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LABELING AND REGISTRATION OF

GOVERNMENT
ECONOMIC POISONS
Storage

HEARING
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON
AGRICULTURE AND FORESTRY
UNITED STATES SENATE
EIGHTY-EIGHTH CONGRESS
FIRST SESSION

ON

S. 1605

A BILL TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE,
AND RODENTICIDE ACT, AS AMENDED, TO PROVIDE FOR
LABELING OF ECONOMIC POISONS WITH REGISTRATION
NUMBERS, TO ELIMINATE REGISTRATION UNDER PROTEST,
AND FOR OTHER PURPOSES

SEPTEMBER 10, 1963

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LABELING AND REGISTRATION OF ECONOMIC POISONS

TUESDAY, SEPTEMBER 10, 1963

U.S. SENATE,
SUBCOMMITTEE ON AGRICULTURAL RESEARCH
AND GENERAL LEGISLATION OF THE
COMMITTEE ON AGRICULTURE AND FORESTRY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m., in room 324, Old Senate Office Building, Senator B. Everett Jordan (chairman of the subcommittee) presiding.

Present: Senators Jordan and Neuberger.

Senator JORDAN. The hearing will come to order, please.

We are here this morning to have a hearing on S. 1605, by Mr. Ribicoff, Mr. Pearson, and others.

I have reports here from the Department of Agriculture, the Department of Health, Education, and Welfare, and the Department of the Interior, which I want to insert in the record at this point.

(S. 1605 and reports referred to follow:)

[S. 1605, 88th Cong., 1st sess.]

A BILL To amend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide for labeling of economic poisons with registration numbers, to eliminate registration under protest, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 2.z(2) (b) of the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163, as amended, 7 U.S.C. 1958 ed., Supp. III, 135(z) (2) (b)) is hereby amended by inserting before the semicolon at the end thereof the following phrase: "other than the registration number assigned to the economic poison".

Sec. 2. Section 3 of said Act (61 Stat. 166; 7 U.S.C. 135a) is hereby amended by deleting the word "and" at the end of section 3.a.(2) (b), changing the period at the end of section 3.a.(2) (c) to a semicolon, and adding after section 3.a.(2) (c), a new provision reading as follows: "and (d), when required by regulation of the Secretary to effectuate the purposes of this Act, the registration number assigned to the article under this Act".

Sec. 3. Section 4 of said Act (61 Stat. 167; 7 U.S.C. 135b) is hereby amended by changing the word "registrant" wherever it appears in subsection a. and in the first sentence of subsection c. to "applicant for registration" and by deleting the remainder of subsection c. and inserting in lieu thereof the following:

"If, upon receipt of such notice, the applicant for registration does not make the corrections, the Secretary shall refuse to register the article. The Secretary, in accordance with the procedures specified herein, may require the modification of the claims or labeling of, or cancel the registration of, an economic poison whenever it does not appear that the article or its labeling or other material required to be submitted complies with the provisions of this Act. Whenever the Secretary determines that registration of an economic poison should be refused, or that an economic poison that is registered does not appear to warrant the claims made for it or that the article or its labeling or other material required to be submitted does not comply with the provisions of this Act, he shall notify the applicant for registration or the registrant of his determination and the

reasons therefor. Within thirty days after service of such notice, the applicant for registration or the registrant may file a petition requesting that the matter be referred to an advisory committee to be appointed by the Secretary. Each such advisory committee shall be composed of experts, qualified in the subject matter and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee. The Secretary shall forthwith submit to such committee the application for registration in the article and all relevant data before him. The petitioner, as well as representatives of the United States Department of Agriculture, shall have the right to consult with the advisory committee. As soon as practicable after any such submission, but not later than sixty days thereafter, unless extended by the Secretary for an additional sixty days, the committee shall, after independent study of the data submitted by the Secretary and all other pertinent information available to it, make a report and recommendation to the Secretary as to the registration of the article. After due consideration of the views of the committee and all other data before him, the Secretary shall make his determination and issue an order, with findings of fact, with respect to registration of the article and notify the applicant for registration or registrant. Any person adversely affected thereby may file objections thereto and request a public hearing thereon. In the event a hearing is requested, the Secretary shall, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and issue an order granting, denying, or canceling the registration or requiring the modification of the claims or the labeling. Such order shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reason certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the order is based. All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary and by such advisory committee until final action is taken concerning registration of the product. Until such final action such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying out of their official duties under this section. Notwithstanding any other provision of this section, the Secretary may, when he finds that such action is necessary to prevent an imminent hazard to the public, by order, suspend the registration of an economic poison immediately. In such case, he shall give the registrant prompt notice of such action and afford the registrant the opportunity to have the matter submitted to an advisory committee and for an expedited hearing under this section. Final orders of the Secretary under this section shall be subject to judicial review, in accordance with the provisions of subsection d. In no event shall registration of an article be construed as a defense for the commission of any offense prohibited under section 3 of this Act."

SEC. 4. Section 4 of said Act (61 Stat. 167; 7 U.S.C. 135b) is hereby further amended by redesignating subsections d. and e. as subsections e. and f., and by adding a new subsection d., as follows:

"d. In a case of actual controversy as to the validity of any order under this section, 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 his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty 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 Secretary, or any officer designated by him for that purpose, and thereupon the Secretary 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 findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee. If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order. 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 18 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section."

SEC. 5. Subsection 8.b. of said Act (61 Stat. 170; 7 U.S.C. 135f.(b)) is hereby amended by deleting the second proviso therein.

SEC. 6. Subsection 3.a.(1) and subsection 9.a.(1)(b) of said Act (61 Stat. 166, 170; 7 U.S.C. 135a.(a)(1), 135g.(a)(1)(b)) are hereby amended by changing the phrase "has not been registered" wherever it appears therein, to read "is not registered."

SEC. 7. This Act and the amendments made hereby shall become effective upon enactment.

DEPARTMENT OF AGRICULTURE,
Washington, D.C., July 12, 1963.

HON. ALLEN J. ELLENDER,
Chairman, Committee on Agriculture and Forestry, U.S. Senate.

DEAR MR. CHAIRMAN: We wish to thank you for your letter of May 28, 1963, giving us the opportunity to report on S. 1605, entitled "A bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide for labeling of economic poisons with registration numbers, to eliminate registration under protest, and for other purposes."

The bill would permit the labels of economic poisons registered under the act to bear the registration numbers and would authorize the Secretary of Agriculture to require by regulation that registration numbers appear on such labels. It would delete the provisions now in the act for registration of economic poisons under protest and would prescribe the procedures to be followed in refusing or canceling registrations, or requiring modification of claims or labeling of registered economic poisons. Provision would be made for referral of the question of the eligibility of an economic poison for registration to an advisory committee; for public hearing, if requested, with respect to the Secretary's order issued after consideration of the views of the committee and other data; and for judicial review of the order issued by the Secretary after such hearing.

In fulfilling its responsibilities under the act, this Department is hampered by a provision in the act which gives the applicant the right to demand and receive registration under protest when regular registration is denied, even though the denial is based upon a hazard to the public involved in its use. The net effect of a registration under protest is to shift the burden of proof from the applicant to the Department. Thus a chemical formulation not acceptable to the Department for registration might be marketed for an extended period on a "registration under protest" basis before proof of its harmfulness could be developed. The

intent of S. 1605 is to eliminate registrations under protest and to give this Department authority to deny or cancel any registration or require modification of claims or labeling in any case, after opportunity for referral of the matter to an advisory committee and a public hearing, but with authority for immediate suspension of any registration when the Secretary of Agriculture finds that such action is necessary to prevent an imminent hazard to the public or any portion thereof.

This Department recommends enactment of the bill if the following changes are made.

In section 3 of the bill, page 3, line 7, after "Secretary.", insert the following new sentence: "The Secretary on his own motion, may at any time refer such a matter to an advisory committee." It is believed that this authority in the Secretary is desirable.

In section 3 of the bill, page 3, line 19, preceding the period, insert the following: " , all of which costs may be assessed against the petitioner, unless the matter was referred to the advisory committee upon the motion of the Secretary without a petition". This change would clarify the responsibility for payment of costs incurred in connection with an advisory committee.

The bill provides that all data submitted to the Secretary or an advisory committee shall be considered confidential until final action is taken concerning registration of the product. However, the bill also provides for such data to be included in the record at the public hearing provided for in the bill. To eliminate this apparent inconsistency, it is suggested that in section 3 of the bill, page 5, lines 20-21, the phrase "final action is taken concerning registration of the product." be deleted and the following be substituted therefor: "the Secretary issues his order concerning registration of the product following consideration of the views of the committee and other data before him." In the next sentence, on line 21, the word "final" preceding "action" should be deleted and "by the Secretary" should be inserted after "action." It is contemplated that under this language the Secretary would be authorized to make such data available to other executive agencies that have an official interest.

Since the provisions of the act for registration under protest would be deleted by the bill, it would appear that the existing registrations under protest would automatically terminate when the amendments made by the bill become effective. However, to avoid any possible question in this respect, it is proposed that in section 7 of the bill, page 8, line 16, the following be inserted preceding the period: " , and all existing registrations under protest issued under said Federal Insecticide, Fungicide, and Rodenticide Act shall thereupon terminate."

The Bureau of the Budget advises that there is no objection to the submission of this report from the standpoint of the administration's program.

Sincerely yours,

ORVILLE L. FREEMAN, *Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,

August 29, 1963.

HON. ALLEN J. ELLENDER,
Chairman, Committee on Agriculture and Forestry,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of June 6, 1963, for a report on S. 1605, a bill "To amend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide for labeling of economic poisons with registration numbers, to eliminate registration under protest, and for other purposes."

The two objectives of this bill—objectives that we fully endorse—are stated in its title. Under present law, if the Secretary of Agriculture determines that an economic poison offered for registration under the Federal Insecticide, Fungicide, and Rodenticide Act would not comply with the various substantive requirements of the act, he still must, if the applicant insists, register the article though "under protest," even when the apparent violation is one that constitutes a hazard to the public health. Likewise, if an economic poison is regularly registered, the Secretary can convert the registration into a registration "under protest" but cannot cancel it outright. And, since the label of the article bears no reference to registration—it is deemed misbranded if it does—purchasers are not apprised of its protested status. The holder of an article registered under protest does incur the risk of greater penalties and automatic termination of the registration

in the event of conviction for a violation of the act, but in order to achieve this, the Government would first have to carry the burden of proving beyond a reasonable doubt noncompliance with the act's substantive requirements, such as labeling giving adequate directions for use and adequate warnings to prevent injury. The burden should, we think, be on the manufacturer to show, before an economic poison may be registered, that the article may be safely and effectively used under the proposed labeling, so that on the one hand an article may be marketed in reliance on the registration so long as it is in effect and the article and its labeling are the same as that which has been registered and, on the other hand, deviation from the registered article or its labeling will per se constitute a violation.

The present bill would—in addition to authorizing the Secretary to require the label of the economic poison to bear a registration number—substitute for the present protest-registration procedure detailed provisions that would authorize the Secretary to refuse registration, or to cancel the registration (or require modification of the labeling), of an economic poison that he considers to be violative of the act, subject to the applicant's right to have the matter referred to an advisory committee of experts and to have a reconsidered decision of the Secretary after the report of the advisory committee has been obtained, and subject to the right of any person adversely affected by such a reconsidered decision to have an opportunity for public hearing and for judicial review of the Secretary's final decision on the basis of the hearing record. (Pending referral to an advisory committee and hearing, the Secretary would be empowered to suspend registration summarily if found necessary to prevent an imminent hazard to the public.)

These provisions would carry out procedurally two of the recommendations (i.e., recommendations D. 1 and 2) in the recent report of the President's Science Advisory Committee on the "Use of Pesticides." We defer to the view of the Secretary of Agriculture as to whether these provisions are adequate, not only to do away with registration under protest but, as above suggested, to put the burden on the applicant to prove compliance with the substantive requirements of the act as to safety and effectiveness before the article may be registered, instead of placing the burden, in the last analysis, on the Secretary to prove that the article does not comply before he may refuse registration. We believe, however, that in any event certain amendments to the bill are needed from the point of view of the impact of the bill on this Department.

1. Amendments to clarify, extend, and improve the relationship between the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act with respect to economic poisons that may leave a residue in or on food

The Food, Drug, and Cosmetic (FDC) Act provides, through various regulatory procedures, for premarketing clearance for safety, including establishment of safe tolerances, for extraneous substances in or on food (including feed) that are either intended as components of food or the use of which may reasonably be expected to result in leaving a residue in food. If such a substance is present in or on food at the time of, or subsequent to, introduction of the food in interstate commerce, the food is deemed unsafe, and hence adulterated, unless the use of the additive and the amount involved are sanctioned by a clearance regulation then in effect or are exempted by the act or regulation. Chemicals that are "economic poisons" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) may be subject to one of two of these premarketing clearance procedures under the Food, Drug, and Cosmetic Act, depending upon whether the chemical is used in the production, storage, or transportation of crops or other raw agricultural commodities—in which event it is referred to as a "pesticide chemical" subject to the clearance procedure of the pesticide chemicals amendment—or is used otherwise, in which event it is, generally, subject to the clearance procedure of the Food Additives Amendment of 1958 as a "food additive" (unless it is classified as a color additive).

In the case of "pesticide chemicals" as above defined, where in the opinion of the Department of Agriculture the proposed use of the chemical in accordance with label directions will leave a residue on a raw agricultural commodity, that Department will ordinarily delay registration until an applicable tolerance or exemption has been established under the Food, Drug, and Cosmetic Act, on the ground that until the establishment of such a tolerance or exemption it cannot be determined whether there will be a violation of the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, which deem an economic poison mis-

branded if the labeling does not contain necessary directions for use "adequate for the protection of the public" or if the label does not contain necessary warning or caution statements "adequate to prevent injury to living man and other * * * animals * * *." (See Regs., 7 CFR 363.11.) We understand that extension of this procedure to situations where an economic poison offered for registration is intended for use in connection with food other than raw agricultural commodities is under consideration, though not as yet in effect. However, we assume that, under present law, the applicant could insist upon registration without awaiting a determination by this Department under the Food, Drug, and Cosmetic Act, though in such cases he might have to accept a registration under protest.

Whatever the basis for the above-mentioned procedure under the Federal Insecticide, Fungicide, and Rodenticide Act in its present form, with its escape hatch of registration under protest, we seriously doubt that, under the amendments proposed by the bill, the Secretary of Agriculture would be authorized to delay his decision, initially or otherwise, on the ground that there has been no determination under the Food, Drug, and Cosmetic Act. The provisions of the bill, with their built-in time limits, emphasize the desirability of expeditious procedure. Moreover, even if the Secretary should manage to defer his decision with respect to registration until a tolerance or exemption under the Food, Drug, and Cosmetic Act has been granted or denied, this would apparently not, as the bill is written, require or authorize him to deny registration simply on the basis of the decision reached under the Food, Drug, and Cosmetic Act; nor could the Secretary, after registration has been granted, cancel such registration simply on the basis of the decisions reached under the Food, Drug, and Cosmetic Act, such as a modification of a previously established tolerance. The hearing provisions of the bill, particularly, seem to contemplate an independent administrative decision of the Secretary of Agriculture (subject to judicial review on the record) "based only on substantial evidence of record at such hearing" (including any report of an expert advisory committee appointed under the bill), and the grounds on which the decision would have to be based would be failure to comply with substantive provisions, including those relating to safety, of the Federal Insecticide, Fungicide, and Rodenticide Act rather than with applicable standards or regulations under the Food, Drug, and Cosmetic Act. This involves the risk of duplicative, and even dichotomous, decisions of the two departments contrary to their mutual desire and contrary to the public interest.

The bill is therefore in need of amendment to prevent these results and to formalize in law, perfect, and extend to all foods the now-existing procedure applied under the Federal Insecticide, Fungicide, and Rodenticide Act with respect to economic poisons used in connection with raw agricultural commodities. This could be accomplished by amendments as follows:

(a) A requirement that an application for registration of an economic poison be accompanied by a satisfactory method of analysis which could be used to determine the presence or absence of residues in food, if the economic poison is intended for use in the production, handling, transportation, or storage of food, or for some other use that may reasonably be expected to result in leaving a residue in food when used as directed or under reasonably foreseeable conditions of use. Such an analytical method is needed both to determine whether the article should be registered on a "no residue" basis and, after such registration, whether its use bears out the expectation of "no residue."

(b) In the case of an economic poison which is intended for a use described in the preceding paragraph, a requirement that the application for registration be accompanied by full reports of adequate scientific investigations as to the amount of residues remaining in or on food.

(c) A requirement that an economic poison may not be registered unless and until this Department has certified a finding either (1) that there is no reasonable likelihood that the article will result in a residue in or on food (at or after the introduction of the food into interstate commerce), or (2) that the residue likely to result will not be deemed unsafe under the Food, Drug, and Cosmetic Act (because of a tolerance or exemption we have established, or because of other facts stated in the certification). Provision should also be made for mandatory cancellation of the registration upon certification by this Department that the earlier findings are no longer applicable by reason of changes in the tolerance or exemption previously established or of other action under the Food, Drug, and Cosmetic Act, or by reason of actual experience as to the residues which result from the use of the economic poison.

(d) The standard to be applied in determining whether a chemical should be registered is the amount of residue, if any, in or on food, that is likely to result if the chemical is used in accordance with directions or otherwise under reasonably foreseeable conditions of use. The standard to be applied in determining whether registration should be canceled is the amount of residue that is resulting from actual use of the chemical, either as directed, or under other conditions of actual use that may reasonably be expected to be followed in practice to a substantial extent.

We are enclosing draft language to carry out these recommendations.

2. *Amendments to make information available to other agencies concerned.*

We believe that the confidentiality provisions of the bill in section 3 could be a bar to proper administration, and we therefore not only endorse the recommendation in the Secretary of Agriculture's comments dealing with the proposed amendments of lines 20 and 21 on page 5 of the bill, but also recommend that the law make a specific provision, along the lines of an amendment enclosed herewith, to make it clear that the Secretary of Agriculture is not barred from providing information submitted to him to any other Federal agency consulted.

Before closing this report, we should like to note that the President has asked the responsible agencies to implement the recommendations in the Science Advisory Committee's report, including in such implementation the preparation of proposals for submission by him to Congress.

With respect to economic poisons that leave no residue in or on food but have other implications with respect to public health, we are currently engaged in evaluating the statement in the report of that Committee that "decisions on registration, clearly related to health, should be the responsibility of the Department of Health, Education, and Welfare," and the Committee's recommendation B. 4, that the "Secretaries of Agriculture, Interior, and Health, Education, and Welfare review and define their roles in the registration of pesticides that are not present on food, but that may impinge on fish and wildlife or come into intimate contact with the public." Additional proposals for the amendment of the Federal Insecticide, Fungicide, and Rodenticide Act could eventuate in the light of these Committee recommendations. We also intend to review the need for special controls over especially hazardous persistent economic poisons, whether used in connection with food or otherwise, and the question whether the availability of a new and less hazardous substance should be ground for changing the status of a previously registered article.

At this time, we recommend, for the above-stated reasons, the enactment of this bill, modified in accordance with the proposed amendments enclosed herewith which would carry out the specific recommendations of our report.

We are advised by the Bureau of the Budget that while there is no objection to the submission of this report from the standpoint of the administration's program, the matter of relationships between the food and drug and pesticide registration programs is still under study in the executive branch and a final decision will be reached thereon as soon as possible.

Sincerely,

(Signed) PHILIP H. DES MARAIS,
Acting Assistant Secretary.

PROPOSED AMENDMENTS TO THE BILL RE ECONOMIC POISONS LEAVING RESIDUES
IN OR ON FOOD

1. On page 6, change lines 15 and 16 to read as follows: "tions d. and e. as subsections f. and g., and by inserting before such redesignated subsections the following new subsections, as follows:."

2. On page 6, line 18, insert "subsection c. of" after "under."

3. Strike out the closing quotation marks on page 8, line 6, and insert between lines 6 and 7 the following:

"e. (1) The provisions of this subsection shall apply notwithstanding any other provisions of this Act.

"(2) For the purposes of this section, the registration of an economic poison shall not be valid with respect to any change from the claims therefor or the labeling or composition thereof as described in the application upon which such registration is based, except upon the filing of a supplement to such application in accordance with such change and issuance of an order confirming such registration: *Provided*, That no such supplement need be filed with respect to a change that is not significant from the standpoint of safety or effectiveness or

from the standpoint of the residue of the economic poison remaining in or on food. As used in the following paragraphs of this subsection, the term "application for registration" includes a proposed supplement to an application on which a previous registration is based and a request pursuant to subsection g. for continuation of a registration, and the terms "register" and "registration" include confirmation or continuation of registration pursuant to such a supplement or pursuant to such a request.

"(3) A copy of every application for registration of an economic poison, and of any statement or other data filed in connection therewith, shall be transmitted by the Secretary to the Secretary of Health, Education, and Welfare, together with an opinion of the Secretary of Agriculture as to whether, on the basis of the data before him, such economic poison, when used as directed or otherwise under reasonably foreseeable conditions of use, is likely to result in a residue in or on food and, if so, the amount of such residue.

"(4) (A) An economic poison shall not be registered unless and until the Secretary of Health, Education, and Welfare has certified, on the basis of the data before him and after appropriate consideration of the opinion of the Secretary of Agriculture submitted under paragraph (3), that he finds (i) that such economic poison, when used in accordance with directions or otherwise under reasonably foreseeable conditions of use, is not likely to result in a residue in or on food (at or after the introduction thereof into interstate commerce), or (ii) that the residue likely to result from such use will, by reason of its conformance with a tolerance or exemption established under the Federal Food, Drug, and Cosmetic Act or by reason of any other facts found and stated in such certification, not be deemed unsafe within the meaning of section 406, 408, 409, or 706 of such Act.

"(B) Such certification shall in any event be refused unless the application and other data submitted to the Secretary of Health, Education, and Welfare under paragraph (3) or submitted to him directly by the applicant include the following:

"(i) Full data showing the chemical identity and composition of the economic poison.

"(ii) Practicable and reliable methods of examination for determining the amount of residue, if any, of such economic poison in or on food if such economic poison is intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, or is intended for any use that may reasonably be expected to result, directly or indirectly, in its leaving a residue in or on food when used as directed or otherwise under reasonably foreseeable conditions of use.

"(iii) Full reports of adequate investigations (made in accordance with the methods referred to in clause (ii)) showing the amount of such residue, if any, remaining in or on food when such economic poison is used as directed or otherwise under reasonably foreseeable conditions of use, except that such investigations, if not made, may be dispensed with by such Secretary if such economic poison is not intended for a use described in clause (ii).

"(5) Whenever the Secretary of Health, Education, and Welfare certifies that he finds (A) that, by reason of action (specified in such certification) taken under section 406, 408, 409, or 706 of the Federal Food, Drug, and Cosmetic Act, as the case may be, the probable residue of an economic poison in or on food assumed as a basis for a prior registration of an economic poison would now be deemed unsafe within the meaning of such section, or (B) that the actual use of such economic poison as directed, or under other conditions of actual use that may reasonably be expected to continue to be followed in practice to a substantial extent, has resulted in leaving in or on food, at or after the introduction thereof in interstate commerce, a residue that for reasons stated in such certification is deemed unsafe within the meaning of any such section of such Act, the Secretary of Agriculture shall cancel such registration on thirty days' notice, except that, if the order of certification of the Secretary of Health, Education, and Welfare includes a finding of imminent hazard to the public health pursuant to clause (C) of the proviso to paragraph (6) of this subsection, such registration shall be suspended without prior notice pending final action of such Secretary.

"(6) Certifications, or refusals of certification, of the Secretary of Health, Education, and Welfare under this subsection shall be made by order. The procedure for the issuance, amendment, or revocation of such orders, including opportunity for hearing on the record to any person adversely affected by the Secretary's action or proposed action, shall be prescribed by such Secretary by

regulations and shall follow as nearly as practicable the procedure governing orders of the Secretary of Agriculture set forth in subsection c.: *Provided*, That (A) the question whether or on what terms a tolerance, or exemption from the requirement of a tolerance, should be established, modified, or revoked under any provision of the Federal Food, Drug, and Cosmetic Act shall not be put in issue in any proceeding under this section; (B) the referral of a matter to an advisory committee shall not be mandatory on the Secretary of Health, Education, and Welfare unless requested by the applicant or registrant; and (C) where such Secretary finds that there is an imminent hazard to the public health he may immediately make the certification provided for in paragraph (5), in which event he shall give prompt notice to the registrant and afford him the opportunity to have the matter submitted to an advisory committee and for an expedited hearing under this paragraph (6) and shall, after such opportunity, issue a final order confirming, modifying, or setting aside his earlier order. Final orders under this paragraph shall be subject to judicial review on the record in accordance with the procedure set forth in subsection d. of this subsection, and for that purpose the term "Secretary" as used in subsection d. shall mean the Secretary of Health, Education, and Welfare. Notwithstanding the foregoing provisions of this paragraph, the two Secretaries may, to the extent they deem it practicable and in the interest of efficiency and convenience of the parties, provide by joint or parallel regulations for joint hearings before them, in which event judicial review of such orders may be initiated by a single petition.

"(7) As used in this subsection, the term 'residue' includes the breakdown products of an economic poison in foods; and the term 'food' means such term as defined in the Federal Food, Drug, and Cosmetic Act."

4. Change the two sentences beginning on page 5, line 16, to read as follows: "All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary, by any other Federal agency officially consulted by the Secretary in connection therewith, and by such advisory committee until the Secretary issues his order concerning registration of the product following consideration of the views of the committee and other data before him. Until such action such data shall not be revealed to any person other than those authorized by the Secretary, or by an advisory committee in the carrying out of the official duties under this section, or by the head of such other Federal agency."

DEPARTMENT OF THE INTERIOR,
OFFICE OF THE SECRETARY,
Washington, D.C., August 19, 1963.

HON. ALLEN J. ELLENDER,
Chairman, Committee on Agriculture and Forestry,
U.S. Senate, Washington, D.C.

DEAR SENATOR ELLENDER: Your committee has requested this Department's report on S. 1605, a bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide for labeling of economic poisons with registration numbers, to eliminate registration under protest, and for other purposes.

We recommend the enactment of S. 1605, if amended as suggested herein.

This Department, in carrying out its responsibilities of administering our national parks and conserving fish and wildlife, is convinced of the need to provide a more effective means of controlling the use of chemicals potentially harmful to living man, domestic animals, and fish and wildlife. S. 1605 is designed to accomplish this by strengthening the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. sec. 135 et seq.). The bill deletes the provisions of that act permitting registration of economic poisons under protest and establishes procedures for granting, denying, or canceling the registration or requiring the modification of the claims or the labeling by the applicant for registration.

In addition S. 1605 establishes procedures for referring the Secretary's determination that registration of an economic poison should be refused, canceled, or the claims or labeling modified, to an advisory committee appointed by the Secretary, if the applicant or registrant requests this. We understand that the Department of Agriculture has suggested that provision also be made for referral to the committee on the Secretary's motion at any time. The committee then reviews the application and all relevant data, and presumably the determination

of the Secretary, and makes its report and recommendations to the Secretary. The bill then provides for the Secretary to consider the committee's views and all other data and to make a new determination and issue a new order with a findings of fact. Following this, any aggrieved person may file objections and request and be granted a hearing for the purpose of receiving evidence relevant and material to the issues raised by the objections. After completion of the hearing the Secretary is again required to issue an order, based on the whole record, denying, or canceling the registration or requiring a modification of the claims or the labeling. The order of the Secretary would then be subject to these lengthy procedures, we believe that the procedures may prove to be too cumbersome and work a hardship on all those concerned.

One of the principal concerns of this Department is the effect of pesticides on fish and wildlife. These effects should be considered during the registration of these chemicals. S. 1605 provides an opportunity for a careful consideration of these effects by an advisory committee, in addition to the consideration given by the Department of Agriculture. Each advisory committee shall include experts selected by the National Academy of Sciences and one or more persons from land-grant colleges. Since the bill specifically provides for representatives of these colleges, we believe that a provision for including on such a committee one or more persons familiar with the effects of pesticides on fish and wildlife also is necessary. Accordingly, we recommend that page 3, line 11, of the bill be amended by striking the period after "colleges" and inserting a comma and the following clause: "and one or more biologists familiar with the effects of pesticides on fish and wildlife."

In the alternative, however, we would not object to deleting the provision for including representatives of land-grant colleges and one or more biologists. We believe that the bill is broad enough to permit the National Academy of Sciences to include such representatives when necessary without specifically providing for such representation. Further, there may be occasions where their representation would serve no useful purpose.

Section 3 of the bill, among other things, authorizes the Secretary of Agriculture to order the suspension of the registration of an economic poison immediately, when he finds such action is necessary to prevent an imminent hazard to the public. This would be applicable to economic poisons now registered under the act. Procedures similar to those described for registering pesticides would be applicable to suspended registrations. We believe this provision is essential. However, we believe that the term "public" may not include fish and wildlife and other natural resources. Accordingly, we recommend that S. 1605 be amended on page 6, line 3, after the word "public," by inserting therein "including an imminent hazard to man, or animals or plants useful to man, including useful fish and wildlife."

The Bureau of the Budget has advised that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely yours,

/s/ STEWART L. UDALL,
Secretary of the Interior.

Senator JORDAN. Mr. Newman, will you come forward?

You have a statement from Senator Ribicoff, who is one of the authors of this bill, and who is on his way to Belgrade right now. He did not know at the time we set this hearing he would be leaving. He asked that his statement might be inserted in the record, which, of course, we are glad to do. And we are sorry he cannot be here in person. But it is understandable. He has gone over to the Inter-parliamentary Union. He has done a lot of work on this bill.

We are glad to have Mr. Newman to bring this.

This will be inserted in the record at the very beginning of this hearing. And we appreciate your bringing it in.

(The statement referred to follows:)

STATEMENT OF HON. ABRAHAM RIBICOFF, A U.S. SENATOR FROM THE STATE OF CONNECTICUT

Mr. Chairman, members of the subcommittee, I appreciate this opportunity to appear here this morning in support of S. 1605. The subcommittee is doing the Nation a real service by the speedy action that is being taken on this important legislation.

My comments will be brief, this morning, as I know you have many expert witnesses to hear in the next 2 hours. I do want to emphasize the importance of the legislation before you. Since its introduction two additional products have reached the market without satisfactory proof of safety. Both were the so-called continuous action lindane vaporizers which have never been proven safe for home use.

As you know, S. 1605 would end the practice of protest registration whereby the manufacturer of a pesticide can market a product despite Department of Agriculture doubts as to its effectiveness or safety.

Fortunately, we have been able to avoid a national tragedy while this gap in consumer protection remained in the law. Only a very few products, a list of which is attached, out of the thousands registered, have been "protest registered" over the past 16 years. Even these have been too many and it is time to close the gap.

Despite our relatively good fortune in the past, the danger of an unsafe product coming on the market is always with us under existing law. Let me give you a few examples of what I mean.

1. A number of manufacturers have submitted for registration under the Federal Insecticide, Fungicide, and Rodenticide Act labeling for chlordane aerosol formulations for household use. These were intended for use in controlling various household pests, including flies and mosquitoes. Registration was refused for products bearing directions for use which would result in an aerosol dispersal of chlordane. USDA pharmacologists did not consider such a use to be safe. Their judgment was based partly on the findings of the Food and Drug Administration, which showed that chlordane formulations in some cases could produce skin and eye irritation. Since aerosol uses risk contact of the spray with skin and eyes, such usage could not be accepted and registration was refused. The Public Health Service was asked to review this matter and endorsed the decision.

2. On a number of occasions registration of floor waxes containing dieldrin has been requested. Such products were intended for use in controlling various household insects. USDA pharmacologists did not consider complete floor coverage with such waxes to be safe, and refused to register them. Dieldrin formulas for household use required directions which would not exceed the patterns set forth in USDA interpretation 19. It was concluded that no directions could be written which would meet the requirements of this interpretation, and still provide a useful floor wax.

3. USDA was asked by one firm to consider registration of a parathion formulation for use in rodent control. Another firm asked USDA about the possibility of obtaining registration for a parathion product for household use, and for the control of fleas and other pet insect parasites. These firms were informed that such uses were unacceptable due to the high toxicity of parathion. USDA toxicological experience and the scientific literature indicated that such use would be hazardous and would risk injury or death. Since there was much more than a "reasonable doubt" as to the propriety of the use, registration was denied.

4. As a result of cases of methemoglobinemia reported in premature infants on whom diapers treated with disinfectants containing TCC were used, USDA reviewed the registration status of all formulations containing this compound. Registration was canceled on several products where directions for use involved industrial laundry soaps wherein the treated diapers or clothing could likely be autoclaved in routine hospital practice. Due to this action, all such products were removed from use. This specific action was taken, since detailed studies have proved that TCC was capable of decomposition, and diapers were able to absorb the breakdown products in hospital autoclaves. In addition, USDA required manufacturers to place on the labels of certain laundry products warnings against boiling or autoclaving.

Each of these four products could be on the market today under protest registration. Only after accumulation of considerable evidence could USDA move against them and cause their removal. The public, in the meantime, would serve as guinea pig. This bill makes sure that such a possibility will not happen.

The policy of this Nation should always be that a pesticide should not come on the market until adequate proof of safety has been established and it should not be left for the public to play the role of guinea pig while the true facts of toxicity are brought out. Today, it is possible under the law to subject the public to that role when the Government is not satisfied with the manufacturer's proof of safety and yet lacks definite evidence of lack of safety. That gray area must be decided in favor of the public—the consumer.

As you know, protest registration was supposedly a technique to force a court review whenever the manufacturer and the Government disagreed on the safety or effectiveness of the product in question. The proposed legislation rejects this archaic concept of consumer protection and substitutes a system under which both the public's interest and a manufacturer's rights are protected. And this protection runs from the initial decision, through an advisory committee, through a hearing on the record, through judicial review.

In addition, the legislation requires that every pesticide formulation carry its official registration number on the label. In this way the public will be able to tell at a glance that the product on the shelf has satisfied the requirements of Federal law as to its effectiveness and safety when used according to the direction on the label.

This legislation is recommended by the President's Science Advisory Committee. It has been endorsed by the heads of the various affected Federal agencies, the regulated industry and by every witness to appear before our Senate subcommittee now studying the problem of the use of pesticides. I know the cosponsors of S. 1605—Senator Pearson of Kansas, Senator Pell of Rhode Island and Senator Javits of New York—join me in urging your favorable consideration of this important measure.

Mr. NEWMAN. May I say for the Senator he is very appreciative of your courtesy in scheduling this hearing at this time. He regrets the scheduling of his trip was such—this very minute his plane is leaving for Belgrade.

Senator JORDAN. For your information—this is just par for the course in the Senate. I set this hearing at his request at the time that suited him. Now he is in Belgrade.

It would have been just about the same thing if I had been absent myself—because that happens quite often—which we cannot help. There is no way we can regulate it.

I was just informed Senator Pearson, another author of this bill, is on his way to Belgrade, also. We will get his statement, and insert it in the record as soon as he supplies one for us—because he was supposed to have been here this morning.

(The statement referred to follows:)

STATEMENT OF THE HON. JAMES B. PEARSON A U.S. SENATOR FROM THE STATE OF KANSAS

Mr. Chairman, members of the subcommittee; I appreciate this opportunity to express my support of S. 1605. Under the able chairmanship of Senator Ribicoff, the Reorganization and International Organizations Subcommittee of the Committee on Government Operations, has been engaged for several months in hearings on the intergovernmental and interagency aspects of the registration and control of use of pesticides. Throughout these hearings, as a member of this subcommittee, I have been impressed with the evidence of the rapid expanse of use of these particular chemicals.

Pesticides have become vital, if not essential tools to the carrying on of a successful agricultural economy. Especially significant is the impact pesticides have made on the improved quality and reduced cost of agricultural products. They have benefited the farmer by reducing fear and labor, as well as the heartbreaking loss which he previously suffered from a crop loss due to infestation of insects, rodents, and weeds.

The health and comfort of our people have also benefited almost beyond belief as we have reduced disease and the insect nuisance by the use of these chemicals.

In total, the benefits from the availability and use of pesticides have been great and the harmful effects have been relatively small. This condition is, I am sure, the result of the general concern for the public interest demonstrated by the chemical industry, the formulators and applicators, and the host of able and dedicated public servants in the Department of Agriculture and the Public Health Service whose responsibility it is to test, register, and observe the use and effects of these chemicals.

The present effective and high level of safe use is also due to the foresight of the Congress as represented by its passage of the Federal Insecticide, Fungicide and Rodenticide Act several years ago.

Nevertheless, times change and we benefit by experience. It has now become obvious that the registration under protest procedure, with which S. 1605 deals, has now proven to be unsatisfactory although at the time the regulatory act was passed, it seemed necessary and adequate. Not only is a better procedure available, but the under protest registration provides an opportunity to negate the beneficial aspects of existing review and regulatory procedures, and in fact, jeopardizes the integrity of legitimate registered products.

It is a fact that a relatively few products have been marketed using the registration under protest procedure. Most manufacturers accept the responsibility which is theirs and comply with the Department of Agriculture's registration requirements. The few products which have reached the market make it clear that we cannot afford that the law now permits a potential danger to exist. A danger which is within our capacity to eliminate. S. 1605 provides a procedure to eliminate the under protest registration which has been tested and accepted for the registration of drugs by the Food and Drug Administration and one which will protect the consumer without placing undue burdens upon the producers of the products involved.

I strongly urge the committee approval of S. 1605 with careful attention to the amendments submitted by the Department of Agriculture and the affected industry.

Senator JORDAN. I have been informed, also, that a third sponsor, Senator Pell, had a statement he wanted to make on this bill, and he will file it later.

(The statement referred to follows:)

STATEMENT OF HON. CLAIBORNE PELL, A U.S. SENATOR FROM THE STATE OF RHODE ISLAND

As a member of the subcommittee of the Committee on Government Operations which has been investigating the dangers of unregulated use of pesticides, I should like to add my full support to S. 1605 which would make it more difficult for a manufacturer to market a pesticide, when the safety or effectiveness of that product is still in doubt.

I am advised that this bill is designed to protect the public against those very few manufacturers who persist in marketing their products over objections raised by the Department of Agriculture. The vast majority of manufacturers now comply with the requests of the Department but there is a very small number, 1 in every 2,280 registrations now granted, who insist on securing protest registrations. Although this is admittedly a very small area of noncompliance, it could be a lethal one if a dangerous product were to be admitted to the market.

S. 1605 would protect the public against this risk by establishing new and more rigorous procedures for registration. At the same time, it would protect the rights of manufacturers by permitting judicial review of adverse decisions. I am fully convinced that this legislation is wholly desirable and that it should be promptly enacted.

Senator JORDAN. We will leave the record open if anyone else wants to file a statement.

Dr. Clarkson, I believe you are first on the agenda here—Associate Administrator, Agricultural Research Service, U.S. Department of Agriculture.

We are glad to hear you, sir.

You have a prepared statement?

Dr. CLARKSON. Yes, it has been distributed, sir.

Senator JORDAN. Are you going to follow your prepared text?

Dr. CLARKSON. I would like to, if I may.

I have with me Mr. Justus Ward, who is the Director of the Pesticides Regulation Division.

Senator JORDAN. Mr. Ward, we are glad to have you, sir.

Mr. WARD. I am glad to be here, sir.

**STATEMENT OF DR. M. R. CLARKSON, ASSOCIATE ADMINISTRATOR,
AGRICULTURAL RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE**

Dr. CLARKSON. We appreciate the opportunity to appear before you to express the views of the Department of Agriculture regarding S. 1605, now under consideration by this committee.

The bill would delete the provisions now in the act for registration of economic poisons under protest, and would prescribe the procedures to be followed in refusing or canceling registration or requiring modification of claims or labeling of registered economic poisons.

The intent of the bill also is to permit the labels of economic poisons registered under the Federal Insecticide, Fungicide, and Rodenticide Act to carry the registration numbers and to authorize the Secretary of Agriculture to require, by regulation, that such registration numbers appear on the labels.

In the registration of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act, the Department must consider both the effectiveness and safety of each product submitted. This requires the most careful evaluation of a wide range of products.

These products are complex. Although many of them have similar properties, each one differs from the others in some important aspect. They vary from insecticides for corn borers to repellants for mosquitoes; from nematocides to protect tobacco to ant and cockroach killers; from herbicides for control of weeds in lawns to killers of rats and mice; from fungicides to prevent decay in wood to insecticides for malaria mosquitoes. Over 50,000 formulations based on more than 500 individual chemical compounds have been registered.

When an applicant is seeking registration of a new pesticide, detailed and convincing data must be furnished to the Department showing that the product will give effective and safe pest control under the proposed conditions of use. He must furnish the labels to be used on the containers. Several hundred pages of charts, formulas, and text setting forth the results of testing may be required to support an application for a new chemical.

The data submitted by the applicant is studied by a competent staff of scientists, including pharmacologists, entomologists, bacteriologists, chemists, biologists, and and plant pathologists. If the Department feels more data are needed for evaluation in support of the claims of the applicant, the Department asks that it be provided. If the Department feels that a proposed label does not contain adequate directions and warnings to protect the public, the applicant is asked to make the necessary corrections. If the evidence is convincing that the proposed

chemical is safe and effective when used as directed and all labeling requirements are met, the Department grants a registration.

The Department is hampered by one feature in the act which gives the applicant the right to demand and receive "registration under protest" when regular registration is denied, even though the denial is based upon lack of adequate data to prove the safety or effectiveness of the proposed use. The net effect of a registration under protest is that: (1) An economic poison which the Department believes is not entitled to registration under the act is nevertheless distributed in commerce; (2) State officials responsible for the regulation of pesticides within their States are hampered in bringing the same or similar products into conformity with State requirements; and (3) the burden of proof as to the safety and effectiveness of the product in relation to the Federal Insecticide, Fungicide, and Rodenticide Act shifts from the applicant to the Department.

Accordingly, a formulation that is not acceptable to the Department for registration might be marketed for an extended period of time on a "registration under protest" basis until the Department can develop the extensive performance and toxicity records essential for effective court action to remove the product from the market.

The proposed legislation would eliminate registrations under protest and give the Department authority to deny or cancel any registration, or require modification of claims on labeling in any case, with provision for the applicant to request that the matter be referred to an advisory committee or to request a public hearing. Additionally, the Secretary would be given authority for immediate suspension of any registration when he finds such action is necessary to prevent an imminent hazard to the public. Such hazard might be directly to human health or safety, or present an imminent danger to livestock, crop, or fish and wildlife values.

The bills under consideration also provide for the presence on the label of the Federal registration number assigned to a product. This would readily identify products registered with the Department for marketing in interstate or foreign commerce. As it now stands, there is nothing on the label to distinguish between those formulations registered with the Federal Government and those that may be packaged and offered for sale without registration, and the law actually forbids any reference to registration on the label or in the labeling. The Department thinks it is advisable to provide for requirement of the registration number on the labels by regulation in order to afford flexibility in applying such requirement to classes of products where it will protect purchasers or otherwise effectuate the purposes of the act.

The Department heartily supports this bill, as indicated in our report on S. 1605 to the committee on July 12, 1963. Secretary Freeman expressed concern over the registration under protest provision in the current law when he testified before the Senate Subcommittee on Reorganization and International Organizations earlier this year.

The Department recommends several changes in language for purposes of clarity and better administration, as follows:

Mr. Chairman, these are all set forth in the Department's report on the bill. They are, for the most part, perfecting language, with one exception.

One of them, item 2 on page 5 of my statement, would provide that the party requesting a review before an advisory committee would pay the costs of such an advisory committee. In other words, if the Secretary should ask it, the Department would pay the costs. If this were requested by someone outside the Department, that party would pay the cost of the advisory committee. These costs are not expected to be great. The committee must wind up its work within a reasonably short period of time. It would be the travel and per diem expenses for the committee members.

Senator JORDAN. This is in the cases where a license has been granted, and he has asked for review; is that right?

Dr. CLARKSON. Where registration either has been denied in the first instance, or it has been granted and then canceled by the Department, and the petitioner, or the registrant, feels that this has been done arbitrarily. He may then ask that it be reviewed by this special committee of scientists nominated by the National Academy of Science.

Senator JORDAN. Well, do they have to review it if he asks for a review, or can they deny a review?

Dr. CLARKSON. They have to. The committee would be appointed by the Secretary, but would be merely nominated by the Academy.

Senator JORDAN. In other words, he does have the right of review.

Dr. CLARKSON. He does have the right of review; yes, sir.

Senator JORDAN. You know, we run into cases sometimes where departments get too much authority, and they just say, "This is final," and you don't have any recourse. That, I don't believe in at all. And I don't think you want to put that in the law.

Dr. CLARKSON. No, sir; this would give the party the right to review by the advisory committee, and the right to a public hearing if he so desires.

Senator JORDAN. Fine. Thank you.

You may proceed.

Dr. CLARKSON. Well, if the chairman wishes to go through the amendments, I will be glad to do so. Otherwise, I will leave them with the committee—at your pleasure, sir.

(The amendments are as follows:)

1. In section 3 of the bill on page 3, line 7, after the word "Secretary," insert the following sentence: "The Secretary on his own motion, may at any time refer such a matter to an advisory committee." It is believed that this authority in the Secretary is desirable in the event that he wishes consultation on questions of pesticide safety or effectiveness with expert authorities in other scientific institutions who could contribute information, experience, and judgment to supplement that already available to the Department, in evaluating data submitted by the applicant.

2. In section 3 of the bill, on page 3, line 19, preceding the period, insert the following: "all of which costs may be assessed against the petitioner, unless the matter was referred to the advisory committee upon the motion of the Secretary without a petition." This change would clarify the responsibility for payment of costs incurred in connection with an advisory committee.

3. In section 3 of the bill, on page 4, line 2, change the word "in" following registration to "of". This appears to have been a typographical error.

4. In section 3 of the bill, on page 5, lines 20 and 21, delete the phrase "final action is taken concerning registration of the product," and substitute the following: "the Secretary issues his order concerning registration of the product following consideration of the views of the committee and other data before him." In the next sentence, on line 21, the word "final" preceding "action" should be deleted and "by the Secretary" should be inserted after "action". These changes are submitted to eliminate an apparent inconsistency by the provision

in the bill that considers all data submitted to the Secretary or an advisory committee confidential until final action is taken concerning registration of the product, but also providing for such data to be included in the record at the public hearing provided for in the bill.

5. In section 7 of the bill, on page 8, line 16, insert the following preceding the period: ", and all existing registrations under protest issued under said Federal Insecticide, Fungicide, and Rodenticide Act shall thereupon terminate." Since the provisions of the act for registration under protest would be deleted by the bill, it would appear that the existing registrations under protest would automatically terminate when the amendments made by the bill become effective. However, to avoid any possible doubt in this respect this change is proposed.

Senator JORDAN. There were some amendments proposed by HEW and Interior. Do you want to comment on them?

Do you have a copy of those amendments?

Dr. CLARKSON. I don't have them before me.

Senator JORDAN. You should have had a copy of these things.

Dr. CLARKSON. We have had them—I just don't have them before me.

Senator JORDAN. Here is HEW. Do you want to comment on those amendments?

Dr. CLARKSON. If I might, Mr. Chairman, call attention, first, to the last paragraph of the letter from the Department of Health, Education, and Welfare, which states as follows: "We are advised by the Bureau of the Budget that while there is no objection to the submission of this report from the standpoint of the administration's program, the matter of relationships between the food and drug and pesticide registration programs is still under study in the executive branch, and a final decision will be reached thereon as soon as possible."

Now, as to the Department of Agriculture's position, we are, of course, participating in the general study of this matter which is referred to by the Bureau of the Budget.

We do not, as a Department, accept the amendments put forward by HEW, for two reasons: One, the bill before the committee does not change the interdepartmental relationships of one department with another, but are such as to perfect the work of one department, the Department of Agriculture, which has the responsibility for enforcement of this act. Therefore, it seems to us that amendments of this broad scope are not appropriate at this time.

Secondly, the amendments are so broad that they would in effect remove the administrative authority for decisions under the basic provisions of this act from the Secretary of Agriculture to the Secretary of Health, Education, and Welfare.

As I say, the Department of Agriculture is not in favor of these amendments.

Senator JORDAN. All right.

Now, you have one from Interior. You have seen that?

Dr. CLARKSON. Yes, sir, I have.

Senator JORDAN. There is the amendment.

Dr. CLARKSON. The Department of Interior amendments are in the alternative. They would suggest, in that provision of the bill where the Academy of Science would be asked to nominate scientists to serve on the advisory committee, that it be required that one or more biologists familiar with the effects of pesticides on fish and wildlife must necessarily be included in the group.

We do not think that the scientists should be designated ahead of time in this way. That is, the current provisions do not say whether they should be biologists, chemists, veterinarians, M.D.'s—they make no specification of this kind.

We think it not wise to make this kind of specification—because one cannot judge ahead of time the particular question that may be under review by the advisory committee.

We note, however, that the Department of the Interior has an alternative. They say, "In the alternative, however, we would not object to deleting the provision for including representatives of land-grant colleges and one or more biologists."

In the current provisions, it does say that one of the members of the committee shall be a representative of the land-grant colleges.

We think that this is desirable.

Senator JORDAN. Would he have to be a scientist?

Dr. CLARKSON. He would be a scientist.

Senator JORDAN. I would not think you would want to take the janitor.

Dr. CLARKSON. No, sir.

Mr. Chairman, the nominations are made by the National Academy of Sciences, so I think we can be content that they will be scientists.

We think it good to draw from the land-grant colleges. We think that almost without exception even without this provision, the Academy would draw one or more of the people from the land-grant colleges. Accordingly, if it were omitted from the bill, I don't think any harm would be done.

Senator JORDAN. Dr. Clarkson, I would be glad to ask Mr. Kirk and Mr. Datt to come up and have a seat at the table, if you would like to ask them any questions.

Dr. CLARKSON. I have no questions.

Senator JORDAN. All right.

Does that complete your testimony?

Dr. CLARKSON. Yes, sir.

Senator JORDAN. Thank you very much. I appreciate it very much, having both of you.

Dr. CLARKSON. Thank you, Mr. Chairman.

Senator JORDAN. Mr. Kirk?

Mr. Kirk is Assistant Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare.

Mr. Kirk, we are mighty glad to have you, sir.

Mr. KIRK. Thank you, sir.

Senator JORDAN. Do you have anyone with you?

Mr. KIRK. No, sir.

Senator JORDAN. Mr. Kirk, you may proceed in any way you like, sir.

Mr. KIRK. I have this prepared statement, sir.

Senator JORDAN. Fine. Would you like to read it?

Mr. KIRK. As you like, sir.

Senator JORDAN. You may proceed with it, if you care to.

STATEMENT OF J. K. KIRK, ASSISTANT COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. KIRK. Mr. Chairman, members of the committee, we appreciate this opportunity to comment on S. 1605.

The Department of Health, Education, and Welfare fully endorses the two objectives of this bill. In the case of foods and drugs, the Federal Food, Drug, and Cosmetic Act clearly requires proof of safety before products are placed on the market for public use or consumption. We believe there are sound reasons for applying the same requirement to pesticide chemicals. The bill has ample safeguards whereby an adverse decision by the Secretary of Agriculture may be reviewed. This follows procedures established in cases involving petitions for regulations under the pesticide chemicals amendment to the Food, Drug and Cosmetic Act, which deals with the establishment of tolerances for pesticide residues in or on food.

The second objective of the bill to require registration numbers to appear on labels, is also valuable. Since we are charged with the responsibility for being sure that food products marketed in interstate commerce do not bear or contain illegal residues, we have conducted and participated with the Department of Agriculture in many educational programs calling attention to the need for proper use of pesticide chemicals to avoid the production of illegal crops.

Senator JORDAN. What do you mean by to avoid the production of illegal crops?

Mr. KIRK. Well, if the man uses the pesticides at the wrong time, too close to harvest, or if he is supposed to use 1 pound per acre and he uses 2, he perhaps will end up with a crop which has too much residue. In other words, if the tolerance is, say, five parts per million, he may end up with something higher than that, and that crop is then contraband, subject to seizure.

Senator JORDAN. You mean to say it is not fit for human consumption?

Mr. KIRK. In its present condition. It may be rendered legal, perhaps, by stripping or washing or even weathering.

Senator JORDAN. I wondered just what that term meant, because I did not see how you could produce another crop. It is what might be absorbed in the growing of the plant.

Mr. KIRK. That is right.

Senator JORDAN. Thank you.

Go ahead, sir.

Mr. KIRK. Our theme throughout these programs has been "Read and heed the label as registered by the Department of Agriculture," since the directions and precautions required on registered labels are so designed that, if followed, excessive or nonpermitted residues should not result. Under the present system, the labels do not bear any indication of registration and we have been asked many times how a grower can be sure that the label on the package he buys is, in fact, one which has been registered by the Department of Agriculture. Printing the registration number on the label should correct this situation.

The Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act present a number of mutual problems to the Department of Agriculture and the Department of Health, Education, and Welfare. Under the pesticide chemicals amendment to the Food, Drug, and Cosmetic Act, a petition for a tolerance in or on a raw agricultural product as submitted by a person who wants a registered label for the pesticide must first be reviewed by the Department of Agriculture. We proceed to evaluate the petition only after the Secretary of Agriculture has certified that the product is useful for the purpose intended. If, however, our scientists conclude that a finite tolerance is not justified, the Department of Agriculture does not register the label with directions which would leave a residue. We believe that, especially in view of the formalization of adjudicative procedures in this bill, it should be amended to insert in the Insecticide, Fungicide, and Rodenticide Act specific provisions requiring the Secretary of Agriculture to refuse registration where a residue in or on a food is reasonably to be expected, but where no tolerance or exemption from tolerance has been established under the Food, Drug, and Cosmetic Act. This should encompass both raw agricultural commodities and processed foods.

Some pesticides are proposed for use on food crops where the intent is to use the pesticide without resulting in any residue at the time the crop is marketed. Others are intended for use where application to a food crop is not intended. Unfortunately, the manufacturer's intentions do not always work out in practice, and a weed killer intended for widespread use on roadsides, for example, may contaminate adjoining crops; or a pesticide which is intended to be so used on a food crop that it will result in no residue, actually does leave such a residue, either through use other than in accordance with directions, or because of unanticipated growing conditions.

When this occurs, we may be faced with a significant regulatory problem in protecting the public health, since we must apprehend the produce, demonstrate the presence of the illegal residue, and take immediate steps to remove the food from the market under the seizure provisions of the law.

Obviously, we cannot fulfill our obligations in such cases unless we have a method of determining the presence of the pesticide residue. In establishing tolerances, the Food, Drug, and Cosmetic Act requires that we be supplied with a method of analysis adequate for enforcement purposes. There is no requirement in the Insecticide, Fungicide, and Rodenticide Act for the submission of adequate methodology where the use of a pesticide submitted for registration involves a nonfood crop, or where the petitioner proposes registration for use on a crop and believes that his data demonstrate that no residue would result from use as directed.

In fact, there is no legal requirement that the FDA even be consulted on these cases if the Department of Agriculture scientists agree with the petitioner, although in actual practice there are informal discussions between the two units in cases where the USDA people believe that there may be unresolved questions.

We are convinced, therefore, that for the safety of our food supply, it is in the public interest to require, by statute, where there is a reasonable expectation that the pesticide may contaminate

food during production, transportation, or storage, including food processing, that the petitioner for registration submit a method of analysis acceptable to the Department of Health, Education, and Welfare. In the case of an application for a "no residue" registration in or on a food, HEW should review the residue data submitted and/or the use restrictions proposed, to support such registration. We contemplate that, in such cases, a prerequisite to registration would be a certification by the Secretary of Health, Education, and Welfare to the Secretary of Agriculture that such method is acceptable and that, where a food is involved, the data adequately show, or the conditions of use are such, that no residue is to be expected.

There should also, in our opinion, be a provision for canceling registration at any time we find that the original conclusion about "no residue" is in error or if a previously established tolerance is reduced. We, of course, do not contemplate that such cancellation would be called for on the basis of an occasional misuse.

Finally, we believe that the confidentiality provisions of the bill should be revised to make it clear that data in an application for registration may be made available at any time to the Department of Health, Education, and Welfare, or to any other Government agency consulted by the Secretary of Agriculture.

I have tried to touch on the highlights of the views of the Department. However, the Department's report on this bill, dated August 29, 1963, discusses these proposed changes in detail.

Thank you, sir.

Senator JORDAN. Thank you very much.

Senator Neuberger, do you have any questions?

Senator NEUBERGER. I believe not.

Senator JORDAN. Thank you, Mr. Kirk.

Mr. Datt?

Mr. Datt is assistant to the director of the Washington office of the American Farm Bureau Federation.

Mr. Datt, we are glad to have you with us, sir. We would be glad to hear from you.

STATEMENT OF JOHN C. DATT, ASSISTANT TO THE DIRECTOR, WASHINGTON OFFICE, AMERICAN FARM BUREAU FEDERATION

Mr. DATT. Thank you very much, Senator.

We appreciate this opportunity to present the statement of the American Farm Bureau Federation on this particular legislation.

This legislation, as we understand it, would amend the Federal Insecticide, Fungicide, and Rodenticide Act to do two things:

(1) Require that when the Secretary of Agriculture registers one of the economic poisons he would provide for the label to contain the registration number assigned to that particular product.

(2) Eliminate the provisions whereby economic poisons can be registered by their manufacturers under protest.

Farm Bureau is a free, independent, voluntary organization of farm and ranch families. Currently we have over 1,600,000 members in some 2,700 counties and 49 States and Puerto Rico. Farm Bureau members use substantial quantities of agricultural chemicals and drugs. Therefore, we are quite interested in any legislation that affects their use.

Agricultural chemicals and drugs have become very essential to the economic production of food. Farmers are vitally interested in protecting the public health and welfare of our consumers at all times. We have a responsibility to see that agricultural chemicals and drugs are properly used. We have conducted educational programs among our members in order to insure proper use.

Farm Bureau in the past has supported legislation to provide for the proper labeling and use of agricultural chemicals and drugs for the protection of public health and welfare.

The proposed legislation is, in our opinion, designed to further provide for proper use of agricultural chemicals and drugs as well as to provide for increased protection to consumers.

The first section of the proposed legislation dealing with the labeling of economic poisons with registration numbers would be of assistance to farmers and ranchers. If these economic poisons contained registration numbers, a producer would then know that the product had been registered and cleared by the U.S. Department of Agriculture for proper use. He would then know that if he used the product according to directions provided him by the manufacturer, the final food product would be safe for consumers.

The second provision of the bill deals with the elimination of registration under protest. Currently a manufacturer of an economic poison can present his product to the Secretary of Agriculture for registration. If the product meets the requirements set forth by the law and carried out by the Secretary, he will register it for proper use. However, in the event that the product fails to meet the procedures established by the Secretary, he can refuse to register the product. Under these circumstances the manufacturer does have the privilege to proceed and market the product under the so-called registration-under-protest provision.

While it is our understanding that very few of the products that have been registered under protest would be directly used by agricultural producers, we are concerned about this provision and support legislation to eliminate it.

From the producer's standpoint, it is important that he know that an agricultural chemical or drug has been properly cleared by the Secretary of Agriculture. Even though a manufacturer of a product may be responsible, it is the farmer who takes much of the blame when an economic poison causes injury or harm. A farmer might use one of the products that had been registered under protest and not fully realize this and therefore subject himself to serious problems.

Because of the discussion that has taken place in recent weeks concerning the use of agricultural chemicals and drugs, we believe it is important that all steps be taken to make it possible for farmers to use them safely. The use of agricultural chemicals and drugs has been largely responsible for providing consumers with low cost, high quality food. The use of these products is essential if we are to continue to maintain this high standard in our food production.

Farm Bureau for a number of years has, through all phases of the organization, conducted an aggressive educational program to be certain that individual farmers adhere strictly to the recommendations for the proper use of agricultural chemicals and drugs. We

shall continue this educational program because we recognize that we have a responsibility as farmers and ranchers to see that these products are properly used.

The Farm Bureau supports the passage of S. 1605 and hopes that the committee will give it favorable early consideration.

We appreciate the opportunity to present our views on this legislation.

Senator JORDAN. Thank you very much, Mr. Datt.

Senator NEUBERGER?

Senator NEUBERGER. Yes.

I was interested in your last statement, that farmers adhere strictly to the recommendations for the proper use of agricultural chemicals and drugs.

Do you recall the cranberry episode of a few years back? Was that the fault of the labeling or was it the fault of the farmer for not doing the spraying according to the directions on the label?

Mr. DATT. Well, from my understanding of the situation, this particular chemical was probably used at the wrong time. If the directions had been followed, there probably would not have been any difficulty. So I expect in this sense it was the responsibility of the farmer.

Senator NEUBERGER. Consequently, no matter what law we pass or what happens, there is still the human element, then—that the farmer is going to have to be responsible, is he not?

Mr. DATT. Certainly, we agree with this, 100 percent. One of the things we tried to do in the last 5 or 6 years has been to intensify our educational efforts among our farmers. That is, they do have a responsibility to use these agricultural chemicals properly. I would say that in 99 times out of 100, they do adhere to the directions. But we always probably will have some who cannot read or don't care, or for some reason don't do what it says on the label.

Senator NEUBERGER. So, if we do have a law setting up standards and requirements, then this really puts the responsibility pretty much on the farmer, that he live up to the law, does it not?

Mr. DATT. That is the current situation, and that is the way the law is today. He has a responsibility to use them properly.

Senator JORDAN. About that same time, Senator, they had this problem—this matter of the chicken feed. I will have to say HEW sort of loused that deal up a little bit. They condemned a lot of chickens that never had that in their food. But that is a current thing.

Senator NEUBERGER. I don't think it is a panacea, though, merely to pass a law like this, unless we coordinate it with some educational program, as your organization says you will, because you still, in spite of all the labeling need this attention to the individual farmer's understanding of the laws and of the use of agricultural chemicals and drugs. It just shows that the human element is there. But, of course, we have laws to say that people should not speed, too, and people get killed by speeding. But we have to set up standards, I think, for it.

But I am interested that a big farm organization is supporting the legislation, because there is a rumor current through the country that the Federal Government is going to step in and prevent them

from growing crops, and try to deter the great agricultural business of this country. So I am delighted that you are supporting this.

Mr. DATT. I would say in the last 10 years we have really intensified our efforts in this area. And among farmers today I think there is a greater recognition that they do have a responsibility to use these agricultural chemicals and drugs properly—much more so than it was 10 years ago. And I am sure as time goes on, they will become more responsive.

Senator NEUBERGER. Thank you.

Senator JORDAN. That concludes your testimony, Mr. Datt?

Mr. DATT. Yes, sir.

Senator JORDAN. Thank you very much. We are glad to have your testimony. You are a fine organization.

Mr. Brinkley?

Mr. Brinkley is president of the National Agricultural Chemicals Association.

Mr. Brinkley, I suppose you represent the people who manufacture these drugs.

Mr. BRINKLEY. Yes, sir.

Senator JORDAN. Insecticides, and so forth and so on.

Please give your name and all the information pertaining to yourself and your associate with you.

STATEMENT OF PARKE C. BRINKLEY, PRESIDENT, AND ROBERT L. ACKERLY, COUNSEL, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Mr. BRINKLEY. Thank you, sir.

Mr. Chairman, Senator Neuberger, accompanying me is Mr. Robert L. Ackerly, of the firm of Cummings and Sellers, a law firm here in Washington. They are our general counsel and our corporate secretary.

Senator JORDAN. Thank you, sir.

Mr. BRINKLEY. And I brought Mr. Ackerly along to help answer some questions if you have some following that he might answer better than I could.

Senator JORDAN. Fine, thank you, sir.

You may proceed.

Mr. BRINKLEY. My name is Parke C. Brinkley. I am president of the National Agricultural Chemicals Association. This association was formed in 1933 as a nonprofit trade association to promote and represent the interests of manufacturers and formulators of agricultural pesticides and related chemicals. The 114 member companies of this association produce 90 percent of the basic and 85 percent of the formulated agricultural pest control chemicals produced in the United States. I am presently completing my first year of service with this association; however, in my former position as commissioner of agriculture for the Commonwealth of Virginia, I had occasion to know the association and its work for the industry. The association has always conducted its affairs in a manner consistent with the public interest and with an attitude of cooperation with the regulatory agencies of the Federal, State, and local governments.

In the middle 1940's, when the present Federal Insecticide, Fungicide, and Rodenticide Act was being considered by the Congress, this association actively supported it. Later, this association had the opportunity to help develop and support the Miller pesticide residue amendment to the Federal Food, Drug, and Cosmetic Act, which regulates and limits the allowable residue of pesticide chemicals of raw agricultural commodities. Again in 1959, when the scope of the Federal Insecticide, Fungicide, and Rodenticide Act was enlarged by act of Congress, this association took an active part in developing and supporting the amendment.

Our comments and views on S. 1605 are submitted to the committee this morning in a sense of cooperation with the committee and the Department of Agriculture in improving the Federal Insecticide, Fungicide, and Rodenticide Act.

We will submit with this statement some amendments which we believe will clarify the procedures provided in the bill, and with these amendments we support and endorse S. 1605.

This bill would accomplish two primary changes in existing law:

First, the Secretary of Agriculture will be authorized to require the Federal registration number of a pesticide to appear on the label. Each product which is registered by the Department of Agriculture receives a registration number. Existing law prohibits any reference on the label or in the labeling to the registration of the product by the Department of Agriculture.

This association has for several years urged that the law be amended to authorize the Secretary to require or at least permit the registration number to appear on the label. This has become more important since the approval of the Miller pesticide residue amendment to the Federal Food, Drug, and Cosmetic Act. The appearance of the Federal registration number on the label will assure growers and users that the product has been registered by the U.S. Department of Agriculture.

Registration of a pesticide intended for use on growing crops is also subject to the approval of the Food and Drug Administration. That agency establishes tolerances for residues of the pesticide chemical on raw agricultural commodities. The Department of Agriculture requires directions for use on the label, which if followed, will either leave no residue on the crop at the time of harvest, or a residue which is within lawful limits of the tolerance for the pesticide chemical. We think it highly desirable that growers be advised at the time of purchase that the product has been registered with the Department of Agriculture and that the Food and Drug Administration has established a tolerance for any residue that will remain on the crop. The appearance of the registration number on the label is a good way of accomplishing this.

There are some hazards to the industry in this feature of the bill. At the present time, 47 States require registration of pesticides in addition to the U.S. Department of Agriculture. The States generally follow the pattern of the Federal act and regulations. If the States should decide to require their registration numbers on the label in addition to the Federal number, the industry could be faced with printing 48 different numbers on a label. This would be impossible with many packages. It would also be quite unneces-

sary. We suggest, therefore, that the committee report on this bill emphasize that the purpose in allowing the Secretary to require the registration number to appear on the label is to give assurance to growers that the product has been registered by the U.S. Department of Agriculture, and to the extent necessary has been approved by the Food and Drug Administration for use on the crops listed on the label. If this point is made clear, perhaps the States will not find it necessary to adopt this requirement with respect to State registration numbers. Thus, while industry supports the principle that the Federal registration number appear on the label, it would be strongly opposed to the States following suit.

The second purpose of this bill is to eliminate registration under protest. Existing law, in section 4(c), provides that if it appears to the Secretary that an article which is submitted for registration does not comply with the requirements of the act, the Secretary is required to notify the applicant and give him an opportunity to make the suggested corrections. In the event the applicant does not agree with the Secretary that the corrections are necessary, the applicant may request that the Secretary register the article under protest. This registration is accompanied by a warning from the Secretary of the apparent failure of the article to comply with the act. Registration of an article is not a defense to any of the prohibited acts set forth in section 3 of the law.

If the Secretary feels that a product registered under protest does not comply with the act, he is free to institute a seizure proceeding to have the product condemned.

S. 1605, in eliminating registration under protest, would substitute a procedure for judicial review of the Secretary's action with respect to the registration of such an article.

A procedure has been developed under the Miller pesticide residue amendment, the food additives amendment and the color additives amendments to the Federal Food, Drug and Cosmetic Act to provide an applicant an opportunity for objective review of data and other material by an advisory committee if the Secretary does not agree with the applicant's evaluation of the data submitted. A similar procedure is provided in S. 1605 with respect to registration under the Federal Insecticide, Fungicide, and Rodenticide Act. If the Secretary of Agriculture should not agree with an applicant that an article should be registered, the bill provides that the applicant may request the issue be referred to an advisory committee to be appointed by the National Academy of Sciences. After the advisory committee has reviewed the data and material filed in support of the application, the committee is required to report its recommendations to the Secretary who thereupon must issue an order with respect to the registration of the article based not solely on the recommendations of the advisory committee but on an evaluation of all the data before him, including the recommendations of the advisory committee.

The bill permits an opportunity for a hearing if objections are filed to the Secretary's order and for judicial review of the final action of the Secretary with respect to the application for registration through a procedure which experience has shown functions well in this area.

One weakness in registration under protest has been that the burden of proof with respect to the Secretary's action is shifted to the Secretary, in a court proceeding. Under this bill the burden of proving that the article complies with the requirements of the law remains with the applicant or registrant throughout the entire administrative and judicial procedure.

After careful review of S. 1605, this association has prepared a few amendments which it would like to submit with a request that these amendments be approved by the committee when it reports the bill to the Senate. The amendments in detail are attached to my statement. For the most part they deal with procedural matters, clarifying some of the procedures set forth in the bill. A detailed explanation is also attached and accompanies the amendments.

These amendments establish time limits within which the Secretary must act at certain stages of the administrative procedure and follow the pattern adopted by Congress in the Miller pesticide residue amendment, food additives amendment, and color additive amendments to the Federal Food, Drug, and Cosmetic Act. One amendment also adopts the standard of judicial review approved by Congress in the food additives amendment and adopted by reference in the color additive amendments and the Federal Hazardous Substances Labeling Act.

In 1957 and 1958 the Congress examined the scope of judicial review of administrative hearings where the administrative hearings involved a wide range of scientific judgment. The report of the House Committee on Interstate and Foreign Commerce, H.R. 2284, 85th Congress, July 28, 1958, explains the committee's conclusions in the following excerpt:

The committee has given long and careful thought to the problem of the scope of judicial review under this legislation. This problem was discussed exhaustively by several witnesses, including a Federal judge who testified on behalf of the Judicial Conference of the United States.

The committee feels that the Secretary's findings of fact and orders should not be based on isolated evidence in the record, which evidence in and of itself may be considered substantial without taking account of contradictory evidence of possible equal or even greater substance.

The bill provides that the reviewing court shall not sustain the order of the Secretary if he failed to base such order upon a fair evaluation of the entire record at such hearing, or if he failed to include in such order a statement setting forth in detail the findings and conclusions upon which the order is based. The court must sustain the findings of the Secretary with respect to questions of fact if based upon a fair evaluation of the entire record.

The Senate Committee on Labor and Public Welfare endorsed the position of the House Committee in Senate Report 2422, 85th Congress, August 18, 1958. The committee report states in part:

Manufacturers of food and of food additives have manifested concern that under an administrative type of control over the use of food additives, such as is provided by H.R. 13254, it would be possible for the institutional decisions of the Secretary of Health, Education, and Welfare to be based, for example, more upon the personal convictions of scientists employed by the Food and Drug Administration regarding the safety of an additive than upon the inferences fairly to be drawn from the scientific evidence of record. H.R. 13254 provides that orders regarding the use of food additives must "be based upon a fair evaluation of the entire record." The committee has endeavored to prescribe a new statutory criterion requiring that a high standard of fairness be observed in administrative rulemaking under this bill. Personal attitudes or preferences of administrative officials could not prevail on the basis of being supported by substantial evidence picked from the record without regard to other evidence of probative value in the record.

If any questions should develop with respect to the suitability or propriety of these amendments or their purpose, we would be glad to discuss them in detail with the committee or with members of the committee staff. We believe that they are sound and will improve and promote the purposes and objectives of the bill.

We appreciate the opportunity to appear before the committee. We endorse and support the principles and objectives of this bill. We believe that this substitute procedure for registration under protest is in keeping with modern developments of administrative and judicial procedure. We assure the committee of the complete cooperation of this industry in the continued enforcement of these provisions, if they are approved by the Congress.

Now, I have these amendments, Mr. Chairman—the amendments plus an explanation of the suggested amendments that are attached to our statement.

(The attachment referred to follows:)

SUGGESTED AMENDMENTS TO S. 1605

Amendment No. 1

Page 2, line 18, before the word "cancel" insert the words "suspend or".

Amendment No. 2

Page 3, line 7, delete the period after the word "Secretary" and insert in lieu thereof a comma and the following words, "or in the alternative the applicant or the registrant may file objections to such notice and request a public hearing thereon. If a petition is not filed within thirty days requesting reference to an advisory committee or if a request for a public hearing is not filed within the time allowed for such filing, this notice shall become the final action of the Secretary with respect to the application or the registration."

Amendment No. 3

Page 4, line 2, delete "in" and insert in lieu thereof the word "of".

Amendment No. 4

Page 4, lines 10 and 11, delete the words "make a report and recommendation to the Secretary as to the registration of the article." and insert the following, "submit a report and recommendations to the Secretary as to the registration of the article, together with all underlying data and a statement of the reasons or basis for the recommendations."

Amendment No. 5

Page 4, line 13, after the word "shall" insert a comma and the words "within ninety days after receipt of the report and recommendations of the advisory committee,".

Amendment No. 6

Page 4, line 16, delete the words "Any person adversely affected thereby" and insert in lieu thereof the words "The applicant for registration, or registrant,".

Amendment No. 7

Page 4, line 17, after the word "may" insert the words "within sixty days from the date of the order of the Secretary,".

Amendment No. 8

Page 5, line 9, after the word "shall" insert the words "evaluate the data and reports before him,".

Amendment No. 9

Page 5, line 20, after the word "until" strike the remainder of that sentence and insert in lieu thereof the following, "a public hearing is held, or where no hearing is requested until the action concerning registration of the product becomes final."

Amendment No. 10

Page 7, line 10, delete the words "by substantial evidence when considered on" and insert in lieu thereof the following, "by a fair evaluation of".

EXPLANATION OF SUGGESTED AMENDMENTS BY PARKE C. BRINKLEY

Amendment No. 1

This amendment merely completes the descriptive introduction to the procedures to be followed in the event of a denial, suspension, or cancellation of a registration. The words "suspend or" which will be added by this amendment were apparently inadvertently omitted.

Amendment No. 2

This amendment provides that if the applicant or the registrant does not request further proceedings following a denial or suspension of a registration by the Secretary, the Secretary's action shall become final. This will alleviate the necessity for the Secretary to issue a subsequent order and permit the Secretary's initial action to become final upon the expiration of the time period if the applicant or registrant desires no further proceedings to be held.

Amendment No. 3

This corrects a typographical error.

Amendment No. 4

The purpose of this amendment is to require an advisory committee to submit with its report a statement of the reasons or basis underlying its recommendations. This will be helpful both to the Secretary and to the registrant or applicant.

Amendment No. 5

This amendment requires the Secretary to act upon the application or registration within 90 days after the receipt of the report of the advisory committee. The bill does not provide a time within which the Secretary must act and it is felt that some time limitation is desirable.

Amendment No. 6

This amendment is for clarification. The phrase "Any person adversely affected thereby" would be in this instance only the applicant or the registrant and substitution of the words "The applicant for registration, or registrant," clarifies this sentence in the bill.

Amendment No. 7

This amendment places a 60-day time limit within which a public hearing may be requested following the order of the Secretary upon which the hearing is to be held. If a hearing is not requested within 60 days, the Secretary's order becomes final.

Amendment No. 8

The purpose of this amendment is to make clear that the Secretary is not bound by the recommendations of the advisory committee but should evaluate the entire record before issuing his order following a public hearing, if one is requested.

Amendment No. 9

This amendment is to clarify the procedure with respect to the confidentiality of data submitted in support of a registration. This amendment removes the confidentiality of such data when a public hearing is held or when the action of the Secretary becomes final.

Amendment No. 10

This amendment provides that in the event of an appeal to the U.S. Court of Appeals the findings of the Secretary with respect to questions of fact shall be sustained if supported by a fair evaluation of the record as a whole. The bill presently provides that the findings shall be sustained if supported by substantial evidence. The scope of judicial review recommended by this amendment, that is a fair evaluation of the record as a whole, is the scope of review provided in the food additives amendment and color additive amendments to the Federal Food, Drug, and Cosmetic Act and in

the Federal Hazardous Substances Labeling Act. This amendment then follows the scope of review provided by the Congress in the three most recent enactments in this field.

Senator JORDAN. How long have you had those amendments? Has the Department of Agriculture had those?

Mr. BRINKLEY. Yes, sir, they have.

Senator NEUBERGER. There is a little overlapping. I don't know whether you have seen them Mr. Brinkley. The recommendations of the Secretary—he recommends some amendments at the same places you do. And that one on amendment No. 2, on page 3, line 7, seems to be pretty much in agreement, except for the actual verbiage. Where the Secretary recommends on page 3, line 7, insert the following new sentence:

“The Secretary on his own motion may at any time refer such a matter to an advisory committee”—which is just about what yours seems to say.

Is that true?

Mr. BRINKLEY. Yes.

Senator NEUBERGER. I notice, since I had not seen your amendments before, that there is quite a lot of similarity.

Amendment No. 9, page 5, line 20—this one I am not quite sure of.

After the word “until,” insert—“a public hearing is held.”

The Secretary recommends that the phrase, “Final action is taken” be deleted, and that the language be “The Secretary issues his order concerning registration.”

In other words, you are putting more emphasis on the public hearing, and he is putting more emphasis on the administrative position of the Secretary.

Would you have any objection to it being in the hands of the Secretary?

Mr. BRINKLEY. Senator, I don't follow that as well as Mr. Ackerly might. Let him comment on that.

I think there is no real difference of opinion.

Senator NEUBERGER. It just seems to me that his recommendation is helpful for purely administrative reasons—but that you are both achieving the same ends.

It gives him a little more leeway to handle this thing if there is a question about it.

Have you seen the Secretary's language?

Mr. BRINKLEY. Yes, ma'am.

Senator JORDAN. May I ask at this time—Dr. Clarkson, do you have a copy of these amendments?

Dr. CLARKSON. Yes, sir.

Senator JORDAN. Come around and have a seat over here. We certainly want your comments, either now, or you may furnish them later.

Senator NEUBERGER. I think the results you are both seeking are the same. But I would like to eliminate all this matter of holding hearings if you can put it in somebody's hands.

Senator JORDAN. Senator Neuberger, I think maybe Dr. Kirk might have something he would like to add in here, too.

Do you have a copy of those amendments?

Mr. KIRK. Not Mr. Brinkley's; no, sir.

Senator JORDAN. I think that he should be supplied a copy of those amendments. Wouldn't you think so? So that they might make comments to the subcommittee, so they could be studied, and have your thoughts.

Do you have any extra copies of those?

Mr. BRINKLEY. Yes, sir, we brought them. And these were offered to the House committee during the hearings. They are exactly the same. Food and Drug has had the opportunity of seeing them.

Senator JORDAN. Go right ahead, sir. I didn't mean to interrupt you. But I wanted everybody to have a chance to be heard who is interested in this.

Mr. BRINKLEY. As Senator Neuberger has said, I don't think there is any difference between us in our thinking on this. It might be a matter of words.

Mr. Clarkson and Mr. Ackerly, both of them having been trained in the law, could probably discuss the wording better than I could.

Dr. CLARKSON. Mr. Chairman, I think Senator Neuberger expressed it very well—that the Department's amendments and the industry amendments are basically for the same purpose, which is to perfect, or to smooth out some of the provisions for administration.

We have looked over their amendments. They propose some alternate language from ours. It might be wise to go over these in detail with the committee counsel. We have no objection to any—except the last one. Item 10 of their amendments, which refers to an item on page 7, having to do with review by the court—we feel that the language now in the bill, which states that the findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report or recommendation of an advisory committee, is preferable.

The amendment as offered here would change that to read:

Findings of the Secretary with respect to questions of fact shall be sustained if supported by a fair evaluation of the record as a whole, including any report or recommendation of an advisory committee.

Now, I might suggest that the precedents for this in an amendment to the Food, Drug, and Cosmetic Act related to administrative actions, rulemaking by the Secretary, whereas the provisions of this act that we are referring to have to do with the review of the record by the U.S. Court of Appeals. The Department's General Counsel feels that the language in the bill as written is preferable, and in line with the precedents.

Senator NEUBERGER. I noticed that one right away, because it seemed to me that in the present bill—the wording, "substantial evidence," is better for everybody. It asks for evidence rather than an evaluation. I would think it would put more responsibility upon the Secretary, does it not?

Mr. BRINKLEY. This is court review, is it not?

Mr. ACKERLY. That is correct.

Mr. BRINKLEY. This is court review. Our contention is that when it goes before the court that the court should have all of the record, and should make the decision based upon all the information that

is available, rather than possibly the taking of a portion of the record to substantiate a particular fact or finding.

Dr. CLARKSON. If the Chair would like, General Counsel of the Department would be glad to submit a statement in regard to this matter.

Senator JORDAN. We would be glad to have that. And, any additional information you would like to have pertaining to this point from your counsel, Mr. Brinkley, we would be glad to have, also.

Mr. BRINKLEY. Thank you, sir.

Senator JORDAN. Senator Neuberger, do you have any other questions?

Senator NEUBERGER. No. The crux of this bill, of course, is the registration question. I think this is the important thing. We don't care too much about that labeling number one way or the other. But I think this is an important question, insofar as I can see.

Now I would like to add that I am delighted that the industry is so cooperative.

I think your suggestion is very good—that they work together on getting this language agreeable to both sides.

But I know that it makes it easier to administer if we don't fool too much with the Secretary's ability to do it. And I am sure that would be agreeable to you, Mr. Brinkley.

Senator JORDAN. I can readily understand where the 50 States might have a labeling law, and it would be almost impossible to have two different numbers and print 50 different kinds of labels. That would have to be worked out.

I would like to ask you, Mr. Brinkley—is there any opposition or any serious opposition from any of the manufacturers to this bill?

Mr. BRINKLEY. No, sir.

Senator JORDAN. I have not heard any. I was just wondering.

Well, that is a very fine attitude that the manufacturers are taking. It is a very important problem, because insecticides, and all these chemicals included in this bill are becoming more and more important to agriculture, in every phase of agriculture, than ever before.

They have learned—pretty well—to throw away the plow for weeding and kill it with chemicals, which is revolutionizing agriculture as I knew it when I was a boy. I have not used a hoe in a long time, thank goodness—I never did like it.

Mr. BRINKLEY. Well, I have used one a good many days, Senator, and I appreciate the fact that these chemicals came along about the time that farm labor became so high we could not afford to use a hoe any more. That saved me and my farming in eastern Virginia. Senator Neuberger said she did not know anything about peanuts. I was born and raised a peanut farmer, Senator. I do know a little bit about peanuts, and I have worked them a good many days with a hoe. And these materials are a tremendous benefit.

I think, Senator, if I may impose for just another minute upon your time, and that of Senator Neuberger—that as I pointed out, you will find that the industry has supported actively all of the legislation that it is regulated under now. We have two sister associations—the Manufacturing Chemists Association and the Chemical Specialties Manufacturing Association. Both of them are supporting this

legislation. The MCA has not filed a statement or taken an active part.

The CSMA, as we refer to it—the Chemical Specialties Manufacturing Association, did appear before the House Committee.

Senator JORDAN. That information is available to us.

Mr. BRINKLEY. Yes, sir. And they have submitted a statement. They are not here because they are having a board meeting in Chicago now, and could not be here. But they are supporting the legislation, as they have in the past.

They are the ones who represent the household manufacturers, or the manufacturers of household products.

Senator JORDAN. Yes, I have that statement here from the Chemical Specialties Manufacturing Association. And I will insert this in the record at this point, or to follow your remarks.

Mr. BRINKLEY. Yes, sir, that will be fine.

(The statement referred to follows:)

STATEMENT FILED BY JOHN A. RODDA, MEMBER, BOARD OF DIRECTORS, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, NEW YORK, N.Y.

This statement is submitted on behalf of the Chemical Specialties Manufacturers Association, a nonprofit trade association, incorporated in 1914. The 500 members of this association represent a major segment of the producers and distributors of chemical specialty products for general household use. The association is divided into six divisions, one of which is the insecticide division. S. 1605 proposes to amend the Federal Insecticide, Fungicide, and Rodenticide Act, under which the products of the members of this association are registered. The association, thus, has a direct interest in this bill.

The position of the pesticide industry generally on this bill has been stated to the committee by Mr. Parke C. Brinkley. Mr. Brinkley has explained, particularly, the impact of the bill on the agricultural chemical industry. This association joins with the National Agricultural Chemicals Association in supporting S. 1605, and also endorses the amendments which Mr. Brinkley has submitted to the committee. The purpose of this statement is to explain, briefly, the possible impact of this bill on the small package or household and garden segment of the industry.

Most insecticides intended for use around the household and in the garden are sold in small packages. The available label space on these containers is limited. At the present time, to comply with the Federal Insecticide, Fungicide, and Rodenticide Act, the label must contain detailed directions for use, a warning or caution statement of any hazards in the handling and use of the product, an ingredient statement in the form required by the Department of Agriculture, a statement of the net contents, and the name and address of the manufacturer, as well as the trade name of the product. The Department of Agriculture has recently redrafted some of its regulations which, in part, require a reference to the directions and precautions to appear on the front panel. Several States, in the enforcement of their weights and measures laws, now require the statement of net contents to appear on the front of the container. We are, therefore, somewhat concerned with the provision of this bill which would authorize the Secretary of Agriculture to require the registration number of the product to appear on the label.

The purpose of this requirement, as we understand it, is primarily to assure growers of agricultural crops that a pesticide has been registered with the Department of Agriculture, and that application of the pesticide, in accordance with the label directions, will result either in no residue of the pesticide at the time of harvest or, if a residue remains, that it will be present in an amount within the official tolerances established by the Food and Drug Administration for such a residue. As the bill is drafted, we interpret it to mean that the Secretary of Agriculture would not be required to insist upon the registration number on the label of every pesticide. It is possible that the Secretary will determine that since the primary purpose of this section of the bill would not have application to household insecticides, the registration number need not appear on these small containers. If the Secretary deter-

mines that the registration number should appear on these products, we would anticipate that the requirement would be limited to a number preceded by some brief designation, such as "U.S.D.A. Reg. No." Space can be found on most labels for a brief statement of this type; however, we are concerned as to the attitude that the 47 States, who also register these products, will take with respect to requiring the State registration number on the label. It would be physically impossible to list a whole series of registration numbers on these small containers.

We request, therefore, that the committee report on this bill point out the seriousness of this problem, and the intent of the committee that products may move freely in interstate commerce with only the Federal registration number on the label.

With respect to the remaining sections of this bill, which would delete registration under protest, and substitute an administrative hearing procedure, our position is that since the bill affords the industry an opportunity of administrative and judicial review of decisions on registration, we support this part of the bill also. Registration under protest has always been viewed by this association as a method of protection against arbitrary action by an administrative official, and a method of obtaining judicial review. We have always understood that a product registered under protest is subject to seizure at any time without notice if the Department of Agriculture decides that the product does not comply with the act. Registration under protest has been used sparingly, which is a tribute to the way in which the industry has cooperated with the U.S. Department of Agriculture in the enforcement of this act.

Substituting an advisory committee procedure along with opportunity for public hearing and judicial review of the decisions of the Secretary under this law is undoubtedly a more orderly and more satisfactory procedure than registration under protest. These procedures will be time consuming and cumbersome, but we recognize that this is necessary where evaluation of research data is required and expert judgments made based upon the results of experimental data. The final decision, of course, rests with the Secretary following exhaustion of the advisory committee and public hearing procedures. The Secretary will thus not be bound by the report and recommendations of the advisory committee, but his judgment will be based upon the entire administrative record. If an appeal is taken to the court, the court should also base its review on a fair evaluation of the administrative record certified to the court by the Secretary. We believe that the bill with the amendments submitted by Mr. Brinkley satisfies these principles.

Once again we do see the possibility of a serious problem at the State level if this procedure should be adopted by the States. A great majority of the products of this association move in interstate commerce and uniformity of requirements between the Federal and State Governments is essential. We are hopeful, therefore, that the State governments will accord great weight to the action of the Secretary of Agriculture under this amendment and accept for registration at the State level products which are approved by the Secretary for registration by the Federal Government.

We endorse the principles and objectives of this bill. No law is static and an important regulatory statute such as the Federal Insecticide, Fungicide, and Rodenticide Act should be subject to constant review and should be amended when necessary to meet changing conditions. We believe that these amendments will improve the enforcement of this law and strengthen the bill, while at the same time preserving and protecting the basic rights of the regulated industry. The committee can be assured that this industry will continue to cooperate fully with the Congress and with the Department of Agriculture in the enforcement of this law and in the implementation of these amendments.

Senator JORDAN. Do you have any further remarks, sir?

Mr. BRINKLEY. No, thank you.

Senator JORDAN. Senator Neuberger?

Dr. Clarkson?

Is there any other witness?

We appreciate very much all of you being with us. Your testimony has been very, very fine and direct.

We will leave the record open until Friday of this week to file any other statements.

You may want to file some answers, Dr. Clarkson, to some of these.

Dr. CLARKSON. On this item 10, I will send up a statement.

Senator JORDAN. If you have it brought over, it will be included in the record—or any statements that you or any of the manufacturers might want to put in, we will be glad to have in the record.

U.S. DEPARTMENT OF AGRICULTURE,
OFFICE OF THE GENERAL COUNSEL,
Washington, D.C., September 13, 1963.

Hon. B. EVERETT JORDAN,
*Chairman, Subcommittee on Agricultural Research and General Legislation,
U.S. Senate, Washington, D.C.*

DEAR SENATOR JORDAN: In compliance with your request during the hearing on S. 1605 on September 10, 1963, the Department of Agriculture submits the following comments on amendment No. 10 to the bill proposed by the National Agricultural Chemicals Association.

This suggested amendment would provide that in case an appeal is taken to the U.S. Court of Appeals from the determination of the Secretary of Agriculture as to the eligibility of an economic poison for registration, the findings of the Secretary with respect to questions of fact would be sustained if supported by a "fair evaluation" by the court of the record as a whole. S. 1605 provides that such findings would be sustained if supported by "substantial evidence" when considered on the record as a whole. The "substantial evidence" standard of review is provided for in the "pesticide chemicals" provisions of section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a). Section 10 of the Administrative Procedure Act (5 U.S.C. 1009) also uses the "substantial evidence" criterion for review of agency action. Prior to the Administrative Procedure Act it was held that administrative determinations were to be sustained if there was evidence to support them. *Swift & Co. v. United States*, 316 U.S. 216 at 231 (1941); *Adams v. Mills*, 286 U.S. 397 at 410 (1932). Some cases required "substantial evidence" to support administrative findings, e.g. *Midwest Farmers v. United States*, 64 Fed. Supp. 91 at 96 (D.C. Minn. 1945). The "fair evaluation" provision provides a different standard than that of "substantial evidence" and would apparently contemplate that the court would weigh the evidence and reach its own conclusion as to the facts established by the whole record. (See Senate Report 2422 on H.R. 13254, 85th Congress (Food Additives Amendment of 1958) in volume 3, U.S. Code, Congressional and Administrative News, p. 5306). We believe this would require the court to pass on factual issues on which the Secretary of Agriculture has greater expertise and that such expertise should be accorded the recognition in the Federal review process which the "substantial evidence" standard affords. It also appears that the Congress in adopting the "fair evaluation" standard in the food additives amendment to the Federal Food, Drug, and Cosmetic Act recognized that the proceedings to which it was there applied were rulemaking proceedings (Senate Report 2422 on H.R. 13254). There is no precedent so far as we know for use of that standard for review of adjudicatory actions such as determination of the eligibility of an economic poison for registration. Therefore, we oppose suggested amendment No. 10.

We appreciate this opportunity to submit our views on this matter.

Sincerely yours,

EDWARD M. SHULMAN,
Acting General Counsel.

Senator JORDAN. Thank all of you very much for being with us. (Whereupon, at 11:10 a.m., the subcommittee recessed, subject to the call of the Chair.)

(Additional statements filed for the record are as follows:)

WASHINGTON, D.C., September 6, 1963.

Hon. B. EVERETT JORDAN,
*Chairman, Committee on Rules and Administration,
Senate Office Building, Washington, D.C.*

DEAR MR. CHAIRMAN: This is to set forth the interest of the National Grange in S. 1605 relating to the registration of pesticides under protest. The National Grange urges the committee to reject in total those amendments offered by the Fish and Wildlife Service of the Department of the Interior and

by the Food and Drug Administration of the Department of Health, Education, and Welfare. We feel these amendments would result in a distortion in the legal responsibilities of government as related to the health of this Nation and its food supply.

We support the bill itself and those amendments offered by the U.S. Department of Agriculture and the National Agricultural Chemicals Association. We note that the U.S. Department of Agriculture does not support amendment No. 10 of the National Agricultural Chemicals Association. Our review shows this to be a legal question involving interpretation of court action, and we suggest this matter be weighed carefully by all members of the committee.

For some time the National Grange has been disturbed by the attitudes and attempts by some of those supporting fish and wildlife interests to put the values of these resources, important as they are, ahead of an abundant, wholesome food supply; and a capability enabling farmers to continually increase the efficiency of production is of first magnitude. We support the upgrading and conservation of this Nation's fish and wildlife resources—but not in a manner which threatens to jeopardize our food supply.

We respectfully invite you to present our views to the members of your committee during discussions on this bill.

Respectfully yours,

HERSCHEL D. NEWSOM,
Master, National Grange.

STATEMENT FILED BY RICHARD T. O'CONNELL, SECRETARY, NATIONAL COUNCIL OF FARMER COOPERATIVES

I am Richard T. O'Connell, secretary, National Council of Farmer Cooperatives. The national council is a federation of farmer cooperatives with several members manufacturing agricultural chemicals and a substantial number of member organizations distributing chemicals to nearly 3 million farmers.

We appreciate this opportunity to express our views on S. 1605.

The national council supports the objectives of S. 1605 for two principal reasons: (1) the statutory inclusion of an advisory committee to assist the Secretary in evaluating data, and the selection of its members from the National Academy of Sciences, will give the broad and objective analysis of economic poisons which we believe essential for their continued effectiveness in agriculture; and (2) the eliminating of the sale of economic poisons "under protest" will substantially remove the potentially adverse public relations position the farmer is placed in when difficulties arise.

However, there are several amendments we wish to recommend to strengthen the measure.

We will briefly discuss each position.

ADVISORY COMMITTEES STIMULATE A BROAD SCALE ANALYSIS

It is our belief when adverse situations arise from the use of economic poisons in the production and marketing phases of agriculture, the farmer generally bears the brunt of the unfavorable publicity and frequently the financial damage as well. We are certain the committee recalls the situations in the cranberry and poultry industries several years ago. The incidents caused a temporary decline in the per capita consumption of these two products and posed a severe financial reversal for farmers until assistance was received from the Government.

We believe the twin tragedies which occurred in cranberries and poultry, although not involving sales "under protest," could have been eliminated or the impact sharply reduced if an advisory committee such as suggested in this measure had been in effect prior to the registration of the chemicals involved and had been operating during the crisis.

The fundamental advantage of employing an advisory committee of competent members of the scientific community is the opportunity to thoroughly analyze, from all aspects and viewpoints, research and other data before a decision is reached. The advisory committee can weigh and judge the conflicts that seem to exist when two or more scientists study the same problem. The committee can also act as a clearinghouse for research work as well as an important adjunct to the Secretary in his decisionmaking processes. We support this procedure.

SALES "UNDER PROTEST" SHOULD BE ELIMINATED

Much of the publicity furor in recent months has, as this committee is well aware, been concentrated on the sale of economic poisons "under protest." We believe the publicity has far overshadowed the beneficial and effective uses of agricultural chemicals. It can easily be considered as a thorn in the side of agriculture, and a strong weapon in the hands of those who wish to see the reduction or elimination of the use of chemicals in agricultural production and marketing.

Therefore, it is imperative that agriculture remove the stigma of sales "under protest" so that the public can judge the effectiveness of those products approved by the USDA as safe.

We believe the removal of sales "under protest" will cause little if any economic hardship on agriculture or the manufacturers of these products. It is our understanding that 7 products are currently being sold "under protest" out of about 50,000 products in use and under approval by the USDA.

AMENDMENTS TO STRENGTHEN THE MEASURE

The amendments we recommend are largely to clarify and improve the procedures contained in S. 1605 and do not alter the objectives of the proposed legislation.

On page 3, line 7, we recommend the deletion of the period after the word "Secretary" and insert in lieu thereof a comma and the following words, "or in the alternative the applicant or the registrant may file objections to such notice and request a public hearing thereon. If a petition is not filed within thirty days requesting reference to an advisory committee or if a request for a public hearing is not filed within the time allowed for such filing, this notice shall become the final action of the Secretary with respect to the application or the registration."

The recommended amendment is an attempt to offer alternatives to the procedures the Secretary or the applicant may follow. We believe it is important that fair and equitable procedures be permitted for both the Secretary and the applicant in stating their cases, either privately or publicly. We also favor the inclusion of time limits, such as a specified number of days to complete actions. Time required to make a decision becomes a matter of judgment, but in most occasions a time limit stimulates and spurs the parties into concrete action. The use of the term "final action" by inaction is also good. This will give notice to both parties that after a stated amount of time has elapsed, the prior decision is the one that stands. This eliminates the possible confusion from two or more statements being rendered on the same subject.

On second recommended amendment is as follows:

On page 4, line 13, after the word "shall" insert a comma and the words "within ninety days after receipt of the report and recommendations of the advisory committee."

Our third amendment is on page 5, line 8. Delete the words "as soon as practicable" and insert in lieu thereof the words, "within ninety days."

Our reasons for the importance of time in expediting the decisions in these last two amendments are the same as we have stated earlier.

Our fourth and final amendment is on page 7, line 10. Delete the words "by substantial evidence when considered on" and insert in lieu thereof the following, "by fair evaluation of."

This amendment, in our judgment, establishes continuity where an advisory committee is employed in assisting the Secretary in evaluating the data supplied. It further reduces hasty judgment and narrow interpretation of research data which we believe has been a possibility in the past.

SUMMARY

The National Council of Farmer Cooperatives favors the passage of S. 1605, and preferably with our recommended amendments. We urge this committee to favorably report S. 1605 and actively support its passage in the Senate.

We appreciate this opportunity to express our views.

The first part of the book is devoted to the history of the United States from the discovery of the continent by Christopher Columbus in 1492 to the establishment of the first permanent settlements. This period is characterized by the gradual expansion of European colonies along the Atlantic coast, the development of a distinct American identity, and the struggle for independence from British rule.

The second part of the book covers the period from the American Revolution to the Civil War. This era is marked by the struggle for independence, the formation of the federal government, and the expansion of the United States into the western territories. The Civil War, which began in 1861, was a pivotal moment in American history, as it resolved the issue of slavery and preserved the Union.

The third part of the book deals with the Reconstruction period and the Gilded Age. Reconstruction, which followed the Civil War, aimed to rebuild the South and integrate freed slaves into society. The Gilded Age, characterized by rapid industrialization and the rise of big business, saw the emergence of powerful industrialists and the growth of the United States as a world power.

The fourth part of the book focuses on the Progressive Era and the early 20th century. This period was marked by social and political reforms aimed at addressing the problems of industrialization, such as child labor, monopolies, and corruption. The Progressive Era also saw the rise of the United States as a major world power, culminating in its entry into World War I.

The fifth part of the book covers the interwar period and the Great Depression. The 1920s were a time of economic prosperity and cultural change, but the Great Depression of the 1930s brought severe economic hardship to the United States. This period also saw the rise of the New Deal, a series of programs and policies designed to provide relief, recovery, and reform.

The sixth part of the book deals with World War II and the Cold War. World War II, which began in 1939, was a global conflict that resulted in the defeat of the Axis powers and the emergence of the United States as a superpower. The Cold War, which followed, was a period of tension and rivalry between the United States and the Soviet Union, characterized by the arms race and proxy wars.

The seventh part of the book covers the Vietnam War and the 1960s. The Vietnam War, which began in 1955, was a conflict that resulted in the withdrawal of U.S. troops and the reunification of Vietnam. The 1960s were a time of social and cultural change, marked by the civil rights movement and the counterculture movement.

The eighth part of the book deals with the 1970s and the 1980s. The 1970s were a time of economic stagnation and social change, marked by the oil crisis and the Watergate scandal. The 1980s were a time of economic recovery and the rise of the Reagan Revolution, characterized by conservative politics and a focus on free-market economics.

The final part of the book covers the 1990s and the 2000s. The 1990s were a time of economic growth and the end of the Cold War, marked by the Gulf War and the Clinton administration. The 2000s were a time of political and social change, marked by the 9/11 attacks and the Bush administration.



