bill, the Federal Clean Air Act, and the Michigan Citizens' Suit Act. The ability of citizens to enforce the Pesticide Act if responsive officials fail to do so is a very important ingredient in the effectiveness of the entire Act.

9. The provisions of Section 10 dealing with disclosure of information should make it clear that registration data submitted in support of a proposed registration by a pesticide maker should be made available to the public *prior* to registration in order to allow informed public comment. Comment *after* a pesticide is registered is too late. Wording such as that of Senators Hart and Nelson's amendment 1004 is embraced by EDF.

10. The provisions of Section 3 should make it perfectly clear that data submitted in support of pesticide registration should not be exclusive, and that the Environmental Protection Agency should be able to use the test data submitted by one company to assess the adequacy of test data submitted by another company. Current wording of this section seems to have two contradictory views juxtaposed within the same sentence on this question.

11. The criteria for registration of pesticides as discussed in various provisions of Section 2 require changes. As is suggested by proposed amendment 1012 of Senator Hart and Nelson, considerations of "benefits" should be dropped from the definition of what constitutes "substantial adverse effect upon the environment" since what is really involved here are two distinct questions: 1, are there adverse environmental effects from the pesticide; and 2, if so, are these adverse effects outweighed by the supposed benefits of the pesticide? There is no reason why these two questions should be blurred as in the present version of the bill. The balancing of benefits and risks, in other words, should not be done *after* it is separately determined whether there are adverse environmental effects from use of the pesticide, and whether the pesticide has benefits.

12. EDF suggests that all reference to lack of essentiality of a pesticide constituting no bar to its registration be dropped from Section 3, since EPA has suggested that the sense of this provision is implicit in other provisions of the Act: in its present wording, the clause seems affirmatively to encourage registration of superfluous pesticides.

We hope the above elaboration of EDF's views supplementing its formal statement will be of use to the Committee in its consideration of this most important legislation, and we thank the Chairman for his invitation to submit our proposals.

Senator HART. Having been involved so heavily with the DDT litigation, how do you react to the questions that are now being raised as to the health threat that is represented by some of the pesticides which are suggested as suitable, appropriate, effective alternatives to DDT?

Mr. BUTLER. In brief, I would answer in this fashion, which incidentally is the answer that both the environmental groups and EPA have accepted. First, 86 percent of DDT's current use domestically is on cotton. Now, there are two, not one, alternative pesticides currently used for DDT. They are the organophosphates about which we have heard so much, and the carbamates, which are in no way as toxic as the organophosphates. The carbamates like carbaryl are less toxic than the organophosphates and frequently are as effective.

Second of all, there is a difference between ethyl parathion and methyl parathion. Ethyl parathion is the one that has been generally involved in the accidents. In contrast, is methyl parthion that is usually use on the cotton fields. Methyl Parathion is, however, acutely toxic, but in the short term, as opposed to chronically, or long term as with DDT. Currently the most commonly used formulation of DDT—DDT is never used alone on cotton—includes methyl parathion. This is to say that methyl parathion is already currently being used with DDT. Therefore, the health hazard posed by methyl parathion without DDT remains about the same as with DDT.

Methyl parathion currently is already the first choice pesticide against the boll weevil, which is the No. 1 cotton pest in the Southern United States.

In those States such as California, Arizona, Arkansas, and Texas, which have either banned DDT on cotton or do not recommend it, methyl parathion has been used for a number of years. With familiarity of usage comes not contempt, but caution. The accident rates with methyl parathion have gone dramtically downward in the last 10 or 15 years, and I think in the last few years there have been no accidental deaths attributable to it whatsoever in the United States.

The last point is that with the banning of DDT there will not be, at least in the long term, an exact one-to-one substitution of methyl parathion, or any other pesticide for DDT. The U.S. Department of Agriculture, the environmental groups, and the scientific witnesses at the DDT hearings agreed that the proper approach for the cotton industry long term is integrated control, which is a many faceted approach.

The objective of integrated control is to use less pesticides overall. On cotton, integrated control includes what is called the diapause method. One uses sex lures releases of sterile males, and then relies largely on predatory insects. Later in the season individual trained farmworkers or "scouts" determine which fields need to be sprayed for what insects and at what intervals. For insecticides, one tries to use less persistent pesticides, such as the carbamates, in small doses only where they need to be used. Last of all, late in the season after the cotton crop has been harvested, one destroys all the cotton stalks by shredding and plowing them under, so as to prevent any of the pest insects from hibernating in them over the winter.

The Department of Agriculture has such a program operating in the State of Mississippi with this very goal in mind. It does not use methyl parathion, and does not use DDT. DDT would kill the beneficial insects over an unacceptably long period of time. Arkansas does not recommend DDT on cotton, uses the diapause system, and gets along without major accidents.

My last point, sir, is this: It is most likely that accidents attributed to "parathion" occur particularly with respect to ethyl parathion, particularly with children, and particularly through the careless discarding of containers which formerly held these substances. There are and should be provisions in this bill to control disposal of the containers and to reduce these accidents.

The small farmer, the illiterate farmer, the man with very few acres, he is the man that is theoretically the most likely to have an accident with a toxic pesticide, since he probably doesn't even have sophisticated ground application equipment. But the sad fact is that this man, in fact, is currently in such financial straits that he does not apply any pesticides at all. He just prays that he will be able to raise a crop on his few acres and earn a few dollars without the additional expense of pesticides.

In summary, we feel, along with EPA, that the banning of DDT will not endanger the farmer's health, and in fact will hasten that day when he uses less pesticides overall, and uses a more sophisticated, broader and cheaper approach to handle the problems of cotton pests. In the very short term, it is possible that there will be increased use of the organophosphates because DDT has been banned, but the organophosphate used will most likely be methyl parathion, not ethyl parathion, which is the real killer.

Senator HART. If the bill that is before us with the amendments that you are supporting had been the law when you first undertook to put DDT out, would the time interval have been shorter?

The professor mentioned the time that it has taken us with respect to DDT. I am asking you would the time have been just about the same even under the legislation we are considering?

Mr. BUTLER. As a lawyer, that is a very difficult question to answer, because it really depends on the other side's legal arguments.

However, I would suggest that had the bill being discussed today been law, we could have gotten to the resolution of this problem sooner, given the creation of the EPA, their new regulations, and their seeming willingness to address these problems. Earlier, before the creation of EPA, there really, I think, was no responsible administration agency that was quite as concerned as EPA currently is about pesticide problems.

In short, while obviously, it is speculation, I think that the amendments to this act, the bill as it is presently written and amended, would have hastened effective pesticide enforcement. However, it is also true that public awareness of pesticide problems in 1972 is much greater than in 1967 and 1968.

People are concerned about these problems now, when in those days they really were not.

Senator HART. Thank you.

Ms. JOHNSON. I am Anita Johnson, attorney with Ralph Nader's research group in Washington.

The bill before us directs the EPA Administrator to make the safety and efficacy data supporting a pesticide registration available to the public within 30 days. I support the principle that registration data be made public for two reasons. First, the Government needs public input into its decisionmaking to make wise decisions. Second, secrecy leads the public to suspect and mistrust all governmental decisions.

As Hart-Nelson amendment No. 1003 provides, however, the pesticide information must be available to the public before the registration decision is made; not after. In the area of pesticides and other toxic substances, the regulatory decisions have such weighty health consequences that we cannot leave them to a few EPA officials. The entire scientific community should participate. Our knowledge about the long-range effect of environmental chemicals is so limited, that every available resource must be available.

The scientific community cannot meaningfully participate unless it has access to the data; since, in many cases, the compounds are new and do not yet have extensive published scientific literature about them.

The only data on the subject is often in EPA files. Scientists must be able to inspect the data to determine if the tests are adequate for the type of substance and its impact, and to determine he significance of the test results. I have just completed a study of the medical officer's job in the FDA Bureau of Drugs. That study indicated that in many cases in the case of new drug applications the raw data is not even being looked at.

That means that decisions on the safety of drugs that we are ingesting are being made, in many cases, on the basis of summaries which the industry provides FDA, not on the raw data which the industry gives FDA.

Now, the pressures and procedures within the Food and Drug Administration are such as to put a premium on quick decisionmaking, on sloppy decisionmaking, on reliance on purely industry summaries of raw safety data.

The point here is that the raw data in the FDA at least is not being looked at. There is no reason to believe, given equally organized industrial forces in the EPA, that that agency in a couple of years' time will be much better.

What this means is that in many cases the only people that would be looking at the raw data on the safety of the pesticides would be a public interest scientist. That is, in the FDA we have not been able to rely on everyday medical officers to review the raw data. If public interest scientists have access to the data, at least someone will be looking at the raw data.

The opportunity for input into decisionmaking also vastly increases the number of participants in the formulation of public policy. This is because imminent safety and efficacy decisions provide a focal point for discussion and concern about public issues. In a country where scientists have traditionally stuck to narrow laboratory routines, encouragement of public activity is extremely important.

A further reason for making data available upon receipt is that agency scientists need to feel free to discuss pending applications with experts outside the agency. They cannot do this if the application data is protected by law until after the registration decision is made. At the present time, agency scientists are virtually sequestered from the scientific sources most equipped to help them make good safety judgments.

The doctors at FDA don't know the intricacies of trade secret information. They think everything is a trade secret, and by secreting all new drug data the scientists are in an atmosphere of intimidation which the pratical effect of is that they do not consult outside experts in that area.

Making data public reduces the chances of arbitrary decisions, since public records increase the need for officials to make decisions consistent with prior decisions. This reduces the charge that permeates all the agencies, of favoritism toward certain companies. Making data available for public scrutiny before the decision is made makes partial decisionmaking impossible.

Public availability of records can also generate support for the agency when it wants to make safety decisions which are unfavorable to the industrial groups. At the present time, the regulatory agencies are vulnerable to the interests which can afford to cultivate inside contacts.

One reason that the industries have been able to control the agencies is that they can get information informally which the public cannot get. The agencies have little way to gather support for making decisions that are in the public interest, when strong behind-the-scenes pressures from private interests are aroused.

Access to specific data before decisions are made enables the public to support the agency in its attempts to fulfill public health mandates.

It is false to suppose that at the present time there is no outside input into agency decisionmaking prior to the time that registration decisions are made. There is just no public input. Private lobbyists and

other industry representatives haunt the corridors of the agencies, greeting, cajoling, supplying reasons, facts, charts, and conferences.

When agency personnel are isolated by secrecy requirements they are completely susceptible to smooth industry lobbyists, to persuasion on a personal, rather than scientific, basis.

Groups which cannot afford private full-time persuaders must have the opportunity to contribute to decisionmaking. They need open information before the decision is made, to do this.

The bill before us, and these are my comments on the second part, says that the Administrator cannot consider the test data submitted in support of an application to support any other application. Hart-Nelson amendment No. 1004 would make it clear that test data in EPA files could be used for determining the adequacy of the test results submitted by different applicants.

This amendment makes it clear that if EPA has evidence of toxic effects from the application of another, related pesticide, it can bring that evidence to bear in its judgment on a new application. The amendment is, then, a necessity. Without it, you have prohibited the Administrator from looking at the scientific information in his own files.

Further, the House's apparent requirement that every new manufacturer submit test data is odious because it creates a monopoly on pesticides beyond that granted by the patent system.

Under present law only the Patent Office is authorized to grant monopolies, and in return for disclosure of the invention, the patentee is granted exclusive rights of commercial exploitation for 17 years. Under this bill, the monopoly grant is virtually perpetual. The cost of test data is substantial in the drug area; for example, test data apparently cost somewhere between $100,000 and $225,000 per drug.

If other companies wish to compete in the sale of these products, they must first provide extensive duplicate animal data—similar to those of the original restraint. For small firms—and even the larger ones—this EPA requirement constitutes a formidable barrier to competition.

(Even for those companies with the money, investing large amounts of money in duplicating tests on pesticides marketed for several years involves no social gain and is a wasteful use of resources.)

The EPA has no power to grant monopolies. Its authority extends only to the protection of the public health and environment. Allowing exclusive rights to commercial exploitation should be done only in the context of reexamining the patent laws, where the Congress can examine the needs for new invention, the costs of invention, the rewards necessary to foster it, et cetera.

The Congress should not so flippantly grant the giant chemical companies perpetual monopolies, monopolies worth billions in profit to them, and worth billions in losses to the farmer and the consumer.

The third provision is this: The bill now contains a requirement that the registrant submit "factual information regarding substantial adverse effects on the environment of the pesticide." Section 6(a)(2). "Substantial adverse effect on the environment" is defined by the act to mean:

> Any injury to man or any substantial adverse effects on environmental values, taking into account the public interest, including benefits from the use of pesticides. Section 2(bb).

The result of this balancing—the good and the bad, definition of substantial adverse effects may be that EPA receives no information from pesticide manufacturers about the health effects of their products. If a pesticide manufacturer receives a report from a buyer that the pesticide causes, say, numbness in his arms or legs, he himself weighs that report against the benefits of the pesticide.

As worded, the present bill apparently allows the manufacturer to do the balancing. When the individual manufacturer does it, the adverse effect will never outweigh the benefits of the pesticide, since he knows of many benefits of his product and only one case of risk.

Inflow of reports from manufacturers of adverse effects of their products is essential to the public health protection activities of EPA. In the case of toxic foods and drugs, reports from manufacturers of individual adverse reactions are almost always the first indication of a public health hazard that the Food and Drug Administration has. Current FDA law requires manufacturers to report any information concerning side effects, injury, toxicity, or sensitivity reaction associated with the use of the drug within 15 days.

Before this requirement went into effect, after the 1962 Kefauver amendments, manufacturers were required to report only those effects which were caused by the drug. The old law thus gave the manufacturer the discretion to determine whether or not the drug caused the reported injuries.

That failure left FDA without sufficient knowledge to protect the public. The companies did not report injuries if they did not have absolute cause-and-effect proof of a drug's guilt. This, of course, is rarely available in any scientific field.

For example, Hoffman LaRoche failed to transmit reports of liver damage from the use of its product Marsalid to FDA. The toll of this product was 53 deaths, preventable if reporting had occurred.

Richardson-Merrell failed to report to FDA that some users of Thalidomide experienced peripheral neuritis, a failure which in part contributed to the widespread investigational use of the product in this country.

Wallace and Tiernan failed to send reports of side effects connected with the use of its tranquilizer Dornwal, reports which showed nine cases of bone marrow disease and three deaths from using the drug.

Pfizer did not report to FDA that Diabinese, an oral antidiabetic had 27 percent side effects, including severe injuries to the central nervous system and liver. Withholding these reports allowed 2 years of unrestricted sales and numerous injuries.

Johnson and Johnson withheld from FDA information it had that Flexin was associated with 15 deaths. As a result FDA did not withdraw it from the market until 1961, 6 years after its widespread sale began.

Other drugs where companies reporting side effects could have prevented serious injury were Sterling's Aralen, and Richardson-Merrell's MER/29.

Complete reporting of toxicity associated with the economic poisons is necessary for FDA to know what the hazards are, and to protect the public from them. EPA's experience has shown that a law

which requires discretionary reporting will result in minimal reporting.

To make it clear that all unintended effects on man and the environment are to be reported, section 6(a) (2) should be amended to read:

> If at any time after the registration of a pesticide the registrant has records or reports concerning any injuries, toxicity, or reactions associated with the pesticide, other than those intended, the registrant shall notify EPA within 15 days.

If I may make one further comment, in terms of practical results on the functioning of the EPA, its public health protection functions, I feel the freedom of information provisions and the citizens suits provisions are by far the most important, in some ways far more important than the different wording on standings.

The reason for this is that at the present time the agencies are in virtually complete control of the industry they regulate because the industries they regulate are the only ones organized to exert pressure. At the present time, the consumer and environmental groups do not have the inputs that the industry representatives do.

Agency procedures in almost all of the agencies are geared to maximize the availability of industry influence and minimize the vulnerability to people's opinions.

I think that the freedom of information regulations are crucial to any kind of public health law because only with freedom of information will there be any chance that we consumers, we citizens, will have a chance to understand what is going on, understand what the issues are and organize ourselves to protect our interests.

I think for exactly the same reasons the citizens suits are of major importance.

Senator HART. I am glad you spoke in support of the amendment that would permit the use of the test data that was on hand in connection with other applicants; and reminded us of the experience that we have had with Food and Drug, where a burden much heavier than a small manufacturer can meet is imposed by the requirement that no matter how deep the agency is in files of tests that would show the safety and efficacy of the new applicant, even with a few more inches of proofs, complete new tests must be run at enormous costs.

Ms. JOHNSON. And in the drug industry, monopoly is apparent in the piddling types of differences in new drugs, incredibly high drug prices, and the burdens fall on the segments of society which are often poor and unable to afford these drugs.

Again, it is important to recognize that the oppression of monopoly falls on two groups: It falls, of course, on the farmer and there has been much talk in connection with this bill about the small farmer and how we want to help him out.

The small farmer if he needs to use pesticides carefully must be able to afford them, and if you have a monopoly situation, that is not going to be available.

Second, the consumer will feel the effects of the monopoly that the bill presently grants in the cost of food.

Ms. WILSON. Mr. Chairman, I am Cynthia Wilson of the Audubon Society. We appreciate the opportunity to present our views on H.R. 10729, the Federal Environmental Pesticide Control Act, as reported

by the Senate Agricultural Committee. Because of your committee's long interest and expertise on pesticides, we consider it most appropriate that you consider this legislation.

The evolution of this legislation from a very strong proposal by the administration to the present battered bill is perhaps typical of the difficulties of getting tough regulatory legislation passed. The bill before you contains some real improvements over the present law (FIFRA), but it also contains some serious defects.

Many of these problems were addressed by the chairman's and Senator Nelson's amendments, but regrettably most of these amendments were not adopted. The Senate Agriculture Committee, did, however, make some improvements in the House passed bill, for which we are grateful.

I would like to discuss some of the amendments along with other problems in the bill and report, and I will skip over some of the things that have been covered by others in order to conserve time.

Before starting, I would like to add a comment about data which came to mind from Anita Johnson's testimony. Not too long ago I tried to get simply a copy of a label from EPA, a label that goes on the bottle of pesticide. I called, thinking this would be a very simple task, and found I had to call about five different offices and get an argument, like it was a defense secret or something, before I could get a simple copy of the label. I think this is indicative of the fear, perhaps of agency people of giving out information they are not sure whether they are supposed to give out, or maybe it is hostility.

I don't know, but it was a small thing. I think it typifies that whole problem. As I say, it is a registered product, and I thought it would be easier to call them and get the label than to go out and buy a bottle, but I guess I should have gone to a hardware store.

CRITERIA FOR REGISTRATION (AMENDMENT NO. 1012)

The criteria for registration is at the heart of the bill, for this key definition determines what pesticides will be registered, and also sets the standards for cancellation proceedings. The bill defines "substantial adverse effects on the environment," as, "any injury to man or any substantial adverse effects on environmental values, taking into account the public interest, including benefits from the use of the pesticide.

What bothers us most about this definition is the inclusion of the phrase "including benefits from the use of the pesticide." We believe that when adverse effects are being measured, they should be measured on the basis of scientific fact to determine whether or not the pesticide does adversely affect man or the environment.

Once this is determined, then it is appropriate to decide whether the economic or other benefits from the use of the pesticide justify its being registered despite any risks it may have.

There are really two questions involved: (1) Are there adverse effects, and (2) Do the benefits outweight the risks? They should be considered in that order.

It seems to us that including the phrase "including benefits from the use . . ." gives special emphasis to one element in the weighing of risks

versus benefits. It would be better either to eliminate this phrase or else to broaden the definition as the Hart-Nelson amendment proposes to make clear the range of factors which will be weighed in deciding whether to register a product.

The Hart-Nelson amendment adds the new definition to the bill "Unreasonable adverse effects," which would be used in registration and classification. EPA commented to the Senate Agricultural Committee that the new term "does not differ in substance" from the definition of "substantial adverse effects."

EPA's comments did not address the full proposed definition but centered around the difference, or lack of difference, between "any injury" and "any risk."

In our view, there is a difference between "any injury" and "any risk." It seems to us that "risk" includes the concept of possibility of injury in addition to actual injury.

As EPA noted in its comments:

> In applying a section like that proposed, we would in practice look at the likelihood of injury and the anticipated benefits, which is what subsection (bb) of H.R. 10729 seeks to achieve.

We would certainly hope that EPA will consider the "likelihood of injury" which is just what "risk" means in our opinion.

So it is kind of hard for us to understand why they don't like the term "risk."

We believe that in the balancing process, EPA should take into account the "economic, social and environmental costs and benefits of the use of the pesticide, including the availability of alternative means of control," and that the Hart-Nelson amendment will make this clear.

The amendment would also strike the phrase, "The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide."

This curious double negative sentence means in plain English that although a pesticide is not essential it should still be registered. The practical effect of this is a proliferation of chemicals for which there is no real need, and we do not believe this serves the public interest.

In commenting to the Senate Agriculture Committee on this amendment, EPA said:

> We believe the present language of section 3(b) is preferable since it states agency policy. (This appears to be a typographical error in giving the section number, and thus makes no sense.) Where two products pose the same degree of risk and are equally necessary and effective, one should not be registered in preference over the other. Of course, where the same control can be achieved more safely than with a product which is being examined, the definition of substantial adverse effects would itself mandate consideration of the alternatives.

In its report, the House committee "felt that continued use of this disputed procedure would place all interested parties involved at a disadvantage. The agency agreed, and the committee therefore adopted the language of the last sentence of section 3(c)(5)."

The essentiality doctrine was used by EPA in the DDT case. We find the concept of limiting uses of pesticides to those uses which are essential is a sensible one, and as far as we can tell the only parties who will be "placed at a disadvantage" by this concept are manufacturers who will not be able to sell products for which there is no real need.

Farmers would not be injured by this doctrine, for presumably if a use of a pesticide were essential (i.e., there was no other means of dealing with the particular problem), they would be able to use it, and this seems to be the way that EPA decisions were made concerning use of DDT on green peppers and onions and sweet potatoes in storage.

The Senate report further muddies the water on this issue, and we hope that this committee will ask EPA to clarify why they agreed to drop the essentiality criterion. I will skip the export section, because it was covered by Senator Nelson.

REGULATION OF RESTRICTED-USE PESTICIDES

The Senate Agriculture Committee considered but did not adopt an industry amendment which would have removed EPA's authority to impose additional restrictions on "restricted use" pesticides. Section 3(d)(1)(c). We are of course very relieved that this crippling amendment was not adopted, but we are disturbed by some language in the Senate committee report on this subject:

> * * * (2) few pesticides which are now registered would be classified for restricted use. Since the present criteria for registration, the criteria for registration under the bill, and the criteria for restricted use classification under the bill are essentially similar, except for the provision for additional restrictions in connection with classification for restricted use; it follows that currently registered pesticides were at the time of registration found to be safe based on present criteria without the imposition of such additional restrictions.

We just don't agree that because pesticides are now registered means that they don't need additional restrictions. A good example of this is for the organophosphates which you all have been discussing.

Obviously when you are dealing with very toxic substances they do need additional restrictions and more than have been on them in the past, and we just don't see how the Senate committee came to that conclusion, and we must question it severely.

That is true particularly in light of the fact that many pesticides were registered in the past during the reign of the Agriculture Department, and frankly as Congressman Fountain's hearings brought out, and your own investigation has brought out, there was a lot of carelessness in registration of pesticides in the past, and some of these products are still around and should be critically examined.

CONTROL OF USE

The mechanisms which would control use of pesticides have been seriously weakened from those in the Administration's original proposal.

The original S. 745 included a permit system, a sort of prescription approach, to control extremely dangerous pesticides. The Agriculture Committees dropped this from the bill, but did included language in section 3 concerning additional restrictions on restricted pesticides.

The proviso that restricted use pesticides be applied only by a "certified applicator" sounds good, but is full of loopholes. For one thing, the phrase "under the supervision of a certified applicator", does not require the certified applicator to be physically present, unless required by the label.

Since this is the case, we believe then at the very least that the bill should make clear that the certified applicator is legally responsible should the pesticide be misused by the persons under his supervision. As the bill now reads, it is not clear whether he is responsible.

Under this bill, a pesticide can be classified for both restricted and general use. This seems to us to pose formidable enforcement problems, and the Senate committee improved the House bill by authorizing the Administrator of EPA to require separate packaging and labeling for restricted and general use products.

Section 3(d)(1)(a). We believe that such separate packaging and labeling should be mandatory to avoid confusion among consumers, and misuse of restricted products by unqualified persons.

To a great extent, control of pesticide use will still depend largely on labeling, which has proven to be an ineffective means of control. Labels are not very useful since many people do not bother to read them, or cannot understand them because they are contradictory and confusing.

For these reasons, the additional regulations which the Administrator may promulgate are exceedingly important and we very much hope that they will be addressed to such issues as control at point of sale.

The bill does not prohibit anyone from buying any pesticide, even though he may not legally use it. Given the difficulties of enforcement, the most effective means of controlling dangerous products is to control their sale so that they will not be bought by persons who do not know how to use them properly.

I also speak to the point of regulations by local government, and that is going to be covered by Mr. Pickelner, so I won't go into that.

In summary, we agree with the other witnesses on the panel in support of the amendments which you and Senator Nelson have put forward and we appreciate the opportunity to testify before you. We also support the farmworker amendments because we feel very strongly that farmworkers do deserve protection that they are not now getting.

Thank you.

Senator HART. Thank you. I wonder if your suggestion, that there be continuing responsibility on the part of the manufacturer to report back adverse effects, might not discourage manufacturers engaging in research, or even undertaking a follow-on study of the results of their product, if we give them the obligation to report back side effects.

They won't look; will they?

Ms. WILSON. I can see that it might discourage them, but morally it should not discourage them. If you see a crime, you should report it. A lot of them say, "That is too much trouble, I don't want to get involved, so I will just look the other way."

It is the same principle.

If you are going to be in business selling a product to the public, to me it is your moral duty to do everything you can to make sure that that product does not endanger the public.

Senator HART. So you don't see any validity in that argument?

Ms. WILSON. No; not really.

Mr. PICKELNER. Mr. Chairman, I am Joel M. Pickelner, and before getting into comments, I would like to say this hearing is a

culmination of a 2-year battle on this issue. This is the fourth time I have testified before this Congress on these bills.

Senator HART. Given our track record around here, that really doesn't put it into the front ranks of obviously valid ideas whose time has not yet been accepted.

Mr. PICKELNER. It is pretty good for one Congress though four separate hearings.

I would like to comment on certain specific things, but before getting back to that, I wanted to add the endorsement of the National Wildlife Federation to the amendments submitted by you and Senator Nelson and the others suggested by the fellow panel members.

My comments on the bill will cover three areas: Federal and State agency exemptions, penalties, and the language in the Senate report prohibiting political subdivisions and States and other local authorities from adopting stricter regulations.

Section 17 of the bill reported out authorizes the Administrator of the Environmental Protection Agency to exempt a Federal or State agency from any provision of the act if he determines the exemption is consistent with the act and in the public interest.

We think the authority granted here is much too broad and can be emphasized at much too low an administrative level.

Section 17 of the bill, reported out by the Agriculture and Forestry Committee authorizes the Administrator of the Environment Protection Agency (EPA) to exempt a Federal or State agency from any provision of the act if he determines that the exemption is consistent with the act and in the public interest. We think that the authority granted here is much too broad and can be exercised at too low an administrative level. First of all, the inclusion of State agencies in the exemption clause has the potential of generating an overwhelming number of requests from the 50 States.

Second, if a substantial number of these requests are granted, the Federal program will be effectively gutted.

Therefore, we feel that in order for the program to work, the potential exemptions for States should be eliminated from section 17. Also, in order to take some of the pressure off the EPA Administrator, the President should be designated as the official granting any exemptions to the provisions of the act.

Section 24 of the committee bill deprives political subdivisions of States and other local authorities of any authority or jurisdiction over pesticides.

We feel that it is unfortunate that neither the Senate committee or the House recognized many of the unique situations of the Nation's towns, counties, villages, or municipalities are in.

There are many municipalities who have the ability to regulate pesticides and are now doing an effective job. So this bill is in effect taking away authority which now exists. Here among other things we run into a problem of transition. Actually they should have the authority to regulate pesticides in a local area as a matter of right.

If a majority of citizens don't want a particular pesticide used in their area they should have the right to ban it. This takes away their protection from the ill-conceived programs which the Department of Agriculture seems to get involved in from time to time.

Also many counties are in unique situations, they may need the authority to regulate pesticides in order to protect local crops.

Finally, Mr. Chairman, the committee bill as reported out limits penalties against private pesticide applicators to $1,000 for knowing violations of the act. While in most cases this would be an adequate deterrent, in those cases where the applicator is a large farming enterprise or part of a large corporation, a $1,000 fine may not be sufficient.

Therefore, we would like to suggest that the fine limit be raised to $10,000. A potential fine of $10,000 would be sufficient deterrent to any large farming organization to prevent them from knowingly violating the act. The effect on the small farmers would actually be unchanged.

Thank you for the opportunity to make these remarks.

Senator HART. Thank you.

Before making a closing comment, may I ask if staff has any questions?

Mr. BICKWIT. I would like to know from Ms. Johnson how she would respond to the argument that the opening up the files of the EPA will, before the decision is reached on the administration, be a disastrous burden on the agency?

Ms. JOHNSON. Yes, I have heard that argument. I do not feel it would be a substantial disruption. I feel it would be very simple for people to make prior appointments to look at raw data and summarize, and I feel that EPA can easily make regulations so that only qualified scientists would be able to come in and examine the data.

I think EPA could legitimately be worried about laymen coming in and looking for items. There is no reason why there cannot be educational qualifications for people who look at the data.

Another thing, in the Bureau of Drugs study that we just did, we found that industry representatives were coming in a couple of times a week to discuss and look at the raw data and summaries connected with the new drug applications. Medical officers were spending between 1 and 5 hours a week with industry representatives, often without prior appointment, and often without prior notification of the exact subject to be discussed.

And the medical officers felt that they had no choice but to suffer these meeetings with pharmaceutical representatives. My point here is that in fact the scientists on the line in the agencies, the scientists making the initial decsions are constantly being visited by outside scientists, but only by outside industry scientists, and that there would be no, or very very little additional burden on the agency to allow public scientists to look at the data.

Mr. BICKWIT. Thank you. That is helpful.

Let me close simply by asking Mr. Butler, and this is not a question really. Could you, when you submit to us your detailed analysis of the bill reported by the Agriculture Committee, look especially hard at the number of lawsuits that might arise against the Administrator initiated by a manufacturer should the Administrator decide to suspend and cancel the registration of a pesticide, and evaluate the possibility of harassment arising from those law suits?

Mr. BUTLER. Harassment on the part of formulators and other manufacturers of pesticides as opposed to those who are normally accused of creating harassment; that is, ourselves?

Mr. BICKWIT. Well, we would like a more detailed analysis of that. Thank you very much.

Senator HART. Thank you very much. I hope this will be the last time.

The testimony from all this morning has been helpful. There are competing claims that we will hear on Monday and the record made this morning will be of some value.

Certainly the testimony will help us evaluate the EPA's decisions which inevitably are going to follow yesterday's welcome action on DDT.

With DDT off the market, it becomes even more important than ever to evaluate the alternatives, because as I understand it, the alternatives are represented as less harmful or more valuable because they are not as persistent as DDT, even though they may be more toxic, and it has been suggested strongly that some of them are unsafe and they are used today.

I want us on this subcommittee to look at the data described, and I hope very much that EPA will do the same, because it is a hard fact that people who are using that product or those products are least able to protect themselves, either because of lack of educational opportunity or the economic pressure of keeping their jobs.

That heightens the obligation both of Congress and of EPA to be sure that those least able to help themselves are protected.

Thank you very much. We will adjourn, to resume in this room at 10 o'clock Monday next.

(The statement follows:)

STATEMENT OF CYNTHIA E. WILSON, WASHINGTON REPRESENTATIVE OF THE NATIONAL AUDUBON SOCIETY

Mr. Chairman and members of the subcommittee, we appreciate the opportunity to present our views on H.R. 10729, the Federal Environmental Pesticide Control Act, as reported by the Senate Agriculture Committee. Because of your Committee's long interest and expertise on pesticides, we consider most appropriate that you consider this legislation.

The evolution of this legislation from a very strong proposal by the Administration to the present battered bill is perhaps typical of the difficulties of getting tough regulatory legislation passed. The bill before you contains some real improvements over the present law (FIFRA), but it also contains some serious defects. Many of these problems were addressed by the Chairman's and Mr. Nelson's amendments, but regrettably most of these amendments were not adopted. I would like to discuss some of these, along with other problems in the bill and report.

CRITERIA FOR REGISTRATION (AMENDMENT NO. 1012)

The criteria for registration is at the heart of the bill, for this key definition determines what pesticides will be registered, and also sets the standard for cancellation proceedings. The bill defines "substantial adverse effects on the environment" as, "any injury to man or any substantial adverse effects on environmental values, taking into account the public interest, *including benefits from the use of the pesticide.*" (Italic added)

What bothers us most about this definition is the inclusion of the phrase "including benefits from the use of the pesticide." We believe that when adverse effects are being measured, they should be measured on the basis of scientific fact to determine whether or not the pesticide does adversely affect man or the environment. Once this is determined, then it is appropriate to decide whether the economic or other benefits from the use of the pesticide justify its being registered despite any adverse effects it may have. There are really two questions involved: (1) are there adverse effects, and (2) do the benefits outweigh the risks?

It seems to us that including the phrase "including benefits from the use . . ." gives special emphasis to one element in the weighing of risks vs. benefits. It would be better either to eliminate this phrase, or else to broaden the definition as the Hart-Nelson amendment proposes to make clear the range of factors which will be weighed in deciding whether to register a product.

The Hart-Nelson amendment adds the new definition to the bill "Unreasonable adverse effects," which would be used in registration and classification. EPA commented to the Senate Agriculture Committee that the new term "does not differ in substance" from the definition of "substantial adverse effects." EPA's comments did not address the full proposed definition, but centered around the difference, or lack of difference, between "any injury" and "any risk."

In our view, there is a difference between "any injury" and "any risk". It seems to us that "risk" includes the concept of possibility of injury in addition to actual injury. As EPA noted in its comments, "In applying a section like that proposed, we would in practice look at the likelihood of injury and the anticipated benefits, which is what subsection (bb) of H.R. 10729 seeks to achieve." We would certainly hope that EPA will consider the "likelihood of injury", which is just what "risk" means in our opinion.

We have had numerous discussions with EPA staff about this definition and have been assured that the bill's definition means exactly what we want it to mean. But we are not certain that some future Administrator or a judge will agree with the interpretation which the EPA staff gives to this term.

We believe that in the balancing process, EPA should take into account the "economic, social and environmental costs and benefits of the use of the pesticide, including the availability of alternative means of control," and that the Hart-Nelson amendment will make this clear.

The amendment would also strike the phrase, "The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide."

The curious double negative sentence means in plain English that although a pesticide is not essential, it should still be registered. The practical effect of this is a proliferation of chemicals for which there is no real need, and we do not believe this serves the public interest.

In commenting to the Senate Agriculture Committee on this amendment, EPA said, "We believe the present language of section 3 (b) is preferable since it states agency policy. [This appears to be a typographical error in giving the section number, and thus makes no sense.] Where two products pose the same degree of risk and are equally necessary and effective, one should not be registered in preference over the other. Of course, where the same control can be achieved more safely than with a product which is being examined, the definition of substantial adverse effects would itself mandate consideration of the alternatives."

In its report, the House Committee "felt that continued use of this disputed procedure would place all interested parties involved at a disadvantage. The agency agreed, and the Committee therefore adopted the language of the last sentence of section 3(c)(5).

The essentiality doctrine was used by EPA in the DDT case. We find the concept of limiting uses of pesticides to those uses which are essential is a sensible one, and as far as we can tell the only parties who will be "placed at a disadvantage" by this concept are manufacturers who will not be able to sell products for which there is no real need. Farmers would not be injured by this doctrine, for presumably if a use of a pesticide were essential (i.e., there was no other means of dealing with the particular problem), they would be able to use it.

The Senate report further muddies the water on this issue, and we hope that this Committee will ask EPA to clarify why they agreed to drop the essentiality criterion.

EXPORTS (AMENDMENT NO. 1013)

This amendment addresses a very serious problem. As the bill stands, manufacturers can export any pesticide they can sell, regardless of its hazardousness or whether it is legal in this country. Regardless of regulations in this country, pesticides misused in other countries can affect our own environment. Persistent mobile pesticides such as DDT move freely through wind and water, so DDT used anywhere can still contaminate this country.

One part of the Hart-Nelson amendment would direct the Administrator to prohibit the export of pesticides which would have "unreasonable adverse effects" on the environment of the United States.

Diplomatically speaking, it is not considered appropriate for this country to tell other countries that they should not use a particular product because it will injure the citizens or environment of that country. This decision must be made by the importing nation. However, at the very least we should make that Nation's government aware of the hazards of the product, so that it can make an informed decision and take steps to protect its citizens and natural resources.

A good example of the danger of exporting pesticides to other countries is the recent mercury poisoning incident in Iraq where several hundred people are reported to have died and many others were seriously injured. According to an article in the New York Times, mercury treated wheat seeds, imported from Canada, were fed to cattle. A warning was printed on the sacks indicating that the seeds were for planting only, but nonetheless the peasant farmers fed the seeds to their cattle with disastrous results.

A similar tragedy on a small scale occurred in Alamogordo, New Mexico several years ago, when three children suffered severe brain damage after having eaten pork from animals fed with mercury treated seed grain. If our own citizens are unable to follow directions and warnings, we should not assume that people of other countries will be able to understand the hazards of pesticides and be able to use them properly. However, by providing more information to their governments about the pesticides, we will be taking a step in the right direction.

Although the bill calls for cooperation with other nations in this problem, we are not so naive as to assume that such international agreements can be worked out quickly. In the meantime, we have a moral obligation to do whatever we can to prevent pesticide poisonings and environmental degradation in other lands, as well as our own.

Regulation of Restricted Use Pesticides

The Senate Agriculture Committee considered but did not adopt an industry amendment which would have removed EPA's authority to impose additional restrictions on "restricted use" pesticides. (Sec. 3(d)(1)(C). We are of course very relieved that this crippling amendment was not adopted, but we are disturbed by some language in the Senate Committee Report on this subject:

". . . (2) few pesticides which are now registered would be classified for restricted use. Since the present criteria for registration, the criteria for registration under the bill, and the criteria for restricted use classification under the bill are essentially similar, except for the provision for additional restrictions in connection with classification for restricted use; *it follows that currently registered pesticides were at the time of registration found to be safe based on present criteria without the imposition of such additional restrictions.*" (page 5) (emphasis added)

Perhaps the Committee's assumption would be true if the misbranding provision of FIFRA, which does contain criteria similar to the proposed bill, had actually been applied consistently. The two key phrases in the misbranding provision are: "(c) if the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public;" and "(g) if in the case of an insecticide, nematocide, fungicide, or herbicide when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds, to which it is applied, or to the person applying such economic poison;".

These phrases were not applied during registration, or many products now on the market or which have been cancelled recently would never have been registered. We question how the Agriculture Committee can say that few pesticides will be classified "restricted" because they were found to be safe at the time of registration. The Committee is ignoring the fact that pesticide regulation in past years has been careless at best and scandalous at worst, as brought out in the Fountain hearings. (1969, House Government Operations Committee).

Although since that time, improvements have been made and authority for pesticides has been transferred to EPA, we sincerely doubt that EPA has had the time or staff to review the 32,400 products which are registered. Some of these are doubtless products which were originally registered by USDA and may well have been inadequately scrutinized at that time.

The fact that a product is now registered does not mean that it should be placed in the "general use" category. A mountain of scientific evidence about adverse effects of pesticides has been accumulated in recent years, and this must be taken into consideration in categorizing pesticides. The Committee Report notes that EPA is upgrading its criteria (as to safety and effectiveness) for regitration and will use the revised criteria for classification of existing pesticides under the new Act. If this is so, it seems logical to expect that a good many pesticides may well have some sort of restirctions on their use.

Control of Use

The mechanisms which would control actual use of pesticides have been seriously weakened from those in the Administration's original proposal.

The original S. 745 included a permit system, a sort of prescription approach, to control extremely dangerous pesticides. The Agriculture Committees dropped this from the bill, but did include language in Sec. 3 concerning additional restrictions on restricted pesticides.

The proviso that restricted use pesticides be applied only by a "certified applicator" sounds good, but is full of loopholes. For one thing, the phrase "under the supervision of a certified applicator" does not require the certified applicator to be physically present, unless required by the label. Since this is the case, we believe at the very least that the bill should make clear that the certified applicator is legally responsible should the pesticide be misused by the persons under his supervision. As the bill now reads, it is not clear whether he is responsible.

Under this bill, a pesticide can be classified for both restricted and general use. This seems to us to pose formidable enforcement problems, and the Senate Committee improved the House bill by authorizing the Administrator of EPA to require separate packaging and labeling for restricted and general use products. (Sec. 3(d)(1)(A).) We belive that such separate packaging and labeling should be mandatory to avoid confusion among consumers, and misuse of restricted products by unqualified persons.

To a great extent, control of pesticide use will still depend largely on labeling, which has proven to be an ineffective means of control. Labels are not very useful since many people do not bother to read them, or cannot understand them because they are contradictory and confusing. For these reasons, the additional regulations which the Administrator may promulgate are exceedingly important and we very much hope that they will be addressed to such issues as control at point of sale. The bill does not prohibit anyone from buying any pesticide, even though he may not legally use it. Given the difficulties of enforcement, the most effective means of controlling dangerous products is to control their sale so that they will not be bought by persons who do not know how to use them.

Regulations by Local Governments

Language in both the House and Senate Agriculture Committees' reports prohibits political subdivisions below the State level from regulating pesticides in any way. We must disagree with this in principle and in practice. If a municipality or a county, for instance, wishes to regulate pesticides more strictly than its state or the federal government, we see no reason why they should be able to do so. A number of local governments have such regulations, often patterned after tough state regulations (in another state than the local government.)

For example, several years ago the Board of Supervisors of Fairfax County, Virginia passed a resolution which set guidelines for use of pesticides by county employees. These guidelines include a prohibited list (which includes such persistent pesticides as DDT, dieldrin, etc., and others which are highly toxic), and a restricted list of products which can only be used if there is an infestation and there is no alternative means of control. (The prohibited and restricted lists are similar to New York State's tough pesticide law.) Although private citizens are not bound by these guidelines, the County Agricultural Extension Agent uses them in advising the public about the use of pesticides.

We believe that such local action is both appropriate and in the public interest. It can help guide users to less dangerous pesticides, as well as guiding county employees. It does not pose a burden on interstate commerce, as the Senate asserts since it puts no requirements on the manufacturer.

Such regulations can be particularly valuable in situations where the State's pesticide law is weak, and in cases where massive spraying programs are underway. It may well be that the citizens of a given community do not wish it to be sprayed with a particular pesticide, and they should have some voice in this decision.

EPA commented on this report language: "EPA opposes the proposed report language which would remove all authority for political subdivisions of States to regulate pesticides. We base our opposition on the principle that Federal regulation of pesticides should only be a minimum level of regulation which could be exceeded by States or political subdivisions if necessary; and the fact that some large municipalities have programs regulating pesticides."

We agree with EPA, but we are disheartened to see their admission that the much-touted pesticide bill will in fact provide only a "minimum level of regulation."

There are numerous other items in H.R. 10729 which deserve comment, but to avoid repetion these will be discussed by representatives of other organizations.

Thank you again for the opportunity to present our views.

(Whereupon, at 12:24 p.m., the subcommittee recessed, to reconvene at 10 a.m., Monday, June 19, 1972.)

FEDERAL ENVIRONMENTAL PESTICIDE CONTROL ACT OF 1971

MONDAY, JUNE 19, 1972

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON THE ENVIRONMENT,
Washington, D.C.

The subcommittee met at 12:05 p.m. in room 1318, New Senate Office Building, Hon. Daniel K. Inouye presiding.

Present: Senator Inouye.

Senator INOUYE. Before proceeding, I would like to convey to all of the witnesses the apologies of this committee. It appears that the temporary inconvenience caused by the airline strike has stranded several of our members in many parts of this Nation. So I am the pinch-hitter today.

The hearing this afternoon will be the second and concluding day of hearings on H.R. 10729, the Federal Environmental Pesticide Control Act.

Last Thursday we heard from several witnesses from the environmental and public interest sector. This afternoon we will hear from the Environmental Protection Agency and witnesses from the pesticide industry.

Hopefully, this hearing this afternoon will give the committee a balanced record upon which to proceed.

First, let me welcome our first witness, Mr. David Phillipson, vice president of Upjohn Co. Mr. Phillipson is representing the National Agricultural Chemicals Association.

I have been advised that he will be accompanied by Mr. John D. Connor, general counsel of the association, and others from the industry.

Mr. Phillipson, once again I apologize for this long delay, and I would appreciate, before we proceed, you introduce your panel members for the record.

STATEMENT OF DAVID A. PHILLIPSON, VICE PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION; ACCOMPANIED BY JOHN D. CONNER, GENERAL COUNSEL; JOHN J. HOOD, VICE PRESIDENT, GEIGY AGRICULTURAL CHEMICALS, DIVISION OF CIBA-GEIGY CORP.; DR. C. BOYD SHAFFER, DIRECTOR OF TOXICOLOGY, AMERICAN CYANAMID CO.; DR. JOHN S. TOBIN, DIRECTOR OF HEALTH AND SAFETY, NIAGARA CHEMICAL DIVISION; AND DR. DONALD SPENCER, ECOLOGIST, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Mr. PHILLIPSON. Mr. Chairman, the members accompanying me today are Mr. John J. Hood, to my immediate right, vice president

and director of research for Geigy Corp.; to his right is Dr. C. Boyd Shaffer, chief of toxicology, American Cyanamid Co.; sitting next to me is Mr. John D. Conner, counsel for National Agricultural Chemicals Association; to his left is Dr. John S. Tobin, director of the department of health and safety, Niagara Chemical Division, and chairman of the NACA Subcommittee on Health and Safety; and to my far left is Dr. Donald Spencer, consulting ecologist, National Agricultural Chemicals Association.

Mr. Chairman, we are delighted that you got here, because some of us have airline problems, also.

My name is David A. Phillipson, I am a vice president of the Upjohn Co., Kalamazoo, Mich.

By profession, I am a doctor of veterinary medicine. I appear before your committee as vice chairman of the board of directors of the National Agricultural Chemicals Association, a membership association consisting of 130 basic manufacturers, formulators, and associated suppliers of the agricultural pesticide industry.

The reports accompanying H.R. 10729 of both the House Committee on Agriculture and Forestry place the problem of pesticide use and regulation in sound perspective. They recognize the vital role of pesticides in promoting public health and in producing an adequate supply of food and fiber.

Nevertheless, there are those, we believe, who either fail to recognize or do not accept for one reason or another, the essentiality of the use of pesticides. It possibly is because of this reason that there are the widely divergent views concerning the underlying philosophies of pesitcide regulation. There are those who appear to believe that pesticides are used primarily for cosmetic purposes—to enhance the appearance of food.

Senator Nelson, in his testimony before the Senate Committee on Agriculture and Forestry, suggested that the current use of pesticides disrupts seriously the economic stability of the farming community in some parts of the country.

It cannot be assumed that ending the use of pesticides raises only the specter of blemished food. Indeed, it has been well recognized that ending the use of pesticides raises the specter of substantially reduced quantities of foods.

Estimates have been made that without pesticides, basic food and fiber yield would be cut 10 percent to 25 percent, and fruit and vegetable yields reduced by 40 percent to 80 percent.

We recognize that the use of pesticides to accomplish these beneficial purposes present inherent risks which must be controlled and regulated. It is in recognition of these factors that the National Agricultural Chemicals Association has supported constructive legislation to regulate pesticides., both at the Federal and State levels.

It supported the enactment of the Federal Insecticide, Fungicide and Rodenticide Act in 1947, the Miller amendment to the Federal Food, Drug, and Cosmetic Act, to regulate pesticide residues in 1954, the 1959 amendments to extend coverage of the Federal Insecticide, Fungicide, and Rodenticide Act, and the 1964 amendment eliminating the so-called registration-under-protest provisions and to require that the Federal registration number appear on the label.

It has cooperated in the development of uniform State laws relating to the regulation of pesticides. It supported the enactment in the House of H.R. 10729 and before the Senate Committee on Agriculture and Forestry, advocated the enactment, with a number of proposed amendments, of H.R. 10729 as it passed the House. Some of these amendments were adopted by the Senate Committee on Agriculture and Forestry, others were not.

H.R. 10729, as reported by the Senate Committee on Agriculture and Forestry, reflects substantial changes in existing law. The primary changes are:

It regulates for the first time, at the Federal level, intrastate marketing of pesticides.

It requires the classification of specific uses of specific pesticides into general or restricted categories depending upon the inherent risks associated with that use.

It requires that pesticide uses which are classified as restricted be applied by or under the direct supervision of a certified applicator or subject to other restrictions imposed by the Administrator.

It prohibits the use of a pesticide in a manner inconsistent with its labeling.

It requires for the first time, the registration with the Administrator of plants in which pesticides are produced.

It provides for the imposition of civil penalties and injunctions.

Accordingly, the regulatory pattern which has evolved is much more comprehensive than are those reflected in present Federal law. For the first time, it authorizes regulation of the local use and marketing of pesticides. For the first time, it authorizes Federal licensing of applicators.

While the National Agricultural Chemicals Association has supported in general, this legislation, the regulatory pattern of H.R. 10729 as it has evolved, does cause serious concern on a number of issues:

One, overlapping Federal and State authority. As has been mentioned, H.R. 10729 regulates local production and use of pesticides. It requires Federal registration of each pesticide produced in the United States.

It requires Federal registration of each plant in which a pesticide is produced. It prohibits any use, however local, of a pesticide in a manner inconsistent with its labeling.

Section 23 preempts labeling and packaging of pesticides. Since it preempts labeling, we construe the bill also as a preempting classification. To this extent this bill, if enacted, will bring a degree of Federal-State uniformity in the regulation of pesticides.

Nevertheless, each State will remain free to impose use restrictions in addition to, or at variance with its Federal registration by way of legislation, regulation, licensing, or permit.

As we construe this bill, there is nothing to prevent the Federal and State governments from imposing overlapping and possibly even conflicting restrictions.

Two, we are concerned also because of the broad authority which the Administrator is given to classify pesticides in the restricted category and to impose controls which are in part, open ended, and undefined on their use. We likewise are concerned with the broad grant of authority to license applicators with few, if any, guidelines as to the qualifications for licensing and with no understanding as to the personnel who is to do the licensing.

Accordingly, it has not been without substantial misgivings that the National Agricultural Chemicals Association and the majority of the pesticide industry to date, has supported the enactment of this legislation.

This position has been premised upon an expectation that this broad grant of authority to the Federal Government will be exercised in a reasonable manner, and that through cooperation between the Federal and the State governments, overlapping and conflicting Federal-State controls will be avoided.

We recognize, Mr. Chairman, that H.R. 10729, as reported by the Senate Committee on Agriculture and Forestry, does not incorporate some of the provisions reflected in the 11 amendments which Senator Hart, and Senator Nelson proposed to that committee.

We assume that it will be primarily to those issues to which our testimony before this committee should be directed. Because of the fact that those issues primarily are legal or regulatory in nature, I have asked Mr. John D. Conner, counsel for the National Agricultural Chemicals Association to discuss those issues.

I have introduced those who are accompanying me for the purpose of answering as fully as possible, any questions which the committee may have, concerning the products and the practices of our industry.

Senator INOUYE. Thank you very much, Dr. Phillipson.

We will be very pleased to hear from Mr. Conner now.

Mr. CONNER. Mr. Chairman, I appear as counsel for the National Agricultural Chemicals Association. My discussion will be directed to the primary issues raised by the 11 amendments that have been presented to the Senate Committee on Agriculture and Forestry by Senators Hart and Nelson.

The first issue, or group of issues, concerns the manner in which data presented in support of an application for registration of a pesticide will be handled. The relevant provisions of the bill relating to this are, first, under section 3(c)(1) (D) and (E), an applicant is required to submit a full description of the tests made and the results thereof, upon which claims are based, and the complete formula of the pesticide.

Second, under section 3(c)(4), the administrator is required to publish in the Federal Register a notice of the filing of each application, if the pesticide contains any new active ingredient or would entail a changed use pattern.

Third, under section 3(c)(2), the administrator is required to make available to the public the data called for in the registration statement within 30 days after registering a pesticide, except that under section 10, with certain exceptions, the Administrator is directed not to make public information which contains or relates to trade secrets, or commercial or financial information obtained from a person privileged or confidential.

Fourth section 3(c)(1) provides:

> * * * that data submitted in support of an application shall not, without permission of the applicant, be considered by the administrator in support of any other application for registration: Provided, that the administrator may refer to any applicant's test data in making a determination of the adequacy of the test data of the applicant under consideration.

That proviso clause was taken from one of the amendments presented by Senators Hart and Nelson on this issue by the Senate Committee on Agriculture and Forestry.

An evaluation of these provisions, and of the effect of the amendments relating to them offered by Senators Hart and Nelson, require an understanding of the nature of the data which must be developed and submitted by an applicant for registration of a new pesticide. This data includes information on the type of pesticide, the type of formulation, the type of containers in which it will be marketed, its proposed labeling, data on its biological efficacy, data on its toxicity to humans, fish, and other wildlife, and data on its fate in the environment, including soil, water, fish, and other wildlife.

Experience of the last few years has shown that substantial research and expenditures are required after this initial registration to maintain a registration in effect.

A more detailed description of the type of information required for registration of a pesticide as described in a joint publication of the United States Departments of Agriculture and Health, Education, and Welfare, is set forth in appendix A to this statement.

In my prepared statement I have included two examples that were prepared by Dr. Richard H. Wellman, vice president and general manager of the Process Chemical Division, Union Carbide Corp., showing the heavy investment, both in money and time, that is required to bring a new pesticide on the market.

Because of the pressure of time, I will not cover the details of that, but will stress that, in the typical case, the development of all of this data requires several years during the development process. This will be before it ever comes on the market. It represents a substantial investment in money that might run up to $5 million to $10 million.

Senator INOUYE. Without objection, your full statement will be made part of the record.

Mr. CONNER. Yes. So I am not reviewing those two examples.

These examples do reflect the fact that to develop a new pesticide and the data to support its registration requires a major investment both in money and in time. This investment cannot be justified if the data developed can be used by a competitor to develop and market a competitive product at a cheaper cost or in a shorter period of time. To the extent that the data developed would confer such an advantage on a competitor, we believe it to be evidence that the applicant originating the data has a proprietary interest which is entitled to protection.

We believe it to be equally evident that if the proprietor is not given reasonable protection, it will discourage investment in the development of such data.

As a practical matter, the proprietary value of such data will vary from case to case, depending upon the circumstances. However, there can be no question but that in the case of a typical new pesticide, some or much of the supporting data will have substantial proprietary data.

H.R. 10729 as reported by the Senate Committee on Agriculture and Forestry provides two protective features:

(1) The provision of section 3(c)(1)(D) that new data submitted in support of an application shall not, without the permission of the applicant, be considered in support of any other application; and

(2) The provisions of section 10 protecting trade secrets from disclosure.

The proposed Hart-Nelson amendment No. 3 would eliminate the provision of section 3(c)(1)(D) which would prohibit the use of one applicant's data to support the application of another. The Senate Committee on Agriculture and Forestry did not adopt this portion of the amendment, although it adopted the proviso clause of the amendment that the Administrator may refer to any applicant's data in making a determination of the adequacy of the test data under consideration.

We consider this provision as so amended to be fully justified. The reasonableness of the provision does not depend upon an appraisal of the particular data under consideration.

If it has no competitive advantage to the second applicant who wishes to piggyback, he is not injured by his inability to rely upon it.

On the other hand, if it would have a competitive advantage to the second applicant, it, by the same token, has a proprietary value to the registrant who originated the data. He should not be deprived of this proprietary value in the absence of compelling policy considerations. We see no such considerations here.

The second applicant is free to develop such data by making the required investment, or by making contractual arrangements with the original applicant.

The protection under section 10 from disclosure of trade secrets does not obviate the necessity for the protection of the piggyback preclusion of section 3(c)(1)(D), because even in the absence of disclosure the administrator, in the absence of the preclusion, could give the second applicant the benefit of another's data by merely taking official notice of the data in his files.

I have noticed in the statement that Senator Dominick has prepared for presentation to the committee the reference to this provision. In it he refers to a letter from the Attorney General which in substance opposes this provision and suggests its deletion.

I have reviewed this letter. The letter is signed by Mr. Kleindienst and, I believe, is based upon a misunderstanding or a lack of understanding of the bill as it is written.

In the letter signed by Mr. Kleindienst, he relies upon or refers to two decisions decided by the U.S. Supreme Court in 1964, the *Sears, Roebuck Co.* v. the *Stiffel Co.*, and *Compco* v. *Day-Brite*, and he says in his letter if there should, however, be a genuine trade secret problem, the administrator is otherwise able, of course, to protect trade secrets under section 10 of the bill.

Section 3(c)(1)(D) in H.R. 10729 would in effect give trade secret or packing-type protection to test data. We believe that that statement does not reflect the circumstances under which the bill will be operating.

It is not necessary that the trade secret data be revealed to a second applicant in order for him to benefit by it. The administrator, in the absence of this provision, could merely take official notice of the fact that he has this other data in his file and transpose it then to the file of the second application. By doing so, he would grant registration to the second applicant, upon the basis of trade secrets compiled by the first applicant at a cost of possibly several million dollars in money and several years in time.

We believe the justification for protection from disclosure of trade secrets will not be questioned. However, in the administration of this section, we do foresee substantial areas of disagreement concerning the types of data which are required in support of an application for registration and are entitled to protection as a trade secret.

Trade secrets are protected from disclosure not only by section 10 of H.R. 10729, but also by the provisions of the United States Code, title 5, section 552, the Freedom of Information Act, and title 18, section 1905, which makes it a criminal offense for an employee of the U.S. Government to divulge a trade secret and other specified categories of information without specific statutory authority. Neither of these statutes nor H.R. 10729, however, define a trade secret or provide any meaningful guidelines.

A special committee of the National Agriculture Chemicals Association, consisting of individuals who have the responsibility for research development for their companies, has recently made a study of the types of information which must be submitted in support of a registration and attempted to appraise the categories of information which they would consider under usual industry practices to constitute a trade secret and the types which would not.

The committee, through this study, sought to determine general guidelines based on customary industry practice, but recognized that what constitutes a trade secret in a particular case will rest on the facts of that case.

As a guide in its appraisals, the committee used the definition of a trade secret as set forth in the Restatement of Torts 1939, and in the proposed Uniform Trade Secret Protection Act which currently is being prepared by a committee of the American Bar Association.

These two definitions are set forth as appendixes B and C. The committee and I, as counsel, working jointly from these definitions, developed the following primary criteria as a basis for the appraisal of what constitutes a trade secret:

(1) Did the acquisition of data represent a substantial investment in: (a) time? (b) money?

(2) To what extent have members of the industry sought to impose conditions of secrecy or nondisclosure on such information?

(3) To what extent could the information be obtained by competitors? What would be the time and cost requirements?

(4) Would the knowledge of the information be of advantage to a competitor? If so, how would competitors be able to use the information to advantage?

The committee then appraised against these criteria the different types of data which must be submitted to support an application.

Some of the types of data, when considered on the basis of customary industry practices, were considered to be valid trade secrets. Other types were considered not to constitute trade secrets because of failure to meet one or more criteria when judged on customary industry practices.

In some classifications, it considered that the detailed data normally would constitute a trade secret because of its value to a competitor and the customary practice of the industry in making a special effort to keep such data confidential. At the same time it concluded that a summary of such detailed data would not normally constitute a trade secret.

Under such an interpretation summaries of data could be made available for public inspection while the detailed data could be protected from disclosure.

This would accord with the procedure which the Food and Drug Administration has proposed for similarly required data. Under the proposed procedure for compliance with the Freedom of Information Act as published in the Federal Register of May 5, 1972, at page 9130, the Food and Drug Administration proposed to treat safety and effectiveness data as trade secrets and to comply at the same time with the requirements of the Freedom of Information Act by releasing summaries of the data. This interpretation is based on the definition of a trade secret in the Restatement of Torts referred to above.

We believe that a similar practice can be followed under H.R. 10729, as it was reported by the Senate Committee on Agriculture and Forestry, and in doing so protect valid trade secrets, and at the same time meet the need of the public to be informed on the nature of the research work which has been conducted, and a summary of the results.

Mr. Chairman, in view of the pressure of time and in view of the fact that you have permitted by statement to go into the record as presented, I think that I will just not summarize or read the remainder of it, and leave whatever time remains for questioning by the committee.

Senator INOUYE. I thank you very much, sir.

In your prepared statement, Mr. Conner, you have cited two very informative case histories that seek to demonstrate why data submitted in support of the registration should not be used in support of another registration.

Mr. Conner, am I correct in assuming that existing law contains no prohibition against using another registrant's data in support of a registration application, and that this has been done in the past?

Mr. CONNER. Mr. Chairman, that is correct. The present law enacted in 1947 has no provision in it relative to this issue one way or another.

I participated in the drafting of this act in 1949. I also participated in drafting the model State bill which later became the pattern for this Federal act. There was no thought at the time of the enactment of this act in 1947 that the data submitted by one applicant would ever be released for public inspection.

This did not appear to be an issue at that time.

It is—since the enactment of the Freedom of Information Act a few years ago requiring the release of data in the files of the Government agencies, except that which constitutes trade secrets, or other specific exemptions, that this issue has become more important.

It is true, however, that even in the absence of the release of the data for publication that as a matter of administrative procedure, the administrators of the act have used data prepared by one applicant in support of another application.

It is the feeling of our industry that this is unfortunate, and that it has had the effect of keeping off of the market a number of pesticides that otherwise would have been placed on the market, because of the fact that they were older pesticides that did not have packing protection, and that under the current standards would have required considerable testing as to their safety.

No one company felt that it was feasible for it to undertake that investment with the knowledge that if it did and subsequently obtained a registration of a nonpatentable product, that any others in the industry then could obtain a similar registration without the necessity of doing independent research.

So as a matter of practice, we feel that this administrative practice which has existed, had the effect of keeping off of the market a number of products that otherwise would have come on the market, either because they were older pesticides that did not have patent protection, or because of the nature of the pesticide, say, a new one, that was not patentable, and under those circumstances the companies did not feel they were warranted in putting it on the market.

Senator INOUYE. But the release of such information has not caused any lack of incentive to develop new pesticides, has it?

Mr. CONNER. Mr. Chairman, there has been no release of information yet under the act, at least to any substance. That is because it is only after the enactment of the Freedom of Information Act that this information became available. EPA published for the first time, in December of last year, its proposal to release some of the information in its files in accordance with requests that had been made for it. It made it clear, however, that it would not release data that had been submitted and was considered to be trade secrets.

There have been no data released, to my knowledge, to date except that which clearly did not constitute trade secrets.

The problem arises here in defining what part of this extensive registration data that must be prepared constitutes a valid trade secret, and what does not.

Some of it clearly does not. But the large part of it clearly does, or at least we believe it clearly does, and the problem to date in the release of the information has been segregating that which does constitute a trade secret from that which is not.

Again, much of the information that had been presented previously was not marked either as trade secret or confidential, because the registrants did not consider that it would ever become an issue, the Freedom of Information Act not having been enacted at that time.

Senator INOUYE. It has been suggested that the prohibition against the use of data by other applicants is a waste of resources, because you would require the second applicant to duplicate work already done, and would thereby reduce his competitive position in the pesticide industry. It has been argued that the money and resources that they would have expended in duplicating these tests could be used for other purposes. Now, the Justice Department in its letter suggested that such an entry fee moreover acts regressively for it is more of a burden for the small manufacturer. What is your response to that?

Mr. CONNER. Mr. Chairman, I believe Dr. Phillipson might either answer that better, or call on some of the personnel from the companies who have the active responsibility in their companies in developing such data, and I believe that they could more appropriately answer that than could I.

Mr. PHILLIPSON. I do not feel that this would be a duplication of effort. Any company that feels that it is worthwhile to make the investment has the option of perhaps buying this information from

a company that is already in, and I feel that if you allow free access to this type of data, that you, in essence, are going to discourage the research of new and innovative compounds.

You are going to discourage innovation in already existing compounds, because a company simply cannot afford the risk of doing a significant amount of development and then having anybody have free access to this data.

We can't commit companies' resources to the use of hormones, viruses, steroids, bacteria, or other biological control agents, since these are not patentable, and we cannot explore chemical compounds and reduce them to practice since we would be afforded no protection in the area.

I think from the standpoint of innovation, of new uses of already existing compounds, of perhaps researching in areas of compounds or other types of products with less ecological impact, that this free access would tend to destroy and disturb and certainly make a company reluctant to make the investment in something that anybody would have access to.

I don't feel, also, Mr. Chairman, that it is the type of regulation that is injurious to the small company.

By the very nature of the work that is necessary to take a compound from initial screening to final marketplace and production is a tremendous investment, and these are the types of things that have discouraged small companies rather than regulation that pertains to the exclusive use of data.

Mr. CONNER. Mr. Chairman, could I add this, and again, referring to Mr. Kleindienst's letter that contained the provision that you just quoted.

To me this shows the difference between what he, I believe, was discussing there and the situation with which the industry is faced in this provision.

The two cases to which he referred, the *Sears* case and the *Compo* case, were cases in which the companies had developed lighting fixtures of a novel design, and they had obtained a design patent.

Sears, the defendant in those cases, copied those designs. They were sued for infringement of their patent and for unfair competition. The Court held that the patent was invalid. The Supreme Court held that the defendants could not be held liable for merely copying a design of a lighting fixture which was not subject to patent under our patent laws because it was a nonpatentable idea.

Now, that is all the Court held there. Here the equivalent would be if the company, say, the Congress would have said to the two companies that developed the designs, you must make data, you must make available for public inspection any data in your files relating to the safety of these lighting devices, or how they can best or most cheaply be manufactured.

We would be talking about the same thing.

Here all they were talking about was an unpatentable design. Here we are talking about something that, I believe, up until now, has always been recognized as being subject to a valid trade secret that is protected by nondisclosure to competitors, that is, information which a company develops that is of commercial value to it and would be of commercial value to its competitors.

The cases to which he refers, and I believe the principle to which the letter refers, does not address itself to that at all, I believe.

Senator INOUYE. Dr. Phillipson, am I correct in concluding from your response that the development of pesticides under the provisions of this bill and under the present law would be the private domain of only those companies with vast resources?

Dr. PHILLIPSON. Not necessarily.

Senator INOUYE. How could a small company carry out all of the activities that you have suggested? I am leading up to this question: Do you think the Government should take over the matter of testing?

Dr. PHILLIPSON. Do I? No; I don't. I don't feel that the practical application of attempting to do Government testing—I can foresee so many problems in the establishment of priority, lack of incentive. I just don't know how it could be done.

Not only is the testing a major investment, but the investment in capital facilities is also significant in these areas, and I feel that there is an incentive to develop new and novel methods, given the appropriate atmosphere and the appropriate regulations, that each of us has to take a critical look.

I think there is an example of what may be happening in part of our industry if you look at the latest report of pharmaceutical products, that 31 of the top 50 are now produced and marketed outside of the United States.

And I think that if we aren't given some degree of incentive, some degree of protection, that certainly this is the type of thing that you would see more and more of in the future.

Senator INOUYE. I would like to continue this dialog, but we have a vote at the present time, so we will stand in recess for about 7 minutes.

(Recess.)

Senator INOUYE. I would like to resume the hearing by asking Mr. Conner a few questions.

In prepared text, you object to the Hart-Nelson amendment, providing that registration data be made available to the public as soon as the application is filed, and you base your objection on a contention that trade secrets would be released. Yet, you have indicated that section 10 of this measure prohibits disclosure of trade secrets and that this section would still apply. Do you not believe that the provisions of section 10 would give you a degree of protection which you find necessary?

Mr. CONNER. I believe not, Senator, because some of the data that would be released or made available for inspection at that time, might not be considered to be a trade secret.

However, let me explain a little more fully, what I mean by that. The term "trade secret" has never been developed by the courts or by statute, in the context with which it appears here.

The extent to which the compilation of scientific data, or research data, constitutes trade secrets, has never been litigated to any extent. We believe that under controlling definitions there is a great deal of the research data that would.

But, there is still information that would be released to the public and to competitive companies, that strictly speaking, might not constitute a trade secret.

Say, for example, if it were a new chemical, the first information that a competitive company would have that the applicant has been experimenting with a particular type of compound would be available for the first time when this data is released.

Now, as to whether or not that would constitute a trade secret, I think, is questionable.

At the same time, it would certainly be valuable information in the hands of the competitor to learn this other company, or the competitive company, has been researching along this particular type of chemical or family of chemicals.

Now, this might be at a time that will be substantially ahead of the time that the product will come on the market, if it would ever come on the market. It is not at all certain, at this time, that the product will ever be marketed. It might well be that EPA would say, "No, we will not register it," or, "We will not register it without this additional data." That might take another year or 2 years to develop.

Yet, the release of the information at that time would have tipped off the competitive companies as to the lines this company was following in its research.

I think, also, that there is the countervailing question as to the need for the release of this data before registration. You always have, I am sure, to balance the need for one policy against the adverse effects it would create.

I question whether or not there is any real need for the release of the data at that time. There is not the compelling need for the release of the data that there would be after it is registered.

It is not until it is registered that the company in the case of a new chemical is going to start the production or the building of its production facilities. It is not a case where they are going to immediately flood the market with material just as soon as it is registered.

So, bearing in mind, that from that time until such time as it is registered, if it is ever registered, might be a substantial period of time, that it may never be registered, in which event, the applicant for registration would have been required to give up information that has, I think, in a great many instances, substantial proprietary value to it.

Senator INOUYE. I understand that in our capitalistic system one should be adequately rewarded for whatever input he makes in the development of any product. However, I am wondering aloud if a new public policy should be enunicated by this Government.

I can see the matter of trade secrets being absolutely validated, for example, in the development of the wet look for lipstick, or for waterproof eyelashes, but on matters that involve life, health, and safety, do you think a new public policy should be enunciated, that the trade secret concept should be amended a little? Those who suggest this approach have maintained that because of the stringent requirements under the laws relating to trade secrets, mankind, especially the citizens of the United States, have been deprived of lifesaving chemicals and health protecting chemicals.

I am not a chemist, I am not a scientist, so I cannot vouch for this. But, I must say that it makes some sense. I can see trade secrets for manufactured brassieres or manufactured wigs. It is all part of the economy, but for something that involves health, life, and safety, should we apply the same rules of trade secrecy?

Mr. CONNER. I don't know. It seems to me that the question that you pose seems to assume the answer that if all of this data were made public, it is going to increase the supply—well, either one of two things: First, that it will increase the supply of your health-promoting or life-saving chemicals, or drugs, and I question very much whether that is a valid assumption or conclusion to draw.

Congress, of course, can enunciate whatever rules it wishes to, such as the making public of data of this nature. Congress cannot, however, repeal the laws of economics. It seems to me if Congress would enunciate such a rule as that, at that time your law of economics, your law of competition would take over and it might very well then just prevent companies from investing in research of this nature.

The second assumption it seems to me is made that by release of this data, it would assure safer products.

Again, I question whether that is the case.

It seems to me that in legislation of this nature, the primary assurance of safety is the expertise of your governmental agency that has the responsibility of appraising the data and making the decision as to the safeness of it.

The governmental officials who have this data have certainly the expertise, or they are presumed to have the expertise of appraising it and making the decisions on the question of public safety.

There might be some added element of safety in making this data available for inspection by the public. I assume there might be.

I question, though, whether or not it is necessary in all of those cases that all of the data, or the details of the data, be made available, or whether or not summaries might be sufficient, such as the procedure that is now being proposed by the Food and Drug Administration in the case of safety and effectiveness data on new drugs and new animal drugs.

If, however, it is the conclusion that you come to the point where you say in the interest of the public, all of this data must be made available, even though it has a proprietary value to the company that has produced it, even though it has competitive advantage to others, then I think you are squarely faced with a decision as to whether or not the benefits that you would get from that would outweigh the disadvantages.

I feel that it would definitely be a deterrent to the investment that must be made to develop this type of information.

Senator INOUYE. We have several governmental agencies with responsibilities for determining the efficacy of drugs and chemicals and foodstuffs and for deciding whether they are fit to be consumed by people of the United States. It has been suggested that these agencies, because of the lack of funds, are unable to really test out the reliability of the data which is being submitted by applicants and companies.

Essentially our agencies have to depend upon the accuracy and the integrity of the data submitted, and we have found in the past that, as in every other segment of our society, people do submit wrong information and wrong data resulting in illness and death among our citizenry.

This being the case, I ask again, would you be in favor of the Government being in charge of research and development in this important area?

Mr. CONNER. Mr. Chairman, could I defer this question to Dr. Phillipson, who I believe would be in a better position than I to evaluate that?

Senator INOUYE. Yes, sir.

Dr. PHILLIPSON. Senator, as I stated before, I do not feel that this is the best approach. I do feel that the agencies have not been hindered in a critical evaluation of the products submitted.

I also feel that if you look at the changing makeup of your research and development cost in the past several years, that each year the testing that is done for safety and efficacy, not only in man, but other species as well, becomes a more significant part of the data that is submitted.

Much of it is not only done by the companies, but by third party contracts as well. So I feel that the agencies, have in essence, done a good job. But from the standpoint of the time involved from submission to ultimate clearance, it is significant.

Senator INOUYE. Can any one of you give this committee an estimate of the percentage of pesticides now being manufactured in the United States that are not subject to the registration requirements of existing laws because they are manufactured solely for export purposes?

Dr. PHILLIPSON. I do not have that data. If anyone on the committee does, I would defer to them.

Senator INOUYE. Would you furnish that information to the committee?

Dr. PHILLIPSON. We will if it is available.

Does anyone know whether this information is available or not? I frankly do not know, sir.

Senator INOUYE. I ask this question because it has been suggested that our industry is moving towards a greater emphasis on exports because they want to get out of regulations, and industries are moving abroad to avoid the stringent requirements of our laws, and I want to see what the trend is, and I believe the subcommittee members would be interested to know, if you could give us a 5-year history.

Mr. CONNER. It seems to me that probably the question as you ask it, Mr. Chairman, there is a built-in factor of distortion. As I understood it, you asked the percentage of pesticides that are not registered under the present act that are being exported.

The present act covers only interstate commerce, and at present there are a very substantial number, and the figure 25,000 pops into my head—I don't know whether that is right or not—that are sold in the United States that are not registered under the act. This is because of the fact that they are not shipped in interstate commerce.

At the same time, they are registered under the laws of the various States.

It seems to me that a large percentage of those that might be exported might come in the same category, that they are not registered under the present act.

Senator INOUYE. If this is for export purposes, more of the laws would apply, would they?

Mr. CONNER. No, I believe that is right.

Senator INOUYE. The subcommittee just wanted to know how large this percentage was, to determine whether capital is flying away or business is leaving the United States. It has been suggested that these laws have the effect of encouraging American capital and American business to fly away to other countries.

Dr. PHILLIPSON. I can't comment as to the pesticide industry, but the DeHahn report on the top 50 pharmaceuticals that I mentioned previously, 31 of these 50 are now produced and marketed outside of the United States. Some of them have been for several years.

So I don't know whether the same trend is evidenced in the pesticide industry or not, and I don't know whether those figures are available, but if they are, we can attempt to find them.

Senator INOUYE. I regret very much that the other members of the subcommittee are not here. These are the closing weeks before the conventions.

If we may, we would like to submit to your panel and your industry questions prepared by the staff for your response. It might serve a better purpose that way and it might give you an opportunity to give responses that are well thought out.

So we will be submitting these questions to you and the staff will be communicating with you.

I thank you very much.

Dr. PHILLIPSON. Mr. Chairman, thank you very much.

Mr. CONNER. Thank you, Mr. Chairman.

(The statement and questions and answers follow:)

STATEMENT OF JOHN D. CONNER, COUNSEL, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

My name is John D. Conner. I am a member of the firm of Sellers, Conner and Cuneo, 1625 K Street, N.W., Washington, D.C. I appear as counsel for the National Agricultural Chemicals Association.

My discussion will be directed to the primary issues raised by the eleven amendments presented to the Senate Committee on Agriculture and Forestry by Senators Hart and Nelson.

The first issue, or related group of issues, concern the manner in which data presented in support of an application for registration of a pesticide will be handled. The relevant provisions of the bill are:

1. Under Sections 3(c)(1)(D) and (E) an applicant is required to submit a full description of the tests made and the results thereof upon which claims are based (if requested by the Administrator) and a complete formula of the pesticide.

2. Under Section 3(c)(4) the Administrator is required to publish in the FEDERAL REGISTER a notice of the filing of each application if the pesticide contains any new active ingredient or would entail a changed use pattern.

3. Under Section 3(c)(2) the Administrator is required to make available to the public the data called for in the registration statement within 30 days after registering a pesticide, *except* that under Section 10, the Administrator is directed not to make public information which contains or relates to trade secrets, or commercial or financial information obtained from a person privileged or confidential, provided that information relating to formulas acquired by authority of the Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings or fact issued by the Administrator.

4. Section 3(c)(1) provides:

". . . that data submitted in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration: *Provided*, that the Administrator may refer to any applicant's test data in making a determination of the adequacy of the test data of the applicant under consideration."

An evaluation of these provisions and of the effect of amendments relating to them offered by Senators Hart and Nelson require an understanding of the nature of the data which must be developed and submitted by an applicant for registration.

The requirements of data to support an application for registration of a new pesticide includes information on the type of pesticide, the type of formulation, the type of containers in which it will be marketed, its proposed labeling, data on its biological efficacy, data on its toxicity to humans, fish and other wildlife, and data on its fate in the environment, including soil, water, fish and other wildlife. Experience of the last few years has shown that substantial research and expenditures are required after initial registration to maintain a registration in effect.

A more detailed description of the type of information rquired for rgistration of a pesticide as described in a joint publication of the United States Departments of Agriculture and Health, Education and Welfare, is set forth in Appendix A to this statement.

Dr. Richard H. Wellman, Vice President and General Manager, Process Chemical Division, Union Carbide Corporation, has recently made an analysis of the cost of developing a new pesticide and the number of marketing years which are required to recover the development cost. In this study he used a portion of the data produced by a National Agricultural Chemicals Association "Cost of Research Survey." A copy of Dr. Wellman's analysis and supporting data in the form of a letter to Dr. N. C. Brady, Associate Dean, New York College of Agriculture, Cornell University, is printed at pages 251–256 of the Hearings Before the Subcommittee on Agriculture Research and General Legislation of the Committee on Agriculture and Forestry on H.R. 10729, Part II, March 7 and 8, 1972.

Dr. Wellman's study involved two examples.

In the first example research and development of the new pesticide was started in 1963. Annual sales of the pesticide were projected at $5 M. He concluded that the cost of developing and putting the pesticide on the market would not have been recovered until 1980. In this case a patent probably would have been applied for in 1964 and issued in 1966 or 1967. By the time the cost would be recovered there would remain only three or four years of the patent life. In this example the accumulative investment of developing and putting the product on the market was $9.5 Million.

In example No. 2, research and development were again begun in 1963. Annual sales of the pesticide were projected at $25 MM. He concluded that the cost of developing and putting the pesticide on the market would not have been recovered until 1976. The accumulative investment in developing and putting the pesticide on the market was $30.5 Million (page 254 of the hearings).

In example No 1, the pay off of the accumulative investment does not occur until 18 years after discovery. In example No. 2, the pay off of the accumulative investment does not occur until 13 years after discovery. Moreover, these examples assume that the process of development and commercialization proceed apace and does not take into account the purely commercial risks involved in developing and commercializing a new pesticide.

The Executive Committee of the National Agricultural Chemicals Association has reviewed this study and considers that these two examples are typical for the industry. The examples reflect the fact that to develop a new pesticide, and the data to support its registration requires a major investment in time and money. This investment cannot be justified if the data developed can be used by a competitor to develop and market a competitive product at a cheaper cost or in a shorter period of time. To the extent that the data developed would confer such an advantage on a competitor, we believe it to be evident that the applicant originating the data has a proprietary interest which is entitled to protection. We believe it to be equally evident that if the proprietor is not given reasonable protection, it will discourage investment in the development of such data.

As a practical matter, the proprietary value of such data will vary from case to case, depending upon the circumstances. However, there can be no question but that in case of a typical new pesticide some of the supporting data will have substantial proprietary data.

H.R. 10729 as reported by the Senate Committee on Agriculture and Forestry provides two protective features:

(1) The provision of Sec. 3(c)(1)(D) that data submitted in support of an application shall not, without the permission of the applicant, be considered in support of any other application, and

(2) The provisions of Sec. 10 protecting trade secrets from disclosure.

Proposed Hart-Nelson amendment No. 3 would eliminate the provision of Sec. 3(c)(1)(D) which would prohibit the use of one applicant's data to support the application of another. The Senate Committee on Agriculture and Forestry did not adopt this portion of this amendment, although it adopted the proviso clause of the amendment that the Administrator may refer to any applicant's data in making a determination of the adequacy of the test data under consideration.

We consider this provision as so amended to be fully justified. The reasonableness of the provision does not depend upon an appraisal of the particular data under consideration. If it has no competitive advantage to the second applicant who wishes to piggy-back, he is not injured by his inability to rely upon it. On the other hand, if it would have a competitive advantage to the second applicant, it by the same token has a proprietary value to the registrant who originated the data. He should not be deprived of this proprietary value in the absence of compelling public policy considerations. We see no such considerations here. The second applicant is free to develop such data by making the required investment, or by making contractual arrangements with the original applicant.

The protection under Sec. 10 from disclosure of trade secrets does not obviate the necessity for the protection of the piggy-back preclusion of Sec. 3(c)(1)(D), because even in the absence of disclosure the Administrator, in the absence of the preclusion, could give the second applicant the benefit of another's data merely by taking official notice of the data in his files.

We believe the justification for protection from disclosure of trade secrets will not be questioned. However, in the administration of this section, we do foresee substantial areas of disagreement concerning the types of data which are required in support of an application for registration that are entitled to protection as a trade secret.

Trade secrets are protected from disclosure not only by Sec. 10 of H.R. 10729 but also by the provisions of 5 U.S.C § 552 (the Freedom of Information Act) and Title 18, § 1905 which makes it a criminal offense for an employee of the United States Government to divulge a trade secret and other specified categories of information without specific statutory authority. Neither of these statutes nor H.R. 10729, however, define a trade secret or provide any meaningful guidlines.

A special committee of the National Agriculture Chemicals Association consisting of individuals who have the responsibility for research development for their companies, has recently made a study of the types of information which must be submitted in support of a registration and attempted to appraise the categories of information which they would consider under usual industry practices to constitute a trade secret and the types which would not. The Committee through this study sought to determine general guidelines based on customary industry practice but recognized that what constitutes a trade secret in a particular case will rest on the facts of that case.

As a guide in is appraisals, the committee used the definition of a trade secret as set forth in the *Restatement of Torts 1939*, and in the proposed Uniform Trade Secret Protection Act which currently is being prepared by a committee of the American Bar Association. These two definitions are set forth as Appendicees B and C. The committee and I, as counsel, working jointly from these two definitions, developed the following primary criteria as a basis for the appraisal of what constitutes a trade secret:

1. Did the acqusition of data represent a substantial investment in—
   (a) Time?
   (b) Money?
2. To what extent have members of the industry sought to impose conditions of secrecy on non-disclosure on such information?
3. To what extent could the information be obtained by competitors? What would be the time and cost requirements?
4. Would the knowledge of the information be of advantage to a competitor? If so, how would competitors be able to use the information to advantage?

The committee then appraised against these criteria the different types of data which must be submitted to support an application.

Some of the types of data when considered on the basis of customary industry practices were considered to be valid trade secrets. Other types were considered not to constitute trade secrets because of failure to meet one or more criteria when judged on customary industry practices.

In some classifications, it considered that the detailed data normally would constitute a trade secret because of its value to a competitor and the customary practice of the industry in making a special effort to keep such data confidential. At the same time it concluded that a summary of such detailed data would not normally constitute a trade secret.

Under such an interpretation summaries of data could be made available for public inspection while the detailed data could be protected from disclosure.

This would accord with the procedure which the Food and Drug Administration has proposed for similarly required data. Under the proposed procedure for compliance with the Freedom of Information Act as published in the FEDERAL REGISTER of May 5, 1972, at page 9130, the Food and Drug Administration proposed to treat safety and effectiveness data as trade secrets and to comply at the same time with the requirements of the Freedom of Information Act by releasing summaries of the data. This interpretation is based on the definition of a trade secret in the *Restatement of Torts* referred to above.

We believe that a similar practice can be followed under H.R. 10729 as it was reported by the Senate Committee on Agriculture and Forestry, and in doing so protect valid trade secrets, and at the same time meet the need of the public to be informed on the nature of the research work which has been conducted, and a summary of the results.

As to those types of research data which do not constitute a trade secret, the complete data would, of course, be available for public inspection.

The second proposed Hart-Nelson amendment would provide that the registration data be made available for public inspection as soon as the application for registration is filed rather than after the registration is issued. We have opposed this amendment primarily because it would result in disclosure to competitors of vital information at a time substantially in advance of the time when the product can be marketed or in fact before it is determined whether or not it can ever be marketed. The registration processes for a new pesticides normally cover an extended period. Frequently it involves development of data additional to that which is originally submitted. Frequently it is withdrawn either permanently or while addiitonal development work is being done rather than having it denied.

If such data is disclosed when the application is first filed, it would be the first notice to competitors that the registrant is developing the particular pesticide or possibly a particular class of pesticides. It could give a competitor an opportunity to start experimental work either along the same lines or parallel lines substantially earlier than he otherwise would be able to do.

We see no compelling public need that the data be made available for public inspection until after it is registered. The first assurance of public protection is the exhaustive administrative review by the Administrator prior to registration. If review of data by a third party after registration leads to the conclusion that the Administrator should not have granted registration, he will have the formal right to petition promptly for the cancellation of such a registration. If he makes a reasonable case for cancellation, a public hearing would automatically follow. If the Administrator considers that he has not made a reasonable case for cancellation, the petitioner would have the right of judicial review.

In summary, we consider those portions of H.R. 10729 dealing with the use and treatment of data submitted in support of an application for registration to reflect a reasonable balance between protection of proprietary data and the right of the public to have access to such data.

The proposed Hart-Nelson amendment No. 10 would authorize citizens' suits to enforce the Act. The National Agricultural Chemicals Association considers that any such grant of authority would not be compatible with the comprehensive policy making and enforcement pattern of the Act. In the majority of enforcement proceedings there will be inherent a discretionary balancing of competitive considerations—benefits against risks. The Administrator is authorized to make these judgments.

The Act provides a comprehensive enforcement pattern embracing for the first time civil penalties, stop-sale orders, the use of injunctions as well as criminal proceedings.

To permit citizens' suits as proposed would subject all those regulated by the Act from farmers to manufacturers to possibly varying and conflicting discretionary decisions. One example may be helpful in clarifying the consequences of the proposed amendment. The proposed amendment would permit citizens'

suits against any person who is alleged to be in violation of any requirement under this Act if certain procedural conditions are met. The most fundamental requirement under the bill is that a pesticide must not be misbranded (Sec. 12(a)(1)(E)). Under the bill, a pesticide is misbranded if—

> . . . the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under Section 3(d) of this Act, are adequate to protect health and the environment. [Sec. 2(q)(1)(F)]

This definition in turn invokes the benefit-risk test which is a determination the Administrator must make as a part of the registration process. Thus, any district court faced with a citizens' suit must either accept the Administrator's determination or ignore it. If the district court were to ignore the Administrator's determination, it must substitute its own judgment. The consequences would be as many EPA Administrators as there are district court judges plus the actual head of the agency. If the court accepts the Administrator's determination, the issue is resolved before it is begun.

An analysis of the other requirements of the bill establishes that they are either of a nature easily enforceable by the agency (e.g. record keeping, labeling) or involve the discretionary factors illustrated above.

In explaining the proposed provision for citizens' suits, the sponsors stated: "In this time of increasing interest by the public in social policies that directly affect every member of the public, I believe it is necessary and important to allow citizens to participate in the enforcement of laws that have an impact on their lives." [Senate Agriculture Committee—Summary of Amendments]

The National Agricultural Chemicals Association recognizes the sincerity of the proposal and its good intentions but submits that the "increasing interest in policy" is a basis for a practical method of participation in policy making procedures, not for participation in enforcement. To this end, the Association has advocated practical methods of bringing the public into the policy making procedures in this complex field of regulation. Although the recommendations of the Association concerning such participation were not adopted by the Agriculture Committee of the House and Senate, the National Agricultural Chemicals Association believes that the procedure adopted by those Committees does provide for a workable system of public participation in policy making decisions.

The amendments proposed by Senators Hart and Nelson raised a number of other significant issues.

Several of these issues were resolved by the Senate Committee on Agriculture and Forestry in a manner which we consider to be satisfactory and which we hope are satisfactory to the sponsors. We realize that there were a number of other proposals in the amendments which were not adopted. We will not attempt to specifically discuss each of these issues but will be glad to attempt to answer any questions concerning them which the Committee may have.

We appreciate the opportunity to appear before the Committee and present the views of our Association.

APPENDIX A*

Criteria for Pesticides Registration and Establishment of Tolerances

Department of Agriculture

Registration requirements

1. Criteria for establishing registration:

The applicant for registration must furnish documented proof to support the claims made for the proposed product. Data required to support registration usually include the following:

A. Toxicity tests.—Toxicity tests on the proposed formulation must be conducted to show that the directed use of the product would not be injurious to

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* Source: "The Regulation of Pesticides in the United States"; U.S. Department of Agriculture; U.S. Department of Health, Education, and Welfare—Food and Drug Administration; March 1968.

exposed man or beneficial animals when warnings and cautions are carefully followed. The extent of toxicological data required will vary with the nature and proposed use of the product. Toxicity studies normally include:

(1) Safety data:
  a. Acute mammalian studies—
    1. Oral.
    2. Dermal.
    3. Inhalation.
    4. Eye and skin irritation.
  b. Subacute studies—
    1. Oral—90 days.
    2. Dermal—21 days.
    3. Inhalation—14 days.
  c. Other studies which may be required include—
    1. Neurotoxicity.
    2. Teratogenicity.
    3. Effects on reproduction.
    4. Synergism.
    5. Potentiation.
    6. Metabolism.
    7. Avian and fish toxicity.

(2) Physical-chemical properties:
  a. Boiling point.
  b. Flash point.
  c. Physical state.
  d. Density.
  e. Vapor pressure.
  f. Solubility.
  g. Stability.

B. Efficacy data.—Biological tests under field and laboratory conditions must be conducted to determine if the product will control the pests named on the label, when used as directed, without causing significant adverse effects to the crop or property being treated. The following factors are considered in determining efficacy:

(1) Effectiveness. The product must be shown to be effective for the intended purposes when used as directed.

(2) Phytotoxicity.

(3) Translocation within the plant or animal being treated.

(4) Persistence in soil, water, or plants.

(5) Compatability with other chemicals.

(6) A thorough search and evaluation of the data submitted as well as other applicable data are made. After such search, the Department of Agriculture specialists concerned with efficacy determine whether or not the proposed formulation would be useful for the intended use without causing significant adverse effects when applied according to the proposed labeling.

2. General labeling requirements:

A. Name of product.

B. Name and address of manufacturer, registrant, or person for whom manufactured.

C. Net contents.

D. Ingredient statement.—Name and percentage (by weight) of each active ingredient, and total percent of inert ingredients, or name of each active and each inert ingredient in descending order, and relative abundance in each category and the total percentage of inert ingredients.

E. Warning or caution statement.

The label of any economic poison must show warnings pertaining to:

(1) Ingestion.

(2) Skin absorption.

(3) Inhalation.

(4) Flammability or explosion.

The required signal word such as "DANGER," "WARNING," or "CAUTION," and the statement "Keep Out of Reach of Children" must appear on the front panel and meet the minimum type size requirements. The front panel of the label of economic poisons which are highly toxic to man must show:

(1) "Poison" in red on a contrasting background.

(2) "Danger."

(3) Skull and crossbones.

(4) Statement of antidote, including directions to call a physician immediately (in immediate vicinity of skull and crossbones and "Poison").

F. The registration number assigned to the product.

G. Directions for use which are adequate to protect the public (optional on label—may appear on accompanying printed or graphic matter).

3. Other required information:

A. Data to support any or all claims on the labeling.

B. A complete statement of the composition of the product, including the percentage by weight of each of the active and inert ingredients, if such information does not appear on the label.

C. Any pertinent information about inert ingredients.

D. Any other information pertaining to physical or biological properties of the product, etc.

4. Review by other agencies:

Petitions for registration filed with the Department of Agriculture are reviewed and commented on by other Departments of the Federal Government. The Department of the Interior reviews all petitions for registration whose use patterns may have an impact on fish or wildlife. The Public Health Service of the Department of Health, Education, and Welfare reviews all petitions from the standpoint of human safety. The comments of these two agencies are forwarded to the Department of Agriculture and are considered before registration is granted or refused.

Opinion on adequacy of residue data and proposed tolerance

An analytical method suitable for enforcement purposes must be provided with the petition, when suggested use patterns will result in residues of the chemical on food or feed. The analytical method and the residue levels presented in the petition are evaluated and an opinion on whether the proposed tolerance reasonably reflects the residue is forwarded to the Food and Drug Administration.

The review includes consideration of the residues of the parent chemical metabolites, and the conversion products that may be formed. Residues occurring in plant parts other than the principal raw agricultural commodity are also considered.

Manpower and funds on criteria and registration

There are 258 people engaged in the work of the Pesticides Regulation Division, 115 in registration and 143 in enforcement. The Division is funded at $3,500,000.

FOOD AND DRUG ADMINISTRATION

If the product is proposed for use in a manner which is likely to result in residues in or on food or feed, it is not registered by the Department of Agriculture until a tolerance or exemption has been granted by the Food and Drug Administration.

The determination of the safety of a tolerance is a scientific judgment and cannot be derived from any arbitrary mathematical calculation. This judgment involves consideration of the "no-effect" levels demonstrated in the experimental animals, the cumulative potential, the metabolic data, the maximum contribution to the diet that could be expected if all commodities for which tolerances are sought bore residues at the tolerance levels taking into account any reduction in residues accomplished in preparing the food ready to eat, the probable exposure to other similar toxicants, and species differences in translating the animal data to possible effects on man. An adequate margin between the tolerance level and the "no-effect" level in the experimental data is required, taking into consideration the proportion of the diet involving crops on which residues might be expected.

Tolerances established under Section 408 of the Food, Drug, and Cosmetic Act are established on raw agricultural commodities, not on processed foods. If the residues remaining in a processed food have been removed to the extent possible in good manufacturing practices and do not exceed the tolerance on the raw product, the processed product complies with the law. In general,

APPENDIX B

Definition of trade secret. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not

know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (see § 759) in that it is not simply information as to a single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operation of the business. Generally, it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

[Restatement of Torts, 1939 § 757, Vol. 4, p. 5]

APPENDIX C

(4) "Trade Secret" means any formula, pattern, device or compilation of scientific, technical, or commercial information which the trade secret owner has taken reasonable precautions to maintain in secrecy so that except by the use of improper means there would be difficulty in acquiring it, and which gives said owner an opportunity to obtain an advantage over others who do not know or use it. In determining whether given matter constitutes a trade secret, the court may consider (a) the extent to which it is independently known to outsiders or is used by outsiders for similar purposes; (b) the extent to which it is known by insiders; (c) the extent of the measures taken by said owner to guard its secrecy; (d) its value to the owner and others, including the extent to which, if used in conduct of a business, it would confer a competitive advantage on said owner; (e) the amount of effort or money expended by said owner in developing it; and (f) the ease or difficulty with which it could properly be acquired or duplicated by others.

Matter which otherwise constitutes a trade secret will not loose its status as such if it is disclosed by the trade secret owner to and accepted by an outsider in confidence and with an agreement express or implied to compensate such owner if such trade secret is used or divulged to others.

The matter constituting the trade secret must be reduced to tangible or recorded form. It need not be specifically labeled or marked to identify it as "confidential" or "proprietary"; but if not appropriately identified as a trade secret, the trade secret owner must prove by clear and convincing evidence that, prior to the alleged misappropriation, the misappropriator knew or should have known that the subject matter involved was considered by the owner to constitute a trade secret.

[Proposed Uniform Trade Secrets Protection Act, Revised Draft 021671, prepared by the American Bar Association Committee 402, Subcommittee C]

SELLERS, CONNER & CUNEO,
ATTORNEYS AND COUNSELORS,
Washington, D.C., June 21, 1972.

Re H.R. 10729.

Hon. DANIEL K. INOUYE,
Member, Committee on Commerce,
U.S. Senate, Washington, D.C.

DEAR SENATOR INOUYE: During the course of the testimony on H.R. 10729 presented upon behalf of the National Agricultural Chemicals Association, you requested that we respond to certain questions which would be given to us by the staff of the Committee. The questions which we subsequently received and our answers are as follows:

Question 1. What is your opinion of that portion of the Hart-Nelson Amendment which would remove the provision in H.R. 10729 insuring that "essentiality" would not be a criterion for denying registration?

Answer: It is felt that "essentiality" should not be a criterion for registration of pesticides for the following reasons:

(1) It is unlikely that two pesticides will have identical properties as

they relate to control of a given pest under all conditions. Alternate pesticides should be available so as to allow the use of the one best suited under a specific set of conditions.

(2) The possibility of pests developing a tolerance of resistance to pesticides is always present. Where such tolerance or resistance develops alternate means of control including alternate pesticides should be immediately available.

(3) There is no reason to believe that the availability of one pesticide for each pest results in greater safety or less risk to the environment than the availability of more than one pesticide for each use.

Question 2. Do you object to full participation by citizens in suspension of a registration in view of the fact that such hearings take place before suspensions and if there is an emergency, a district court may stay that effect of such suspension pending a hearing?

Answer: This question refers to the expedited hearing provided by section 6(c)(2). This would be a hearing held prior to issuance by the Administrator of a suspension order as contrasted to a hearing which would be held pursuant to Section 6(c)(3) following the issuance of an emergency suspension order.

Although the National Agricultural Chemicals Association did not propose the procedure for an expedited hearing prior to the issuance of a suspension order, we did concur in it. This concurrence was based upon the opinion that the procedure reflects a reasonable balance between the necessity for prompt action in making a suspension decision and the right of a registrant to notification and the opportunity to present evidence and views responsive to the issue of suspension prior to the issuance. We considered that the right of a third party to present briefs reflected a reasonable balance of the right of third parties to provide an input in a suspension proceeding, particularly when coupled with recognition of the fact that third parties have ample opportunity to present data and express views to the Administrator outside of a hearing. Unquestionably, the right of third parties to participate in such a hearing including the right to present evidence and cross-examine witnesses would protract the hearing.

Although I consider the present provision of the bill as reported by the Senate Committe on Agriculture and Forestry to be reasonable, I, personally, would consider that the only objection to a right of more extensive participation by third parties in such a hearing would be the proliferation of time required for such a hearing. If such a right were granted, the presiding officer would need authority to limit cross-examination and the presentation of evidence to reasonable length.

Question 3. What is your opinion on the Hart-Nelson amendment that would give the Administrator the right to grant to any party the opportunity to subpena documents during public hearings?

Answer: We assume this question refers to Amendment No. 5 proposed by Senators Hart and Nelson. We support the provisions of Section 6(d) of H.R. 10729 as reported by the Senate Committee on Agriculture and Forestry. This section authorizes the hearing examiner to issue a subpoena to compel testimony or production of documents upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing. We construe this language as adopted by the Senate Committee on Agriculture and Forestry to be substantially in accord with the proposed Amendment No. 5.

During the course of our testimony you asked whether we could give an estimate of the percentage of pesticides now being manufactured in the United States that are not subject to the registration requirements of existing law because they are manufactured solely for export purposes. So far as we are aware there is no data upon which such an estimate could be premised. In the year 1971 domestic sales of pesticides were 477 million pounds as against sales for export of 404 million pounds according to "Pesticide Review" published by the United States Department of Agriculture, Agriculture Stabilization and Conservation Service, 1971 edition. A significant quantity of the export sales constituted purchases by the United States Government for shipment abroad (including purchases by the United States Army which were treated as domestic sales). There is no way of estimating, however, the quantity of these export sales which were federally registered pesticides and those which were not.

Very truly yours,

JOHN D. CONNER,
Counsel for the National Agricultural Chemicals Association.

Senator INOUYE. Our next witness is Mr. David Dominick, Assistant Administrator for Categorical Programs, Environmental Protection Agency.

Welcome to the committee, sir.

Before proceeding, I would like to submit to you for your consideration several pages of questions which were prepared by Senator Baker, and will you respond to these questions for the record, sir?

STATEMENT OF HON. DAVID D. DOMINICK, ASSISTANT ADMINISTRATOR FOR CATEGORICAL PROGRAMS, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY DR. WILLIAM M. UPHOLT, DEPUTY ASSISTANT ADMINISTRATOR FOR PESTICIDE PROGRAMS; AND CHARLES FABRIKANT, SPECIAL ASSISTANT FOR REGULATORY AFFAIRS

Mr. DOMINICK. We certainly will.

Senator INOUYE. Please proceed, sir.

Mr. DOMINICK. Mr. Chairman, before reading my prepared statement, I would like to introduce, on my right, Dr. William Upholt, who is our Deputy Assistant Administrator for Pesticide Programs, and on my left, Mr. Charles Fabrikant, who is my special assistant for regulatory affairs.

I would also like to comment that this hearing today culminates many hearings held in the Congress, hearings at which Administrator Ruckelshaus and I have testified both in the House and in the House Agriculture Committee, and in the Senate, the Senate Agriculture Committee.

As you know, the House passed out legislation in response to the administration's request last fall. We commented on that legislation in great depth before the Senate Agriculture Committee, and particularly Senator Allen's subcommittee.

We feel that the work done there was of a very workmanlike nature. A very large number of amendments were considered, and we feel that great progress has been made in the development of legislation which will give us adequate protection for both the public health and the environment over the use and control of pesticides.

It is a pleasure to testify before you on H.R. 10729, the proposed Federal Environmental Pesticide Control Act of 1972.

As I indicated when I testified before the Senate Agriculture and Forestry Committee, we believe H.R. 10729 is an improvement over present law. That committee, particularly Senator Allen's subcommittee, has taken pains to consider numerous amendments and has produced a better bill. We believe, however, a few provisions do require amendment.

I. PRESENT LAW

Present law, the Federal Insecticide, Fungicide, and Rodenticide Act, has been in existence since 1947, when it replaced the Insecticides Act of 1910. The FIFRA, as it is known, was administered by the Department of Agriculture until authority was transferred to this Agency under Reorganization Plan No. 3 on December 2, 1970.

The two keys to the present statute are the labeling/registration requirement, which is the basic scheme for regulation, and the interstate requirement. FIFRA applies only to pesticides shipped in interstate commerce.

The FIFRA primarily authorizes the regulation of pesticides in interstate commerce through Federal registration requirements which include regulation of labeling and content. To obtain a registration for his product the pesticide manufacturer or formulator must show that it is effective and, when applied as directed, safe. A pesticide container must contain what its registration says it contains and carry the label approved in its registration which bears information on safe, effective, and allowed uses.

The defect in the labeling approach to regulation is that it provides no direct authority to impose regulation on the use of a pesticide once the user buys it.

II. PROPOSED BILL

H.R. 10729 as reported by the Senate Agriculture and Forestry Committee contains a number of authorities not found in present law as well as provisions improving present law. Here is a brief analysis of the important improvements:

(1) H.R. 10729 would extend Federal regulation to all pesticides in the United States.

(2) H.R. 10729 broadens the scope of Federal regulation beyond registration and labeling to user requirements.

Present law contains no use controls beyond directions, warnings, and cautions on the labeling, and registration restricted to certain uses, tools which would remain available under the bill.

The bill makes it an unlawful act to use a pesticide in a manner inconsistent with its labeling.

The bill provides two use classifications, general and restricted; and imposes requirements additional to the labeling on the restricted use classification.

If a pesticide is classified for restricted use it must be used by or under a certified applicator or under such other restrictions as the Administrator may require by regulation. This authority supplements the direct enforcement provisions by giving the Administrator the flexibility he needs to enforce use restrictions on the label by placing appropriate restrictions on distribution and use so he can keep track of these chemicals.

(3) The bill improves the procedures governing registration actions and appeals by combining the separate remedies of present law for scientific review and public hearings and by requiring that all questions to be submitted for scientific review must be submitted at the outset of the hearing. In addition, the bill provides that any judicial review of any action taken by the Administrator after a public hearing would be in a court of appeals, and any review of an action prior to which there was no hearing would be in a district court. Also, third-party access to the decisionmaking process and the criteria for cancellation are clarified. These provisions basically conform to present law as interpreted by the courts and agency practice. Provision is made for the Administrator to hold a hearing on a registration without initiating cancellation proceedings; and hearing prior to a suspension or—where an emergency exists—an expedited hearing subsequent to suspension is also provided.

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(4) The bill would require the registration of all pesticide producing establishments, and regular submission by them of production and sales volume information. Present law contains no such requirement.

(5) The provision of FIFRA requiring maintenance and availability for inspection of books and records would be continued and authority to inspect and sample pesticides and devices is added.

(6) Enforcement is strengthened in several other ways: authority for stop sale, use, or removal orders and seizure is provided; civil as well as criminal penalties are made available, and penalties are increased; the enumertion of unlawful acts is extended commensurate with the new regulatory authorities; and enforcement cooperation with the States is authorized. All enforcement provisions of FIFRA are retained.

(7) In other authorities not in present law the bill authorizes the Administrator to:

(*a*) establish pesticide packaging standards;

(*b*) regulate pesticide and container disposal;

(*c*) issue permits for the experimental use of pesticides under his terms and condition;

(*d*) conduct research on pesticides and alternatives; and

(*e*) monitor pesticide use and presence in the environment.

(8) H.R. 10729 would establish a Federal-State cooperative program. Certification of applicators according to the Administrator's standards would be accomplished by the States under a program approved by the Administrator. State enforcement could be aided by Federal assistance. In addition, the States are authorize to issue conditional registrations for pesticides intended for a specific local use and experimental use permits if the Administrator finds they are able to exercise adequate controls; and States may impose greater regulation on a pesticide than that of the Federal Government.

That is a brief statement, Mr. Chairman, of the provisions of the new bill which would strengthen Federal regulation of pesticides in order to protect health and the environment. Those provisions, which are all or part of provisions sought by the administration in S. 745 which was originally proposed in February 1971, merit the bill our strong support for enactment. However, we would like to suggest ways to improve the bill further and to offer to work with the committee in completing its work on this legislation.

We recommend deletion or amendment of certain provisions of the bill.

Section 3: Registration of Pesticides, provides that an applicant for registration must submit information on the pesticide which include, when requested by the Administrator, test data and results on the effectiveness and health and environmental safety of the pesticide. This data when submitted to the Administrator could not, under the present text of the bill, be considered by him in support of any other registration application unless the originator of the data permitted it.

A letter from the Attorney General to Senator Hart as chairman of the Senate Judiciary Committee Subcommittee on Antitrust and Monopoly explains in some detail the consequences of this provision on free competition. The Justice letter held in part "this limitation on the use of similar test data by the Administrator does not further the remedial purposes of the bill, it serves rather to insulate the first applicant for registration from the competition from later applicants."

Briefly, the effect of this provision is to afford additional economic protection, and to tend to restrict the pesticide business to large manufacturers. One result is to cut out the smaller formulator who, through efficiencies in production and marketing on a local scale, may presently be able to service local agricultural users more cheaply.

Also we believe that the Administrator should be allowed to rely on information from other applications as well as other sources in passing upon the adequacy of submitted test data. It may result in a competitive advantage to late applicants who may be relieved of certain testing requirements. However, to require each applicant to submit a complete set of test data would appear to us to be wasteful. In addition, the inefficiency necessitated would increase not only Federal administrative cost but those of the manufacturers as well, aside from unnecessarily increasing the application processing time. We, therefore, recommend that this provision be deleted.

Section 23(c) of H.R. 10729 as reported by the Senate Agriculture and Forestry Committee authorizes the Administrator to permit a State to register pesticides formulated for distribution and use within the State to meet specific local needs if the Administrator determines that the State can exercise adequate controls. If this authority is provided for States we recommend that it be extended only to meet local emergency needs and that registration be effective for not more than 90 days unless extended by the Administrator. We suggest that section 23(c) be revised to read as follows, and the text is before you for your consideration:

> A state may recommend registration for pesticides formulated for distribution and use within that state to meet specific local emergency needs. If that state is certified by the Administrator as capable of exercising adequate controls and if registration for such use has not previously been denied, disapproved, or cancelled by the Administrator, such recommendation shall be deemed registration under section 3 for all purposes of this Act consistent with this section. Copies of all data pertaining to registration shall be forwarded to the Administrator, but the registration under this section shall not be effective for more than 90 days unless extended by the Administrator or unless the pesticide is registered by him in accordance with section 3 of this Act.

The bill also provides that private pesticide applicators will not be required to maintain any records or file any reports with the regulatory agency. While we believe that no unnecessary records should be required to be kept or filed the availability of some minimal records would under particular circumstances be necessary in the use of some pesticides by private applicators. We therefore recommend deletion of this provision on the basis that in certain cases, such as use of great volumes of any environmentally deleterious restricted use pesticide by a large farming operation which met the definition of private applicator, that this agency would need to require minimal reporting.

The authority to gather information on possible violations of the act by inspection and sampling is curtailed in H.R. 10729 from the administration's proposals in S. 745, and we recommend that it be broadened in order to authorize adequate enforcement of the act.

The bill presently does not permit inspection of places where pesticides are used or held for use, and where it does permit inspection and sampling, only those pesticides packaged, labeled, and released for shipment are subject to that authority.

The bill has been amended by adding a provision to the definition of "plant regulator" which excludes vitamin-hormone products intended for propagation of plants.

Nutritional chemicals are now specifically excluded from the definition of a plant regulator. While the amendment changes the scope of present law, we have no objection to it.

We do not view this language as placing beyond our jurisdiction metabolically active chemicals.

The present version would exempt only those hormone and hormone-like products having such a degree of "low" toxicity that they are not harmful to man or the environment. Hormone-like chemicals such as 2,4,5-T and 2,4-D, are toxic poisons which would continue to be covered by the act.

The criteria for determining those products considered to be nontoxic and nonpoisonous would need to be set forth in regulations if the "plant regulator" amendment is enacted.

We would expect the following to be eliminated from the purview of the act:

1. Naphthalene acetic acid, used for fruit thinning in apples and pears, and to induce flowering in pineapples.
2. Beta naphthoxyacetic acid, which increases fruit size and delays maturity.
3. Fatty alcohols, which are tobacco sucker control chemicals.
4. Gibberellic acid, the only true hormone in this listing, which increases height and hastens maturity.

III. OTHER PROPOSED AMENDMENTS

I would now like to discuss the amendments proposed by Senators Hart, Nelson, and Stevenson at the hearings on H.R. 10729 held in March 1972 by the Senate Agriculture and Forestry Committee.

My comments on these amendments will be brief, as we have provided detailed comments on most of them to the Agriculture and Forestry Committee, which are in the hearing record and a copy of which can be provided to you.

The action by the other committee on H.R. 10729 has, we believe, made some provisions of these amendments inapplicable and we need to clarify our comments on several points.

Amendment 1012 would add a new definition to the bill: "unreasonable adverse effects on the environment"; and would change the criteria for registration and classification by adding the above defined term as the pivotal criterion.

The amendment would also delete the provision that the Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide.

We view the new registration criterion as not differing in substance from the present criterion of "substantial adverse effects on the environment." Both adopt the risk/benefits approach of present law which recognizes that, there being no pesticide not presenting some risk to the environment, any pesticide can be made available only by a finding that its benefits will exceed its risk.

Where two or more pesticides carry the same degree of risk and benefits, our policy is that each can be registered if it meets the other requirements of the act. The provision of H.R. 10729 which states that nonessentiality may not be a registration criterion was written against this background of administrative practice.

Amendment 1003 would make submission to the Administrator of safety and effectiveness test data by every registration applicant mandatory; permit public access to nontrade secret data in support of a registration application once it has been submitted to the Administrator and before he has made his determination; and would specify those persons to whom a trade secret may be revealed.

Requiring the submission of test data with every registration application is unnecessary since this Agency in many cases already has sufficient information to make a judgment consistent with the purposes of the act.

We also feel that public access to registration application information before a registration decision by the Administrator could lead to interminable delay of the entire registration process.

There is a constant flow of documents which come into the Agency while a registration is pending. The sheer volume of paperwork involved in making these public prior to assembling a file and receiving comments from our reviewers would create a major and unnecessary administrative burden.

We believe that under present law—and rules promulgated pursuant to present law—persons adversely affected by a registration action of the Administrator have—and under the bill would continue to have—all necessary and reasonable access to registration information.

Regarding instances in which trade secrets may be revealed, we view the amendments as too broad and suggest the provision be revised to control revelation of trade secrets to the public and to provide that revelation during administrative and judicial proceedings would be in camera. We have submitted specific language to accomplish this, which is part of the Senate Agriculture Committee's hearing record and we urge you to consider it.

Amendment 1004 would delete from section 3(c)(1)(D) the provision which prohibits the Administrator from considering certain test data submitted in support of a registration; and would insert a provision which would explicitly state his authority to consider any test data submitted to determine the adequacy of an applicant's test data.

We fully concur with both proposals. I have already commented on both provisions of this amendment. The latter provision was incorporated in the bill reported by the Senate Agriculture and Forestry Committee.

Amendment 1005 would amend the criteria for classifying a pesticide as general or restricted use by clarifying the Administrator's flexibility to determine that some products, no matter how labeled, cannot be rendered safe for use without additional regulatory restrictions.

We feel the amendment to the classification criteria which is contained in the reported bill adequately solves the problem which amendment 1005 was aimed at.

The Senate Agriculture and Forestry Committee has restored the "commonly recognized practice" language from present law which, we believe, permits this Agency to take into account the possibility for misuse and negligent handling.

While one Federal court has placed a narrow construction on this language, we feel that decision is wrong and that this language, as construed by Agency decisions, gives us the flexibility we need. If the subcommittee feels further amendment is necessary, we would be glad to work with you on it.

Amendment 1006 would emphasize the right of any interested person to participate as a party to any hearing requested following an order of the Administrator cancelling a registration. The amendment would also authorize the Administrator to impose conditions or limitations on the hearing.

We agree that any interested person should be able to intervene in a hearing. This is the practice under the present law and that practice is, we believe, carried forward by H.R. 10729 as reported and no further language is necessary.

We believe that the deletion by amendment 1006 of the provision authorizing the Administrator to determine on his own initiative that a hearing should be held is undesirable as is deletion of the provision governing issuance of subpenas by the hearing examiner to compel testimony. We view both as important means for the resolution of issues involving pesticides, and we support the revised language of the reported H.R. 10729 which clarifies those authorities.

Amendment 1007 would eliminate the right of any party to a hearing on a registration to insist that relevant scientific issues be submitted to a scientific committee, giving the hearing examiner the exclusive authority to determine what questions of scientific fact should be submitted.

We do not concur with the amendment, which would appear to give a hearing examiner freedom to ignore a request to refer a scientific question to an expert body. We believe the revised language in the reported bill gives the examiner discretion to determine what relevant issues of fact should be submitted to the advisory committee and we favor such discretionary authority.

The amendment would also prescribe the makeup of an advisory committee, which we regard as impractical, and would provide that the recommendations of an advisory committee report are not binding on the Administrator, which we now concur with and practice.

We note that as drafted the reported bill could be construed so as not to permit reference of a question of scientific fact, which arises during the course of a hearing and was not anticipated at the outset. We would, in such cases, read the language as authorizing the hearing examiner to refer such unforeseen questions to a committee during the course of a hearing.

Amendment 1008 would increase from $1,000 to $10,000 the maximum criminal penalty for a violation of the act by a private pesticide applicator. We do not object, as the court may set the penalty to fit the particular violation.

Amendment 1009 would delete all of section 15, indemnities. This deletion has already been made by the Agriculture and Forestry Committee, and we fully support the deletion.

Amendment 1010 would provide that a petitioner for an order or rule by the Administrator may request judicial review if his petition is denied in whole or in part. We do not object, but view the provisions of the reported bill as not preventing such a request for review.

The amendment would also provide that a stay of an EPA action may be granted by a reviewing court only under certain conditions.

Again, in our view the present provisions of the reported bill are fully adequate. If the subcommittee prefers more explicit language, we would be pleased to assist in drafting such provisions.

Amendment 1011 would insert a new section, "Citizen Civil Actions," which would provide for citizen suits against any person, including any Government agency, upon an alleged violation of the act; and against the Administrator upon his alleged failure to perform any required, nondiscretionary act or duty under the act.

While there was no provision for citizen suits in the administration's bill, we would not object to such an authorization here under the following circumstances:

We feel strongly that it should be limited to suits alleging violations only against users and producers.

We also feel that such actions should be required to be brought initially where the alleged violation has occurred, and that express provision should be made for consolidation in appropriate circumstances.

We have submitted specific language to accomplish this and urge its consideration.

Amendment 1013 would impose recordkeeping and reporting requirements on producers of exported pesticides. The amendment also requires the Administrator to furnish foreign governments with notice of the availability of registration application information, all registered labels, and all suspensions, cancellations, and changes in classification.

The administration's bill, S. 745, would have required that notices of cancellation and suspension actions be furnished to foreign governments.

In our earlier comments on additional provisions of amendment 1013, we stated that they would create a heavy administrative burden.

However, upon further review, we do not believe that this would be the case and do not object.

Amendment 1017, proposed by Senator Stevenson, would impose pesticide labeling, testing, classification, and user certification requirements in order to protect the health of farmers, farmworkers, and others who may come into contact with pesticides or pesticide residues.

We are in accord with the Senate Agriculture and Forest Committee report on H.R. 10729, which states that the bill, "Provides complete safeguards to protect farmers and others." And emphasizes that the bill requires the Administrator to impose such requirements as are the subject of the proposed amendment.

Mr. Chairman, that completes my prepared statement. We would be glad to respond to any questions.

Senator INOUYE. Mr. Dominick, the subcommittee has prepared several questions which we would like to submit to you for your response.

In addition, Mr. Bickwit, the staff counsel, has a few questions to ask at this time.

Mr. BICKWIT. What is your reaction to the Senate Agriculture reported provisions relating to cancellation and suspension, and judicial review of each? Do you support those?

Mr. DOMINICK. We do.

Mr. BICKWIT. Can you not see those provisions leading to numerous harassing lawsuits if legal action were initiated after your decision to suspend a pesticide summarily, followed by legal action after your decision to suspend it after a public hearing, followed by legal action after your action to cancel it, finally?

Mr. DOMINICK. Mr. Bickwit, I think that, in order for this committee to have a full record for it, it would be helpful in this regard for you to have the proposed rules of practice that we have published in EPA, and would intend to formalize in the near future.

We view the judicial review provisions as very workable, as reported by the Senate Agriculture Committee.

We feel that it is important that review of such concepts as risk-benefit, a substantial question of safety and other major areas of administrative law should take place in the circuit court of appeals.

We also agree that where there has been no full administrative record developed through a hearing, review immediately in the district court is in order.

Therefore, we feel that the proper mechanism has been established in the bill as reported.

Mr. BICKWIT. But, as I read those provisions, it is your intention to suspend on an emergency basis, and follow that suspension with a cancellation order.

After your decision to suspend summarily, you would be subject to a suit for judicial review in the district court. Following your decision to conduct your suspension hearing, if you were to conclude that the suspension was justified, you would then be subject to judicial review in the circuit court, and then after you initiated cancellation proceedings, which would be incumbent upon you, while you were in the process of suspending, you would be subject, again, to judicial review in the circuit court.

The prospect of those three lawsuits, it would seem to me, could be one that might lead you to refrain from action that on the merits you might feel was justifiable. If you said it would not, we would accept that.

But, having outlined that prospect, let me ask you whether you think it might?

Mr. DOMINICK. Well, I think that as a matter of practice, once we had reached a decision that suspension of any given registered pesticide was warranted because there was an imminent hazard posed by the continued use of this pesticide, that such a decision would be sustainable against court challenge to the degree that the suspension could remain in effect until a full record was developed.

That is, in response to your question, I feel that action could be taken in those instances where suspension was needed in order to protect public health, and the environment, and that an orderly process of administrative and then, judicial review could take place.

Mr. BICKWIT. My only concern is that it will take place many times under those provisions.

Mr. DOMINICK. Well, I cannot state with assurance what is going to happen in the future. We feel this is one of the complex provisions of the law that we are going to have to gain experience with; so, I cannot give you a flat answer on that. Mr. Bickwit.

Mr. BICKWIT. How do you justify giving your support for those provisions, keeping parties other than the applicant out of the hearings on suspension?

Mr. DOMINICK. Because the hearing on suspension presumably would be based on a finding by the Administrator that an imminent hazard did exist. The reason for limitiing the parties, is to limit the time involved in such a hearing, to insure that any other information on the part of registrants was made available to the Administrator immediately, and final orders could thereby be issued.

Mr. BICKWIT. But if the Administrator has heard only the applicant, and not those who would oppose his position, is it not likely that the court, on review, would have a somewhat unbalanced record?

Mr. DOMINICK. We presume that in these cases, the agency would have taken a very firm advocacy position with respect to the suspension in the first place, or it would not have occurred. And in many cases, information has come to the attention of the agency by virtue of public interest groups, by virtue of petitions from third parties, and it is on the basis of that information that action has been taken.

So, we feel that a full record could be developed within the constraints of the time that we are trying to operate under.

Mr. BICKWIT. And you feel it could not be developed within those constraints if we allowed those other than the applicant into the hearing?

Mr. DOMINICK. We do not view that as a very significant point at the present time. As you know, we have taken many steps to insure that there is access to our entire decisionmaking process by all parties, and as you know, we are taking into account the viewpoints of all parties in reaching those final decisions.

So, I do not view this as something that is of great significance with respect to the total bill that we have before us.

Mr. BICKWIT. Can you conceive of a hearing examiner with a forceful hand keeping the time down if you did let in those other than the applicant?

Mr. DOMINICK. We could conceive of that situation. We could conceive of a situation where cross-examination and rebuttal would be very severely limited; yes.

Mr. BICKWIT. You mentioned a decision relating to the term "commonly recognized practice" and you gave us your reaction to that decision, and you said that you thought it was wrong.

Could you describe to us briefly, for the record, what was involved in that case, and why you think the decision is wrong, so that we can insure that the committee either agrees or disagrees, to adopt similar language?

Mr. DOMINICK. Well, I will have Mr. Charles Fabrikant speak to that point. I believe this is of significance by virtue of the fact that there have been conflicting decisions in the various circuit courts, and we have chosen to interpret the present authority under FIFRA, as carried forward under the new bill, as giving us authority to recognize the principle of commonly recognized practices.

Mr. FABRIKANT. The decision involved the *Stearns Phosphorus Paste Co.* v. *Environmental Protection Agency.*

That case was decided by the seventh circuit court of appeals, several weeks ago. What was involved in that case was an action taken by the EPA to cancel a product involving a highly toxic substance used around the home.

While no particular facts involving an individual product could be pointed to, general experience with products involving this chemical showed extensive household accidents, and a tendency to misuse the product in such a way that deaths were caused to children.

The agency took the position that under the present provisions of FIFRA, this constituted a commonly recognized practice, and that the product could not be used safely.

The court disagreed with the decision of, I believe it was Mr. Pearlman, in concluding that the agency had made out its case, and the extensive hazard involved in this use, constituted misbranding under the law.

The courts of appeal and the Agency explored, in great detail, the legislative history of the commonly recognized practice language in the present law. That provision was greatly debated before it was inserted into present law, and it is the Agency's view that the legislative history leading up to the inclusion of that language meant to give USDA, at the time, and subsequently the EPA, the authority to make sure that certain products could be regulated, when proved through experience that labels were inadequate to prevent hazards in terms of the likelihood of the directions being followed.

Mr. BICKWIT. So it is your analysis of that case, that the decision involved did create a commonly recognized practice.

Mr. FABRIKANT. Yes.

Mr. BICKWIT. Speaking for the staff of the committee, I would not contradict that.

I have one final question, and that is: With regard to the Hart-Nelson amendment which was discussed earlier by the industry witnesses, that relating to the use of an applicant's data for evaluation of those pieces of data submitted by other than the applicant, do you find that using the data of the first applicant in that hypothetical to evaluate the data of the second applicant, or for use of the second applicant, has led to an incentive to develop pesticides?

Mr. DOMINICK. I do not believe that we have any hard figures to which we could point concerning incentive in the research and development and bringing forward of new products in the pesticide industry.

We feel that this is a matter of general principle, and we feel that this is a matter of real concern to the administration and other portions of Government agency responsibility, and we feel that in this regard, the Administrator should have available to him all informationtion in reaching decisions on registration.

So, the short answer to your question is, I do not have any evidence before me that would indicate incentive or disincentive by virtue of this particular issue.

Mr. BICKWIT. Thank you very much.

Senator INOUYE. I would like to call a short recess at this time.

We are having a vote on the floor.

So, if you would remain, I have a few questions I would like to ask.

Mr. DOMINICK. Very well, Mr. Chairman.

Senator INOUYE. We will stand in recess for 10 minutes.

(Recess.)

Senator INOUYE. The hearings will please come to order.

Mr. Dominick, I have a few questions I would like to ask before adjourning this hearing. I believe one can safely assume that H.R. 10729 in some form will be passed by this Congress this year. It has gone through the necessary stages, and one can make that assumption. Have you made that assumption?

Mr. DOMINICK. Yes, we have, Mr. Chairman, and I think it is critical to the proper administration of this area that we do get a bill this year.

Senator INOUYE. Now, if you have made that assumption, have you made plans to implement some of the new authorities which would rest in the Administrator's office?

Mr. DOMINICK. We have, Mr. Chairman. We have not submitted any requests for supplemental funds. We would do so, of course, under the guidance given us by the Office of Management and Budget, but we have laid the ground work in terms of planning for the implementation of this new bill.

Senator INOUYE. Among the new authorities, the Administrator will conduct research on pesticides alternatives and will monitor pesticide use and presence in the environment. What kind of money will you be asking for to implement these two new authorities?

Mr. DOMINICK. We don't view the conduct of research and the monitoring of pesticides in the environment as a new authority. That has been conducted by a number of Federal agencies in the past. Many of their functions were transferred to EPA when it was formed in December of 1970, and there is a good deal of research and monitoring going on at the present time.

We can describe to the committee in detail what is being done at our various laboratories, and would be happy to provide that for the record.

Senator INOUYE. I just quoted from your prepared statement, in which you said that authority is not under present law.

Mr. DOMINICK. I take it that goes to the question of pesticide use.

I apologize for misinterpreting your question.

Senator INOUYE. What sort of money will you be asking for to implement these two authorities?

Mr. DOMINICK. We will refer to our previous submission to the Congress which outlined the new finances required to implement S. 745, and provide that to the committee.

Senator INOUYE. In your statement, you refer to section 23(c), which authorizes the Administrator to permit a State to register pesticides formulated for distribution and use within the State to meet specific local needs. I presume that this amendment was initiated or supported by wide interest. Now, does the fact that a State is isolated from the rest of the continent make any difference?

Mr. DOMINICK. It should not make a difference, Mr. Chairman. We should be able to register and establish tolerances for pesticides no matter where they are being used.

I am aware of instances that have been recently called to my attention where tolerances have not been established for certain pesticides which are used uniquely in Hawaai.

We are taking steps to address that problem, and to, if possible, within the restraints of technical difficulties, make such pesticides available.

Senator INOUYE. It has been suggested by industry members in Hawaii that because of the insular nature of our State that insects can have a greater devastating effect than any other environment. Does that make any sense?

Mr. DOMINICK. I think it would. I think that there are unique crop situations, there are unique weather situations in Hawaii which we would not find anywhere else in the continental United States, sir.

Senator INOUYE. Mr. Dominick, as you may be aware, at our first hearing several witnesses charged EPA with failing to disclose certain information to the Congress relating to the dangers to farmworkers posed by certain dangerous pesticides, and I am certain you are aware that this charge is now on the record, and I would like to give you an opportunity to provide this subcommittee with your responses if you so wish.

Mr. DOMINICK. I would be happy to, Mr. Chairman. We feel that charge is unwarranted for a number of reasons.

In the first place, the bill clearly does call for the protection of applicators and the protection of farmers, the protection of farmworkers.

I refer you to page 83 of the committee print which says that if the Administrator classifies a pesticide or one or more uses of such pesticide for restricted use because of a determination that acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restrictive classification applies only by or under the direct supervision of the certified applicator.

That indeed is one of the cornerstones of this bill, classifying pesticides in such a way that they will be applied only under strict regulation and supervision.

Additionally, I would point out that the data which the group testifying before this committee discussed has been the subject of numerous publications in the past, and indeed we have over 200 published documents reporting results of the so-called community studies, and we are publishing more all the time.

In order to accommodate all groups who are interested in this difficult area of pesticide control, and in keeping with our Agency's practice to make all information available to the public which is not covered by the trade secret provisions of federal law, and which would serve some public interest by its release, we have made available all of the draft studies to which Mr. Krebbs and others have referred.

They can be obtained in our pesticides office from Dr. Upholt or his colleagues at 1750 K Street here in Washington.

I would also point out that a Dr. Milby who has been conducting a number of studies on farmworkers and on the public health problem related to pesticides is the chairman of the Subcommittee of the Federal Working Group on Pest Management, a working group involving all Federal agencies involved in this question.

And that subcommittee will be making a report to us on the question, on the issue of field reentry standards.

They are meeting in California this week. They will meet here in Washington later in July, and, of course, we will keep this committee and any other committee that is interested up to date on the progress of our efforts at the Federal level and at the State level, in this case the State of California, to establish adequate and protective field reentry standards.

Finally, Mr. Chairman, I would refer to some of the press accounts that resulted from the testimony before this committee, and say that with respect to the DDT decision, first of all, I am enjoined by the Justice Department to confine my remarks concerning that decision to the matters of record and to the matters which are contained in the Administrator's formal opinion by virtue of the fact that this has been appealed already by both parties, but within that constraint I can say that a careful reading of that opinion indicates that the Administrator and myself and others involved in that decision took into very careful account the whole question of toxicity of potential substitutes for DDT.

Indeed, a whole section of the opinion starting at page 36 deals with that question.

So that in summary, Mr. Chairman, is our response.

This is a matter of concern, a matter of serious attention on the part of the Environmental Protection Agency.

Senator INOUYE. I believe the charge was not made on the basis that the Agency refused to disclose information, but failed to volunteer such information when such information would have been relevant to the consideration of the committee.

I realize that if I wanted information, or the staff people wanted information, they may go to your office and pick it up, but I believe these witnesses felt that the information should have been disclosed voluntarily and the committee advised of the availability of such data.

Mr. DOMINICK. Well, in that regard, Mr. Chairman, it has been a matter of public record, and a matter of continuing awareness on the part of the Congress that this Agency and our predecessor agencies have been carrying out community studies in some 15 States around the Nation for many, many years.

Additionally, it has been a matter of record by virtue of the publication of the results of those community studies that this is available to the scientific, professional community, as well as, of course, available to the Congress.

Now, with respect to the immediate results of recent studies, we feel that these should be available for review by any interested person, and we feel that in reviewing them they should be aware of the fact that these studies are not complete, that there may be additional information required before you can have a scientifically credible study suitable for publication.

But we are not in any way attempting to withhold any of this information from or mislead anyone who is interested in obtaining it.

If we had information present which would be of interest to the committee in response to any particular amendment, we are happy to discuss that with the committee.

Additionally, as I say, in reaching decisions, the most instant decision being the DDT decision, a decision of great public importance, the whole question of the toxic effect of substitute chemicals, and a very thorough review of the most recent information available, and present in the record, following 7 months of testimony, all of that went into the deliberations and consideration of the Administrator.

I feel that that is a complete response to this matter.

Senator INOUYE. During our first day of hearings, it was revealed that certain studies in California had raised serious questions as to whether the currently registered labels for ethion and guthion adequately protect the farmworkers.

One of those studies indicated that, depending on when the measurements were taken, 13 to 21 of 23 workers suffered serious losses of an enzyme necessary to transmit nerve impulses, and that those pesticides were used in accordance with label instructions. Under EPA criteria, if substantial question as to the safety of a registered pesticide exists, a cancellation notice should ensue. Would you respond either now or for the record as to whether the requisite substantial question as to safety exists with respect to those two pesticides, Ethion and Guthion:

Mr. DOMINICK. We would be very happy to respond. I think it would be more appropriate to do so for the record.[1] These are extremely complex scientific questions, and I would not want to give you a top-of-the-head answer to that.

Senator INOUYE. Thank you very much, Mr. Dominick.

As indicated earlier, we wish to submit questions which were referred to us by Senator Baker for your response.

I have been advised that Mr. Thomas Garrett, representing the Friends of the Earth and the Defenders of Wildlife, has submitted a prepared text, which text without objection will be made part of the record.

(The statement follows:)

STATEMENT OF THOMAS GARRETT, WILDLIFE CONSERVATION DIRECTOR, FRIENDS OF THE EARTH

Mr. Chairman, I am Tom Garrett. I appreciate this opportunty to appear. I am testifying on behalf of two conservation organizations, Friends of the Earth and Defenders of Wildlife.

FOE is a national organization with 27,000 members, dedicated to the preservation and rational use of the earth. We have active sister organizations in six European countries. Our Washington office is at 620 C Street SE.

Defenders of Wildlife is a national organization of 39,000 members, active in defending wildlife and wildlife habitat, with offices at 2000 N Street NW., Washington, D.C. Mary Harris is executive director and editor of Defenders of Wildlife News.

FOE and Defenders of Wildlife strongly endorse all of the Hart-Nelson amendments. We also endorse the Stevenson amendments designed to protect farm workers and farmers, as well as consumers, from acute and chronic poisoning. We wish to commend and thank the sponsors.

We consider it particularly important that 1003, which will permit the public and the scientific community to examine evidence, and influence registration decisions before they are made, be included in the eventual bill. This will ventilate the closed decision making process, and reduce the influence of the industry in the decision making process.

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[1] See p. 273.

This amendment, along with 1012, 1011, and 1007 will tend to reform a system in which the arena of proof as to the effects of a pesticide on the environment has, in fact, been the environment. The use of hard chemical pesticides over the past 25 years has taken the form of a vast, and often disastrous experiment, in which we have all to some extent been victims.

We are, of course, gratified, that EPA has set a date for the curtailment of DDT. We cannot become too ecstatic however. Many marshes and estuaries show concentrations of thirty pounds or more per acre, most of which has not yet entered food chains. They can be expected to act as reservoirs for the continuing release of this poison into organic systems, for decades and perhaps centuries. The situation, in as far as the marine environment is concerned, will obviously get worse before it improves. Concentrations in upper trophic levels will doubtless continue to increase for years. The committee is, of course, well aware of the effects of DDT on various marine and freshwater organisms, fish and birds. Last year, for the first time, solid evidence became available linking reproductive failure in marine mammals with high concentrations of DDT.

The curtailment of DDT came at least a decade after overwhelming evidence has been available of its disastrous effects on wildilfe, and of the bankruptcy of agricultural practices based on its indiscriminate application. As Senator Nelson has pointed out, the situation with respect to mercury fungicides, which are still being applied, is equally scandalous. There are, of course, numerous other stable chlorinated hydrocarbon and heavy metal compounds on the market.

The chemical industry has been permitted to engage in a completely irresponsible competition for the sale of vast amounts of deadly poisons which contribute to the decline of the environment in a way which affects all of us. Even after the accumulation of overwhelming evidence of large scale, and often already irrevocable damage, there has been interminable foot dragging on the part of government agencies empowered to act in the public interest.

We consider it very important that the amendment concerning exports be passed. In fact, we would prefer an even stronger measure. It seems completely irresponsible to export abroad items which are demonstrably unsafe for use at home. The impact of U.S. technology on rural and peasant societies, in which humans have been components of more or less balanced ecological systems, has been, more often than not, disastrous. This is true even without considering Vietnam.

Guatamala, to cite a minor example, is apparently worse off from a standpoint of malaria than before the beginning of massive spraying programs. In the meantime, concentrations of DDT in foodstuffs and milk are extremely high, and infant mortality is double the national average in treated areas . . . through no causal relationship has been established.

In any case, misuse of poisons abroad is bound to have some effect on U.S. citizens. In particular, stable poisons are certain to show up in the oceans, and will eventually permeate the marine continuem and affect commercial fish stocks. The U.S. delegation to Stockholm was instructed to strive hard to reduce ocean pollution.

We would like to commend Senator Nelson for his previous legislation providing for pilot field research programs for control of pests by integrated biological-cultural methods. It seems to me that we need a far greater effort in this area. It is far cheaper to spend money on selective insect control now, than to spend a great deal more later attempting clean up the results of misuse of broad spectrum poisons. An ideal Pesticide bill would set aside whatever funds might be required for study, and the development of alternative methodologies for controlling insects.

In previous testimony, I noted that the "plight of the modern farmer, highly dependent on chemical zooicides, involved in a blindly escalating economically ruinous chemical warfare in which he cannot win, and in which all of us lose" is analogous to drug addition in an individual.

We belive that some of the chief victims of the situation have been farmers, particularly small farmers. It seems to us that an ideal bill should not only aim at systematically phasing out hard pesticides, replacing them with integrated methods, but should subsidize the farmer during the transition period to the degree necessary to end his fatal addiction.

The pesticide industry has spent many millions of dollars on advertising, and hired many thousands of salesman, to induce farmers to use, and become addicted to, ecologically crude and deadly poisons. Every farm magazine is heavily dependent on advertisements placed by these companies, and the tone of articles

concerning pesticide use is guided by sensitivity to the reaction of the corporations. The same mentality, with similar overtones of economic dependence, imbues the agricultural departments of many colleges. It will require a major effort to overcome this, and to educate farmers to alternative selective methods. Adequate funds to accomplish this should certainly be set aside.

We consider the acquisition of large acreages of farmland by large corporations, and especially chemical companies, as a particularly sinister development, which, if not corrected by legislation such as Senator Nelson's Family Farm Act will complicate efforts to achieve pesticide reform. Pesticide abuse, and other dangerous and unsound practices, seem far more prevalent on large, corporately owned enterprises than on family farms.

The fact that the House, in the face of overwhelming evidence of environmental damage would pass a bill which weakened already sadly inadequate legislation, and which even provides indemnity to pesticide manufacturers, is evidence of the prodigious influence of the chemical companies in this country. However, we are heartened by the activities of this committee, and we hope and expect that the Senate will fully understand what the House apparently failed to grasp; that the action taken on this legislation may amplify profoundly, and that the issues at stake far transcend the comparatively trivial considerations of vested economic interests.

Senator INOUYE. Is Mr. McIntire here?

VOICE. He left, sir.

Senator INOUYE. He had a statement and I will insert it in the record. I would like to thank all of you for being patient with this subcommittee, and once again I apologize for the undue delay this morning.

With this, the hearing is adjourned.

(The statement follows:)

STATEMENT OF CLIFFORD G. MCINTIRE, LEGISLATIVE DIRECTOR, THE AMERICAN FARM BUREAU FEDERATION

Mr. Chairman and members of the subcommittee, the hearings now being held by this subcommittee are of deep interest to farmers and ranchers, woodland owners, nurserymen, wildlife interests, recreationists—in fact, all citizens of this country as well as millions abroad.

The American Farm Bureau Federation is a nationwide general farm organization with membership as of December 1, 1971 of 2,057,665 families who are voluntary, paid up members of 2,820 County Farm Bureaus in 49 states and Puerto Rico. Any action taken by the Environmental Protection Agency relative to pesticides or other materials and practices needed for a productive agriculture in this country is of interest to this membership.

The voting delegates of member State Farm Bureaus to the 53rd Annual Meeting of the American Farm Bureau Federation in Chicago, Illinois in December of 1971 adopted the following policy relating to agricultural chemicals and environmental protection:

"AGRICULTURAL DRUGS AND CHEMICALS

"Modern agriculture cannot continue to provide sufficient quantities of high quality food and fiber to meet the nation's needs without the use of agricultural chemicals and drugs. Any undue curtailment of the safe and appropriate usage of these products will result in lower quality food and fiber at higher costs to consumers.

"We recognize the problems involved in the use of agricultural chemicals as they relate to our environment. We are concerned that farmers and ranchers may lose the opportunity to use essential agricultural chemicals and drugs in an appropriate and safe manner. We urge users of these products to be aware of the dangers involved and to conform to recommended usage.

"In any evaluation of chemicals and drugs, the possible detrimental effects must be considered in relation to the benefits derived. Only through this means can a balance between environmental control and chemical control be effectively attained.

"We urge that Farm Bureau at all levels seek to inform users of the necessity of proper use of these products. State Farm Bureaus should take leadership in

developing programs and legislation to insure continued safe use of agricultural chemicals.

"We oppose a complete ban on the use of any agricultural chemical or drug unless it can be demonstrated positively by prolonged and responsible research that the use of such product represents a clear and present danger to health or that such use would seriously jeopardize our environment.

"We recommend that the Environmental Protection Agency establish an agricultural advisory committee, including representatives of farmers and ranchers, to advise in determinations affecting environmental matters relating to agriculture.

"We support expanded biological pest control research to determine where biological pest control measures can provide a practical and feasible substitute for chemical controls.

"The use of antibiotics, feed additives, and hormones is essential to efficient modern-day production of high quality animal products, and substantial safeguards are employed by producers to eliminate harmful residues. We oppose proposals to ban use of such materials in livestock and poultry production.

"Farm Bureau, the U.S. Department of Agriculture, the Cooperative Extension Service, and the state departments of agriculture should assist farmers and the public to obtain a better understanding of the significance of agricultural chemicals and the laws and regulations covering their usage.

"ENVIRONMENTAL PROTECTION

"State and County Farm Bureaus should take the initiative and provide leadership in representing the interest and responsibility of agriculture in all issues encompassed by the term "quality of environment."

"Existing federal laws already provide that state laws relating to water and air quality, solid waste disposal, and environmental quality, including noise and radioactive materials, must be consistent with federal laws and must provide for adequate enforcement. If complete federal domination of this field is to be avoided it is urgent that Farm Bureau take leadership in the counties and states to construct and enforce adequate programs.

"The capabilities of the membership and leaders of Farm Bureau at local, state, and national levels should be used to assist citizens, organizations, legislators, and public officials to understand the interrelationship of a productive agriculture to decisions involving controls and regulations relating to the environment.

"As a farm organization we accept our responsibilities to:

"(1) Advise farmers and ranchers of environment problems related to agricultural operations.

"(2) Report the findings of responsible research regarding possible solutions to agricultural pollution problems.

"(3) Provide State Farm Bureaus information as to provisions in state legislation relative to environmental protection.

"(4) Bring to the attention of farmers and ranchers the hazards associated with the careless, excessive, or improper uses of agricultural chemicals and pesticides.

"(5) Counsel with private interests and government agencies on environmental problems as related to agriculture.

"(6) Assist and encourage the appropriate state agencies in developing responsible, reasonable, and economically feasible regulations and standards based upon reliable research for:

"(a) The use of agricultural chemicals and pesticides.

"(b) The construction of agricultural waste disposal systems or facilities.

"(c) The management of soil, water, and related natural resources to minimize detrimental effects upon the environment.

"(7) Support adequate appropriations for research concerning sources, causes, and practical and reasonable means of preventing, controlling, or abating any possible pollution from farming operations.

"Farmers and ranchers have made sincere efforts to comply with—and have committed heavy capital expenditures to meet—federal and state guidelines or standards relative to water, air, and solid waste. These efforts are frustrated and often nullified by the imposition of poorly developed standards and regulations.

"Federal and state statutes and regulations should be so written as to give assurance to the owners of approved agricultural, industrial, or municipal air,

water, or solid waste treatment facilities and systems that will allow an orderly amortization of the investment made in such facilities or systems, as allowed by laws and regulations under the Internal Revenue Code.

"Owners and operators of such approved waste treatment facilities, or systems, should be further protected from harassing environmental lawsuits that concern the design or the adequacy of treatment of such when operated in an approved manner to handle up to the maximum load of waste for which they were designed and approved by the federal, state, or local regulatory agency of government."

These resolutions constitute a firm commitment, sincerely made. This policy presupposes that public officials making decisions relative to the use of pesticides, other materials and practices used in the agriculture of the 70's and 80's understand that modern agriculture is far from the agriculture of the 30's, 40's, 50's, and early 60's. The technology of materials, cultural practices, equipment and use of manpower is constantly changing, thus making the food supply of this country and the level of agricultural exports increasingly dependent on fewer and fewer people. The four percent of our people who live on farms and ranches provide food for the 96 percent who live off the farm and millions abroad. These domestic and foreign consumers are dependent on the capacity of the American farmer to adopt new methods, meet large demands for capital, adjust to less help on the farm and meet higher demands for quality in both fresh and processed foods. The capacity to do this has taken America over the threshold to an abundant supply of food of the highest quality and safety in the history of any nation.

Some people place these attainments very low in their priorities as they live comfortably in this abundance, little appreciating or understanding the narrow margins on which this capability rests, the close relationship of supply to weather and the fragile margin which stands between our food supply and the incessant efforts of the forces of nature—insects, disease, and ever present weeds—to take over the fields, meadows, and ranges.

As structured by Reorganization Plan No. 3, the Environmental Protection Agency is responsible for decisions that greatly affect the capacity of the American farmers and ranchers to continue their proven capacity to feed this nation. Decisions must weigh the needs of Americans for adequate supplies of food at reasonable prices against the needs of the same citizens for a quality environment. We have confidence that those making these decisions will understand fully that while there are situations in nature that are fragile, there are equally fragile situations in a productive agriculture wherein an unwise decision—whether due to a lack of information or to misinformation—will have wide and serious consequences.

It is extremely important that there be greater understanding of the reasons pesticides are used. Pesticides not only determine the essential economic factor of our ability to have certain products; pesticides also are essential to managing the pollution of all types of vermin and disease organisms within our homes, schools, public places, business offices—in fact, every element of our daily living.

People need housing and they want forests. The same people want nearly 5000 products that are derived basically from wood fibre. Forest fires are spectacular and devastating but fire losses are not comparable to insect damage even with current methods of pest and disease control. To yield the forest environment to the full mercy of pests and diseases, to surrender farm production and food quality to the first call of their natural enemies is to callously ignore the importance of meeting human needs for food, fibre and shelter and to risk the progress now being made in increasing the wildlife and recreational potential of the resources available to this and future generations.

This Subcommittee has under legislative study H.R. 10729, "The Federal Environmental Pesticide Control Act of 1972." This bill proposes to amend the Federal Insecticide, Fungicide and Rodenticide Act. In its place, H.R. 10729, as proposed in the title, places substantial emphasis on environmental considerations and control of the use of pesticide materials. This bill uses a substantial part of the language of the present law with changes to grant greater authority to the Environmental Protection Agency and shorten the time involved in procedural matters as the Administrator considers suspension, cancellation, stop sale orders and the recall of pesticides already registered for sale in interstate commerce.

A major objective of the bill is to impose disciplines on the users of pesticides whether in agriculture, forestry, recreational areas, gardens, industrial or home use.

The careful handling and effective use of pesticide materials by thousands of farmers, ranchers and woodland managers on millions of acres of land across America is given little credence. The use of research data gathered from experiments unrelated to normal usage, coupled with emotional interpretive commentary, places before this Congress the serious problem of how best to develop constructive legislation placing workable disciplines on the use of pesticides. It is our purpose to assist this Committee in this effort.

We recommend that this Subcommittee study in depth the present and future prospects of pesticides manufacturers continuing both the production of presently registered pesticide products and the research and developmental work that is necessary to bring new products to market. There is little purpose in writing a body of law regarding the use of pesticides if the manufacturers are going to find the possibility of recovering their investments seriously impaired. The manufacturers are well able to speak for themselves, but their decisions in this regard are critical to the farmers and ranchers who use their products.

This bill requires the Administrator of EPA to classify the use of all pesticides into two classes: (a) for general use, and (b) for restricted use.

It will be appreciated that this legislation has been of deep interest to farmers and ranchers and, as a general farm organization, the American Farm Bureau Federation has endeavored to participate constructively in the legislative developments.

Very extensive and constructive hearings have been held both by the Committee on Agriculture of the House of Representatives and the Committee on Agriculture and Forestry of the U.S. Senate.

As a part of this testimony there is attached a communication dated October 1, 1971, signed by Mr. Marvin L. McLain, then legislative director of the American Farm Bureau Federation, to all members of the House of Representatives in support of H.R. 10729 as reported by the House Committee on Agriculture.

We had previously testified before the Senate Committee on Agriculture relative to this legislation, but on March 3, 1972, we filed a letter with the Subcommittee on Agricultural Research and General Legislation, chaired by the Honorable James B. Allen of Alabama, in support of H. R. 10729, recommending that the Subcommittee and the full Committee report the bill essentially as passed by the House of Representatives. A copy of this letter is attached.

Mr. Chairman and Members of the Subcommittee, we appreciate the opportunity to express these views relative to legislation that is of vital interest and concern to the farmers and ranchers who have so ably provided food and fiber for America and millions abroad and who look forward to fulfilling these basic needs of people both presently and in the future.

AMERICAN FARM BUREAU FEDERATION,
Washington, D.C., October 1, 1971.

To All Members, U.S. House of Representatives:

It is our understanding that H.R. 10729, the Federal Environmental Pesticide Control Act of 1971, will be before the House for consideration during the week beginning October 4.

The House Agriculture Committee held very extensive hearings on this legislation and gave it careful consideration in executive sessions. This resulted in many changes in the earlier bill submitted by the Administration and introduced as H.R. 4152 on February 10, 1971.

Chairman Poage and Ranking Minority Member Belcher co-sponsored H.R. 10729. A majority of the members of the House Agriculture Committee of both parties support the bill. Mr. Ruckelshaus, administrator of the Environmental Protection Agency, has a letter in the Committee Report supporting the bill.

Farm Bureau has worked closely with the Committee for many weeks in developing this bill. While the bill is a compromise of many views, it is a good bill. We congratulate the members of the House Agriculture Committee for their good work.

Farm Bureau supports H.R. 10729 as it came from the Committee. We urge you to support it.

Sincerely yours,

MARVIN L. MCLAIN.
Legislative Director.

AMERICAN FARM BUREAU FEDERATION,
Washington, D.C., March 3, 1972.

Hon. JAMES B. ALLEN,
Chairman, Subcommittee on Agricultural Research and General Legislation, Committee on Agriculture and Forestry, U.S. Senate, Washington, D.C.

DEAR SENATOR ALLEN: As you know, the Subcommittee on Agricultural Research and General Legislation of the Senate Committee on Agriculture and Forestry, of which you are chairman, held hearings in March of 1971 on S. 745, "The Federal Environmental Pesticide Control Act of 1971."

The Committee on Agriculture of the House of Representatives held extensive hearings on H.R. 4152, a similar bill carrying the same title. After careful consideration the House Committee on Agriculture reported a clean bill, H. R. 10729, carrying the same title, namely, "The Federal Environmental Pesticide Control Act of 1971."

The American Farm Bureau Federation by a letter dated October 1, 1971, advised each member of the House of Representatives of its support of H. R. 10729 as reported by the Committee. This legislation was considered by the House of Representatives on November 9, 1971. One amendment was accepted and the bill given endorsement by the members of the House by a roll call vote of 288–91.

Under date of November 6, 1971 we wrote to each member of the subcommittee and the full committee as follows:

"We assume the provisions of the House-passed bill, H. R. 10729 will now be considered by the Senate Committee on Agriculture and Forestry along with S. 745, the bill that was the subject of hearings by the Subcommittee on Agricultural Research and General Legislation.

"We believe provisions of H. R. 10729 have been carefully considered, and we respectfully request the subcommittee and the full committee report to the Senate the language of the House-passed bill."

Your subcommittee has announced plans to hold public hearings on the House-passed bill, H. R. 10729, on March 7 and 8. It is fully understood that there may be a need for minor technical or clarifying amendments to H. R. 10729 but we wish to reiterate our recommendation that the subcommittee and the full committee report H. R. 10729, essentially as passed by the House, or a committee bill carrying essentially the provisions and language of H. R. 10729 with only minor technical or clarifying amendments.

We request that this letter be made a part of the hearings on H. R. 10729.

Sincerely yours,

MARVIN L. MCLAIN,
Legislative Director.

(Whereupon, at 2:30 p.m., the hearing was adjourned.)

ADDITIONAL ARTICLES, LETTERS, AND STATEMENTS

STATEMENT OF JOHN W. SCOTT, MASTER OF THE NATIONAL GRANGE

Mr. Chairman and members of the subcommittee, the National Grange supports H.R. 10729 as amended by the Senate Committee on Agriculture and Forestry, to amend the Federal Insecticide, Fungicide and Rodenticide Act. In our judgment, the bill as passed by the House and improved by the Senate Agriculture Committee is a major improvement over the legislation as it was first introduced by the Administration.

The bill is basically sound and is a substantial improvement over present law. We supported passage of the House Agriculture Committee bill before the House.

We were opposed to all the Hart-Nelson amendments that were presented to the Senate Agriculture Subcommittee. There was one exception, however. We did support the striking of the indemnity section (Section 15) unless it was amended to cover any crop loss suffered by a producer which is the result of the concellation, suspension and/or stop-sale and seizure of a previously approved and registered pesticide by the Administrator of E.P.A. Since that time the full Senate Agriculture Committee has approved H.R. 10729 with amendments. We have studied the Committee Report and are in agreement with the amendments added by the full Committee and believe that only minor amendments are necessary in order for the Administrator of E.P.A. to properly control the use of pesticides in protecting human health and the environment.

The delegates at the 105th Annual Session of the National Grange adopted the following resolution which fully explains our position:

INDEMNIFICATION TO AGRICULTURAL PRODUCERS

"*Be it Resolved*, That the National Grange recommends that agricultural producers be indemnified for financial losses sustained due to the confiscation of any agricultural commodity because of contamination by the application of pesticides and/or from any other source, by the appropriate regulatory agency, Congress or persons responsible for the contamination, if such contamination is due to no fault on the part of the producer; and be it further

"*Resolved*, That agricultural producers be indemnified for financial losses sustained due to crop losses which are the result of the cancellation, suspension and/or stop-sale and seizure of a previously approved and registered pesticide by the Environment Protection Agency, if such cancellation, suspension and/or stop-sale and seizure regulation is issued after the start of the growing season of the crop in question. Such indemnification shall be made by the regulatory agency issuing the regulation or by the United States Congress; and be it further

"*Resolved*, That no language be permitted in any pesticide legislation now pending or proposed in the future before the Congress that would foreclose an agricultural producer from seeking indemnification from the courts or from the U.S. Congress."

We were concerned about Sec. 15, pertaining to indemnification, particularly if the section could not be amended to cover crop or livestock losses sustained by producers when a pesticide was suspended, cancelled or otherwise denied a producer, if such cancellation came during the middle of a crop year. Sec. 15 was not amended as we requested, so therefore we support the deletion of this section. Furthermore, the committee report set out guidelines for the Administrator to follow in such situations and we do not believe this section is any longer necessary in order to indemnify dealers, distributors and users for any product they may have on hand at the time of cancellation.

The National Grange will support needed minor technical or clarifying amendments to H.R. 10729 as reported by the Senate Agriculture and Forestry Committee. In addition, we support the following proposed amendments:

1. A provision on page 78, lines 14 through 20, prevents data submitted by an applicant to substantiate claims for registration from also being considered

in support of any other application. Admittedly, agricultural chemical manufacturers invest huge sums in research. The fact still remains that much of the data, particularly in the area of effectiveness, is derived from land grant colleges which are publicly financed. Chemical manufacturers today are provided patent protection for some 17 years. However, the secrecy provision in the bill as written in effect extends the exclusive right to produce and market beyond any patent coverage, and thus subverts patent laws. We strongly urge the removal of this provision as it can only result in higher costs to farmers. If this recommendation is accepted, page 78, lines 14 through 20 will require modest rewording.

2. The provision on page 82, lines 14 through 24, gives the Administrator broad powers for classification of products for restricted use. Certain compounds—aldrin, dieldrin, DDT, 2,4,5-T, 2,4-D, toxaphene and others—have been on the market for many years. They have been tested and tried not only for their effectiveness but also for the effect of their application upon the environment and human health. We would hope that this committee, with the help of the EPA, could spell out the intent of this legislation with respect to classification for use of those pesticides which have been thoroughly tried and tested in actual field use over a long period of time and for which no conclusive scientific evidence has been submitted that proves these chemicals harmful to health or environment when used as directed.

3. We are puzzled by the specific instruction given on page 117, lines 20 through 22, to give priority to biologically integrated alternatives for pest control. We recognize that this language may have special appeal to some, but it really is meaningless. If the intent is to limit choice of research by emphasizing methods of biological pest control, then we question whether this is in the best interest of the public. There is ample proof that biological methods are not necessarily free of hazard, more economical or more effective to any greater extent than are chemical methods. We suggest that the Administrator not be limited in the pursuit of practical, safe and economical means of pest control.

At the time H.R. 10729 was being considered by the Subcommittee on Agricultural Research and General Legislation of the Committee on Agriculture and Forestry, four amendments were suggested on which the Subcommittee could not reach agreement:

1. Authorize third parties to petition for cancellation or suspension and obtain judicial review;

2. Would strike out the provision for indemnities to owners of pesticides for which registration is first suspended and then cancelled;

3. Would provide for citizens' civil actions for injunctive relief against the United States, the Administrator or any other person; and

4. Would strike the provision of section 3(d)(1)(C) authorizing the Administrator to impose restrictions other than the requirement that the pesticide be applied by or under the direct supervision of a certified applicator.

With respect to these four amendments the National Grange is in complete agreement with the disposition made by the Senate Committee on Agriculture and Forestry. The language contained in H.R. 10729, as reported by the Senate Agriculture Committee and Committee Report No. 92–838 accompanying H.R. 10729, covers the objectives and objections of the National Grange.

The Committee compromise proposal for Amendments 1 and 4 is far better than the amendments suggested by the National Agricultural Chemicals Association, Amendent No. 1010 by Senator Hart and Senator Nelson, and the suggestion made by the Environmental Protection Agency.

The compromise language adopted by the Senate Agriculture Committee makes it clear that the provision for cancellation hearings initiated by the Administrator is an alternative method of initiating cancellation proceedings, and that its purpose is to provide a method of examining the need for cancellation in a way that will not automatically result in cancellation simply through the default of the registrant in responding to the notice. The crieria for initiaing cancellation proceedings are those now in the Act. We believe they provide more definite guidelines than those approved by the House which would appear to give the Administrator almost unbridled discretion.

We therefore respectfully urge, Mr. Chairman, that after a review by this Subcommittee and the full Commerce Committee, the bill reported by the Senate Agriculture Committee be reported to the Senate for immediate action.

The almost complete ban of D.D.T. by the E.P.A. (announced June 14) would not have been necessary had the pending legislation been in effect. The legislation would allow the administrator of E.P.A. to require that if a pesticide is classified for restricted use it must be applied by or under the direct supervision of a certified applicator and would be subject to other control restrictions. For example, it could permit the Administrator to enforce the regulation of essential uses of pesticides for use only in supervised programs, for use only in specific instances in which it is essential, and for use only in the minimum quantities required in each instance, for use.

Thus, the Administrator would have the authority to enforce pesticide use under strict control, in contrast to the current law which often forces the Administrator to permit indiscriminate use or effect an outright ban.

In our judgment this is a reasonable and acceptable solution. It protects the farmer's use of a necessary product for use on specific pest problems and at the same time assures adequate protection to human health and environment.

In conclusion, Mr. Chairman, we strongly support the Federal-State approach contained in H.R. 10729 for carrying out the purposes of the Act. However, we also are just as strong in our support for adequate Federal monies being authorized so that the participation by the States will be encouraged. The States are now struggling under severe financial strains in carrying out their responsibilities under various Federal programs. We therefore respectfully request that the Subcommittee keep this in mind during the drafting of the final legislation.

We appreciate this opportunity to present the Grange's views on H.R. 10729 and wish to express our appreciation to you and the Subcommittee for conducting further hearings on such a vital and important legislative matter that will affect the lives of everyone.

STATEMENT OF JOHN W. GRANDY IV, ADMINISTRATIVE ASSISTANT FOR WILDLIFE, NATIONAL PARKS AND CONSERVATION ASSOCIATION, WASHINGTON, D.C.

My name is John W. Grandy, IV. I am Administrative Assistant for Wildlife at the National Parks and Conservation Association, 1701 18th Street, N.W., Washington, D.C. 20009 I appreciate the invitation of the Committee to testify in these hearings.

The National Parks and Conservation Association is the leading national conservation organization concerned primarily with the protection of the National Park System, but also with other major environmental and conservation subjects such as wildlife and forestry.

The NPCA is an independent, private, non-profit membership institution, educational and scientific in character, with more than 50,000 members throughout the United States and abroad, all of whom receive the monthly *National Parks and Conservation Magazine: The Environmental Journal.*

Mr. Chairman, the National Parks and Conservation Association has supported, on invitation, and continues to support the amendments proposed by you (Senator Hart) and Senator Nelson to H.R. 10729. We are extremely pleased and gratified that the Senate Committee on Agriculture and Forestry adopted strengthening suggestions concerning judicial review, the elimination of indemnities, and categories of general and restricted use. We are distressed, however, that other strengthening amendments proposed by you and Senator Nelson have not yet been included. Specifically, we strongly urge that the following proposals be adopted:

1. Citizen suits should be allowed so that private parties or organizations can force other private or public individuals or bodies to comply with the provisions of the legislation. There is absolutely no persuasive reason why this should not be allowed.

2. Registrants should be required to divulge test data to the Administrator (of EPA) at least sixty (60) days prior to registration of a pesticide, and the Administrator should be required to release such data. Of course, trade secrets would not be divulged by the Administrator.

3. Maximum penalties for violation of the Act should be increased to $10,000 so that wealthy corporations, for example, may be effectively penalized for violations.

4. The principle of "unreasonable adverse effect" should be used as a criterion for registration, rather than the proposed "substantial adverse effect." Obviously,

this should embody the concept, put forth by Senators Hart and Nelson, that a pesticide causing even "insubstantial affects" should not be registered if there is a (are) safe, effective substitute(s).

5. Interested parties should be allowed to intervene in cancellation hearings.

Mr. Chairman, I would like to compliment you and Senator Nelson for the fine amendments you have submitted. You will note that our suggestions (above) follow your proposed amendments, with very few changes. On behalf of the more than 50,000 members of the National Parks and Conservation Association, I urge you and this good subcommittee to do everything possible to have these provisions incorporated into H.R. 10729.

I thank you again for the invitation to submit these views.

VITAMIN INSTITUTE,
North Hollywood, Calif., July 6, 1972.

COMMITTEE ON COMMERCE,
Subcommittee on Environment,
U.S. Senate, Washington, D.C.

GENTLEMEN: I appreciate your Committee's concurrence with the Committee on Agriculture and Forestry in including the Plant Regulator Clarification Amendment, after studying it, in your Committee's recommendations for H.R. 10729.

I also appreciate your Staff's having advised me that you find "absolutely no problem with it." This coincides with similar observations by the Senate Agriculture Committee and Office of Environmental Quality personnel.

Welcome, too, is the clause ". . . we have no objection to it . . ." in the Hearings statement (sent me through the courtesy of one of the 34 associations sponsoring this needed Amendment) of a spokesman for the Environmental Protection Agency.

Actually, the Amendment was provided containing such unusually tight a qualification as *non-toxicity even in the undiluted packaged container*, in order to bend over backwards to avoid any basis for objection, valid or invalid, because of the belated time of its subject problem's arising, long after both Houses' 1971 hearings.

Thus, when the EPA Office of Legislation suggested that a non-objection waiver from the EPA Pesticide science side would enable that Office to acknowledge that the EPA has no basis for objection to this Amendment, the EPA's number-one scientist who is also the Deputy Assistant Administrator for Pesticides Programs, answered "That is wording that we would not object to. So go ahead and give it to the Senate and let's see what happens."

In fact, I have yet to hear of any citizen's being able to think of any disadvantage to the Amendment. The Council on Environmental Quality staff told men that they "would have no problems with it," "no difficulty at all," that they "can't imagine it's causing anybody any difficulty."

They stated that no problem like that occasioning the need for the Plant Regulator Clarification Amendment had come to the attention of government agency staff members when they were working upon recommendations for revision of the Pesticide Act. Also that a number of people over a period of time have checker it for loop-holes, and have found none.

However, it has been suggested to me that it would serve a useful purpose to forward to you, for inclusion in the record of your Hearings on H.R. 10729, this statement, to aid to avoid future misconstruing of the legislative intent of the Plant Regulator Clarification Amendment, through a reading alone of the EPA other remarks related to it, lacking intimation that differing view abounds.

It is my understanding that personnel of each of the Senate Committees involved, with some of whom I have had brief conversations on the subject, by phone, agree with me that the intent of the Senate bodies in this respect will be found far more accurately in the wording of the Amendment itself, as well as in my statement (which needs only slight allowance for type-setter's errors in the Hearing Record) with exhibits of March 7, 1972 before the Subcommittee an Agricultural Research and General Legislation of the Committee on Agriculture and Forestry of the Senate, and inter-spaced questions and comments of the Chairman (plus any history reflecting Senatorial conferences in executive session in involved Committees).

This is particularly to the point since the purpose of the Amendment being discussed is to take cognizance of the need to clarify and improve wording to implement the original legal purposes of the Congress in the 1959 amendment to the FIFR Act.

Although I respect the EPA's effort to be of service in discussing this, only a few examples of the various repeated needs to look to the Amendment itself, with my testimony, exhibits and Senatorial comments include among others:

Whole actual products, not isolated ingredients, are what are mentioned in this Amendment.

A purpose of this Amendment is to iron out confusion in interpretation connected with previous Regulations of the Pesticide Regulation Division, which seemed to have the effect of defeating the proper, Constitutional purposes of the Act. My Senate Agriculture Hearing statement mentioned that a Member of the Congress already observed, in the 1971 House Hearings connected with revision of this Pesticide Act, in interviewing another top official of the EPA (page 25 of the Hearing Record): ". . . we get a little head-shy of your regulations. We think we write the law and then you regulate us out of court; we do not like that. We would not like it when yo do this, if you do."

He was answered: "Then we will not do it."

But, still apparently feeling further injunction in order, the Congressman pursued "So I hope you take that as a kind of a red flag."

The Plant Regulator Clarification Amendment was written with the aid of the intelligent thinking of men involved with Senate and House Agriculture Committees, and purposes to be able to stand alone without need to project regulations which might have the effect of cancelling again its purpose. Also, if products not the subject of the Plant Regulator Clarification Amendment should be treated by EPA regulations, it would be appropriate for that not to be attributed to this Amendment.

The EPA Administrator has stated that environmental decisions are societal, for the public arena. In the present case, the subject is non-controversial, as no one can think of any basis for objection to the Amendment. Persons and groups aware of the problem and having an opinion have turned out to be informed enough to favor the Amendment. Therefore, and because of the clear environment and equitable benefits to the nation, the favorable reporting of it by the Committee on Agriculture and Forestry, and then again by your Committee in further review, is responsive to the public will and need.

This, of course, is the American way to handle a subject when the legislature is aware of it in time, to legislate, with the resultant always preferable "government by law, rather than by man." Unfortunately, the balance of the part of the EPA statement related to this Amendment illustrates well the need for this and all other available clarifying directive from the Congress. Projection at this early time of various regulations (which would probably be unnoticed in the Federal Register) pursuant to this Amendment sound like an inappropriate plan on the part of EPA. Particularly is this true because of the disconnection from and non-responsiveness to the Amendment exhibited in the Agency comments. Certainly, should this Amendment become enacted, I would trust that the EPA would be expected simply to adjust fairly to the legislative purposes of the Amendment, and that responsible officials would expect the same of lower echelons.

No one sympathizes more than I do with the avowed purpose of EPA, but though the EPA spokesman and his colleagues seem to be conscientiously trying to work toward it, I am sure that he has grown used to finding in the course of his public interchanges throughout the nation, occasional sincere taking issue. In this case, it is necessary to take issue with the various features of all the brief EPA Hearing statement relating to this Amendment—except for the part wherein it was stated "we have no objection to it."

It is believed that one or more EPA staff persons, apparently within the Pesticide Regulation Division, presumably acting through a mistaken sense of conscientious loyalty to the Division, may be responsible for a continued cropping up from way back, long before the Committees' Hearings of 1972, of admittedly stock phrases plugged into comments that fail to respond or relate adequately to the Amendment itself, the Agriculture Subcommittee Hearings record, or even realistically to current and past interpretations of the Act and Regulations by the Pesticide Regulation Division.

I would be glad to explain further to any interested Senator or staff member or any other official, including the EPA Administrators, the disparities of the EPA statement with respect to this Amendment.

It is true that until the Amendment is on the books to spell out the meaning of the law, a need exists for relief, to protect the public convenience and necessity, as well as the maker of the unique products needed by the public.

Totaling 1670 as of this date, the number of allied-field professional persons who have added petitions like those previously filed with the Committee on Agriculture and Forestry in support of this relief and this Amendment has now grown, since its recent Hearings, to 235 more, nearly all graduate, or higher level degree, landscapes architects or horticulturists or university instructors.

All these petitions and, I believe, all communications to the Senate in support of the Plant Regulator, Clarification Amendment have been for the specific purpose of saving on the market my valuable products—which I positively will not teach other manufacturers how to make, on my labels—and to abate attempts forcibly to expropriate to public competition piracy my property, my proprietary formulas of my 60, 50 and 40 ingredient formulas of CUTstart 60-in-1, SUPERthrive 50-in-1, SEEDyield 40-in-1 and my equivalent products.

These are the original, and perhaps still in some cases the only vitamins-hormones products on the market for their purposes, long established and known to be far above any competitive materials for their purposes.

Because the evidence presented to the Senate Committees has been deemed adequate, that these products and their maker have sufficient record of unique and high value to the nation, and its environment, and need for legislative relief from illogical treatment, your Committees have favorably reported my Amendment, which is gratifying and encouraging, in contrast to the early discouraging demands from EPA. (Who have apparently been kind enough lately to hold off from renewing their demands while this legislation is in process.)

However, speaking frankly, to my observation, reading, by persons familiar with the problem, of the EPA comments on the Amendment, evince an unbelieving "What are they trying to do now?"

It is certainly impossible for me or perhaps even for the EPA spokesman to read the minds of the EPA staff on their future plans. But the indications from the comments are surely worry-provoking.

It is understandable that the 6000 EPA staff people, who have to work with 49,000 pesticides and other problems, have an immense amount of system to try to keep functioning, and that anything out of the ordinary can cause an EPA staff member to feel it loyalty to the Agency and its purpose to hold the same line as before.

The question whether a habitual treatment method might be truly contrary to the purpose of the Agency, unreasonable, or in violation of the purpose or wording of the law, or even unconstitutional, might not occur to the minds of the Agency staff.

By the same token, we should sympathize with this new Agency's problems when we observe as I have the identical 76-word series in letters sent over various Agency heads' signatures, starting last year, even when we note that the first such signer told me that he was unfamiliar with the subject, and did not remember writing the letter. These words included "nutritional chemicals," "hormone," "hormone-type" and "metabolically active chemicals," in an odd array that I felt to be pointless each time I saw them, in letters sent to various directions.

By this means and others, I have come to the additional belief that some of the EPA heads have had to depend, in the press of circumstances, especially when often having to travel to discharge Agency speaking obligations, upon others for much of the material connected with this whole topic.

I have been advised that these lower-ranked persons, in turn, may feel unempowered to use discretion, and that they may perhaps feel mistakenly that it would be good to try to get all the control that they can for the Agency, although they might conceivably thus reach a position of being, in effect, on occasion, substitute combination legislature, judge, jury and prosecutor.

If some one in EPA has in mind throwing up road-blocks to force me to go to court, should the Amendment remain, before being able to get recognition from EPA that this Amendment is to protect the described products from being claimed to be under the Pesticide Act, EPA should surely have said so before, it would seem. Extreme court expense would violate my equal rights under the law, as I outlined in my Agriculture Subcommittee statement. If there is something about the Amendment that EPA has planned to take issue about, whether it effectively protects my products from the Agency's improperly claiming purview as "pesticides" while actually as opposite as possible—EPA should have said so, rather than planning any backdoor method of reprisal.

After all, I was told by EPA officials, and the Senate Agriculture Committee staff were also, that some kind of legislation was needed before EPA would

consider its arms untied from requirement to reach (wrongly) to claim purview of my products.

I knew, of course, that I would still be dependent upon the integrity and good sportsmanship of all related EPA personnel to recognize such legislation, should it materialize, without any ensuing harassment, unconscious or otherwise. In phrasing the Amendment, I was betting that I was not misplacing my confidence in their willingness to accept Congressional spelling out of the intent of the law, and to be big enough to fit with it without sulking about it.

Unawareness of the background and purposes of the Amendment seems an unlikely explanation for these Hearings comments respective to it, since:

EPA Office of Legislation picked up a copy of my statement and exhibits on the same day that I was heard by the Senate Agriculture Subcommittee; also, this statement, with recommending letters, was long ago published in the Hearings Record; I placed my Hearings statement in the hand of the Administrator personally at a public meeting in March; my problem and its proposed remedial legislation have been explained to Pesticide heads of EPA (although not by me directly as yet to the Assistant Administrator for Categorical Programs or to the new head of EPA Office of Legislation).

Other possible explanations occur to mind. It is hard to imagine that EPA may indeed soon entirely "liberate" soon the sprays listed by it. Although perhaps listed officially as soil amendments, as my products have been, they are not indicated as specific products at all, and it would appear unlikely, not to say unprecedented, were products solely so described to be "commonly known as vitamin-hormone products," etc., as the Amendment describes, or claimed to be either a vitamin or a hormone product, let alone a vitamin-hormone product, in the case of the fatty alcohol, tobacco sucker "control." Whereas it is desirable that such of these as might partake of no characteristic of a pesticide should not be called a pesticide, nonetheless such products would each be separate subjects. Suggesting a tie-in with this Amendment for this group list places improperly at least some potential "scare" burden onto the Amendment which might have been expected to worry the Envrionment Subcommittee, had it not been for the fact, as I am told, that your Environment Subcommittee was aware, and penetrated there being no reason for the Amendment to carry responsibility for products not described by it.

The most obvious other possible explanation for the EPA comments is that some one in EPA believes that its comments could somehow muddy or even warp the legislative history. It seems such a possible bid should be rejected totally—except for the part acknowledging non-objection to the Amendment—as in no wise coming to grips with the Amendment's terms and purposes, which are quite clear.

With reference to a few other inappropriate remarks in the EPA material:

Use of the expression "metabolically active," recurrently seems pointless when thus used, inaccurately and misleadingly inferring that this may be a black term referring to (non-existent) per se problem—that EPA might have some special reason for hugging to itself. This Amendment cuts through against-the-public-interest writing of just such indefinably objectless and frothy wording, used so inappropriately as to block and negate the projected law, if allowed, contradictorily.

This Amendment, far from "changing the scope of present law," solely spells out the spirit and the letter of present law, as I understand it, to check the Pesticide Regulation Division's claiming adherence to it when they have in effect said "Certainly, you may go in to swim, but don't go near the water," as in the latter case.

Similarly, it is less than frank for the EPA repeatedly to propagate the unfounded impression that it has been interpreting the "plant regulator" definition (for treatment as pesticides)—and its listed exclusions—as it sounds when anyone reads it without being aware of the legalese interpretations put upon it by the Pesticide Regulation Division. Again, when it is repeated "Nutritional chemicals are now specifically excluded from the definition of a plant regulator," the full facts would require much further explanation, since it has been regularly found that anyone not familiar with what the practice has been would never guess.

A number of unpredictable-seeming twists are used here. First, any substance or mixture to be used as a plant regulator "is" a pesticide; second, any substance or mixture affecting a plant "through physiological, rather than physical" action is defined as a plant regulator, and thence a pesticide; third,

if supposedly excluded "plant nutrients, trace elements, nutritional chemicals, plant innoculants and soil amendments" have *any trace of physiological, rather than physical effect upon a plant*—to that extent, they are "pesticides"—whether or not actually so.

For practical purposes, therefore, in reality, only, roughly-speaking, hardware, water and plain commercial fertilizer, with or without trace minerals are apparently all that are admitted by the Pesticide Regulation Division, of materials that affect plants in any way, to be non-pesticides. (There may be other, unknown, so-called "physical" exceptions.)

With a straight face, EPA personnel will insist that nutritional chemicals are excluded as pesticides—without denying that it has been claiming purview as a plant regulator and therefore pesticide of even any most healthful, non-toxic nutriment (or substance or mixture), even such as a vitamin, the second it helps a plant to revive, grow better, grow its roots longer, keep a cut flower, Christmas tree or bare root shrub fresher, or is itself (though a vitamin, for example) also a plant hormone and does a hormone job or does anything life-saving, beneficially or healthfully for a plant, cutting, seed, bulb, etc., which would therefore be called "through physiological rather than physical action!"

An example of another problem involved in the EPA short remarks connected with this Amendment bobbed up in EPA recognition of common meaning when the word "hormone" is used.

For a long time, the Pesticide Regulation Division has attempted to obtain, as have some few others, public use and acceptance of the term "hormone-like." This has been a statistical 100% failure. Only force has extracted even label use of the hyphenated designation. In a parallel case, most of the world and much of the population in the United States refers mainly or only to manure when talking about "fertilizer." Commercial or manufactured chemicals are looked upon by most of these as different and artificial. But none refer to "fertilizer-likes" when talking about them. Also, vitamins in many cases are not the identical naturally occurring ones, but are still known to be vitamins. No one would suggest calling the manufactured equivalent life-saving vitamins "vitamin-likes." Whereas, too, human and animal hormones are a definitely separate field from horticultural ones—in that field no one goes about talking of "hormone-likes" either.

In the case of the horticultural hormones, the word "hormone" was used for all kinds of hormones some twenty years before any concerted effort was initiated, to try to get people to speak with this elongated terminology. After most of these years of campaign, the newest, 3d edition of the Merriam Webster Unabridged Dictionary gives as a definition of hormone: "A synthetic substance that resembles a naturally occurring hormone in producing a specific biological effect."—Page 1091

Nobody buys, sells, asks for, tells about use of, or catalogues "hormone-likes," any more than they do, with equal reason, "vitamin-likes" or "fertilizer-likes." It is time to give up on governmental forcing of this lost campaign.

Also, the government should do all that it can to ease, and to popularize, the use of my vitamins-hormones products, to aid further in their public recognition for the great environmental contributions and potential for which they are and can be used, as outlined in my Agriculture Subcommittee exhibits.

I have no doubt that after such abbreviated references, on the part of the EPA Assistant Administrator, to the Plant Regulator Clarification Amendment, and his statement that the EPA has no objection to it, he may consider much of my statement to be unappreciative and even unwarranted. Having heard him give his statement to the Agriculture Subcommitee, I am sorry to find so much to talk about in his comments, as I feel that both his and his Agency's attitude are constructive, and that he would not deliberately have occasioned my concern as expressed in this statement, in apparently needed defense.

Unaccustomed as I am to legislative contact, it is easily possible that I may have unproductively over-reacted in this answering statement. In risking this, I pray that your Committee and any other readers of your record will accept in advance my apology, if this is so.

In all fairness, however, it should be borne in mind that this is only, from my standpoint, the most recent in a series of occasions on which this topic has drawn a frustratingly non-relating communication from EPA, albeit interspersed with these proper statements by responsible officials of non-objection to the Plant Regulator Clarification Amendment.

It is fair to ask, too, that it be borne in mind that I am expected to carry the word for the nationally scattered persons and organizations and public units

that depend upon my products, even to the extent in various cases of the continued success of their livelihood, as well as for civic environmental health improvements, as outlined in my Agriculture Subcommittee statement and exhibits, and in letters to that Subcommittee's perspicacious Chairman, Senator James B. Allen, as well as to other members of the Agriculture Committee, from professional, park official and industry leaders all over the country.

Additionally, it is difficult to know what to do or say under the circumstances, when my own lifetime of scientific accomplishment is in the balance.

One thing, though, I do know for certain. My case proves that any unknown citizen can come across the country to the Nation's Capital, and find that the Congress will receptively hear and heed a need for righting a legislative inequity.

Thank you again for your support in further backing the original inclusion of this Amendment by Senator Allen and his Subcommittee on Agricultural Research and General Legislation, as adopted also by the full Committee on Agriculture before your additional review.

Also please accept my appreciation for affording me this opportunity to call to your attention, for the record, these points which seemed to need to be expressed.

Respectfully,

JOHN A. THOMSON.

EXHIBIT A

LIST OF ASSOCIATIONS THAT HAVE FORWARDED TO THE SENATE THEIR WRITTEN EXPRESSION OF SUPPORT FOT THE PLANT REGULATOR CLARIFICATION AMENDMENT TO H.R. 10729

NATIONAL

National Recreation and Park Association of America
American Forestry Association
American Institute of Landscape Architects
American Association of Nurserymen
Associated Landscape Contractors of America
Society of American Florists and Ornamental Horticulturists
National Landscape Association
National Council of State Garden Clubs (400,000+ members)
Men's Garden Clubs of America
Mail Order Association of Nurserymen

REGIONAL

American Society of Landscape Architects, Southeastern Chapter
New England Nurserymen's Association
Southern Nurserymen's Association
Western Association of Nurserymen

STATE

Alabama Recreation and Parks Society
California Association of Nurserymen
California Landscape Contractors Association
Florida Association of Nurserymen
Florida Institute of Park Personnel
Florida Nurserymen and Growers Association
Georgia Nurserymen's Association
Georgia Recreation and Park Society, Inc.
Georgia State Florists Association
Iowa Nurserymen's Association
Kansas Recreation and Park Association
Louisiana Association of Nurserymen
Louisana State Florists Association
Minnesota Nurserymen's Association
Mississippi Nurserymen's Association
Nebraska Florists Society
North Dakota Nurserymen's Association
South Dakota Nurserymen's Association
Southern California Turfgrass Council
Vermont Recreation and Park Society

STATEMENT OF REUBEN L. JOHNSON, DIRECTOR OF LEGISLATIVE SERVICES, NATIONAL FARMERS UNION

Mr. Chairman and Members of the Subcommittee: The delegates to the convention of National Farmers Union, February 28–March 2, in Houston, Texas, passed policy statements concerning the environment which are attached hereto as Exhibit A.

Farmers Union is an organization of operating farm families. In view of this fact, our organization is heavily oriented toward the interest of full-time farm operator families. The environment is just one of the broad range of issues on which our convention delegates make policy each year.

On the matter of pesticides and the environment our members and delegates believe that family farming is a far superior means of protecting the environment. More prudent and safe use of pesticides is possible on family farms than is possible under a system of corporate agricultural productive processes.

Therefore, our membership takes strong exception to those national policies which continue to force migration from rural areas into cities. In short, we believe that the family farm system of agriculture affords the best protection from pollutants in the air, soil and water.

Our policy statement proclaims that ecological balance "can best be achieved through maintenance of a family-type agriculture in which crops are rotated, livestock waste is not in excess of the volume that can be returned to soil through organic decay, a farm forestry plot is protected, and other conservation measures are common practice. Corporate agriculture, on the other hand, is less sensitive to natural resource conservation. There is particular need for control of corporate-dominated industrial livestock feeding—which has resulted in serious water and soil pollution."

Many of the decisions which the Administrator of the Environmental Protection Agency must make under the provisions of pesticide control legislation will be difficult decisions. There undoubtedly will be considerable area of disagreement at times. The reconciliation of differences, therefore, is extremely important. In this regard, we believe that the recommendations made to the Senate Agriculture and Forestry Subcommittee on Agricultural Research and General Legislation by the Environmental Protection Agency witness, David D. Dominick, to be constructive. We view other changes in H.R. 10729, recommended by Mr. Dominick, also to be constructive and helpful.

In this connection there is one amendment Mr. Dominick mentioned which Farmers Union strongly supports. That is the provision in Section III that test data submitted in support of a pesticide registration application cannot be considered by the EPA Administrator without permission of the originator of the data if such data tends to support another registration application.

The objectionable language that we recommend be deleted from the bill as reported by the Senate Agriculture and Forestry Committee is found on Page 19, beginning on Line 10 after the comma, and extending through the colon on Line 14. The language that we recommend be deleted from the bill is as follows:

> " . . . except that data submitted in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration:"

To further explain our objection to this provision of the bill, I would like to quote briefly from a letter received from Mr. Art Wolcott, Manager, Chemical Department, Agri Products Division, Farmers Union Central Exchange, 1185 North Concord Street, South St. Paul, Minnesota, as follows:

> "The Protection offered chemical producers in this bill would virtually prohibit any other producer from competing. The investment in money and time to develop the data for registration would not be available in the face of the 17 years protected profits of the original registrant.
>
> "To cite an example using the pesticide product, Atrazine. It was patented in 1956 and is protected by a 17-year United States Patent until 1973. No one else can produce it during the life of the patent. If HR 10729, section 3(c)(1)(D) were law, it would protect (Geigy) Atrazine from competitive production, registration and marketing for another several years. It would be protected for the period required to produce efficacy data, tissue study data and a complete file of data suitable for registration, which may take five years. This would duplicate the data already on file with EPA registration section and serve no useful purpose. Of the chemical products now being marketed, 90% are protected throughout the 17 years of the patent duration.

"Hence, this section of the Act is designed to provide chemical producers with additional exclusive production, pricing and marketing. Such a restriction would deprive farmers of benefits of competitive chemical production and marketing."

Also, Mr. Chairman, to supplement the quote from Mr. Wolcott, I would like to quote from the testimony of the EPA witness, Mr. Dominick, who said:

"The effect of this provision is to afford additional economic protection, foster monopoly, and it may tend to restrict pesticide business to large manufacturers. In addition, it would increase not only Federal administrative cost, but those of the manufacturer as well, aside from unnecessarily increasing the application processing time."

The cost of such protection as this provision affords large manufacturers of agricultural chemical pesticides will be borne solely by the user—the farmer.

Many of the products developed by large manufacturers of pesticides would not have been possible without access to federal research. It is our conclusion that not to strike the objectionable language referred to above would constitute a gross injustice to farmers, to farmer cooperatives and to small business distributors of pesticides, as well as adding unnecessary "red tape" procedures to the administration of the program.

I respectfully request that the attached Supplementary Statement be made a part of the record of hearings.

SUPPLEMENTARY STATEMENT OF NATIONAL FARMERS UNION, JUNE 5, 1972

In our correspondence to you dated November 11, 1971 we pointed out a phrase that is objectionable in HR 10729, the Federal Environmental Pesticides Control Act. It is objectionable for these important reasons:

HR 10729 is an Act conceived and designed to more closely regulate the use of pesticides. The "exclusive use of data" phrase is totally unrelated to this concept and should be removed.

The objectionable part would provide indefinite extension of the 17 years of that protection, to the exclusive benefit of the producers of patented chemical compounds and at the expense of the farmers who use chemical compounds.

In addition to the information in our November 11, 1971 statement we here list excerpts from and cite the testimony of the following which was presented in the hearings before the Subcommittee on Agricultural Research and General Legislation of the Committee on Agriculture and Forestry of the U.S. Senate on HR 10729, Part II, March 7 and 8, 1972.

Pages 364 through 369, testimony from Senator Hart, Chairman, Committee on Judiciary Subcommittee on Antitrust and Monopoly Legislation. Senator Hart also encloses the opinions of two noted scholars regarding the effect and advisability of the so-called "exclusive use data" section of the bill. I quote from Senator Hart's testimony, page 363, third amendment, and page 365:

"Efficiency and barriers to entry.—The House bill requires that in evaluating the acceptability of a pesticide for registration the Administrator may not consider the data of any similar pesticide, or for that matter, the data of any other manufacturer of the same pesticide. Our amendment would eliminate this requirement on the grounds that the duplication of test data which would result from it is wasteful and that the provision may pose a barrier to entry of competitors into the market above and beyond those provided by our patent laws." . . . .

"Obviously, the Administrator is needlessly hamstrung in his duties having information on file which could reflect either positively or negatively on pending applications for pesticide registration but not being able to use it.

"This restriction is unnecessary because Title 35—the Patent Code—provides complete protection against infringement of the particular patent in question provided, of course, a patent has been sought. If a patent has not been sought or granted, then the applicant should not be entitled to the protection afforded by our Patent System; and efforts to expand patent protection outside the confines of Title 35 should not be enacted without full and expert deliberation.

"Similarly, should the information proferred pursuant to section 3(c)(1)(D) be proprietary information in the nature of a trade secret, full protection is afforded by the elaborate trade secret provisions of section 10."

I quote from the testimony of John C. Stedman, Professor of Law, University of Wisconsin:

"There is almost always in the regulatory process, an on-going conflict between the salutary public purpose (in this case, protection of the environment against damaging pesticides) and the danger that the regulatory process will be misused by protecting those already in the field through denial to qualified competitors of the right to enter. The present proposal constitutes a real threat in the latter sense while serving no useful purpose in the former. The only conceivable legitimate purpose to be served by the proposal, as I see it, is the protection of equities in one who has pioneered in the development of a drug—and gone to considerable research effort and expense, especially with respect to its impact on the environment—by preventing others from getting a 'free ride' on his experience with no cost to themselves. But the 'free ride' is endemic in our society and something to be legislated against only occasionally (as in the patent system, the recent 'tape-piracy' legislation, etc.) and after careful attention to the countervailing adverse effects of such legislation.

"This does not seem to be such a case, and certainly not one to be resolved in the broad, loose terms of the clause here in question. (1) There is no necessary correlation between the advantages gained by the applicant whose data is withheld and the burdens he has borne in collecting the data. (2) The provision gives no attention to, and makes no allowance for, the offsetting advantages the applicant has enjoyed as a result of his 'headstart' or his continuing benefits from the genuine trade secrets he may have developed (it should be emphasized that this provision is *not* needed to protect legitimate trade secrets—these are adequately protected by Section 10, and in any event the clause in question goes far beyond trade secret protection and prohibits the Administrator from even using the knowledge he possesses not just from publicly disclosing it). (3) The collection of his data may well have entered into, and been part of the consideration for, the grant of his pesticide patent (if he has one) in view of the 'utility' requirement contained in our patent law. (4) It is quite possible that some or all of his expense may already have been paid through Government funding (see, e.g., Section 20 of the bill). (5) Assuming, arguendo, that the data collector is entitled to some form of remuneration for his efforts, the proposal here picks one of the worst possible forms for achieving this, namely, protection against legitimate competition. (6) While the provision contains sufficient loopholes that a strongly public-interest-oriented Administrator could probably avoid the more serious impacts, it could easily become an instrument of obstruction in the hands of a timid Administrator or one more fully attuned to the interests of selected suppliers than to the interests of the public.

"For the reasons given, I agree with Congressman Kastenmeier's recommendation that the underlined clause be deleted."

I quote from the testimony of John J. Flynn, Professor of Law, University of Utah:

". . . I could find nothing in the report supporting any claimed injury or abuse of the existing statute that would justify the language added by Section 3(c)(1)(D). Moreover, the following analysis would seem to be logical and appropriate: the registration requirements of the Act establish a government created barrier to entry in the pesticide business; a major feature of that barrier to entry is the requirement of testing new pesticides, a cost which is to be borne by applicants; this cost can be assumed by some applicants better than others, but it is not a cost relating to economic efficiency; it is a cost that is government imposed and, as such, it is a cost which should not be imposed any further than is necessary. Vesting control over this cost in an applicant, so that he can use a government cost barrier to entry to hamper subsequent competitors is totally wrong. The information required is and should become public information, it should be freely used by the agency in the performance of its duties under the Act, and the provision as it now stands only serves the purpose of allowing applicants to hamper competition and efficient administration of the Act. . . ."

I quote from the testimony of David D. Dominick, Assistant Administrator, Environmental Protection Agency, page 95, Section 2:

"The effect of this provision is to afford additional economic protection, foster monopoly, and it may tend to restrict pesticide business to large manufacturers. In addition, it would increase not only Federal administrative costs, but those of the manufacturer as well, aside from unnecessarily increasing the application processing time. . . ."

The complete testimony of the above participants is in agreement with request that the phrase on "exclusive use of data" be stricken from the Act.

However, in view of possibility that some unforseen situation may arise, it is agreeable to us that the following be inserted in place of the "exclusive use of data":

"Except that a hearing may be requested by the original registrants to determine the advisability of withholding the data submitted by the original registrant from use in substantiating the label claims of a subsequent applicant."

SPORT FISHING INSTITUTE,
Washington, D.C., April 5, 1972.

Hon. PHILIP A. HART,
Senate Office Building,
Washington, D.C.

DEAR SENATOR HART: The Sport Fishing Institute, a national non-profit, professionally-staffed fish conservation organization supported largely by interested anglers and the sport fishing industry of the United States, strongly supports your proposed amendments Numbers 1003 through 1013 to H.R. 10729.

It is our belief that these amendments will provide a basis for more effective pesticides regulation by strengthening H.R. 10729, the Federal Environmental Pesticides Control Act of 1971.

It will be much appreciated if this communication of views may be included in any record of related public hearings. Thank you.

Sincerely,

RICHARD A. WADE,
Executive Secretary.

ENVIRONMENTAL PROTECTION AGENCY,
DIVISION OF PESTICIDE COMMUNITY STUDIES,
Chamblee, Ga., May 12, 1972.

MS. JEANNE C. DANGERFIELD,
1000 Wisconsin Avenue,
Washington, D.C.

DEAR MS. DANGERFIELD: We have your letter of May 3 requesting copies of annual reports from our Community Studies projects. We regret that we are unable to send copies of these to you. We have no extra copies available and they are too bulky to copy. In addition, they are interim, unpublished and often incomplete reports, and as such would not be too suitable for your purposes.

Much of the work of the Community Studies has been published in a wide variety of technical journals. A list of these publications is attached. We will be happy to send you single copies of any of these. An article describing our program is attached for your general information.

We are also enclosing a listing of all of our publications. Single copies of most of these are available upon request.

We hope this information will be of use to you. Please do not hesitate to contact us for copies of individual articles.

Sincerely yours,

CLAUDIA B. LEWIS,
Technical Information Specialist,
Publications and Information Section.

Enclosures

[Reprinted from FDA Papers, May 1969]

LIVING LABS THAT STUDY HOW PESTICIDES AFFECT MAN

(By Samuel W. Simmons, Ph. D.)

In New Jersey, a worker in a pesticide chemicals factory reports after his shift to the plant clinic near Trenton for a thorough medical examination. In Texas, the pilot of a plane used for dusting agricultural crops with pesticides visits his doctor, and afterward, the physician reports his observations on the state of the pilot's health to the State Department of Health office in San

Benito. In Mississippi, a farm laborer who lives near a cotton field regularly sprayed with pesticides reports to the University of Mississippi Medical Center at Jackson for intensive medical checkups. In Utah, a worker who applies pesticides in mosquito control work drops by the State Department of Health office in Salt Lake City for a medical going over.

These people have two things in common. They are regularly exposed by occupation or environment to pesticides with unusual frequency or in unusual amounts; for this reason, they have agreed to act as volunteer experimental subjects in a nationwide program aimed at bringing to light the effects this exposure may have on the various systems and organic processes of their bodies.

The Community Studies Pesticides Projects, collectively one of the most ambitious health observation programs ever undertaken on a countrywide scale, has been in operation since 1965. Since last July, the projects have operated under the Division of Community Studies of the FDA Bureau of Medicine's Office of Product Safety. The projects are carried out under Federal contract by State Health Departments or universities in 15 widely scattered areas or communities in the contiguous States and Hawaii.

Their objective: to collect and evaluate information aimed at finding whether and how exposure to pesticides, as experienced in an occupation or in the environment, is affecting the health of Americans.

For the basic study in each community, the contractor keeps close tabs on the medical history of an average of 100 volunteers who, because of their occupations or their environment, are subject to greater exposure to pesticides than the population at large. They include workers in pesticide formulating plants; employees of plant nurseries; agricultural workers on farms, ranches, or orchards where pesticides are used heavily or often; pilots of aircraft that dust crops or ranges; pest control workers; or those who live in localities where pesticides may be expected to permeate the living area to a greater extent than would be found normally. In addition, a limited number of people from the general population known to have had only minimal exposure to pesticides are selected to serve as controls for comparison purposes.

These volunteers are given a complete annual physical and neurological examination by their physicians, and in some cases, the contractor carries out the medical examinations. Followup examinations are made periodically, and the results, including samples of urine, blood, and sputum, are analyzed in the contractor's laboratory for determination of any changes or effects. Fatty tissues or tissues from various organs are collected when available, as when a subject undergoes surgery, and are supplied to the laboratory.

The information emanating from the studies is evaluated medically and statistically and published in scientific journals. More comprehensive data is funneled on standardized forms to the Community Studies Division in Atlanta, where it will be processed for input into a computer system being developed to see if medical, scientific, or statistical conclusions can be drawn that will have general significance or application. The Community Studies are supported with research in analytical chemistry, primate toxicology, quality control, and other services by the Perrine Primate Research Branch of the FDA Bureau of Science's Division of Pesticides (see color photo story) to assure consistent and uniform quality and high standards of laboratory work that will permit the findings in one community study to be evaluated on the same basis as those of another.

An important extension to the Federal Government's activities on the effects of pesticides on man and animals was the establishment by the Public Health Service of a toxicology laboratory at Savannah, Ga. In November 1964, the PHS Bureau of State Services established an Office of Pesticides to deal with a number of recommendations relating to public health that were made by the Life Sciences Panel of the President's Science Advisory Committee after its comprehensive study of the benefits and hazards of pesticides. The Office of Pesticides, which had been formed in Washington, D.C., was transferred in August 1966 to PHS's National Communicable Disease Center in Atlanta and consolidated with that Center's toxicological activities. The new organization was named the Pesticides Program, and in a PHS reorganization last July 1, the program was assigned as the Community Studies Pesticides Projects to the Division of Community Studies of the FDA Bureau of Medicine's Office of Product Safety.

Some of the project contractors are conducting one or more additional studies, usually by subcontract with other nonprofit medical or scientific groups, on special medical or health aspects that can be related to exposure to pesticides, to the effects of specific types of pesticides, or to special problems characteristic of one of the communities under study as related to crop, climate, temperature, working conditions, or other conditions worth considering.

The contractors put together a pesticide usage "profile" of their particular areas that includes the kinds and quantities of pesticides used, the amounts per acre, the time and location, the method of applying, the purposes of application, the strength at which the pesticide is applied, and whether it is applied from the air or on the ground. The laboratories analyze samples of the water and soil representative of the area, and determine if the area's food supply differs from the national average in pesticide residue content as published in FDA's continuing "market basket" statistics on pesticide residues in the national food supply.

The geographical areas involved were selected for the Community Studies because they are areas of high pesticide use; represent a cross-section of the climate, temperatures, and seasonal conditions to be found in various parts of the country; cover a variety of socioeconomic population levels ranging from poor crop workers to well-to-do farmers; or have eligible contractor groups available who are competent enough to take over the projects and carry them out.

The contractors and the Community Studies Division in examining their human subjects look not only for overt clinical illness or immediate changes, but also for the more subtle biochemical, functional, and behavioral changes, and for those that may occur on a more gradual or delayed basis.

The contractors also keep records on acute poisoning cases in their areas, investigating the kind of poison involved, how the incident happened and why. The physician attending such a case through prior arrangement supplies information on his findings and the contractor carries out diagnostic tests for organic, neurological, and physiological changes or effects. The Federal Aviation Administration keeps the contractors informed about crashes of aerial spray pilots, so they may carry out epidemiological studies and laboratory analyses to determine if pesticides are a contributing factor in these crashes. The acute poisoning cases provide valuable information not only on chemical, physiological, and behavioral effects caused by the chemicals, but also on the dose-and-effect relationship, the factors in the relationship of the victims to environments, and the methods being used to treat the various types of poisonings.

Poisonings are not uncommon in areas where intensive agriculture, horticulture, or pest control are practiced. The Florida study of Dade County disease and deaths revealed 133 cases of documented pesticide poisoning from 1964 through 1967 in a population of around one million people. Of these cases, attempted suicides accounted for 37, accidents for 67, and occupational poisoning for 25. Eight of the cases were homicides and two were unclassified. Of the 133 cases, 47 were fatalities.

Nationwide, the recorded death rate in 1965 from poisonings caused by all chemical solids, liquids, gases, and vapors was 5.0 per 100,000 people. The death rate associated with all pesticides in the United States for that year was reported at 1.0 per one mililon of population. Although there is no reliable data on disease and illness due to pesticides, the estimate is that for every fatal poisoning there are 100 non-fatal cases. Since poisonings do continue to occur, the persons who study these cases can help the attending physician in determining the causative agent, the dose, the effects, the contributing factors, and ways to help eliminate this public health problem.

Their investigations of acute poisonings have given the contractors in the Community Studies an awareness of the chemical or clinical effects that merit further study. The Colorado project reports definite, if temporary, deficiencies in the memories, reaction times, visual and auditory responses, and muscular coordination of the victims of organophosphate poisoning during the first 3 days after poisonning. An electroencephalogram (EEG) may show definite changes; nerve conduction changes have been detected in patients with acute toxicity. Studies of blood coagulation after acute organophosphate poisoning have indicated a phase of abnormally rapid coagulation, then a phase of prolonged coagulation. Sugar in the urine and protein disorders of the blood are common after acute exposure.

The Florida project, analyzing clinical, chemical, and epidemiological aspects of 89 acute organophosphate poisoning cases, noted depression of the enzyme

cholinesterase, glycosuria (sugar in urine), aminoaciduria, excretion of paranitrophenol, decreased reabsorption, decreased ability to acidify urine, and impaired ability of the kidney to concentrate urine.

These observations of acute poisoning victims provide valuable leads to the contractors for examining the subjects in the Community Studies who are occupationally exposed on a long-term basis. Their investigation of poisoning epidemics also gives the contracting health officials a better understanding of the circumstances that led to an event and provides a basis for planning preventive measures.

In a 1967 poisoning epidemic in Tijuana, investigated by Mexican officials over 500 people reportedly became ill and 16 died as a result of contamination by parathion of ingredients in bread. In 1967, in Qatar and Saudi Arabia, 1,874 people were hospitalized and 26 died from eating bread made from flour that had been stored in the holds of two ships under drums of endrin that leaked into the flour. Last July in Texas, 23 farmworkers became ill 2 hours after they entered a cotton field that had been sprayed the previous evening with parathion. In a recent homicide in Florida, seven children died from parathion poisoning. Three men were made ill last year from exposure to arsenic while repairing equipment in a New Jersey pesticide plant. A father in Mississippi brought home a concentrated organophosphate insecticide last year to combat flies, sprinkled it liberally around the house, and as a result, he and two of his children were severely poisoned. In 1967 in a small nursery for newborns in St. Louis, 20 babies developed an unusual illness and two died from exposure to sodium pentachlorophenate in a disinfectant that had been used by mistake in laundering their diapers.

These examples demonstrate something of the problem and the need for continuing investigation of poisoning epidemics so as to prevent similar misuse of such chemicals in the future.

The 15 Community Studies, although each is designated by the name of the State, do not usually cover the entire State. The typical pattern is a county or a small group of counties in a part of the State where a special problem is presented because of the kind of crop grown, the kind of pesticides used, the convenience to the contractor's laboratory and other facilities, or an urban area where pest control or pesticide manufacturing is centered.

New Jersey—State Department of Health, Trenton. A large number of pesticide products are manufactured in this heavily industrialized area.

South Carolina—Medical College of South Carolina, Charleston, and State Department of Health, Columbia. Study groups include pesticide plant employees, farmworkers, Corps of Engineers applicators of 2, 4-D, and family units living near waterways that receive herbicide treatment. The State Department of Health provides analytical chemistry facilities under subcontract.

Texas—State Department of Health, Hidalgo and Cameron Counties, around Brownsville and McAllen. Warm temperatures and modern irrigation make possible a long growing season and large amounts of pesticides are applied from the air and the ground. A cooperative study with the Department of the Interior's Fish and Wildlife Service is seeking to determine the doses of pesticide man receives from eating certain game and fish taken in the area.

Louisiana—Louisiana State University Medical School and State Department of Health, New Orleans. Study groups include agricultural workers, family units, and pest control workers in the heavily treated cotton-growing and urban areas within the general vicinity of the city.

Mississippi—Mississippi State University, Greenville. Analytical facilities are at the MSU campus in Starkville. The University of Mississippi Medical Center, Jackson, under subcontract carries out intensive medical examination of exposed persons. The study groups are farm labor family units living near heavily sprayed cotton or other fields, staff members of MSU's Delta Experiment Station who work with either herbicides or insecticides, spray-plane pilots, and experimental farms run by pesticide manufacturers.

Florida—In two major parts. A statewide study by the State Department of Health is collecting death statistics on persons registered in the structural pest control industry for any 2 years during the period 1949-1965, and disease and death statistics on persons in structural pest control or lawn spraying for 2 or more years since July 1965, including State employees in mosquito control districts. In Dade County (Miami area), the University of Florida Medical School is studying acute poisonings among the general population, as well as studies of persons occupationally exposed and of the general population.

Arizona—University of Arizona, Tucson, in Pima and Maricopa Counties. The study groups are sprayplane pilots, pest control workers, and farmworkers. In a special study in cooperation with the State Game and Fish Department, the project is comparing wildlife levels in uninhabied areas with those in heavily sprayed agricultural areas.

Iowa—Institute of Agricultural Medicine of University of Iowa College of Medicine, Iowa City. Under study is the nature of human exposure to pesticides and metabolites in tissues of domestic animals used for food; metabolism and storage of pesticide residues in domestic animals; effects of dose upon biochemical, physiologic, and pathologic changes; causal relationship of pesticide exposure to prolonged recovery time of surgical patients who have received the anesthetic succinylcholine, and of patients with blood dyscrasias. Iowa State University's Veterinary Diagnostic Laboratory, Ames, is under subcontract.

Michigan—State Department of Public Health, Lansing. Study groups are fruit growers, truck warmers, commercial sprayers, dairy farmers, and urban dwellers. Michigan State University is a subcontractor. A steering committee includes representatives of medical associations and health agencies, the State Departments of Agriculture and Health, and the State Water Resources Commission. This group helps in program planning.

Utah—State Department of Health, Salt Lake City. Study groups include area and urban mosquito spray workers, agricultural ground applicators of pesticides, and pesticide formulating plant workers.

Idaho—State Department of Health, Boise. Covers an agricultural area where large amounts of pesticides are used during a short growing season and where extensive irrigation is used. Study groups include persons exposed environmentally and occupationally, along with a control group of persons who have had minimal exposure.

Washington—State Department of Health, Wenatchee. This is a center for growing apples and pears. Study groups include workers exposed to pesticides from spraying orchards. The project also is investigating the pharmacological effects of acute poisonings from accidents, suicides, and homicides, and is studying crashes of aircraft carrying pesticide sprays and health hazards involved in pesticide storage.

California—State Department of Public Health, Berkely. Under study are blood dyscrasias in persons exposed to lindane and causal relationships between seasonal neonatal jaundice and the use of cotton defoliants in the Imperial Valley. One study is evaluating the changes in sputum cytology of persons exposed to pesticides. Study groups include State mosquito control workers.

Colorado—State Department of Health, Greeley (Weld County). This area raises crops of carrots and sugar beets and contains extensive cattle feeding lots. The project has concentrated on family units to determine the source of family exposure to pesticides in house dust, soil, food, water, and drift from treated fields. The units are under continuous medical and biochemical surveillance. Other study groups include crews of aerial spray companies and, under subcontract with the University of Denver Medical Center, Denver, industry personnel in pesticide manufacturing and processing.

Hawaii—University of Hawaii in cooperation with the National Institutes of Health Hawaiian Cardiovascular Study and the State Department of Health. The study group includes thousands of men of Japanese ancestry on the Island of Oahu, with particular attention to cardiovascular disease, asthma, bronchitis, and sinusitis. Hawaii's tropical climate makes possible year-round agricultural work. Termites are a problem here. Pesticides are heavily used for both crop treatment and termite control.

Although the Community Studies Pesticides Projects are learning much about pesticides and their effects on man and animals and the environment, there is no end in sight for the projects so long as pesticides continue to be used by man in his efforts to control pests that threaten his comfort, his health, and the food supply. Although some aspects of the studies may be attenuated or terminated when the information they seek is complete or conclusive, many problems will remain and new ones will arise, among them those created by the many new pesticide compounds and formulations put on the market each year.

The pollution of the environment by a growing number of synthetic and natural chemical agents presents a potentially serious challenge to the health of present and future generations of both man and animals. The Community

Studies thus are contributing importantly to the research efforts in pesticides that are essential to maintaining the well-being of our society: they are enlisted in a wide and comprehensive undertaking to help make some order and sense out of a major problem to health and to find ways to successfully cope with it in the interest of the public welfare. The data that they gather and evaluate will provide a better understanding of the risks versus the benefits of using pesticides as part of the larger pattern of our continued existence and prosperity.

[Reprinted from The American Journal of Nursing, April, 1971, Vol. 71, No. 4]

Pesticides—An Occupational Hazard on Farms

(By Keith R. Long*)

Concern for farm workers and their families should prompt closer control over the use of pesticides, declares this author. He assesses what the poisoning hazard is and suggests what needs doing. Among the answers are legislation and permits or prescriptions to use pesticides.

In this topsy-turvy world of consumer-oriented supply and demand, concern for pesticides and their threat to the ecological world has reached almost hysterical proportions. The use of pesticides has increased at a phenomenal rate. Their residues are everywhere, particularly those of the so-called "hard pesticides" or organochlorine compounds, DDT being the culprit singled out most frequently.

The farmer is caught up in an economic whirlwind to meet consumer demands for more, better, and cleaner agricultural products. Coming to his aid are a battery of chewing, cutting, digging, and biting machinery supported by protoplasmic poisons to promote, retard, defoliate, control, or destroy. These machines and poisons make no distinction between product and producer nor between farmer and pest.

Until recently, the need for studying the relationship between pesticides and illness in farmers went unmet. The Community Studies Division, Pesticide Office, Environmental Protection Agency, is the only branch of the federal government now studying the effects of pesticides on human health. This program includes study of the occupationally exposed—the farm worker, the commercial pest-control operator, and the formulator of the chemicals.

The primary efforts of this program are centered in 15 community studies in selected geographic areas of the United States. The studies are related to the kinds of agriculture practiced in the area.

A few years ago, the incidence of injury from economic poisons (pesticides) in the United States was called difficult to determine (1). Facts are still meager and unavailable from a single source. One report lists a variety of explanations for lack of reported cases of illnesses from pesticides among farmers (2). It is possible that farmers are not being made ill, that those who are ill are not seeing physicians, or are not properly diagnosed, or are diagnosed but the results are not published (2).

The latter three reasons are the most likely. *Over half of a small group of Iowa farmers we interviewed believed that they had been adversely affected by farm chemicals* (3).

Recent reports indicate that pesticides adversely affect farmers. Manifestations of illness include effects on the central nervous system resulting in impaired mental alertness, increased tension, anxiety, and nervousness, which provoke sleep difficulties with excessive dreaming and nightmares and impairment of memory and slowing of reaction (4). Wtihdrawal, apathy, and depression have occurred with exposure to organophosphorus pesticides (5).

One controlled study found chronic complaints of forgetfulness, difficulty in thinking, visual difficulty, and persistent muscular aches and pains along with fatigability and loss of interest in work by persons with a history of exposure to organophosphorus substances (6).

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*Dr. Long earned his Ph.D. in microbiology at the University of Iowa, where he is professor and chief of the Environmental Toxicology Section of the Institute of Agricultural Medicine, Department of Preventive Medicine and Environmental Health, College of Medicine. He is project director of the Iowa Community Pesticides Study, supported by a contract with the Division of Community Studies, Office of Pesticides, Environmental Protection Agency, Chamblee, Ga.

Two such cases were studied at University Hospitals here in Iowa City. Both patients were farmers, white men in their early forties, judged by medical and clinical laboratory examinations to be of sound mind and normal responses.

These men complained of anorexia, anxiety, hyperirritability, and depression. Symptomatic treatment was prescribed. Complete epidemiologic follow-ups including occupational histories revealed no unusual activities. The only influencing factor appeared to be their rather high and sometimes careless use of organochlorine and organophosphate pesticides.

Such dyscrasias of the central nervous system are not the only effects. Dermatitis and other skin diseases have been reported among farmers employing pesticides (6,7).

CALIFORNIA REPORTS

In a 1967 report from California, more than 80 percent of reported occupational disease among farmers fell into one of the four categories—skin conditions, eye conditions, systemic poisonings, or chemical burns, in order of magnitude (8). Reports of respiratory conditions accounted for 5 percent of the cases, about the same as in previous years. The remaining reports describe digestive disorders and other signs and symptoms due to toxic materials.

The California report provides several examples of the kinds of poisoning farmers are incurring. One example is that of a farm laborer who was cleaning a vat where potatoes were dipped. He felt nauseated and a burning sensation in his lungs from breathing the chemical vapors. His physician kept him under observation for suspected chemical poisoning from mercury bichloride.

Another example is that of a ranch foreman who was using Thimet® and experienced nausea and vomiting for about a month. He also reported having blurred vision and respiratory difficulty. His condition was diagnosed as organophosphate poisoning.

In another example, from the California report, a farm laborer exposed to agricultural chemicals including sulphur sprays suffered severe erythematous, oozing, crusted, and edematous lesions of the exposed skin of his face, arms, and neck. His physician estimated that the worker would need six weeks treatment and would be disabled from work for one to three weeks.

Another example is that of a swamper who was wearing a mask and goggles loading a plane with 50-lb. sacks of Sevin® (a carbamate insecticide) and sulphur. When he transferred the chemicals to a bucket to take to the plane, he felt sudden weakness, was dizzy, and could not get his breath. Two days earlier the same thing had occurred. The diagnosis was chemical toxemia. The physician noted that the employer reported four other employees had been sick or had similar attacks. None had see a doctor.

IN IOWA

In Iowa, a farmer had used dichlorovos in a systemic hog dewormer feed additive and had cultivated ground treated with Thimet® for the control of corn rootworm (9). This man suffered diarrhea, upper respiratory effects, and was hospitalized for a time under intensive care. His signs and symptoms coincided exactly with the time sequence of employing the agricultural chemicals.

Another Iowa man accidentally spilled concentrated Di-Syston® (an organophosphate insecticide) on his lower extremities while loading a spray tank.

He subsequently suffered a complicated series of effects including marked paralysis of the lower part of his legs, numbness in his fingers, and marked depression and anxiety, which were treated symptomatically. Again, the occurrence of these effects fitted into the time sequence of this farmer's use of agricultural chemicals.

We have seen one case in which a farmer had cultivated soil treated with an allylacetamide herbicide. Upon breathing the dust, the farmer experienced irritation of the bronchii and lungs resulting in a secondary infection and pneumonia.

Every investigation that has looked for manifestations of acute and subacute illnesses in farmers from pesticides has found them.

No distinction has been made between the extensive user of pesticides and one who uses them little or occasionally. The health professions must express concern for occupational exposure of commercial operators, farm operators, or uninformed persons employed in agriculture.

Exposures can be subtle and can occur by several routes. Inhalation exposure and contact dermal exposure are almost unavoidable in the handling of agricultural chemicals. The goal is to cut down the duration of exposure as much as

possible. These exposures can be as simple as inhaling the dust from a paper bag at the time of loading the hopper of an applicator or the contact on the skin from cleaning a plugged nozzle of a spray machine. We have shown contact exposure occurs in migrant workers as revealed by build up of residues in their blood(9). Such residues derive from close contact with treated soil and crops being processed by the migrant farm workers.

In addition to the symptoms just described, the 15 community studies previously mentioned have revealed that changes occur in the central nervous system as reflected by alteration in the electroencephalographic tracings, in kidney and liver functions as revealed by altered amino acid values, and phosphorus resorption indices in urine and in blood values where differences in hemoglobin and hematocrit levels have been observed in people occupationally exposed to pesticides(6,10-11).

RECENT REPORTS

In Iowa, lower activity values of serum lactic dehydrogenase have been observed in a carefully controlled study of farmers who have a high use of pesticides(12). Scientists have recognized for many years that organophosphorus pesticides inhibit cholinesterase activity with the subsequent cholinergic effects.

Whether these observed conditions are prologues to chronic disease or enhance existing disease is a matter of speculative interest. The fact remains that a variety of acute illnesses and physiologic changes have been observed in farmers pursuing their usual activities in handling agricultural chemicals.

These exposures may be subtle or great. The farmer's method of handling agricultural chemicals is rooted in attitudinally conditioned action. Farmers accept the uncomfortable working conditions, the skin rashes, the headaches, and the upper respiratory effects suffered in farming as their lot in life.

The farm environment is not the safe, healthy, wholesome way of life that many believe. It is beset with infectious diseases such as brucellosis, leptospirosis, and a host of other zoonoses. Farm accidents from the chewing, biting, snapping, and twisting equipment exert their toll in diminishing the health and safety of the farmer and his family. A major concern should be exerted for the farmer and his welfare by the chemical and equipment industries and the health professions.

As a part of the workman's compensation program, California requires illness reports which encompasses about 80 percent of the state's agricultural work force(13). It is unfortunate that other states have not followed suit with such reports.

Morbidity data are difficult to obtain at best. Other sources of reporting include medical reports from the pesticide manufacturing industry or formulation plants. Workers in manufacturing are usually governed by fairly strict safety regulations. The farmer overlooks the usual safety precautions in the haste of job performance, so industrial and farm safety are not comparable. What is of importance, however, is the fact that illnesses and injuries occurring in the plants are typical of the compounds being manufactured or formulated and usually are explained by degree or duration of the worker's exposure.

NEED FOR ACTION

The first step to decrease the occurrence of illness in farmers associated with the use of pesticides is to document the incidence of cases. How to achieve documentation is not immediately clear. A concerted interdisciplinary effort to explore and improve the health and safety of farmers is one suggestion. Farmers should be encouraged to report their illnesses and use of agricultural chemicals to physicians or health agencies.

Permits for all agricultural users of pesticides is another suggestion. After an evaluation and recommendation has been made for the appropriate type of pesticide treatment, the farmer could take this permit or "prescription" to a source of supply and buy the pesticide. Copies of the permit could be submitted to the appropriate health and environmental control agencies.

Action within the scientific community is not enough. Political and social action are needed. Legislation can do much. An example is the recent federal action taken against DDT. This action states that DDT shall not be used except for control of pests of public health importance and pests subject to state for federal quarantines where applications of pesticides are made under the direct supervision of public health or state or federal quarantine officials. (PR Notice 70–19 USDA, Agricultural Research Service, Pesticides Regulation Division.) A similar fate can be forecast for all the "persistent" pesticides.

Recent legislation by the states of Florida (Ref. House Bill 3188 1970) and New York (Ref. Assembly Bill 5881–B 1970) give further evidence of things being done to control the use of pesticides. Legislation designates certain pesticides as restricted-use substances if they persist in the environment, accumulate as a pesticide or metabolic degradation product in plant or animal tissues or their products, and are not excreted or eliminated within a reasonable length of time. In addition these laws go on to state that if such a compound creates or presents a future risk or harmful effect on any organism other than the target organism the restriction of its sale, purchase, possession, or use is in the public interest.

Indiscriminate use of pesticidal chemicals has been largely responsible for many of the problems that people do not attribute to pesticides. People must somehow be made to realize that pesticides are poisons and should be used in response to a specific problem and not for convenience.

Our present technologically oriented society is responsible for many of the problems such as those associated with the use of pesticides. First of all, our colleges and universities have produced narrowly educated scientists and technicians who have produced a highly sophisticated technology without considering the means of controlling it.

Industrial giants have developed highly sophisticated products and machines that are tremendously efficient in carrying out their specific purposes. These products are released to the public, and unfortunately the public lacks sufficient knowledge to understand what constitutes abuse or misuse of a product. The orientation of an industrial world toward obtaining a quick and dirty dollar has resulted in the provision of only the information required by law in the labeling of products. Therefore, if a given use is not contraindicated on the label, the public is apt to use pesticides for almost any purpose.

An informed public would help, but the most feasible solution seems to be legislation. This entails drawing up rules and regulations which control the misuse, indiscriminate use, and identification of restricted use of pesticide chemicals.

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Thimet® is the registered trademark of the American Cyanamid Company. Sevin® is the registered trademark of the Union Carbide Company, and Di-Syston® is the registered trademark of the Chemagro Corporation. Dr. Long says, "Commercial sources and trade names are provided for identification only. Their mention does not constitute endorsement by the Environmental Protection Agency or by the University of Iowa."

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Physician's Pesticides Primer*

(By Donald S. Kwalick, M.D./Trenton)

In suspected pesticide poisoning your State Department of Health offers services essential for confirmatory diagnosis. These services include:

1. Determinations of serum and RBC cholinesterase in suspected organophosphate or carbamate intoxications;
2. Analyses of serum, urine, and gastric contents for identification of various pesticides or their metabolites; and;
3. Identification of whether unknown substances suspected of poisoning a patient contain pesticides.

In suspected pesticide poisoning, collect the following specimens as soon as possible during treatment: (1) Blood—heparinized and clotted; (2) Urine; and (3) Gastric Contents—if ingestion is suspected.

Refrigerate all specimens but *don't freeze them.* Telephone the Pesticide Project—Area Code 609—292–7608, Monday through Friday, 9 a.m. to 5 p.m. After hours, call—Area Code 609—392–2020.

The New Jersey Community Study on Pesticides (hereafter referred to as the Pesticide Project) is sponsored jointly by the Office of Pesticides and Product Safety of the Federal Food and Drug Administration and the New Jersey Department of Health, and is part of a nationally coordinated study in fifteen states.

The acute effects of pesticide poisonings are well understood, but the effects of long-term, low-level exposure are unknown. To determine whether chronic effects exist, the Project has selected 200 individuals (farmers, pest control applicators, aerial applicators, and formulators) who are occupationally-exposed to high levels of pesticides. If these persons do not demonstrate any effects from prolonged exposure, then the general population whose exposure is far less should show no effects. These persons are compared with a group of 50 minimally-exposed "controls" for any differences in blood and urine biochemistry, renal and liver function tests, complete blood counts, urinalyses, pesticide residues, and physical signs or symptoms. Each subject is given an annual physical examination, an electrocardiogram, and a chest X-ray.

The Pesticide Project has found, as would be expected, that persons exposed to pesticides in their occupation have higher serum residues of pesticides than general population or control individuals. For example, the mean residue for DDT in our exposed industrial population is 28.8. ppb†, while in the minimally-exposed and general population it is 4.4 ppb†. Thus far, no *abnormal* biochemical chronic changes have been found in the exposed individuals compared with our minimally-exposed control group. However, comparing 40 controls with 52 exposed (farmers and pest control operators) disclosed a statistically significant difference in the number of individuals with hearing and eye problems, chronic cough and sinusitis, dizziness and headaches, and hypertension.

TABLE I.—GENERAL GUIDE FOR ESTIMATING LETHAL DOSE OF POISONOUS SUBSTANCES[1]

Acute toxicity rating	Acute oral LD^{50} any animal (mg kg)	Probable lethal oral dose of technical grade material for human adult
Extremely high	5	Few drops.
High	5 to 50	"A pinch" to 1 teaspoon.
Moderate	50 to 500	1 teaspoon to 1 tablespoon.
Mild	500 to 5,000	1 ounce to 1 pint (lb.).
Very mild	5,000 to 15,000	1 pint to 1 quart (2 lb.).

[1] This table has been adapted from "Clinical Handbook on Economic Poisons," Hayes, W. J., Jr., U.S. Public Health Service Publication No. 476, reprinted January 1967, p. 4.

* Kwalick is Director of our State Health Department's Community Study on Pesticides. This comes from material presented as a scientific exhibit at the Annual Meeting of The Medical Society of New Jersey, Atlantic City, New Jersey, May 16–19. The work was supported by the U.S. Department of Health, Education, and Welfare; the Public Health Service; and the Food and Drug Administration.

† Parts per billion

The acute toxicity of pesticides varies from very mild to extremely high. The relative differences are seen in Table I, which presents a general guide of lethal dose for any poisonous material. Many compounds are best classified by generic and/or chemical type. The most commonly used pesticides in New Jersey and their relative toxicity are presented alphabetically in Table II.

TABLE II.—COMMONLY USED PESTICIDES IN NEW JERSEY—TYPE AND RELATIVE TOXICITY

Generic and/or chemical type	Common examples	Acute toxicity rating
Anticoagulant rodenticides	Warfarin	Mild—depends upon dosage.
Arsenicals and other heavy metals (Hg, Pb, Cu).	Arsenic, arsenic trioxide, sodium arsenite	Extremely high.
Botanical insecticides	Cube, Derris; pyrethrum, rotenone	Mild.
Carbamates	Carbaryl (Sevin), Ferbam Maneb, Furan Zectan; Nabam, Zineb.	Mild to moderate.
Chlorinated Hydrocarbons	Aldrin, Dieldrin, Endrin, Benzene hexachloride (BHC), Chlordane; DDT, toxaphene, heptachlor, Lindane, methoxychlor.	Very mild to high.
Herbicides (chlorphenoxy)	2,4-dichlorophenoxyacetic acid (2,4-D); 2,4,5-trichlorophenoxyacetic acid (2,4,5-T); (MCPA) 2-methyl-4-chlorophenoxyacetic acid.	Very mild to mild.
Organophosphates	Chlorthion, Decapthon, DDVP (Vapona), Diazinon; Malathion, Parathion, Phosdrin, TEPP.	Moderate to extremely high.

Organophosphates have caused over 60 percent (52 of 82) of the reported pesticide poisonings. Since 1967 the number of organophosphate poisonings has greatly exceeded poisoning from other pesticides. With the decreased use of persistent pesticides (such as DDT) there will be a corresponding increase in the use of less persistent compounds such as carbamate and organophosphates. Although less persistent, the organophosphates include some of the most dangerous chemicals known to man. An increased number of poisonings with possible the use of less persistent compounds such as carbamates and organophosphates. usage unless there is stringent control on the purchase and use of these substances, and unless there is intensive education of the public and many occupationally-exposed individuals.

The pharmacology, onset, signs and symptoms, and treatment of the more common pesticide poisonings are summarized in Table III.

Many clinical effects of pesticide poisonings are similar but treatment varies. In any poisoning where ingestion is suspected, gastric lavage with several liters of water is indicated. If the patient is conscious, an emetic may be administered or sodium sulfate catharsis may be useful. Therapy should not await laboratory confirmation, but begun at the earliest suspicion.

TABLE III.—ONSET, PHARMACOLOGY, SIGNS AND SYMPTOMS, AND TREATMENT OF COMMON ACUTE PESTICIDE POISONINGS

	Chlorinated hydrocarbons	Carbamates	Organic phosphates
Onset of action	30 minutes to several hours	15 to 30 minutes to 1 to 2 hours	Minutes to several hours—usually very rapid.
Pharmacology	CNS depression and/or stimulation (varies)	Reversible cholinesterase inhibition	Irreversible cholinesterase inhibition.
Absorption	All portals except skin with Dilan and DDT	All portals including skin	All portals including skin.
Acute signs and symptoms	General: Apprehension, headache, nervousness, respiratory failure, weakness; gastrointestinal: anorexia, nausea, vomiting, diarrhea; neuromuscular: coma, convulsions, muscular twitching and fibrillation, paresthesia, tremors.	General: giddiness, headache, lightheadedness, nervousness; cardiovascular: bradycardia, bounding pulse, decreased blood pressure, palpitation; glandular: salivation, sweating, lacrimation; gastrointestinal: abdominal cramps, nausea, vomitting, diarrhea; neuromuscular: arreflexia, comma, convulsions, miosis, blurred vision, fibrillation, tremor; respiratory: cyanosis, dyspnea, pulmonary edema.	See Carbamates.
General	Symptomatic dependent upon condition; artificial respiration p.r.n.; remove toxicants—emesis or lavage as indicated; decontaminate skin, hair and nails with soap and water.	See Organic phosphates	Maintain patent airway, suction excessive secretions, artificial respiration if necessary, oxygnation to overcome cyanosis, gastric lavage as indicated, decontamination of skin, hair and nails with soap and water followed by alcohol sponging.
Specific	For control of convulsions use sodium pentobarbital p.o., i.m., i.v., sodium phenobarbital, sodium calcium gluconate, sodium valium.	Atropine sulfate p.o. or i.m. 1–4 mg depending upon severity of symptoms.	Severe cases: atropine sulfate parenterally 2–4 mg. q. 5–15 minutes until atropinized (dry, warm skin and tachycardia) Child dose .015–.05 mg/kg; pralidoxime (2-PAM) 1–1.5 gram deep i.m. or i.v., Child dose 25–50 mg/kg, May double doses if necessary, milder cases: atropine 1–2 mg p.o. or i.m.qlh; pralidoxime (2-PAM) 1–2 gram p.o.
Cautions and contraindications	Avoid using oily cathartics, as these enhance absorption of organochlorines, Epinephrine contraindicated.	Pralidoxime (2-PAM) is NOT recommended, tranquilizers, aminophylline, morphine contraindicated.	Observe closely 24–48 hours after symptoms subside; handle contaminated materials carefully; discard contaminated clothing carefully; phenothiazines, aminophylline, morphine, theophylline contraindicated.

Selected Bibliography

For those interested in more extensive reading on pesticides, a selected reference list is included below.

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2. *Cleaning Our Environment, The Chemical Basis for Action*, pp. 195–244, Sept. '69, Price $2.75.††
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5. *Organic Pesticides in the Environment*, Advances in Chemistry Series, 1966, Price $8.50.††
6. *Pesticides Monitoring Journal*, monthly journal from Pesticides Program of FDA, Price $1.75 per year.***
7. *Report of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health*, Dec. '69, Price $3.***
8. *Safe Use of Pesticides*, a manual for public health personnel, 1967, APHA, 1740 Broadway, New York 10019, Price $3.

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Criteria for Defining Pesticides Levels To Be Considered an Alert to Potential Problems

(Panel on Pesticide Monitoring Working Group on Pesticides[1] (W. S. Murray, Executive Secretary))

The objective of the National Pesticide Monitoring Program is to determine levels and trends of pesticides in the various substrates sampled. The establishment of mean levels of specific pesticides through the NPMP provides baselines necessary for determining whether levels of specific pesticides are high or low.

We have not yet determined, however, just what would be considered the levels of concern for each pesticide in certain environmental components. For example, we know what the actionable level of DDT is in human food, but there has been no level established for DDT in human tissues that would result in action to reduce exposure. On the other hand, for some elements of the environment, there have been maximum allowable levels set based on known adverse effects, although these levels may include a built-in margin of safety.

The following criteria may be used to define pesticide levels to be considered an alert to potential problems:

Environmental component	*Criteria for identifying potential problems*
Wildlife	(1) Any concentration of a pesticide known to be potentially harmful (based on research demonstrating harm).
	(2) Increasing trends.
Fish	(1) Any concentration of a pesticide known to be potentially harmful (based on research demonstrating harm).
	(2) Evidence of exceeding established levels.
	(3) Increasing trends.
Soil	(1) Evidence of exceeding established levels in soil-associated items.
	(2) Increasing trends.
Water	(1) Evidence of exceeding established water quality standards.
	(2) Increasing trends.
Food and Feed	(1) Evidence of exceeding established levels and standards.
	(2) Increasing trends.
Humans	(1) Increasing trends.
	(2) Recognition of adverse effects.

††Available from American Chemical Society, 1155 Sixteenth Street, N.W., Washington, D.C. 20036.

***For Sale by Superintendent of Documents, U.S. Government Printing Office, P.O. Box 1540, Washington, D.C. 20402.

[1] Responsible to the Council on Environmental Quality.

Condensed even further, the five bases for concern are:

(1) Any concentration of a pesticide known to be potentially harmful.
(2) Increasing trends.
(3) Exceeding standards.
(4) Recognition of adverse effects in humans.
(5) Erratic variability *

Some combinations of these criteria are apparently already used to distinguish possible problem areas. Different combinations of the five may be desirable for different environmental components.

Formulas for the bases of concern for each component and a more precise definition of what comprises each in terms of each component of the NPMP appear to be the next logical step. For example, depressed cholinesterase cases represent a basis for concern in human monitoring.

These five are the bases of concern that may be understood by scientists, administrators, and the public. In accord with research advances, agencies should develop specific possible problem-area definitions for each medium being monitored.

[From Industrial Medicine and Surgery, 37(7) : 519, July 1968]

Some Health Related Needs in Pesticide Investagations

(By Samuel W. Simmons, Ph. D., Chief, Pesticides Program, National Communicable Disease Center)

Pesticides have become inescapable elements of our environment and it is important that we use them safely. Methods for screening pesticides for hazard to man must be improved. The problem of potentiation and antagonism in the simultaneous exposure to certain pesticides and drugs and between different pesticides should be investigated further. A study is needed of storage of the organochlorines by the fetus *in utero* and possible effects. Improvement of analytical techniques and a certain degree of standardization of procedures is needed so that data can be more meaningful. Other major areas of concern are the relative lack of epidemiological investigations of chemical poisonings, the need for surveillance of occupationally exposed persons, routine monitoring of man and the environment, and the lack of reporting of poisoning cases. Additional needs include development of improved diagnostic procedures for poisoning and studies on mode of action of pesticides. State training programs for chemists and epidemiologists are needed, and information on the safe use of pesticides should be made available to the public. Problems associated with disposal of pesticide wastes and containers and transportation and storage of pesticides, particularly with edible materials, are urgent. There is a need for more uniformity in State regulations governing pesticides. The biological magnification of pesticides in their passage through the food chain needs to be better understood. Non-chemical means of pest control based on microorganism or toxins derived from them require the same intense investigation for health hazards as synthetic pesticides.

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National Pesticide Monitoring Program (Revised)

INTRODUCTION

The National Pesticide Monitoring Program was first described in the Pesticides Monitoring Journal, Vol. 1, No. 1 (1967). The Program was initially designed on the basis of the minimum monitoring needed to establish baseline levels of pesticides in substrates of food and feed, humans, soil, water, air, wildlife, fish, and estuaries and to assess changes in these levels. Monitoring activities are subject to changes—changes to incorporate research investigations, utilize improved methodology, reflect changes in program emphasis, and to

*A statistically oriented observation that is potentially common to each of the stratum sampled.

accommodate findings within existing programs. In 1968, a review of the components of the National Pesticide Monitoring Program was initiated by the original Subcommittee on Monitoring; the review has been completed by the Subcommittee's successor, the Monitoring Panel of the Working Group on Pesticides responsible to the Council on Environmental Quality.

Recent realignments have been made in the pesticide activities of the Federal agencies. The focal point of Federal policies and activities for pesticides is within the Environmental Protection Agency. However, many of the monitoring activities on pesticides have remained in other agencies, and the need still exists for a coordinated approach to pesticide monitoring. The Panel notes that the scope of the existing estuarine monitoring program is limited compared to other substrates, which is due in part to the responsible agency's primary mission and resources. Also, there is no operational National Monitoring Program for pesticides in air, and no comprehensive information on this important substrate is developed in other programs. The statement on air monitoring outlines a program needed to develop minimal data which can be correlated with data from other parts of the National Pesticide Monitoring Program.

R. E. DUGGAN,
Chairman, Monitoring Panel.

EXPERIENCES WITH THE EXPOSURE OF HUMAN SUBJECTS TO AGRICULTURAL CHEMICALS AND A DISCUSSION OF THE LEGAL POSITION OF INVESTIGATIONS USING PEOPLE

(By Wayland J. Hayes, Jr., Toxicology Section, Technology Branch
Communicable Disease Center, Public Health Service)

INTRODUCTION

In promoting human safety, the basic reason for making studies in man is species difference. Differences in toxic as well as therapeutic effects frequently depend on differences in biotransformation, which are well documented and may be qualitative (Williams, 1963), quantitative (Brodie, 1964), or both. Undoubtedly, only a small proportion of the true variation has been described. The facts that man is unique and that studies in man are desirable are taken as axiomatic in this paper. The body of the paper is concerned with the organization and execution of studies in volunteers and with the legal implications of such studies.

Although this paper is concerned with the broad subject of studies with volunteers, many of the illustrations used in the first section are, for convenience, drawn from our own experience, which may be summarized as follows: It is necessary to have a clear picture of the safety of a compound if it is to be used to combat human disease. This is equally true whether the compound is a drug administered directly to the patient or a pesticide applied to his environment. Some of our studies have concerned compounds proposed for use (Durham *et al.*, 1959; Hayes *et al.*, 1960; Rasmussen *et al.*, 1963; Witter *et al.*, 1961) or actually in use (Hayes *et al.*, 1956) for the control of vector-borne disease. Other studies concerned compounds that were especially adapted for studying a fundamental property of an important group of pesticides (Fredriksson, 1961a,b; Upholt *et al.*, 1956).

Our own work constitutes only a small portion of the investigations of pesticides that have been carried out with volunteers (see Table I).

TABLE I.—STUDIES OF PESTICIDES IN VOLUNTEERS

Pesticide[1]	Parameter or condition	References
Organic phosphorus insecticides:		
DDVP	Cholinesterase	Durham et al., 1959; Witter et al., 1961; Rasmussen et al., 1963.
	Visual and respiratory functions, reaction time.	Rasmussen et al., 1963.
	Function of sweat glands	McLaughlin and Sonnenschein, 1960.
Demetron (Systox)	Cholinesterase	Upholt et al., 1954; Rider and Moeller, 1960, 1964; Moeller and Rider, 1959, 1962b, 1963.
DEP	Cholinesterase	Leopold and Comroe, 1946; Comroe et al., 1946b; Rowntree et al., 1950; Munkner et al., 1961; Grob et al., 1947a.
	Intestinal mobility	Grob et al., 1947b.
	Mental effects in normal people and psychotic patients.	Rowntree et al., 1950.
	Central nervous system effects	Grob et al., 1947c.
	EEG	Grob et al,. 1947c; Rowntree et al., 1950.
	Neuromuscular function	Harvey et al., 1946, 1947.
	General systemic effect	Grob et al., 1947a.
	Visual functions	Leopold and Comroe, 1946; Scholz and Wallen, 1946.
	Myasthenia gravis	Harvey et al., 1946, 1947 Comroe et al., 1946a,; b; Grob et al., 1947a; Gaddum and Wilson, 1947; Buchthal and Engback, 1948.
	Glaucoma	Comroe et al., 1946b; Marr, 1947; Leopold and McDonald, 1948; Grant, 1950; Stone, 1950.
	Abdominal distention	Grob et al., 1947b.
Diazinon	Creeping eruption	Hayes, 1963, p. 30.
Dimefox	Cholinesterase	Edson, 1956; Edson et al., 1964.
Dimethoate	Excretion, cholinesterase	Sanderson and Edson, 1964.
Dioxathion (Delnav)	Cholinesterase	Frawley et al., 1963.
EPN	Cholinesterase	Rider et al., 1959; Moeller and Rider, 1959, 1962a; Rider and Moeller, 1960.
HETP	Myasthenia gravis	Westerberg and Luros, 1948.
Malaoxon	Function of sweat glands	McLaughlin and Sonnenschein, 1960.
Malathion	Cholinesterase	Golz, 1959; Gutentag, 1959; Moeller and Rider, 1959, 1962a; Rider et al., 1959; Hayes et al., 1960; Mattson and Sedlak, 1960; Rider and Moeller, 1960.
	Excretion	Hayes et al., 1960; Mattson and Sedlak, 1960.
	Pediculosis	Cole et al., 1958; Barnes et al., 1962; Shawarby et al., 1963.
Methyl demeton	Cholinesterase	Klimmer and Pfaff, 1955.
Methyl parathion	do	Moeller and Rider, 1959, 1961, 1962b, 1963; Rider and Moeller, 1960, 1964.
Naled (Dibrom)	Dermatitis	Kohn, 1962.
Paraoxon	Function of sweat glands	McLaughlin and Sonnenschein, 1960.
Parathion	Cholinesterase	Edson, 1957; Rider et al., 1958; Rider and Moeller, 1960; Moeller and Rider, 1961; Funckes et al., 1963; Hartwell et al., 1964; G. R. Hayes et al., 1964; Edson et al., 1964.
	General systemic effect	Goldblatt, 1950.
	Absorption	Fredriksson, 1961a,b.
	Excretion	Funckes et al., 1963; Hartwell et al., 1964; G.R. Hayes et al., 1964.
Schradan (OMPA)	Cholinesterase	Edson, 1955; Edson et al., 1964.
	Myasthenia gravis	Rider et al., 1951; Gregory et al., 1952; Schulman et al., 1953; Osserman and Kaplan, 1954; Rider and Moeller, 1960; Hayes, 1963, p. 39.
TEPP	Cholinesterase	Grob and Harvey, 1949; Upholt et al., 1956.
	Symptomatology	Grob and Harvey, 1949.
	Visual effects	Grant, 1948; Marr and Grob, 1950; Upholt et al., 1956.
	Myasthenia gravis	Burgen et al., 1948; Grob and Harvey, 1949; Stone and Rider, 1949; Rider and Moeller, 1960.
	Glaucoma	Grant, 1948, 1950; Marr and Grob, 1950.
Trichlorofon (Dipterex)	Cholinesterase	Lebrum and Cerf, 1960.
	Symptomatology	Cerf et al., 1962.
	Helminthiasis	Beheyt et al., 1961; Cerf et al., 1962; Talaat, 1964.
Carbamate insecticides:		
Baygon (Bayer 39007)	Excretion	Dawson et al., 1964.
Carbaryl (Sevin)	General systemic effect	Hayes, 1963, p. 44.
Chlorinated hydrocarbon insecticides:		
Aldrin	Symptomatology	Baker et al., 1959.

See footnotes at end of table.

TABLE I.—STUDIES OF PESTICIDES IN VOLUNTEERS—Continued

Pesticide [1]	Parameter or condition	References
DDD	Skin irritation, sensitization	Haag et al., 1948.
	Cushing's syndrome	Sheehan et al., 1953; Southren et al., 1961; Wallace et al., 1961; Weisenfeld and Goldner, 1962.
	Adrenal tumors	Molnar et al., 1961 Nichols et al., 1961.
	Metastatic carcinoma, especially of prostate and breast.	Zimmermann et al., 1956; Weisenfeld and Goldner, 1962.
	Diabetes	Tornblom, 1959.
DDT	Symptomatology	Domenjoz, 1944; Neal et al., 1944; Cameron and Burgess, 1945; Case, 1945; Dangerfield, 1946; Velbinger, 1947a,b; Stammers and Whitfield, 1947.
	General systemic effect	Neal et al., 1944, 1946; Cameron and Burgess, 1945; Case, 1945; Velbinger, 1947a,b; Stammers and Whitfield, 1947.
	Sensitization	Draize et al., 1944; Wasicky and Unti, 1944; Cameron and Burgess, 1945; Wigglesworth, 1945; Chin and T'ant, 1946; Haag et al., 1948.
	Storage	Hayes et al., 1956.
	Excretion	Neal et al., 1946; Hayes et al., 1956.
	Pediculosis	Domenjoz, 1944; MacCormack, 1945; Kaiser, 1946; Zein-El-Dine, 1946.
	Scabies	Zein-El-Dine, 1946.
Dieldrin	Skin irritation, sensitization	Suskind, 1959.
	Absorption, excretion, and concentration in blood.	Abery et al., 1959.
BHC and lindane	Symptomatology	Batterman, cited by Halpern et al., 1950.
	Skin irritation, sensitization	Halpern et al., 1950.
	Pediculosis	Cannon and McRae, 1948; Gardner, 1958.
	Scabies	Cannon and McRae, 1948; Wooldridge, 1948; Halpern et al., 1950.
Perthane	17-Hydroxycorticosteroids and clinical effect in tumor patients.	Taliaferro and Leone, 1947; Weisenfeld and Goldner, 1962.
Toxaphene	Symptomatology and general systemic effect.	Keplinger, 1963.
Mixture of lindane and DDT	Symptomatology	Baker et al., 1959.
Chlorinated hydrocarbon fumigants:		
Carbon tetrachloride	Concentration in blood, urine, and expired air.	Stewart et al., 1961a.
Tetrachloroethylene	Concentration in blood and expired air.	Stewart et al., 1961b.
	Symptomatology	Rowe et al., 1952.
1,1,1-Trichloroethane	Concentration in blood and expired air.	Stewart et al., 1961c.
Trichloroethylene	Excretion in urine	Soucek and Vlachová, 1960; Bartoníček, 1962; Bartoníček and Teisinger, 1962.
	Concentration in blood	Bartoníček, 1962; Stewart et al., 1962.
	Concentration in saliva and sweat	Bartoníček, 1962.
	Concentration in expired air	Stewart et al., 1962.
Botanical insecticides and synthetic analogs:		
Barthrin	Primary irritation, sensitization, and allergic response.	Ambrose, 1963.
Derris	Dermititis	Ambrose and Haag, 1936.
Pyrethrum	do	Feinberg, 1934; Lord and Johnson, 1947; Martin and Hester, 1941.
	Scabies	Sweitzer and Tedder, 1935.
	Intestinal helminthiasis	Chevalier, 1930.
Miscellaneous insecticides:		
Azoxybenzene	Symptomatology	Baker et al., 1959.
DNOC	Concentration in blood and excretion in urine.	Harvey et al., 1951.
Isobornyl thiocyanoacetate (Thanite).	Excretion, primary irritation, sensitization effects, and symptomatology.	Keplinger, 1963.
Rodenticides:		
Thallium	Distribution and excretion	Barclay et al., 1953.
Warfarin	Thromboembolic disease	Shapiro, 1953; Pollock, 1955; Friedman 1959; Wolff et al., 1953; Clatanoff et al. 1954; Baer et al., 1958; Fremont et al. 1963.
Herbicides: 2,4-D	Coccidioidomycosis	Seabury, 1963.

[1] Identification of the compounds listed can be found in the "Pesticide Index," edited by D. E. H. Frear (College Science Publishers, 1963).

Some of the volunteers were normal subjects who contributed to an understanding of the pharmacology of a pesticide. Others were patients who received the compounds identified as pesticides for treatment of disease (indicated by italics in

Table I). However, in many of these latter instances observations were made that are applicable not only to the patients but to healthy people also. Although it is a fine point, the table omits studies of patients treated with compounds well recognized as drugs at the time they were studied even though the compounds are, *inter alia*, pesticides. Examples include quantitative studies of the toxicity of white phosphorus (Magnus, 1914), arsenic trioxide (Sollmann, 1957), and thallium compounds(Munch, 1934). The table also excludes studies of people with occupational exposure to pesticides even though success in such work usually depends on the subjects' voluntary cooperation.

Information on the effect of pesticides on man, whether obtained by study of volunteers or workers or cases of poisoning, is the subject of another paper in the series (Durham, 1965).

PRACTICAL CONSIDERATION

Parameters for study

In planning any study with human subjects, provision must be made to examine every parameter known to be affected in animals exposed to harmless doses of the same compound. The first parameter to be considered is measurement of the compound under study: Is it absorbed at all? If absorbed, how is it distributed in the body, and how is it excreted? How much of it is stored and for how long? These questions are related to a second parameter, the metabolism of the compound within the body: Is the compound altered in any way? If so, what are the biotransformation products? Is the material excreted as a conjugate?

A third parameter involves enzymes, especially those which occur in the blood and which are known to be affected bysubclinical doses of some drugs or other chemicals, for example cholinesterase (Holmstedt, 1959) or serum alkaline phosphatase (Mountain, 1960). In a similar way, elevation of neuraminic acid in the serum (Stokinger and Wagner, 1958) and decrease of cystine in the fingernails (Mountain *et al.*, 1955) have been demonstrated in the absence of illness in persons exposed, respectively, to vanadium and cobalt. Finally, a whole series of physiological functions such as taste, odor, visual acuity, complex reaction time, or airway resistance may be explored. As already suggested, the exact choice of tests will depend on the results of earlier animal studies, but it may depend also on functions considered critical to persons (e.g., pilots) who may use the material to be studied.

Certain sensitive criteria such as depression of growth rate or altered ratios of organ to body weight cannot be explored in man. However, the fact that human subjects can communicate makes it possible to study many parameters that may be altered in animals, but not in a way that the experimenter can detect. For example, depth perception in monkeys would probably be impaired by unilateral miosis caused by tetraethyl pyrophosphate, just as it is in man (Upholt *et al.*, 1956). However, any experiment designed to detect alteration of depth perception in monkeys would be so complex that it would be difficult to interpret the results—much less to extrapolate them to people.

In addition to the special studies just mentioned, there must be a general surveillance of the subjects of the sort ordinarily involved in hospital admission. Thus, there must be be a history and physical and clinical laboratory examinations. These studies must be repeated at suitable intervals, partly to determine whether any dose-related change is occurring that was not predicted by animal studies. One should always be alert to the possibility of sensitization. The same examinations serve to reveal illnesses which, though basically unrelated to the chemical under study, many nevertheless affect the response of the body to it or merely serve to confuse the results.

Selection of dosage

The highest dosage selected should be one which is believed to be (a) harmless on the basis of animal studies and all other available information, and (b) capable of influencing some measurable parameter. For compounds of low toxicity, measurement of excretion of the compound or its metabolites may be the only parameter influenced. For compounds of moderate or high toxicity, it may be desirable to use a graduated series of doses beginning with a very low one. Regardless of the toxicity, it is usually desirable to have more than one dosage either in a single test or in succeeding tests in order to determine whether responses are dose-related. Even if dose response is not under investigation, it is necessary that a control group be included in every study. Its use may serve to detect laboratory error and other factors that might influence the results without having any relation to the agent under study.

In connection with agricultural chemicals, the highest dosage chosen for study in volunteers is frequently less than that absorbed by some men with occupational exposure. It is seldom practical to continue a study of volunteers for as many years as occupational exposure may last. Thus, study of people with heavy occupational exposure is more likely to reveal whether the chemical influences conditions that occur spontaneously in its complete absence. Studies in workers may reveal effects that would never be detected in the general population subject to only minor exposure. Of course, the occurrence of some ill effect among workers does not necessarily mean that the same effect will occur among persons with only a fraction of their exposure. However, the finding of an effect among workers is a warning of effects that may occur in a few sensitive people, generally after a very long period of continuous, though limited exposure.

Although studies in volunteers are limited in dosage and duration, these defects are compensated by the important fact that the dosage and route of exposure are known exactly. Thus, studies with volunteers may make it possible to estimate the amount absorbed by men under occupational conditions. For example, Ortelee (1958), basing his extrapolation on a study of volunteers, was able to conclude from a study of excretion that the average quantity of DDT absorbed by formulators with maximal exposure to the compound was approximately 42 mg/man/day.

Thus, studies both on volunteers and on persons with heavy occupational exposure have special merits, and neither can fully replace the other. This paper is concerned only with studies on volunteers, but some of the matters discussed have application in studies of people with occupational or other special exposure to chemicals.

Choice of subjects

The choice of subjects for a study is determined by the number of people required and the duration of the work. It is practical to use civilian subjects for investigations requiring a small number of persons, relatively brief sessions of participation, and a short overall duration. Institutional subjects are necessary when relatively large groups must be used in order to ensure significant results or when frequent or prolonged participation is essential. For example, such a simple thing as oral administration of a drug 7 days a week for a year becomes complicated except in an institutional situation. Business trips, vacations, or the demands of home or business wil interfere with daily participation by the ordinary civilian. Even worse, these factors will interfere with the civilian volunteer's recording of his activities related to the investigation. Of course, there will be missed doses and other lapses in an institutional setting, but it is easier to ensure faithful participation and, especially, complete recording in an institution.

No absolute rules can be laid down to distinguish studies that will be successful in a civilian setting and those requiring institutional organization. Our own studies with civilians have laster no more than a few weeks. In some of these studies some volunteers participated for less than half a day on a single occasion and yet made a valuable contribution. We have never used civilian volunteers for a study requiring surgical biopsy or any other procedure that would require subsequent medical attention or even inconvenience to the person at the end of the working day. This does not mean that biopsies might not be practical in some studies of civilians.

Our own studies in institutions have scheduled the participation of individual volunteers for periods as short as 8 weeks and as long as 4 years. Actual participation has frequently exceeded the schedule. Seventeen men participated 5 years in a study of the storage of DDT originally scheduled for 4 years. Furthermore, some of these studies in institutions involved biopsies, which, of course, left small permanent scars. Some studies carried out by others have required the production of serious disease in the volunteers. Most, and perhaps all, such studies were done under institutional situations that permitted hospital care of the volunteers for whatever period was required. Examples include studies of antimalarial drugs (Coatney *et al.*, 1953) and of the transmission of yellow fever (Reed *et al.*, 1911). In the first instance, a meaningful study of drugs required that men who had never had malaria must be infected with recognized laboratory strains of it under standardized conditions. In the second instance, the transmission of yellow fever to man was the question under investigation.

Our own studies of civilians have included laboratory personnel, men who had a special interest in a study directly related to their occupation, and, finally, people whose only motivation was an interest in science. All our institutional studies have been carried out in federal prisons. In addition to federal prisoners, others have used state prisoners (Goldberger, 1916), military personnel (Reed *et al.*, 1911), conscientious objectors, students (Winkelstein *et al.*, 1962), and hospital patients (Steiner *et al.*, 1962). It is clear that the suitability of each class will vary for any particular study.

Minors, incompetents, or married women should not be accepted as subjects, except perhaps for therapeutic or diagnostic studies, because they may be unable to enter into a valid contract.

Protocol for a study

Every study involving people should be carefully planned in advance. Before a written plan is drawn up, an informal agreement should be reached with the administration of any institution where a study is to be made. However, the plan should be documented even in those instances in which a written protocol is not required as a basis for approval by (a) custodial authorities, for administrative feasibility; or (b) academic or comparable authorities, for scientific merit and safety. The protocol should cover at least the following topics: (1) account of the problem and justification of the study; (2) specific purpose of the study; (3) experimental design; (4) safety of the study; (5) reward to volunteers; (6) proposed contract.

The "problem" referred to in item (1) above is the underlying condition that justifies the study. For example, the problem may be a mosquito-borne disease for the control of which a pesticide is proposed. The importance of the disease will be a significant factor in determining whether a study is justified. As another example, the problem may be an observed condition such as air pollution or factory noise or the need to use a pesticide in agriculture.

The "problem" may be large and even ill-defined, but never unimportant. By contrast, the purpose of any study with people should be clearly defined and frequently very limited. Thus, study of a drug to treat hypertension might be limited to investigation of the metabolism of safe doses in normotensive and hypertensive men.

The section of the protocol dealing with experimental design should state the number of volunteers to be studied and outline their distribution into control and experimental groups. The rate and duration of dosage should be given, and the predosage and postdosage observation periods should be defined. The study need not be confined to a pre-established interval, but may be planned to continue after the dosage period until some parameter (e.g., excretion of a metabolite of a drug) has reached a predetermined level (e.g., the same level found in controls). The section on experimental design should give particular attention to those things that will concern the volunteers directly. It is necessary to specify the approximate number and extent of blood samples, surgical biopsies, and other procedures to be carried out that may involve pain or risk. It is equally necessary to describe procedures that involve merely inconvenience or interference with institutional routine. We have never had any administrative difficulty with biopsies, but we almost lost an entire project because the way in which timed urine samples were collected interfered with the employment of a few of the volunteers in a weaving mill, which was a part of the occupational training and therapy program of the prison. Fortunately, it was possible to change the schedule for collecting samples without decreasing their number or value, and the study was saved. Not all difficulties can be foreseen, but they can be reduced by careful planning.

The section on safety is one of the most important parts of the protocol. Ideally, the section is brief and depends for depth on one or more supporting documents, constituting an appendix. Regardless of the form of presentation, the section must define the nature of any possible hazard, the probability of danger, the surveillance available to detect or—if possible—predict injury, and the possibility of specific treatment. Finally, it must state that individual volunteers or the entire group will be withdrawn from dosage or other active participation if circumstances require this action. Of course, a volunteer whose dosage is stopped will continue under observation, and he will be treated if necessary.

The protocol should specify the rewards (e.g., money) that the investigator is prepared to give volunteers. It may also propose other rewards (e.g., reduction of prison sentence) that would be appropriate and desirable but are not under the control of the investigator.

The final section of the protocol should refer to a proposed contract, offered as an appendix. The contract should be written in the first person, for each volunteer to sign. It is my impression that release forms similar to those used for diagnostic and surgical procedures in hospitals are frequently used in connection with investigations with civilian volunteers, and the American Medical Association (1961) has supplied a model release form (Form 29) for use with investigational drugs. We have used simple releases for civilians. On the contrary, our contracts for studies in institutions have been more elaborate. They include the following features:

(a) date
(b) name of organization (or person) making the study
(c) name of institution where study is made
(d) name of applicant
(e) description of the study
(f) kind and approximate number of services applicant will be expected to contribute and the approximate duration of service
(g) statement by the applicant that the procedure, value, and danger of the study have been explained to him and that he is fully aware that there can be no guarantee that he will not become ill (in a study in which illness is really anticipated, its nature should be defined in the contract)
(h) statement by the applicant that he knowingly and voluntarily accepts the risks. and agrees to cooperate in the work
(i) amount of money and other rewards the applicant will receive in exchange for his services, provided his participation is satisfactory
(j) applicant's statement on behalf of himself, his representatives, and heirs that he releases the investigators and the organization they represent from all liability, including claims, and suits at law or in equity for any injury, fatal or otherwise, that may result from his participation in the investigation
(k) signature of the applicant
(l) signature of witnesses
(m) signature of responsible investigator who accepts the applicant as a volunteer
(n) signature of officer who approves contract for the institution where the work is done

NOTE.—The contract omits any statement that the application agrees to remain in the project.

Method of obtaining volunteers

The method of obtaining volunteers varies with circumstances. In an institution, the best way to begin is for the administration to issue a general notice—in the form of an announcement at general assembly, a statement over the public address system, a poster, an article in the institution's newspaper or newsletter, or a mimeographed handbill issued to all personnel. Such a notice should state the purpose and nature of the study very briefly and invite anyone interested to attend a meeting at which further explanation will be offered. In the notice, it is best not to mention the number of volunteers needed, because a small number may discourage some people from further inquiry. If possible, the custodial staff of a prison should screen those who propose to attend an introductory meeting, to exlude those who are unsiutable. For example, some prisoners with a 6-month sentence will not hesitate to volunteer for a 5-year study.

At the meeting the principal investigators (and perhaps others) explain the proposed study, placing special emphasis on: (a) the value of the work; (b) what each volunteer will be asked to do; and (c) the hazards—not matter how remote—that the volunteers may encounter. Of course, the rewards, the contract, and the other administrative arrangements also should be explained. Questions from the audience are answered. The audience is then asked to express its interest in participation. A list is made of those who wish to apply. and they are instructed when and where to go for preliminary examination.

Before the medical examination is actually carried out, the custodial authorities should screen the applicants to exclude those who are known trouble-makers, malingerers, phychotics, or custodial risks.

A complete study as well as appropriate physical and laboratory examinations must be done on each applicant. Special laboratory tests may be indicated, depending on the nature of the study. All the examinations may serve to exclude

some applicants from the study, and all are used as a baseline for judging future findings in the others.

Those who are found satisfactory for the work are then asked to sign the contract.

Motivation of volunteers

Factors that may play a part in motivating people to participate in projects include: (a) tangible rewards; (b) a desire for new experience; (c) occupational or other interest in a specific project; (d) interest in science generally; and (e) a desire to contribute to society.

Tangible rewards include money and (in the case of prisoners) reduction of prison term. The reduction may be guaranteed and prorated according to the duration of participation in the project, or it may be merely potential—a hope that participation will influence parole or the dropping of detainers by another court. Persons who have no direct experience with human studies often assume that need for money or desire for a reduction in prison term are major factors in the motivation of volunteers in prison. This may be true in some instances. We have always paid prisoner volunteers, but the amount of money was so small that it is probably not an important factor in motivation, and some civilians were not paid at all. We have recruited prisoner volunteers without difficulty when no reduction in prison term could be offered.

Probably the most general reason people have for participating in studies is a genuine interest in science. People want to help in solving any problem they understand.

Prisoners share an interest in science with people in general. However, many prisoners have a special, often unrecognized urge to do something useful. They wish to compensate for records indicating little contribution to society and little positive attention from society. They want to contrbute as well as to be recognized. Few prisoners will admit this except, perhaps, in time of war, when any worthwhile act can be attributed to patriotism. Even though prisoners deny it, I believe that an urge to serve society is their most important single motivation for participating in projects.

Miscellaneous remarks

In our studies, volunteers are free to stop their participation at any time. The number of dropouts (exclusive of transfers and paroles) has been inversely proportional to the amount of initial screening. We have had more applicants for each project than we could accept. However, in only one instance were there so many applicants that we could practically dare them to withdraw; the men who were finally accepted were of such character that none dropped out during the entire project. In studies in which only a few applicants were excluded, a few dropouts occurred for no apparent reason, usually very early in the program. One man quit after the first biopsy (Hayes *et al.*, 1956). Once a project has settled down to a routine, it is most unusual for a volunteer to drop out. Even the few who for a time considered that a transient illness was related to their dosage were willing to continue participation and accept our judgment that no relationship existed. Of course, they were more assured when the illness resolved.

In studies such as those on antimalarial drugs, in which production of the disease was a necessary part of the work, the men accepted their illness with true heroism.

Although volunteers should be told the complete design of the study, it should be a part of the agreement that no volunteer is told the dosage group to which he belongs. A device we have used to avoid errors is to give placebos to all dosage groups for about a week at the beginning of a study. It is entirely natural that people should be apprehensive when they start a project. Ideas circulate among them by suggestion. We have had those who thought they had improved appetite and felt better, as well as those who lost appetite and felt worse while taking placebos.

If volunteers know there is a control group but have no hint of who is in it, many of them tend to complain less, because they realize they may be in that group from whom a complaint would be evidence of weakness or neurosis. Of course, the controls do complain just as often as others. Among the most extensive complaints we ever received came from a man who had taken only placebos. Rather than merely refusing a biopsy he did not wish to take, he reported that he was generally unwell. As examples, he mentioned dermatitis and a febrile illness, for which he was hospitalized for 1 day. He attributed all his troubles to

participation in the project. Examination confirmed the dermatitis and some congestion of the nose, residual from the upper respiratory infection a week before, but offered no evidence of other illness (Haynes *et al.*, 1956).

Complaints are distinctly more frequent among certain highly emotional ethnic groups. However, others in these same groups are the ones most likely to express gratitude for the benefit they have received from the study.

In addition to tangible rewards, benefits may include a sense of accomplishment. One prisoner told me that participation in the project had led to his reinstatement in his family. His father was pleased that he had finally done something useful.

LEGAL CONSIDERATIONS

Outline of present thinking

Background information on investigations using human subjects has been reviewed at length elsewhere from various points of view (Anonymous, 1955, 1959; Beecher, 1959; Flood, 1955; Heger and Gloriaux, 1957; Herings, 1955; Ladimer, 1954, 1957; Larebeyrette, 1954; Markel, 1963; Thomson, 1955; Wiggers, 1950; World Medical Association, 1957). An anthology of papers on the subject, edited by Ladimer and Newman (1963), is available in book form. An editorial (Anonymous, 1959) published in the *Canadian Medical Journal* gave an excellent summary of present thinking and, incidentally, reflected some of the inconsistencies in that thinking. Some of the points raised by the editorial appear irrefutable. They may be rephrased as follows:

1. Scientific investigations on human subjects have been conducted since time immemorial.
2. In the past 20 years or so, for the first time, much attention has been given to a study of the ethical, moral, and legal implications of investigations on man. This has resulted, doubtless, not only from the growth of this field of medical endeavor but also from the widspread disgust at revelations at the Nuremberg trials after World War II.
3. It is agreed that man is the ultimate necessary test subject in many instances, and medical investigations with people are unavoidable.
4. Abuses of this type of research are likely to be due more to ignorance or thoughtlessness than to deliberate malice.
5. To keep investigations within permissible moral and ethical bounds, the first consideration is that the subject should give consent with in the full legal meaning of that word.

The same editorial (Anonymous, 1959) states: "It is a curious fact that the legal profession seems to have taken little notice of human research so far." This statement seems to me to reflect a confusion that underlies the major difficulty medical scientists are having in reaching a satisfactory overall concept regarding such research. However, before undertaking any discussion of legal problems, it would be well to review the codes that have been proposed for the regulation of research on people.

Codes

Although they are not a source of law as it relates to liability, a number of codes are important for the guidance of investigations. After the hippocratic oath, which applies to medical investigations as well as to medicine in general, the best known of the formal codes is the famous Ten Points laid down by the Nuremberg Military Tribunal. These ten principles have been carefully considered from many points of view by Ladimer (1954, 1957), Beecher (1959), and others (American Medical Association, 1946; Flood, 1955; Guttentag, 1953; Ivy, 1948; Shimkin, 1953). They may be summarized as follows:

1. Voluntary consent of the subject is absolutely essential. Consent must be based on knowledge and understanding of the elements of the study and awareness of possible consequences. The duty of ascertaining the quality of consent rests on the individual scientist and cannot be delegated.
2. The test should seek some benefit to society unobtainable by any other method.
3. The investigation should be designed and based on prior animal study, the natural history of the disease or problem, and other data, so that anticipated results may justify the action taken.
4. It should be so conducted as to avoid unnecessary physical and mental suffering.

5. No test should be undertaken where there is reason to believe that death or lasting disability will occur, except perhaps where the investigator may serve as his own subject.

6. The degree of risk should never exceed that which the importance of the problem warrants.

7. There should be preparation and adequate facilities to protect the subject against even remote possibility of injury, disability, or death.

8. Only scientifically qualified persons, exercising a high degree of skill and care, should conduct investigations on human beings.

9. The subject should be permitted to end the test whenever he reaches a mental or physical state in which its continuation seems to him impossible.

10. The investigator must be prepared to end the test if he has reason to believe that its continuation is likely to result in injury, lasting disability, or death.

Additional guidance for human investigation as given by Beecher (1959), is provided by the following: (a) the Declarations of Geneva and Rome, each of which is essentially a rephrasing and amplification of the hippocratic oath; (b) pertinent statements from the French National Academy of Medicine, from representatives of the French Academy of Moral and Political Sciences, representatives of the Paris Hospitals, and from the chief of the French Army's central laboratory for bacteriology; (c) the British view as stated by a Briton acting as Special Consultant to the United States Public Health Service; (d) opinions expressed by Pope Pius XII; (e) the World Medical Association's presentation of a report from a study into all phases of human investigation; (f) Wigger's statements (1950); and (g) the expressed views of the U.S. Public Health Service and the American Medical Association. The most recent statements include that of the World Medical Association (1964) known as the Declaration of Helsinki and that of the Medical Research Council (1964). Some of the codes are less comprehensive than others, but in spirit they are all generally consistent.

Beecher (1959) observed that, in effect, the Public Health Service has adopted the Nuremberg Ten Points, with added comment on the importance of group review and group approval of all procedures where even remote possibilities for hazard exist. The American Medical Association (1946) also endorses the principles expressed in the Nuremberg Code. Succinctly put, to conform to the ethics of the Association, investigations on human subjects must meet three requirements: (1) There must be voluntary consent of the person on whom the investigation is to be performed. (2) The danger of each study must be previously investigated by animal experimentation. (3) The investigation must be performed under proper medical protection and management.

In an editorial summary (Anonymous 1959) of Beecher's review (1959), it was concluded that in the last analysis the moral and ethical standing of human investigation depends upon the good sense and integrity of the participating physicians, rather than on an elaborate code of ethics.

Necessity for definition of kind of investigation

Much of the confusion that exists not only in popular concepts, but also in professional articles and reviews, about investigations on human beings would be minimized if a classification such as the one given in Table II or the one implicit in the most recent annual report of Britain's Medical Research Council (1964) were kept in mind. For example, it has been stated that use of the "hopelessly incurable" suggests that the sicker a patient is, the less consideration he deserves from his physician. This notion is the direct result of confusing investigational *therapy* with investigational *physiology*. If the investigation involves a new therapy that the physician is fully capable of giving and that offers the patient his only hope of recovery, then the physician not only is justified in offering it to the patient, but is under some obligation to do so. If, on the other hand, investigation involves a physiological study and if the patient is capable of consent, then there is no reason he should not volunteer for such work, particularly if it is carried out by a qualified investigator other than his personal physician. By cooperation between the physician and the investigator, impairment of the relationship between the patient and his physician may be avoided, and yet the dying man may make a useful contribution to a study that might otherwise be impossible (e.g., a study of the distribution of a drug in all tissues, to be determined by analyses after death).

TABLE II—CLASSIFICATION OF INVESTIGATIONS ON MAN

I. INVESTIGATIONAL DIAGNOSTIC PROCEDURES OR THERAPY

This class presupposes a calculated risk by the patient, who is sick at the time and who freely consents[1] to a new procedure in order to benefit his own health, but usually without any other reward. The following subdivisions may be recognized:

1. Systematic[2] testing of new, animal-explored treatment in selected groups of patients	Examples: (a) test of pyrimethamine for malaria (Coatney *et al.*, 1953) and isoniazid for tuberculosis (Mount and Ferebee, 1952)
2. Opportunistic[2] use of candidate treatments previously explored fully in animals	Examples: (a) tests of rare surgery Woodruff *et al.*, 1963); (b) tests of antidotes for poisons (Namba, 1961)[2]

II. INVESTIGATIONAL PHYSIOLOGY (LATO SENSU)

This class presupposes a calculated risk by the subject who may be well, sick, or moribund at the time and who freely consents to a study without any hope of individual benefit to health but often for other rewards. The following subdivisions may be recognized:

1. Systematic[2] testing of animal-explored phenomena in selected groups of subjects	Examples: studies of the safety of malathion (Hayes *et al.*, 1960); study of oxygen and carbon dioxide (Consolazio *et al.*, 1947)
2. Opportunistic[2] exploration of phenomena previously explored fully in animals	Examples: (a) study by Beaumont (1833); (b) a large portion of good occupational medicine

Legal problems

The entire question of investigations on man has been greatly complicated by memory of what went on in Nazi Germany and by the fact that a large proportion of the strictly legal consideration of investigations on man has been concerned directly with the Nazi activity. The memory of the Nazi experiments is widespread and lasting, for they have been brought to public attention through all mass media by the Nuremberg trials and the Eichmann trial. The most obvious medical contrast between these experiments and legitimate investigations concerns the degree of danger to the subjects. The character of some of the tests excluded any possibility of voluntary participation, and the major legal contrast involves the coercion of the subjects. There can be no proper medical investigation of man without consent. Another contrast relates to the real need for using human subjects. Certain types of investigations cannot be advanced through animal studies (Jefferson, 1955; Ladimer, 1957), but most of the work done by the Nazi physicians could very well have been completed in lower animals.

A more subtle but probably more fundamental contract concerns the freedom of the experimenters. The Nazi physicians were subject to political pressure and were under military orders to carry out the work. The personal guilt of the Nazis or the legal basis of their trial is not germane to this discussion. It is germane to observe that similar misuse of people has not occurred when investigators were free.

Let us now consider the legal status of new procedures that do fall within the tradition of medicine. Although history shows that human experimentation in medical science is as old as the medical profession itself, courts generally have not wavered from their original stand that human experimentation is at the peril of those who conduct the tests. Ladimer (1957) cites English and American court cases going back to *Slater* vs. *Baker*, in the year 1767. In that case, under

[1] In the case of patients who are unable to give consent because of their age or medical condition, consent should be obtained from the parents or next of kin, just as is true in connection with any diagnostic procedure or therapy for such patients.

[2] It should be noted that the difference between "opportunistic" and "systematic" study has no relation to the care with which the work is planned and executed but is determined by the frequency of suitable subjects available for study.

the English jury system, the fact was established that the physician lacked proper skill and failed to obtain the patient's consent in using a previously untested medical procedure. The case established a rule that has been followed in both English and American law, and, indeed, perhaps in much of the world.

A review of pertinent cases reveals that most litigation has been between a single physician and one patient. The unhappy patient has charged the physician with "experimenting," and the physician has denied the charge and set up a defense that the practice employed was: (a) of recent origin, successfully used elsewhere; (b) a rare procedure, previously tried with success by the physician and known to be sometimes used; or (c) proper in view of its comparability to similar accepted procedures.

Under such a defense an unfavorable verdict would be a finding of negligence (malpractice), and the true issue of investigation would not arise. Should a claim arise in the course of a planned investigation, the best defense is proof that the subject assumed the risk knowingly and voluntarily.

Because the word "experimentation" carries the legal implication of malpractice, it is only common sense to avoid its use in connection with proper medical investigation.

The inference from judicial opinions does not necessarily imply that well-planned, properly controlled, and carefully executed human investigation would result in liability of the physician, where consent was obtained and the study carefully explained to an adult capable of understanding the possible consequences. In fact, such investigation of new drugs is subject to extensive regulation under the Federal Food, Drug, and Cosmetic Act (1963).

The view cited above that it is curious that the legal profession seems to have taken little notice of human research is naïve. The legal profession has not traditionally regulated the other professions. The licensing of physicians and the regulation of their professional affairs is carried out by the *medical* profession under authority of legislation sponsored largely by the *medical* profession. Even the Ten Points laid down by the Nuremberg Military Tribunal are based on previously accepted medical views. On the other hand, it is one of the duties of the legal profession to adjudicate claims of injury no matter from whom they arise. Thus, medical malpractice, whether experimental or not, is a natural concern of the legal profession because it gives rise to claims.

Practical measures to protect investigators

Wiggers (1950) has proposed that investigations should be so conducted that legal liability under malpractice or personal injury laws "never comes into question." It is obvious that this represents the ideal situation, but equally obvious that there will be failurs in the best laid plans of men. Over and above the scrupulous care that should be exercised in planning and carrying out any medical investigation on human beings, attention should be given to the inevitable *possibility* of claims growing out of the work.

Investigations should not be carried out without consent. The best way to establish the fact of consent is through a written statement or contract signed by witnesses as well as by the volunteer. The content of such agreements was outlined in the section "Protocol for a Study." While written consent will not protect the investigator against liability for his negligence, it will constitute a defense against claims for injuries resulting from foreseeable and assumed risks (Office of General Counsel, U.S. Department of Health, Education, and Welfare, December 1959).

Another important evidence of consent is the recognized ability of the volunteer to discontinue participation at any time, with or without reason.

The investigator or his organization should be in a position to underwrite the care of any injury that truly results from his investigation. This does not imply that the volunteer should be permitted to abuse the privilege by bringing claims for ailments quite unrelated to his participation in a project.

One way of meeting the obligations for justified care of the volunteer is through special insurance. In a study recently carried out by a private institute on the irritant effect of air pollution on the eyes, insurance for three million dollars was purchased for $278.90 (Zavon, personal communication to the author).

Ballard (1964) has discussed the possibility of legal and financial support from the manufacturer of a compound in the event that an authorized investigator of the compound is sued.

Another substantial evidence of support of medical research would be the passage by governments of malpractice tort legislation covering research as well as clinical practice for all professional health workers. A well-written law of this sort would, of course, require the consent of subjects and set other standards for conduct of investigations; compliance with these standards would then place the health worker within the scope of his employment and the protection of the law. Willingness of the government to accept claims or to defend the employee in a suit not only would tend to protect the individual physician or scientist but—perhaps even more important—would be an evidence of good faith in medical practice and research.

Claims are less likely to be successful if the research is carried out by someone of standing and reputation. Review of the work by a recognized authority, group, or agency offers objective evidence that the project is justified and that it has been carefully planned. In view of the recognized value of medical investigations on human beings, there is a double obligation on the part of official medical associations, medical schools, and governmental health agencies. First, they should make sure that only proper investigations are carried out on human beings. When they have done this, and have given their permission for studies on people, they have a second and equal obligation to make it clear that their approval has been granted. Approval should not be a one-sided affair in which the group in authority reserves the right to prevent poorly conceived research but evades responsibility for the research it does permit. A letter signed by the president, dean, or other responsible officer of the authorizing agency should be in the hands of the chief investigator before the work is actually begun.

Leading national and international medical and health organizations have an obligation to make it clear by editorials or other public statements of policy that the organization does approve and does actively promote proper medical investigations on human beings. No doubt discussions must continue about the details of codes or criteria that already exist for the guidance of such investigations. In fact, the very existence of these discussions, coming as they do from leading research institutions such as the Medical Research Council (1964) and the World Medical Association (1964), is evidence for the firm position that investigations on people now hold in medicine. However, such discussions, no matter how desirable, do not take the place of clear official medical statements championing the kind of research that now, in fact, constitutes accepted practice.

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[From Natural History, March 1972]

Down on the Farm—A Letter From Another Farmer

(By E. Raymond Hall)

In the January, 1972, issue of Natural History Magazine the letter from farmer J. O. Harvey urges "respect for the land . . . used to support us all" and succinctly catalogs half a dozen important sources of pollution. But she doesn't mention pesticides, possibly the single most important source of pollution facing us in the 1970's.

On the same evening, January 17, that I read the letter, I also read an Associated Press dispatch (*Kansas City Star*) crediting our new Secretary of Agriculture with stating that if pesticides were banned from farming, we could not feed all Americans. That dispatch followed the departmental line, as expressed by the administrator of the Research Service of the U.S. Department of Agriculture: "As we cope with . . . a more populous world . . . one of the greatest needs is production of food for billions of people. At present such production requires the use of pesticides" (*Science*, June 19, 1970).

The statement that pesticides are required to grow food crops is repeated so often by employees of the Department of Agriculture that many citizens believe it is true. Actually, it isn't. Individuals and local organizations of agriculturists in many parts of the United States have been, and are, demonstrating that the use of pesticides (herbicides and insecticides) is not necessary in food production.

One example is a 107-acre farm that I manage in Marysville Township, Miami County, Kansas. Five acres are pasture, 22 are woodland along a creek, and 80 are cultivated. No pesticides have ever been used on growing crops on this farm. Corn, milo, soybeans, and wheat are the crops raised now. For any given year in the period from 1886 through 1964 there was little or no difference in the yields from farms with comparable ground throughout the township. However, in the seven years since then, herbicides were introduced on neighboring farms and the yield per acre on my 80 acres has been greater than on comparable land, especially when soybeans were planted where corn had been grown the year before. On the comparable land, residues of herbicides applied to inhibit the growth of broad-leaved weeds in corn fields accumulate in the soil, causing the soybeans, themselves broad-leaved plants, to be puny. Other kinds of herbicides applied in order to inhibit the growth of grasses in soybean fields accumulate in the soil and cause the corn plants, themselves grasses, to be puny,

especially when corn is planted where soybeans had been grown the year before.

The following paragraphs explain how application of herbicides results in smaller yields per acre.

The farmer who plants and harvests row crops on 500 acres (260 corn and 240 soybeans), by means of four-row machinery and without using pesticides, likely passes over the land eight times to prepare the seed bed, plant, cultivate, and harvest the crop. In doing this, he averages about 30 acres in a nine-hour day—more acres when disking, and fewer when planting. For 100 bushels of corn per acre and 40 bushels of soybeans per acre he may gross $50,000 ($1 per bushel for corn and $2.50 per bushel for soybeans).

If the farmer attempts to eliminate weeds by spraying an herbicide once instead of by cultivating three times, he passes over the land a total of only six instead of eight times. This reduces his time spent in the field by 25 percent. The use of herbicides may reduce the yield per acre by 10 percent. Under these conditions, the farmer, who ordinarily wishes to produce in one year as many bushels as possible, attempts to rent 33⅓ percent more land (167 acres) and farm it (using herbicides) in the extra time he has. Even with a 10 percent reduction in yield per acre, from 667 acres (347 acres of corn and 320 of soybeans) he could gross $60,030—or $10,030 more than from 500 acres. But is there a better way to farm? (In 1971, the difference was 30 percent— 79 vs. 113 bushels—on corn, but less than 30 percent on milo and soybeans. Corn blight lowered the yield in fields adjoining the land managed by me, which was blight-free. Presence or absence of blight is not known to be related to pesticides or their residues in the soils, however.)

Considering the common interest it would seem that, in Miami County, for each 2,500 acres of cultivated land there should be at least five instead of four farmers and that they should control weeds by cultivation and should not use pesticides. This system produces more bushels per acre and more total bushels.

Furthermore, under this system the fish in the creek grow big and do not die prematurely because of pesticide residues, which have already stilled the spring voices of five bird species in the woodland on and around the land that I manage.

The example outlined above is only one strand of the web that regulates the lives of man, other animals, and plants in the current green (agricultural) revolution, but illustrates why I am very tired of being informed that pesticides are required to grow enough food crops.

I yield to the temptation to comment upon two other points made by the administrator of the Agricultural Research Service in his article in *Science*. First, with respect to certain newly developed dangerous pesticides, the administrator of the USDA's Research Service wrote that "scientists argue their data and conclusions . . . until shreds of truth can be aggregated to establish the fact" that use of those pesticides should or should not be banned. To my way of thinking, the reverse procedure is in order; that is, those pesticides should be banned until exhaustive testing proves their use to be in the public interest.

Second, his statement that "no data on humans are available" concerning the effects of the herbicide 2,4,5-T is surprising because some acquaintances of mine who used considerable amounts of it became ill and died shortly after. They reported having been told at the clinics where they went for treatment that their illness and accompanying blood dyscrasia probably resulted from 2,4,5-T. In my immediate neighborhood such information circulates by word of mouth, and as a consequence less 2,4,5-T is used than agents of the U.S. Department of Agriculture recommend. Many persons feel that, as one farmer put it, "If you'll notice, a fellow who uses a lot of that brush killer is apt to die in about six months of leukemia."

FARMERS UNION CENTRAL EXCHANGE, INC.,
St. Paul, Minn., June 1, 1972.

Re H.R. 10729, Federal Environmental Pesticide Control Act.

WALTER F. MONDALE,
U.S. Senate,
Washington, D.C.

DEAR MR. MONDALE: In our correspondence to you dated October 21, 1971, we pointed out a phrase that is objectionable in H.R. 10729, the Federal Environmental Pesticide Control Act. It is the "exclusive use of data" provision (section (3) (c) (1) (d)). *"Except that data submitted in support of an application shall not, without permission of the applicant, be considered by the administrator in support of any other registration;".*

It is objectionable for these important reasons:

—H.R. 10729 is an act conceived and designed to more closely regulate the uses of pesticides.

However the part we object to "the exclusive use of data" phrase, is totally unrelated to this concept and should be removed.

—The objectionable part would provide an indefinite extension of the 17 years of patent protection, to the exclusive benefit of the producers of patented chemical compounds, and at an exorbitant expense to the farmers who use the chemical compounds.

In addition to the information in our October 21, 1971 statement we list excerpts from, and cite the testimony of the following which was presented in the hearings before the subcommittee on Agri Research and general legislation of the committee on Agri and Forestry U.S. Senate of H.R. 10729 part II March 7 & 8, 1972.

a. Page 364 thru 369 testimony from Senator Philip A. Hart, Chairman of U.S. Senate Committee on Judiciary, Subcommittee on Antitrust and Monopoly.

Senator Hart also encloses the opinions of two noted scholars regarding the effect and advisability of the so called "exclusive use data" section of the bill.

I quote from Senator Hart's testimony—Page 363 Third amendment and Page 365:

"Efficiency and barriers to entry.—The House bill requires that in evaluating and acceptability of a pesticide for registration the administrator may not consider the data of any similar pesticide, or for that matter, the data of any other manufacturer of the same pesticide. Our amendment would eliminate this requirement on the grounds that the duplication of test data which would result from it is wasteful and that the provision may pose a barrier to entry of competitors into the market above and beyond those provided by our patent laws.

Obviously, the Administrator is needlessly hamstrung in his duties having information on file which could reflect either positively or negatively on pending applications for pesticide registration but not being able to use it."

"This restriction is unnecessary because title 35—the Patent Code—provides complete protection against infringement of the particular patent in question provided, of course, a patent has been sought. If a patent has not been sought or granted, then the applicant should not be entitled to the protection afforded by our Patent System; and efforts to expand patent protection outside the confines of title 35 should not be enacted without full and careful expert deliberation.

Similarly, should the information proffered pursuant to section 3(c)(1)(d) be proprietary information in the nature of a trade secret, full protection is afforded by the elaborate trade secret provisions of section 10."

I quote from the testimony of John C. Stedman, Professor of Law, University of Wisconsin:

"There is almost always, in the regulatory process, an ongoing conflict between the salutary public purpose (in this case, protection of the environment against damaging pesticides) and the danger that the regulatory process will be misused by protecting those already in the field through denial to qualified competitors of the right to center. The present proposal constitutes a real threat in the latter sense while serving no useful purpose in the former. The only conceivable legitimate purpose to be served by the proposal, as I see it, is the protection of equities in one who has pioneered in the development of a drug—and gone to considerable research effort and expense, especially with respect to its impact on the environment—by preventing others from getting a "free ride" on his experience with no cost to themselves.

But the "free ride" is endemic in our society and something to be legislated against only occasionally (as in the patent system, the recent "tape piracy" legislation, etc.) and careful attention to the countervailing adverse effects of such legislation.

This does not seem to be such a case, and certainly not one to be resolved in the broad, loose terms of the clause here in question. (1) There is no necessary correlation between the advantages gained by the applicant whose data is withheld and the burdens he has borne in collecting the data. (2) The provision gives no attention to, and makes no allowance for, the offsetting advantages the applicant has enjoyed as a result of his "headstart" or his continuing benefits from the genuine trade secrets he may have developed (it should be emphasized that

this provision is not needed to protect legitimate trade secrets—these are adequately protected by Section 10, and in any event the clause in question goes far beyond trade secret protection and prohibits the administrator from even using the knowledge he possesses not just from publicly disclosing it). (3) The collection of his data may well have entered into, and been part of the consideration for, the grant of his pesticide patent (if he has one) in view of the "utility" requirement contained in our patent law. (4) It is quite possible that some or all of his expense may already have been paid for through Government funding (see, e.g., Section 20 of the bill). (5) Assuming, arguendo, that the data collector is entitled to some form of remuneration for his efforts, the proposal here picks one of the worst possible forms for achieving this, namely, protection against legitimate competition.

(6) While the provision contains sufficient loopholes that a strongly public-interest-oriented Administrator could probably avoid the more serious impacts, it could easily become an instrument of obstruction in the hands of a timid Administrator or one more fully attuned to the interests of selected suppliers than to the interests of the public."

For the reasons given, I agree with Congressman Kastenmeier's recommendation that the underlined clause be deleted."

I quote from testimony of John J. Flynn, Professor of Law, University of Utah:

"I could find nothing in the report supporting any claimed injury or abuse of the existing statute that would justify the language added by Section 3(c)(1)(d). Moreover, the following analysis would seem to be logical and appropriate: The registration requirements of the Act establish a government created barrier to entry in the pesticide business; a major feature of that barrier to entry is the requirement of testing new pesticides, a cost which is to be borne by applicants; this cost can be assumed by some applicants better than others, but is not a cost relating to economic efficiency; it is a cost that is government imposed and, as such, it is a cost which should not be imposed any further than is necessary. Vesting control over this cost in an applicant, so that he can use a government cost barrier to entry to hamper subsequent competitors is totally wrong.

The information required is and should become public information, it should be freely used by the agency in the performance of its duties under the Act, and the provision as it now stands only serves the purpose of allowing applicants to hamper competition and efficient administration of the Act."

I quote from testimony of David D. Dominick, Assistant Administrator E.P.A. Page 95 section 2:

"The effect of this provision is to afford additional economic protection, foster monopoly, and it may tend to restrict pesticide business to large manufacturers. In addition, it would increase not only Federal administrative cost but those of the manufacturer as well aside from unnecessarily increasing the application processing time."

In answer to the testimony of N.A.C.A. wherein they state that the "exclusive use of data" provision is needed to protect the Chemical producer because the registration statement is published in the Federal Register, we comment as follows:

The disclosures in the Federal Register are not considered detrimental to the chemical producer. The chemical compounds of significance are patented *before* publication in the Federal Register.

The data on patented compounds is public record.

The complete testimony of the above participants is in agreement with our request that the phrase on "exclusive use of data" be stricken from the act.

Respectfully yours,

T. H. STEICHEN, *President.*

U.S. SENATE,
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington D.C., June 14, 1972.

Hon. PHILIP HART,
Chairman, Subcommitee on the Environment, Committee on Commerce, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: As Chairman of the Migratory Labor Subcommittee, I am particularly interested in the possibility that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) should be strengthened to guarantee protections for farmers and farmworkers exposed to agricultural chemicals.

In this regard, I was most encouraged to learn that as Chairman of the Commerce Committee's Subcommittee on the Environment, you will be holding hearings on proposed amendments to FIFRA.

The hearing record of the Migratory Labor Subcommittee contains substantial and compelling evidence concerning the need to adequately protect farmworkers exposed to agricultural chemicals. On March 8, I introduced in the Senate several amendments to H.R. 10729. I also suggested that several witnesses representing the interests of farmers and farmworkers be permitted to submit testimony at the Agriculture Committee hearings, and that Committee's hearing record reflects the need for the amendments. Unfortunately, however, none were included in the bill reported by that Committee.

I am enclosing a copy of my proposed amendments to H.R. 10729, together with explanatory information, as they appeared in the Congressional Record.

I would be most appreciative if this material could be printed in your Subcommittee's hearing record on H.R. 10729, and I am hopeful that the amendments will receive due consideration as your Subcommittee proceeds with deliberations on this important legislation.

With best wishes.

Sincerely,

ADLAI E. STEVENSON III,
Chairman, Subcommittee on Migratory Labor.

Enclosure.

[From the Congressional Record, Mar. 8, 1972]

FEDERAL INSECTICIDE, FUNDICIDE, AND RODENTICIDE ACT—AMENDMENT
AMENDMENT NO. 1017

(Ordered to be printed and referred to the Committee on Agriculture and Forestry.)

PROTECTION FOR FARMERS AND FARMWORKERS AGAINST THE HAZARDS OF AGRICULTURAL CHEMICALS

Mr. STEVENSON. Mr. President, the Senate Agriculture Committee is presently holding hearings on H.R. 10729. This is an important piece of legislation that, by changing the focus of the Federal Insecticide, Fungicide, and Rodenticide Act, could provide a more equitable and effective regulatory scheme for the control of the manufacture, distribution, and use of pesticides.

As the committee deliberates on this legislation, I hope it will not overlook the effects on farmers and farmworkers that can accrue from the unscrupulous use of agricultural chemicals. Many such chemicals are harmful not only to the environment but also hazardous to man and particularly to those who are most closely associated with farming.

The Migratory Labor Subcommittee, which I now chair, conducted 3 days of hearings during the 91st Congress on pesticides and the farmworker, which indicated the great need to protect farmers and farmworkers who are subjected to the unseen prils of toxic chemicals, gases, and airborne particulates. Special attention must be paid to providing explicit statutory protection of the farm and rural community faced with these hidden dangers. These citizens number in the millions, and include, among others, the self-employed family farmers as well as migrant and seasonal farmworkers. Injury and fatality figures are very high. An expert from the Department of Health, Education, and Welfare estimated that, during subcommittee hearings in 1970, possibly as many as 800 workers were killed and over 80,000 were injured each year by the improper and unwise use of agricultural chemicals.

To protect these citizens living and working in rural America, I today propose an amendment to H.R. 10729, the bill now being considered by the Agriculture Committee. In this regard, the committee must be commended for taking the opportunity to hear witnesses from a broad and representative community of people concerned about the welfare of all those in rural America.

Sections 1 and 2 of my amendment make it clear that a pesticide is misbranded within the meaning of section 2(q)(1) of the act if the directions or warnings do not adequately protect the health of farmers, farmworkers, and others who may come into contact with pesticides or pesticide residues.

Section 3 provides that test data may be relied upon to support an application for registration under section 3(c) of the act only if the tests are conducted in accordance with applicable law and participation therein is based on a free, voluntary, and informed choice.

Section 4 makes it clear that a pesticide shall be classified for restricted use if it might otherwise cause injury to farmers, farmworkers, or others who may come into contact with the pesticide or its residues.

Section 5 makes it clear that certified applicators must be competent to take measures needed to protect the health of farmers, farmworkers, and others who may come into contact with pesticides or pesticide residues.

Mr. President, I ask unanimous consent that the text of my amendment be printed at this point in the Record.

There being no objection, the amendment was ordered to be printed in the RECORD, as follows:

AMENDMENT NO. 1017

On page 11, line 16, change the semicolon to a comma and insert the following immediately thereafter: "including the protection of the health of farmers, farmworkers, and others who may come into contact with such pesticides or pesticide residues; or".

On page 11, line 21, change the period to a comma and add the following immediately thereafter: "including the protection of the health of farmers, farmworkers, and others who may come into contact with such pesticides or pesticide residues.".

On page 17, line 16, change the semicolon to a comma and add the following immediately thereafter: "*Provided*, That the Administrator shall not rely on test results submitted pursuant to this subsection unless he determines that (i) the tests were conducted in accordance with applicable federal, state, or local law, and (ii) participation in the tests was the result of a free, voluntary, and informed choice by each participant.".

On page 23, line 22, change the period to a comma and add the following im- worker, or other person who may come into contact with the pesticide or pesticide residues.".

On page 23, line 22, change the period to a comma and add the following immediately thereafter: "and such competence shall include the ability to undertake such measures as the Administrator may by regulation require to protect the health of farmers, farmworkers, and others who may come into contact with such pesicides or pesicide residues.".

ROLLINSON, LONG & STEIN,
Washington, D.C., June 16, 1972.

Hon. PHILIP A. HART,
Committee on Commerce, U.S. Senate,
Washington, D.C.

DEAR SENATOR HART: I regret not being able to testify before your Subcommittee holding hearings on H.R. 10729 but hope you will insert the following statements in your hearing letter.

We respectfully would recommend that Sec. 4(a) (1) of H.R. 10729 be expanded by adding the italicized language as follows:

(1) Federal Certification. Subject to paragraph (2), the Administrator shall prescribe standards for the *periodic* certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides *to be* covered by such individual's certification, *and must be determined to possess a reasonable working knowledge of the science known as integrated control as such science relates to the pest or pests to be covered by such individual's certification.*

The reason for suggesting "periodic" is that technology relating to pest control is changing rapidly. It would not seem an undue interference with the Administrator's prerogatives to require periodic renewal of certification.

The reason for our fundamental suggestion regarding integrated control goes to the very heart of the proposed legislation. In our judgment the technical ability to apply chemical pesticides is relatively unimportant compared to the more sophisticated ability to judge when to apply and what sort of pest control technique will be least damaging to beneficial creatures, the neighbor's crops and

the eco-system generally. Although the certification standard which we suggest will not insure such considerations, it would seem likely to tend to encourage such practices, particularly as knowledge becomes more widely circulated of the Federal, State, and privately funded demonstrations of the significant economic savings from integrated control usage.

These comments on H.R. 10729 are submitted solely as our views as private citizens. This firm represents no interests with direct or, to the best of our knowledge and belief, indirect, financial stakes in the subject proposed legislation. Our familiarity with the subject matter comes as a result of an investigation of agricultural usage of chemical pesticides under retainer from an eleemosynary institution, one of whose present stated objectives is to explore economically feasible methods for reducing chemical pesticide usage.

We intentionally refrain from expressing our views as to the merits of H.R. 10729 in whole and as to the merits of entrusting to EPA, as opposed to a possibly less political, independent body, the certification function.

Respectfully submitted,

MARK ROLLINSON.

AMERICAN PULPWOOD ASSOCIATION,
New York, N.Y., June 19, 1792.

Hon. PHILIP A. HART,
Chairman, Subcommittee on Environment, Committee on Commerce, Senate Office Building, Washington, D.C.

DEAR SENATOR HART: When we requested time for a representative of the American Pulpwood Association to testify before the Subcommittee on Environment on H.R. 10729, the Federal Environmental Pesticide Control Act of 1972, Mr. Bickwit of the committee staff requested that we file our comments since time was very limited. We are glad to do so and will outline our comments in this letter. We request that it be made a part of the record.

The American Pulpwood Association is a national trade association of pulpwood producers, dealers, consumers and others directly concerned with growing and harvesting pulpwood—the principle raw material used in the manufacture of pulp, paper, paper board and other products.

Many members of the American Pulpwood Association use pesticides in forest management. The amount of pesticides used for this purpose, however, is very small compared to the total pesticides used, but this small amount is very necessary. Therefore any regulations that affect pesticides are likely to affect members of the American Pulpwood Association.

We endorse H.R. 10729 as reported by the Senate Committee on Agriculture and Forestry. We are interested primarily in two provisions in the act.

1. *Cancellation.*—Registration of a pesticide should be considered evidence that all requirements have been met. Therefore we believe that any effort or request to cancel registration of a pesticide should be accompanied by new scientific information. The burden of proof should be on the party requesting cancellation. We think the third party petition and judicial review provisions of the bill as amended are fair and request that they be retained.

2. *Further restrictions by the Administrator.*—We note that the Senate Committee on Agriculture and Forestry emphasized that Section 3 (d) (1) (C) (ii) authorizing ". . . the Administrator to impose alternative restrictions does not constitute open-ended authorization for the Administrator." (Senate Report No. 92–838). We request that no change be made in this amendment or in its interpretation.

In summary, we urge that the Senate Subcommittee on Environment give favorable consideration to H.R. 10729 as reported by the Senate Committee on Agriculture and Forestry.

Very truly yours,

J. E. MOORE,
Manager, Forestry Programs.

NATIONAL PEST CONTROL ASSOCIATION, INC.,
Elizabeth, N.J., July 21, 1972.

Hon. PHILIP A. HART,
Chairman, Subcommittee on the Environment, Committee on Commerce, U.S. Senate, Washington, D.C.

DEAR SENATOR HART: We have had notice of the hearings on H.R. 10729, the proposed Federal Environmental Pesticide Control Act. I have been advised by

your staff that they would find it difficult to schedule me to present a statement at the hearings and they have encouraged me to place a written statement from our Association on record with your Subcommittee.

The National Pest Control Association is a nonprofit trade association representing 1,200 member companies providing structural pest control service to more than 3 million customers annually in the United States. In their work in keeping homes, food plants, markets, offices and factories free of insect, rodent and bird pests these firms have a need for pesticides which are effective and which can be used with safety to man and his environment. Thus our Association has a very direct interest in the regulations proposed in the development, distribution and use of pesticides. Our Association presented statements at the Hearings before the Committee on Agriculture, House of Representatives on March 15, 1971, and at the Hearings before the Subcommittee on Agricultural Research and General Legislation of the Committee on Agriculture and Forestry, United States Senate on March 25, 1971 and on March 8, 1972. Detailed statements concerning the nature of our industry and its pesticide needs will be found in the records of these hearings.

We find that H.R. 10729 as reported by Mr. Allen has provided adequate and acceptable compromises on the points that were of most direct concern to our industry. We think that the clarification on the interpretation of "under the direct supervision of" will provide responsible supervision and at the same time permit EPA to require immediate-presence supervision for the operations that they consider critically hazardous

We also are satisfied that the clarification on "inconsistent with its labelling" given in the Committee Report will provide the latitude that is necessary for effective and legal operation in control of minor pests.

We would restate for you our concern that our manufacturers and formulators retain their proprietary rights on research that they have had to conduct to qualify a product for registration. Our industry is not directly involved in the registration of pesticides in most of our operations, but we are quite dependent on the continued research, development and registration of pesticides by our suppliers. If our structural pest control industry is to respond to the public need for freedom from pests in our homes, restaurants, markets, and public areas we have need for continuing research to have safe and effective pest control techniques available. We can assure you from our past experience and from the analysis of the future that we can make, that these pest control techniques are not likely to be developed by the agencies of our government. Their source in the past, and their most likely source in the future is industry. We feel that industry has legitimate proprietary rights. These appear to be protected in H.R. 10729 as reported. The bill also provides control by EPA and permits public review to a significant and workable level For the above reasons, we feel we must recommend strongly against the amendments that you and Senator Nelson have proposed to give early public access to registration data and to permit the use of data filed by one for the support of all subsequent applications from others at no cost. It almost casts EPA in the role of a "Robin Hood," extracting from those that have for the benefit of those that would like to have.

Speaking personally, I would impress upon you that your proposal would not merely impose a penalty on the large companies, the "monopolies" as I have heard them described at your hearings. It would also take the same proprietary rights away from the small firm that also can have a spark of research genius. As the small firm may try to get recognition for its development, your proposal lays it open to everyone, "monopolies" and scavengers included. The small firm would have no protection.

Our Association hopes that your Subcommittee will give full and careful thought to our concerns and we appreciate the priviledge of placing these on record with you. We endorse the reported version of H.R. 10729.

Sincerely yours,

RALPH E. HEAL,
Executive Secretary.

NATIONAL CANNERS ASSOCIATION,
Washington, D.C., June 23, 1972.

Hon. PHILIP A. HART,
Chairman, Subcommittee on the Environment, Committee on Commerce, U.S. Senate, Washington, D.C.

DEAR SENATOR HART: The National Canners Association is pleased to advise your Subcommittee that it supports the passage of the "Federal Environmental

Pesticide Control Act of 1972," (H.R. 10729) as reported by the Committee on Agriculture and Forestry on June 7, 1972. We ask, however, the adoption of the amendment described below.

We believe the bill will help assure future safe use of pesticides in agriculture while providing protection for the applicator, rural and urban residents, and the environment. We further believe that it is extremely important to the welfare of agriculture and American consumers that controls over the use of pesticides be practical in the light of commercial farming practices.

The National Canners Association is concerned about the wording of Section 23, subsection (c), which provides that a state may register pesticides formulated for distribution and use within that state to meet specific local needs if the state is certified by the Administrator as capable of exercising adequate control and if registration for such use has not previously been denied, disapproved or cancelled by the Administrator. Such registrations shall be deemed registration under section 3 for all purposes of the Act, but shall authorize distribution and use only within such state and shall not be effective for more than 90 days if disapproved by the Administrator within that period.

As has been suggested by Mr. Dominick of the Environmental Protection Agency, state registrations should not be valid for more than 90 days and should not be renewable unless *approved* by the Administrator. It is also important that tolerances for residues be required for any food, feed, or forage crop uses of pesticides registered by the states, and that supplements and amendments to state registrations be handled as new state registrations. In keeping with these concerns, the following amendments to Section 23(c) are recommended:

(1) After the word "Administrator", line 18, page 120, add: "*provided no state may register a pesticide for use on a food, feed, or forage crop unless a tolerance has been established by the Administrator for residues of the pesticide on the crop.*"

(2) After the word "Act", line 20, page 120, add: "*unless disapproved by the Administrator.*"

(3) Commencing with the word "if", line 22, page 120, strike the remainder of the sentence and add: "*or renewable unless approved by the Administrator within that period. Each supplement or amendment to a state registration shall be deemed a new registration for the purposes of this section.*"

We urge your Subcommittee's consideration of these proposed amendments in light of the need to assure that pesticides registered for use by a state within that state shall not result in the production of a food, feed, or forage crop that would be unacceptable for shipment in interstate commerce.

As background to this support for the legislation and our interest in the amendment described above, we wish to point out that the proper and effective use of pesticides in the production of fruits and vegetables for canning has been of direct concern to the canning industry for many years. To assure the delivery of wholesome food products, free of illegal pesticide residues, to canning plants throughout this nation, the National Canners Association initiated in 1960 a "Protective Screen Program" that provides for contract agreement between processor and grower for the use of pesticides and the maintenance of records by growers on what pesticides have been used, when, and how much, on crops to be delivered to canners.

Very truly yours,

EDWIN A. CROSBY,
Director.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., June 27, 1972.

LEONARD BICKWIT, JR., ESQ.,
Counsel, Senate Commerce Committee, Subcommittee on the Environment, U.S. Senate, Washington, D.C.

DEAR MR. BICKWIT: You indicated that the Committee would like to have an indication of how the Environmental Protection Agency construes "substantial question of safety," "imminent hazard" and "risks and benefits" in the administration of FIFRA. I am enclosing three separate orders which set forth the Agency's administrative construction of these criteria. As you are aware, we have under present law three separate stages of review: the initial stage where

we determine whether or not "substantial question of safety exists," a review after receiving a report from scientific advisory committee, and a determination after a public hearing.

You have also asked us to furnish our administrative construction of the "commonly recognized practice" criterion in present law. I have enclosed a copy of our decision and order in *In Re Neodane Co. et al*, which is now pending before the Eighth Circuit for judicial review. As you are aware from Mr. Dominick's testimony, the Seventh Circuit has disapproved a similar position taken by the Agency in *In Re Stearns* in its decision, *Stearns Phosphorous Paste Co.* v. *EPA*.

Sincerely, yours,

CHARLES FABRIKANT,
Special Assistant for Regulatory Affairs.

Enclosures.

NOTICE TO MANUFACTURERS, FORMULATORS, DISTRIBUTORS, AND RESTRANTS OF ECONOMIC POISONS

Attention: Person Responsible for Federal Registration of Economic Poisons.

CANCELLATION OF REGISTRATION FOR CERTAIN PRODUCTS CONTAINING MERCURY

While mercury is an element and occurs naturally in the environment, its location and form are of grave concern from the standpoint of public health and safety. There is strong evidence that man-made mercury compounds and uses of mercury by man alter its natural distribution and form in a way to create a hazard over and above that posed by natural mercury.

This concern caused the Agency to review all pesticidal uses of mercury and two studies have now been completed. We have also had the benefit of a report by a Scientific Advisory Committee convened to consider mercury algicide uses in the aquatic environment. Based on the information in those and other reports, I am persuaded that all pesticide uses of mercury should be ended, and certain uses halted immediately since they create an imminent hazard in the environment.

Suspension

Mercury in pesticides occurs in the alkyl, aryl and salt states. The most toxic form is the alkyl which can be readily absorbed by the human brain and stored by man and lower forms of animal life.

On March 9, 1970, the United States Department of Agriculture, then in charge of pesticide registrations, issued orders of suspension of alkyl mercury seed treatments. Alkyl mercury is, however, still registered for use as a treatment on cotton, farm and greenhouse equipment, ornamentals, turf, surface fungistat, wood preservative, anthranacose on trees and shrubs, leaf spots and blights.

This Agency has also recognized the severity of the hazard from use of other forms of mercury that, of necessity, involve direct and present contact with the marine environment. This hazard arises from the ready convertibility of other forms of mercury to the alkyl form in the marine environment. Thus, uses of mercury algicides in swimming pools and cooling towers and uses for treating laundry were cancelled by the Department of Agriculture in 1970. Subsequently, on October 7, 1971, this Agency affirmed the cancellation and suspended the pool and cooling tower use after a report by a Scientific Advisory Committee requested by a registrant of these products.[1] Other uses which present a possibility of immediate aquatic contact include marine paints and treatment of rice seeds for use in flooded growing.

Because of the toxicity to man of alkyl mercury and its tendency to build up in the environment and food chain, it is imperative to delay and, if possible, prevent additional accumulation. Any additional use of alkyls, as such, or nonalkyls that have a direct and immediate contact with the aquatic environment in the foreseeable future create an "imminent hazard" to the environment.

The standard of suspension has most recently been reiterated in our order suspending registrations for predator control uses of strychnine, 1080, cyanide, and thallium sulfate. We there talked about conditions that are "irremediable and uncorrectable by subsequent actions." We have previously stated in our

[1] The Agency's Order of October 7, 1971, which is in part incorporated herein (see Finding 13, *infra*), appears at 36 FR 20259.

DDT Statement of March 18, 1971, that what we look to is not an imminent disaster, but rather a "point in the chain of events which may ultimately result in harm to the public." To allow a course of conduct today that may create an uncorrectable and highly dangerous situation tomorrow is to engage in environmental brinksmanship.

These tests are met where we are concerned by the use of a highly toxic, persistent substance, which can be stored by man and his food chain and to which, in the normal course of events, substantial numbers of individuals may be exposed. While levels of alkyl mercury may not now be at the critical threshold, it is important to control this build-up now before it reaches an acute level in the future.

While these circumstances might not be decisive of the issue of suspension, there are no compelling benefits from the uses in question that would justify continued registration pending further administrative review. Neither disease control nor maintenance of a diet staple is here involved.

In accordance with this notice and attached findings and order, the registration of all alkylmercury products and the registration of other mercury products for rice treatment, laundry uses and marine paints are suspended.

B.

Cancellation

There remains the further problem of what ation should be taken on other mercury registrations involving its use in aryl or salt forms in a manner that does not promise immediate contact with the aquatic environment. Such uses are numerous.

Our statutory obligation is to cancel a registration wherever its use presents a "substantial question of safety." See DDT Statement, March 18, 1971, *EDF* v. *Ruckelshaus*, 439 F.2d 584.

While available evidence suggests that only the uses of mercury heretofore or today suspended create an imminent hazard, all pesticidal uses of mercury pose a substantial question of safety. Given the basic chemical properties of mercury and its pattern of activity in the environment, it cannot be said that any use is not a potential contaminant to water and the food chain. Whether it be soil carrying mercury eroded from treated farm areas, or chips of mercury-treated paint, or mercury vaporized into the air and returned to earth by rain, once mercury reaches an aquatic environment it is converted to the highly toxic alkyl mercury by microorganisms in the bottom sediment. There is no effective way to control and monitor the environmental activity and circulation of man-placed mercury.

In view of the long-range risks involved, we believe that it is appropriate to commence formal administrative proceedings to review them.

I.

FINDINGS

1. Mercury, in many forms and degrees of volatility, can circulate in the environment: water, soil and the atmosphere.

2. Aryl mercury and mercury salts in river and lake bottoms can be converted into highly toxic methyl or alkyl mercury.

3. Mercury levels accumulate in the aquatic biota with the result that potentially dangerous residue levels are reached in aquatic foods consumed by man and animals.

4. There are no clearances, as required by the Federal Food, Drug, and Cosmetic Act, for any level of mercury residues that may accumulate in food or feed.

5. Once entered into the environment, no feasible means of reducing mercurial levels exist. Therefore, contamination is virtually irreversible.

6. Alkylmercury has a particularly high degree of toxicity and it has a propensity for accumulation in the brain.

7. Alkylmercury may be stored in the body and build up to critical levels leading to symptoms associated with damage to the central nervous system. It may be stored in fish.

8. Since alkylmercury is readily transported, it poses a threat to the entire public.

9. There is no effective way to monitor all sources of direct contact man may have to mercury.

10. Mercury when used for treatment of rice seeds, laundry, and in marine-anti-fouling paint is likely to come quickly into contact with the aquatic environment.

11. All man-made uses of mercury alter its natural distribution in the environment.

12. Such uses may cause additional deposits of mercury into water over and above those occurring naturally or hasten such deposits thereby building up aquatic concentrations.

13. In addition to the above findings, the general findings contained in our mercury order of October 7, 1971, IFR Nos. 15 and 53 are adopted herein.

II.

CONCLUSIONS AND ORDER

In accordance with Sections 2(z)(2)(c), 2(z)(2)(d), and 2(z)(2)(g) and Section (c) of the Federal Insecticide, Fungicide and Rodenticide Act, all present registrations for mercury products create a "substantial question of safety" as to whether or not their use, even in accordance with label directions, is not injurious to man and other living animals. All uses are hereby cancelled. In addition, registrations for alkyl compounds and non-alkyl uses on rice seed, in laundry, and marine anti-fouling paint create an imminent hazard and these registrations are hereby suspended.

WILLIAM D. RUCKELSHAUS.

MARCH 22, 1972.

BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

STEVENS INDUSTRIES, INC., ET AL. (CONSOLIDATED DDT HEARINGS)

(I.F. & R. Docket Nos. 63, et al.)

OPINION OF THE ADMINISTRATOR

This hearing represents the culmination of approximately three years of intensive administrative inquiry into the uses of DDT. Part I sets forth the background of these proceedings and Part II contains a discussion of the evidence and law and my factual conclusions. I am persuaded for reasons set forth in Part III of this opinion that the long-range risks of continued use of DDT for use on cotton and most other crops is unacceptable and outweighs any benefits. Cancellation for all uses of DDT for crop production and non-health purposes is hereby reaffirmed and will become effective Demeber 31, 1972, in accordance with Part V of this opinion and the accompanying order, except that certain uses, for green peppers, onions, and sweet potatoes in storage may continue on terms and conditions set forth in Part V of this opinion and the accompanying order.

A. Background

DDT is the familiar abbreviation for the chemical (1,1,1, trichlorophenyl ethane), which was for many years the most widely-used chemical pesticide in this country. DDT's insecticidal properties were originally discovered, apparently by accident, in 1939, and during World War II it was used extensively for typhus control. Since 1945 DDT has been used for general control of mosquitos, boll weevil infestation in cotton-growing areas, and a variety of other uses. Peak use of DDT occurred at the end of the 1950's and present domestic use of DDT in various formulations has been estimated at 6,000 tons per year.[1] According to

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[1] Admission 6 shows that domestic shipments of DDT by its sole manufacturer, Montrose Chemical Company, totaled 8,827,900 pounds between January 1 and August 1, 1971. Total domestic sales in 1970 were 11,966,196, as stipulated in Admission No. 7. The Examiner found, apparently based on Admission 7, that domestic use in 1970 "was just under 12 million pounds." Exam. Report at 92.

Counsel for the Agency has called to our attention publication of the Department of Agriculture, *The Pesticide Review of 1971*, which estimates "a domestic disappearance" rate of 25,457 pounds for DDT in 1970. See p. 28. The motion to incorporate this publication is granted, as is the motion by registrants to supplement the record, see *infra*. I do not believe, however, that the Pesticide Review figure can be accepted, on its face, without further explanation. Since the result I reach today would, if anything, only be reenforced by the higher figure, I see no need to remand.

Admission 7 of the record, approximately 86% or 10,277,258 pounds of domestically used DDT is applied to cotton crops. The same admission indicates that 603,053 pounds and 937,901 pounds, or approximately 5 and 9% of the total formulated by twenty-seven of the petitioners in these hearings are used respectively on soybean and peanut crops. All other uses of the 11,966,196 pounds amount to 158,833 of the total, or little over 1 percent.[2]

Public concern over the widespread use of pesticides was stirred by Rachel Carson's book, *Silent Spring*, and a natural outgrowth was the investigation of this popular and widely-sprayed chemical. DDT, which for many years had been used with apparent safety, was, the critics alleged, a highly dangerous substance which killed beneficial insects, upset the natural ecological balance, and collected in the food chain, thus posing a hazard to man, and other forms of advanced aquatic and avian life. In 1969 the United State Department of Agriculture commenced a review of the health and environmental hazards attendant to the use of DDT.

Certain uses of DDT were canceled by the Department of Agriculture in 1969 and informal review of remaining uses continued through 1970.[3] In early 1971 this Agency commenced formal administrative review of DDT registrations by the cancellation of all registrations for DDT products and uses pursuant to Section 4(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) 7 U.S.C. § 135 (1972).[4]

B. Statement of the Case

This hearing is the final stage of formal administrative review.[5] Thirty-one registrants have challenged fifteen of the canceled uses of DDT and its metabolite, TDE.[6] These uses of DDT include applications to cotton fields to control the boll weevil and bollworm applications to various vegetable crops, and a variety of lesser uses in public programs. The case for cancellation has been presented by counsel for the Pesticides Office of the Environmental Protection Agency and attorneys for the Environmental Defense Fund which is an intervenor. Other parties include Eli Lilly & Co., which held a DDT registration for "topocide," a prescription drug,[7] H. P. Cannon & Son, a user of DDT,[8] and representatives of the chemical manufacturing industry and various wildlife groups.[9]

The testimony and exhibits cover in exhaustive fashion all aspects of DDT's chemical and toxicological properties. The evidence of record, however, is not

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[2] Some discrepancy in the figures exists since the figures given in breakdown of use categories total 11,977,065 pounds, slightly more than the total sold by the 27 formulators who supplied figures.

For the above uses it appears that DDT is sold in four different formulations: emulsifiable sprays; dust; wettable powder; and granular form.

[3] PR Notice 69–17. Among the canceled uses were applications to trees for control of Dutch Elm disease, tobacco, home uses, and aquatic uses. 34 Fed. Reg. 18827 (1969).

[4] In *Environmental Defense Fund* v. *Ruckelshaus*, 439 F.2d 584 (D.C. Cir. 1971), the Court of Appeals held that cancellation proceedings should be commenced whenever a registration of a pesticide raises a "substantial question of safety" which warrants further study. On January 15, 1971, all uses of DDT not canceled in 1969 were canceled. PR Notice 71–1. And on March 18, 1971, notices of cancellation were issued for all registered uses of TDE, a DDT metabolite. PR Notice 71–5.

[5] Under FIFRA a registrant is entitled to either a public hearing or a scientific advisory committee or both to review his registration. Pending completion of that review, a registrant is allowed to continue shipment of his product.

[6] Unless specified, discussion of DDT in this opinion applies to TDE. DDT has three major breakdown products, DDA, DDE, and DDD; separate registrations exist for TDE (DDE).

[7] There has been some controversy over Eli Lilly's status because it failed to appeal cancellation of its registration within 30 days as required by Section 4(c) of FIFRA. For the purposes of this case I believe they should be accorded status as parties.

[8] There has been some question as to whether or not a "user" has standing to appeal a cancellation and thus seek reinstatement of a canceled use even though no registrant has stepped forward to appeal. The same reasoning employed by the court in *Environmental Defense Fund* v. *Ruckelshaus*, *supra*, and *Environmental Defense Fund* v. *Hardin*, 428 F.2d 1093 (D.C. Cir. 1970), which accords standing to "public interest" groups gives "users" a right to appeal a cancellation.

[9] The groups are: National Agricultural Chemicals Association; National Audubon Society; The Sierra Club; and West Michigan Environmental Action Council. As already noted, the Secretary of Agriculture, in addition to being a party-registrant by virtue of registrations held by its Plant Regulation Division, has appeared as an intervenor.

so extensive concerning the benefits from using DDT, and most of it has been directed to the major use, which is on cotton crops.[10]

The Pesticides Office and Environmental Defense Fund (EDF), in presenting their cases against continued registration for DDT, lean most heavily on evidence which, they contend, establishes: (1) that DDT and its metabolites are toxicants which persist in soil and the aquasphere; (2) that once unleashed, DDT is an uncontrollable chemical which can be transported by leaching, erosion, run-off and volatilization; (3) that DDT is not water-soluble and collects in fat tissue; (4) that organisms tend to collect and concentrate DDT; (5) that these qualities result in accumulations of DDT in wildlife and humans; that once stored or consumed, DDT can be toxic to both animals and humans, and in the case of fish and wildlife inhibit regeneration of species; and (7) that the benefits accruing from DDT usage are marginal, given the availability of alternative insecticides and pest management programs, and also the fact that crops produced with DDT are in ample supply. The testimony and exhibits include numerous reports of expert scientists who have described observed effects of DDT in the environment and the laboratory.

Group Petitioners and the United States Department of Agriculture (USDA) seek to discredit the Agency's case by citing the record of safety DDT has compiled throughout the years, and point to the negative findings of epidemiological and human feeding studies carried out over the years on industrial workers and volunteers exposed to concentrated levels of DDT far in excess of that to which the average individual is exposed. Proponents of continued registration have also introduced expert testimony to the effect that DDT's chronic toxicity to man or animals has not been established by adequate proof. The registrants have attacked the assumption that laboratory data, as to effects of exaggerated doses of DDT, can provide a meaningful basis for extrapolating effects on man or the environment. In the alternative, Group Petitioners contend that whatever harm to the environment might be attributed to DDT, it results from misuse and overdosing that occurred in years past. Lastly, Group Petitioners and USDA have attempted to prove that DDT is effective and that its use is more desirable than the organophosphates which are more acutely toxic and costly than DDT.

On April 25, the Hearing Examiner issued an opinion with proposed findings, conclusions and orders recommending that all "essential" uses of DDT be retained and that cancellation be lifted.[11] The Examiner's report which has findings, conclusions and an opinion, is attached as an appendix. The Examiner apparently accepted in his report the Agency's proof that DDT is a hazard to aquatic and terrestrial wildlife and substitutes exist. He found, as a "matter of fact," DDT can have adverse effects on beneficial animals; that it is transferred through the food chain; that DDT is fat soluble. He concluded, however, as a "matter of law," that DDT is neither a carcinogen nor teratogen, that the particular uses at issue do not adversely affect wildlife, that DDT use has rapidly declined. Examiner's Rept. p. 93.

The Pesticides Office of this Agency and intervenor Environmental Defense Fund (EDF) filed exceptions to the Examiner's report,[12] challenging his application of the burden of proof to this case, his findings of fact, conclusions of law, and numerous evidentiary rulings. Exception was also taken to the Examiner's application of the so-called "risk and benefit" standard of FIFRA.

On May 2, 1972, the Judicial Officer propounded by order, at my direction, a series of questions for briefing and discussion at oral argument, and oral argument was held on May 16. That argument was transcribed and is part of this record. Group Petitioners, USDA, Eli Lilly and H. P. Cannon & Sons have also responded to the briefs on exceptions.

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[10] The following uses are involved: for cotton; for military use on clothing; for peppers and pimentos; for fresh market corn; for peanuts; for cabbage, cauliflower, and brussel sprouts; for tomatoes; for lettuce; for potatoes; for sweet potatoes in storage (southern states only); for use in commercial greenhouses and nurseries; for beans (dry, lima, snap); for bat and rodent control; for emergency use for agriculture, health or quarantine purposes; and for onions and garlic; and for lice control. There has been considerable controversy as to what uses were at issue during the hearing. Admission No. 2 sets forth those uses which the Department of Agriculture considers essential. Many of those uses have been canceled and no appeal was taken. The uses at issue in this hearing are only those noted in Admission 11.

[11] There is some confusion as to what the term "essential" means. By Admission No. 2 the parties stipulated that certain uses were "essential" in the view of USDA. No stipulation exists that these uses are, in fact, essential in that no alternatives exist or that a shortage of a crop would result without DDT.

[12] Exceptions have also been received in Docket 106, *In re Wallerstein*. Stark Bros. Nurseries held a registration for use of DDT on nursery plants. The Examiner recommended cancellation on the grounds that this was not an "essential" use according to USDA.

II.

A. Applicable Law

The basic FIFRA scheme has been outlined in court opinions and Agency decisions (see *EDF* v. *EPA*, D.C. Cir. Slip. Op. 71-1365, —— F.2d ——, May 5, 1972 (Opinion of Judge Leventhal); *Stearns Elec. Paste Co.* v. *EPA*, 7th Cir. Slip. Op. No. 71-1112, —— F.2d ——, May 11, 1972; *Continental Chemiste Co.* v. *EPA*, 7th Cir. Slip. Op. No. 71-1828, ——F.2d ——, May 11, 1972; *EDF* v. *Ruckelshaus* (Opinion of Judge Bazelon), *supra;* Statement of Reasons Concerning the Registration of Products Containing DDT, 2,4,5-T, and Aldrin/Dieldrin, March 18, 1972; *In re Hari-Kari Lindane Pellets, et al.*, I.F.&R. No. 6 (1971). While there is no need to trace in detail once again the statutory scheme, a brief summary provides a useful prism for filtering the evidence.

1. FIFRA

The Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 135 (1972), establishes a strict standard for the registration of pesticides. Any "economic poison" which cannot be used without injury to "man or other vertebrate animals, vegetation, and useful invertebrate animals" is "misbranded,"[13] and is

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(c) if the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public;

(d) if the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vetebrate animals, vegetation, and useful invertebrate animals;

* * * * * * *

(g) if in the case of an insecticide, nematocide, fungicide, or herbicide when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds, to which it is applied, or to the person applying such economic poison;

* * * * * * *

therefore subject to cancellation.[14]

While the language of the statute, taken literally, requires only a finding of injury to non-target species, the inquiry cannot, however, end with a simplistic application of this plain statutory language. Both judicial and administrative precedent recognize that Congress intended the application of a balancing test, that would measure the risks of using a particular chemical against its benefits.[15] If a product is "misbranded" within the meaning of the Act, *i.e.*, if it bears a label for use that does not meet the criteria of Section 2, it may no longer be shipped in interstate commerce and stocks in hand in the original package may be seized. 7 U.S.C. § 135(g) (1972).

2. Risks and Benefits

It follows from the statutory scheme and this Agency's decisions that evidence of each alleged risk must be reviewed and a conclusion reached as to whether or not, and in what degree, such risk is incident to the directed use of a particular product. The task, however, is complicated in the case of a "persistent" pesticide by its possible chronic effects. The degree of persistence, extent of overall usage and mobility all bear on the amplitude or indeed the existence of the risk curve.[16] I believe, however, it is useful to isolate the alleged risks and

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[13] Sections 2(z)(2)(c), (d) and (g), respectively, provide:
"The term 'misbranded' shall apply—
(a) to any economic poison * * *

[14] Section 4 permits the Administrator to cancel a registration "if it appears that "the article and its labeling * * * do not comply with [the Act]." Since the Act prohibits distribution of a "misbranded" pesticide, Section 3(a)(5), the registration for a "misbranded" product may be canceled.

[15] *See EDF* v. *EPA* (Opinion of Judge Leventhal), *supra*; *EDF* v. *Ruckelshaus* (Opinion of Judge Bazelon), *supra*, DDT Statement of Reasons, *supra*; *see also* Statement of Reasons Underlying Suspension and Cancellation of Products Containing Mercury, 37 Fed. Reg. 6419 (1972).

[16] Other factors bearing on risk may include the geographical location of application, *see, e.g.*, Statement of Reasons Underlying Registrations for Strychnine, 1080, and Sodium Cyanide, 37 Fed. Reg. 5718 (1972), although this may not be as significant where the chemical is highly volatile as is the case with DDT. *See also* Statement of Reasons Underlying the Cancellation of Mirex, Determination and Order of the Administrator at 7, 32 Fed. Reg. 106, June 1, 1972.

evaluate each on the assumption that they are unaffected by overall levels of use, and defer to Part IV the discussion of the significance of the relationship between risk and overall use.

III

A. Analysis of Evidence

1. Risks

a. Health Effects and Environmental Properties.—There is no dispute on this record that DDT is a non-specific chemical that kills both target and non-target species in the immediate area of application. Few chemicals, however, are so selective that they can be used without causing some injury to "non-target" species. We must therefore proceed to the evidence bearing on other "risks" and the "benefits" from using DDT.

I am convinced by a preponderance of the evidence that, once disbursed, DDT is an uncontrollable, durable chemical that perists in the aquatic and terrestrial environments. Given its insolubility in water and its propensity to be stored in tissues, it collects in the food chain and is passed up to higher forms of aquatic and terrestrial life. There is ample evidence to show that under certain conditions DDT or its metabolites can persist in soil for many years,[17] that it will volatilize or move along with eroding soil.[18] While the degree of transportability is unknown, evidence of record shows that it is occasionally found in remote areas or in ocean species, such as whales, far from any known area of application.

Persistence and biomagnification in the food chain are, of themselves, a cause for concern, given the unknown and possibly forever undeterminable long-range effects of DDT in man, and the environment.[19] Laboratory tests have, however, produced tumorigenic effects on mice when DDT was fed to them at high levels.[20] Most of the cancer research experts who testified at this hearing indicated that it was their opinion that the tumorigenic results of tests thus far conducted are an indicator of carcinogenity and that DDT should be considered a potential carcinogen.[21]

Group Petitioners argue that the testimony is in conflict and fasten on to the testimony of the Surgeon General that of Drs. Loomis and Butler. The Surgeon General's Statement was, however, cautious and, by no means, carries the burden that the Group Petitioners seek to place on it. In very general terms the Surgeon General stated: "We have no information on which to indict DDT either as a tumorigen or as a carcinogen for man and on the basis now available, I cannot conclude DDT represents an imminent health hazard." (Tr. 1350) This testimony, however, does not bear on the long-term effects of DDT, nor did the Surgeon General express a view on what uses, apart from health uses, would justify continued use of DDT. Indeed, the entire thrust of the Surgeon General's testimony was only that use for immediate health needs outweighs the possible long-range effects of DDT on human health. Group Petitioners' other witnesses, Drs. Loomis and Butler, while men of stature in their fields—toxicology and pathology—and knowledgeable about cancer treatment and diagnosis, are not specialists in cancer research as is Dr. Saffiotti. Indeed, Dr. Butler disclaimed such expertise.

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[17] Method of application and type of soil and climate can affect persistence in soil and likewise run-off into aquatic areas.

[18] Registrants have made much of the fact that aquatic contamination and the spread of DDT have resulted from drift during aerial application. While the Examiner's Report dwells at some length on improved methods of application, it recognizes run-off as a significant source of aquatic contamination, even with improved aerial spraying techniques.

[19] It is particularly difficult to anticipate the long-range effects of exposure to a low dose of a chemical. It may take many years before adverse effects would take place. Diseases like cancer have an extended latency period. Mutagenic effects will be apparent only in future generations. Lastly, it may be impossible to relate observed pathology in man to a particular chemical because of the inability to isolate control groups which are not exposed in the same degree as the rest of the population.

[20] Tumorigenic effects have been noted in a number of laboratory experiments. The most positive results were developed by the Bionetics Study and the Lyons and Milan tests. The Bionetics Study of the National Cancer Institute fed 120 compounds to two strains of mice. DDT was one of 11 compounds to produce an elevated incidence of tumors. The Lyons and Milan Studies of the International Agency for Research of the World Health Orgaization is a multigenerational study (still in progress) of 6,000 mice of in- and outbred strains. Increased hepatomas were noted in male and female mice fed DDT at 250 ppm. Metastasis to the lungs or kidneys has been recorded in five instances.

[21] Witnesses testifying to the positive correlation between tumorigens and carcinogens were Dr. Umberto Saffiotti, Associate Scientific Director for Carcinogenesis, Etiology Area, National Cancer Institute; Dr. Marvin Schneiderman, Associate Chief, Biometry Branch and Associated Director for Demography, National Cancer Institute; Dr. Samuel Epstein, Senior Research Associate in Pathology, Children's Cancer Research Foundation, Inc., Boston.

Group Petitioners also take refuge under a broad canopy of data—human feeding studies and epidemiological studies—and support it with the increasingly familiar argument that exposure to any substance in sufficient quantities may cause cancer.

None of the feeding studies carried out with DDT have been designed adequately to detect carcinogenicity; and given the latency period of cancer, these studies would have to be carried out for a much longer period. Statistical population samples for epidemiological studies are also virtually impossible given the latency period for cancer and the long-term exposure of the general population. Since there is no sharp distinction between population groups exposed to low doses and higher doses of DDT, adequate control groups cannot be established. The "everything is cancerous argument" falls because it ignores the fact that not all chemicals fed to animals in equally concentrated doses have produced the same tumorigenic results.

b. Environmental Effects.—The case against DDT involves more, however, than a long-range hazard to man's health. The evidence presented by the Agency's Pesticides Office and the intervenors, EDF, compellingly demonstrates the adverse impact of DDT on fish and birdlife. Several witnesses testified to first-hand observed effects of DDT on fish and birdlife, reporting lethal or subacute effects on aquatic and avian life exposed in DDT-treated areas. Laboratory evidence is also impressively abundant to show the acute and chronic effects of DDT on avian animal species and suggest that DDT impairs their reproductive capabilities.[22]

The Petitioner-registrants' assertion that there is no evidence of declining aquatic or avian populations, even if actually true, is an attempt at confession and avoidance. It does not refute the basic proposition that DDT causes damage to wildlife species. Group Petitioners' argument that DDT is only one toxic substance in a polluted environment, and thus, whatever its laboratory effects, it cannot be shown to be the causative agent of damage in nature, does not redeem DDT, but only underscores the magnitude of effort that will be necessary for cleaning up the environment. Were we forced to isolate in nature, rather than in the laboratory, the effects of various toxic substances, it would be difficult if not impossible to make a judgment as to the chronic effects of any chemical. As our DDT Statement of March, 1971, has noted: "Development of adequate testing protocols and facilities is a priority undertaking. But in the short term, extrapolation from small-scale laboratory analyses must err on the side of safety. See DDT Statement of Reasons, at 11.

Finally, I am persuaded that a preponderance of the evidence shows that DDT causes thinning of eggshells in certain bird species. The evidence presented included both laboratory data and observational data. Thus, results of feeding experiments were introduced to show that birds in the laboratory, when fed DDT, produced abnormally thin eggshells. In addition, researchers have also correlated thinning of shells by comparing the thickness of eggs found in nature with that of eggs taken from museums. The museum eggs show little thinning whereas eggs taken from the wild after DDT use had become extensive reveal reduced thickness.

Group Petitioners and USDA argue that the laboratory feeding studies, conducted with exaggerated doses of DDT and under stress conditions, provide no basis for extrapolating to nature. They suggest that the study results are contradictory and place particular emphasis on documents which were not part of the original record and the inconsistencies in Dr. Heath's testimony as brought out during cross-examination. Group Petitioners also contend that the observed phenomenon of eggshell thinning and DDT residue data are tied by a statistical thread too slender to connect the two in any meaningful way.

Viewing the evidence as a total picture, a preponderance supports the conclusion that DDT does cause eggshell thinning. Whether or not the laboratory

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[22] See the testimony of Drs. Tarzwell, Nicholson, Philip Butler, Duke, Burdick, Dimond, Risebrough, Hickey, and Cade.

While the Examiner erroneously excluded testimony as to economic losses caused by DDT's contamination of the aquatic environment—losses to commercial fishermen caused by inability to market contaminated fish—this risk is significant, even if it could not be economically quantified. Not all risks can be translated into dollars and cents, nor can all benefits be assessed in cash terms.

data above would sustain this conclusion is beside the point. For here there is laboratory data and observational data, and in addition, a scientific hypothesis, which might explain the phenomenon.[23]

B. Benefits

1. Cotton

I am convinced by the evidence that continued use of DDT is not necessary to insure an adequate supply of cotton at a reasonable cost. Only 38% of cotton-producing acreage is treated with DDT, although the approximately 10,277,258 pounds used in cotton production is a substantial volume of DDT and accounts for most of its use. The record contains testimony by witnesses called by registrants and USDA attesting to the efficacy of organophosphate chemicals as substitutes for DDT and, long-range, the viability of pest management methods, such as the diapause program. At present most areas that use DDT combine it with an organophosphate and toxaphene in a 4–2–1 mixture (4 lbs. toxaphene, 2 DDT, 1 methyl parathion). Some areas, however, according to the testimony, which normally use DDT occasionally apply concentrated methyl parathion in a 4-lb. mixture.

There is evidence that organophosphates would not raise costs to the farmer and might, indeed, be cheaper. Any suggestion that the organophosphates are not economically viable cannot be maintained in face of the undisputed evidence that cotton continues to be tenable crop in Arkansas and Texas where DDT use has declined.[24] There is also testimony in the record to the effect that methyl parathion costs less per application than the DDT-toxaphene formula. Nor are the testimony and exhibits that show cotton insects develop resistance to organophosphate chemicals to the point. The very same exhibits make clear that DDT is also subject to resistance.[25]

Group Petitioners and USDA, while not disputing the lesser persistence of organophosphates, have stressed their demonstrated acute toxicity. While they are toxic to beneficial soil insects and non-target species, particularly birds alighting on treated fields, these organophosphates break down more readily than DDT. They apparently are not transported in their toxic state to remote areas, unlike DDT which has been found far from treated areas, and consequently do not pose the same magnitude of risk to the aquasphere. Both testimony and exhibits also demonstrate that organophosphates are less acutely toxic to aquatic life, although different compounds have different toxicities. The effect of organophosphates on non-target terrestrial life can, unlike the effects of DDT, also be minimized by prudent use. Application in known nesting areas for rare or extinct birds can be avoided.

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[23] The chief witness introduced to rebut Drs. Risebrough, Hickey and Cade was a graduate student with limited training in statistical analysis. In view of the credentials of EDF's witnesses—Dr. Hickey, Professor of Wildlife Ecology at College of Agriculture, University of Wisconsin; Dr. Risebrough, Associate Ecologist, University of California at Berkeley; and Dr. Cade, Professor of Zoology at Cornell and Research Director of Cornell Ornithology Laboratory—I cannot credit this attempt at rebuttal.

The Hearing Examiner apparently resolved the conflict in the evidence by concluding that "there was no evidence that DDT was the only factor in a decline of bird populations . . ." and that no evidence "focused its direct thrust on damage to birds by the uses of DDT that are permitted under the registrations in question." Examiner's Report, 70–71. In view of DDT's persistence and mobility, evidence as to the causal effect of these uses was not required.

At argument and by motion Group Petitioners have offered additional evidence, some of which bears on the issue of eggshell thinning. I have granted that motion and considered all that data.

[24] The parties have referred neither in briefs nor argument to testimony or exhibits describing in detail the economics of cotton production or substitutes. There is general testimony that cotton producers receive a per bushel subsidy and that this subsidy is the difference between profit and break-even. It is not clear whether or not break-even includes a return to the farm owner in terms of salary or return on his investment. While some evidence suggests that organophosphates are more costly, because of higher price and the need for repeated applications in concentrated quantities, there is little to suggest that the possible increased variable cost from use of organophosphates would be a disincentive to producers. Indeed, with subsidies it is not clear what rate of return a cotton producer receives for invested capital. There was a reference made to an unidentified study showing that the cost of using substitutes would involve $15 million. This figure alone has no meaning. While later testimony suggests that elimination of DDT would increase variable costs per acre by 5 percent, this, too, is of limited significance since the record does not relate it to the support progarm and the study looked at only a limited area.

[25] I cannot accept the suggestion that we should continue to use DDT until it is good to the very last drop. Whatever the long-term efficacy of the organophosphates the fact remains that they generally work. While the fact of insect resistance is important and underscores the need for retaining a variety of chemicals or methods to manage the same pest problem, this fact does not justify an avoidable use of a harmful chemical.

2. Other Crop and Produce Uses

The testimony of record, while sparse, shows that registered alternatives, primarily organophosphates, exist for all other crop and ornamental uses of DDT, except for storage use on sweet potatoes to control weevils, on heavy corn borer infestations of green peppers, and perhaps onions.[26]

3. Noncrop Uses

In addition to the registrations for use on crops and in nurseries, several registrations for noncrop uses are also in issue. Admission 11 lists "public health pests—bats and rodents," "Agricultural, Health and Quarantine Treatments in Emergencies as Recommended by and Under Direction of State-federal Officials" and "fabric treatent" by the military.

The record is not, unfortunately, well developed as to the scope or method of application for these uses nor as to the overall volume applied for these purposes. While use for bat and mice control is characterized in Admission 11 as a "public health use," application for these purposes is not supervised by public health officials. The briefs suggest that use for control of bats and mice is a proprietary use by the military, even though a private pest control operator testified that use for bats was considered essential by private operators.[27] With respect to "Agricultural and Quarantine" uses it is difficult to determine to what extent applications are for health purposes or for nuisance prevention.

With respect to all of these uses, both for public health programs and proprietary use, alternatives do exist. The Public Health Service testified that DDT is no longer the chemical of choice for controlling disease vectors. As for mice, warfarin is used effectively, and fumigation and non-chemical means are available for use on bats. Colonel Fowler testified that the military has not used DDT in this country for two years for mothproofing purposes and stated that he was aware of alternatives.

C. Weight to Be Accorded the Examiner's Opinion

In reaching the factual conclusions set forth in the preceding sections, I have been mindful of Group Petitioners' argument, stressed in their briefs and at oral argument, that the Hearing Examiner's findings deserve particular deference in view of his opportunity to resolve contradictions in testimony based on demeanor evidence.

Nowhere does the Examiner state that his conclusions were based on credibility choices.[28] Whatever extra weight, then, that might be due findings based expressly on a credibility judgment is not appropriate in the case before me. See, *e.g.*, *NLRB v. Dinion Coil Co.*, 201 F.2d 484 (2d Cir. 1952) where the Examiner's report set forth his assessment of the witnesses' credibility.[29]

IV.

The application of the risk-benefit test to the facts of record is, by no means, simple. We have noted in our Statement of March 18, 1971, that the variables are numerous. It should also be borne in mind that the variables are not static in point of time. As build-up of a chemical occurs or is detected in the environment, risk increases. Indeed, it may be that the same tendency of a chemical to persist or build up in the food chain is present but not known about substitute chemicals. It may also be that circumspect application of a chemical in

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[26] Toxaphene and diazinon are registered for control of cutworms but it is not clear from the record as to whether or not these chemicals are registered or effective to control cutworm infestations on onions. While none of the parties have pointed to helpful evidence in connection with use for controlling cutworms on onions and weevils on stored sweet potatoes, I have taken judicial notice of the non-existence of registered alternatives.

[27] The only evidence as to the amount of DDT used for these purposes was given by Col. Fowler, who said the total used by the military for bat and mouse control is approximately 800–900 pounds.

[28] During oral argument counsel admitted that the Examiner's report did not purport to make findings based on credibility of witnesses, nor could he point to findings which might be explained in light of a credibility contest. (Transcript of Argument, pp. 96–98.) The basic questions of fact in this case, the hazard to man and the environment, were cast and resolved by the Examiner as "conclusions of law."

[29] The precedents, moreover, make clear that the Agency is free to make its own findings and that the Examiner's findings and report only comprise part of the record which a court will then evaluate. *FCC* v. *Allentown Broadcasting Corp.*, 349 U.S. 358 (1955); *Universal Camara Corp.* v. *NLRB*, 340 U.S. 474 (1951). Even where an Examiner's findings are based on credibility, the Agency may reach a contrary conclusion. See *FCC* v. *Allentown Broadcasting Corp., supra.*

limited quantities for those uses most necessary changes the benefit-risk coefficients so as to tilt the scales differently then when we weigh aggregate use for all purposes against aggregate benefits. See generally *EDF* v. *EPA* (Opinion of Judge Leventhal), *supra.*

A. Burden of Proof

The crux of a cancellation proceeding is the safety of the product when used as directed or in accordance with "commonly-recognized practice." *Stearns Phosphorus Paste Co.* v. *EPA, supra.* This, simply stated, means that this Agency has the burden of going forward to establish those risks which it believes to require cancellation.[30] In addition, an affirmative aspect of the Agency's case should be the availability of preferable substitute means of controlling the pests that are controlled by the canceled chemical where the Agency is relying on this fact to establish that risks outweigh benefits.[31] Evidence showing the availability of a registered chemical or other means of control which this Agency's Pesticides Office is prepared to recommend as a substitute at that point in time, coupled with the Agency's proof on risk, makes out an affirmative case.[32]

The burden of rebuttal then falls on registrants or users. They may either seek to negate the proof on risks either by rebutting the basic scientific data or by showing that a particular use is so limited as not to engender the risks from widespread use of the chemical. They can also seek to establish aggregate benefits. Where, as here, the existence of alternatives bears on the benefit of the chemical under review they may choose to show non-viability of alternatives, either for general substitution or in a particular geographical region.[33] They may also seek to show the non-desirability (or risks) of the alternative if they disagree with the staff judgment of this Agency.

B. Application of Risk-Benefit to Crop Uses of DDT

The Agency and EDF have established that DDT is toxic to nontarget insects and animals, persistent, mobile and transferable and that it builds up in the food chain. No label directions for use can completely prevent these hazards. In short, they have established at the very least the risk of the unknown. That risk is compounded where, as is the case with DDT, man and animals tend to accumulate and store the chemical.[34] These facts alone constitute risks that are unjustified where apparently safer alternatives exist to achieve the same benefit. Where, however, there is a demonstrated laboratory relationship between the chemical and toxic effects in man or animals, this risk is, generally speaking, rendered even more unacceptable, if alternatives exist. In the case before us the risk to human health from using DDT cannot be discounted. While these risks might be acceptable were we forced to use DDT, they are not so trivial that we can be indifferent to assuming them unnecessarily.

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[30] The legislative history of FIFRA, judicial decisions and Agency pronouncements all state that the "burden of proof" remains on the registrant to demonstrate that his product satisfies the requirements for registration under the Act. See S. Rept. No. 573 at 5 (88th Cong., 1st Sess. 1963); H. Rept. No. 1125 at 4 (88th Cong., 1st Sess. 1963); *EDF* v. *EPA, supra; EDF* v. *Ruckelshaus, supra;* Statement of Reasons, March 18, 1971. There has, unfortunately, been a great deal of misunderstanding concerning these statements. Simply stated, the burden of proof referred to by the legislative history is the burden of persuasion which requires a party to establish the existence of primary facts. It should not be confused with the burden of going forward which is generally a rule to establish the order for the presentation of evidence. The burden of going forward may, however, have substantive consequences. Where a party which has the burden of going forward fails to satisfy that burden, the facts will be decided against him, even though the other party may have been responsible for the burden of persuasion.

While in most legal proceedings the party which has the burden of going forward bears the burden of persuasion, this is not necessarily the case. On some issues, like contributory negligence in some jurisdictions, it may be that once one party has introduced evidence to put the issue in the case, the other party bears the burden of persuasion on that point. In the FIFRA cancellation hearing the proponent of cancellation bears the burden of going forward, but does not bear the burden of persuasion.

[31] While a mere showing of a high degree of risk would make out a prima facie case for cancellation, where the Agency is relying on the existence of an alternative rather than simply a showing of risk, it should, as here, present its own witnesses.

[32] This hearing was conducted under rules which have since been amended. (See 37 Fed. Reg. 9476 (May 11, 1972)). Under the Agency's former rules registrants proceeded first at the hearing. This order of presentation, which is now changed, was not prejudicial in this case. The Agency more than discharged its burden to put on a prima facie case. Registrants had an ample opportunity for rebuttal. At worst this inverted presentation unnecessarily protracted the hearing.

[33] Where there is a generally viable substitute, which will insure an adequate crop supply, the non-viability of the alternative in a particular area will bear on the advisability of a transition period. See Part IV, *infra.*

[34] In enacting the present law one of the greatest concerns expressed to Congress was the risk of the unknown. See Statement of Congressman Dingell, Hearings Before the Subcommittee on Departmental Oversight and Consumer Relations of the House Committee on Agriculture, at 39 (88th Cong., 1st Sess. 1963).

The evidence of record showing storage in man and magnification in the food chain is a warning to the prudent that man may be exposing himself to a substance that may ultimately have a serious effect on his health.

As Judge Leventhal recently pointed out, cancer is a "sensitive and fright-laden" matter and noted earlier in his opinion that carcinogenic effects are "generally cumulative and irreversible when discovered." *EDF* v. *EPA*, Slip Op. at 12 and 16. The possibility that DDT is a carcinogen is at present remote and unquantifiable; but if it is not a siren to panic, it is a semaphore which suggests that an identifiable public benefit is required to justify continued use of DDT. Where one chemical tests tumorigenic in a laboratory and one does not, and both accomplish the same task, the latter is to be preferred, absent some extenuating circumstances.

The risks to the environment from continued use of DDT are more clearly established. There is no doubt that DDT run-off can cause contamination of waters and given its propensity to volatilize and disperse during application, there is no assurance that curtailed usage on the order of 12,000,000 pounds per year will not continue to affect widespread areas beyond the location of application. The Agency staff established, as well, the existence of acceptable substitutes for all crop uses of DDT except on onions and sweet potatoes in storage and green peppers.

Registrants attempted but failed to surmount the evidence of established risks and the existence of substitutes by arguing that the build-up of DDT in the environment and its migration to remote areas has resulted from past uses and misuses. There is, however, no persuasive evidence of record to show that the aggregate volume of use of DDT for all uses in question, given the method of application, will not result in continuing dispersal and build-up in the environment and thus add to or maintain the stress on the environment resulting from past use. The Department of Agriculture has, for its part, emphasized DDT's low acute toxicity in camparison to that of alternative chemicals and thus tried to make the risk and benefit equation balance out favorably for the continued use of DDT. While the acute toxicity of methyl parathion must, in the short run, be taken into account, see *infra*, it does not justify continued use of DDT on a long-term basis. Where a chemical can be safety used if label directions are followed, a producer cannot avoid the risk of his own negligence by exposing third-parties and the environment to a long-term hazard.

Accordingly, all crop uses of DDT are hereby canceled except for application to onions for control of cutworm, weevils on stored sweet potatoes, and sweet peppers. Shipments of DDT labeled for those uses may continue on terms set forth in Part V–A. We defer to Part V–B, *infra*, consideration of the proper timing of cancellation of other uses in light of the short-run dangers of switching to the use of organophosphates without providing training.[35]

C. Application of Risk-Benefit to Non-Crop Uses.

There remains the question of the disposition on the registered health and government uses and other non-crop uses of DDT. It should be emphasized that these hearings have never involved the use of DDT by other nations in their health control programs. As we said in our DDT Statement of March, 1971, "this Agency will not presume to regulate the felt necessities of other countries. Statement, at 8. Indeed, the FIFRA does not apply to exports. Section 7, 7 U.S.C. § 135 (1972).

Given the alternatives for mothproofing and control of bats and mice—proprietary governmental uses of DDT—I am persuaded that the benefits are even more de minimis than the risks. On the other hand, public health and quarantine programs fall into a wholly separate category. See *EDF* v. *Ruckelshaus* 439 F.2d at 594; DDT Statement of Reasons at 11.

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[35] Registrants adduced considerable testimony on the effects of organophosphates on non-target species. Sevin, it appears, is highly toxic to bees and most witnesses agreed that the organophosphates were toxic to non-target animals, usually birds and insect life, present when a field is sprayed. The present evidence demonstrates, however, that these organophosphate compounds are less "persistent," and thus do not leach or erode into waters or collect in the human food chain. While it may be that in time the familiar phrase "familiarity breeds contempt" will apply, as we learn more about these compounds, they appear not to present a long-range hazard to man or aquatic areas. Where registrants have scored, is by demonstrating the acute toxicity of methyl parathion which is the primary alternative chemical for many of the crop uses in question. That fact does not, however, alter the long-term balance between the risks and benefits, in view of the non-persistence of the organophosphates.

While alternatives also exist for use in public health-quarantine programs and in most instances DDT is no longer the yeoman chemical, I believe that it would be unwise to restrict knowledgeable public officials to the choice of one or two chemicals. Like a physician, the public official must have an ample arsenal for the combat of disease and infestation.

I cannot, however, be indifferent to the fact that the record suggests that "health and quarantine" uses have, in the past, apparently included proprietary uses by government. Nor can I be complacent about non-supervised use for these purposes by private citizens. I am, accordingly, requiring a label which will restrain indiscriminate use of DDT for a wide variety of purposes under the rubric of official use. That label language is set forth in the order accompanying this opinion, and is designed to restrict shipment of DDT only to U.S. Government officials and State Health Departments who will be knowledgeable as to the most effective means for control and mindful of the risks of using DDT. Thus, on an application-by-application basis for necessary health and quarantine purposes, the benefits will be maximized and outweigh the risks.[36] Cf. 42 U.S.C. § 4332 (1971) which requires an environmental impact statement on ongoing official programs.

* * * profitably produced. The Agency staff has conceded in its April 15 brief in support of proposed findings, conclusions and order that this use of DDT "comes closest—of all the uses in issue—to being necessary in the sense that no real alternative insect control method exists under certain conditions." (Brief, at 93.)

The evidence concerning use of DDT to control cutworms is less clear-cut. Apparently cutworm infestations in the northwest are sporadic and localized. While it would appear that other chemicals could be used to control cutworm infestations on onions as with peanuts, none are apparently registered. No party has cited evidence of record showing what percent of the onion-producing acreage would be affected by a cancellation of DDT.

The evidence with respect to use of DDT as a "dip" to protect stored sweet potatoes against weevil infestation is even spottier Neither counsel for the parties nor our research has pointed us to evidence of record showing the precise volume of DDT use for this purpose, its likely effect on the environment, or the degree of loss that might be sustained by producers.

While it would be far easier simply to cancel or not cancel the registrations for these uses, I believe that environmental problems should be parsed with a scalpel, not a hacksaw. While EDF and my own staff urge cancellation, on the ground that producers can easily shift to producing different crops, there is no evidence as to how long such transition might require. Moreover, it may be that continued use of a limited volume of DDT in these few areas, taken in conjunction with aggregate volume of use for other purposes, like health, present no risk to the environment. Obviously much of the stress on the "global" environment is reduced by curtailing overall volume of usage and we must then estimate the impact of use, both on the environment as a whole, and the local surroundings. Lastly, it may well be relevant to examine the impact on overall supply of a commodity. Even though peppers, onions and sweet potatoes may not be food "staples," it may be that the other acreage is not suited for producing these crops. In that event, it will be necessary to determine whether or not supplies will satisfy demand, and whether or not a transition period should be fixed to permit a market adjustment.[37]

It follows that additional evidence is required to determine the answers to these questions. In the interim the cancellation orders will remain in effect, subject to registrants or users petitioning to present additional evidence. In that event, a stay order will issue pending the determination on remand. If these users or registrants can demonstrate that a produce shortage will result and their particular use of DDT, taken with other uses, does not create undue stress on the general or local environment, particularly the aquasphere, cancellation

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[36] The use of DDT in Topocide, a prescription drug, is regulated by both the Food and Drug Administration and this Agency. The alternative, Kwell, is a lindane product. I am however, taking judicial notice of the fact that lindane registrations are presently under review by this Agency's Pesticides Office and several uses of lindane have, in the past, been the subject of cancellation proceedings. *See In Re Hari Kari Lindane, supra.* I am not prepared to judge on this record whether or not the risk to the environment and the public at large from DDT shampoo is greater than from lindane shampoo. As for the direct effects on the user of the drug, this matter is for FDA and the prescribing physician.

[37] It is a recognized policy of common law nuisance and also of Federal environmental legislation to afford affected producers a transitional period for implementing new requirements.

should be lifted. If no produce shortage will result because other acreage is suitable for these crops, it shall still be open to demonstrate that a transitional period is required for switching to new crops. If the interim use of DDT does not constitute an environmental risk, final orders of cancellation for these uses will be deferred until the transition can be accomplished, provided assurances are received at the hearing that formulators and users will not permit bootlegging.

B. The Switch to Methyl Parathion

The need for a transition period arises also in connection with those uses that are being canceled based on the existence of methyl parathion.

The record before me leaves no doubt that the chief substitute for most uses of DDT, methyl parathion, is a highly toxic chemical and, if misused, is dangerous to applicators.[38] This was the virtually unanimous opinion of all the witnesses. The introduction into use of organophosphates has, in the past, caused deaths among users who are untrained in their application and the testimony and exhibits of record point to the unhappy experience of several years ago where four deaths occurred at the time ethyl parathion began to be used on tobacco crops. Other testimony noted the increase in nonfatal accidents and attributed almost one-half reported pesticide poisonings to the organophosphate group. A survey conducted after the organophosphates began to replace chlorinated hydrocarbons in Texas suggests a significantly increased incidence of poisonings.

That the skilled and trained user may apply organophosphates with complete safety is of comfort only if there is an orderly transition from DDT to methyl parathion so as to train workers now untutored in the ways of proper use.

I am accordingly making this order effective as of December 31, 1972, insofar as the cancellations of any particular use is predicated on the availability of methyl parathion as a substitute. In the months that follow the Department of Agriculture and state extension services and representatives of EPA will have time to begin educating those workers who will have to use methyl parathion in future growing seasons. Such a program can also introduce farmers to the less acutely toxic organophosphates, like carbaryl, which may be satisfactory for many uses.

VI.

Far from being inconsistent with the general congressional mandate of FIFRA, a period of adjustment to train users of methyl parathion or permit a needed transition where no substitutes exist is a logical outgrowth of a sensible application of risk-benefit analysis. While the legislative history does not address the specific problem before me—the timing of cancellation orders—the hearings that preceded the enactment of FIFRA indicate that congressional concern for safety of the farmer-user of pesticides was no less than Congress' solicitude for the environment. While Congress ultimately struck a balance that generally places the risk of negligence on the applicator, see Stearns v. EPA, supra, it did so in light of assurances that farmers are for their own safety as well as that of the environment being trained in proper methods of application. See Hearings before the Subcommittee on Departmental Oversight and Consumer Relations of the House Committee on Agriculture, *supra*, at 54, 68.[39]

The risk-benefit equation is a dynamic one. Timing is a variable in that equation. What may, in the long run, be necessary to protect the environment could be a short-term threat to human health. This is exactly the case before me now.

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[38] Not all of the possible substitutes for DDT are equally potent. For example, trichlorofon, monocrotophos, malathion and carbaryl, among others, are available to control many cotton pests; carbaryl is an all-purpose chemical for most cotton pests. It is, however, abundantly clear that methyl parathion will be widely used.

[39] At least two courts have given express recognition to the similarity between the regulatory schemes in FIFRA and the Food, Drug, and Cosmetic Act. See *Welford* v. *Ruckelshaus*, 439 F.2d 598 (D.C. Cir. 1971); *Nor-Am* v. *Hardin*, 435 F.2d 1133 (7th Cir. 1970) (en banc). I believe that the trail Congress intended me to follow is marked by its directive in Section 348 of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 348(f)(3) (1971), which permits the Secretary to set an effective date for his orders. While similar language has not been expressly included in FIFRA, its omission can hardly be considered advertent in view of the legislative history. *See* S. Rept. No. 573 (88th Cong., 1st Sess. 1963); H. Rept. No. 1125 (88th Cong., 2d Sess. 1964). The purpose of the 1964 amendments was to eliminate registration under protest.

The benefits of using organophosphates are a long-range benefit and the risks of DDT result from continued long-term use. In the very short run, however, the equation balances out very differently.[40] Likewise, the prospect of dislocation which might ensue were the use of DDT immediately halted where no alternatives exist is a factor we must reckon with. The major environmental regulatory statutes, enacted and pending, provide "lead time" for an adjustment to new requirements.[41]

While impatience is understandable in view of the past history of delay, we must not be lulled into the belief that long-standing problems can be corrected by overnight solutions. Today's decision provides a definitive answer to the status of DDT registrations and all concerned: to this Agency, farmers, manufacturers, the Department of Agriculture, and extension services; all must proceed with alacrity toward the implementation of this order.

Factual Findings

I. Scope of Case

A. PR Notices 71–1, 71–3, 71–5 canceled all registered uses of DDT and TDE.

B. Appeals have been received by 31 formulators who held registrations for formulating DDT or TDE. These formulators appeared at this proceeding by a single counsel.

C. Wyco, Inc. and The Wallerstein Co. and Stark Bros' Nurseries have also appeared by separate counsel.

D. The Plant Regulation Division of the Department of Agriculture was a party to this hearing as a registrant and the Department was an intervenor as to all uses.

E. Eli Lilly & Co. and H. P. Cannon & Sons were parties to this hearing.

F. National Agricultural Chemicals Association; Environmental Defense Fund; The Sierra Club; West Michigan Environmental Action Council; and National Audubon Society are intervenor parties

G. The following canceled uses were appealed and at issue in this hearing:

Crop Uses

1. Cotton.
2. Beans (dry, lima, snap).
3. Sweet potatoes.
4. Peanuts.
5. Cabbage, cauliflower and brussel sprouts.
6. Tomatoes.
7. Fresh market corn.
8. Sweet peppers and pimentoes.
9. Onions.
10. Garlic.
11. Commercial greenhouses.

Noncrop Uses

1. Control of house mice and bats (military only).
2. Fabric treatment (military only).
3. Disease vectors.
4. Quarantine.
5. Control of body lice in prescription drugs.

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[40] I do not believe that the Seventh Circuit's decision in *Stearns Phosphorous Paste Co.* v. *EPA, supra,* precludes me from taking into account the short-term dangers that could result from increased use of methyl parathion by untrained users. *Stearns* holds that a product is not "misbranded" simply because it can be highly dangerous if the user is careless. This reasoning does not, however, compel me to ignore the tendency of human beings to be negligent where we are dealing with the implementation of an order that will increase use of a highly dangerous substance. Even negligence can be minimized by training.

[41] While the Examiner excluded from evidence a study of the DDT problem for this Agency undertaken by a Committee of the National Academy of Sciences, it is appropriate to note that Committee recommended a phase-out period for the same reasons outlined in this opinion. While I reach my conclusions without relying on that report's factual findings and recommendations, and base them on the record as compiled below, I believe the report was erroneously excluded from the record, particularly in view of the offer by counsel for the Agency to produce a committee member for cross-examination.

II. CHEMICAL PROPERTIES OF DDT

A. Basic Findings

1. DDT can persist in soils for years and even decades.
2. DDT can persist in aquatic ecosystems.
3. Because of persistence, DDT is subject to transport from sites of application.
   (*a*) DDT can be transported by drift during aerial application.
   (*b*) DDT can vaporize from crops and soils.
   (*c*) DDT can be attached to eroding soil particles.
4. DDT is a contaminant of freshwaters, estuaries and the open ocean, and it is difficult or impossible to prevent DDT from reaching aquatic areas and topography non-adjacent and remote from the site of application.

B. Ultimate Finding

The above factors constitute a risk to the environment.

III. ACTIVITY IN FOOD CHAIN AND IMPACT ON ORGANISMS

A. Basic Findings

1. DDT is concentrated in organisms and transferred through food webs.
   (*a*) DDT can be concentrated in and transferred through terrestrial invertebrates, mammals, amphibians, reptiles and birds.
   (*b*) DDT can be concentrated and transferred in freshwater and marine plankton, insects, molluscs, other invertebrates and fish.
2. The accumulation in the food chain and crop residues results in human exposure.
3. Human beings store DDT.

B. Ultimate Finding

The above factors constitute an unknown, unquantifiable risk to man and lower organisms.

IV. TOXICOLOGICAL EFFECTS

A. Basic Findings

1. DDT affects phytoplankton species' composition and the natural balance in aquatic ecosystems.
2. DDT is lethal to many beneficial agricultural insects.
3. DDT can have lethal and sublethal effects on useful aquatic freshwater invertebrates, including arthopods and molluscs.
4. DDT is toxic to fish.
5. DDT can affect the reproductive success of fish.
6. DDT can have a variety of sublethal physiological and behavioral effects on fish.
7. Birds can mobilize lethal amounts of DDT residues.
8. DDT can cause thinning of bird eggshells and thus impair reproductive success.
9. DDT is a potential human carcinogen.
   (*a*) Experiments demonstrate that DDT causes tumors in laboratory animals.
   (*b*) There is some indication of metastasis of tumors attributed to exposure of animals to DDT in the laboratory.
   (*c*) Responsible scientists believe tumor induction in mice is a valid warning of possible carcinogenic properties.
   (*d*) There are no adequate negative experimental studies in other mammalian species.
   (*e*) There is no adequate human epidemiological data on the carcinogenicity of DDT, nor is it likely that it can be obtained.
   (*f*) Not all chemicals show the same tumorigenic properties in laboratory tests on animals.

B. Ultimate Finding

DDT present a carcinogenic risk.

V. BENEFITS

A. Basic Findings

1. DDT is useful for the control of certain cotton insect pests.
2. Cotton pests are becoming resistant to DDT.
3. Methyl parathion and other organophosphate chemicals are effective for the control of cotton pests.
   (*a*) Methyl parathion and organophosphates are less toxic to aquatic life than DDT.
   (*b*) Methyl parathion and organophosphates appear to be less "persistent" and do not build up in the food chain.
   (*c*) Methyl parathion is acutely toxic by dermal, respiratory exposure and oral ingestion.
4. By using methyl parathion or other means of pest control cotton producers can generally produce satisfactory yields at acceptable cost.
5. DDT is considered useful to have in reserve for public health purposes in disease vector control.
6. DDT is considered useful as a mothproofing agent.
   (*a*) DDT is not presently used by the military for treatment of fabric.
   (*b*) Alternatives exist.
7. DDT is useful for public quarantine programs.
8. Quarantine programs are administered by public officials and are a non-proprietary use of DDT.
   (*a*) This is of little use in controlling the overall gypsy moth problem.
9. DDT is useful for controlling certain insects that attack the crops listed in finding number (I)G.
10. Adequate substitute chemicals, namely, methyl parathion and other organophosphates—for the most part—exist for controlling the diseases that attack the crops listed in finding number (I)G except:
   (*a*) sweet potatoes
   (*b*) heavy infestations of corn borer attacking sweet peppers grown on the Del Marva Penninsula
   (*c*) onions attacked by cutworms
11. DDT is effective for controlling body lice
   (*a*) Kwell, a Lindane product, is a substitute.
   (*b*) Lindane registrations are being reviewed.
12. DDT is used for exterminating bats and mice by the military.
   (*a*) Fumigation and non-chemical methods can guard against bat infestation.
   (*b*) Warfarin is effective for exterminating house mice.

B. Ultimate Findings

1. The use of DDT is not necessary for the production of crops listed in finding (I) 7 except that it may be necessary to produce those crops listed in Finding V 10(a), (b) and (c).
2. Non-crop uses of DDT for mothproofing and to control bats and mice are proprietary uses for which DDT is not necessary.

VI. MATTERS RELATING TO METHYL PARATHION

A. Basic Findings

1. Many poisonings have been attributed to the use of methyl parathion.
2. Untrained users of methyl parathion are frequently not sufficiently careful in its use despite label directions.
3. Methyl parathion can be used safely.
4. Training programs are useful in averting the negligent use of methyl parathion.
5. Methyl parathion is a substitute for most crop uses of DDT.

B. Ultimate Findings

1. Methyl parathion is dangerous to users and presents a risk to them.
2. An opportunity to train users will minimize the risks and keep down the number of accidents.

VII. GENERAL FINDINGS

A. No directions for use of DDT, even if followed, can over the long-run completely eliminate DDT's injury to man or other vertebrate animals.

B. No warning or caution for use of DDT, even if followed, can over the long-run prevent injury to living man and other vertebrate animals and useful invertebrate animals.

C. The present total volume of use of DDT in this country for all purposes is an unacceptable risk to man and his environment.

D. The use of DDT in controlled situations in limited amounts may present less risk than usage in greater amounts, but still contaminates the environment.

E. The public health program and quarantine uses of DDT by officials, when deemed necessary, can be judged on an application-by-application basis by professionals.

F. A particular official use, in an isolated instance, may be important.

CONCLUSIONS OF LAW

1. DDT formulations when labeled with directions for use in the production of those crops named in finding (I) G and for use on bats, mice and fabric are "misbranded," within the meaning of Sections 2(z)(2)(c), (d) and (e) of FIFRA, 7 U.S.C. § 135.

2. DDT when labeled with directions "for use by and distribution to only U.S. Public Health Service officials or for distribution by or on approval by the U.S. Public Health Service to other health service officials for control of vector diseases, for use by and distribution to the Public Health Service, USDA, and military for quarantine use; for use in prescription drugs to be dispensed only on authorization by a certified medical doctor" along with the caution printed in bold type "use for any purpose not specified or not in accordance with directions and use by unauthorized persons is disapproved by the Federal Government: this substance is harmful to the environment," is not "misbranded."

BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

STEVENS INDUSTRIES, INC., *et al.* (*Consolidated DDT Hearings*)

I.F. & R. Docket Nos. 63, et al.)

ORDER

In accordance with the foregoing opinion, findings and conclusions of law, use of DDT on cotton, beans (snap, lima, and dry), peanuts, cabbage, cauliflower, brussels sprouts, tomatoes, fresh market corn, garlic, pimentoes, in commercial greenhouses, for mothproofing and control of bats and rodents are hereby canceled as of December 31, 1972.

Use of DDT for control of weevils on stored sweet potatoes, green peppers in the Del Marva Peninsula and cutworms on onions are canceled unless within 30 days users or registrants move to supplement the record in accordance with Part V of my opinion of today. In such event the order shall be stayed, pending the completion of the record, on terms and conditions set by the Hearing Examiner, provided that this stay may be dissolved if interested users or registrants do not present the required evidence in an expeditious fashion. At the conclusion of such proceedings, the issue of cancellation shall be resolved in accordance with my opinion today.

Cancellation for uses of DDT by public health officials in disease control programs and by USDA and the military for health quarantine and use in prescription drugs is lifted.

In order to implement this decision no DDT shall be shipped in interstate commerce or within the District of Columbia or any American territory after December 31, 1972, unless its label bears in a prominent fashion in bold type and capital letters, in a manner satisfactory to the Pesticides Regulation Division, the following language:

"(1) For use by and distribution to only U.S. Public Health Service officials or for distribution by or on approval by the U.S. Public Health Service to other health service officials for control of vector diseases; (2) For use by and distribution to the USDA or military for health quarantine use; (3) For use in the formulation for prescription drugs for controlling body lice; (4) Or in drug; for use in controlling body lice—to be dispensed only by physicians.

"Use by or distribution to unauthorized users or use for a purpose not specified hereon or not in accordance with directions is disapproved by the Federal Government: This substance is harmful to the environment."

The Pesticides Regulation Division may require such other language as it considers appropriate.

This label may be adjusted to reflect the terms and conditions for shipment for use on green peppers in Del Marva, cutworms on onions, and weevils on stored sweet potatoes if a stay is in effect.

WILLIAM D. RUCKELSHAUS.

Dated: June 2, 1972.

BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

SHELL CHEMICAL CO., ET AL.

(ALDRIN-DIELDRIN REGISTRATIONS)

(I.F. & R. Nos. 145, etc.)

DETERMINATION AND ORDER

This proceeding, which arises under Section 4.c of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 135b(c)), involves a challenge by eighty-four registrants to a notice cancelling the registrations of all pesticides containing aldrin and dieldrin. Pursuant to a request by the registrants under the governing statute the matter has been referred to a scientific advisory committee, which has furnished me its report. For the reasons that follow, I have determined, based on that report and all other data before me, to affirm the cancellation of all registered label uses of aldrin-dieldrin except those involving (1) the dipping of roots or tops of non-food plants; (2) subsurface ground insertions for termite control; (3) mothproofing by those manufacturing processes which utilize the pesticide in a closed system.

I. Background

Aldrin-dieldrin, a chlorinated hydrocarbon, is a broad spectrum insecticide that is one of the most widely used domestic chemical insecticides. Figures for 1970 show that approximately 11 million pounds of aldrin were used that year and 7 million pounds of dieldrin. Since after application aldrin readily converts to dieldrin, the ultimate concern is with the environmental and toxicological effects of dieldrin.

The chief virtues of aldrin-dieldrin are its persistence and toxicity to a wide range of insect pests. By far the major agricultural use of aldrin-dieldrin is soil application to control soil insects. Corn crops, in particular, are subject to damage from soil insects. Other uses include application to turf; home pest control; dipping of plant roots; treatment of foundations for termite control; seed treatments; and mothproofing of fabric. Method of application for different uses varies greatly. Thus, some uses involve ground-injection; some involve dipping of seeds; others involve aerial spraying; and there may be different methods of application for the same use.

On January 7, 1971, the United States Court of Appeals for the District of Columbia Circuit held, in a case involving the registrations of products containing DDT, that the FIFRA requires the Government "to issue notices [of cancellation] and thereby initiate the administrative process whenever there is a substaintial question about the safety of a registered pesticide." *Environmental Defense Fund* v. *Ruckelshaus*, 439 F.2d 584, 594.

After reviewing all the information on aldrin and dieldrin available to the Agency, I concluded on March 18, 1971, that the impact of aldrin and dieldrin on the environment raised a substantial question as to the safety of all registered products containing those chemicals. Accordingly, I determined to com-

mence the administrative process by cancelling all remaining registrations of products containing aldrin or dieldrin.[1] At the same time, I determined, based on the evidence then available, that the continued use of aldrin or dieldrin products did not create "an imminent hazard to the public" which would necessitate immediate suspension of the registration. I stressed at that time that the Agency would be prepared to re-evaluate the question of suspension at any later stage in the administrative proceedings (March 18 Statement, p. 12).

My March 18, 1971, decision on aldrin-dieldrin was assaulted from two directions. Specifically, 84 registrants invoked their statutory right to take administrative appeals from my cancellation order, while the Environmental Defense Fund challenged in Court the refusal to order immediate suspension of registrations pending the completion of the cancellation process.[2]

The 84 registrants took administrative appeals by filing petitions for referral of the matter to a scientific advisory committee.[3] The first such petition was filed on April 5, 1971. The Advisory Committee was appointed on November 11, 1971, and received the relevant data, and its charge, on November 29, 1971.

The charge directed the Committee to determine and weigh the nature and magnitude of the foreseeable hazards associated with their continued use. More specifically, the Committee was charged to consider and evaluate all relevant scientific evidence and, based thereon, express its opinion and recommendations concerning the scientific issues involved. With respect to the hazards associated with the several uses of aldrin and dieldrin, the Committee was to evaluate *inter alia*, the nature, scope, and possibility of occurrence of any (1) direct hazard to the user and to the general public; (2) hazards to vegetation; (3) hazard to non-target vertebrate and invertebrate animals; and (4) hazard to the environment generally. On the other hand, it was to evaluate the benefits of aldrin and dieldrin by reporting on, *inter alia*, (1) the nature and extent of the problem posed by the various insects which aldrin and dieldrin products are used to control; (2) the benefits expected to be achieved by the use of control measures which utilize aldrin and dieldrin, measured against the damage which will occur if no control is undertaken; and (3) the availability and effectiveness of, and the hazards connected with, alternative control measures.

The Committee submitted its report on March 28, 1972, having been given, as authorized by statute, a 60-day extension beyond the original due date of January 28, 1972. Under the law, I am required within 90 days of my receipt of the report to "make [a] determination and issue an order, with findings of fact, with respect to registration . . ." 7 U.S.C. 135b(c).

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[1] Under the FIFRA, a registrant who does invoke an administrative appeal from a "cancellation" order may continue to distribute his product in interstate commerce during the pendency of the appeal process. In contrast, a "suspension" order, which may be issued when "necessary to prevent an imminent hazard to the public" is effective immediately and precludes product distribution pending the outcome of further administrative proceedings. On March 6, 1970, the Department of Agriculture's Pesticides Regulation Division issued a notice of cancellation of registrations for all products containing aldrin or dieldrin intended for use in aquatic environments, marshes, wetlands and adjacent areas, including treatments for control of mosquito larvae, filter fly, larvae in sewage systems and tabanid larvae in outdoor areas. This action was taken primarily in response to the 1969 recommendation of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health (Mrak Commission) that uses of persistent pesticides, including aldrin and dieldrin, be eliminated except where essential to the preservation of human health and welfare. No administrative appeals were taken from those cancellations, and they took effect and became final 30 days later.

Thereafter, on May 22, 1970, the Department of Agriculture published a notice in the Federal Register affording interested persons an opportunity to submit views and comments on the importance of aldrin-dieldrin in pest control. A special review group was established within the Department to evaluate the substantial number of replies which were received. That review group's final report was forwarded to this Agency—which had by that time succeeded to the Department of Agriculture's regulatory function under the FIFRA—in January 1971.

[2] The Environmental Defense Fund suit in the court of appeals to challenge my refusal to suspend registrations was decided May 5, 1972. Environmental Defense Fund v. EPA, F.2d (C.A.D.C.—No. 71–1365). While the Court upheld certain factual conclusions I had relied upon as supported by respectable scientific authority (slip opinion, p. 16), the court determined that the policies and standards that had been applied to reaching the determination not to suspend registrations required further explanation (slip opinion, pp. 17–18, 19–20, 21–22). The matter has been remanded for consideration of its opinion in light of the advisory committee report (slip opinion, p. 24), and the standards of suspension articulated by the court. (Slip. Op. 18–19, 20–22.) After the issuance of this order, I shall review the matter of suspension. As noted by the Advisory Committee, the compilation of scientific data on aldrin-dieldrin is not complete. When I receive further information, I shall be able to make a determination based on the pertinent evidence. (See Part V of this Order.)

[3] The FIFRA reserves to registrants the right to request a public hearing if they are dissatisfied by the action I take after I receive the advisory committee report. Registrants may, at their option, bypass the committee and ask directly for a public hearing. One registrant did this. That request for a public hearing has been held in abeyance pending the completion of the advisory committee proceedings requested by the other registrants.

II. Applicable Law

The FIFRA, as interpreted by the courts, requires this Agency to initiate administratice review proceedings whenever a substantial question of safety arises in connection with particular use or directions for use. *EDF* v. *Ruckelshaus, supra.* Having commenced the statutory review process, this Agency then reconsiders the nature of any questions of safety in light of a scientific advisory group's assessment or risks (assuming registrants have sought review). It may be that upon review of the literature and after hearing testimony the Committee will find that the "substantial question of safety" initially triggering cancellation does not in fact exist. Where, however, the Committee's findings bear out the Agency's original scientific judgments, the Agency must then determine if the benefits of use outweigh the risks. As we stated in our final opinion and order in *In Re Stevens*, I.F. & R. 63 (June 14, 1972), a prima facie case for cancellation is made when substantial risks to man or the likelihood of harm to non-target aquatic or terrestrial species are established. This prima facie case can be rebutted by a showing of benefits that would justify a prudent man in taking such risks.

Evidence of benefits may be submitted both to the Advisory Committee and also to the Agency, which must review the Scientific Advisory Committee's report and such "other evidence" as is submitted. If the record contains sufficient data of a reliable nature to permit this Agency to conclude that the benefits outweigh the risks, cancellation will be lifted. Where, as here, little data is available, or the data is so contradictory as to require further scrutiny through the more formal record compiled after a hearing, the cancellation must be affirmed since no evidence of record exists to overcome the established risks.

Thus, in viewing the Committee's findings I must look to see if the risks which caused the Agency to cancel do, in fact, exist, and if these risks are real, evidence of record exists to show benefits which overcome them.

Here, I do not find the clear and strong data as to benefits. Consequently, I am continuing the cancellation of all uses except those three listed on page one which pose *de minimis* risks. Thereby, the procedure for full study and presentation of evidence by both proponents of cancellation and registrants will be initiated.

III. Discussion of Evidence

At the time I initially instituted these proceedings my primary concern was the general long-range persistence and mobility of aldrin-dieldrin in the environment, its tendency to concentrate in the food chain due to its storage in fatty tissues, and its acute toxicity to aquatic life. Of particular concern were laboratory tests showing that aldrin-dieldrin might be a low-level carcinogen. There was also evidence to indicate that aldrin-dieldrin may also have other sublethal chronic effects not apparent immediately following direct contact with the chemical.[4]

After reviewing the discussion of the Advisory Committee, I am persuaded that cancellations for most uses must be affirmed. The Committee's review of the literature led it to the same factual determinations that originally caused me to cancel.

Aldrin and dieldrin are both chlorinated hydrocarbons, which are in the same family of chemical pesticides as DDT. They possess characteristics similar to those of DDT (*i.e.*, persistence, mobility, solubility in lipids, and bioconcentration with resulting toxicological effects) which make them serious potential and actual threats to a wide variety of living organisms, both aquatic and terrestrial with which they come in contact.

It has been demonstrated both experimentally and from past use that very low levels of exposure to aldrin-dieldrin can have serious toxocological effects on various species of fish and birds. The persistence of these two pesticides allows them through the processes of erosion and runoff from soil application, drift from spraying and dusting application techniques, and volatilization, to find their way into rivers, lakes and other habitats for wildlife. One instance in which 1 lb/acre of dieldrin was applied to a salt marsh for sandfly control produced a fish kill of drastic proportions (20–30 tons of fish). While direct application of aldrin-dieldrin to aquatic habitats has previously been canceled, there still remains a serious threat of indirect contamination of waterways through many of the remaining uses.

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[4] The possibility that aldrin-dieldrin may lead to long-term chronic ailments has caused this Agency's Pesticide Tolerance Division to refuse to set a tolerance for aldrin-dieldrin residues in milk and meat. Additionally petitions for revocation of tolerances on other crops are now pending.

One study, for example, has shown that significant amounts of dieldrin residues are still finding their way, through runoff and erosion, into key river systems annually even where soil applications—which offer a greater possibility of control than aerial spraying—are primarily utilized. Moreover, the Committee found that three percent of aldrin-dieldrin applied directly to soil will volatilize and thus contaminate the environment. When aerial or other methods of spraying or dusting are employed, the chances of aldrin-dieldrin affecting non-target organisms are even greater. In either instance it presently appears that no label language is capable of protecting non-target organisms, including man, from actual and potential injury. On the other hand, the Committee found that certain methods of application, dipping or soil injection introduced *de minimis* quantities of aldrin-dieldrin into the environment.

The Advisory Committee reached no definitive conclusion on the carcinogenicity of dieldrin. It stated that "if there is a carcinogenic action in dieldrin, it likely is a weak one at a level much like DDT." (Report, p. 45). In the recently concluded DDT proceeding, I found, based on all the evidence introduced at a full public hearing, that DDT is a potential human carcinogen. Appraisal of the similar laboratory evidence concerning dieldrin leads me to make the same finding here.

This finding, and the possibility of chronic effects or acute effects from chronic exposure, point up the need for caution with respect to any use of aldrin and dieldrin which can be expected to result in residues in food.[5]

On the question of benefits the Committee found the evidence before it too inadequate to make any findings. The Committee found that the need for aldrin-dieldrin, in many instances, is by no means clear. Some farmers use it even though it may be ineffective or unnecessary. There is some suggestion that the persistence of soil residues makes annual application unnecessary. One economic study is cited in the Committee report for its "rough estimates" that the unavailability of aldrin-dieldrin would lead to crop losses of 14 million dollars and 34 million dollars increased cost to replace it with alternative chemicals. That report itself takes note of the disagreement among entomologists as to the efficacy of the substitutes for aldrin-dieldrin. It is not clear what per cent increase in variable cost this 34 million dollars represents. Nor is it precisely clear whether or not the acreage most dependent on aldrin-dieldrin could shift to different crops. *Compare In Re Stevens, supra.*

IV. Weighing of Risks and Benefits

Against the information just discussed, I must hold that, with the exception of the three uses set out on page 1, the evidence thus far available does not justify retention of the uses of aldrin-dieldrin.

The vast bulk of the use of aldrin and dieldrin involves direct application to soils. While these methods of application are environmentally safer than aerial and other methods of spraying and dusting, the evidence before me indicates that widespread ground application results in large amounts of the chemicals escaping from the point of application and threatening harm to the aquasphere and wildlife. Uses for protection of food or feed crops pose additional hazards from residues in food. This same residue hazard attends the dipping of roots or tops of food plants. Against these risks, there is, as the Committee found, almost a complete lack of reliable scientific data indicating with precision the degree of need for and effectiveness of aldrin-dieldrin. For example, the data before me demonstrate not only that some farmers are unaware of the economic threshold involved in aldrin-dieldrin use on their crops, but that in some instances their use of these pesticides is entirely unnecessary to achieve control of certain insect pests. In this regard some farmers claim that they do not use, nor do they need, aldrin-dieldrin to grow corn successfully in the midwest.

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[5] While the Committee found that there is no evidence of human injury from present or past use of aldrin or dieldrin, it neither discussed nor referenced in its bibliography the report by Dr. Wayland J. Hayes, Jr. *Clinical Handbook on Economic Poisons—Emergency Information for Treating Poisonings* (U.S.P.H.S. 1963) which noted that "in different countries 2% to 40% of men applying 0.5% to 2.5% suspensions or emulsions of [aldrin-dieldrin] at the rate of about 1 gram per square meter developed poisoning within two weeks to 24 months after first exposure." This evidence suggests possible chronic toxicity, a danger which could be due to the persistence of aldrin-dieldrin in the body. On the other hand, it may be these applicators did not observe the proper cautions and directions on the label. *Cf. In Re Stevens, supra.*

The dieldrin registrations for use as a seed protectant present two principal risks. First, while the residues may be quite small, use on seeds of food crops may leave potentially hazardous residues. Second, several documented incidents of bird poisonings illustrate the risk that birds and other wildlife will ingest the seeds after planting.

An additional danger arises when treated seed is packaged in bulk (as opposed to small packs suitable for home gardening). There is always the possibility that such seed may later be diverted or otherwise ingested by animals. While the precise extent to which this occurs is not clear, I am not prepared to find, in the light of evidence that treated corn grain, for example, is used as a feed supplement for cattle, swine and chickens, that this risk can be disregarded.

Environmental hazards also surround surface application to turf, both on grazing and non-grazing areas. An attempt to control such use by requiring the supervision of trained professionals, as recommended by the Advisory Committee, would contribute little to the alleviation of the substantial question of environmental safety that is involved, particularly by use in grazing areas. While it may be that more specific label directions could minimize the risks and maximize benefits, by restricting use to certain areas or recommending application on a cyclical basis, this has not yet been established. *Cf. In Re Stevens, supra.*

I must also cancel use of dieldrin in the home or in other structures occupied by humans or livestock. Aldrin has never been registered for use in homes or in agricultural premises.

Dieldrin, however, is marketed for use in households for insect (*e.g.*, roach) control, even though insect tolerance has rendered it relatively ineffective. In some cases it is painted on floorboards and woodwork and thus presents the possibility of direct exposure to children and pets. There are recorded incidents of dieldrin poisonings attributed to accidental ingestion of products used in the home. There are much less toxic insecticides which can and are presently being used effectively. All inside use of dieldrin must be cancelled.[6]

On the other hand, certain uses present at most a negligible hazard although they result in introduction of aldrin-dieldrin into the soil. Sub-surface ground insertions for termite control achieves needed and extremely valuable protection for wooden structures and poses no demonstrable hazard.[7] The dipping of non-food plants achieves the desired control of insects with the least possible contamination of surrounding soil and does not raise the problem of possible hazard from food residues. Consequently, those uses can be permitted.

I am also permitting retention of use for mothproofing in manufacturing processes where the chemicals are not discharged into aquatic systems. All uses involving direct application to water have previously been finally cancelled; the same reasoning which required those cancellations requires cancellation of any mothproofing uses which result in discharge of the chemicals into aquatic systems.

V. Deferral of Determination on Suspension

There remains the question of whether any of the uses for which I have maintained cancellation in effect should also be suspended. At this time, I have not reached a determination on that question. I am, however, particularly concerned over the lack of evidence currently before me on the degree of need for and benefits to be achieved from those of the cancelled uses which apparently involve the gratest hazard, *i.e.*, for those uses involving aerial and ground methods of spraying and dusting, and those involving use in and around the home and other buildings, and uses for fire ant control.

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[6] This Agency on one previous occasion cancelled an insecticide paint used in the home which contained 9.75 percent dieldrin in its solution. *In re King Paint & Supply Company*, I.F. & R. Docket No. 46, Order of the Judicial Officer, 2 ERC 1819, July 27, 1971.

[7] I should add that, while I am withdrawing the cancellation of one type of termite control use, there has been no showing that other types of termite control use, which are also of considerable apparent benefit, are without substantial risk of environmental injury. Some uses for termite control do not involve burying the aldrin-dieldrin several feet below the soil close to the foundations of the dwelling. Rather, surface or near surface application appears prevalent, although the precise extent to which this method is used does not appear in the data before me. However, when aldrin-dieldrin are used on or near the surface, the same problems of runoff or accidental poisoning involved with other uses are present. In fact, one such application for termite control resulted in a substantial fish kill when the pesticides ran off the land and into a nearby body of water. Until these safety questions have been clarified and answered, I see no reason at this time to retain additional uses.

In view of the absence of any existing formal mechanism for a hearing prior to suspension or for rapid administrative or judicial review of decisions to suspend registrations,[8] I am hereby inviting the informal submission of additional information bearing on the benefits and hazards of the uses just listed. I will announce a decision on the question of the suspension of these and other uses within the next several weeks.

VI. Further Appeals from this Decision

Section 4.c. of the FIFRA (7 USC 135b(c)) provides that administrative appeals from my decision today to maintain cancellations in effect may be taken "within sixty days from the date" of this order, *e.g.*, by August 25, 1972.[9] Appeals are taken by filing objections to this order and requesting a public hearing.

The regulations governing the filing of such appeals are contained in 40 CFR (1972 ed.) Part 164.[10] Subparts A and B of the regulations appearing in the 1972 CFR are presently in effect (see particularly 40 CFR 164.4(d)); Subpart C was recently amended and appears at 37 Fed. Reg. 9478 (May 11, 1972).

The governing statute and regulations provide expressly for administrative appeals only by registrants or applicants. The Agency has determined, however, that other interested persons (*e.g.*, pesticides users) who have standing to seek judicial review of final agency orders under 7 USC 135b(d), also should be accorded the right to take administrative appeals. See *EDF* v. *Ruckelshaus*, *supra*, 439 F.2d 584 (C.A. D.C. 1972); *In re Stevens Industries*, I.F. & R. No. 63 (June 14, 1972), Fn. 8. Notification to such persons of the entry of this decision will be made by publication in the Federal Register; appeals by such persons must be filed within the time allotted to registrants.[11]

Administrative appeals complying with the applicable regulations should be submitted to the Agency's Hearing Clerk at the following address: Mrs. Betty J. Billings, Hearing Clerk, Environmental Protection Agency, Room 3125, South Agriculture Building, 14th & Independence Avenue, S.W., Washington, D.C. 20250.

Particular attention is directed to the requirement that the document filed contain *inter alia*, the registration number of the pesticides which are the subject of the appeal. 40 CFR 164.21(a) (37 Fed. Reg. 9478).

In the absence of administrative appeals, the cancellation of registrations announced in this order will take effect on August 25, 1972. However, subject to any action which I may take in announcing my decision on the question of suspension, finally canceled registrations will be deemed to continue in effect after that date for the limited purpose of further distribution and use of products which have by that time left the possession and control of the registrants.

VII. Order

For the foregoing reasons, the cancellation of the registrations of all products containing aldrin or dieldrin is affirmed, except that the cancellation is lifted with respect to those registered uses involving (1) the dipping of roots or tops of non-food plants; (2) sub-surface ground insertions for termite control; and (3) moth-proofing by manufacturing processes which utilize the pesticide in a closed system.

WILLIAM D. RUCKELSHAUS,
Administrator.

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[8] Such mechanisms may soon be created. Cf. the regulation proposed at 37 Fed. Reg. 5707 with Section 6(c) of H.R. 10729 as recently reported by the Senate Committee on Agriculture and Forestry.

[9] In contrast, the 30-day time period for appeals from initial notices of cancellation runs from the date of *service* of the notice. 7 USC 135b(c).

[10] Those regulations formerly appeared at 7 CFR (1971 ed.), Part 2764.

[11] Interested persons may seek to participate by other methods in appeals taken by registrants. See 40 CFR 164.25 (37 Fed. Reg. 9479).

HARI-KARI LINDANE PELLETS U.S.D.A. REG. NO. 4770–8, NEODANE COMPANY, INC., PETITIONER,

(I.F. & R. Docket No. 6)

BUGMASTER CRYSTALS MODEL "G" U.S.D.A. REG. NO. 4782–1, BUGMASTER CRYSTALS MODEL "H" U.S.D.A. REG. NO. 4782–2, BUGMASTER REFILL FOR ALADEN'S MAGIC LAMP, MODEL "O" U.S.D.A. REG. NO. 4782–3, SOUTHERN NATIONAL MANUFACTURING COMPANY, INC., PETITIONER

(I.F. & R. Docket No. 11)

OPINION OF THE JUDICIAL OFFICER

This case involves notices of cancellation issued to the Neodane Company and the Southern National Manufacturing Company (Southern) concerning certain registrations required by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 135–135K (1968). The registrations in issue are Neodane's lindane pellets, Reg. No. 4770–8, and Southern's registration for lindane pellets, Nos. 4782–1, 4782–2, 4782–3.

I

A. FIFRA requires that all "economic poisons" be registered with the Federal Government and bear an appropriate "label". Respondents' registrations are for the chemical substance, lindane, the gamma isomer of hexachlorobenzene, which is used in vaporizing devices. Southern makes three devices, Models O, G, and H "Bugmasters". The latter two, differing in size, and Neodane's Hari Kari product release vapors at a continuous rate and are authorized only for commercial use. Bugmaster O is a fumigating device designed for "one-shot" use, and is authorized for home application. These devices are used to control roaches and also flying insects.[1]

On April 24, 1969, the Pesticide Regulation Division, at that time a constituent bureau of the Department of Agriculture, sent out notices of cancellation citing questions of safety in connection with lindane use.[2] The notices cited excessive residues of lindane on food as a by-product of lindane vaporization, and referred also to the association of blood disorders with chronic lindane exposure. Other charges in the notice included the inadequacy of the label for preventing home use.[3]

Neodane exercised its rights under the Federal Insecticide, Fungicide, and Rodenticide Act to call for a scientific advisory committee to review the scientific properties of lindane, thus deferring final cancellation. The Scientific Advisory Committee issued its report on July 2, 1970, recommending that the cancellation of lindane products be continued. While the Committee found that lindane "is not strongly cumulative in animals or man," it concluded that the crystals released vapors at acutely toxic levels.

Based on data involving animal experiments, the Committee extrapolated an oral LD_{50} (a dose that is lethal to 50% of an exposed group) of 5 mg. of lindane per kg. of body weight, and an inhalation LD_{50} of 0.5 mg/kg. The Committee concluded that "in the matter of inhalation, it makes little difference whether the chemical is continuously vaporized or applied as a one-shot fumigation (repeated no sooner than two weeks) because in either case the concentration of lindane vapor maintained will be on the order of 0.2 micrograms/liter of air." Advisory Committee Report at 7. Based on an estimate of the daily human intake of air, the Committee reasoned that an average individual might inhale 4 mg/kg/day or $\frac{1}{9}$ of the LD_{50} computed for a 70 kilogram man based on a specific LD_{50} of 0.5 mg/kg. The acute oral toxicity and the hazard of inhalation led the Committee to recommend cancellation of the lindane products.

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[1] These devices do not work, contrary to what one might assume, by choking insects by their fumes. Rather, crystals settle out of the vapors, and persist on surfaces. Insects are apparently killed by contact. See testimony of Dr. Zavon (TR. 140–141).

[2] Under FIFRA, the Administrator may cancel a registration for a product any time it appears that the terms of the Act are not satisfied. Section 4(c), 7 U.S.C. § 135b. A key requirement is that a product not be "misbranded," which, in turn, is basically defined as bearing a label adequate to protect the public when used as directed. Section 2z(2), 7 U.S.C. § 135(z)(2).

[3] The Neodane notice reads in part: "Although the continuous type of vaporizers were acceptable for use only in industrial and commercial premises, experience has showed that they have been, and are continuing to be, used in the home. The caution statement on the label against use of the vaporizers in the home has not been effective in preventing home use and is not a safeguard to public protection."

By an order issued October 5, 1970, the Secretary of Agriculture reaffirmed the notice of cancellation. The order generally accepted the findings of the Advisory Committee and concluded that the products were "misbranded" within the meaning of sections 2(z)(2)(c), 2(z)(2)(d) and 2(z)(2)(g) of the FIFRA.

Neodane pursued its statutory rights by requesting a public hearing under section 4(c), and Southern, whose request for a hearing had been deferred pending the referral to the Advisory Committee, joined in the trial.

B. The crux of the controversy in this case, as regards "persistence," is what level of exposure results from the vaporization of lindane and what effects this exposure has on human health. Other matters of controversy at the hearing were the implications of lindane's ability to penetrate most matter including most food coverings. The Agency contends that this property renders lindane compounds inappropriate for use in homes or food handling establishments since section 406 or 409 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346, 348) prohibits unregulated use of poisons and additives on food for human consumption.[4]

There is no serious dispute between the parties relating to the oral toxicity of lindane, although there is disagreement as to the precise dosage that is harmful;[5] nor is there any rest dispute as to the fact that continuous vaporizers, notwithstanding the label restricting their use to commercial establishments, are used in the home, have been promoted for home use, and are accessible to consumers. The record shows that these products can be found in drugstores, supermarkets, and hardware stores.

On September 14, 1971, Hearing Examiner submitted Findings and Conclusions recommending that cancellation be dropped. The Examiner concluded that lindane, as vaporized by registrants' continuous and one-shot products at the prescribed rate, does not constitute a "serious hazard" to health. The contention that registrants' continuous products were "misbranded" by virtue of their use in the home was rejected.

No specific finding, however, was made as to the safety of either one-shot or continuous devices for home use. The opinion does not differentiate between the possible hazard from continuous vaporization in the home and in a commercial establishment.[6]

Counsel for the Pesticides Offices filed timely exceptions challenging certain findings, and urged acceptance of other findings, favorable to the Agency.[7] Oral argument was held on October 18, 1971.

A. Continuous Vaporizers

I. Counsel's basic exception is to the Examiner's failure to find that lindane vapors pose a health hazard and that these products are, when used as directed, "injurious to man," and, consequently, "misbranded". The factual argument evolves as a syllogism that rests on four pillars: a lethal dose by way of inhalation is 0.5 mg/kg or 35 kg for an average man; when used as directed these lindane products emit vapors in concentration of 0.2 micrograms/liter of air; an average 70 kilogram individual will inhale 4 milligrams per day; 4 milligrams

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[4] The Agency points out that while tolerances for residues of lindane on raw agricultural products have been set, there are no such tolerances or exemptions for lindane established pursuant to section 406 (21 U.S.C. 346) and 409 (21 U.S.C. 348) for the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a) concerning poisonous ingredients in food for human consumption. Section 406 reads: "Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe." The section further provides that residues of such poison, where required or unavoidable, shall be within tolerance limits established by regulation. Section 409 reads that "A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe," unless its use conforms to the terms of an exemption or its use is prescribed by regulation. The Agency argues that since sections 406 and 409 "affect food that might be found in a home or restaurant" (Respondent's Exceptions to Examiner's Opinion at 4), contamination of food by lindane results in violation of the Act, since no tolerances exist.

[5] The Advisory Committee, as noted, concluded that 5 mg/kg was a lethal dose. Dr. Zavon testified that .125 mg/kg was a "daily acceptable intake." While he testified that by some standards a chemical with a .125 ADI would not be toxic, he admitted that lindane, in his opinion, was toxic.

[6] It is not clear whether or not this failure to make a more specific finding is the result of the Examiner's ruling that section 2(z)(2)(d), requiring a caution statement which is necessary to protect the public, was beyond the scope of the case. Counsel's argument that all lindane products posed a threat of accidental ingestion by children was apparently dismissed on the ground that the Act requires only a label that will be a caution to the hypothetical "prudent man".

[7] Insofar as this opinion or the attached findings does not discuss a particular exception, it shall be deemed overruled.

per day is one-ninth of a lethal dose; relying on the finding of the Scientific Advisory Committee, association of lindane exposure with blood dyscrasias (blood abnormalities) suggests that this one-ninth figure could be injurious to health.

The pillars of this syllogism are not grounded in a firm evidentiary foundation of record. The 0.2 microgram/liter concentration ratio is not based on any experimental data as to concentration in a 15,000 cubic foot room vaporized with one gram per day. The daily inhalation computation of the Committee is questionable and makes blanket assumptions that do not account for variables, such as degree of activity, the likelihood of certain activities in commercial establishments, and daily duration of exposure.[8] Lastly, there is no proof submitted by the Agency to show that one-ninth of the supposed lethal dose has any sublethal effects that are injurious to health.[9]

The Pesticides Office in oral argument and in its brief retreats to Rule 364.28 of the Rules of Practice which places the burden of proof in cancellation proceedings on the registrant to demonstrate that its product satisfies the criteria of the Act, and that registrants have not shown that their product is safe.

The Agency's position with regard to the burden of proof is buttressed by ample authority. See *EDF* v. *Ruckelshaus*, 439 F.2d at 599; *In re Stearns*, I. F. & R. Docket No. 13, Jan. 4, 1971.[10] The burden of proof is identical in cancellation or initial registration: the registrant must demonstrate that his product satisfies FIFRA requirements.[11]

That registrant bears a burden does not rescue the Agency's case in the proceeding. While registrants have not made an airtight case for the safety of their product, I am convinced that these continuous vaporizers pose no threat to human health when used in a commercial establishment that does not serve, handle, or process food. Registrants have introduced into the record a study showing that examination of seventy-nine workers exposed, from several weeks to several years, to lindane in two factories engaged in lindane processing revealed, in the judgment of the researchers, no significant results. Based on an exposure to a lindane concentration that ranged generally, depending on location in the factory, from 6 to 93 parts per billion (or 11 to 1,770 micrograms per cubic meter), no physiological changes occurred in the workers that could be correlated with health disorders. While the increased presence of lindane in the blood and increased monocyte count and uric acid levels were noted in the subjects, only the increased level of lindane in blood was clearly related to exposure; the latter two factors were not proved to be casually related to lindane nor were any conclusions drawn to suggest any of these changes might constitute a health hazard. In calling for additional study, Dr. Milby's report did not register any alarm as to a health hazard.

Counsel for the Agency urges that this study be discounted in view of the limited statistical sample. No evidence appears as to what kind of sampling would be significant. The negative results of the study are, moreover, rendered more impressive by the fact that the level of exposure, which ranged from 11 to

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[8] There was a great deal of discussion at the hearing as to patterns of human inhalation (Tr. 104, 161, 218–221, 243).

[9] Registrants' argument is focused by an analogy: that eighteen sleeping pills are apt to produce death does not mean that two pills, one-ninth of a lethal dose, will produce any harmful effects.

[10] See remarks of Congresswoman Sullivan, 110 Cong. Rec. 2948–49, and the statements in Committee Hearings, Hearing before a Subcommittee of the Senate Committee on Agriculture and Forestry, 88th Congress, 1st Sess. (Sept. 10, 1963), at 27. Rule 364.28 is entitled to the deference that courts accord the regulations of an agency charged with the administration of statute. See *Zuber* v. *Allen*, 396 U.S. 168, 192 (1969); *Udall* v. *Talman*, 380 U.S. 1, 16 (1965).

[11] The burden of proof under FIFRA is not the typical "preponderance of the evidence" test we associate with a civil trial. Where the health or safety of the public is at stake, more is required than simply a finding that it is "more probable than not" that a product is safe. To the extent that words can convey a flavor for a standard, it is my view that "clear and convincing evidence" is what Congress intended. Compare the requirements for registration of drugs, 21 C.F.R. § 130, *et seq.* (1971). This standard must, of course, be viewed in the context of the kind of evidence that is available in the absence of actual experience. This can be a particular problem where humans will be directly exposed to a poison. In such circumstances the evidence required is the best available laboratory data. Thereafter, controlled usage and reporting should be required to provide more reliable data. Compare the specificity of the FDA regulations, *supra*. It should also be remembered that FIFRA does not require the manufacturer to establish absolute safety if there is some compelling contervailing benefit that outweight a possible threat to the environment. Of course, here, too, the burden is on the registrant to demonstrate these benefits. *EDF* v. *Ruckelshaus, supra*.

1,170 micrograms per cubic meter, was significantly higher than the 0.2 microgram/liter concentration which the Advisory Committee took as the basis for its conclusions.[12] When it is remembered that the intensity and duration of exposure in an average commercial establishment using registrants' vaporizer would be less than that in the Milby Study, I am bound to conclude that registrants have discharged their burden, particularly in the absence of any rebuttal testimony discussing the Milby Study, and any particular mention of it by the Advisory Committee.[13]

My conclusion as to the safety for eight hour exposure is reinforced by Dr. Zavon's testimony that the yield of registrants' products, when used as directed, is less than the 0.05 mg/cubic meter safety level established by the Threshold Limits Committee of the American Conference of Governmental Hygienists. (Tr. 188–189.)[14]

2. That lindane is not a hazard in commercial establishments does not, however, settle the fate of commercial vaporizers. Counsel for the Agency stresses the fact that lindane vaporizers registered for commercial use are also used in the home. This practice has been encouraged by advertising and is facilitated by the fact that the products are marketed through independent agents engaged in mailorder business. These devices are also widely available since they can be bought in commercial establishments, such as drugstores, hardware stores, and supermarkets, which engage in resale to home consumers.

There can be no doubt that these products have been promoted for home use and are so used. The Agency has introduced evidence to this effect, and registrants do not dispute it.[15] The fact that it has been determined in the registration process than these products are unsuited for home use is sufficent to require adjustment of the label to achieve that and, if it be concluded that the products are "misbranded".[16]

Counsel for registrants disputes the Agency's contention that, in view of the hazard and the fact that home use is prevalent, registrants' continuous products are "misbranded" within the meaning of sections 2(z)(2)(c), 2(z)(2)(d), and

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[12] A microgram is one-millionth of a gram. One thousand, one hundred and seventy micrograms are equivalent to 1.17 milligrams. One liter is equivalent to a cubic decimeter. One thousand cubic decimeters are equivalent to a meter; therefore, there are one thousand (1,000) liters per cubic meter. One thousand, one hundred and seventy micrograms per cubic meter equals 1.17 micrograms per liter.

[13] It would, of course, be open to the Agency to require by regulation further data as a condition of registering any product on the ground that available evidence increases with experience, and data that satisfies the burden of proof at initial registration will not suffice as experience develops. It would also be open to the Agency to promulgate a regulation requiring any physiological changes (such as increased lindane in the blood) associated with a product be explained before reregistration. I am not, however, willing to make this a basis for cancellation without some evidence that rebuts the conclusions of Drs. Zavon and Milby that this is not a disorder or threat to health.

[14] Dr. Zavon testified as follows: "Based on all the data I've seen, that [0.5 mg./cubic meter] would be somewhat higher than the level we achieve when you dispense one gram in 15,000 cubic feet." (Tr. 189.)

[15] The Agency's offer into evidence of advertisements promoting continuous vaporizers for home use was not accepted by the Examiner. This was error. To the extent his determination was bound up with his ruling that compliance with section 2(z)(2)(d) was outside the scope of the hearing, that was incorrect. The notice of cancellation, while not citing 2(z)(2)(d), focused at length on the fact that these products are distributed to consumers and used in the home. The Order of the Secretary, moreover, specifically cited 2(z)(2)(d). This proof was, in any event, pertinent to a case of misbranding under section 2(z)(2)(g), *see infra*.

[16] More, however, is involved than mere reliance on the limited registration. The hazard from home use is very real. There are six known deaths from lindane ingestion. Evidence in the record, including testimony by registrants' witness, Dr. Zavon, shows that instances of this type are underreported. It is likely that lindane has been the cause of more household mishaps. As for the effect of lindane vapors in the home, registrants' proof does not convince me that no threat exists to health. Unlike a commercial establishment, very young children and sick people are apt to be in the home for an unusually extended period of time. Misuse in the home is also more likely than in a commercial establishment where responsibility for operations is apt to be in the hands of an employee who has a regular assignment of attending the machine. Dr. Zavon's testimony, to the effect that repeated instances of ill effects from lindane are quite possibly the result of abuse, coupled with the fact that most cited instances of toxification attributed to lindane occurred in the home, supports this conclusion. Registrants have not, moreover, established that the yield of their continuous products is within an established level of safety. Dr. Zavon's testimony indicates that the safe background level for lindane for a 24 hour day is 0.1 mg/cubic meter, based on the Threshold Limits Committee's tolerances. While the Hearing Examiner ruled out of order Dr. Zavon's opinion that the Committee's 0.5 tolerance for an eight hour day was equivalent to a 0.1 tolerance for a 24-hour day, the witness was qualified to give his view of what would be a safe background for a 24-hour exposure, even if it was not a figure endorsed by the Committee. Dr. Zavon volunteered that the yield of the 1 gram/15,000 cu. ft. product is "somewhat" less than the 0.5 tolerance for an 8-hour day. On the basis of this answer it is fair to assume that the yield of these products would be higher than 0.1. (Tr. 189–190.)

2(z)(2)(g) of FIFRA, and registration should be cancelled, Counsel in the Agency places particular emphasis on the language of section 2(z)(2)(g) which provides that a product is "misbranded," if "in the case of an insecticide, . . . when used as directed or in accordance with commonly recognized practice it shall be injurious to living man . . ." (emphasis added).[17]

At oral argument counsel for registrants contended that the "commonly recognized practice" language means in the case of a continuous vaporizer, the prescribed use, dispersed at 1 gram/15,000 cu. ft/24 hour period, and does not refer to abuses of the product. A reading of the *In re Stearns* reading of 2(z)(2)(g) would, according to registrants' counsel, create large responsibility for industry.

The Judicial Officer in *In re Stearns* ruled that the language of 2(z)(2)(g) was meant to cover the situation of a warning which practical experience demonstrates to be the kind of caution that is ignored. I agree. It is part of human nature to be careless and defiant, and experience teaches us that certain directions are apt to be ignored. In requiring a product to be safe when used "in accordance with commonly recognized practice," Congress was anticipating that certain products would be used other than in accordance with their label.

The language of 2(z)(2)(g) and the legislative history make it unmistakably clear that Congress intended just the opposite of what counsel for registrants urges. The "or commonly recognized practice" language was added to FIFRA in 1947. It appeared in the first print of the bill, H.R. 4851, 79th Cong., 1st Sess. (1945), that later was enacted, 61 Stat. 163. At hearings before the House Agriculture Committee, the representative of the Agricultural Insecticide and Fungicide Association objected strenuously to this new language pointing out that custom "might or might not represent the proper use of the materials" and that it was unfair to make industry "responsible for anything except [its own] . . . claims. . . ." Hearings Before The Committee on Agriculture of the House of Representatives on A Bill To Regulate the Marketing of Economic Poisons and Devices, and For Other Purposes, 79th Cong., 2d Sess., at 32 (1945).[18] The 2(z)(2)(g) language was retained in the final legislation notwithstanding the protest of industry. The language of the section and the signposts in the legislative history point down a path that leads to a common sense result. It taxes credulity to attribute to Congress an intent to permit distribution of any product, no matter how dangerous, simply because a warning, that no one follows, appears on the label.[19]

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[17] Counsel for the Agency urges also that the circumstances of this case fall under the rubric of a label which "does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man . . ." (section 2(z)(2)(d), and also that of a labeling "accompanying [an economic poison] which does not contain directions for use which are necessary and if complied with adequate for the protection of the public" (section 2(z)(2)(c)).

[18] See, generally, Hearings 31–38, Hitchner's protest as to the breadth of the "commonly recognized practice" language and the burden is placed on industry * * *, at this late date, registrants' strained interpretation of this language. Hitchner testified as follows:

"We are making a chemical product. We are responsible for the formulation and directions for use, and we sell a chemical product. That we must recognize, and we must assume that responsibility. But for us to assume the responsibility of an indefinite requirement in accordance with commonly recognized practices which nobody can determine, which will vary all over the country, is going way beyond any necessary requirement under the Act." [Hearings at 33.]

[19] The Judicial Officer in *In re Stearns* relied not only on 2(z)(2)(g) for his conclusion that a warning was inadequate if unlikely to be observed, but also on sections 2(z)(2)(c) and (d). While at first blush sections 2(z)(2) (d) and (g) appear almost identical, there are differences. Directions for use involve the method and place of proper application; a caution involves ancillary matters, such as the storage of a poison, or a caveat as to skin contact, etc.; and commonly recognized practice means the manner and place in which the user is apt to apply the product. Further, subsections (c) and (d) simply require that the label bear the warning; subsection (g) defines the product as misbranded if the product is not safe under the prescribed circumstances.

3. The record in this case shows that it is a "commonly recognized practice" to use continuous vaporizers in the home, notwithstanding directions to the contrary,[20] and affords ample justification for cancelling them under 2(z)(2)(g). This is, however, a harsh result. The situation would be quite different if registrants had not discharged their burden of proof as regards the safety of these products in commercial establishments; having done so, it would require a fairly compelling demonstration that alternatives exist in order to cancel all uses of these vaporizers simply to prevent their use in the home.[21] I do not have before me an extensive discussion of the alternatives for pest control in commercial establishments, although the record is not entirely barren on this subject.[22] Thus, rather than cancel all uses of continuous vaporizers, I have attempted to devise a label that will effectively deter and prevent their use in the home.[23] This label will be required on all lindane packages or refill packages for use in Hari Kari, Bugmaster Model G, and Bugmaster Model H vaporizers, as well as on the boxes containing the vaporizers.[24]

The warning "NOT FOR HOME USE" should appear on all advertising surfaces, i.e., on any side of a vaporizer box or lindane package that bears any printed matter. The "Not for Home Use" warning shall be the most prominent print on the surface. Second, the packaging for both vaporizer and pellets shall prominently bear a warning as follows: "Not for Use or Sale to Drugstores, Supermarkets, or Hardware Stores or Other Establishments That Sell Insecticides to Consumers. Not for Sale to or Use in Food Handling, Processing or Serving Establishments.[25]

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[20] While the package containing lindane pellets for Bugmasters Model G and H bears a caution against home use, no such warning appears on the container in which the actual Bugmaster devices are sold. (The Hari Kari vaporizer does bear a caution against home use.) The provisions of section 2(z)(2) do not apply to "devices". The Act, however, provides that a "device" is "misbranded" if its "labeling bears any statement, design, or graphic representation relative thereto . . . which is false or misleading in any particular." See section 2(z)(1). Where a device is designed to dispense a particular chemical in a specified fashion and the label on the packaging of that device refers to the particular chemical, the label on that packaging, in order not to be false and misleading, should refer to the cautions and restrictions that are required to appear on the label for the poison. The public, otherwise, will be tempted to buy the dispenser under a false impression as to where, and how and when it can be used. See n. 24, *infra*.

[21] The result might well be different if Dr. Zavon's testimony with respect to alternative control measures were weighed with different variables in the cancellation equation. See Part B 2, *infra*.

[22] Unlike *In re Stearns*, *supra*, there is only bare mention of alternative methods of control in the record. Registrants' own witness acknowledged the existence of alternatives, although he thought that none of them were available for use in vaporizers except for pyrethrins. He also testified that continuous vaporizers have the advantage over other types of applicators in that the vaporizer controls the rate of chemical release. Tr. 184–85.

[23] Section 4(c) specifically provides that the Administrator may require "modifications of the claims or the labeling" as an alternative to cancellation.

[24] Section 2(b) sets forth a definition for "device": ". . . any instrument or contrivance intended for . . . destroying . . . insects . . . but not including equipment used for the application of economic poisons when sold separately therefrom."

Registrants' vaporizers fall within the scope of section 2(b); the exception for equipment used for the application of economic poisons separately sold applies to generic equipment like spray guns that are applicators for numerous different products, each of which would be dispensed in a different fashion and under different directions. Here the vaporizers are tied to the use of a specific poison. Registrants' products all refer to their lindane pellets, in the case of Southern's Models G and H, to Bugmaster crystals. In addition the packages containing the lindane pellets refer, in turn to the vaporizers. The labels on the vaporizer box and the actual lindane crystals are so cross-referenced and intertwined that the label on the vaporizer box is as much controlled by section 2(z)(2)(g) as is the labeling on the package containing the poison. *See* n. 20, *supra*, noting that it would be "false and misleading" if the label on the vaporizer did not conform to the required label on the lindane; *see, also,* sections 2(x) (2) and (3), pointing out that labeling is any matter accompanying a device or poison, or to which reference is made on the label or literature accompanying the economic poison or device. *See, generally,* Hearings Before a Subcommittee of the Committee on Agriculture House of Representatives on A Bill to Regulate the Marketing of Economic Poisons, 80th Cong., 1st Sess. (1947).

[25] In view of lindane's ability to penetrate most coverings except sealed containers, I believe that there is no way to insure against contamination of food by lindane, short of cancelling these products for use in establishments where food is kept. It is too much to expect a restaurant, or establishment where food is regularly kept, to keep food properly covered at all times that a continuous vaporizer might be in use.

Whether or not the failure of the FDA to set a tolerance for lindane on food for human consumption is intentional or a result of oversight, the presence of lindane residues appears to be unlawful. The label for lindane products must, at the very least, insure their use in accordance with the present state of the law and federal regulations. *See* n. 4, *supra*.

The foregoing label would permit these products to be used in factories, laundries, retail department stores, and other commercial establishments that may require constant insect control. At the same time, it offers some prospect of limiting the availability of this product to consumers.[26] While individuals may typically disregard a label, professional merchandisers are less apt to do so if a warning is directed specifically at them.

As already indicated, I feel constrained not to cancel this product in view of the fact that registrants, on the one hand, have submitted proof that it causes no harm to normal, healthy individuals exposed for an eight hour day, and, because, on the other hand, it may have significant uses for commercial pest control. It should, however, be noted that the penalty provisions of the Act create a Hobson's choice. Under the Act there is no penalty for selling, as such, not in accordance with the requirements of a label; penalties attach for distributing an improperly labeled product or one that is not registered.[27]

It is particularly unfortunate that registrants can with impunity disregard the terms of a label. As registrants' own witness, Dr. Zavon, remarked, labels protect distributors, not the public, at least under the FIFRA scheme. While the Pesticides Regulation Division has disclaimed jurisdiction over advertising of economic poisons, it is hoped that the partnership with the Federal Trade Commission established by the Division's interpretation 9 can be a fruitful collaboration for protecting the public.[28]

B. "One-Shot" Vaporizers

1. I turn next to Southern's Model O Bugmaster, a "one-shot" device registered for home use. The box containing the Model O suggests 1 gram/1,000 cubic feet of room with instructions to "use proportionately more or less as space dictates." The package suggests that no more than 2 grams be used per unit and recommends additional units for space larger than 1,500 feet. The label instructs the user to vacate the room and allow two hours before returning. It is recommended that fumigation not occur more frequently than once every two weeks.

Counsel for the Agency has emphasized the higher degree of possible danger incidental to home use of lindane, and contends that there is no adequate safety margin. Again, he stresses persistence and the possibility of exposure to lingering fumes, contamination of food, and possibility of accidental ingestion.

In footnote 16, I pointed out some of the unknowns with regard to home use of lindane that are less troublesome in connection with commercial use of lindane. There is no study showing the effect of 24-hour exposure, certainly a possibility in the home. The Milby Report suggests only that frequent exposure to lindane, with intermittent respites, will not produce ill health effects. There is, moreover, no evidence in the record establishing the concentration of lindane released by the one-shot device. If it be assumed, as the Advisory Committee did, that the yield of a "one-shot" device is identical to that of a vaporizer, then it is possible that its by-product exceeds the 0.1 mg./cubic meter tolerance which Dr. Zavon thought would be acceptable for 24-hour exposure based on extrapolation from the Threshold Limits Committee's eight hour figure. Dr. Zavon, moreover, remarked as to the high degree of danger associated with one-shot fumigation devices: "One-shot fumigation devices . . . constitutes too great a hazard . . . for the householder or the lay person to apply" (Tr. 186).

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[26] The warning "NOT FOR HOME USE" may well be sufficient on products sold in bulk or a form so as not to be susceptible of resale to consumers. This is not true of the products involved in this case, as demonstrated by the record. Attention should be given to the possibility of devising by way of regulation a warning that might be sufficient to prevent home use of restricted products that are packaged in such a way as to make them attractive and convenient for resale to consumers.

[27] The success of keeping lindane out of the home, because the Agency has no enforcement authority under the FIFRA over distribution, will depend essentially on the voluntary compliance of the manufacturer and the distributor in order to accomplish the stated objective. Should the proposed label not prevent the home use of lindane vaporizer products registered only for use in commercial establishments, the Agency would be justified in again cancelling or suspending.

[28] Labeling, as noted at n. 20, *supra,* includes only "graphic matter" (1) "upon the economic poison . . ." (2) "accompanying the economic poison or device *at any time*" (emphasis added). The Pesticides Regulation Division in an interpretation rendered in 1965 has taken the view that advertising such as "counter displays, window displays, or handouts distributed with the product" falls within 2x(2), but that radio and newspaper advertising does not fall within its jurisdiction. 7 C.F.R. 362.107. See 1941 Hearings, u. 24, *supra.*

2. Given registrants' failures to demonstrate the safety of the "one-shot" device, it would require a compelling demonstration of benefits to justify noncancellation. To the extent that this record touches the question of alternatives to lindane, the evidence, in this content, weighs against the registrant. As noted earlier, Dr. Zavon testified as to the existence of alternatives.[29] This testimony looms larger against the inconclusive proof regarding safety around the home than it did when it was viewed in the positive light of the Milby Report. The determination to cancel is taken in view of the greater unknowns surrounding home use and the apparent availability of alternatives. *EDF* v. *Ruckelshaus, supra.* Southern's registration No. 4782–3 is hereby cancelled.

CHARLES L. FABRIKANT,
Judicial Officer.

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 164]

RULES GOVERNING ADVISORY COMMITTEES AND RULES OF PRACTICE GOVERNING HEARINGS UNDER FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

NOTICE OF PROPOSED RULEMAKING

Notice is hereby given that Part 164 of Chapter I of Title 40 of the Code of Federal Regulations, issued pursuant to sections 4 and 6 of the Federal Insecticide Fungicide, and Rodenticide Act, as amended (7 U.S.C. 135b, 153d), is proposed to be revised to read as set forth below. Any person may file comments on this proposal within 30 days from the date of publication of this notice in the Federal Register. Such comments should be filed in duplicate and addressed to the Hearing Clerk, Environmental Protection Agency, Room 3125, South Agriculture Building, 14th and Independence Avenue SW., Washington, D.C. All written submissions filed pursuant to this notice will be available for public inspection.

It is proposed that these rules when adopted in final form, will govern all future cancellation and suspension proceedings under this part and shall apply to any proceeding now underway insofar as it is practicable and will not be prejudicial to any party. In developing these rules this Agency has taken into account prior experience under this part and also recent judicial pronouncements.

Dated: January 19, 1972.

DAVID D. DOMINICK,
Assistant Administrator for Categorical Programs.

Explanatory statement. This explanatory statement should assist interested persons in the preparation of comments on one aspect of the proposed rules, viz, the sections dealing with the relationship between the Agency's decisions whether to issue or continue in effect notices of cancellation and the right of persons adversely affected by such decisions to take administrative appeals (§§ 164.4(b) and 164.12(j)).

Recent judicial decisions have underscored the importance of bringing "the public into the decision-making process, and creat[ing] a record that facilitates judicial review" of decisions concerning the registration and cancellation of pesticides. Environmental Defense Fund v. Ruckelshaus, 439 F. 2d 594 (C.A.D.C., 1971); Wellford v. Ruckelshaus, 439 F. 2d 598 (C.A.D.C., 1971). Of particular concern to the courts was the absence of any procedure whereby administrative appeals could be taken from the Agency's refusal to issue notices of cancellation.

These rules represent an attempt by the Agency to be responsive to those decisions and to insure that the public voice is heard in the decision-making process. The rules provide that, in considering whether to issue notices of cancellation initially or continue them in effect after review by an advisory committee, the Agency staff will weigh benefits against risks and make a determination on the

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[29] Dr. Zavon noted the general availability of registered substitutes for lindane. He noted that the alternative chemicals for use in vaporizers was limited; this would presumably be true of fumigating devices as well. The range of alternatives is not, however, vaporizing products or "one-shot" fumigators; it is, rather, any alternative mode of household pest control. See *In re King Poison Co.*, I.F. & R. Docket No. 46, 2, LRC 1819, 1823 n. 16 (1971).

merits of the registration. If that determination is for cancellation, administrative review will proceed as it has previously. If, on the other hand, the determination is for continued registration, the Agency will at the same time state whether that registration presented at least a substantial question of safety. If it did, persons who oppose that determination will be able to demand the issuance, or continuation in effect, of the notices of cancellation as a means of triggering further administrative review. Adoption of this procedure now, to govern the Agency's broad review of registrations, will result in a more reasonable approach to cancellation decisions. That approach should be satisfactory, on the one hand, to registrants and users of pesticides, for they will not be faced with cancellation decisions which have the support of neither the Agency nor other interested persons. On the other hand, it will afford to persons who oppose registration a mechanism, not previously available, for insuring that a full public hearing is held when necessary. In addition, this approach will assist the office of the General Counsel in taking a position at the administrative hearings consistent with the Agency's policy determinations, for it is difficult to make the initial decision to cancel in vacuum that ignores overriding benefits which this Agency's staff would, itself, wish to emphasize at a public hearing.

Subpart A—General

Subpart B—Rules Governing the Advisory Committees

Subpart C—Rules of Practice Governing Hearings

Subpart A—General

§ 164.1 Meaning of words.

As used in this part, words in the singular form shall be deemed to import the plural, and vice-versa, as the case may require.

§ 164.2 Definitions.

For the purposes of this part, the following terms shall be construed, respectively, to mean:

(a) The term "Act" means the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163, et seq. as amended, 7 U.S.C. 135–135k).

(b) The term "Administrator" means the Administrator, Environmental Protection Agency, or any officer or employee of the Agency to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead. When used in Subpart C of this part the term Administrator shall be interchangeable with judicial officer.

(c) The term "Advisory Committee" means a group of qualified scientists referred by the National Academy of Sciences and designated to submit an independent report to the Administrator regarding the registration of an economic poison.

(d) The term "Agency", unless otherwise specified, means Environmental Protection Agency.

(e) The term "applicant" means any person who has made application to have an economic poison registered pursuant to the provisions of the Act.

(f) The term "examiner" means a hearing examiner appointed pursuant to section 3105 of title 5 of the United States Code.

(g) The term "hearing" means a public hearing which is conducted pursuant to the provisions of the Administrative Procedure Act and the regulations in this part.

(h) The term "hearing clerk" means the Hearing Clerk, Environmental Protection Agency, Washington, D.C.

(i) The term "judicial officer" shall mean an officer or employee of the Agency appointed pursuant to these rules and who shall perform functions as herein provided.

(1) *Office.* There may be designated for the Agency one or more judicial officers, one of whom may be Chief Judicial Officer. As work requires, there may be a judicial officer designated to act for the purpose of a particular case. All prior designations of judicial officer shall stay in force until further notice.

(2) *Qualifications.* A judicial officer may be a permanent or temporary employee of the Agency who performs other duties for the Agency. Such judicial officer shall not be employed by the office of pesticides, or have any connection with the preparation or presentation of evidence for a hearing.

(3) *Functions.* The Administrator may delegate any or part of his authority to act in a given case under Subpart C of this part to a judicial officer. The Administrator can separately delegate his authority to rule on interlocutory orders and motions, and may also delegate his authority to make findings of fact and draw conclusions of law in a particular proceeding, providing that this delegation shall not preclude the judicial officer from referring any motion or case to the Administrator when the judicial officer determines such referral to be appropriate. The Administrator, in deciding a case himself, may consult with and assign the preliminary drafting of conclusions of law and findings of fact to any judicial officer.

(4) *Other duties.* The chief judicial officer shall supervise the hearing clerk in the performance of the duties assigned by these rules, and be responsible for scheduling hearings.

(j) The term "party" means any person, group, organization, or any Federal agency or department that participates in a hearing.

(k) The term "person" includes any individual, partnership, association, corporation, or any organized group of persons, whether incorporated or not.

(l) The term "recommended decision" means a report made by an examiner to the Administrator containing (1) proposed findings of fact and conclusions regarding all material issues of fact, law or discretion, as well as the reasons or basis therefor and (2) a proposed order.

(m) The term "registrant" means any person who has registered an economic poison pursuant to the provisions of the Act.

§ 164.3 Scope and applicability of this part.

The provisions of Subpart B of this part shall be applicable to the appointment, compensation, and proceedings of an advisory committee; and the provisions of Subpart C of this part shall govern hearings conducted pursuant to the provisions of the Act. The rules in this part upon adoption in final form shall apply to remaining phases of all proceedings underway insofar as practicable and fair, provided that once commenced or passed, any phase of a proceeding which might have been conducted differently under the rules in this part shall not be affected. For the purpose of the rules in this part, the advisory committee proceeding and Administrator's determination thereafter, pleading, prehearing discovery, the hearing, post-hearing objections and briefs, final and interlocultory appeals to the Administrator shall each constitute a separate phase.

§ 164.4 Administrative review of determinations respecting economic poisons.

(a) *Applications for registration of an economic poison under the Act.* Whenever the Administrator determines, in connection with an application for registration of an economic poison under the Act, that it does not appear that the

article or its labeling or other material required to be submitted complies with the provisions of the Act, the Administrator shall notify the applicant of the manner in which the article, labeling or other material required to be submitted fails to comply with the Act and the applicant shall have an opportunity to make the necessary corrections, where possible. If the applicant does not make the corrections, or if no corrections are possible, the Administrator will refuse to register the article. An applicant may, within 30 days after service of notice of refusal to register and the reasons therefor:

(1) File a petition with the hearing clerk requesting that the matter be referred to an advisory committee, or

(2) File objections with the hearing clerk and request a public hearing respecting the matter.

(b) *Cancellation of the registration of an economic poison under the Act.* The Administrator may, upon his own initiative or in response to a petition filed by any person with him, review the registration of an economic poison to determine whether such registration should be canceled. The Administrator may cancel any registration whenever he determines that the article or its labeling or other material required to be submitted does not comply with the provisions of the Act.

(1) When cancellation or suspension action is requested by petition, immediate notice of receipt of the petition shall be given in the FEDERAL REGISTER and the Administrator shall act on such petition within 120 days of its receipt by the Agency Hearing Clerk.

(2) Whenever, after review of the registration of an economic poison, the Administrator determines that a registration of an economic poison should be canceled, he will notify the registrant of his action and state the reasons therefor. He may at the same time, or at any time thereafter, suspend the registration, pursuant to paragraph (c) of this section. A cancellation of registration shall be effective 30 days after service of the cancellation notice on the registrant unless within such time the registrant:

(i) Makes the necessary corrections, if possible in light of the reasons for cancellation;

(ii) Files a petition with the hearing clerk requesting that the matter be referred to an advisory committee and serves a copy on the Administrator; or

(iii) Files objections with the hearing clerk and requests a public hearing and serves a copy on the Administrator.

(3) (i) Whenever, following either the filing of a petition by any person pursuant to the opening language of this paragraph or any major, intensive review of a registration undertaken on his own initiative, the Administrator determines that, considering all relevant factors, an economic poison is entitled to retain its registration, he shall within 120 days of the receipt of the petition publish a notice of his decision in the FEDERAL REGISTER and, if his review was occasioned by the filing of a petition, shall notify the person filing such petition directly. In his decision the Administrator shall state whether he found, in the course of evaluating the registration, the existence of a substantial question of safety.

(ii) Within 30 days after such publication or notification, whichever occurs later, any person may file a petition requesting that, notwithstanding the decision that the product is entitled to retain its registration, the Administrator issue a notice of cancellation of the registration of the product on the ground that its continued registration presents a substantial question of safety. If the Administrator has stated in his decision that such a question exists, he shall forthwith issue the notice of cancellation. In such case, the registrant shall have the same opportunity to correct his registration or request administrative review as is provided under subparagraph (1) of this paragraph. If the registrant requests a hearing, the hearing shall proceed on the same basis as a hearing held pursuant to subparagraph (1) of this paragraph, except with respect to the position taken by counsel for the Agency. The burden to establish all the elements necessary to continued registration shall be on the registrant at the hearing: *Provided*, That no person appears at the hearing to oppose registration, the examiner shall order that the notice of cancellation be withdrawn.

(iii) If the Administrator's order finds that no substantial question of safety arises in connection with the registration, that shall be a final Agency order.

(c) *Suspension of the registration of an economic poison under the Act.* Whenever the Administrator finds that such action is necessary to prevent an

imminent hazard to the public, he may suspend the registration of the economic poison immediately. Unless he has previously done so, he shall at the same time issue a notice of cancellation of the registration. Whenever the Administrator suspends the registration of an economic poison he will give the registrant notice of that action and the registrant shall have the opportunity to have the matter submitted to an advisory committee and shall have the opportunity for an expedited hearing regarding the matter in accordance with the provisions of the regulations in this part governing refusals to register and cancellations of registrations.

§ 164.5 Arrangements for monitoring Agency records, transcripts, and decisions.

(a) *Reporting of opinions and reports.* All advisory committee reports and other decisions required by the rules in this part, including conclusions of law and findings of fact, whether issued by an examiner, judicial officer, or the Administrator, shall be made available to the public and notice of availability shall be given in the FEDERAL REGISTER.

(b) *Establishment of an Agency repository.* All transcripts and docket entries shall become part of the official docket and shall be retained by the hearing clerk. At least two copies of all opinions and reports shall be retained by the hearing clerk and filed chronologically according to the date of issuance. These shall be periodically bound and indexed. All documents shall be made available to the public for reasonable inspection during agency hours.

Subpart B—Rules Governing the Advisory Committees

§ 164.10 Docketing of request for advisory committee.

Whenever a petition requesting that a matter be refered to an advisory committee is filed with the hearing clerk, the hearing clerk shall docket the matter and assign it an "I.F.&R." docket number.

§ 164.11 Appointment of advisory committee.

(a) *Selection of members.* Whenever a petition for an advisory committee is filed or the Administrator otherwise deems such referral desirable, the Administrator shall request the National Academy of Sciences, National Research Council, to refer a specified number of experts of adequately diversified professional background, including at least one representative from a land-grant college, willing to serve on the advisory committee. The Administrator shall request the National Academy of Sciences, when it furnishes the names of such experts, to supply biographical sketches showing the background of their experience and education. Copies of such biographical sketches will be available to any person upon request.

(1) Upon receipt of the names of the experts, the Administrator shall ascertain whether any of them is affected by a financial or other conflict of interest. Any experts found to be so affected or who express unwillingness to serve or who fail to respond to inquiries as to availability or conflict of interest within a reasonable period of time shall be disqualified by the Administrator.

(2) In the event the number of eligible experts referred by the Academy and available for service exceeds in number the size of the proposed committee, the Administrator shall select a panel of appropriately diversified background and discipline, including one representative from a land-grant college.

(3) In the event that at any time experts selected by the Academy and available for service constitute less than the number required to fill the committee or reflect insufficient diversity, the Administrator shall request the National Academy of Sciences to refer additional experts.

(4) At the earliest opportunity, the advisory committee shall select one of its members to act as chairman. The chairman shall be the spokesman for the committee and shall carry out such other functions for the committee as may be necessary.

(b) *Compensation for members.* The Administrator shall appoint the experts so selected and fix their compensation at $75 per day for actual time spent in committee work, plus necessary traveling and subsistence expenses while the members are serving away from their places of residence. Subsistence expenses shall not exceed the maximum per diem permitted by this Agency.

§ 164.12 Procedure for advisory committee.

(a) *Secretariat.* A secretariat to assist advisory committees will be established by the Administrator.

(b) *Submission of information to advisory committee.* The Administrator shall submit to the secretariat for distribution to the chairman of the committee the petition filed by the applicant or registrant and such other relevant information, including any petition filed pursuant to § 164.4(b), as he may have available with respect to registration of the product. At that time, the Administration shall charge the committee to report to him concerning the scienific questions posed by the registration or application involved. When the secretariat submits a matter to an advisory committee he shall furnish the applicant or registrant and any person who has filed a petition pursuant to § 164.4(b) with copies of the material that is furnished to the committee. A copy of such material shall be available for public inspection in the office of the hearing clerk. The chairman shall acknowledge receipt of the information and the readiness of the committee to act. A copy of this acknowledgement shall be forwarded by the secretariat to the applicant or registrant and to any person who has filed a petition pursuant to § 164.4(b).

(c) *Advisory committee meetings.* If the chairman of the committee believes that a meeting of the committee is necessary before making a recommendation, he shall so advise the secretariat. The secretariat shall advise the applicant and registrant and other persons who have requested that they receive such advice of the date and place of any such meetings. Such meeting shall be held in Washington, D.C., or such other appropriate place as the chairman may designate. The secretariat shall arrange a suitable meeting place for the committee. If a meeting is held, the secretariat shall keep the minutes and provide clerical and such other assistance as may be required.

(d) *Presentation of evidence*—(1) *Consultation with advisory committee.* The applicant or a registrant, any person who has submitted a petition pursuant to § 164.10(b), and representatives of the Environmental Protection Agency shall have the right to consult with the advisory committee. Such persons shall notify the chairman of a desire to consult with the committee and, if practicable, make appointments through him. In addition, the committee may request or permit any other person to appear before it or submit written data relevant to the matter under consideration. The report of the advisory committee shall show the names of all persons, other than committee members, discussing the petition or referral with the committee or a committee member.

(2) *Submission of written data to the committee and to the Administrator.* As soon as practicable after the referral of a matter to an advisory committee, the committee shall establish a time period of not less than 30 days within which the committee will entertain the submission of any additional written data pertaining to the scientific effects of the registered product in accordance with the procedure established below. The secretariat shall publish notice of that time period, or any extension thereof similarly established and published, in the FEDERAL REGISTER. Any person may submit to the secretariat in duplicate data in written form bearing on the scientific questions before the committee concerning the registration of the article. The secretariat shall promptly inform the members of the committee of the receipt of such data. One copy of such data shall be available for public inspection in the office of the hearing clerk.

(e) *Confidentiality of data.* All data in support of a petition submitted by the registrant or applicant to an advisory committee shall be considered confidential by such committee, unless the registrant or applicant waives its right to confidentiality. This paragraph shall not be construed as prohibiting the use of such data by the committee in connection with its consultation with the applicant or registrant or representatives of the Agency, and in connection with its report and recommendations to the Administrator. After the submission of the committee's report, such data shall be available for public inspection in the office of the hearing clerk, except for matters contained therein the disclosure of which is prohibited by statute.

(f) *Report of the advisory committee.* As soon as practicable, but not later than 60 days after the date on which the information referred to in paragraph (b) of this section has been received by the committee (unless the time has been extended as provided in paragraph (g) of this section), the chairman shall certify to the Administrator the report of the committee including any minority report. The report shall respond to the charge given to the committee and be

accompanied by copies of all data or material submitted to or considered by the committee (including information received under paragraph (d)(2) of this section) except that in the case of scientific literature readily available in scientific libraries, proper reference may be made to it instead of furnishing actual copies. Notice of the certification of the report shall be given in the FEDERAL REGISTER. The report of the advisory committee shall be furnished upon request by any person. The Agency may charge for the cost of reproducing the report.

(g) *Extension of time for advisory committee report.* If at any time within the 60-day period referred to in paragraph (f) of this section the chairman believes that the advisory committee needs more time, he shall so inform the Administrator in writing, in which case the Administrator may extend said time not to exceed 60 additional days. Notification of any such extension of time will be sent to the applicant or registrant and other interested persons by the secretariat.

(h) *Assessment of costs of submission to an advisory committee.* (1) In the event that an applicant or a registrant requests that a matter concerning the registration of an economic poison be referred to an advisory committee, the costs of such referral shall be borne by the applicant or the registrant unless the committee shall recommend in favor of the applicant or the registrant.

(2) Costs of the advisory committee shall include compensation for experts as provided in § 164.10(b) and the expense of the secretariat, including the costs of duplicating petitions and other related material referred to the committee.

(3) An advance deposit shall be made in the amount of $5,000 to cover the costs. Further advance deposits of $2,500 each shall be made upon request of the Administrator when necessary to cover additional costs. Any deposits in excess of actual expenses will be refunded to the depositor.

(4) All deposits and fees required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Environmental Protection Agency, Washington, D.C., whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States, for deposit to the proper account.

(5) The Administrator may waive or refund such fees in whole or in part when in his judgment such action will be warranted and equitable under the particular circumstances and promote the public interest.

(i) *Submission of comments.* Any person may within 45 days of publication of the notice of certification of the report to the Administrator from the advisory committee submit comments pertaining to the issues before the Administrator. Such comments shall not be in the nature of evidence or data that could have been submitted to the advisory committee pursuant to paragraph (d) of this section.

(j) *Order of the Administrator.* Within 90 days of the date of his receipt of the advisory committee report and recommendations, the Administrator shall make the determination and issue the order required by the Act and file that decision with the hearing clerk. Any applicant or registrant aggrieved by such an order may, within 60 days from the date of such order, file objections thereto and request a public hearing thereon. Any person aggrieved by an order granting or continuing registration may, if the Administrator's determination includes the statement that a substantial question of safety exists concerning the registration, request that the Administrator reconsider his order and continue the cancellation in effect on that basis. The Administrator shall forthwith grant any such request and issue a notice continuing cancellation. Any applicant or registrant aggrieved by such reconsidered order may, within 60 days from that date of that reconsidered order, file objections thereto and request a public hearing thereon. Such a hearing shall proceed on the same basis as one held pursuant to § 164.4(b)(2).

(k) *Chairman to designate committee member to testify.* At the request of the examiner or any party to the hearing, the Chairman or another member of the committee designated by the Chairman will be available to appear and testify at a public hearing, if one occurs, with respect to the report and recommendations of the committee: *Provided, however,* That this shall not preclude any other member of the committee from being requested to appear and testify at such hearing.

Subpart C—Rules of Practice Governing Hearings

§ 164.20 Docketing of request for hearing.

Whenever a document setting forth objections and requesting a public hearing is filed with the hearing clerk, the matter shall be docketed and assigned and "I.F.&R." docket number: *Provided*, That if the matter has previously been assigned an "I.F.&R." number pursuant to § 164.10, it shall be assigned that same number. Notice of the filing of such objection shall be given to the public by appropriate announcement in the Federal Register.

§ 164.21 Contents of document setting forth objections.

(a) *Concise statement required.* Any document containing objections to an order of the Administrator refusing to register an economic poison or determining to cancel or suspend the registration of such a product, shall clearly and concisely set forth such objections and the basis for each objection, including relevant allegations of fact concerning the economic poison under consideration.

(b) *Amendments to objections.* Objections may be amended at any time prior to the public hearing by leave of the examiner or by written consent of all adverse parties. The examiner shall freely grant such leave when justice so requires. If the examiner determines that additional time is necessary in order to permit a party to prepare for matters raised by amendments to objections, the commencement of the hearing shall be delayed for an appropriate period.

§ 164.22 Filing copies of notification respecting registration.

After a copy of the document setting forth the objections and requesting a public hearing is served upon the Administrator, the Administrator shall file with the hearing clerk a copy of the notice of cancellation or suspension of the registration of such economic poison.

§ 164.23 Answer to objections not required.

The filing of an answer to objections is not required. An answer may be filed within 30 days after service of the objections.

§ 164.24 Motions and requests.

(a) *General.* All motions and requests except those made orally during the course of a public hearing must be in writing and shall be filed with the hearing clerk. The examiner is authorized to rule upon all motions and requests filed or made prior to the filing of his report with the hearing clerk as hereinafter provided in § 164.32. The Administrator will rule upon all motions and requests filed after that time.

(b) *Motions.* All motions and requests concerning the sufficiency of the objections must be made within 30 days after service of the objections. All such motions and requests shall state with particularity the ground upon which the objection is alleged to be insufficient and shall state the nature of the relief requested.

(c) *Answers to motions and requests.* Within 10 days after service of any written motion or request filed pursuant to this subpart, or within any longer period fixed by the Administrator or the examiner, an opposing party shall file an answer to the motion or request or shall be deemed to have no objection to the granting of the relief asked for in the motion or request. Unless specifically permitted by the Administrator or the examiner on motion made by a party, the movant shall have no right to respond to the answer to his motion.

(d) *Certification of interlocutory issues to the Administrator.* Except as provided herein, appeals shall lie to the Administrator only from a final judgment by the hearing examiner. Appeals from other rulings will, except as provided in this section, lie only if the examiner certifies such rulings for appeal. The examiner shall certify a ruling for appeal to the Administrator when: (1) The ruling involves an important question of law or policy about which there is substantial ground for difference of opinion; and (2) either an immediate appeal from the ruling will materially advance the ultimate termination of the proceeding or review after the final judgment is issued will be inadequate or ineffective. The examiner shall certify rulings for appeal only upon the request of a party. If the Administrator determines that certification was improvidently granted, or takes no action within 30 days of the certification, the appeal shall be deemed dismissed. When a ruling is not certified by the examiner, it shall be reviewed by the Administrator only upon appeal from the final

judgment except when the Administrator determines, upon request of a party and in exceptional circumstances, that delaying review would be deleterious to vital public or private interest. Except under extraordinary circumstances, proceedings will not be stayed pending an interlocutory appeal; a stay of more than 30 days must be approved by the Administrator. Ordinarily, the interlocutory appeal will be decided on the basis of the submission made to the examiner, but the Administrator may allow further briefs or oral argument.

§ 164.25 Intervention.

(a) *Pleading.* Any person may file a petition for leave to intervene in a hearing conducted under the Subpart. A petition must set forth the grounds for the proposed intervention, the position and interest of the petitioner in the proceeding, and whether petitioner's position is in support of or opposition to the order of the Administrator to which objection has been taken.

(b) *When filed.* A petition for leave to intervene in a hearing may be filed any time prior to the commencement of the hearing. Any petition filed after that time shall contain, in addition to the information set forth in paragraph (a) of this section, a statement of good cause for the failure to file the petition prior to the commencement of the hearing. A motion to intervene for the purpose of appeal may be filed and submitted to the Administrator.

(c) *Reply.* Any opposition to a petition for leave to intervene must be filed within 10 days after service of the petition.

(d) *Disposition.* Leave to intervene will be freely granted but only insofar as it raises matters which are reasonably pertinent to and do not unreasonably broaden the issues already presented. If leave is granted, the petitioner thereby shall become a party to the proceeding.

§ 164.26 Depositions.

(a) *Application for taking deposition.* Upon the application of a party to the proceeding, the examiner may, at any time after the filing of the moving paper, authorize, under the facsimile signature of the Administrator, the taking of testimony by deposition. The application shall be in writing and shall be filed with the hearing clerk and shall set forth: (1) The name and address of the proposed deponent; (2) the name and address of the person (referred to in this section as the "officer"), qualified under the rules in this part to take depositions, before whom the proposed examination is to be made; (3) the proposed time and place of the examination, which should be at least 15 days after the date of the mailing of the application; and (4) the reasons why deposition should be taken.

(b) *Examiner's order for taking deposition.* If the examiner is satisfied that good cause for taking the deposition is present, he may order its taking. The order shall be filed with the hearing clerk and shall be served upon the parties and shall state: (1) The time and place of the examination (which shall not be less than 10 days after the filing of the order); (2) the name of the officer before whom the examination is to be made; and (3) the name of the deponent. The officer and the time and place need not be the same as those suggested in the application.

(c) *Qualifications of officer.* The deposition shall be made before the examiner, or before an officer authorized by the law of the United States or by the law of the place of the examination to administer oaths, or before an officer authorized by the Administrator to administer oaths. No deposition shall be made before an officer who is a relative (within the third degree of blood or marriage), employee, attorney, or counsel of any party or who is a relative (within the third degree by blood or marriage) or employee of any attorney or counsel for any party or who is financially interested in the result of the proceeding.

(d) *Procedure on examination.* (1) The deponent shall be examined under oath or affirmation and shall be subject to cross-examination. The testimony of the deponent shall be recorded by the officer or by some person under his direction and in his presence. In lieu of oral cross-examination, parties may transmit written cross-interrogatories to the officer prior to the examination and the officer shall propound such cross-interrogatories to the deponent.

(2) The applicant must arrange for the examination of the witness either by oral examination or by written interrogatories. If it is found by the examiner, upon protest of a party to the proceeding, that such party has his residence and his place of business more than 100 miles from the place of the examination and that it would constitute an undue hardship upon such party to

be represented at the examination, the applicant will be required to conduct the examination by means of interrogatories. When the examination is conducted by means of interrogatories, copies of the interrogatories shall be served upon the other parties to the proceeding at least 5 days prior to the date set for the examination, and the other parties shall be afforded an opportunity to file with the officer cross-interrogatories at any time prior to the time of the examination.

(e) *Signature by witness.* The transcript of the deposition shall be read to or by the deponent, unless such reading is waived by the parties and the deponent. Any changes which the deponent wishes to make shall be entered upon the deposition by the officer, with a statement of the reasons given by the deponent for such changes. The deposition shall be signed by the deponent, unless the parties by stipulation waive such signing, or unless the deponent is ill or cannot be found or refuses to sign. If the deponent does not sign the officer shall sign and shall state on the record the reason why the deponent did not sign. In such case the deposition shall be as valid as though signed by the deponent, unless the examiner finds that the reason given by the deponent for his refusal to sign requires rejection of the deposition in whole or in part.

(f) *Certification by officer.* The officer shall certify on the deposition that the deponent was duly sworn by him and that the deposition is a true record of the deponent's testimony. He shall then securely seal the deposition, together with two copies thereof, in an envelope and mail the same by registered mail to the hearing clerk.

(g) *Use of depositions.* A deposition ordered and taken in accord with the provisions of this section, or in accord with the provisions of the Rules of Civil Procedure of the Courts of the United States, may be used in a proceeding under the act if the examiner finds that the evidence is relevant and material and (1) that the witness is dead; or (2) that the witness is at a greater distance than 100 miles from the place of hearing, unless it appears that the absence of the witness was procured by the party offering the deposition; or (3) that the witness is unable to attend or testify because of age, sickness, infirmity, or imprisonment; or (4), in any event, upon application and notice that such exceptional circumstances exist as to make it desirable, in the interests of justice and with due regard to the importance of presenting the testimony orally before the examiner, to allow the deposition to be used. If any part of a deposition is put in evidence by a party, any other party may require the production of the remainder, or any portion, of the deposition.

§ 164.27 Fees of witnesses.

Witnesses who appear before the examiner or the Administrator shall be paid the same fees and mileage that are paid witnesses in the courts of the United States, and witnesses whose depositions are taken, and the persons taking the same shall be entitled to the same fees as are paid for like services in the courts of the United States. Fees shall be paid by the party at whose instance the witness appears or the deposition is taken.

§ 164.28 Consolidation.

Whenever it appears to the examiner, by motion or otherwise, that it will expedite or simplify consideration of the issues in two or more docketed proceedings involving the same economic poison under this subpart, he may consolidate such proceedings. Consolidation shall not preclude the right of any party to raise issues that could otherwise be raised if such consolidation had not occurred. At the conclusion of proceedings consolidated under this section, the examiner shall issue one report under § 164.36.

§ 164.29 Prehearing conference.

(a) Except as otherwise provided herein, the examiner shall, prior to the commencement of the hearing and for the purpose of expediting the hearing, file with the hearing clerk an order for a prehearing conference. Such order shall request the parties or their counsel to consider (1) the simplification of issues; (2) the necessity or desirability of amendments to the pleadings; (3) the possibility of obtaining stipulations of fact and documents which will avoid unnecessary proof; (4) the limitation of the number of experts and other witnesses; and (5) any other matter that may expedite the hearing or aid in the disposition of the matter. No transcript of such prehearing conference shall be made unless a request therefor by one of the parties is granted by the examiner

in view of the nature of the matters to be considered at the conference and the purposes of the conference. In the absence of a transcript, the examiner shall prepare and file for the record a written summary of the action taken at such conference, which shall incorporate any written stipulations or agreements made by the parties at or as a result of the conference.

(b) If circumstances render a prehearing impracticable, the examiner may request the parties to correspond with him for the purpose of accomplishing any of the objectives set forth in this section. The examiner shall forward copies of letters and documents sent to him in this connection to the parties as the circumstances require. Correspondence in such negotiations shall not be a part of the record, but the examiner shall submit a written summary for the record if any action is taken.

§ 164.30 Qualifications and duties of examiner.

(a) *Qualifications.* Examiners shall have the qualifications required by statute and shall not have any direct connection with the office of pesticides. No person shall act to decide any matter in connection with a hearing where such person has a financial interest in any of the parties or a relationship with a party that would make it otherwise inappropriate for him to act.

(b) *Disqualification of the examiner.* (1) Any party may, by motion made to the examiner, request that the examiner disqualify himself and withdraw from the proceeding. The examiner shall then rule upon the motion and, upon request of the movant, shall certify an adverse ruling for appeal.

(2) An examiner may withdraw from any proceeding in which he deems himself disqualified for any reason.

(c) *Conduct.* The examiner shall conduct the proceeding in a fair and impartial manner, and shall not consult with any party or person on any matter in issue unless upon notice and opportunity for all parties to participate.

(d) *Power.* Subject to review, as provided elsewhere in this part, the examiner shall have power to:

(1) Rule upon motions and requests;

(2) Set the time and place of hearings, adjourn the hearing from time to time, and change the time and place of hearing;

(3) Administer oaths and affirmations and take affidavits;

(4) Examine witnesses;

(5) Rule on objections and admit evidence relevant and material to the issues and exclude other evidence;

(6) Hear oral argument on the facts or on the law; and

(7) Do all acts and take all measures necessary for the maintenance of order at the hearing and for the efficient, fair and impartial conduct of the proceeding.

(e) *Who may act in the absence of the examiner.* In case of the absence of the examiner or his inability to act, the powers and duties to be performed by him under this part in connection with a hearing assigned to him may, without abatement of the proceeding unless otherwise directed by the Administrator, be assigned to another examiner.

§ 164.31 Procedure for a public hearing.

(a) *Time and place of hearing.* After a proceeding has been instituted in accordance with the procedures set forth in this part the examiner, after giving careful consideration to the convenience of all the parties and the public interest, shall set a time and place for hearing and shall file with the hearing clerk a notice stating the time and place of hearing which shall be served upon the parties. If any change in the time or place of hearing is made, the examiner shall file with the hearing clerk a notice of such change, which notice shall be served upon the parties unless the change is made during the course of the public hearing and is made a part of the transcript.

(b) *Appearances*—(1) *Representatives.* Parties may appear in person or by counsel or other representative. Persons who appear as counsel or in a representative capacity must conform to the standards of ethical conduct required of practitioners before the courts of the United States. Whenever the Administrator finds, after notice and opportunity for hearing, that a person who is acting or has acted as counsel or representative for another person in any proceeding before the Administrator is unfit to act as such counsel or representative, he will order that such person be precluded from acting as counsel or representative in any proceeding under the Act.

(2) *Failure to appear.* If any party to the proceeding after being duly notified, fails to appear at the hearing, he shall be deemed to have waived the right to

participate in the public hearing in the proceeding. Except as provided in § 164.4(b)(2), in the event that a party appears at the hearing and no party appears for the opposing side, the examiner shall recommend that a decision be entered in favor of the party who is present and the Administrator shall enter his decision in accordance with such recommendation.

(c) *Broadcasting of proceedings.* The hearing examiner shall grant any request for permission to record hearings for subsequent radio, television, or other form of broadcasting. The hearing examiner may impose such limitations upon the manner in which the recording is obtained, including the nature of the equipment utilized, as he deems necessary to minimize the physical disruption of the proceedings. The hearing examiner shall, upon the request of any witness, prohibit the recording of the testimony of that witness and may, if he believes that the recording process is generally having an adverse impact upon the conduct of proceedings, order that the recording be discontinued entirely.

§ 164.32 Order of proceeding and burden of proof.

At the hearing, the registrant or applicant shall have the burden to establish the elements necessary to entitle the product to registration. If, after pretrial proceedings, the examiner determines in the interest of justice, or clarifying the issues, or expediting the hearing, that another party other than the registrant should proceed first at the hearing, he may so order.

§ 164.33 Evidence.

(a) *General.* The examiner shall admit all relevant and material evidence, except evidence that is unduly repetitious. Relevant and material evidence may be received at any hearing even though inadmissible under the rules or evidence applicable to judicial proceedings. The weight to be given evidence shall be determined by its reliability and probative value. Parties shall have the right to cross-examine a witness who appears at the hearing. In multiparty proceedings the examiner may limit cross-examination to the Agency and to one other party on each side if it appears that the cross-examination by one party will adequately protect parties similarly situated. Other parties may, however, engage in cross-examination if they can demonstrate that their cross-examination will go into matters not already covered by previous cross-examination.

(b) *Report of an advisory committee.* If a matter concerning the registration of an economic poison had been submitted to an advisory committee, the report of the advisory committee and the material accompanying it shall be made a part of the record of the hearing in accordance with the provisions of 7 U.S.C. 135b(c).

(c) *Testimony of member of advisory committee.* If a matter concerning the registration of an economic poison had been submitted to an advisory committee, the testimony of the chairman of the advisory committee, or other member designated by him pursuant to § 164.12(k), with respect to the report and recommendations of such committee shall be received on request of any party or the examiner: *Provided, however,* That this shall not preclude any other member of the advisory committee from appearing and testifying at the hearing pursuant to such a request.

(d) *Objections.* If a party objects to the admission or rejection of any evidence or the limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection. The transcript shall include any argument or debate thereon, unless the examiner, with the consent of all parties, orders that such argument not be transcribed. The ruling of the examiner on any objection shall be a part of the transcript. An automatic exception will follow if the objection is overruled by the examiner.

(e) *Records of the agency.* A true copy of every written entry in the records of the Environmental Protection Agency, made by an officer or employee thereof in the course of his official duty and relevant and material to the issues involved in the hearing, shall be admissible as prima facie evidence of the facts stated therein, without the production of such officer or employee.

(f) *Exhibits.* Except where the examiner finds that the furnishing of copies is impracticable, a copy of each exhibit filed with the examiner shall be furnished to each other party. A true copy of an exhibit may, in the discretion of the examiner be substituted for the original.

(g) *Official notice.* Official notice may be taken of the official publications of the Environmental Protection Agency and other Federal agencies, of such matters as are judicially noticed in the courts of the United States, and of any other

matter of technical or scientific fact of established character: *Provided, however*, That the parties shall be given adequate opportunity to show that such facts are erroneously noticed.

(h) *Offer of proof.* Whenever evidence is excluded from the record, the party offering such evidence may make an offer of proof, which shall be included in the transcript. The offer of proof for excluded oral testimony shall consist of a brief statement describing the nature of the evidence excluded. If the evidence consists of an exhibit, it shall be inserted in the record in total. In the event the Administrator decides that the examiner's ruling in excluding the evidence was erroneous and prejudicial, the hearing may be reopened to permit the taking of such evidence, or, where appropriate, the Administrator may evaluate the evidence and proceed to a final decision.

(i) *Verified statements.* With the approval of the examiner, a witness may read into the record, as his testimony, statements of fact or opinion prepared by him, or written answers to interrogatories of counsel, or may submit as an exhibit his prepared statement, provided that such statements or answers must not include argument. Before any such statement or answer is read or admitted in evidence the witness shall deliver to the examiner, the reporter, and opposing counsel a copy of such. The admissibility of the evidence contained in such statement shall be subject to the same rules as if such testimony were produced in the usual manner, including the right of cross-examination of the witness. Such approval may be denied when it appears to the examiner that the memory or the demeanor of the witness is of importance.

§ 164.34 Transcripts.

(a) *Filing and certification.* Oral hearings shall be stenographically reported and transcribed. As soon as practicable after the taking of the last evidence, the examiner shall certify (1) that the original transcript is a true transcript of the testimony offered or received at the hearing, except in such particulars as he shall specify and (2) that the exhibits accompanying the transcript are all the exhibits introduced at the hearing, with such exceptions as he shall specify. A copy of such certificate shall be attached to each of the copies of the transcript.

(b) *Ordering copies.* Parties to the proceeding or other persons who desire a copy of the transcript of the hearing may place orders with the reporter who will furnish and deliver such copies directly to the purchaser upon payment therefor at the rate per page provided by the contract between the reporter and purchaser.

§ 164.35 Proposed findings of fact, conclusions and order.

Within 30 days after the last evidence is taken, each party may file with the hearing clerk proposed findings of fact, conclusions and orders, based solely on the record, and a brief in support thereof. A copy of each such document filed by a party shall be served upon the other party or parties. The hearing shall be deemed closed at the conclusion of that 30-day period.

§ 164.36 Examiner's report.

The examiner, within 25 days after the close of the hearing, shall prepare on the basis of the record and shall file with the hearing clerk, his recommended decision, a copy of which shall be served upon each of the parties.

§ 164.37 Exceptions, objections, request for oral argument.

(a) Within 20 days after service of the examiner's recommended decision, each party may take exception to any matter set forth in such decision and in such case shall file exceptions in writing with the hearing clerk, with an attachment reproducing the relevant portions of the record including a complete copy of the examiner's finding and conclusions, and suggesting corrected findings of fact, conclusions or order. Within the same period of time, each party may file with the hearing clerk a brief statement in writing upon which the party wishes to rely concerning each of the objections taken to the action of the examiner at the hearing, as set out in § 164.33(d). There shall be an attachment reproducing if any, the relevant portions of the record. A party may file a brief in support of any exceptions or objections which he may file.

(b) Where more than one party is filing objections or exceptions the parties may agree to submit a joint appendix reproducing the relevant portions of the record and other information required as an attachment under paragraph (a) of this section.

(c) Within 7 days of the service of exceptions, objections or a brief under paragraph (a) of this section, any other party may file and serve a brief responding to exceptions and objections or arguments raised by any other party by the papers submitted pursuant to paragraph (a) of this section. Such brief shall include an appendix reproducing any additional portions of the record on which respondent chooses to rely. Such brief shall not, however, raise additional exceptions or objections.

(d) A party, if he files exceptions or a statement of objections, or a brief, shall state in writing whether he desires to make an oral argument thereon before the Administrator; otherwise, he shall be deemed to have waived such oral argument.

(e) Copies of all material filed under this section shall be filed with the clerk.

§ 164.38 Argument before the Administrator.

Except where the Administrator determines that argument on additional issues would be helpful, argument whether oral or on brief, shall be limited to the issues raised by the exceptions and statement of objections to action of the examiner. If the Administrator determines that additional issues should be argued, counsel for the parties shall be given reasonable notice of such determination so as to permit preparation of adequate argument on all the issues to be argued.

§ 164.39 Final order.

As soon as practicable, but no later than after the expiration of the period for filing exceptions, objections and responding briefs, three copies of objections, exceptions, briefs, attachments, and appendices, and the record shall be submitted to the Administrator by the clerk. As soon as practicable thereafter, but not more than 90 days after the close of the hearing, unless otherwise stipulated by the parties, the Administrator shall issue his final decision and order, including his rulings on any exceptions or objections filed by the parties. Such final order may accept or reject the recommended findings of the examiner even if acceptable to the parties.

§ 164.40 Ex parte discussion of proceeding.

At no stage of the hearing between its institution and the issuance of the final order shall the Administrator discuss ex parte the merits of the proceeding with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate, or in an investigative or expert capacity, or with any representative of such person: *Provided, however,* That the Administrator may discuss the merits of the case with any such person if all parties to the proceeding, or their representatives, have been given reasonable notice and opportunity to be present. Any memorandum or other communication addressed to the Administrator, during the pendency of the proceeding, and relating to the merits thereof, by or on behalf of any party, shall be regarded as argument made in the proceeding. The Administrator shall cause any such communication to be filed with the hearing clerk and served upon all other parties to the proceeding, who will be given the opportunity to file a reply thereto.

§ 164.41 Application for reopening hearings; for rehearing; or reargument of proceeding; or for reconsideration of order.

(a) *Filing; service.* An application for reopening the hearing to take further evidence, or for rehearing or reargument of the proceeding or for reconsideration of the order, must be made by petition to the Administrator filed with the hearing clerk. Every such petition must state specifically the grounds relied upon.

(b) *Petitions to reopen hearings.* A petition to reopen a hearing to take further evidence may be filed at any time prior to the issuance of the final order. Every such petition shall state briefly the nature and purpose of the evidence to be adduced, shall show that such evidence is not merely cumulative, and shall set forth a good reason why such evidence was not adduced at a hearing.

(c) *Petitions to rehear or reargue proceedings, or to reconsider orders.* A petition to rehear or reargue or reopen the proceeding or to reconsider the order shall be filed within 10 days after the date of service of the order. Every such petition must state specifically the matters claimed to have been erroneously decided and alleged errors must be briefly stated.

§ 164.42 Procedure for disposition of petitions.

Within 7 days following the service of any petition provided for in § 164.41, any other party to the proceeding may file with the hearing clerk an answer thereto. As soon as practicable thereafter, the Administrator shall announce his decision whether to grant or to deny the petition. Unless the Administrator shall determine otherwise, operation of the order shall not be stayed pending the decision to grant or to deny the petition. In the event that any such petition is granted by the Administrator, the applicable rules of practice, as set out elsewhere herein, shall be followed.

§ 164.43 Filing and service.

(a) All documents or papers required or authorized to be filed, except as provided otherwise in this part, shall be filed with the hearing clerk and shall be accompanied by sufficient copies for all other parties. If filing is accomplished by mail addressed to the clerk, filing shall be deemed timely if the papers are mailed on the due date. The hearing clerk shall promptly cause the copies to be served upon all other parties.

(b) Each document filed shall contain the I.F. & R. docket number and, if the document affects less than all of the registrations included under that docket number, the registration number or file symbol of each product which is the subject of the document.

(c) In addition to copies served on other parties, each party shall file three (3) copies of any memoranda, briefs, reply briefs or memoranda or appendices filed in connection with an appeal to the Administrator.

§ 164.44 Computation and extensions of time.

(a) Saturdays, Sundays, and holidays shall be included in computing the time allowed for the filing of any document or paper: *Provided, however*, That, when such time expires on a Saturday, Sunday, or legal holiday, such period shall be extended to include the next following business day.

(b) Whenever a party is required or permitted to do an act within a prescribed period after service of a paper upon him, the period shall be computed from the day on which the paper is mailed or otherwise served by the hearing clerk.

(c) The time for the filing of any document or paper required or authorized to be filed under the rules in this party may be extended by the examnier (before the examiner's report is filed), or by the Administrator (after the examiner's report is filed) if request for such extension of time is made prior to the final date allowed for such filing and if in the judgment of the Administrator, after notice to and consideration of the views of the other party when practicable there is good reason for the extension. In this connection, consideration shall also be given to the fact that, under the provisions of the Act (7 U.S.C. 135)b, the Administrator must issue his order not later than 90 days after the completion of the hearing, unless all parties agree by stipulation to extend this period of time pursuant to § 164.39.

[FR Doc. 72-993 Filed 1-21-72; 8:48 a.m.]

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., July 14, 1972.

Hon. DANIEL K. INOUYE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR INOUYE: During our testimony on H.R. 10729 you invited us to furnish additional budget estimates for research and monitoring and comment on the matter of reentry times and safety of Ethion and Guthion.

The safety of field entry period for Ethion and Guthion was rather thoroughly discussed in the testimony offered by Mr. A. V. Krebs, Agribusiness Accountability Project, before the Senate Subcommittee on Agricultural Research and General Legislation on March 8, 1972. We are glad to add our comments.

There are two distinctive aspects of this subject. First, there is the question of the acceptability of research involving human subjects as a means of obtaining information to be considered in registration of a pesticide. Second, there is the question of safety of Ethion and Guthion to agricultural workers and the adequacy of precautionary labelling.

We do not make it a practice to require or even encourage experiments on human volunteers as a source of safety information on pesticides. On the other hand, there is no way in which research on experimental animals can be extrapolated to humans with certainty. Consequently, there can be no assurance that precautionary labelling will provide absolute safety.

As we gain experience with a chemical over time, based on observations of individuals who are occupationally or accidentally exposed, we must reexamine the original label and make improvements, if necessary. In the case of Ethion and Guthion the State of California is investigating the possibility of special effects, apparently not encountered in other states, which may be due to climatic conditions. We are cooperating with California and support their effort, to study and investigate appropriate reentry times for other organophosphates as well.

The problem of reentry time has been known and studied for over twenty years. During this period cases of human poisonings have been very sporadic, numerous crop workers being poisoned in a few fields in certain years with no such incidents occurring in other similar fields in the same year and often with several years intervening before the next incident. Five days has generally proved a safe reentry period and those cases where it has been insufficient have occurred in the Central Valley of California. This has led to the belief that some unidentified climatological factors may be involved. We have searched unsuccessfully for similar problems in other States. (Reported deaths from parathion in North Carolina and elsewhere are not similar since the reentry times were five days or less and the residues were clearly there, irrespective of any special factors.) Moreover, so far as we have been able to learn none of these California poisonings of crop workers resulting from reentry after more than five days have been critical—that is, recovery has been prompt and complete with the possible exception of a death from an automobile accident in which the driver could have been less alert due to such poisoning.

At this time we are satisfied with the label for reentry time for Guthion (considerably more toxic than Ethion) for nationwide purposes even though we support the longer reentry time required by California.

Our present projection for monitoring is as follows:

	Million
Fiscal year 1973	$5.5
Fiscal year 1974	10.5
Fiscal year 1975	16.8
Fiscal year 1976	18.0
Fiscal year 1977	18.5

Research activities will emphasize particularly biological controls research including: toxicology of chemosterilants, irradiation of male insect pests, use of fish and noxious plants, parasitic predation and pathogen approach, genetic factors for insect and disease resistance, population studies at crop sites, and cropping and habitat modification studies.

If you desire any further clarification, I will be happy to furnish additional information.

Sincerely yours,

DAVID D. DOMINICK,
Assistant Administrator for Categorical Programs.

MOFFAT, WELLING, TAYLOR & PAULSEN,
Salt Lake City, Utah, August 17, 1972.

Hon. FRANK E. MOSS,
Senate Office Building,
Washington, D.C.

DEAR SENATOR: I am writing you on behalf of Federated Dairy Farms, Inc. You have rendered various services on behalf of this farmers' organization in the past, and they have asked me to call a matter to your attention.

I understand that you are a member of the Senate Commerce Committee, which has before it the Federal Environmental Pesticide Control Act of 1972 (HR 10729). I am informed that the bill has been approved by the Senate Committee on Agriculture and Forestry, and as so approved is supported by the members of Federated Dairy Farms, Inc.

We are advised that several amendments have been introduced by the Senate Commerce Committee which, in the opinion of the people I represent, would impose unnecessary burdens on those who must use pesticides.

One amendment would impose a maximum civil penalty of $10,000 for a violation by a farmer, householder, or any other person judged guilty of improperly using a pesticide. This maximum civil penalty would be ten times as great as the maximum fine which could be imposed in a criminal case against the same person ($1,000), and twice as great as the civil penalty which could be imposed on a manufacturer or distributor of a dangerous, unregistered pesticide or on a professional applicator ($5,000).

Farmers recognize the importance of observing reasonable user restrictions regarding chemical pesticides. Reasonable user restrictions can be implemented, however, without imposing undue burdens and restrictions that might pose grave implications for farmers and others who must depend upon the use of pesticides to produce quality food at a price consumers can afford to pay.

Uneconomic production of foods and fibers can only lead to higher prices to be borne by the public.

I am sure that your cooperation in this matter would be appreciated by the members of Federated who, as I have indicated to you in the past, are truly representative of a substantial part of the agricultural community in Utah.

Best personal regards,

Sincerely yours,

D. HOWE MOFFAT.

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