**Comment:**

There is no better way to understand the operation of a government agency than to ask the principle executive of that agency. This occasionally produces as much humor and pathos as it does information. Witness the testimony of Dr. Harry W. Hays, the Director of the Pesticides Regulation Division of the United States Department of Agriculture.

HARRY W. HAYS

being first duly sworn, testified as follows:

EXAMINATION BY ASST. UNITED STATES ATTORNEY

**Q. Will you please state your name, position, and business address, Dr. Hays?**

A. My name is Harry W. Hays; Director of the Pesticides Regulation Division, United States Department of Agriculture, Washington, D. C.

**Q. Dr. Hays, for the record will you state your educational background?**

A. I took my Bachelor of Science degree from Franklin and Marshall College, Lancaster, Pennsylvania, in 1933; my Master of Science degree from Princeton University in 1937; and my Doctor of Philosophy degree at Princeton University, 1938.

**Q. Dr. Hays, you stated you are the Director of the Pesticides Regulation Division. Will you please state the functions of that division?**

A. The function of the Pesticides Regulation Division is to carry out the provisions for registration and enforcement pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act. . . . (FIFRA)

EXAMINATION BY MR. ROBERTSON

**Q. Dr. Hays, will you please set out or state the procedures that are followed in connection with registration of an economic poison pursuant to the provisions of the FIFRA?**

A. Let me say that since the Act was passed in 1947 there have been several amendments to the Act to include such things as plant regulators, plant defoliants, desiccants, to eliminate the protest registration provisions that were inherent in the original Act.

The two primary functions in the Act are registration and enforcement. And we have in the Pesticides Regulation Division a Registration Branch and an Enforcement Branch.

Now under the Registration Branch we have a group of reg-

istration specialists as well as a staff of competent scientists in the various areas of disciplines involving pesticides. Now to register an economic poison, the applicant must first submit a formal application for the economic poison; he must submit a proposed label, a statement of the chemical composition of the product, and effectiveness data and safety data in support of the application.

Now the application and the data are first reviewed by what we call the New Chemicals Evaluation Staff. The chemical composition is reviewed for its accuracy, the ingredients statements, and the proper nomenclature, the net content, and the product name. The application, the label, the data are then submitted to what we call the Product Evaluation Staff. Here we have a group of entomologists, agronomists, plant pathologists, bacteriologists, animal biologists.

Now in general the criteria that are used that have been submitted to me by the professional people in general include such things as the pest to be controlled, the dosage and the rate of application, phytotoxicity, metabolism, migration, translocation, and persistence. And from this they then review very carefully the directions for use as proposed by the applicant to see whether or not the product, used in accordance with the directions of use, would in fact be effective.

Now the data and the label and the chemical composition are then submitted to the Safety Evaluation Staff. And here again the staff is made up of specialists in biology and toxicology. And they review the data submitted in support of safety insofar as the directions for use. This would involve in general such things as the oral, acute oral, dermal and inhalation toxicology, subacute studies designed primarily to determine if the product has cumulative effects, subacute feeding studies. Eye and skin irritation is a very important part in terms of the applicator. Such things as sensitization, reproduction, and carcinogenicity tests.

Now from this it is possible then to determine what signal word would be used on a pesticide container. And there are three principal words: "Danger", "Warning", and "Caution". In addition, the data in support of safety would provide a means of determining what precautionary statements are necessary, when complied with, are adequate for the protection of man and vertebrate animals. . . . And vegetation.

Now if the product is to be used on food or feed crops and there is a likelihood that a residue would remain from such use, this matter, your Honor, is transmitted to the Food and Drug Administration for the establishment of a tolerance. This usually involves a very extensive petition, considerable

data on feeding, and long term studies for evaluation by the scientists in Food and Drug.

Now when all of the review has been completed by each of the individual staffs, it is then reviewed in its entirety by representatives of each of these divisions so that we can take a look at it as a whole. If the data appear to us to be adequate, or to our scientists, and all provisions of the registration have been met, the product is registered. If, on the other hand, the data do not appear to be adequate in support of effectiveness or safety, the applicant is so notified of the deficiencies and the need to submit additional data.

Now in 1963 the President's Science Advisory Committee recommended in its report on the use of pesticides, recommended that other departments in the government should be consulted and to provide information and advice to the Pesticides Regulation Division prior to registering any product. In 1964 there was drawn up what is known as an interdepartmental agreement which was signed by Secretary Udall, Secretary Celebrezze, and Secretary Freeman.

Now this agreement states that all labels, all proposed labels, applications should be referred to the proper agencies within those departments such as the Public Health Service in the Department of Health, Education and Welfare; to the Food and Drug Administration to the Bureau of Veterinary Medicine; and to the Department of the Interior for review and advice as to the adequacy of the labeling and the adequacy of the data in support of the registration. This has now been in effect since 1964. Applications are submitted to the interdepartmental groups on a daily basis; we receive their advice; we take their advice seriously in terms of the adequacy of the labeling to protect the interests of the public health aspects and fish and wildlife.

Now the second important activity of course in the Federal Insecticide, Fungicide, and Rodenticide Act is the enforcement. And so we have under constant surveillance an inspection system that our inspectors, who are located in various geographical areas of the United States, will collect samples of the products that have been shipped in interstate commerce. I stress again interstate commerce.

These samples are submitted to the laboratory for analysis for biological testing, and results are sent to the Washington office. If the product is found to be in violation of the Act, is misbranded, it is then subject to criminal prosecution.

We have in this past year sampled over 8,000 products that have been shipped in interstate commerce for the protection of

the public that have been sampled and analyzed by our various laboratories.

Now in addition to the general functions of the division, we have of course a departmental committee on pesticides in the Department of Agriculture. The Department reviews all of the programs of the Department. We get information from this committee as well as the research activities that go on within the Department of Agriculture. And there is the Federal Committee on Pest Control that is represented by many agencies in the government that review the federal programs before any are implemented. Then we also have a very close working relationship with the state officials under the Association of the American Pesticide Control Officials, with our primary aim to have as uniform procedures and registration and enforcement as possible.

We have in the past two years met with representatives of the states at some eight regional meetings to discuss our problems at both the federal and the state level. We believe this has been a very important part of our regulatory function.

That, I believe, Mr. Robertson, states our procedure.

EXAMINATION BY MR. ROBERTSON

**Q. Dr. Hays, you set forth the procedure in connection with submission of data and review of all that data to support the registration of an economic poison.**

**. . . Is there any provision for canceling the registration of an economic poison?**

A. Yes, section 4.c. of the Act provides that when the secretary deems it necessary to cancel a registration, he shall so notify the registrant, and the reasons therefor. These reasons must be based on good evidence for such a cancellation. I think the President's Science Advisory Committee report on the use of pesticides emphasizes this point, that there needs to be some relief for industry from any arbitrary or capricious act on the part of a regulatory agency, and they have a right to file a complaint or objection to any cancellation.

**Comment:**

Direct examination was short and pointed. It was the apparent intention of the U.S. Department of Agriculture to establish that the environment was in goods hands in the care of the Pesticides Registration Division. It was the opportunity for the Plaintiffs to establish that at least the Pesticides Registration Division was not capable of doing the job of protecting the environment.

This is an opportunity that occasionally arises in every action involving a federal or state regulatory agency. It must never be

overlooked. The challenge must always be accepted. Cross-examine—carefully.

EXAMINATION BY MR. YANNACONE

**Q. Dr. Hays, how long have you been in charge of the division?**

A. Since July 1, 1966.

**Q. And prior to that time . . .**

A. I was not with the department prior to that time.

**Q. All right. What was your job prior to that time?**

A. I was with the National Academy of Sciences. . . . As a director of the advisory center of toxicology.

**Q. And will you tell us how the Food and Drug Administration and the U. S. Department of Agriculture act together in the registration of those pesticides that leave residues on food crops?**

A. That is under the Federal Food, Drug and Cosmetics Act.

**Q. And that act then refers to what?**

A. To the requirement of the establishment of a tolerance under the Miller Bill of the Food Additives Amendment.

**Q. Now which agency initiates this tolerance procedure for pesticides that leave residues on food crops?**

A. The applicant initiates the request for a tolerance if it is to be used on food or feed.

**Q. Does the applicant make the initial determination that there will be a residue?**

A. Yes.

**Q. Is this checked by your department?**

A. No, sir.

Chemically, you mean?

**Q. Yes?**

A. No.

**Q. In other words, then if the applicant says there is no residue or will be no residue, your department does not check that statement?**

A. We look at the data, sir, we review the data submitted with the application to see whether or not there would in fact be any residue if the applicant has said there was no residue.

EXAMINER VAN SUSTEREN: Before that you stated you did not run any—

WITNESS: Analytical determinations.

**Q. Who supplies the data?**

A. The applicant.

**Q. From his own research?**

A. Yes.

**Q. In other words, a chemical company furnishes you data from its own research?**

A. That's right.

**Q. And if it doesn't measure any residues, you don't check that statement that there were no residues found?**

A. We do not.

**Q. Does anybody?**

A. I would imagine that Food and Drug may test the method.

**Q. Didn't you just say, Dr. Hays, that Food and Drug doesn't evaluate pesticides unless the petition is brought to them?**

A. We are talking about data and residue data.

**Q. You have gotten me a little confused, Doctor. I think you testified that the petitioner, the applicant for the registration submits to your department—**

A. That's correct.

**Q. The applicant, the registrant, submits the data, right, to your department?**

A. That's correct.

**Q. And if that applicant says there's no residue detectable on the food stuffs to which the pesticide going to be applied, your department does not scientifically, analytically check the statement, does it?**

A. We check it; not by the laboratory method—

**Q. You read his data?**

A. That's correct, we read the data.

**Q. All right. And you evaluate it; and if it is logically consistent within itself, you accept it, right?**

A. That's right.

**Q. The only thing you can determine is internal inconsistencies in the data?**

A. That's right.

**Q. Now at that point if the applicant does not tell you that there is going to be a residue and if his data internally consistent within itself shows no residues, there is no referral to FDA under the Food, Drug and Cosmetics Act, is there?**

A. That's right.

**Q. Now, Dr. Hays, have you ever seen the registration application of DDT?**

A. The original?

**Q. Yes?**

A. No.

**Q. Have you ever seen any—have there been any subsequent applications for either the registration or reregistration or further consideration of DDT?**

A. Yes.

**Q. When was the most recent?**

A. I have no idea.

**Q. Have you seen them?**

A. Not personally.

**Q. Well, Doctor, do you know anything about the registration of DDT?**

A. I know there have been a number of registrations for DDT.

**Q. All right. Have you seen personally any of them?**

A. No.

**Q. What did you say your job title was with the department?**

A. I am the administrator and director of the division.

**Q. Of?**

A. Of the Pesticides Regulation Division.

**Q. And unfortunately, as bureaucratic operations are conducted, the buck stops as for as pesticide registration is concerned with you?**

A. That's right.

**Q. You have never seen a DDT formulation registration statement?**

A. Oh, yes, I have seen registrations; but I have not actively participated in each registration.

**Q. That isn't what I asked you, Doctor. I asked: Did you ever see any?**

A. Oh, yes, I have seen—

**Q. Okay. When was the most recent you saw?**

A. I wouldn't have any idea, sir.

**Q. You have been with the department since 1966, right?**

A. Yes.

**Q. Prior to that time did you examine any?**

A. No.

**Q. So between 1966 and now in 1969—**
**You are still with the department, right?**

A. Yes.

**Q. Still with the same title?**

A. Yes.

**Q. You have seen some DDT registration statements, have you not?**

A. Yes.

**Q. Now in those DDT registration statements was data furnished as to any sublethal effects of DDT?**

A. If they were, they were submitted to the Safety Evaluation Staff.

**Q. You don't know?**

A. I wouldn't know.

**Q. Doctor, who asked you to come here and testify?**

A. The Department of Agriculture wishes to discuss the procedures used in the registration of pesticides.

MR. ROBERTSON: Mr. Examiner, the Department of Agriculture filed a petition for leave to intervene in this proceeding as a result of learning of the proceeding and analysis of the record disclosing that the federal registration procedures were discussed.

I don't think that Dr. Hays personally is in a position to say who may have requested him. This determination was made within the department.

MR. YANNACONE: All right, that's good enough.

**Q. Dr. Hays, you did know why you were coming here?**

A. Oh, yes.

**Q. You did know the purpose of this hearing?**

A. Yes.

**Q. You are a representative of the U.S. Department of Agriculture?**

A. Yes.

**Q. Now, Doctor, what was your official job title again?**

A. I am the director of the Pesticides Regulation Division.

**Q. And you are in charge of the regulation of pesticides, right?**

A. Yes.

**Q. And you are responsible for the regulation of pesticides?**

A. I am responsible to see that the activities of the registration are carried out by those assigned to the duty of reviewing each application.

**Q. Okay. And the scope of your duties or the extent of your duties are defined in the Federal Insecticide, Fungicide, and Rodenticide Act officially?**

A. Right, yes.

**Q. Now, Doctor, your duties—and when I say "your", I don't mean your personal duties—the duties of your agency and your department include a study of the safety of a chemical such as DDT—withdrawn.**

**Do your duties comprehend a study of the safety of DDT and its metabolites as they may be formulated as economic poisons?**

A. Not directly.

**Q. All right. Just what are the duties of your department—withdrawn.**

**Is there any other department in the Federal government that you know of that is responsible for the approval of the registration of an economic poison for use in interstate applications other than the Department of Agriculture?**

A. There's no other department responsible except the Department of Agriculture.

**Q. Your department, the United States Department of Agriculture, is wholly and completely responsible then for determining whether or not an economic poison may be used in interstate commerce, right?**

A. That's right.

**Q. And is there any other division within the Department of Agriculture other than the one that you are the head of that is responsible for the approval of a particular registration for use?**

A. There is no other division.

**Q. In other words, then you are the top of that division of the U.S. Department of Agriculture which is responsible for determining whether or not a particular economic poison, in this case say DDT, is registered for use in interstate applications, right?**

A. That's right.

**Q. All right. Now, Doctor, tell us from your duties and the duties of your division as set forth in the Act as you read it and it's interpreted to you by your department's legal talent, tell us, Doctor, what specific information about a pesticide being proposed for registration your department is interested in?**

A. I leave that entirely, sir, to the people responsible for the various scientific disciplines within the division.

**Q. All right. Doctor, there is a policy and there are rules and regulations set forth as to what information a registration application must contain, is that right?**

A. In general, yes, sir.

**Q. What are these general requirements, please?**

A. I think I have stated those.

**Q. We want to review them for the record.**

A. Chemical composition—

**Q. This is simply the chemical formulation of the compound as it's going to be used, right?**

A. Right.

**Q. And I think you testified that this is checked by your staff for accuracy?**

A. That's correct.

**Q. It's also checked for nomenclature in that it conforms with whatever the current scientific nomenclature for the substance is?**

A. Yes.

**Q. And if it's a substance like technical DDT, which is a mixture of isomers, your department checks to make sure that the isomer mixture concentration is set forth on the label accurately, right?**

A. Not necessarily. . . .

**Q. All right. Isn't that part of the chemical composition?**

A. If it's a technical grade, it need not state on the label what the percentages are.

**Q. But does it have to say what the isomers are?**

A. No.

**Q. In other words, then a technical grade such as tech DDT need only state on the label that its major constituent is thus and so?**

A. That's correct.

**Q. And that's all your department then checks for, right?**

A. Yes. Checks.

**Q. Okay. Now what's the next element that's checked for?**

A. The next would be the matter of effectiveness.

**Q. Now, effectiveness. Will you tell us what to your agency "effectiveness" means?**

A. That, I again, sir, rely entirely upon the scientists within the division of that discipline to determine what they consider to be effective.

**Q. What discipline?**

A. Entomology.

**Q. Entomology. Any other disciplines?**

A. If it were a herbicide, it would be agronomy.

**Q. Any other?**

A. If it would be a fungicide, it would be plant pathology.

**Q. With respect to DDT, then the check would be by entomologists?**

A. That's correct.

**Q. And they would be checking on effectiveness, right?**

A. Yes.

**Q. The effectiveness they check for is what?**

A. Whether it controls the pest.

**Q. The target insect?**

A. That's correct.

**Q. Now when we say "pest" in your department, we are referring to "pest" as defined by the Act, are we not?**

A. That's correct.

**Q. All right. Are we referring to any kind of insect that isn't defined by the Act?**

A. Not that I would know of.

**Q. In other words, then a pest is like an officer and a gentlemen, it's determined by an Act of Congress and set forth in the Act; and if it's named as a pest in the Act, it's subject to the jurisdiction of your department?**

ASST. U.S. ATTY.: The term "pest" is not used in the Federal Insecticide, Fungicide, and Rodenticide Act. The term "insect" is used as well as "fungus", and so forth; so just for clarification I thought I would—

**Q. Dr. Hays, where is the word "pest" defined then if it's not in the Federal Insecticide, Fungicide, and Rodenticide Act?**

A. I don't know of any other place anywhere it's defined. . . .

A. As we just stated, it did not mention just "pest" but specified "insects".

**Q. It sets forth in that section that these insects are subject to control, doesn't it?**

A. Yes, I guess you would say that.

**Q. For the purpose of policy determinations at your level in the department, effectiveness is considered as what? In other words, what do you understand by "effectiveness"?**

A. As I said, I'm relying solely on the scientists to determine what in their opinion would be an effective control.

**Q. This effectiveness then, this is determined by an entomologist on a staff, right?**

A. That's correct.

**Q. Aren't there any published guidelines as to what is effective or not effective control?**

A. No published guidelines.

**Q. Aren't there any internal memoranda or understandings at various levels of your department that might tell us what "effective" is?**

A. I'm sure that this could be found in many scientific journals.

**Q. Oh, Doctor, you are the head of the only section of the U.S.D.A. that is responsible for the registration, which means the actual interstate sale ultimately, of economic poisons like DDT. And you have told us that one of the criteria for registering of these economic poisons is their effectiveness. You're telling me that effectiveness is left to the independent judgment of some technician or some entomologist on a scientific staff well down the line, so far down the line in your department that you don't know what his criteria for effectiveness are?**

A. We have chief staff officers in the Product Evaluation Staff who are not well down the line, but who are competent entomologists, agronomists, plant pathologists.

**Q. All right Doctor—**

A. They are not technicians.

**Q. It's a matter of opinion.**
**But, Doctor who determines their competence? Don't you as chief of the department?**

A. Yes, their background, their training, their years of experience, their education, yes, all these.

**Q. That's all you use as criteria?**

A. Yes.

**Q. Once you have determined that, you make—you come to no understanding of what is effective control; if an entomologist says it's effective, you believe it without any checking?**

A. That's right. Why shouldn't I?

EXAMINER VAN SUSTEREN: The examiner is going to break in here. It seems to me that you gentlemen are going around in circles. Mr. Yannacone means one thing and you are talking about another.

And I believe, Mr. Yannacone, that when you talk about effectiveness, you are talking about percentage effectiveness in regards to the compound itself so far as the target organism is concerned?

MR. YANNACONE: No.

EXAMINER VAN SUSTEREN: You are not?

MR. YANNACONE: No, absolutely not. I would like Dr. Hays, who is chief of this department, one of whose criteria for determining whether or not DDT, for instance, is registered, is it effectiveness, I want him to tell you, the court, the record, the world just what is effectiveness.

EXAMINER VAN SUSTEREN: And that is what the examiner is talking about, and how else you gauge the effectiveness of a compound except as to what control it may have over the target organism.

MR. YANNACONE: That might be your opinion and my opinion; but I want to know what Dr. Hays uses in his department.

EXAMINER VAN SUSTEREN: And the examiner merely broke in to find out if that is what you had in mind so far as your question is concerned.

MR. YANNACONE: Right.

EXAMINER VAN SUSTEREN: And Dr. Hays obviously is talking about something else in his answers.

MR. YANNACONE: All right.

EXAMINATION BY MR. YANNACONE

**Q. Now the safety data that's submitted with the registration statement, who furnishes this in the first case?**

A. The applicant.

**Q. All right. And are there set forms or set criteria or set elements of this safety type data? In other words, what do they check for and furnish you in the way of information?**

A. Well, Mr. Yannacone, the first information that is provided by the applicant is information, data on the acute oral, dermal and inhalation toxicology. . . .

**Q. Does this include $LD_{50}$'s?**

A. That is correct. . . .

A. It includes cumulative studies, repeated studies, repeated daily doses; it includes, as I said, eye and skin irritation studies—These are on animals. . . .

A. That's correct.

**Q. What else is included in this initial safety evaluation?**

A. In addition, there are studies on reproduction. . . .

**Q. All right. Now when you say studies on reproduction, what are the usual kind of reproduction studies that are considered in that?**

A. In laboratory animals.

**Q. And what do they measure, fecundity or fertility?**

A. That's correct.

**Q. They measure basically the number of offspring reproduced and whether there's any statistical difference between the control and the sample?**

A. That's correct.

**Q. Anything else?**

A. Sensitization.

**Q. And this again is with an experimental animal population?**

A. That's correct. And at times human patch tests are involved.

**Q. All right. And this is by normal allergic reaction study procedure?**

A. That's correct.

**Q. Anything else included?**

A. In some instances antidote studies.

**Q. All right. This is assuming that there is a poison problem, they determine the basic antidotes, and they furnish you with that information?**

A. That is correct.

**Q. All right. And that would then be included on the label?**

A. That's correct. . . .

A. This is done by the Safety Evaluation Staff, by review of the interagency staff of the Public Health Service.

**Q. Now the New Chemicals Evaluation Staff does what?**

A. They are primarily concerned with the ingredients statement on the label, the net content, the product name, any matter dealing with flammability, the nomenclature of the compound, whether or not it is consistent with the chemical abstract nomenclature.

**Q. Now, the Product Evaluation Staff does what?**

A. Well now, let me try to make something clear here, Mr. Yannacone, in that we have two general groups of compounds that we would categorize as non-food use compounds and those which may be used on food or feed. So that if we have an insecticide that does not in any way have any connection with food or feed, then our Product Evaluation Staff in the insecticide section will review the data in terms of whether the product is effective against that particular insect which is named on the label.

**Q. I see. Now in other words, any substance such as DDT might have multiple registrations; and if it was going to be used for the control of certain insect vectors such as mosquitoes, and not on human foodstuffs it would then be evaluated as a non-foodstuff pesticide?**

A. That is correct.

**Q. And if it were going to be used for a particular food crop, it would then be evaluated by a different group within the section or under different criteria?**

A. It would be reviewed by the same entomologists, but in addition would be reviewed by the Food and Drug Administration.

**Q. I see. All right, now the review by the entomology group for an insecticide that is only to be used on non-foodstuffs includes only a study of its effectiveness against the target organism, is that correct?**

A. That's part of it.

**Q. All right, what else does it do?**

A. Then we get into the question of where it might be used in getting into areas involving fish and wildlife.

**Q. All right. Now would you elaborate for us on how this work with fish and wildlife is done?**

A. Well, there are certain data that are required by our division in support of the registration, in that any use that might possibly affect our fish and wildlife, and studies would be required, or data would be required to see what doses would in fact affect any fish or wildlife.

**Q. All right. Would you back up a moment? Who makes the determination on whether or not there will be an effect on fish and wildlife?**

A. The applicant usually is quite cognizant of the need for any

**Q. Now what kind of studies are presented to you generally on data with respect to fish and wildlife safety?**

A. Well in general, as I recall the scientists review, they require $LC_{50}$ concentrations in a variety of fish species; they require $LD_{50}$ studies for certain types of birds.

**Q. All right. Anything else?**

A. I can't recall at the moment anything else.

**Q. Do you recall whether they do reproduction studies with fish?**

A. We have not in the past required these extensive studies on reproduction. But this again would be in concert with the Department of Interior in terms of advice from them as to what would be needed.

**Q. All right. Now when you speak in terms of advice from the Interior Department, is this advice in any way binding on the Department of Agriculture?**

A. Well, I don't know that any advice is always binding. We certainly do take into consideration any information and advice that the Interior or any other agency would give us.

**Q. Are you familiar with the testimony of Dr. Lucille Stickel, head of the Pesticide Research Group at Patuxent for the U.S. Department of the Interior, which was made a part of this report; and Dr. Kenneth Macek who is with the Fisheries Section at Columbia, Missouri, on the effects of DDT on fish and certain birds, respectively?**

A. I am in general familiar with it, yes.

**Q. And is there any doubt on the part of your department experts as to the validity of this data that you know of.**

A. I wouldn't know of what their feelings are in the matter at all.

**Q. Well, have you at the policy level considered this data?**

A. I have not thoroughly reviewed all of the data; just in general familiar.

**Q. I want you to assume, Doctor, then the substance of the data and the testimony of Dr. Stickel and Dr. Macek, Dr. Stickel having testified that she observed in laboratory populations eggshell thinning and reproduction failure in kestrels, a bird of prey, and ducks, a particular kind of ducks; and Dr. Macek observed reproduction failure in the lake trout with sublethal concentrations of DDT at levels now already present in the respective environments that these species inhabit naturally.**

**Now assuming that, Doctor, is there anything you in your capacity can or would do about the registration of DDT?**

A. Well, we would have to have certainly some very extensive and definitive data as it pertains to the normal usage of any pesticide, and not based solely on any laboratory finding.

**Q. Well, Doctor, do you require this type of data from the applicant when he makes up his registration statement?**

A. We have not required this kind of data in the past; although we have recently reviewed our criteria or our data for fish and wildlife and have indeed added other kinds of data such as field studies that we think will be very useful. But it is too early now to evaluate this kind of approach.

**Q. Well, what other data is now required, and when did these— First of all, when did you make the changes?**

A. Oh, in about the last year we have been requiring field studies particularly in areas where there's very large and heavy wildlife populations.

**Q. Does this apply to a chemical that is already registered such as DDT?**

A. Yes.

**Q. And who performs these experiments?**

A. We have requested the applicants to consider and to initiate studies in the matter of field testing.

**Q. All right. And what kind of field tests are you comprehending within this kind of study?**

A. Well, we have contemplated putting certain types of bird species such as pheasants and ducks in areas where we know that this could well be a problem and to see whether from the normal use of the pesticide there is in fact any serious hazards associated with such use.

**Q. What about the fact that a great many of these experiments have already been done, both by private individuals working for academic institutions and by the U.S. Department of the Interior itself?**

A. We consider the data from a variety of sources, not only what we get from the applicant, but what is available from whatever source.

**Q. Let's back off a moment, Doctor.**
**You are now aware, you have testified, of the work of the U.S.**

**Department of the Interior, Dr. Macek's fish work, and Dr. Stickel's work with the hawks and the ducks, right?**

A. Yes.

**Q. I take it from this that you don't question their scientific accuracy. And you have considered them laboratory studies. You should by now also be aware of a great many field studies that have been done over the past five or six years.**

**Now, Doctor, isn't this more evidence against the use of DDT than was ever submitted on the safety of DDT to you originally —or your department originally on the registration of DDT?**

A. Well, there's no doubt but what there has been new data presented in the last few years on a variety of pesticides about which we knew little a few years ago.

**Q. All right. Doctor, whenever possible at this hearing we are trying to discuss DDT and its metabolites exclusively. So I know this might restrict you a little bit, since you are responsible for a great many more pesticides than just DDT. However, DDT is the subject matter of this action.**

**Now isn't it a fact, Doctor, that there is already accumulated in the scientific literature and in the data submitted to your department from the U.S. Department of the Interior more data indicating damage to wildlife populations on a broad scale from DDT than there is data on the safety to wildlife populations already in your records?**
**Isn't that a fact, Doctor?**

A. I wouldn't go so far as to say that is a fact.

**Q. All right. Doctor, then you tell us for the record what data your department does have on the safety of DDT to wildlife populations that conflicts with the data that you already are aware of the fact that DDT is not safe to wildlife populations?**

A. Well, I think we can say in general that from the wide usage of DDT there has been a remarkably good record of the use of DDT without any evidence of any widespread adverse effects.

MR. YANNACONE: Hold the record for a moment. May we take about a 30 second break.
(Mr. Yannacone examines documents)

EXAMINATION BY MR. YANNACONE

**Q. All right, Doctor, are you aware of studies by Dr. Robert Risebrough, who happens to be sitting right here, but who has already testified at great length at this particular hearing; are**

**you aware of his studies with respect to DDT and the worldwide distribution of it?**

MR. STAFFORD: Mr. Examiner, I ask that the witness be shown what studies counsel refers to.

MR. YANNACONE: If I am referring to a specific study, I will show it to him. I would like to test the witness' general knowledge.

MR. STAFFORD: I object to asking this general a question without the witness knowing what particular study counsel is referring to.

EXAMINER VAN SUSTEREN: Well, he can ask him generally if—ask the witness generally if he is aware of any work, if any, done by Dr. Risebrough.

MR. STAFFORD: I have no objection to that.

MR. YANNACONE: I will withdraw the question and rephrase it.

EXAMINATION BY MR. YANNACONE

**Q. Doctor Hays, have you ever heard of Dr. Robert Risebrough?**

A. Yes.

**Q. Are you aware of any of his published material?**

A. I am aware that he has published material.

**Q. Have you evaluated any of that published material?**

A. I have not.

**Q. Are you aware of the general subject area of that published material?**

A. In a very general sense.

**Q. What is your understanding of the subject material?**

A. It in general is a review of the widespread effects on wildlife.

**Q. Of?**

A. Of DDT.

**Q. Have you ever heard of Dr. Charles F. Wurster, Jr.?**

A. Only during his testimony.

**Q. Then you are not aware of any of his publications?**

A. No, sir.

**Q. Do you read Science?**

A. I read a lot of journals, not Science particularly.

**Q. Read the Journal of Applied Ecology?**

A. No.

**Q. What journals do you read, Doctor, in the regular course of your daily duties?**

A. Well, I read the Journal of Toxicology and Applied Pharmacology, the Journal of Pharmacology and Experimental Therapeutics; articles that are brought to my attention by our staff, the journals of which I am not particularly aware of at the moment, however.

**Q. Basically then you read the two big toxicology journals?**

A. That's correct, yes.

**Q. And that natural, because you are originally a toxicologist, right?**

A. Pharmacologist, rather.

**Q. Oh, pharmacologist. You ever heard of Doctor Conney?**

A. No.

**Q. You have never heard of Dr. Conney, C-o-n-n-e-y?**

A. No.

**Q. Ever heard of Dr. Richard Welch?**

A. Yes.

**Q. And you have never heard of Dr. Conney?**

A. I don't recall his name.

**Q. All right. You are familiar with the Burroughs Wellcome Laboratories?**

A. Yes.

**Q. You know what they do?**

A. Well, I think they are primarily in the drug field.

**Q. Uh-huh. Do you know Dr. Welch works for them?**

A. Yes.

MR. ROBERTSON: Mr. Examiner, I would like to know just perhaps where this line of questioning will get us to, in view of the fact Dr. Hays has testified that he is the director of the Division,

that he has a staff of competent qualified scientists that are under him who may, no doubt do, read and evaluate all of the scientific publications available.

EXAMINER VAN SUSTEREN: Well, Dr. Hays—

MR. YANNACONE: He makes the decision.

EXAMINER VAN SUSTEREN: He testified, if the examiner recalls properly, only in regards to registration procedures within the Department of Agriculture so far as the Act, FIFRA, and as to procedures; and Dr. Hays did not testify in any way as to any definitive work, if any, that he may have done personally in regards to any of the matters at hand.

MR. YANNACONE: All right. What I am trying to establish—so we don't get the record confused and we don't get counsel or the witness upset—I am trying to set forth for the record once and for all from the man who is responsible for the activities of the Department of Agriculture division in charge of pesticide registration exactly what the materials they make their decisions—which have wide-sweeping effects apparently—what these materials are and what his knowledge is based on.

EXAMINATION BY MR. YANNACONE

**Q. Is there any interest in the United States Department of Agriculture division that you head in the status of DDT and its metabolites as an economic poison?**

**Q. Okay. Is the subject of the status of DDT and its metabolites as an economic poison under consideration at this time or under investigation at this time by your department?**

A. The subject of DDT is under consideration by the Department of Agriculture through the National Academy of Sciences, National Research Council.

**Q. Is this the only pesticide that's being considered in this way?**

A. No, it involves all persistent pesticides.

**Q. I see. But what is the interest of the Department of Agriculture, the division that you head that's responsible for registration, in DDT and its metabolites, if any?**

A. I just remarked that we are interested in the total concept of persistent pesticides including DDT as it relates to our environment, and have asked the National Academy of Sciences to make such a study.

**Q. But what about your department, Doctor; what work is your department doing, if any, on this matter? . . .**

EXAMINER VAN SUSTEREN: On what matter?

MR. YANNACONE: On the matter of DDT.

EXAMINER VAN SUSTEREN: Well, is it evaluation, or reevaluation?

MR. YANNACONE: I don't know. I would like to know from Dr. Hays what, if anything, other than referring the matter to the National Academy of Sciences, has his department done with respect to DDT, which apparently was of sufficient magnitude or problem to refer to the National Academy of Sciences.

EXAMINATION BY MR. YANNACONE

**Q. What is your division doing, if anything?**

A. We are not doing anything.

**Q. Okay. Now in other words, then the registration of DDT as it now exists is not under direct review by your department now?**

A. No, sir.

MR. ROBERTSON: Mr. Examiner, may I inject at this point the matter here in line with Mr. Yannacone's question; he's speaking to Dr. Hays as the director of the division on the one hand; and I would like to know, for the record at least, whether he's referring specifically to that division, or the department as a whole; or where are we in this line of questioning?

MR. YANNACONE: Well, I thought I established in the beginning—and if I'm wrong, Dr. Hays, you correct me right now so we don't foul up the record—I thought I established that U.S.D.A., the Department, has sole and exclusive jurisdiction of the registration of economic poisons, and that the division which Dr. Hays heads within the U.S. Department of Agriculture is solely and exclusively responsible for this registration proceeding.

MR. ROBERTSON: Correct.

MR. YANNACONE: Now if that's right, when I ask Dr. Hays about what he is doing with respect to DDT, it's my understanding that he and his department is the only area of U.S.D.A.—

MR. ROBERTSON: Excuse me. He and his division, or he and his department?

MR. YANNACONE: No, I mean division within the department.

MR. ROBERTSON: All right.

MR. YANNACONE: And you understand that now throughout, even if I slip, division and department—I have yet to figure out how the government bureaus are really organized.

**Q. But now, Doctor, you testified on direct examination that among the criteria used by the Product Evaluation Staff are evidence of phytotoxicity and metabolism of the pesticide, and migration of the pesticide, and translocation of the pesticide, and persistence of the pesticide; is that correct?**

A. That's correct.

**Q. Okay. This data then is furnished to you by the applicant, is that correct?**

A. That's correct.

**Q. And it's not checked independently in a scientific analytical sense by your department, is it?**

A. That's correct.

**Q. In other words, Doctor, your department is dependent for data in these registration cases on the applicant's good faith, isn't it?**

A. The Act requires the applicant to submit the data.

**Q. Yes, but your department doesn't independently verify or check this data?**

A. No.

**Q. But you do have a staff of analytical chemists and biologists and what not that do work and just check this data, don't you?**

A. Check only from the point of view of enforcement.

**Q. I see. And the enforcement provisions of the Federal Insecticide, Fungicide, and Rodenticide Act are solely limited to whether or not the product is mislabeled?**

A. That's correct.

**Q. And the label need only contain its proper chemical name and ingredients and contents and weight and a general safety warning?**

A. And directions for use.

**Q. Directions for use. All right.**
**Now what data is generally required for a pesticide such as DDT on the matter of persistence? Soil persistence?**

**Q. I'm talking about these current new registrations. You said since '66 there have been some registrations of specific uses of DDT. What kind of data—**

A. Persistence in soil.

**Q. That's all?**

A. Essentially.

**Q. I don't want to ask you a technical question unless you feel you want to answer it. But if you can tell us, tell us how this soil persistence data is gathered; in other words, what kind of tests do they make; do they just measure the amount of DDT applied, and then the amount in the soil later on?**

A. I would have to leave that detail to the scientists.

**Q. Okay. But the only persistent data you are interested in in the department as far as registration is concerned is soil persistence?**

A. I said mostly in the soil, in general. I'm sure that water is also included.

**Q. Well, persistence in water. Do you have any idea how they measure persistence in water?**

A. I should think—

I'm sure that one could take samples of water at varying times to see how quickly it is either hydrolyzed or is broken down in the presence of water. If it's highly soluble in water, it may persist for some time.

**Q. Okay. Doctor, we are now talking about DDT. Do you know anything about the behavior of DDT in water?**

A. It's very insoluble.

**Q. Then how are you supposed to measure its persistence in water? Do you have any idea of its solubility?**

A. No.

**Q. Would you believe it if I told you that, according to Mr. McLean, who I think is probably accurate, its solubility is something on the order of one part per billion in water? And you know of course, I'm sure, from your toxicological studies that the relative minimal sensitivity, accurate sensitivity in the gas chromatograph is on the one part per billion range. So we are talking about a substance which is soluble in water only at the lower threshold of detectability.**

**Now you don't really measure honestly and accurately persistence in water, do you, for DDT?**

A. Not for DDT.

**Q. All right. Now you indicated that translocation is a consideration?**

A. That's right.

**Q. Now again speaking with reference to general criteria, now what kind of data do you get on translocation of pesticides?**

A. Well, we are I'm sure primarily concerned with the uptake of a pesticide from the soil to the plant and whether it's translocated from the roots into the plant.

**Q. Any other types of translocation?**

A. I don't know.

**Q. All right. And this translocation data would be with reference to the plant on which the pesticide, in this case DDT, is applied?**

A. That's right.

**Q. All right. You are not interested in generally translocation from, in, through, and about plants that might be nontarget plants?**

A. No.

**Q. In fact, most of this information and research is directed towards the target insect and the target plant, is that correct?**

A. That's right.

**Q. In fact, all of it is, isn't it?**

A. Insofar as the use of that particular pesticide is concerned.

**Q. Now, Doctor, there are no studies that you know of submitted with these registration statements on the effects of DDT on phytoplankton, are there?**

A. I'm not in that field at all.

**Q. I think you also indicated that studies are made of the migration of the pesticide, is that correct?**

A. That's right.

**Q. All right. Now again with respect to DDT, what kind of migration studies are we talking about?**

A. Migration in soil. And I think there have been studies in the recent years on the migration of DDT in soil that have been done by a variety of agencies.

**Q. Is that all? . . .**

**Q. The only migration we are interested in—in other words, your department in reviewing the registration of this pesticide is only interested in its migration through soil?**

A. No, I'm sure they are interested in many other things. I wouldn't know particularly just what their scope of interest would be.

EXAMINER VAN SUSTEREN: By "they", you mean the evaluators in your division or the evaluators of the applicant.

WITNESS: The evaluators of the applicant as well as the review scientists.

MR. ROBERTSON: And again, sir, this element of the department and the division.

MR. YANNACONE: Right. His division is what we're talking about.

**Q. In other words then, the evaluators in your division essentially cooperate rather extensively with the applicant in determining criteria for measurement, don't they?**

A. Yes, I would say we work closely together in developing good criteria.

**Q. Good to or for whom, Doctor?**

A. For the—for everyone concerned.

**Q. All right, Doctor. In other words, then the real mission of your department is the greatest good for the greatest number; isn't that so?**

A. Oh, I think that's right, yes.

MR. ROBERTSON: Along those lines, Mr. Examiner, I also would like to inject that as Dr. Hays has testified in his direct testimony, the mission of this particular division within the Department of Agriculture is to see to it that the provisions of this Act are complied with in all cases.

MR. YANNACONE: Okay. That's what I wanted to get on the record.

**Q. Now, Dr. Hays, your mission in your division in your department is to see to it that the Federal Insecticide, Fungicide, and Rodenticide Act is met in all its requirements? Isn't that right?**

**Q. All right. And nowhere in the federal—well, withdrawn. Of your own knowledge of the Federal Insecticide, Fungicide, and Rodenticide Act, can you point to any portion therein where considerations are given to, for or about fish and wildlife? . . .**

EXAMINER VAN SUSTEREN: Dr. Hays has already stated on direct that there is an interdepartmental agreement between Agriculture, Interior, and Health, Education and Welfare.

MR. YANNACONE: I'm aware of the agreement, Mr. Examiner, but I want the statutory provision in from this witness that governs his department. . . .

MR. ROBERTSON: Well, can I—

One of the provisions in the statutes is that a product will be misbranded "if the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public;"

At this point I would inject that this term "public" has always been considered to mean man, all of his beneficial animals, his wildlife, his livestock, and so forth. . . .

MR. ROBERTSON: Now the second provision deals with the warning or caution statement. A product would be misbranded: "if the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals;" . . .

MR. YANNACONE: Now we are referring to subdivisions (c) and (d) of subsection z.—

MR. ROBERTSON: Two.

MR. YANNACONE: Of 7 United States Code, Section 135, general section 2 entitled commonly the Federal Insecticide, Fungicide, and Rodenticide Act.

EXAMINATION BY MR. YANNACONE

**Q. And now, Doctor, you are aware of those two provisions?**

A. Yes.

**Q. Can you tell us now whether or not any new data has been required by your division for DDT since 1966?**

A. Not to my knowledge.

**Q. Doctor, you are aware that there is now some evidence that there is injury to vertebrate animals and useful invertebrates attributable to DDT and its metabolites?**

A. Yes.

**Q. You are aware, are you not, Doctor, that there is at present some evidence that a great many of the world's in general and the United States' in particular ecosystems are contaminated with DDT and its metabolites; are you not?**

A. Yes.

**Q. You are aware that DDT is still recommended for use by the Department of Agriculture; are you not? . . .**

A. If there are, there are certainly only very limited uses.

**Q. Some of these are outdoor uses, are they not?**

A. I'm immediately familiar with what is in the recommendation of the department.

**Q. But the pesticide is still registered and still may be sold with the label that was on it prior to 1966, is that right?**

A. That's correct.

**Q. Now, Doctor, is there a procedure available to you or your division upon receipt of evidence that a particular registered compound may be causing some damage, significant damage to vertebrate animals and useful invertebrates; is there any procedure for your department, your division of the Department of Agriculture to take some action?**

A. The division could well receive such data if it were available and presented to the division. . . .

EXAMINER VAN SUSTEREN: The division could receive such data and what?

WITNESS: For review.

EXAMINATION BY MR. YANNACONE

**Q. All right. You have received such data, have you not?**

A. Formally? No.

**Q. You have not received such data formally?**

A. For review. . . .

EXAMINATION BY MR. YANNACONE

**Q. Okay. Tell us how you get that data to the U.S.D.A. formally and we will get it to you.**

MR. STAFFORD: I object to the form of the question.

MR. YANNACONE: I will withdraw the question.

**Q. Doctor, tell us what your department considers a formal request for review?**

A. We, as I said, have reviewed data wherever it may be found for our daily responsibilities of the registration of pesticides.

Now in regard to DDT, we have received no specific request to review any data gathered by anyone for our evaluation.

**Q. Now would you please answer the question, Doctor? What is a formal request for review? How do you make a formal request for review?**

A. Well, I don't know there is any formal procedure, Mr. Yannacone. But it would seem to me that if anyone wished to submit any data relevant to the effects of DDT, it can be done by simply sending it to the division for review and evaluation.

**Q. All right, Doctor. I don't mean to be nasty. But you just told us your department has not received a formal request for review. Yet you said just before that you have knowledge of Dr. Stickel's data, Dr. Macek's data, both of which from competent federal government agencies, plus the fact that you know about Dr. Welch's and Dr. Risebrough's data. What is necessary to make a formal request for review? Isn't that enough? Isn't that enough to raise a question in your mind, Doctor?**

EXAMINER VAN SUSTEREN: Now just a moment, Mr. Yannacone.

MR. STAFFORD: I object.

EXAMINER VAN SUSTEREN: The examiner has spent all of his, almost all of his adult life in the state bureaucracy. And some of the material and information that is submitted to the various departments of this state in his opinion is nonsense. It would seem that perhaps what Dr. Hays is talking about, that if it comes from what appears to be a responsible source on a subject of some importance with some data that appears to have some significance or validity on its face—I presume that that is the type of situation that Dr. Hays is referring to.

MR. YANNACONE: Mr. Examiner, you—

EXAMINER VAN SUSTEREN: Am I correct, Doctor?

WITNESS: That's correct.

MR. YANNACONE: Mr. Examiner, you have apparently survived your years with the state bureaucracy with some measure of talent, competency and public spirit left. What I'm trying to establish now very simply—and I ask the question again:

**Q. What constitutes a formal request or a request for review that you would consider formally made to your department?**

MR. ROBERTSON: Mr. Examiner, I would like to know what Mr. Yannacone means by a formal request for review.

MR. YANNACONE: He said he received no—this witness stated that he received no formal request for review of any of this so-called new data since 1966 with respect to DDT. I asked him, since he's already testified, he has knowledge of this data, personal knowledge, much less certainly at the lower levels of his department has knowledge, but he's got personal knowledge; I would like to know for the record and for our own personal information so we can see to it that a formal request is made, what constitutes a formal request. . . .

MR. YANNACONE: And he just testified there is no such thing, there is no such procedure.

You can't have your cake and eat it too, Counselor.

EXAMINER VAN SUSTEREN: The examiner would ask the witness some questions.

Is there anything in the Act, Dr. Hays, any specific legal permission for your department to establish a procedure, or does the Act itself establish a procedure for review and evaluation of a license or registration that has been legally granted to an applicant?

WITNESS: As I recall, your Honor, only under the provisions of the enforcement where there may be action taken on the part of the secretary for cancellation wherein then the applicant has the right to request either a hearing or an advisory committee or to make such corrections as may be necessary as it applies to that particular product. So that in this instance then there is a provision to submit evidence in support of any complaint on the part of the registrant.

MR. ROBERTSON: It appears in section 4.c. of the Act—that would

be 7 U.S. Code, 135 b. The whole section deals with registration, but the pertinent parts here would deal with the cancellation. I will read the whole sentence. It goes as follows: "Whenever the Secretary refuses registration of an economic poison or determines that registration of an economic poison should be cancelled, he shall notify the applicant for registration or the registrant of his action and the reasons therefor."

So there is a specific authority in the statutes for the secretary to initiate a formal cancellation.

EXAMINER VAN SUSTEREN: Is there any requirement so far as giving the applicant a hearing whereby he can defend his product?

MR. ROBERTSON: Right. The statute goes on to state that: "A cancellation . . . shall be effective thirty days after service of the foregoing notice unless within such time the registrant (1) makes the necessary corrections; (2) files a petition requesting that the matter be referred to an advisory committee; or (3) files objections and requests a public hearing."

And the section goes on through to specify the procedures by which this is carried out.

EXAMINER VAN SUSTEREN: Is there any provision in the Act which permits the department to act on its own motion in this respect for revocation, cancellation, and so on?

MR. ROBERTSON: The way the statute is phrased, it is only the secretary, in accordance with the procedures specified in the Act, that can initiate the cancellation of registration. The secretary granted the registration, and pursuant to the procedures can initiate procedures to cancel that registration.

EXAMINER VAN SUSTEREN: And the initiation then would have to be made by a formal request on the secretary. Is that your interpretation of the Act?

MR. ROBERTSON: Right. The secretary, or Dr. Hays through his division.

MR. ROBERTSON: Such a formal request perhaps as Mr. Yannacone has been referring to I think would properly be addressed to the secretary.

MR. YANNACONE: And this is basically the procedure under the Federal Insecticide, Fungicide, and Rodenticide Act for cancellation?

MR. ROBERTSON: That's the statutory authority, yes.

MR. YANNACONE: Okay.

EXAMINATION BY MR. YANNACONE:

**Q. To your knowledge, Dr. Hays—or if Mr. Roberts can fill it in—is there any other procedure for the deregistration or cancellation or suspension of a registration that you know of?**

A. I don't know of any other procedure.

**Q. Okay. Now, Doctor, were you with the department on December 6, 1967?**

A. Yes.

**Q. And did you in the course of your regular activities ever have occasion to become advised of a pending lawsuit in the United States District Court for the Southern District of New York entitled: The Environmental Defense Fund Individually and on Behalf of All Those Entitled to Full Benefits, Use and Enjoyment of the Natural Resource, that is, the Lake Michigan Regional Ecosystem, and All Other Similarly Situated Plaintiffs Against Orvil W. Freeman, Secretary of Agriculture, United States Department of Agriculture, Defendant?**

A. I am aware of that.

**Q. You are aware of that lawsuit?**

A. Yes.

**Q. And do you know what the disposition in January of that lawsuit was?**

A. I can't state it precisely, no.

**Q. Do you know what the subject matter of that lawsuit was?**

A. No.

MR. YANNACONE: Since I was the attorney of record for the plaintiffs, I will state for the record that the subject matter of that lawsuit was a demand for cancellation—

MR. STAFFORD: I object to this, your Honor, self-serving statement, no relevancy to this proceeding.

MR. YANNACONE: Withdrawn.

**Q. Doctor, assume that the subject matter of that lawsuit was a demand for the cancellation of the registration of DDT for**

**Dutch Elm disease control together with such other and further relief as the court might deem just and proper under the circumstances; and assume further that the attorney's, U.S. attorney's solicitor for the Secretary of Agriculture defended that action, not by answer, but by motion to dismiss for failure to state a cause of action, asserting that the Secretary of Agriculture was not subject to the jurisdiction of the United States District Court in an action of this type unless statutorily so made subject, and indicating that there was no such statutory authority and that there was no procedure for the initiation of a procedure outside the Department of Agriculture for the cancellation of the registration of an economic poison having been duly registered under the Federal Insecticide, Fungicide, and Rodenticide Act; assuming that, Doctor, can you point out to me, the people, this hearing examiner, any procedure you know of for compelling a review and a cancellation or suspension of the registration of DDT on the grounds that there is scientific evidence that it does indeed cause injury to vertebrate animals and useful invertebrate animals?**

MR. STAFFORD: Object to the form of the question. Same objection. Calls for a conclusion of law.

EXAMINER VAN SUSTEREN: It's asking for a legal conclusion of the witness.

**Q. Making the same assumptions of fact, Dr. Hays, is there to your knowledge within the jurisdiction of the division that you head any procedure whereby an independent outside request for review of the registration of DDT can be initiated?**

MR. STAFFORD: I object for the same reason stated; and the further objection that the assumptions made by Counsel are not in evidence and record in this proceeding. We do not concede that they are accurate and correct as stated by Counsel; to supplement my objection.

MR. YANNACONE: Would you like me to read the pleadings?

EXAMINER VAN SUSTEREN: The examiner will instruct the witness he can disregard the assumptions. But I'm sure that the question propounded by Mr. Yannacone can stand by itself.

EXAMINER VAN SUSTEREN: And, Dr. Hays, do you know of any procedure then for reevaluation specifically by either department rule, which would have the force of law, or policy requirements as handed down by the secretary, or procedures that your

division has initiated and promulgated, or anything of that nature, any procedure whatsoever? And that was the extent of Mr. Yannacone's question.

MR. STAFFORD: Your Honor, may I supplement by saying: Other than the procedures this witness has already testified to: 4.c.

EXAMINER VAN SUSTEREN: Mr. Robertson has already pointed out what the Act says, and that formal procedures are instituted by a direct and formal request of the secretary. But I'm sure Dr. Hays can explain if there are other ancillary procedures or procedures established by the department to implement the procedure as outlined in the statute.

MR. STAFFORD: That's all I was requiring.

WITNESS: There is no other procedure other than that which is in the statute.

EXAMINATION BY MR. YANNACONE:

**Q. No other procedure than set forth in 7 U.S. Code, Section 135 b, Section 4, Subsection c. thereof, is that correct?**

A. That's correct.

**Q. Doctor, exhibit 115, the agreement published in the code of the Federal Register setting forth a memorandum of understanding between the Secretary of Agriculture; Health, Education and Welfare; and Interior on the safe use of pesticides, does this agreement have any binding effect on the operations of your division?**

MR. STAFFORD: Objection. Conclusion of law.

EXAMINER VAN SUSTEREN: The objection is sustained.

MR. YANNACONE: All right, I will rephrase the question.

**Q. Doctor, in your operation as chief of your division within the Department of Agriculture, do you observe specifically in your activities any regulations which might be set forth in this memorandum which you introduced as exhibit No. 115? . . .**

**Q. Yes, what I'm interested in finding out is: Does your division within the Department of Agricuture have anything to do with anything that might be set forth in that memorandum of understanding? If so, tell us what it is?**

A. Well, this is a memorandum of understanding in terms of review of the applicant's product in terms of the label and data for review and consultation with the other agencies.

**Q. I see. Okay. It's a review and consultation understanding?**

A. Yes.

**Q. Now you are familiar with it?**

A. Yes.

**Q. With exhibit No. 115, memorandum of understanding between the three secretaries on the safe use of pesticides.**

A. Yes.

**Q. And in the regular course of your activities in the regular course of business of your division within the Department of Agriculture what specific activities do you undertake to: ". . . keep each of the other departments . . ."—being Interior, and Health, Education and Welfare—" . . . fully informed of developments in knowledge on this subject . . ."—the subject of pesticides—". . . from research or other sources which may come into its possession."?**

A. We exchange information that we have on any work that may be done that relates to registration of pesticides.

**Q. I see. Have you exchanged information with Interior and Health, Education and Welfare on DDT?**

A. I wouldn't know whether information has been sent back and forth or not. This would have been done by the scientists within each of the sections.

**Q. All right. Can you, when you get back to Washington, produce for the record here the information on DDT which may have been furnished by your department pursuant to subdivision one of this agreement to the other two departments; could you furnish us with copies for the record?**

MR. STAFFORD: Your Honor, I object to this request unless it's established that it's, first, relevant. Proper demand has been made. There are subpeona powers in the statutes which can be utilized by Counsel to prove his own case, if he has a case.

MR. YANNACONE: I will withdraw the demand right now.

**Q. Dr. Hays, do you know whether or not your department is subject to a subpoena duces tecum issued by this agency?**

MR. STAFFORD: Objected to as a conclusion of law, clearly outside the competence of this witness.

EXAMINER VAN SUSTEREN: And it's sustained.

MR. YANNACONE: All right.

EXAMINER VAN SUSTEREN: Counsel, I'm sure you will recognize that in the lower echelons of every bureaucracy there is an exchange of information and data which can be rough unevaluated, and may in some way or another express some of the opinions and conclusions of the persons in those lower echelons which might subject them to disciplinary measures of the department or even bring themselves or make themselves susceptible to damage suits for some of the statements contained therein. And so if you were going to make a statement of Dr. Hays, you would have to make it more specific.

EXAMINER VAN SUSTEREN: And the objection is sustained so far as asking him as to subpoena power. But if you were to—

MR. YANNACONE: I'm going down by the numbers, and item by item.

**Q. First, can you make available to this hearing the registration statements for DDT since the first registration was filed back, I think, in '64?**

EXAMINER VAN SUSTEREN: And Dr. Hays would not be in a position to make any decisions of a legal nature in that regard as to what can be submitted or what cannot be submitted; and that question would have to be directed to Mr. Robertson.

MR. YANNACONES Then I will ask Counsel—

MR. ROBERTSON: In that connection the statute also has specific provisions in there with respect to disclosure of confidential information.

MR. YANNACONE: Would you put the disclosure in the statutes into the record?

EXAMINER VAN SUSTEREN: Oh, the examiner merely stated that you would have the right to ask Mr. Robertson if he would be willing to explore this type of activity and see what could be submitted. But this type of statement or this type of request to a witness is improper. And the examiner so ruled.

MR. YANNACONE: The basis for that question is to determine for the record now whether or not Dr. Hays, who is the director of

the division in charge of pesticide registration, has in the regular course of his business as such a director and such administrator, the care, custody, and control of these registration statements; and secondly, whether or not these are deemed confidential and not subject to public disclosure within the meaning of that Act. I submit that this witnes as chief of that division is the man—and I will ask the questions, and by the number order, so as to obviate any necessity for Mr. Stafford to make general objections; first as to care, custody and control, and we will find out if they're business records; then we will find out if they're confidential; then I will make a formal demand on Mr. Robertson.

EXAMINER VAN SUSTEREN: No, the examiner has already ruled if you wish to make a request, the request would have to be made to Mr. Robertson. Mr. Robertson is representing the United States Department of Agriculture here today, and not Dr. Hays.

MR. YANNACONE: All right, then I intend to call Mr. Robertson as a witness.

EXAMINER VAN SUSTEREN: We can face that bridge when we come to it. But if you have any request for any information from the Department of Agriculture, the examiner has ruled that that request would have to go to Mr. Robertson. He's representing the Department of Agriculture here today and is its attorney, not Dr. Hays.

MR. YANNACONE: All right, I will not make the request for information from Dr. Hays. I will now put the material on the record.

**Q. Dr. Hays, in the regular course of your work for the United States Department of Agriculture as chief of the division that you are director of, do you have care, custody and/or control of the actual filed documents, the registration applications?**

MR. STAFFORD: Haven't we had a ruling on this line of questioning?

MR. YANNACONE: I'm asking him whether or not he's got them. They cannot be found. They have been denied to us; they have been denied to Senator Nelson. Now somebody is here from the U.S.D.A.; let's find out who's got the papers.

MR. STAFFORD: I ask that the record—that your Honor direct that

that statement of Counsel, this gratuitous statement be stricken from the record and expunged from this proceeding.

EXAMINER VAN SUSTEREN: It may stand. But the examiner has already ruled, Mr. Yannacone, that the request will need to go to Mr. Robertson; he represents the department here today; and as to—

MR. YANNACONE: What is Dr. Hays?

EXAMINER VAN SUSTEREN: No, Dr. Hays does not represent the United States Department of Agriculture here today; it is represented by an attorney.

Mr. Yannacone, are you going to tell me that your various witnesses, or former witnesses here represent the Environmental Defense Fund; or do you?

MR. YANNACONE: No, but I'm not asking him to make a legal decision, I'm asking for information as to his regular care and custody to find out if these are business records. That's all.

MR. STAFFORD: There has been a ruling, has there not, your Honor?

EXAMINER VAN SUSTEREN: You may submit your request to Mr. Robertson.

MR. YANNACONE: All right.

**Q. Dr. Hays, did you in the course of your regular professional activities—ever do any research work on DDT or its metabolites?**

A. No.

MR. ROBERTSON: On that question, Mr. Examiner, I'd like to ask Mr. Yannacone, does he mean Dr. Hays personally, or does he mean the division or the department?

MR. YANNACONE: I'm asking Dr. Hays personally first.

MR. ROBERTSON: All right.

**Q. Now, Doctor, since 1966 have you ever had occasion to examine any of the data or information prepared by any of the departments under your control, such as the Product Evaluation Staff or the Safety Evaluation Staff or the New Chemicals Evaluation Staff, with respect to DDT registration applications?**

A. I have not personally reviewed—

**Q. Who in your department, if you know, has?**

A. I stated before, your Honor, that the scientists within each of the sections are responsible for the review of the data in support of the registration.

**Q. All right. Dr. Hays, are you the head of this division?**

A. Yes.

**Q. Who do you report to at the next higher level?**

A. I report to the Deputy Administrator.

**Q. Of?**

A. Agriculture and Research Service.

**Q. What is his name?**

A. Dr. Frank Mulhern.

**Q. And do you report to anyone else?**

A. Not directly.

**Q. Who reports to you in your division? Directly?**

A. The assistant directors.

**Q. How many are there; what are their names?**

A. Two. The assistant director for registration, Mr. Harold Alford; assistant director for enforcement, Mr. Lowell Miller.

**Q. Anyone else?**

A. No.

**Q. Have either of these two men ever reported to you on DDT or its metabolites?**

A. They may have discussed some registration. I would not know which—what in particular.

**Q. Is it in the regular course of your activities as director of this division a practice to require written reports from either of these two assistants?**

A. No.

**Q. I see.**

**In other words, then, you conduct all your business with your two associates by conference and by verbal communication?**

A. That's correct.

**Q. Whenever possible, you don't put anything in writing, do you?**

MR. ROBERTSON: Objection.

MR. STAFFORD: Objection.

MR. YANNACONE: I will withdraw the question.

**Q. Do you put any directives in writing to either of those two assistants?**

A. Yes.

**Q. Okay. What kind of directives, Doctor?**

A. They are directives that have to do with division activities.

**Q. Such as?**

A. Procedures.

**Q. Such as procedures for registration, or consideration of registrations?**

A. Procedures largely in the conduct of our daily affairs.

**Q. Which include registrations?**

A. It may.

**Q. What do you mean, "it may", Doctor? Does it or does it not?**

EXAMINER VAN SUSTEREN: Just a moment, Counsel. First of all, perhaps we are all assuming something here that we are wrongly assuming—

MR. YANNACONE: That the witness knows anything?

MR. ROBERTSON: Mr. Examiner—

MR. STAFFORD: I object.

MR. YANNACONE: I will withdraw the comment.

EXAMINER VAN SUSTEREN: It's not only going to be withdrawn, but I think you owe the witness an apology.

MR. YANNACONE: I will owe the witness an apology when I see that he does know something.

EXAMINER VAN SUSTEREN: I feel that a remark like that addressed to Dr. Hays in this type situation is reprehensible.

MR. YANNACONE: All right. I will apologize for the dignity of the court and the dignity of the profession.

I'm sorry, Dr. Hays.

EXAMINER VAN SUSTEREN: Perhaps we are erroneously assuming that you are aware of some of the intricacies of bureaucracy. But sometimes there are two different lines of authority in an agency. There may be administrative authority and there might be what you might call professional or line authority.

MR. YANNACONE: Okay, let's find out.

EXAMINER VAN SUSTEREN: And perhaps—
I don't know how the Department of Agriculture is set up, but I do know how certain other agencies are set up.

MR. YANNACONE: All right. It can't be set up as badly as some.

**Q. But, Doctor, are you responsible for the—withdrawn.**
**Is there a division of functions within your department between professional activities, which involves scientific evaluation of the pesticide, and non-professional administrative and clerical activities?**

A. Yes.

**Q. Now are you responsible for both of those divisions of function?**

A. As head of the division, yes.

**Q. Now who is directly on a day to day basis responsible for the professional activities or the scientific activities?**

A. This, as I have stated, your Honor, are the chief staff officers of each of the sections.

**Q. All right. Would you name the section and its chief staff officer, for the record?**

A. Well, we have the chief staff officer in the insecticide section, Mr. Billings; Dr. Ernest Walker, chief staff officer for herbicides; Dr. L. S. Stuart, chief staff officer in bacteriology; Mr. Ed Carter, chief staff officer for plant pathology. These are the section heads.

**Q. Now these gentlemen are all scientists responsible for scientific activities, is that correct?**

A. That's correct.

**Q. Now who do these chiefs report to? Directly?**

A. For registration?

**Q. Yes?**

A. To the assistant director for registration.

**Q. And that man reports directly to you?**

A. Yes.

**Q. Now do these section chiefs make their reports to your assistant in writing, if you know?**

A. I don't know, your Honor, what Mr. Yannacone means by reports, because—

**Q. Okay. I will pare it down.**
**Do you have any prior experience with the U.S.D.A., the division you are now chief of, prior to 1966?**

A. No.

**Q. Okay. Since 1966, Doctor—and from now on you can preface everything with that—since 1966 have any reports been made in writing from these section chiefs to your assistant in charge of registration with respect to DDT registrations?**

A. I wouldn't know precisely if there had been specific reports that would necessarily have come to my attention.

**Q. Do you ever confer directly with these section chiefs?**

A. We have our chief staff—or, a staff meeting.

**Q. How often.**

A. Usually once a month.

**Q. Since 1966 have you at these meetings ever discussed the registration of DDT?**

A. That I couldn't remember, whether we have or not.

**Q. Have you ever, since you took over, in the course of your regular activities as chief of this division issued orders or memoranda to any of these section chiefs directly or through your assistant in charge of registration?**

A. I'm not sure I understand your question.

**Q. All right, I will rephrase the question.**
**Doctor, since you took over as chief, have you communicated directly, or indirectly through your assistant in charge of registration to these section chiefs, professional section chiefs with respect to the registration of pesticides?**

A. Yes.

**Q. Have these communications been in writing or verbally?**

A. Some have been in writing.

**Q. Have any of these communications involved registration procedures applicable to the registration of DDT?**

A. I couldn't answer that.

**Q. Doctor, when did you first know you were coming here to testify?**

MR. STAFFORD: Object to that as irrelevant, your Honor. What does it matter when he first knew?

EXAMINER VAN SUSTEREN: What's the—

**Q. Doctor, did you prepare an outline of your direct testimony before you testified here today?**

A. I—

MR. STAFFORD: Object to that, your Honor.

MR. YANNACONE: I want to find out what he does know, if anything.

MR. STAFFORD: Also on the basis of relevance.

MR. YANNACONE: He testified now "I don't know," "I don't know" about the day to day operations of his department—

MR. ROBERTSON: Mr. Examiner, he has on his direct testimony explained his function as director of that division and what function that division performs.

EXAMINER VAN SUSTEREN: And if he doesn't know what two little people down in some section are doing—

MR. YANNACONE: These are the next level.

MR. STAFFORD: I would like to hear what the examiner has to say. Including who?

EXAMINER VAN SUSTEREN: I say, if you are asking Dr. Hays if he knows what is going on down at the staff level, of an incident or a specific point or a specific paper or anything of any specificity, that might be all right; but you are asking Dr. Hays a lot of questions that would seem to ask him for a direct knowledge of something that's going on down at various levels.

MR. YANNACONE: I'm now dealing—and I hope I made myself clear. We have Dr. Hays as the head of the department, we have two assistants, one of whom is completely in charge of registration. Is that correct?

WITNESS: Yes.

MR. YANNACONE: Under that chief of registrations we have a group of staff level scientists who are chiefs of their individual subsections.

Now Dr. Hays has testified that all scientific evaluations are done at that staff chief level which is separated from Dr. Hays only by his assistant for registration.

By the way, you are all in the same building, aren't you?

Now all I'm trying to find out is whether or not there's any flow of information or communication or regulation or rule or internal policy that might be applicable to the registration or have any bearing on the registration of DDT that flows, not from the bottom up where Dr. Hays might not understand or know or might have been stopped at his assistant's level; but from Dr. Hays down. That's the question I have asked. Has he made any recommendations orally or in writing with reference to—that might be applicable to the registrations of DDT as they come in from his office either directly to these section chiefs or through his administrative assistants to these section chiefs. That's all I'd like to know.

EXAMINER VAN SUSTEREN: Can you answer the question?

WITNESS: No, I don't really; no, I can't remember the details of every little memorandum; I do not know of any—

EXAMINER VAN SUSTEREN: That's not the question. He merely asked you if this was the hierarchy and this was the work flow pattern within your division.

WITNESS: Yes, that's correct.

**Q. Now to your knowledge since 1966 have there been any changes in the criteria for registration of pesticides, in particular DDT?**

MR. STAFFORD: Objected to as a conclusion of law.

MR. YANNACONE: I don't want a legal conclusion, I want his policy conclusion.

MR. STAFFORD: Very well, I have no objection then.

EXAMINER VAN SUSTEREN: Very well. I was going to overrule the objection anyway.

Can you answer the question? Have there been any changes?

WITNESS: Your Honor, I think there has been only one change that

was recommended by the chief staff officer for the limitation of the use of DDT for cockroaches.

**Q. All right. That's the only change?**

A. As far as I know.

**Q. What staff officer made that recommendation?**

A. Mr. Billings.

**Q. And he's chief officer of what division?**

A. Entomology.

**Q. And when he made that recommendation, how did that become enforceable?**

**That is enforceable now by your enforcement section, isn't it?**

A. This would not have required an enforcement action, but rather a registration action.

**Q. Would you tell us, please, so we get the record a little bit clearer, what do you mean by registration action?**

A. There are times when there needs to be a modification in the directions for use. And where in this instance there was some evidence to indicate the resistance on the part of the cockroaches to the actions of DDT, it seemed that there was no longer any need for this particular use; and therefore the entomology chief staff officer instructed his staff that in the future these uses would be phased out in the case of cockroaches.