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# FIFRA EXTENSION

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## HEARING

BEFORE THE

SUBCOMMITTEE ON AGRICULTURAL RESEARCH  
AND GENERAL LEGISLATION

OF THE

COMMITTEE ON  
AGRICULTURE, NUTRITION,  
AND FORESTRY

UNITED STATES SENATE

NINETY-SIXTH CONGRESS

FIRST SESSION

ON

S. 717

A BILL TO EXTEND THE FEDERAL INSECTICIDE, FUNGICIDE,  
AND RODENTICIDE ACT, AS AMENDED, FOR TWO YEARS

APRIL 26, 1979

Printed for the use of the Committee on Agriculture, Nutrition, and Forestry



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# CONSTITUTION

Article I  
Section 1  
All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.

Section 2  
The House of Representatives shall be composed of Members chosen every second Year by the People of the several States, and the Electors in each State shall have the Qualifications requisite for Electors of the most numerous Branch of the State Legislature.

Section 3  
The Senate of the United States shall be composed of two Senators from each State, chosen by the Legislature thereof, for six Years; and each Senator shall have the Qualifications requisite for Senators of the most numerous Branch of the State Legislature.



## FIFRA EXTENSION

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THURSDAY, APRIL 26, 1979

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

The subcommittee met, pursuant to notice, in room 324, Russell Senate Office Building, at 10 a.m., Hon. Donald W. Stewart (chairman of the subcommittee) presiding.

Present: Senator Stewart.

### STATEMENT OF HON. DONALD W. STEWART, A U.S. SENATOR FROM ALABAMA

Senator STEWART. Let's get started. I wish to welcome everyone to the hearing of the Subcommittee on Agricultural Research and General Legislation. This hearing is on the extension of the authorization for appropriations to support the pesticide regulation program under the Federal Insecticide, Fungicide, and Rodenticide Act enacted last year, which made a number of amendments to FIFRA to improve the operation of the Government's pesticide program and to facilitate the reregistration of all pesticides called for by legislation enacted in 1971. However, it only extended through fiscal year 1979, the authorization for appropriations to carry out the program. The Agriculture Committee will have to act by May 15 on legislation to extend the authorization for appropriations beyond September 30, 1979.

Chairman Talmadge has introduced the administration bill, Senate 717, to extend the FIFRA authorization for 2 years. The subcommittee hopes to receive testimony today on this proposal and on the amount requested, some \$52,550,000 for 1980, and such sums as may be necessary for fiscal year 1981.

[A copy of S. 717 follows:]

(1)



96TH CONGRESS  
1ST SESSION

# S. 717

To extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended,  
for two years.

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## IN THE SENATE OF THE UNITED STATES

MARCH 21 (legislative day, FEBRUARY 22), 1979

Mr. TALMADGE (by request) introduced the following bill; which was read twice  
and referred to the Committee on Agriculture, Nutrition, and Forestry

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## A BILL

To extend the Federal Insecticide, Fungicide, and Rodenticide  
Act, as amended, for two years.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*  
3       That section 31 of the Federal Insecticide, Fungicide, and  
4       Rodenticide Act, as amended (7 U.S.C. 136y), is amended by  
5       inserting before the period at the end thereof the following: “;  
6       and for the period beginning October 1, 1979, and ending  
7       September 30, 1980; the sum of \$52,550,000; and for the  
8       period beginning October 1, 1980, and ending September 30,  
9       1981, such sums as may be necessary”.



Senator STEWART. Before we begin, there are a couple of matters that should be mentioned. First, I would appreciate it if the administration witnesses, besides addressing themselves to the bill itself, will give the subcommittee a brief status report on their progress to date in implementing the provisions of the Federal Pesticide Act of 1978. I am sure you will do that.

Second, it appears that Senate bill 717 does not include appropriations to support FIFRA research activity. This is a change from the past practice. All EPA activities under FIFRA, including research, were covered in one authorization bill.

I believe the administration has sent a second requested bill to Congress to cover FIFRA research. I hope the administration witnesses will clarify this situation with respect to the various pending pieces of legislation on FIFRA and also provide us testimony by agencies of FIFRA research needs for the next 2 years.

Our first witness is Mr. Jellinek. He is Assistant Administrator for Toxic Substances, Environmental Protection Agency.

If you will approach the table, Mr. Jellinek, and you may begin your testimony.

**STATEMENT OF HON. STEVEN JELLINEK, ASSISTANT ADMINISTRATOR FOR TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY**

Mr. JELLINEK. Thank you very much, Mr. Chairman. I am happy to be here this morning, and, Mr. Chairman, at your preference, I can either read the prepared statement or I can deliver a summary statement.<sup>1</sup>

Senator STEWART. Why don't we just submit the prepared statement for the record and then you can provide us with a summary statement. I have some questions that have been prepared by staff and some that have been submitted to me by other members of the committee, and we will ask those questions and others that your answers might suggest, and that would save us some time.

Mr. JELLINEK. Thank you, Senator.

I would like to note for the record that there is a rather important typographical error on page 7 of my prepared statement which, with your permission, we would like to correct for the record.

Senator STEWART. If you will read that for the record, or have you already corrected it?

Mr. JELLINEK. The second sentence on page 7 should read:

Generally, we are not going to waive efficacy data for those products intended to protect public health—that is, where failure to perform could adversely affect public health.

Senator STEWART. What did it say previously?

Mr. JELLINEK. The word "not" was left out, which is rather significant.

Senator STEWART. That is a rather important change for us to make. Let the record reflect that change.

Mr. JELLINEK. Thank you, Mr. Chairman.

<sup>1</sup> See p. 31 for the prepared statement of Mr. Jellinek.



I appreciate the opportunity to discuss with you our progress in implementing the Federal Pesticide Act of 1978, and to discuss the bill, S. 717, to extend the Agency's authorization to administer FIFRA for 2 years.

The new pesticide amendments are, to a large extent, a tribute to this subcommittee's diligence and willingness to tackle very complex issues. Working with you on that legislation was one of my first and, frankly, most regarding tasks after joining EPA. The new amendment remedies for an ailing pesticide program have proved, and I believe they will continue to prove to be a crucial factor in revitalizing our program.

I am happy to report we are making substantial progress in implementing those amendments, and I would like to go over some of the highlights.

We have devoted considerable thought and effort to implementing those that affect the registration program—conditional registration, generic registration, simplified registration, data compensation, and waiver of efficacy data.

Proposed regulations are due to be signed by the Administrator and published in the Federal Register in a matter of days now.

The most controversial aspect of the conditional registration is, I believe, our requirement that applicants of technical products cite all basic health and safety data pertaining to that chemical. I explained at some length why we feel this requirement is necessary when I transmitted the regulation package to the committee in March, and I have also explained it in my longer prepared statement.

Because the cite-all approach for technical products has proven to be the most controversial aspect of the regulations, we are allowing 60 additional days of comment on that issue. We can, of course, alter the regulations on an as-needed basis at any time in the future based on further consideration and experience.

We have already exercised our conditional registration authority in granting conditional registrations to several new products for use against cotton insects: Ambush, Pydrin, Bolstar, Pounce, and Dimilin. We have also proposed conditional registration for BAAM on pears.

You may also be interested to know that we have issued over 300 me-too registrations since January 1.

Conditional registration is our major stepping stone to another effort that is the real wave of the future, and I am referring to generic standards. We have been developing the conceptual framework for generic standards, and are about to issue an advance notice of proposed rulemaking that explains our thinking to the public in great detail. As we discussed during the hearings leading to the new amendments, it is time we stopped reinventing the wheel each time an application for registration comes along and develop a system which identifies approvable uses and formulations of all products containing the same active ingredient at one time.

We have also been making considerable progress in implementing the amendment pertaining to State authorities under the law. Regulations implementing section 5(f) of the act are in final form, and new proposed regulations implementing section 24(c) governing State registrations should be published in the Federal Register in June. States have been involved in developing this rulemaking and reaction has been favorable.



As you are aware, there are also a number of important enforcement issues in the 1978 Federal Pesticide Act. These are all discussed in my prepared statement. One provision which will be coming to your attention soon is the new export policy. A document detailing the labeling requirements for exported pesticide devices and pesticide active ingredients and the procedures for exporting unregistered pesticides is now under review. The Agency has consulted at length with industry and environmentalists on the contents of this notice. We are concerned that we not place unnecessary or cumbersome procedures upon exporters so as to hinder commerce. Yet we also must be sure that these requirements meet congressional intent and the information given foreign governments concerning exports from the United States must be both useful and informative. This notice will appear in the Federal Register shortly.

We have acted on or taken steps to implement many more of the amendments incorporated in the 1978 legislation. Definitions of "validated test and other significant evidence" have been published. The interim policy on handling trade secret information in accordance with section 10 has been published. Fourteen pesticides have been proposed for restricted classification. Thirteen more will be transmitted to you, the Department of Agriculture and the scientific advisory panel.

A minor use policy statement has been published. You should also be interested to know there are some new faces in the pesticide program. Three new division directors were announced last week, and I think we are building an excellent management team that should bring additional support and expertise to the program.

Before closing, I would like to add, we filed our study on ultra-low-volume methods, as promised, with the committee. Users of this must consider all risks and various options that are available. Five chemicals have gone through the process to a recommended decision and all have had some or all uses retained, subject to appropriate restrictions.

I believe, Mr. Chairman, that we are making excellent progress in implementing the 1978 amendments and that the pesticide program is beginning to deliver decisions made possible by the beneficial authorities provided in that new legislation. We intend to keep the committee involved as we proceed with full implementation of the amendments.

I would like to turn briefly to your questions about the FIFRA research authorization and about pesticide research in EPA. Frankly, Mr. Chairman, our situation in the issue of whether the administration submits an authorization bill for research on the pesticide program to this committee or to another committee of the Senate is that of being a person in the middle. We are operating under what we understand the rules of the Senate are in terms of the jurisdiction overall—

Senator STEWART. If you are talking about a jurisdictional battle and that is the reason you got involved in submitting two authorization proposals, that is not your problem, that is our problem.

Mr. JELLINEK. That is essentially what I am saying. OMB, for the administration's part, just doesn't particularly like us to send up two authorization bills for the same program and we think that we are trying to meet what we understand the rules of the Senate are.

Senator STEWART. Well, heaven forbid that I would raise any questions about them at this point.



Mr. JELLINEK. What we would be very happy to do in terms of the substance of the research program and the money involved is to provide you with a description of what our research accomplishments have been in the last year or two and what our proposals are for the future and we would be happy to meet with the committee and go into any detail on those programs.

Senator STEWART. If you do that, that would be all right. What I was saying to you is, frankly, if you are submitting to the rules of this body, you are doing what this body is requesting you to do and for us to raise a question about you complying with our rules——

Mr. JELLINEK. It is probably a fuzzy situation.

Senator STEWART. That is not unusual.

Mr. JELLINEK. We are caught between the rules of the Senate and the rules of OMB and as far as we are concerned we want to make everybody happy, and it is sometimes difficult to do that, which is an understatement.

Senator STEWART. What committee has oversight on this?

Mr. WAYLAND. Frankly, Senator, we thought the bill might be jointly referred. We produced a separate consolidated research bill for all agency research activity, under the Safe Drinking Water Act and Clean Air Act et cetera, and it is our understanding that our proposed research bill was referred to the Public Works Committee.

Senator STEWART. If you could provide some information about what you do in research with regard to pesticides, that would probably satisfy some of the questions of the committee.

Why don't we hold on that request until we get some opportunity to discuss it with the other members of the committee and Senator Talmadge? We don't want you to do something that would not be necessary.

Mr. JELLINEK. We would be happy to provide any information that you wish.

Senator STEWART. Let me check about that.

I have a number of questions that have been provided for me by staff. Some of them—well, the first one I have some interest in. If the proposal is made that FIFRA be extended for just 1 year instead of 2, would you please give us your Agency's position on that particular matter?

The reason I ask that question or the reason I am interested is this is a relatively new program and it would seem to me in the area of imposing regulations on an industry that you ought to have some kind of congressional oversight perhaps in the early stages just to see how the program is working. We got into a discussion last night about a program that is supposed to be implementing regulations as a result of an act passed in 1977 and it is 1979 and they are not doing it. I don't think the concern here is that you are not imposing regulations, but it may be that you are imposing too many.

Mr. JELLINEK. Let me try to deal with that. The last couple years have been spent in developing some major and significant new amendments to the Pesticide Act that we think will help us do our job the way Congress intended us to do when they overhauled the act in 1972. Accompanying that very important legislative activity has been a redirection and recommitment within the administration to try to get the job done and do it effectively. And the building of the new management team I mentioned is a very important part of that.



I think that the Congress will have a much better basis on which to judge the Agency's implementation of the new amendments in a couple years from now.

In terms of our oversight as to how we are doing, we are absolutely happy to appear for oversight and questioning at any time, on a weekly or monthly basis, if that is what you would like, and I am not being facetious. We do want to stay very close to the committee.

In terms of changes in the law itself, major, significant changes in the law, I think next year will be too soon to tell. I think that in a couple years we will have a much better idea whether the law itself needs to be changed, and I think we need that time to try to make this law work, and that is essentially why we are asking for a 2-year authorization.

Senator STEWART. You indicated in your statement that EPA will be issuing its first generic standards in 1980. How long do you estimate it will take EPA to issue all of the standards for conditional chemicals and how many standards would it be, if you have some idea?

Mr. JELLINEK. The short answer to that question is that we are estimating somewhere around approximately 500-plus technical grade chemicals that will require generic standards and that it will take us approximately 10 years to complete the entire job. We are trying to plan the development of those standards so that the more important chemicals in terms of amount of use, amount of exposure, get dealt with in the early part of that 10-year period, so within the next 5 years or so, the major chemicals that are really widely used will be attended to.

Senator STEWART. So the answer to the question is, the bulk of the chemicals will be involved in the issuance of generic standards and it would be 5 years for the bulk of them? Is that a fair assessment?

Mr. JELLINEK. It is a management problem because we cannot do work exclusively on the major chemicals that have major volume production, dozens and dozens of uses, thousands of literature citations. You can't work on those all at once, first, because we wouldn't get anything out for 2 or 3 years. The bigger the chemical is in terms of its use, the number of tolerances, the number of studies that have been done on it, the longer it will take to build a generic standard.

Senator STEWART. Wouldn't the better part of discretion be to take those chemicals that are most important, most widely used and most critical to the industry itself? Wouldn't that be the important area to deal with first?

Mr. JELLINEK. I think that is right, and we are planning to deal with them toward the beginning of the process.

Senator STEWART. I mean I would think commonsense would tell us that is where the greatest concern would be.

Mr. JELLINEK. That is right, but it is a practical management problem to arrange our workload so that people are working on something all of the time while we are waiting for something to happen on a big chemical. There are things that they can get done on little chemicals so that we use the time of our technical staff most efficiently. We intend to plan the process so that somebody is working on something at all times, and that is going to mean that some of the earlier standards that will be developed because they will be the easiest to produce will be on some of the smaller chemicals. We consider around 60 to 70



chemicals to be major chemicals because of the variety of uses, the number of tolerances and the number of literature citations. We hope to get the bulk of those out of the way within the first half of that process.

In terms of the volume of pesticides used in the country, we will cover the overwhelming majority of pesticides used in the standards covering those 60 or 65 major chemicals.

Senator STEWART. That would be in the first 5 years?

Mr. JELLINEK. That is what we are shooting for.

Senator STEWART. The other part of the question is, how many standards would there be?

Mr. JELLINEK. Approximately 500, 540 total.

The way we have arranged our initial cut of the workload, there are about 60 to 70 major chemicals, about 120 or so moderately sized chemicals, and about 300 or so minor chemicals. It is the major chemicals and the moderately sized chemicals that are going to take us the most time to deliver, so we are mixing the smaller chemicals with those as we plan our workload.

Senator STEWART. What would your criteria be in deciding which chemicals to put on generic standards first?

You may have already answered that.

Mr. JELLINEK. Well, we are concerned about major food uses and other major avenues of exposure. A number of those high-exposure chemicals will be in the first year's program. We will also be including in the initial standards some nonagricultural chemicals. Roughly half of the chemicals registered, or perhaps even more than that, are not agricultural chemicals. They are disinfectants and other types of pesticides that aren't used by farmers. We will be putting some chemicals on our first group in order to learn how to do the standards. We have been through a prototype on one chemical—a fairly easy chemical—and we are going to want to climb further up the learning curve in this first year or so.

I can supply for the record a list of the chemicals we have identified and scheduled for early generic standards.

Senator STEWART. Why don't you submit it for the record because there may be some specific questions, or I have some specific questions for some of these things by some members of the committee that we will get to in a minute.

With respect to your generic standard program, you indicated you will begin a systematic call-in of data. To clarify the record, what does the term "call-in of data" mean and how does it relate to generic standards?

Mr. JELLINEK. The theory of generic standards is to take a look at all of the data available on a chemical in order to make a decision on that technical chemical and on formulations of that chemical. We know right now, based on our review of the data in our files, that for many of these chemicals, some very significant studies have never been done.

When I say "very significant studies," I am referring to studies to determine whether the chemical may cause cancer, studies to determine whether the chemical may cause birth defects.

Senator STEWART. Are you all planning on doing that as part of your program to qualify these pesticides?



Mr. JELLINEK. What the early call-in would do is to put the companies on notice that to the extent that the existing data on the chemical which is known to them and known to us does not include some of the very important studies that are needed to make decisions, they are going to have to start planning for those studies and start doing those studies now. We don't want to get to the point 3 or 4 years from now when we are ready to work on a chemical only to discover that vital information is missing and there is no effort underway to generate the information. Many of these studies take a long time to complete, and there must be a systematic process to initiate testing so that the information needed to make decisions and the decisionmaking process arrive at the same point at the same time.

Senator STEWART. That would be a good idea because we are going to hold hearings in this subcommittee on a bill that has to do with a substance that affects a \$12 billion industry, so it would be good if they got a little bit of advance notice about that.

Mr. JELLINEK. That is precisely what the purpose of that is.

Senator STEWART. That is what the call-in data program is all about?

Mr. JELLINEK. That is right, to say you know generally what the gaps are in your data base and you know what kind of information is required, because we have laid it out in testing guidelines and you had better start filling in those gaps now, rather than waiting for us to come around 4 years later and then take 4 years to fill in the gaps.

Senator STEWART. What is the status of development by EPA in the Federal Mediation and Conciliation Service of the arbitration mechanism for resolution of data compensation that needs to be provided for in the Pesticide Act of 1979?

Mr. JELLINEK. I may have to get some help from the staff on this.

Senator STEWART. If you need that, go right ahead. Let's have them identify themselves for the record.

Mr. JELLINEK. My understanding is, frankly, limited in the way of what EPA is doing to require the Federal Mediation and Conciliation Service to set up this process. They are experts at mediating and arbitrating disputes when disputes are brought to them.

Perhaps Ed Gray, who is with our General Counsel's office, or Bob Wayland, who is with our Office of Legislation, might want to add to that.

Mr. WAYLAND. I have met several times with officials—

Senator STEWART. Please state for the record what you do, so we will have that.

Mr. WAYLAND. I am a congressional liaison officer in EPA's Office of Legislation. I have had several meetings with officials of the Federal Mediation and Conciliation Service. They have developed a draft regulation which would satisfy the requirement in the statute that they have a roster of arbitrators available to adjudicate these disputes and a set of rules under which those arbitrations would occur. I have worked with them on the development of a preamble to that regulation in the hopes that we might have something proposed, hopefully, in a very few weeks.

Senator STEWART. It seems to me that would be a fairly critical area, in view of what you are going to be doing in regard to these chemicals, to have some kind of a dispute mechanism.



Mr. WAYLAND. It was certainly one of the impediments to accomplishing the act's requirements prior to the 1978 amendments. In the development of pesticide amendments last year, there was an "industry compromise." Two major trade associations of pesticide producers, who disagreed over many issues, agreed that they preferred outside binding arbitration of compensation disputes. The Federal Mediation and Conciliation Service was later identified as a Government entity that could provide the infrastructure for that. The arbitrators themselves would be private independent commercial arbitrators who would not be Federal officials, not employees of the Labor Department or the Federal Mediation and Conciliation Service.

The guidelines that FMCS is thinking about proposing would convey a great deal of discretion to the arbitrator in terms of the factors that he could consider in trying to arrive at a settlement and giving compensation in a dispute, to permit the parties to present whatever evidence they have as to their interpretation of the value of the data.

I think that is about all that can be said about it at this time. I think that we have been encouraging FMCS—

Senator STEWART. I think the critical point is what part you all have to play in that and what are you all doing about setting the mechanism up. That is all our committee would be concerned about, just so it is there and available. Give me a time frame on that. You told me basically what you are doing and I think we could be able to solve or satisfy the questions that might be asked, unless there are others, and if there are, we will get back to you.

Mr. WAYLAND. I think probably a proposed rule within the next 30 days and a final rule would be, probably, 60 days thereafter.

Senator STEWART. Sixty days thereafter. You are talking about 90 days all together?

Mr. WAYLAND. That may be optimistic. Frankly, there should not be much in the way of controversy because the arbitrator is going to be conducting his own proceedings.

I might also mention that the committee staff is generally aware of this. We have had meetings with the staff of the committee periodically to bring them up to date. FMCS intends to use the American Arbitration Association and its pool of arbitrators.

Senator STEWART. One of the most amazing things about serving up here is that the staff from the Department works with the staff of the Congressmen and every once in awhile we hear what you are all doing. I am just trying to find out for myself.

Mr. JELLINEK. Senator, I would just like to add that I hope that this will be managed by the Federal Mediation and Conciliation Service's regulatory process because we couldn't get it out in 90 days.

Senator STEWART. I know you couldn't.

Mr. JELLINEK. We will help them as much as we can.

Senator STEWART. The primary controversy that has arisen in the short time since the Federal Pesticide Act of 1978 was enacted appears to concern the cite-all provision, the proposed conditional registration program. Would it be possible under the cite-all provision that applicant would end up paying more to compensate others for data than it would cost for it to generate the data independently.

Mr. JELLINEK. I don't think I can answer that issue definitively. This is the kind of question where if that situation were facing an applicant that the arbitrator would resolve it.



Senator STEWART. Have you made any estimate on the cost, and this is per chemical, of the data submitted by the applicants for the additional paperwork and redtape that will be generated by the cite-all procedure?

Mr. JELLINEK. We have. As you may know, we originally proposed that the cite-all procedure apply to both the formulators and to manufacturers of technical grade chemicals. Because of our estimate of paperwork costs and the transaction costs that would be borne or have to be borne by formulators, we changed our proposal to permit formulators to either cite data or provide their own. In some cases we found that formulators might have to write and then offer to pay for statements to as many as 100 or 200 different data owners. So with a technical grade chemical, we did a similar analysis and we discovered this was not the same kind of paperwork and redtape transaction cost issue involved because there is relatively less data to be cited, even through each test may, individually, cost more and be more important in making decisions.

Senator STEWART. I think what they are trying to find in the staff's questions, and I would be interested in this, too, is whether or not you can make valid decisions on the safety of pesticides and chemicals without reviewing duplicative kinds of testing, redundant tests or a lot of redtape, you know, and save a little money, which I think is basically what they are talking about and what they want to know is what you are doing to cut back on this, because this is a fairly sensitive program and there is a lot of money involved.

Mr. JELLINEK. I think that is a good line of questioning, Senator, and I think our modification from our initial proposal to our final regulation, as far as the formulator is concerned, is an example of our sensitivity to that need and to wanting to come out with a regulation that makes sense, and that doesn't put people through burdensome or unnecessary hoops. We asked ourselves the same questions with the technical grade chemicals and just decided two things: First of all, focusing on the paperwork question, that the paperwork products just aren't there because there was just not the same number of studies on the technical grade chemicals that would have to be reviewed, that would have to be cited by the applicant. It is a much easier job for the applicant to cite, to know what to cite, to make the contacts, to offer to pay contacts on a technical grade chemical than it is for a formulated product.

The other issue though is, frankly, on the types of studies done on the basic or technical chemicals, which tend to be the chronic toxicity studies, the cancer studies, the teratogenetic studies. There is literally no such thing as identical studies or duplications. Every study can tell scientists something, and we think that it is extremely important in our decisionmaking to be able to review all studies and it is artificial for us to say that because a company comes in with its set of studies that we are going to ignore or not pay attention or shouldn't pay attention to other studies that exist.

We should pay attention to them; we will pay attention to them, we can't help but pay attention to them, and in that sense they are used in our decisionmaking process, and under the law the applicants should pay for them.



Senator STEWART. Of course, I think I am asking what is necessary in the way of studies, as sufficient studies, for you all to make the decision and to hold the costs within a reasonable level. I think that is basically what they are asking. You are telling me that is what you are all working toward.

Mr. JELLINEK. Yes, and we recognize the intensity of concern on this issue and that is why even though these are interim final rules we will provide another 60-day comment period specifically to hear comments on this issue again when the rule is promulgated.

Senator STEWART. Senator Cochran had a question that he wanted to ask, so let's, so we are in order of seniority, let's ask the question first for Senator Helms.

In light of the emergency action taken by EPA on 2, 4, 5-T recently, is the current funding level anywhere sufficient to indemnify the losses that are anticipated from this action?

Let's add a footnote here and say we understand such losses are at least \$50 million and under FIFRA such indemnification is required particularly for surveys.

Mr. JELLINEK. I think that is too early to reach that issue because the indemnification provision will come into play only if we finally cancel those uses. We suspended those uses and the decision on final cancellation simply hasn't been made yet. In fact, the hearing on suspension requested by producers is still underway and the decision on whether indeed those chemicals will remain suspended hasn't been made yet. When we reach the point and if we reach the point of final cancellation, we have to face the issue of indemnification.

Senator STEWART. I think what he wanted to know is if you have to indemnify, would the current funding level be sufficient to indemnify the loss. I think that is the question he was asking.

Mr. JELLINEK. The way Congress wrote that section of the bill, as I understand it, they created a special torture for EPA as it goes through that decisionmaking process, which is that the money would just come right out of the already authorized funding for the Agency, so I might say that the EPA authorized funding is something, if our request is granted for this bill, it is something in excess of \$50 million and the funding would be there, technically. We would have to close up shop, but technically the funding would be there.

Senator STEWART. Then you are saying that the current funding level would not be adequate, is that correct?

Mr. JELLINEK. This is not budgeted for. The indemnification is not budgeted for.

Senator STEWART. I know you have some more questions on that. This is one Senator Cochran wanted to ask. He says:

I understand that the major reason USDA did not request funds in the fiscal year 1980 budget is that Federal quarantine of chloradane would be phased out by December 1979. This creates a particular hardship for the nursery industry since they depend on treatment of interstate shipments, I assume, with that particular chemical. So the 1978 FIFRA amendment called for consideration of the payment of proposals for minor use of pesticides. EPA action for extension of the use of chloradane on field crops may be appropriate. However, I believe the intent of the law provides special consideration for such uses of chloradane on nursery stock. Are there commercially available substitutes for chloradane which can be used to treat nursery stock for interstate shipments.

That is his first question and, frankly, I would like to know the answer to that because I have some nursery folks in Alabama very



much concerned about this. We don't want you all to destroy the economy of the southern part of the State of Alabama or Mississippi.

Mr. JELLINEK. Senator, I can provide a response for the record on that. We are aware of that problem and are considering that issue. We have been approached by a couple of States on it, I believe.

Senator STEWART. It is important in that industry and he wants you to list those for the record, the commercially available substitutes. I would join with him in that request.

Mr. JELLINEK. We will give you a complete report on those.

Senator STEWART. Then he wanted to know if not, what alternatives would you suggest for the use of chloradane on nursery stock.

Then this is for Senator Lugar: As I understand, EPA has a severe shortage of personnel, especially scientists, to process pesticide registrations. Is this true, and, if so, what do you plan to do about it?

Mr. JELLINEK. I think that our authorized budget levels for this year and our proposal for 1980, if the Congress approves it, are sufficient to do the job that we have been asked to do. We have a number of vacancies based on our 1979 authorization that we are trying to fill; we are not filling them as rapidly as we would like to, but we are optimistic as to that. Getting good scientific talent in this area is very difficult because there is a highly competitive market for those skills, but I think we have a sufficient authorized staff.

Senator STEWART. That is apparently as much a part of your problem as funding is.

Mr. JELLINEK. Funding is generally not a problem.

Senator STEWART. You know what happened to you in the budget activity in the committee? Are you familiar with that?

Mr. JELLINEK. The committee?

Senator STEWART. I am talking about the Budget Committee.

Mr. JELLINEK. The Appropriations Committee has not yet decided on our fiscal year 1980 request. We had a constructive session with them and we are optimistic.

Senator STEWART. I have no further questions from any members of the committee. Thank you very much. I appreciate your testimony and appreciate the members of the staff being here.

Dr. Jack Early, president of the National Agricultural Chemicals Association is here to testify. Are you all coming up as a panel?

Dr. EARLY. I will introduce my colleagues.

Senator STEWART. We would appreciate that.

**STATEMENT OF DR. JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION; ACCOMPANIED BY JONATHAN P. ROGERS, MOBIL CHEMICAL CO., AND JOHN D. CONNER, ASSOCIATION COUNSEL**

Dr. EARLY. Thank you, Mr. Chairman, for this opportunity to testify. I am Jack D. Early, president of the National Agricultural Chemicals Association. I have with me this morning, on my immediate right, Jonathan Rogers, who is with Mobil Chemical Co., and also serves as chairman of our board of directors, and on my far right I have John Conner, who is our general counsel.

We appreciate the opportunity to testify before your committee this morning, Mr. Chairman, and with your permission we would like



to ask our statement be made part of the record and perhaps, in the interest of time, I could read certain parts of it and summarize certain parts of it.

Senator STEWART. That would be perfectly agreeable with me, and that is exactly the way we want to operate, so without objection we will make your full statement a part of the record.<sup>1</sup>

If you will go ahead and summarize your statement, that will be fine.

Are the other gentlemen going to testify?

Dr. EARLY. They are not prepared to testify, but are here to assist me in case the questions get too difficult.

Senator STEWART. Fine.

Dr. EARLY. At the outset, let me say that NACA opposes S. 717 to authorize funding for implementation of the Federal Insecticide, Fungicide, and Rodenticide Act for 2 years. It is our feeling, Mr. Chairman, that a 1-year extension of authorization would be perfectly sufficient at this time and we believe would give the Congress a realistic period of time to make sure that the Environmental Protection Agency is indeed carrying out the intent of Congress as they implement the 1978 amendments to FIFRA, so we would like to be on record opposing S. 717.

We would also like to take this opportunity—

Senator STEWART. Just a minute. Let me clarify that. You oppose the extension for a 2-year period; 1 year would be all right with you?

Dr. EARLY. I should have said that. We are in favor of a 1-year extension.

Senator STEWART. I just wanted to clarify that for the record.

Dr. EARLY. We also would like to take this opportunity to congratulate EPA and Mr. Jellinek on some progress that we have seen since the 1978 amendments became law, particularly in the area of conditional registration, which is a new, simplified registration process they implemented, and to date we are quite happy to see some labels being registered by EPA. We went through a long period of time where we saw no labels coming out of EPA, so we are pleased that part of the program is working.

Having paid a compliment to EPA, let me say I think it is also appropriate that we call to your attention some of the areas where we are seeing some difficulties develop or some potential difficulties. The first I would like to call to your attention is the area of cite-all requirements, which you have heard about and discussed earlier this morning. We have quite a bit of concern about this area.

In implementing the data compensation under the 1978 FIFRA amendments, the EPA, in our opinion, is violating the express congressional directions in section 3(c)(1)(D) of amended FIFRA by forcing applicants of technical materials to pay compensation for all data in EPA files which pertain to those materials. This is contrary to the clear language of section 3(c)(1)(D), which states, and I will quote part of that:

A full description of the tests made and the results thereof \* \* \* or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator \* \* \*

<sup>1</sup> See p. 35 for the prepared statement of Dr. Early.



This statute gives the applicant an alternative to either supply the necessary information to register his product or he has the option to cite data that exist.

Senator STEWART. Do you mind if I interrupt you at that point?

Dr. EARLY. Not at all.

Senator STEWART. How about giving me a practical example of how that affects you, the tactic that the EPA is now taking, or how it affects your industry? You know a lot of these things. If you have an example that you can offer members of the committee, they might understand it a whole lot better. How about breaking it down in commonsense terms?

Dr. EARLY. Let me see if I can do that. In order to do that, and I think Mr. Jellinek touched on this, they are approaching the registration process two ways: First is the registration of what we would call end use of formulated products, that is, the products that the user would use in the field for applications. In addition to that, they have what they call above the line registration, which is a registration of a technical material that is used to further formulate into end-use products. They have indicated that they are allowing an applicant to supply data or give citation below the line for end-use products.

Senator STEWART. You are talking about above the line products?

Dr. EARLY. I am talking about above the line.

Senator STEWART. All right.

Dr. EARLY. I think the clearest situation here is that if one of my manufacturers were to come in with a brand new chemical pesticide that EPA has never seen before and they come in to register this product, it seems to me to be ridiculous to require that registrant or applicant to offer to pay or to cite data that doesn't really exist anywhere except the research he has done on this new product. I think that is the cleaner example on a brand new product. Why you have to go through the cite-all situation is beyond me.

Now you have less clear examples on down into the situation for technical materials for which data have already been supplied or already registered. We believe the registrant should have the option. It may be, as you asked the question earlier this morning, cheaper for a potential registrant to generate his own data necessary to register a product, rather than paying compensation for the data that already exist in the file. At least the applicants should have the option of going one way or the other, as specified, we believe very clearly, in the law.

I don't know whether that helps or not.

Senator STEWART. It clarifies it somewhat.

What is the objection of EPA to doing it that way? Let me get the bone of contention here, the crux of the problem. What is the problem?

Mr. ROGERS. One other area that is troublesome, Senator, is, let's take an older pesticide that has been in use many years and still may be of a patent and still has protected data because it has been developed in recent years and they develop a new use. It has nothing to do with toxicity of safety or anything else. It is just a new weed to tack on to this product.

During these many years, other people may have used that pesticide as a standard in measuring this pesticide for EPA, the efficacy of the pesticide, so the files are full of references to that chemical, so they come in for a new use and they may have literally thousands of references that they have to go to companies and cite to those companies.



EPA supplies the list and they have to write all of those people on each specific citation.

Maybe I used one of my competitor's products as a new chemical and all I did was cite his chemical as the standard for which I measured gains for efficacy and therefore they have to write me and offer to pay me for that data. The data is worth nothing, obviously, so I would not get paid and I would not claim to be paid for it, but they have to spend whatever it costs them to write that letter and I have to answer the letter, and it is not an exaggeration that we are trading the letters back and forth and the U.S. mail ought to be less with the volume they get from us. A small company like ours—and Mobil is not small, really—we are writing 30 or 40 letters a month to people saying, we don't want your money. It just doesn't make sense to do it that way. It is a morass of paperwork. That is another objection.

Senator STEWART. You are not talking about the cost of writing 30 letters a month as being the prohibitive part of this, though?

Mr. ROGERS. No, sir. I am saying the whole process should not be done that way. They should not ask for people to cite data on that kind of basis.

Senator STEWART. How much would you have to compensate somebody if they wanted you to compensate them? What is the cost?

Mr. ROGERS. The cost would depend on the quality of the data.

Senator STEWART. Who determines that?

Mr. ROGERS. If the companies could not agree, then they would go to this arbitration.

Dr. EARLY. It goes to binding arbitration, as you were discussing with the Agency this morning.

Mr. ROGERS. Some of these tests cost literally hundreds of thousands. The one we are in now cost \$425,000. So if somebody wanted that, we would try to get as much out of it as we could.

Mr. CONNER. May I add this, Senator, to that? Another problem that I think this raises is this: Say a company wishes to register a pesticide that has been registered by a number of others. He has produced his own data which in his opinion, establishes the safety of the material that he wishes to register, but EPA says you must also write any other person who has submitted data that we eventually will determine is relevant to determining the safety of your material and promise to pay. That requires that applicant or proposed registrant write to these number of companies—it might be 10 or it might be 100—and offer to pay whatever is eventually determined to be the value of that particular data. In response to the questions that you raised a while ago as to how the arbitration—how the Mediation and Conciliation Service—is going about determining this compensation, the regulations have not been issued yet. A person in signing such a promise to pay is, in effect, signing a blank check to pay whatever the U.S. Arbitration and Mediation Service arbitrators eventually determine is to be the fair value of the use of that data. Whatever the total is would then have to be divided between 10 or 100 different persons. I think that that is going to cause a serious financial question. I think a CPA auditing the books of that company would have to raise the question, well, what is the nature of this obligation that you have signed? The person I think would have to say at the present time, well, we don't know; it is just a blank check.



Senator STEWART. Let me ask you some questions—I agree that those are legitimate concerns on your part—that come to my mind that ought to be asked at this point. Just so I can clarify this, do you have to cite all of the tests that have been done by anybody or is there a sufficient number that you could cite that would be adequate for EPA to make their determination? Where are you in that milieu?

Dr. EARLY. Under the present system, Mr. Chairman, you are not allowed to pick and choose the data you wish to cite.

Senator STEWART. Who picks and chooses?

Dr. EARLY. You cannot pick and choose. You have to cite all of the data.

Senator STEWART. Who picks and chooses the data that you would then, after you cited it all, would have to actually provide EPA, or do you have to provide them all of it?

Dr. EARLY. The way it is structured now, I think you would have to pay for all of the data because they are assuming they are relying on all of the data. That may not be true. There may be some data in there that perhaps are not valid data but right now it is a total data package.

Senator STEWART. Who makes that decision?

Dr. EARLY. EPA.

Mr. ROGERS. They do. In their files they have a chemical listed, and every place it is listed, there is a reference to it, so if someone comes in and wants to register a use of chemical A, then every reference to that either in safety, efficacy, or any other reference to that in all of EPA's files is produced by EPA.

Senator STEWART. What is the danger in it?

I can see some inherent danger or what I think the danger is in allowing someone to cite the tests. Would you cite a test if you developed a pesticide that might indicate—if the distinction between those tests you would cite or not cite would be left to the manufacturer? Would you cite a test that might prove that that particular product would be dangerous to the environment or dangerous to somebody's health? This I think is what the concern would be on the part of Congress, what the concern would be on the part of EPA—what the concern would be on the part of the general public.

Mr. CONNER. Senator, in response to that, I think the legislative history of the 1978 and the earlier act is that it is clear that the Administrator has the legal right to consider any data in his file relating to the safety of a product without the payment of compensation for that, to judge the adequacy of subsequent data or any other data in the file, and that the compensation provision is intended to apply only to data that the person relies upon to support the determination of the safety of the product which he wishes to register, but that the Administrator has an unqualified right to consider any other data in his file that might show that the product is harmful.

Senator STEWART. Well, do you believe that the EPA can make valid decisions on the safety of pesticides, pesticide chemicals without revealing all of the tests that were done, including, perhaps, those tests that I mentioned that might indicate those chemicals have some harmful effects?

Dr. EARLY. I think they can, Mr. Chairman.

To go back to a brand new product situation, EPA is in the process of developing rather voluminous guidelines one must go through to



register a new product, and you must meet those minimum test requirements. For example, if EPA would require new material to supply to long-term feeding studies, if that is the minimal requirement, he comes in and could register a new product based on that information, but if you require a registrant, one that is coming in with a me-too product, to cite all and you are sitting there with five or six long-term feeding studies, all of equal value, then the Administrator is saying I want to rely on all of this information, so what we are saying is that you have standards developed to register a product and you could use that standard based on your guidelines to register that product so in some respects I think you are discriminating a little bit against the me-too versus the new product.

Senator STEWART. What you are saying is that in the above the line products there ought to be some minimum standards and you ought to be able to pick and choose from those tests that are available, say the two feeding tests over a certain stated period of time, and indicate the safety of that product?

Dr. EARLY. I think that is basically right. I think that the bottom line is that we think it is quite clear that in the 1978 amendments it provided that a registrant could supply the necessary information to register his products, whatever that requirement may be by EPA, or alternatively he can cite data that already exist within the files.

Mr. ROGERS. May I make one more distinction? Suppose these two gentlemen have an old chemical and I may strike a deal with Jack—he has a registration—to buy his data to support my registration. Then if the EPA chooses to do so, they can, in order to be sure that this product is safe, which they have already registered by two other people, if they want to they can check John's data, too, but I should not have to offer to pay John since I have already bought the data from Jack. That, I think, maybe gets down to paying more than you would have to if you did it yourself. If they want to look at his data, they can do that. They have that unilateral right now, but I should not have to pay both of them. I ought to be able to buy one automobile and not pay for two.

Senator STEWART. You are talking about data already available to EPA?

Mr. ROGERS. Yes, sir.

Senator STEWART. Why do they expect you all to pay for the second? I don't understand that. If they have it, why are they requiring that?

Mr. ROGERS. I think it is an offer to pay and then I have to go to the mediator and the mediator says well, what would you pay? I don't know. Maybe I have already gotten a deal with him.

Dr. EARLY. If I may, let me point this out: I think this is part of EPA's concern. I should not be supporting their argument here this morning, but I will point out what I think their concern is, as in the case Mr. Rogers just used, if he struck a deal with me and he wanted to use my data, which is all that is necessary to support his registration, and he should not have to pay Mr. Conner for his data. EPA says, if they take that position, they are concerned Mr. Conner might come in and sue the Agency and State that he did, by reference, use Mr. Conner's data and Mr. Conner should receive some compensation.

Senator STEWART. If I were in competition with you and had data on a product and you were trying to submit it for registration, one



of the best ways in the world I could hold my competitor's feet to the fire would be to sue the Agency and say they didn't need it. That couldn't be going on, could it?

Mr. ROGERS. Not to my knowledge, but I can't answer that.

Senator STEWART. Would you want to comment? Phil has indicated you might want to comment, the representative from EPA.

Mr. WAYLAND. I think the illustration you just made is exactly the situation we are concerned about, that Mr. Conner will want compensation and that if the Agency has implicitly relied on his data a rightful opportunity for compensation attaches, but the "solution" to the data problem NACA has just described fails to take account of that. Pesticide companies situated similarly to the hypothetical company Mr. Conner played the part of just now have not been loathe to assert their rights either to obtain compensation or block registrations that are supported by their data. The constitutionality of the 1978 act has already been challenged by about 11 companies in 2 courts, and in those cases the complaint is that any scheme of compensation, any disclosure mechanism that attaches to common law trade secrets is invalid under the constitution. The result of such an interpretation is what was deemed in last year's legislative battle "exclusive use" for all data all of the time. That is the way you defeat your competitor. You say I am sorry, I am not interested in your compensation.

I think we have crossed back and forth several times in the discussion this morning between the sides of the horizontal line in terms of the circumstances in which data citation would be required under EPA's draft rule. Where the chemical involved is a technical chemical and where the data involved is chronic data which is fundamental to decisions about health and safety, we have taken the position that it is an artifice to say I have looked at Mr. Early's two studies, I know Mr. Conner's two studies exist, but I won't look at them. The situation we would be driven to from a resources standpoint would be that when Mr. Early comes to us and says register me on the basis of my two studies, we would have to look at his two studies separate from any systematic "generic standards" review and evaluate them for sufficiency. If most manufacturers opt for this "pick and choose" approach, we would have a product-by-product data evaluation and decision-making process, which is what we, frankly, hoped to escape in the proposal for amendment last year to provide conditional registration until the systematic review could be completed. It is a problem we have given a great deal of attention to. For formulators, we have provided a submit or cite option. We have asked to continue to talk to the National Agricultural Chemicals Association. It may be that at some point we will be able to resolve this satisfactorily, but we are in fact in certain courts—

Senator STEWART. You all going to include us again?

Mr. WAYLAND. Absolutely.

Mr. CONNER. May I respond to one statement that was made concerning the litigation that has been instituted relating to these? None of that litigation—I believe I am correct in stating this—challenges the constitutionality of these provisions based on the cite-all or the lack of cite-all data. The challenge is based upon the fact that the legislation results in a taking of property and then the settling of



that property by arbitrators, with no judicial appeal. In other words, taking of the property without fair compensation or the assurance of due process is, in substance, the basis of it.

Senator STEWART. Phil pointed out one of the lawsuits had been decided, apparently, and decided on the ground that you couldn't take somebody's work product, in effect, and use it without that particular individual receiving compensation, which is what would occur if you allowed or assumed Environmental Protection Agency would take a look at tests that they had available to them and allow somebody to come in and register a product on the basis of that test and work that they had done.

Now how do you respond to that raises an interesting point.

Mr. CONNER. I would respond to it this way: Assume a case where there has been two registrants of the same chemical. Say the first one did his test to establish the safety and efficacy of the product. It was registered on the basis of that. The second one in his application did the same thing, did his test, say, parallel to those of the first one, and on the basis of those tests and his own data established the safety of his product and registration was granted. Now, should not the third applicant have the right to go to those two and say you have submitted substantially the same data and I want to bargain with you for the use of this data?

First applicant says all right, I will let you have mine for \$25,000. The other says oh, no, I think it is worth \$750,000, and he stands firm on that position. The result of cite-all data would be that the applicant would not be able to buy at a reasonable price the data of the first and EPA has determined in the past that the data submitted by the first applicant was sufficient to support the safety and the efficacy of the product. Is there any reason under those circumstances to say you must rely also upon the data of the second, even though the first product or the data of the first establishes the safety of the product? EPA has determined in the past it was sufficient to establish the safety of it. I can readily see if EPA, under those circumstances, said no, you have to rely upon the data of both of them that the applicant would be in a position to go into court and say well, now, you are refusing to register my product on the basis of data that you have already used to register another product and therefore you are discriminating against me by not allowing me to rely upon the data of the first, but are forcing me at an exorbitant price to pay this second applicant.

Senator STEWART. That is where the arbitration procedure comes in for decision between the parties to prevent that discrimination from taking place.

Mr. CONNER. It might or it might not. If you forced them to go to arbitration and the arbitrators were faced with a situation well, the first company over here was willing to sell its data for \$50,000, the second one wanted \$750,000 for his, I don't know what the arbitrators would do in a case like that, whether they would strike a medium.

Senator STEWART. I see the problem with this. I, frankly, would appreciate your providing information on that. I am going to take a look at some of these other things because I have been led to believe this morning, and I am going to talk to Senator Talmadge about it, that what we ought to do is take a look at 1-year authorization. He



might disagree with me, but I am going to at least talk to him along those lines because I personally feel, based on what you gentlemen have raised and, frankly, what the folks from EPA raised, that there is a need for Congress to be as involved in this as perhaps they have been in the past.

Of course we are implementing a new program and a lot of times people say there is not enough time for us to give you some data that would be adequate, but, heck, I think that is the time that Congress ought to get involved, when they are developing a new program. It just makes sense to me. It might be because it makes sense to me it won't make sense to anybody else.

Do you have some other testimony? If you would, emphasize your other points. We have some other witnesses to hear this morning. We got a little long winded here.

Dr. EARLY. Let me mention one other point. Hopefully, this has been helpful to all of us.

Senator STEWART. It was to me. I hope it will be to members of the committee. Anybody that gets bored or upset or a little tired can get up and walk around.

Dr. EARLY. I can assure you it is a very technical and complicated statute we are looking at.

Mr. ROGERS. It is not easy for EPA to deal with.

Senator STEWART. I understand that. That is basically what it was sent up here to do. It might not be the most glamorous job in the world. I can't issue a press release about this this morning. I would like to be able to. But it was a job I was given by the Senate to do and I am going to do it.

Dr. EARLY. Let me raise a couple other areas we are concerned about. You heard some comment about generic registration this morning. We as an association of industry supported the concept of generic registration last year before this committee and also before the House. We are still concerned about how this generic registration concept will be fully implemented. Frankly, I am a little bit concerned about any program that is going to take 10 or maybe 15 years to fully implement. That bothers me a little bit. It may be a great program that takes 15 years, but somebody else is going to be doing this. So that concerns me.

What we have done in our written statement is we have raised a number of questions that we think the Congress should look at as EPA goes ahead to implement the generic registration. I won't go through those this morning.

Another area that gives us a great deal of concern is an area Congress agreed to last year and that was an effort to try to protect these data, confidential data, and trade secret information from disclosure to foreign corporations or foreign multinationals. There is a provision in FIFRA that deals with this disclosure or nondisclosure of trade secrets to foreign and multinational corporations.

Senator STEWART. Are you all satisfied with the way that is being done?

Dr. EARLY. We are not satisfied with the way it is being done right now, and I think even deeper than that I am not sure we are totally satisfied with the way the statute is written. We believe it can be written in a little better language and we would like to take the opportunity sometime under some more drawnout oversight hearings to recommend some changes in the statute, perhaps next year, that



might bring about a more reasonable approach to protection of these data that we believe the Congress has rightfully recognized as essential. The prime concern we are most concerned about right now is the fact that we believe before EPA releases any of this information to any party they should give the owner of the data at least 30 days' notice prior to release of these data. The party that owns the data is the best one to judge whether or not a party is a foreign national or an agent of a foreign national company, so the notification issue is of prime concern to us. But this statute does need to be rewritten, at some time, and we give some examples why we think it should be.

Another area that concerns me is under section 6 of FIFRA, which requires a registrant to report to the Administrator any additional factual information that may come to the registrant's attention. EPA, we believe in violation of the provision, has gone around the Congress intent and they are asking a registrant to supply any information, and they have left the word "factual" out. We have been in discussions with EPA on this area. In fact, we have gone to the courts and under the direction of the courts we have been trying to resolve this matter in discussions with EPA and this is why we brought this suit against the Agency. EPA to date has refused to budge from their position that we believe is an unlawful position, so we are now in the posture to have to return to the courts within the next few weeks to request they invalidate EPA's reporting requirements.

One other area we are somewhat concerned about and a more recent development: We have seen a number of States begin to look at pesticide registration laws within their own States. Several States have already had bills before their State assemblies that would, in effect, if they passed, circumvent this protection of data that we have seen Congress give us through this foreign and multinational area. There was no protection at the State level and some States are beginning to ask for exactly the same amount of data that the Federal Government is asking for and putting it in the hands of the States we believe is another way in which these data, these private data, can be made available to competition. We think Congress ought to look at some legislative history under section 24 of FIFRA that would try to correct that situation, and we would be glad to work with the staff in any way you would like to try to correct that if you believe that is a problem, and we think it is.

One final thing I would like to call to the committee's attention is that as you heard this morning there were some questions on it, and that is the EPA recently ordered the emergency ban on pesticide 2,4, 5-T and silvex. There were questions about that this morning. We are concerned because the court decision that came down on this area found that there were serious questions of deficiencies in the evidence relied upon by EPA to support the suspension, but the court did uphold the EPA with—quote—great reluctance for the reason that the order was not completely without basis. We believe that under section 6(c)(4) of FIFRA the courts are empowered to set aside a suspension order when they find that the evidence relied upon by EPA is seriously deficient and does not support a conclusion that there is a likelihood of unreasonable adverse effects on the environment.

Congress could and should clarify the legislative history that the courts may stay in an emergency suspension order where the evidence



relied on by EPA demonstrates there has been a clear error in the judgment of the Administrator.

Senator STEWART. Thank you very much, Dr. Early, for your testimony. I am sure we will be back in touch with you. We will read your testimony carefully and we might make some of the suggested changes or at least move to consider it. It has been very interesting and we appreciate your testimony.

Mr. Stephen Kellner, director of legislative and regulatory affairs, Chemical Specialties Manufacturers Association.

Mr. KELLNER. Thank you, Mr. Chairman.

Senator STEWART. Will your testimony follow, to some extent, basically the testimony that has previously been given by Dr. Early and others or are there differences you would want to cite?

Mr. KELLNER. There are some differences, sir. Generally we would follow the same track. We represent a different portion of the industry. We are the nonagricultural portion of the industry. NACA is more agriculturally oriented. We have disinfectants and sanitizers, home and garden insecticides in our companies we represent.

Senator STEWART. Would you please just highlight for me the testimony and then I have some questions here I want to ask you. I would ask that you do that. If you are not prepared to do so, you can read your whole testimony, but I would ask, if you would, that you summarize it and we will submit your full statement and make it a part of the record.<sup>1</sup>

**STATEMENT OF STEPHEN KELLNER, DIRECTOR, LEGISLATIVE AND REGULATORY AFFAIRS, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION**

Mr. KELLNER. I will be glad to summarize my statement, Mr. Chairman. CSMA has appeared on numerous occasions before this committee in development of the amendments, and I wish to note for the record that we are pleased to be here again and we applaud the committee in attempting to iron out some very difficult problems, as you can see from questions this morning.

Senator STEWART. I didn't realize it was all in court. If I had known it was all in court—I am not being facetious—I would have read some opinions before we came here this morning.

Mr. KELLNER. It is not all in court. I don't think we want to paint a picture that that is the case. I think the industries are very gratified and we do feel we are making some progress. We all knew this was a very difficult task when we got started and there might be some problem areas, and I think those are what you are facing. I wouldn't want to say we are not making progress. Dr. Early said the same thing, that there is progress being made. The Agency is certainly trying very hard and we are working with them at every juncture to see we do make progress.

We have just two problems to talk about this morning, in addition to the funding aspect. Now with respect to S. 717, we would be opposed to a 2-year funding. We feel that the continuing 2-year level of authorization does act in itself as a most important oversight function to ensure that progress continues in the implementation of the pesticide amendments and therefore we would oppose S. 717 because of the 2-year authorization that it would afford.

<sup>1</sup> See p. 37 for the prepared statement of Mr. Kellner.



There are two other areas we are concerned about: Methods for submission of new and pending applications and registrations and State requirements for submission of safety and environmental data. Dr. Early touched on the cite-all approach and I will just briefly add a few things.

Back in December 1978 EPA did publish a public relations notice which basically set forth the policies and steps that would be necessary in bringing applications for registrations into compliance with the 1978 amendments. There are three options, two of which are important. Option II would permit the applicant to submit an application or revise a pending application which relies on specific items of data either generated by the applicant or cited from Agency files, provided that the registrant complies with applicable compensation provisions of FIFRA and further, that any registration issued on such basis would be conditioned upon the registrant's compliance within 120 days with the final regulations governing conditional registration and compensation.

That is option II. Option III is the cite-all approach, which was amply covered, and that would compel the applicant to offer to pay compensation for all items of data contained in the Agency files which pertain to the product, its active ingredients, et cetera.

Our initial communications from within the Agency indicated that option II would not be included in the final regulations. Instead Agency personnel have pushed the use of option III. As was said this morning, the requirement to cite all data in the Agency files and make offers to pay compensation to all registrants having data has resulted in an avalanche of letter-writing and exchanges and does necessitate making marketing decisions not knowing what the ultimate aggregate compensation fees will be.

Senator STEWART. So your basic opposition is the same as Dr. Early's and his association; is that correct?

Mr. KELLNER. Yes, sir. We were pleased to recently learn, however, that the Agency policy with respect to the use of the second option, the one that would allow you to cite your own data, develop our own data or cite another person's data has changed somewhat with revision being made in draft final compensation regulations for an alternate method for use by registrants of end-use or formulated products. This is the formulation of the end-use product as distinguished from the manufacturer use product. The applicant using the alternate method of supporting an application will not be required to acknowledge reliance on all the data in EPA's files, which is option III. Instead he could provide copies of data either self-generated or otherwise obtained, which are necessary to satisfy the requirements pertaining to safety, efficacy and other properties of the product and may direct EPA not to consider other data in support of the application.

We believe that the alternate method should be expanded to include manufacturing use or raw material product registrations. We agree with the previous testimony. We do not believe Congress intended that an applicant for registration could not develop his own data or specifically cite the data upon which the registration would be based. We perceive, therefore, this is an area which needs further clarification to allow all registrants the option to generate their own data or cite other specific data.



Senator STEWART. You are just saying that the above line products ought to be treated in the same way as the below line; is that correct?

Mr. KELLNER. That is correct.

Senator STEWART. Which is what Dr. Early stated?

Mr. KELLNER. Yes.

State requirements for submission of safety and environmental data: The 1978 amendment incorporated into section 10(d)(1) the principle that information concerning safety and environmental data be available for disclosure to the public. However, in doing this there were stringent requirements placed upon access to that data, and of course there was compensation involved.

In modifying the trade secret provisions to allow this information to be available to the public, we do not believe Congress ever intended that the States should likewise require submission of the same data.

Senator STEWART. Let me get to the crux of the example, I think this question could get it answered fairly quickly to my satisfaction. You can go ahead and submit your testimony with regard to that. You said that a possible problem is State registration, that they had imposed onerous data requirements. What kind of requirements did the State impose and did they exceed the EPA requirement for Federal registration?

Mr. KELLNER. They pick up the limitation language in section 10. Essentially they would require submission of all of the same data on an across-the-board data that you would have to submit to EPA.

Senator STEWART. They didn't exceed the data requirement of EPA?

Mr. KELLNER. At this point they have not exceeded the data requirement, but this could be volumes of data. I left a photograph with the State officials that showed if we take about half of this table here and stack it about 1½ or 2 feet high, that is the data for one product.

Senator STEWART. Are you concerned about the fact that that data or that information will not be protected as it is at the Federal level? Is that your basic concern, and also the cost involved?

Mr. KELLNER. That is right. The cost would be horrendous and the States could not really keep the data. The States, frankly, are very reluctant to take the position that this data is going to be available to them as FIFRA indicates it will be by sending representatives down to take a look at the data here in Washington where there are stringent controls and where the data, if it is subject to compensation, would be protected. If we start sending that data out to all of the States, we have a massive problem, and that is the crux of the issue.

Senator STEWART. And that is beginning to crop up?

Mr. KELLNER. It is beginning to take place. They are taking the language of section 10 and just plugging that into the various regulations and we feel that some preemptive language is necessary there, that we ought to shore up that area. We don't feel Congress ever intended that that should take place. This was a compromise, as you are now aware, and the industry feels that to the extent that the law is written, so be it, but that data must be protected and it can only be protected by going through the Federal processes set up in FIFRA.

Senator STEWART. Is that basically the crux of your testimony?

Mr. KELLNER. Yes, sir. I just wanted to mention one other thing. CSMA is also a coplaintiff with NACA in the FIFRA 6(a)(2) litigation, I just wanted to mention that for the record.



That, sir, will conclude a summation of my testimony.

Senator STEWART. I have asked the questions that have been provided by my staff. I appreciate your testimony and thank you for coming here this morning. We will be back in touch with you about some other matters that, frankly, I am concerned about. Thank you very much.

Mr. Victor Winik, chairman, International Sanitary Supply Association, Chicago, Ill.

Let me ask, just for purposes of information, is Mr. Scott Whitney here.

Mr. WHITNEY. Yes, sir.

**STATEMENT OF VICTOR WINIK, CHAIRMAN, INTERNATIONAL  
SANITARY SUPPLY ASSOCIATION, CHICAGO, ILL.**

Mr. WINIK. Good morning, Mr. Chairman. I would like to first ask our text be made part of the official record.

Senator STEWART. Without objection, that will be done.<sup>1</sup>

Mr. WINIK. Rather than dwell on a subject that many people have spoken about here this morning, I first would like to introduce myself and say who we are and what it is that we represent and then enter on to a subject that nobody in industry or in Government has touched on to this point.

Senator STEWART. If you can find something that industry or Government hasn't touched on to this point, I want to hear it.

Mr. WINIK. First, let me introduce myself and say who we are, and then we will go from there. Our association is composed of, roughly, 2,200 companies. We supply the United States and most of the world with sanitary maintenance cleaners. They are used in hospitals, schools, and institutions. They help the health standards of our country.

We do not get involved in the hard agricultural pesticides or agricultural chemicals, so-called.

The point that I would like to touch on today that has not been touched on by anybody yet is a separation which has been clearly asked for in section 25(a) of FIFRA. Essentially what it states is this: Section 25(a) (1) provides ample FIFRA authority for the separation of nonagricultural from agricultural pesticides on the basis of differences in their concept and usage. Section 25(a)(1) clearly provides, and this is the regulation—

Senator STEWART. I know now why you sat on that side of the room and Dr. Early sat over here.

Mr. WINIK. The regulation reads:

The Administrator is authorized, in accordance with the procedure described in paragraph 2, to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

We feel that if this provision were looked into and closely studied, and we would do all within our power to help a study of this sort, we would be able to create almost a complete break of the logjam which

<sup>1</sup> See p. 39 for the prepared statement of Mr. Winik.



the EPA now has. They openly admit to 5 years to do some more work and possibly as much as 10 to 15 to get all of the registrations through. If our portion of this program were to be separated from the hard agricultural pesticides, there would be an enormous break in the logjam EPA now has. It would help the Nation in terms of inflation and it would also create more competition in areas because it would open up easier processes for registration of new items and registration of existing items.

There is one suggestion that we have and I would like to read it to you. I can paraphrase it, but I think it would be better if I read it exactly the way it is stated.

EPA should either establish separate guidelines for nonagricultural pesticides, such as household disinfectants, or designate in the final guideline document specific exceptions which take into account the environmental concentration and fate of the nonagricultural products. Spending the time now to make such a distinction as part of the final guidelines will spare the Agency a great deal of time in the future from evaluating the many exception petitions which may inundate the Agency.

The thing that troubles us, and we look upon this as an interesting point of view—I am not an attorney and I can only look at it from a businessman's point of view—

Senator STEWART. You are probably better off. I am an attorney.

Mr. WINIK. We don't understand why we are asked to fully comply with an act when the Agency itself blatantly disregards the will of Congress in the way it abides by the act as amended in 1978, and in this we get involved in the cite-all procedure which originally stated that cite-all would only be given to the original supplier of information.

Now no one has touched on that this morning either. It specifically states in the act original supplier of data. There are other things which to us seem almost foolhardy, but you know we understand this is the way things have to take place in Government and possibly in industry we can do it a little quicker. We don't understand why, if a law is stated to be such, why it is it cannot be enacted as such and why it is we get something one day and then have EPA come back and say we need 9 months to put in six more tests on one thing and 8 more on this. All it does is cause more of a logjam and costs industry a lot of money and creates an enormous burden on an industry such as ours where we have, essentially, 2,200 small businesses.

Senator STEWART. We have one located in my hometown of Anniston, Ala.

Mr. WINIK. Who is that?

Senator STEWART. Miller Weberly. I don't know whether it is a member of your outfit or not.

I appreciate your testimony. You stated the answer to the two questions we have. There is one you did not answer. What is your position as to the extension of authorization for a 2-year period of time?

Mr. WINIK. We feel that if it should be extended at all, it should be extended for 1 year.

Senator STEWART. I assume it is going to be extended.

Mr. WINIK. I know that. That is why I said "if." I figured I would get that in.



Senator STEWART. I assumed from the tenor of your testimony you might feel that way. I have gotten your position and I thank you very much. We appreciate it.

I am going to say to our next witness my longwindedness and others have caused us a little bit of difficulty. I have a majority leader who indicated to me I was to preside in the Senate at 12 o'clock. On one occasion he had to sit in that chair until I got there. He is not going to ever do that again.

Mr. WHITNEY. I wouldn't want to be a party to anything like that.

I would request that our statement be made a part of the record and then I would just like to address two brief points, one which I don't think was addressed at all this morning.<sup>1</sup>

Senator STEWART. If you would make them brief, I would appreciate it.

**STATEMENT OF SCOTT WHITNEY, COUNSEL, LONZA CHEMICAL, INC., FAIR LAWN, N.J.**

Mr. WHITNEY. One point I would like to make I think is confused at this stage. Let me take that one first. This is the conditional registration. The real point in this is there are two kinds of data we are talking about. There is data generated after the 1978 enactment and the statute says that the Administrator cannot use this data without the written permission of the original data submitter. The other category of data is that that was generated after December 31, 1969, up to date, and the statute says with respect to that that the Administrator may, without the permission of the original data submitter, use it, but only if there has been an offer to compensate the original submitter.

Now how do you find this original submitter, because he is the only one with rights? We have a proposal in our statement on how that can be done without going into that cite-all.

I would also direct your attention to this appendix which shows a typical case of 1,166 letters for one product.

Now the way you locate the original data submitter is to simply, with any application, publish it in the Federal Register disclosing these substances. This is legal notice. The original data citer has the duty of coming forward proving that he is the data submitter and the amount of compensation, so instead of looking at every piece of hay in the haystack to find the needle, you have a magnet that pulls the needle out.

The other point is with respect to the simplified standards, they are not being implemented and if you would look just to page 3 you will see that the end use product formulators are being saddled with a minimum of eight complex long-term testing requirements that clearly are unlawful and cannot be enforced under the act.

Those are my two points and I urge that you consider more fully the statement that I have submitted on behalf of Lonza.

Senator STEWART. I don't mean to hurry you at all, but I have two questions, and I believe EPA would want to comment on this.

<sup>1</sup> See p. 43 for the prepared statement of Mr. Whitney.



Mr. WAYLAND. I think Professor Whitney cited a regulation which was proposed but not promulgated prior to the passage of the 1978 act. On the page preceding the one Professor Whitney cited, EPA states clearly, "amendments are pending and should those amendments be enacted, the guidelines would have to change."

We have subsequently described in a Federal Register notice that the law is in effect and those guidelines, to the extent we were following guidelines, do not apply. The horizontal line exists today and applications are being submitted and implemented, so we haven't failed to implement that provision.

Mr. WHITNEY. One final comment on that. If that is the case, I am very gratified, but I will check and get that reference because at the present time these proposed guidelines are being enforced at the operating level by product managers.

Senator STEWART. I would appreciate your providing the committee with that information, and also EPA, and see if we can't work that out.

There are two questions I want to submit to you. You say that the cite-all system is, for unscrupulous operators, a license to extort. I want you to provide later for the record the type of information you had in mind in coming to that conclusion. That is one question.

The other is, do you believe EPA's recent decision—and I will provide you with a copy of these questions because I believe you ought to have them, in all fairness—that EPA's recent decision to exempt pesticide formulators from the cite-all decision will alleviate the problem you allude to in your statement?

If you will answer those two questions for us, that will cover the questions the staff has.<sup>1</sup>

I deeply appreciate your being so cooperative with us. I apologize for not giving you adequate time, but if you will answer those two questions, and your statement is a part of the record, and we will clear up this other matter, too. Thank you very much for coming here to testify.

We will leave the record open for 1 week for purposes of providing that information and any additional information you want to provide.

[Whereupon, at 11:50 a.m., the subcommittee adjourned, subject to call of the Chair.]

<sup>1</sup> See p. 45.







## APPENDIX

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### STATEMENT OF HON. STEVEN D. JELLINEK, ASSISTANT ADMINISTRATOR FOR TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Good morning, Mr. Chairman. I appreciate this opportunity to discuss with you our progress in implementing the Federal Pesticide Act of 1978 and the bill, S. 717, to extend the Agency's authorization to administer the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for 2 years.

The new pesticide amendments are, to a large extent, a tribute to this subcommittee's diligence and willingness to tackle very complex issues. Working with this subcommittee on that legislation was one of my first, and most rewarding, tasks after joining EPA. The new amendments' remedies for an ailing pesticide program have proved—and will continue to prove to be—crucial to revitalizing our program.

I'm happy to report that we are making substantial progress in implementing those amendments. Let me go over some of the highlights.

We outlined our plans for implementing each section of the act in an Implementation Plan published in the Federal Register in January. I think this plan has been a useful guide both to the Agency and to the public in understanding the new amendments and how they will work.

We have devoted considerable thought and effort to implementing those amendments that affect the registration program—conditional registration, generic registration, simplified registration, data compensation, and waiver of efficacy data.

The need for conditional registration arose from the "double standard" created under the old FIFRA provisions—products already on the market enjoyed a competitive advantage over like products which were denied EPA registration because they could not meet current data requirements. The new law allows EPA to issue conditional product registrations, thereby giving companies the necessary time to generate missing data in the future. Conditional registration will be the mainstay of our registration program until all products are finally through the reregistration review.

In July 1978, we issued an Advance Notice of Proposed Rulemaking for conditional registration and data compensation regulations. These will implement those portions of the Federal Pesticide Act of 1978 covering the registration provisions I just mentioned. We stated our intent to issue interim final regulations, which is the fastest way to implement rules, in order to provide the relief offered by conditional registration authority as soon as possible. We circulated draft regulations in October 1978, and held 3 days of public meetings in November to encourage a full range of comments on key issues, including risk assessment criteria, data review, and compensation for use of data. Public participation in these meetings was substantial and ultimately influential in shaping the interim final regulations for conditional registration which will be published in the next several days.

One of the most controversial aspects of the regulations was our decision not to permit applicants to "pick and choose" supporting data. The draft regulations required all applicants to cite all pertinent data in our files for compensation purposes. FIFRA provides for reasonable compensation to the owners of data used by others to support their own registration.

However, formulators especially objected to the proposed new approach, principally because of the perceived increase in paperwork and uncertainty about the scope of compensation disputes which they might or might not be facing in the future. In response to these concerns, we changed our approach to allow formulators the option of providing their own data in lieu of citing data already in the data base.



We are not extending this option to the applicants of technical materials, however, for several important reasons. First, the number of tests done with the technical material are much fewer than those conducted with the formulated product, but are of much greater regulatory significance. Thus, the paperwork costs involved in the cite-all approach will be much lower for the technical producer. Moreover, basic health and safety studies conducted with the technical material—both by the original registrants and subsequent registrants—are scientifically pertinent to new applications. These studies are the backbone of the registration program, and they are significant and supportive of future conditional registration decisions whether or not a detailed review is conducted for each individual application.

Second, we believe that creating a system which would allow a registrant not to cite basic health and safety studies would be immediately challenged in the courts, and could result in the shutdown of the conditional registration program before it ever gets started. At least one Federal court has concluded that EPA must have relied implicitly on studies that were pertinent to certain applications even though the applicants had not cited such studies. Over 10 registrants have already challenged the constitutionality of the Federal Pesticide Act of 1978; further litigation could nullify the long-awaited benefits of conditional registration. We are, by the way, vigorously defending the constitutionality of the amendments which, we believe, were passed with full consideration of the rights and interests of the diverse parties who testified before this committee.

Because the cite-all approach for technical products has proven to be the most controversial aspect of the regulations, we are allowing 60 additional days of comment on that issue. We can, of course, alter the regulations on an as-needed basis any time in the future based on further consideration and experience.

The Scientific Advisory Panel reviewed and endorsed the regulations and the Department of Agriculture has made several comments that we are addressing in the final package. We also sent a copy of the regulations to the committee at the same time they were forwarded to the Secretary of Agriculture.

The interim final regulations package also contains the new policy on waiving efficacy data, the final data compensation 3(c)(1)(D) regulations, and the "simplified registration" procedure in which formulators do not have to compensate basic chemical manufacturers for the health and safety studies supporting technical products.

The regulations address conditional registration of "old" chemicals (me-too and new uses); conditional registration of new chemicals will proceed on a case-by-case basis until regulations can be developed later this year. Recognizing the essential importance of having adequate pest control tools available to the farmer, we have already exercised our conditional registration authority in granting conditional registrations to several new products for use against cotton insects—Ambush, Pydrin, Bolstar, Pounce and Dimilin. We have also proposed conditional registration for BAAM on pears.

Conditional registration promises many benefits. The registration process is moving again. The double standard between old and new registrants of similar products is gone. Conditional registration should promote industry competition, resulting in lower prices for users, yet still provide for data compensation so that innovators are not taken advantage of—and, at the same time, it will not sacrifice our basic responsibility to protect the public health.

We are implementing the efficacy waiver policy along the lines outlined in our testimony before the committee 2 years ago. Generally, we are not going to waive efficacy data for those products intended to protect public health—that is, where failure to perform could adversely affect public health. Thus, we will ask for efficacy data for products which control disease vectors, such as mosquitoes or fleas, but not ask for data for most agricultural or forestry products. As we discussed during the deliberations on the efficacy waiver amendment, efficacy is often a fleeting determination, given pest resistance and mitigating regional factors, and farmers know far better than EPA what product works best for what need. However, we are considering the efficacy waiver policy as an experiment, and will take whatever measures are appropriate in the future if we find the policy is not working as intended.

Conditional registration is our major stepping stone to another effort that is the real wave of the future—generic standards. We have been developing the conceptual framework for generic standards, and are about to issue an advance notice of proposed rulemaking that explains our thinking to the public in great detail. As we discussed during the hearings leading to the new amendments, it is time we stopped reinventing the wheel each time an application for registration comes



along. A generic standard will be a statement of all approvable uses and formulations of all products containing the same active ingredient. It will be based on a full examination of all available data on that active ingredient. There will be opportunity for public participation and peer review. In short, standards will be a time-efficient, comprehensive way to make basic health and safety decisions once per chemical instead of thousands of times over as each application is submitted. I will be happy to make drafts of the advance notice available to you and your staffs in the next several weeks.

Some generic standards are in their infant stage—that is, we have started the literature and data searches which are the first step in the process. The average standard will take approximately 14 months to build; some less, others more. We expect to have out first standards ready in 1980.

Obviously, the more information we have on a chemical before we start a standard, the better informed and able we will be to reach the soundest conclusions possible. There is a lot of data now required by today's scientific standards which simply have not yet been generated on most pesticides currently registered. It is critical to begin generating that data in order to make the standards development process meaningful. We are, in the Advance Notice, proposing to initiate a systematic call-in of data in order to start the industry generating the missing data. This early call-in will not benefit the standards development process in the first few years; however, it should yield very good information prior to developing standards for pesticides five years hence and after.

We've also been making considerable progress in implementing the amendments pertaining to State authorities under the law. Regulations implementing section 5(f) of the Act—governing State experimental use permits—are in final form and we expect to publish them in the FEDERAL REGISTER in the coming weeks. We have worked closely with the States in developing the regulations, and each State lead agency has a copy of the regulations soon to be final. Thus far, reaction from the States has been positive.

New proposed regulations implementing section 24(c)—governing State registrations to meet special local needs—are also coming along well. We expect the new proposals to be published in the Federal Register in June. A State representative has been a member of the Working Group developing the regulations, and the drafts have received wide distribution in the States. Again, we have had generally positive response from the States to the draft regulations, and we expect to continue to develop the rulemaking in a harmonious atmosphere.

Because we realize that rulemaking would take several months to accomplish, we issued a Guidance document on the new 24(c) provisions last October to guard against any confusion between the old and new statutory authority. We shared a copy of this document with the Committee back then. That Guidance made clear that the amendments had brought about some changes in the 24(c) registration program. States no longer had to win EPA approval to issue such registrations. EPA's veto authority was limited to several criteria explicit in the law, and any decision to veto had to be discussed first with State officials. This Guidance policy has worked well, and proven to be just what we had hoped—an orderly, understandable bridge to the new rulemaking.

As you are aware, there are a number of important enforcement issues in the 1978 Federal Pesticide Act.

One area, which was considered at length by the Subcommittee, is that of enforcement responsibility for pesticide use violations. Thirty-eight States and territories automatically have gained the primary responsibility for handling pesticide use violations by virtue of their having a cooperative enforcement agreement with this Agency since the signing of the legislation by the President. Since that time the Agency has reviewed, for enforcement adequacy, the State applicator certification plans of another 13 states. We have prepared letters to the governors of those States informing them as to whether or not their State is eligible for primary use enforcement authority. The results will also be published in the Federal Register.

Another area of concern to the Subcommittee during its deliberations was the subject of what constitutes use inconsistent with labeling. The new amendments carve out four specific use practices which would generally not be considered as inconsistent with labeling. These exemptions in the law made unnecessary certain Pesticide Enforcement Policy Statements (PEPS) that had previously addressed the same use practices. Since passage of the amendments, we have often said publicly and in our January 19 Implementation Plan that many of the PEPS were automatically rescinded. In addition, we have prepared a Federal Register notice, which should appear shortly, which will formally rescind the affected PEPS and



describe some areas of enforcement policy which have changed as a result of the recent amendments.

As a result of the amendment to the Books and Records section of FIFRA, EPA inspectors were instructed to present their official credentials and a statement as to the reason for the inspection before undertaking an inspection of any firm's records. EPA personnel who are responsible for the institution of civil proceedings have been apprised of the new maximum penalty under FIFRA section 14 for misuse of a general use pesticide.

The revised export provisions of FIFRA were also an important new amendment. There is under review in the Agency a document for Federal Register publication which will detail the labeling requirements for exported pesticides, devices and pesticide active ingredients and the procedures for exporting unregistered pesticides. The Agency has consulted at length with industry and environmentalists on the contents of this notice and this has delayed the document. We are concerned that we not place unnecessary or cumbersome procedures upon exporters so as to hinder commerce. Yet we also must be sure that these requirements meet Congressional intent and the information given foreign governments concerning exports from the U.S. must be both useful and informative. This notice will appear in the Federal Register shortly.

We have acted on, or are taking steps to enact, many more of the amendments incorporated in the 1978 legislation. We have published definitions of "validated test and other significant evidence" as mandated by the law and discussed in the Conference Report. We have issued (in December) an interim policy on handling trade secret information in accordance with section 10. Fourteen pesticides proposed for restricted classification by regulation last January will be addressed in a final rule in a matter of weeks. They join 23 pesticides which were restricted by rulemaking in February of 1978. A proposed rule to restrict 13 additional pesticides to use by certified applicators will soon be transmitted to you, USDA, and the Scientific Advisory Panel. We have issued a minor use policy statement in the Federal Register (March 5, 1979), and are working on the study on minor uses due the Committee in June of this year.

As you know, we filed our study on ultra-low-volume methods of application to the Committee on March 29 in accordance with the time deadline imposed by the statute. As I explained in my letter to the Committee, our study shows that there is an extra hazard which ULV may pose—a hazard due to drift, the possibility of excess residues on food crops, and additional hazard to field workers or other persons who may come into contact with the more concentrated residues. We also know, after having discussed this area with the Committee during the hearings preceding the 1978 amendments, many Members are concerned that users have appropriate discretion to vary label directions when appropriate. Therefore, we are issuing an Advisory Opinion on ULV application in two stages which I believe will accommodate both safety concerns and user discretion concerns.

The first stage, which will be issued imminently, requires, for this growing season, that the amounts of dilution be followed in accordance with (1) a Federally registered label, (2) a State label issued under section 24(c), or (3) an emergency exemption under section 18. Then, by next growing season, after we have had time to work on a second policy with USDA and the States, we will issue another Advisory Opinion which will outline criteria or parameters or other guidelines which will allow for more user discretion in diluting registered products. In this way, we can best meet the needs of the applicators and also develop a responsible, scientifically supportable policy which will properly protect the public health. The Department of Agriculture has sent me a letter endorsing this approach which I have made available to the Committee.

I believe, Mr. Chairman, that we are making excellent progress in implementing the 1978 amendments and that the pesticide program is beginning to deliver decisions made possible by the beneficial authorities provided in that new legislation. We intend to keep the Committee involved as we proceed with full implementation of the amendments.

I thank you for your time, and would be pleased to answer any questions you may have.



STATEMENT OF DR. JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURAL  
CHEMICALS ASSOCIATION

I am Jack D. Early, President of the National Agricultural Chemicals Association (NACA). Our members produce and sell virtually all of the basic pest control chemicals, and a substantial portion of the pesticides formulated from those basic chemicals used for agricultural production in the United States. I have with me Mr. Jonathan P. Rogers of Mobil Chemical Company, Chairman of our Board of Directors, and Mr. John D. Conner, our Association Counsel, to assist in answering any questions which there may be.

EXTENSION FOR ONE YEAR

NACA opposes S. 717 to authorize funding for implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for two years. We foresee several problems with the Environmental Protection Agency's (EPA) implementation of the amendments to FIFRA enacted in the Federal Pesticide Act of 1978. Therefore, we believe that FIFRA should be funded for only one year at this time so that Congress can examine the progress that has been made in resolving these problems in implementing the law before it makes further funding commitments.

CONDITIONAL REGISTRATION

NACA endorsed the conditional registration amendments in the 1978 legislation and we applaud the EPA's efforts to reactivate the long delayed pesticide registration program under this new provision. The EPA appears to be issuing conditional registrations and we are pleased with the success of the program to date.

DATA COMPENSATION AND "CITE-ALL"

Despite the general success of conditional registration, we have serious problems with the manner in which the agency is implementing the data compensation provisions, particularly EPA's so-called "cite-all" requirement.

In implementing data compensation under the 1978 FIFRA amendments, the EPA is violating express congressional directions in Section 3(c)(1)(D) by forcing applicants of technical materials to pay compensation for all data in EPA files which pertain to the material. Even if an applicant submits all his own data to satisfy the EPA data requirements, the EPA will still require the applicant to pay compensation for all other data in the EPA files regarding the material.

This is contrary to the clear language of Section 3(c)(1)(D). The law states the Administrator can require the applicant to submit "a full description of the test made and the results thereof \* \* \* or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator \* \* \*." This statute gives the applicant an alternative: he must either submit his own test data or cite data submitted by others. The EPA's "cite-all" requirement eliminates the applicant's option to submit his own data. Instead, the applicant is forced to pay for data submitted by others, even though he has supplied the agency with the data required by the registration guidelines.

The inappropriateness of the "cite-all" requirement is illustrated by the fact that under "cite-all", an applicant could be required to pay more to others in compensation than it would cost him to do the tests himself. For example, if an applicant is required to pay compensation to each of four registrants who have submitted basically duplicative data concerning the same kind of test, the applicant could end up paying more than if he conducted the test himself. Again, in the case of new active ingredients, it would be absurd to require an applicant to "cite-all" data, and offer to pay compensation for data, when there are no data except those submitted by the applicant.

FIFRA expressly gives applicants the alternative of submitting their own data or citing data submitted by others. We believe the EPA "cite-all" requirement ignores explicit congressional language and serves no legitimate purpose.

GENERIC REGISTRATION

While we support the concept of generic registration in general, we are deeply troubled by the confusion and complexity which a generic registration program may pose in connection with data compensation and key provisions of the 1978



Act. It is apparent that the EPA has adopted a program of generic registration in the interest of administrative efficiency, which we also support; but, because of practical problems, we are not sure the generic program will work. It is significant that Congress did not require or recommend that the EPA register all pesticides on a generic basis. In fact, there is nothing in the Federal Pesticide Act of 1978 specifically requiring generic registration.

We feel that the concept of generic registration has raised numerous problems which will only interfere with the administration of the pesticide program:

1. What effect will a generic standard have on the ability of a company to develop its own data? It is our concern that, except in the case of a new active ingredient, the generic standard will preclude any company from exercising its option, vis-a-vis 3(c)(1)(D), of developing all its own data necessary to support registration.

2. How will EPA keep data confidential under the generic standard?

3. What emphasis will EPA give to various items in the data base? How will obsolescent data be handled?

4. Where data from numerous submitters are included under a generic standard, will the data compensation issues be so complex as to become unmanageable? It seems that EPA did not fully consider generic standards in this light since they in fact are no longer in the compensation business.

In short, generic registration may be a useful administrative tool, but it should not be permitted to hamstring the registration programs required by FIFRA.

#### DISCLOSURE OF TRADE SECRETS TO FOREIGN AND MULTINATIONAL CORPORATIONS

FIFRA section 10(g) prohibits the Administrator from disclosing information submitted by a registrant, including trade secrets, to any foreign or multinational pesticide producer or its agents. In enacting this provision in 1978, Congress recognized that registration data may contain trade secrets and other valuable commercial information, often obtained at a cost of millions of dollars, which should not be disclosed to foreign competitors.

We believe that the protection of trade secrets and confidential commercial information from disclosure to foreign competitors is of the utmost importance and should be vigorously enforced by the EPA. FIFRA section 10(c) requires the Administrator to provide 30 days notice before disclosing any information claimed to be confidential or trade secret. Although section 10(g) requires the Administrator to keep records of all persons to whom a registrant's data are disclosed, and to inform the registrant of the identity of such persons, the Administrator does not propose to give 30 days notice prior to disclosure of such information.

We think it is clear that FIFRA requires the Administrator to provide 30 days notice prior to disclosure of any information claimed to be confidential or trade secret.

Prior notice is essential under section 10(g), because the registrant is usually in a much better position than the Administrator to know whether the person seeking access to the registrant's data is an agent or employee of a foreign or multinational corporation. The EPA has stated it will not investigate the truthfulness of such person's affirmation. Unless the registrant has prior notice, a person who executes a false affirmation may obtain the data and abscond beyond U.S. territorial jurisdiction before the registrant can prevent the fraud. Congress should make it clear to the Administrator that the 30 day notice provision in section 10 applies to all disclosures under that section, including section 10(g).

We are also deeply concerned by the Administrator's inability to enforce the congressional intent of section 10(g), as it is presently written. Although any person receiving a registrant's data from the Administrator can sign an affirmation that will not deliver the data to a foreign or multinational corporation, there are no legal restrictions in section 10(g) on the actions of persons who subsequently receive the data.

For example, if Mr. Jones lawfully obtains registration data from the Administrator, and lawfully provides the data to Mr. Smith, who is not an agent or employee of a foreign corporation, there seems to be no legal restriction on Mr. Smith to prevent him from disclosing or selling the data to foreign or multinational pesticide producers.

There are numerous other ways for foreign and multinational corporations to lawfully evade Congress' intent and obtain valuable registration data to use for competitive purposes. We believe this is an extremely serious problem which



will require resolution by Congress in subsequent legislative action. We will suggest at that time a practical system for prohibiting any disclosure whatsoever of valuable pesticide data to competitors, while permitting disclosure of needed information to members of the public with a legitimate interest, such as public interest scientists, consumer groups, and so forth.

#### REPORTING OF INFORMATION SHOWING SERIOUS NEW HAZARDS

Section 6 of FIFRA requires a registrant, after he receives a registration, to report to the Administrator any "additional factual information" showing serious new hazards of the pesticide. In violation of this provision, and of Congress' intent, the EPA has issued an interpretation which requires registrants to submit any information regarding an adverse effect of a pesticide, even if the information has no factual basis; even if the information is not new or additional, but is already known by the agency; and even if the information pertains to an insignificant or inconsequential effect, rather than a serious or substantial hazard. The EPA is asking for a morass of useless information, which will defeat the congressional purpose of alerting the Administrator to important new information concerning serious hazards which were not previously known.

The industry has brought suit against the EPA, requesting the Court to set aside the agency's invalid interpretation of this reporting requirement. Although the industry offered to negotiate a settlement of the case, by stipulating to the kinds of new hazard information which are of serious concern and should be reported, the EPA has refused to budge from its patently unlawful and over-broad position.

We will therefore return to the Court and request that it invalidate the EPA's reporting requirement because of its complete inconsistency with the intent of Congress.

#### STATE PESTICIDE LAWS

Some states are considering enacting their own pesticide regulation laws under the authority of section 24 of FIFRA. In several cases, however, these laws are inconsistent with, and would undermine, carefully formulated provisions of FIFRA.

For example, several proposed state bills authorize the disclosure of pesticides registration data to the public, but contain no prohibition against the disclosure of such information to foreign or multinational pesticide producers, as does FIFRA. The effect of proposed state laws would be to nullify the prohibition in FIFRA against disclosure of registration data to foreign and multinational corporations.

We believe that Congress should reaffirm through legislative history that states are not authorized under section 24 of FIFRA to enact laws which undermine and nullify any express statutory provisions that Congress has placed in the federal law.

We thank the Committee, and request that our written testimony be made a part of the record of these proceedings.

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#### STATEMENT OF STEPHEN S. KELLNER, DIRECTOR, LEGISLATIVE AND REGULATORY AFFAIRS, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

My name is Stephen Kellner, I am Director of Legislative and Regulatory Affairs of the Chemical Specialties Manufacturers Association (CSMA), headquartered at 1001 Connecticut Avenue, Washington, D.C. CSMA has a membership of over 425 firms engaged in the manufacture, formulation, distribution and sale of insecticides, disinfectants and sanitizers, detergents and cleaning compounds, aerosols, transportation chemicals, waxes and floor finishes for household, institutional and industrial uses. A significant number of these products have pesticidal claims and are therefore subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA). Specifically, CSMA represents the non-agricultural pesticide industry, including disinfectants and sanitizers, home, lawn and garden insecticides and a wide variety of other pesticides for home, industrial and institutional use.

CSMA has appeared before this Subcommittee on several occasions during the legislative process to develop amendments to FIFRA which resulted in the



Federal Pesticide Act of 1978. We realize the Subcommittee's function at this juncture is primarily one of recommending funding authorization for the Agency. In this regard, we believe only a 1-year authorization should be granted. This continuing level of authorization acts in itself as an oversight function to ensure that progress continues in the implementation of the Pesticide Amendments. We also wish to take this opportunity to advise the Subcommittee of our concern with respect to two areas which have developed subsequent to 1978 Amendments: (1) Methods for Submission of New and Pending Applications for Registrations, and (2) State Requirements for Submission of Safety and Environmental Data. We wish to emphasize that CSMA has and will continue to participate with the Agency in the implementation of the 1978 Amendments but we feel that the Subcommittee should be made aware of problems that could develop in the near future.

#### METHODS FOR SUBMISSION OF NEW AND PENDING APPLICATIONS FOR REGISTRATIONS

On December 8, 1978 EPA issued PR Notice 78-5 which advised registrants and applicants of policies and steps that will be necessary to bring applications for registrations into compliance with the 1978 Amendments. The PR Notice was and is intended to fill the gap until final conditional registration regulations are promulgated. The PR Notice created three options under which an applicant could proceed with respect to submission of new and pending applications for registrations:

*Option I.*—Allowed the applicant to elect to await promulgation of final regulations and submit new applications or revised pending applications to comply with the final regulations.

*Option II.*—Would permit the applicant to submit an application or revise a pending application which relies on specific items of data either generated by the applicant or cited from Agency files, provided that the registrant complies with applicable compensation provisions of FIFRA and further, that any registration issued on such basis would be conditioned upon the registrant's compliance within 120 days with the final regulations governing conditional registration and compensation.

*Option III.*—Permits an applicant to submit its application using the "cite-all" method of data compensation. This option compels the applicant to offer to pay compensation for all items of data contained in the Agency files which pertain to the product, its active ingredients, to a similar product or a type of data required by registration guidelines to be submitted in support of registration or added use.

Initial communications from within the Agency indicated that Option II would not be included in the final regulations relating to submission of new or pending applications. Instead Agency personnel have pushed the use of Option III. The requirement to cite all data in agency files and make offers to pay compensation to all registrants having data has resulted in an avalanche of letter writing and further necessitates making marketing decisions not knowing what the ultimate aggregate compensation fees will be. CSMA was pleased to learn recently that the agency policy with respect to use of the second option has changed somewhat with the revision being made in draft final compensation regulations for an alternate method for use by registrants of end-use or formulated products. An applicant using the alternate method for supporting an application will *not* be required to acknowledge reliance on all the data in EPA's files (Option III). Instead the applicant may provide copies of data either self-generated or otherwise obtained, which are necessary to satisfy the requirements pertaining to safety, efficacy and other properties of the product and may direct EPA not to consider other data in support of the application.

CSMA believes that the alternate method should be expanded to include manufacturing use raw material product registrations. We do not believe that Congress intended that an applicant for registration could not develop his own data or specifically cite the data upon which the registration would be based. CSMA perceives therefore, that this is an area which needs further modification to allow all registrants the option to generate their own data or cite other specific data and offer compensation. This proposed modification together with the present EPA alternate method and cite-all approach would, in our opinion, result in procedures that would allow for the administration of registration and compensation provisions to go forward.



## STATE REQUIREMENTS FOR SUBMISSION OF SAFETY AND ENVIRONMENTAL DATA

The 1978 Amendments incorporated in section 10(d)(1) of FIFRA, embodied the principle that information concerning safety and environmental data be available for disclosure to the public. In doing so however, Congress placed stringent requirements upon such availability by subjecting such data for registration purposes to compensation provisions of section 3 and incorporating protection from disclosure to foreign and multinational pesticide producers who might use such information to gain a marketing advantage.

Clearly in modifying the trade secret provisions to allow this information to be made available to the public, Congress never intended that the states could likewise require submission of the same data and similarly make it available to the public. However, already we have seen one state which is attempting to have applicants submit data on an across-the-board basis for inspection by the state prior to the granting of any registration. To permit such conduct will result in a short-circuiting of the compensation provisions of section 3, not to mention the excess burden required for submission to any and all 50 states. We believe therefore that at some point in the very near future some preemptive language may be necessary to make it abundantly clear that although Congress intended to make certain information publicly available, it must be obtained through the U.S. Environmental Protection Agency where proper controls as to access and compensation are stipulated.

## CONCLUSION

Mr. Chairman, we appreciate this opportunity to present our views to you. I repeat again our good faith intent to work with Congress and the Agency to assist in fair and equitable administration of FIFRA.

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STATEMENT OF VICTOR WINIK, CHAIRMAN, REGULATORY ADVISORY COMMITTEE,  
INTERNATIONAL SANITARY SUPPLY ASSOCIATION, CHICAGO, ILL.

My name is Victor Winik. I am Chairman of the Regulatory Advisory Committee of the International Sanitary Supply Association. ISSA is located at 5330 North Elston Avenue, Chicago, Illinois 60630. It has been in existence nearly 56 years and is composed of more than 2,200 manufacturing and distributing, small business firms engaged in producing and selling cleaning and maintenance products and supplies used in hospitals, schools, food establishments, commercial businesses and institutions. ISSA supplies janitors and maintenance workers throughout the United States and is concerned with the vital role which sanitary maintenance plays in providing better public health in the United States.

The Regulatory Advisory Committee, on which I serve as Chairman, is composed of fourteen representatives from the various member companies. This membership rotates and is representative of the various interests in ISSA—manufacturers of basic chemicals, formulators and distributors. The purpose of the Committee is to advise the Board of Directors of ISSA concerning what position the Association should take with respect to legislation and regulations affecting the business activities of ISSA members. We also seek to keep members informed about the voluminous and complicated laws and regulations that relate to their business to foster compliance and avoid inadvertent violations. I assure you, Mr. Chairman and Members of this Committee, that we are devoted to the objective of protecting public health and the environment. Our advisory and members information program is especially important because a significant percentage of ISSA members are small businesses and most members simply cannot afford to hire an expert to keep them informed about the ever-increasing number of laws and regulations that affect their business.

Today I want to focus on EPA's regulation of the pesticide industry and especially the manufacturers of sanitizers and antimicrobials for household and industrial uses. We believe EPA is mishandling the implementation of the Federal Pesticide Act of 1978 with the result that it places an impossible burden on companies such as the ISSA members and also constitutes a serious waste of EPA's resources, results in higher prices to consumers and contributes significantly to inflation.

By way of background, it is fair to say that since as early as 1969 in the Eleventh Report of the House Committee on Government Operations entitled "Deficiencies in Administration of FIFRA", pesticide regulation in the United States has been



universally recognized as a failure. The Senate Judiciary Subcommittee on Administrative Practice and Procedure and the Comptroller General have explicitly recognized this failure. The environmentalist community concurs, and the pesticide industry likewise concurs.

The primary reason for this failure was expressed by the present Administrator of the Environmental Protection Agency (EPA) in testimony before Congress last year:

"\* \* \* it has become increasingly clear that we are spending far too much time on individual end-use formulation applications, and that the whole structure for registration needs to be focused primarily on the chemicals themselves rather than thousands of individual applications for products containing mixtures of chemicals."

In other words, EPA by indulging in regulatory overkill in the form of excessive data requirements from formulators effectively paralyzed the Agency with respect to pesticide regulation. Overregulation has effectively produced no regulation. This paralysis has slowed or prevented altogether the development of new products and the entry of new competition into the pesticide industry. It has inflicted particularly harsh burdens on small business, which is least able to sustain high regulatory costs and is most vulnerable to delays in receiving approvals to market formulated products.

Accordingly, EPA Administrator Costle requested specific legislative relief to rectify this situation and to clear up a registration backlog that would otherwise require some twenty years to process, not counting new applications.

Among the new authorities the Administrator requested Congress to enact was generic registration:

"We envision a system in which it is the technical material which becomes the focal point for registration, with the bulk of the safety data obtained from manufacturing-use rather than end-use registrations."

Congress enacted the following provision as a part of the Pesticide Act of 1978: "Section 3(c)(2)(C) Simplified procedures.—Within nine months after the date of enactment of this subparagraph, the Administrator *shall*, by regulation, prescribe simplified procedures for the registration of pesticides, *which shall include* the provisions of subparagraph (D) of this paragraph.

"(D) Exemption.—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to—

"(i) submit or cite data pertaining to the safety of such purchased product; or  
"(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data." (Emphasis added.)

The meaning of this language is crystal clear. The Administrator is directed to prescribe regulations within nine months of enactment, which include simplified regulation provisions that specifically include the exemption that formulators need not submit or cite data pertaining to the safety of a purchased pesticide product. If there were any doubt of this meaning, the legislative history of the Pesticide Act of 1978 makes the intent of Congress completely clear:

"This streamlined approach is contrasted to the existing process that treats each registered product independently, with a concomitant repetition of active ingredient review and evaluation. Generic registration will permit the 4,200 businesses engaged in formulation or labeling of end-use products to submit simplified applications to EPA, and will relieve them of responsibility to offer to pay for the registration data submitted by suppliers of technical material (except in the price structure of the technical material)."

In the face of this clear language and past history, EPA nevertheless in the new proposed guidelines has announced:

"Registrants of formulated products, however, would also be required to submit or cite data derived from testing the active ingredients in their products. In addition, they would have to submit or cite data from testing formulated products to obtain registration for a formulated product." (43 Fed. Reg. p. 37337)

The proposed guidelines proceed to list six testing regimes that must be satisfied by formulators of end-use products:

#### FORMULATED PRODUCT

Acute oral toxicity—Section 163.81-1.

Acute dermal toxicity—Section 163.81-2.

Acute inhalation toxicity—Section 163.81-3.

Primary eye irritation—Section 163.81-4.



Primary dermal irritation—Section 163.81-5.

Dermal sensitization—Section 163.81-6 (Id. p. 37340).

Moreover, the proposed guidelines would require testing of “use dilutions” of formulated products in addition to the formulated products themselves. This latter requirement would not only vastly multiply the volume of data required, but would require data that is essentially meaningless in scientific terms since use dilution is totally subjective and varies with the whim of the user.

The above-noted list of tests that would be required of formulators is, however, by no means all of the testing and data requirements the proposed guidelines would impose on formulators. In addition to the aforementioned six test protocols (multiplied by the use dilution formulations), the proposed guidelines would impose:

1. Subchronic oral dosing studies (Section 163.82-1).
2. Subchronic 21-day dermal toxicity studies (Section 163.82-2).
3. Chronic feeding studies (Section 163.83-1).
4. Oncogenicity studies (Section 163.83-2).
5. Teratogenicity studies (Section 163.83-3).
6. Reproduction studies (Section 163.83-4).
7. General metabolism studies (Section 163.85-1).
8. Domestic animal safety tests (Section 163.86-1).

The proposed guidelines also discuss extensively the standards and battery of possible tests for mutagenicity, including standards for detecting heritable chromosomal mutation and standards for detecting effects on DNA repair or recombination as an indicator of genetic damage. The proposed guidelines do not indicate clearly whether EPA intends to impose these tests on formulators.

Imposition of the aforementioned testing and data requirements on formulators would clearly violate the above-noted provisions of the Federal Pesticide Act of 1978. Although the proposed guidelines were prepared by EPA and published in the Federal Register shortly before the enactment of the 1978 Act, EPA has not withdrawn these proposed regulations. Instead EPA on January 19, 1979 announced in the Federal Register that it “plans to publish a Federal Register Notice” within the next month describing how EPA will go about the development of generic standards and the reregistration program (44 Fed. Reg. No. 14,4355). Elsewhere in this Notice EPA indicates it will require 10-15 years to develop generic standards. (Id. 4352).

This lengthy lead time that EPA forecasts is clearly the result of the excessive data requirements on formulators that is described above.

#### CONDITIONAL REGISTRATION

Moreover, EPA's proposed implementation of the conditional registration amendment would produce a more burdensome and inefficient system than the system Congress sought to reform by the 1978 Act. EPA has announced the following implementation plan:

“Conditional registration will under sections 3(c)(7) (A) and (B) serve as a bridge to generic standards involving “old” chemicals over a 10-15 year period. In other words, a product will be conditionally registered until the generic standard for its active ingredient is developed, after that time it will be reregistered unconditionally if it is in compliance with the new standard.” (Id.)

“Because the Agency is relying on its “institutional knowledge” about pesticides, based on all data already in the files, rather than relying on individual ad hoc review of discrete items of data, we are proposing that applicants for conditional registration must rely on (and offer to pay for) all items of data in Agency files pertinent to the active ingredient contained in the product for which registration is sought, if those data are the kinds of data required under today's criteria to support the initial registration of such a product. These procedures are contained in draft conditional registration regulations now out for public review. During the interim three options are available to the registrant which are detailed in PR Notice 78-5, issued on December 8, 1978.” (Id.)

“This means that in addition to furnishing to EPA a statement offering to pay reasonable compensation when applicable as in the past, applicants must also write directly to the submitters of data pertinent to their registration, and EPA must be notified by the applicant that the data submitters have been contacted.” (Id. 4355.)

Initially, EPA did not in fact allow applicants to avail themselves of the interim three options detailed in PR Notice 78-5, but insisted that applicants either wait



indefinitely before they could market a product or go through the "cite-all process". Under this process, EPA requires the registrant to rely on *all* items of data contained in the Agency's files which pertain to his product, its active ingredients, or to any product which is identical or substantially similar to his product and are a type of data required by the Registration Guidelines to be submitted in support of registration of his product or added use.

This "cite-all" system requires the proposed registrant to notify and offer to pay all companies that have submitted data to EPA. The list of companies that must be notified and tendered an offer to compensate for a single registration can run into the thousands and even a small formulator faces notification of many thousands of companies.

The crowning irony of the "cite-all" approach is that EPA does not intend to actually use the cited data in processing conditional registrations.

"As the Agency explained in Congressional testimony, it has no intention of examining the existing data base on a chemical in reaching conditional registration decisions, for product uses similar or identical to currently registered products. Comprehensive review of this data base will occur systematically with the establishment of generic standards. Therefore, EPA will be implicitly relying on what is already known (i.e., the existing decision base) about pesticides now on the market in granting conditional registrations; only new data in support of a new use or a new chemical will be actually reviewed and scientifically assessed." (Id. 4353.)

EPA has now relaxed this position somewhat, at least as to formulators, to permit them to supply their own test data rather than be compelled to cite-all and write numerous letters and offers to compensate. However, many ISSA members find it most economical and efficient to supply some of the required data on their own and cite other data. Whenever they cite other data, EPA still requires them to notify and offer to pay *all* companies that have submitted data on that particular ingredient. In addition, EPA still requires basic chemical manufacturers to cite-all which has the effect of increasing the cost to formulators and ultimately to the consumer.

I am advised by Counsel that under the Federal Pesticide Act of 1978, Congress provided that whenever an applicant for registration relied on data generated by someone else, that he need notify and offer to compensate only the *original* data submitter, not the "cite-all" approach.

EPA's proposed implementation both as to generic and conditional registration clearly thwart the reform Congress intended for regulation of pesticides.

#### DISTINCT SEPARATION OF NON-AGRICULTURAL AND AGRICULTURAL PESTICIDES

It is not scientifically reasonable nor even valid to subject the broad spectrum of all pesticide products, from household disinfectant cleaners to highly biologically active insecticides to the same mandated guidelines or standards.

Because the definition of a "pesticide" is broad in FIFRA, many non-agricultural specialty chemical products, such as household disinfectants, have been grouped into the same regulatory category as the agricultural pesticide commodities.

Section 25(a)(1) provides ample FIFRA authority for the separation of non-agricultural from agricultural pesticides on the basis of differences in their concept and usage; § 25(a)(1) clearly provides:

"*Regulations.*—The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides and differences in Environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides.

(2) *Procedure.*— \* \* \*."

The House and Senate debates leading to the 1953 FIFRA amendments reinforce the Congressional view that there should be a separation in agency regulatory approaches. There is nothing in the proposed standards on pesticides programs to suggest that EPA intends to sort out the sanitizers, disinfectants or other antimicrobial formulations from the hard agricultural pesticides. Unless and until this is done, small business formulators of nonagricultural pesticides may not survive the horrendous paper-work and costly testing data requirements for registration and reregistration of their end product formulations. The separation is long overdue—it should never have been allowed initially.



## CONCLUSION

The 1978 Act empowers EPA to implement a speedy and effective system of regulating pesticides:

1. An expedited inventory and evaluation of data on file for the approximately 1,200-1,400 basic pesticide chemicals presently in production;

2. Pending this evaluation, grant of conditional registration for formulations using these basic chemicals;

3. Require notification and offers to compensate *only* as to data upon which the registrant actually relies, (instead of the cumbersome and unnecessary "cite-all" system);

4. Where an applicant for registration does cite another's data, he be required to notify and offer to compensate only the *original* data submitter;

5. Pesticide formulators be granted registration solely upon the basis of the registration number of the basic chemical supplier from whom it buys the basic active ingredient and be relieved of the unnecessary testing that the proposed EPA Guidelines would require.

6. The Administrator be required to determine the feasibility for imposing separate guidelines or standards for non-agricultural pesticides (antimicrobials) from agricultural pesticides.

We respectfully urge that this Committee and the Congress direct EPA to utilize its authority as I have indicated, and to spend its budget and agency resources in accordance with the law. We appreciate this opportunity to testify and respectfully direct the attention of the Committee to what we believe to be a serious misuse of Federal revenue, a major economic burden on our industry and a further aggravation of inflation.

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STATEMENT OF SCOTT C. WHITNEY, COUNSEL, LONZA CHEMICAL, INC., FAIR LAWN, N.J.

My name is Scott C. Whitney. I am Professor of Law at the College of William and Mary, and also of Counsel to the Washington law firm Bechhoefer, Sharlitt and Lyman. I represent LONZA, Inc. a company that manufactures basic pesticide chemicals, formulates such chemicals into pesticides and distributes pesticides in commerce. LONZA's headquarters is located in Fair Lawn, New Jersey.

I appreciate this opportunity to direct this Committee's attention to a problem that has substantial budgetary impact on the Environmental Protection Agency (EPA), serious financial consequences to the pesticide industry, higher prices for consumers of pesticide products and, inevitably, adverse inflationary consequences.

I am referring to the manner EPA has chosen to implement the Federal Pesticide Act of 1978. I am sure this Committee is aware that Congress passed the Federal Pesticide Act of 1978 for the purpose of reforming a regulatory process that was widely recognized to be a failure. The EPA had accumulated a staggering backlog of applications for registration and reregistration which under the prior law would take an estimated 15 to 20 years to process, not counting new applications. The EPA Administrator accurately identified the cause of this regulatory breakdown. The Administrator testified to Congress that EPA was spending far too much time processing applications for end-use pesticide formulations and stated that the whole structure for registration needed to be focused primarily on the basic chemicals rather than thousands of individual applications to register formulations containing mixtures of chemicals.

The Pesticide Industry heartily agree with this view and strongly supported the reform legislation which the Administrator proposed and which Congress in fact enacted. The 1978 legislation contained numerous amendments, but essentially two basic changes in the registration process—generic registration and conditional registration.

The generic registration provisions (Section 3(C)(2)(C) and (D)) were intended to simplify the registration process by making the technical material, i.e. the basic chemical, the focal point for registration with the bulk of the safety data obtained from the manufacturing-use rather than the end-use applications. This is a very sensible reform. Under this system EPA would evaluate the safety of approximately 1,200 basic chemicals instead of some 50,000 or more end-use formulations. Applicants for registration of an end-use formulation would under the new legislation simply disclose the contents of the formulation and EPA would be able to refer to the safety data already supplied by the Manufacturer of the basic chemical. Compensation for generating the data would be automatically contained in the price of the chemical purchased by the formulator.



The conditional registration provisions (Section 3(C)(7)(A) and (B) authorize the Administrator of EPA to conditionally register a pesticide under certain circumstances while the safety data for the basic chemical is being completed. Conditional registration is thus a "bridge" or interim mechanism to allow pesticide products to be marketed during the transition period until the data basis for basic chemicals is being completed. Once again, this is a sensible provision, the Pesticide Industry supported it and Congress enacted it.

Unfortunately, when it came to EPA implementation, that Agency, for reasons that frankly remain obscure, has undertaken to impose registration requirements which not only do not utilize these simplified procedures, but actually create a situation which is worse than before.

Despite the enactment of the simplified registration procedures in Section 3(C)(2)(C) and (D), EPA announced in the Federal Register:

"Registrants of formulated products, however, would also be required to submit or cite data derived from testing the active ingredients in their products. In addition, they would have to submit or cite data from testing formulated products to obtain registration for a formulated product." (43 Fed. Reg. p. 37337)

In the same lengthy Federal Register Notice of Proposed Registration Guidelines, EPA listed six specific testing regimes that must be done by formulators of end-use products before registration will be granted by EPA. Moreover, the proposed guidelines would impose eight further complex and costly data requirements on end-use formulators plus possible additional tests for mutagenicity.

These proposed guidelines have been in preparation in the EPA since 1975 and apparently what has happened is that once this bureaucratic juggernaut got into motion, it has continued despite the enactment of the simplified registration procedures in the 1978 Act. The consequences of disregarding the simplified procedure provisions is that EPA now expressly contemplates that it will take between 10 and 15 years to evolve standards—in other words, a period nearly as long as that which the Administrator of EPA found intolerable under the old law. These proposed guidelines would place even greater data burdens on end-use formulators than those imposed under the prior law and totally nullifies the intent of Congress to streamline the registration process.

EPA's implementation of the Conditional Registration provisions in Section 3(C)(7)(A) and (B) may well be even more disastrous in terms of unnecessary cost and regulatory confusion. EPA initially released PR Notice 78-5 in December 1978 as the rules until it prepared and published conditional registration regulations. EPA initially imposed a mandatory "cite-all" system on both manufacturers of basic chemicals and formulators. Under this "cite-all" system EPA required the applicant for registration of a basic chemical or a formulation to rely on all data contained in the EPA files which apply to his product, its active ingredients, or to any product which is identical or substantially similar to his product and are the type of data required by EPA guidelines to be submitted in support of registration.

In addition, EPA required the applicant to notify and offer to pay all companies whose data is cited under the "cite-all" system. The complete list of data suppliers as of December 1978 consisted of some 1,700 pages on microfiche and ran into the thousands. Appendix A, attached hereto, will give you an example of the burden entailed for a single commonly marketed product. LONZA was faced with sending 1,166 letters of notice and offer to pay. This is not only costly, more than \$11,000 unnecessary secretarial expense, but it triggers a complicated and costly mediation process to resolve disputes over whether compensation is due and over the amount of compensation.

The "cite-all" system has already created a situation in which spurious claims for compensation have been made by companies that are not original data submitters presumably under the hope that companies upon whom claims are made will settle for some payment rather than go through the costly and protracted mediation process. For unscrupulous operators the "cite-all" system is a license to extort.

Naturally, there was an emphatic outcry of protest by the Pesticide Industry and EPA reacted to relieve formulators from the mandatory "cite-all" system. Formulators may now cite their own data to support a registration. However, if they rely on their own data for some of the ingredients and cite other data for some other ingredient, they are required to use the "cite-all" notification and offer to pay as to the cited data rather than notifying and offering to pay only the original data submitter. A formulator is thus confronted with the dilemma that he must either generate all of his own data or go through the rigors of the



"cite-all" process. This creates a situation in which the formulator is compelled to pay for redundant testing to get all his own data or engage in the wasteful "cite-all" process.

Moreover, EPA has announced that it intends to impose mandatory "cite-all" on manufacturers of basic chemicals.

The mandatory "cite-all" system is clearly illegal. Section 3(C)(1)(D) provides that the notice and offer to pay is required only as to the original data submitter not to the multitude of companies that may have referenced the substance at one time or another. EPA's answer to this is that it is difficult to identify who the original data submitter is and that "cite-all" is the only alternative. The EPA data files are so voluminous and chaotic that a literature search for the original data submitter would be infeasible. However, these are not the only alternatives. EPA can resolve this problem simply by publishing pesticide registration applications in the Federal Register disclosing the substances contained in the formulation. This puts the original submitter on notice that his data is being relied upon and he can then come forward and shoulder the burden of proving he is the original submitter, that compensation is claimed and negotiate the amount. This procedure clearly satisfied the requirements of Section 3(C)(1)(D).

In summary, Mr. Chairman, the intent of Congress to simplify or streamline the pesticide registration process can readily be achieved by directing EPA to adopt two measures:

1. to concentrate on developing adequate safety data for the basic chemicals and scrap the ponderous draft guidelines that are presently pending which would impose even greater data burdens on formulators of end-use products than existed under the prior law; and

2. to abolish the "cite-all" system with regard to Conditional Registration and substitute the Federal Register Notice system which enables the original data submitter to protect his rights while relieving the Pesticide Industry of an incredibly costly and onerous notice and offer to pay procedure entailed in the unlawful "cite-all" system.

These suggestions would save incalculable agency resources to apply to other important environmental protection programs. It would greatly expedite the registration process and better protect public health and the environment and finally, it would avoid unnecessary costs that pass to the consumer and aggravate inflation.

Therefore, we earnestly urge that you direct EPA to adopt the foregoing suggestions.

APPENDIX A.—*Conditional registration for a disinfectant/sanitizer cleaner based on EPA PR notice 78-5 option III*

| Component                                                     | Data submitters |
|---------------------------------------------------------------|-----------------|
| Antimicrobial.....                                            | 204             |
| Tetra Sodium Ethylene Diamine Tetraacetate <sup>1</sup> ..... | 280             |
| Sodium Carbonate <sup>1</sup> .....                           | 233             |
| Sodium Metasilicate <sup>1</sup> .....                        | 158             |
| Isopropyl Alcohol.....                                        | 291             |
| Total.....                                                    | 1,166           |

<sup>1</sup> Detergent builders.

This would require that 1,166 offer to pay compensation letters be written by a formulator at a cost of approximately \$10/letter: \$11,660.

NAXERA, VA. April 30, 1979.

DONALD W. STEWART,  
U.S. Senate.  
110 Russell Senate Office Building,  
Washington, D.C.

DEAR SENATOR STEWART: In the course of the hearing on April 26, 1979, concerning the extension of authorization for the Environmental Protection Agency with respect to the Federal Pesticide Legislation, you asked two questions concerning the statement I submitted on behalf of LONZA Chemical Company. There was not sufficient time remaining to answer these questions in the hearing and accordingly you left the record open to receive written responses. I am here-with submitting these responses on behalf of LONZA.



*Question 1.* "In your statement, you say that the 'cite-all' system is, for unscrupulous operators, a license to extort. Could you describe for the Subcommittee the type of fact situation you had in mind in coming to this conclusion?"

Answer. Under the terms of Section 3(C)(1)(D) of the Federal Pesticide Act of 1978 with respect to data generated after September 30, 1978, the EPA can consider such data to support another application for registration only with the written permission of the original data submitter. With respect to data submitted after December 31, 1969, the EPA may consider such data to support another application for registration without permission from the original data submitter provided that the applicant has made an offer to compensate the original data submitter.

LONZA takes the position that the law requires dealing only with the original data submitter as to any chemical substance not every company that may have referenced the substance during the period 1969-1978. Under the "cite-all" system as delineated in EPA's PR78-5 and the attached notice and offer to pay form, applicants (both basic chemical manufacturers and formulators) were initially compelled to send offers to pay to all companies contained on a 1,700 page list who had referenced the particular substances involved in the application. EPA has subsequently partially relaxed this mandatory "cite-all" requirement with respect to formulators but not as to manufacturers.

LONZA submitted Appendix A as a part of its statement to the Subcommittee to illustrate the magnitude of offers to pay that must under the "cite-all" system be undertaken by an applicant for registration of a common sanitizer for use on hard surfaces such as walls, floors or counters. A copy of Appendix A is attached hereto for your convenience.

LONZA contends that it is self-evident that there can be only one original data submitter for each of the five substances contained in the formulation described in Appendix A. Instead of dealing with five original data submitters, the "cite-all" system would require sending 1,166 offers to pay. This opens the door for multiple claims for compensation as to each ingredient. If this occurs, it is evident that some of these claims must be spurious. If a spurious claimant perseveres with his claim, this triggers the compulsory arbitration procedures to resolve the dispute. As you know, there are as yet no implementing regulations to provide ground rules for such arbitration. Regardless how simplified such rules may be, the arbitration procedure is bound to be costly and time consuming. Applicants are likely to face the choice of settling spurious claims in order to get on with business rather than subjecting themselves to potentially lengthy, costly and uncertain arbitration litigation.

As LONZA noted in its statement which has heretofore been received in the record of the Subcommittee, the difficulty is locating or identifying the original data submitter. The EPA data files are so voluminous that a literature search for the original data submitter is infeasible. LONZA contends that EPA can resolve this problem by publishing pesticide registration applications in the Federal Register disclosing the substances contained in the formulation. This publication would put the original data submitter on notice that his data is being relied upon and provide opportunity to come forward and shoulder the burden of proving he is the original data submitter, that compensation is claimed and establish the amount of compensation that is appropriate. This procedure clearly satisfies the requirements of Section 3(C)(1)(D). This procedure would also deter possible spurious claims inasmuch as the burden of proof would be on the claimant to establish that he is the original data submitter.

EPA's Office of General Counsel apparently holds the view that this admittedly practical and expeditious procedure is somehow barred by judicial decision. As Counsel for LONZA I cannot agree. Under either the Common Law or the Federal Pesticide Act of 1978, the only party having protected rights to proprietary data is the original submitter of the data. Inasmuch as the original submitter would under the proposed procedure receive reasonable compensation there would be no basis for a claim of taking without due process or fair compensation. Other parties that may have referenced the given substance would have no standing to sue inasmuch as they were not the original data submitter and accordingly possess no proprietary rights.

*Question 2.*—"Do you believe that EPA's recent decision to exempt pesticide formulators from the 'cite-all' provision will alleviate the problems you allude to in your statement for LONZA, Incorporated?"

Answer. First, EPA has not exempted formulators from "cite-all". Rather, EPA has allowed formulators to generate and cite their own data, but if a formu-



lator applicant for registration relies in part on his own data and cites data as to some ingredients, the cite must be done on a "cite-all" basis. In addition, there is presently some confusion at the working level in the Office of Pesticide Programs (OPP). Some EPA Product Managers interpret the current policy as allowing a "cite-all" or "generate-all" alternative. Others apparently allow a "mixed" submission, i.e. in a given application some Product Managers allow applicants to rely on their own data for some ingredients and to cite (on a "cite-all" basis) with respect to other ingredients. Thus even as to formulators it is possible to avoid "cite-all" only if the applicant generates all of the data on which it relies. This confronts small business with the burdensome alternative of the costly "cite-all" system of offers to pay or the expensive alternative of generating all of its own data, a system that would result in enormous redundant testing and related unproductive duplicative expense.

Secondly, EPA continues to require "cite-all" with regard to manufacturers of basic chemicals. LONZA takes issue with EPA's reasons for persevering with this policy. While it may be true that the paperwork costs are less if EPA imposes "cite-all" on manufacturers than formulators, these are still substantial, unnecessary, and, as shown hereafter, unlawful. Moreover, there is simply no basis for EPA's assumption that it must rely on its "institutional knowledge" to evaluate a basic pesticide chemical. EPA's proposed Guidelines for Registration of Pesticides, which are presently being enforced, adduce fully adequate data for all regulatory purposes. Indeed, the present round of proposed Guidelines go far beyond the data requirements of EPA's 1975 Guidelines (and earlier versions) on the basis of which most of the substances were registered that would be cited under the "cite-all" system. EPA should therefore be encouraging manufacturers of basic chemicals to generate their own data in order to have up-to-date and more comprehensive data on which to base regulatory action.

The bottom-line on the "cite-all" system is that it clearly goes beyond the statutory requirement of section 3(C)(1)(D) that only original data submitters be notified and offered compensation.

Finally, in the course of my testimony on behalf of LONZA I indicated that despite the enactment of the simplified registration procedures in Section 3(c)(2)(C) and (D) that EPA announced in the Federal Register:

"Registrants of formulated products, however, would also be required to submit or cite data derived from testing the active ingredients in their products. In addition, they would have to submit or cite data from testing formulated products to obtain registration for a formulated product." (43 Fed. Reg. p. 37337)

I also indicated that in addition to six specified acute toxicity testing requirements (the Ss 163.81-1 through 163.81-6 series), that despite enactment of the simplified procedures, pending EPA Guidelines would impose the following requirements on formulators of end-use products:

1. Subchronic oral dosing studies (Section 163.82-1).
2. Subchronic 21-day dermal toxicity studies (Section 163.82-2).
3. Chronic feeding studies (Section 163.83-1).
4. Oncogenicity studies (Section 163.83-2).
5. Teratogenicity studies (Section 163.83-3).
6. Reproduction studies (Section 163.83-4).
7. General metabolism studies (Section 163.85-1).
8. Domestic animal safety tests (Section 163.86-1).

In addition the proposed Guidelines also discuss extensively the standards and battery of possible tests for mutagenicity, including standards for detecting heritable chromosomal mutation and standards for detecting effects on DNA repair or recombination as an indicator of genetic damage.

In the course of my testimony, an EPA representative, Mr. Robert Wayland of the Office of Legislation, indicated that these Guidelines were only in the proposed rulemaking stage, that EPA did not intend to enforce these Guidelines as to formulators and that the Guidelines would be amended to reflect the 1978 Pesticide amendments. LONZA's response to this assertion is:

1. that the 1975 Guidelines which EPA has enforced over the past 4 years are still in the "Notice of Proposed Rulemaking State";
2. that the OPP is in fact enforcing the proposed Guidelines referenced above at the present time; and
3. that despite numerous formal and informal requests, EPA has declined as yet to modify the Guidelines in question and has not either made an unequivocal commitment to do so or indicated when this might happen with reasonable specificity.



Moreover, EPA is presently enforcing Subpart G, Efficacy Guidelines, which is a part of this EPA Guideline series, despite the fact that Subpart G is still in Draft form and has not as yet even been published in the Federal Register.

Accordingly, LONZA stands by the statement in its testimony and the foregoing amplifications as being an accurate account of EPA's regulatory practices. LONZA would naturally be gratified if EPA in fact modifies its proposed Guidelines to take account of the Simplified Registration Procedures that Congress enacted to streamline the registration process.

Respectfully submitted,

SCOTT C. WHITNEY,  
*Counsel for LONZA, Inc.*

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