Hearing: EPA Pesticide Regulatory Program Study

Before the Subcommittee on Department Operations, Research, and Foreign Agriculture of the Committee on Agriculture

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[1] Resigned from House of Representatives Aug. 25, 1982.
[2] Resigned from committee Oct. 7, 1981.
[3] Elected to committee Dec. 16, 1981.

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Mr. WAMPLER. Mr. Chairman, I was wondering, have we had any indication from EPA as to their reaction to the study, or have they had an opportunity to review it, to make any comments on it?

Mr. BROWN. I will ask Dr. Benbrook to give a brief explanation of the procedures and the degree to which that has occurred, but I will merely comment that the report was reviewed by Dr. Benbrook with the Agency. They have had opportunities to comment on it, and I suspect that they have to some degree the same sensitivity about the contents of the report that other people have. I will ask Dr. Benbrook to comment on that point.

REMARKS OF CHARLES M. BENBROOK, SUBCOMMITTEE STAFF DIRECTOR

Mr. BENBROOK. When the first draft of the report was circulated early in December, the Agency received it at about the same time that the subcommittee did. Subsequent to their review of it, you received a call from Dr. Todhunter, as you may remember, and met with him. In addition, I met several times with Agency officials to go over the specific points in the report which the Agency felt were not adequately developed or balanced, and also the Agency provided more up-to-date material on several of the issues addressed. The majority of the report tries to present factual and descriptive material about the program.

In addition, when the second draft now before the members was completed, it was provided to the Agency although we have not yet received any formal comments in writing from them.

However, I have had several conversations with officials in the program with regard to various aspects of it, some favorable, some not favorable.

In addition, the Agency has answered your letter of September 13, 1982, containing several questions on the policy and scientific issues addressed in the report. The Agency's response, Mr. Brown, spans 39 pages. It was received just 2 days ago. It would be included in this draft, had it been received earlier.

The intention is to include the Agency's response to your questions throughout the text where the topics are discussed. They separate nicely into the same topics addressed by the balance of the report, so the Agency's views have been expressed in great detail in this letter which has been made available to the members of the subcommittee.

Mr. BROWN. Do you think it appropriate to include that letter in the hearing record?

Mr. BENBROOK. Yes, sir, I do.

Mr. BROWN. Without objection, the letter will be made a part of the record.

[The letter appears at the conclusion of the hearing.]

Mr. BROWN. I may say I have talked to Dr. Todhunter several times. He has been most cooperative, and occasionally when he expressed some questions about whether or not it was my intention or the staff's intention to do something flamboyant with this, such as issuing it with an appropriate press release or something, I assured him that we would not release this to the press, and explained that it had only the status of a draft document, and that at

such time as it represented the views of the committee, the committee would decide what appropriate action to take.

Mr. PANETTA. Mr. Chairman.

Mr. BROWN. Mr. Panetta.

Mr. PANETTA. Mr. Chairman, could I ask what are the intentions of the Chair as far as publication of the report?

Mr. BROWN. It is the intention of the Chair to proceed in the normal course of handling this as it would any other investigative report.

You asked me what that means in terms of printing. I don't know. I assume that there are certain rules and regulations with regard to the handling of investigative reports. It was not my intention to make any special effort at this point because it is only a draft, and I did not think that it would be useful to, for example, order 10,000 copies or something of that sort, but, whatever the rules provide, and I assume that I and the chairman of the full committee will discuss that matter.

I announced earlier that it is my intention, if I continue as chairman of this subcommittee, to conduct a full hearing on the report early in the next session, and on the basis of that full hearing we will make further decisions as to any action of whatever type the subcommittee should take.

Mr. PANETTA. My only concern is that the report, if it finds its way out into the public sector in some way, is not indicative of the fact that it is a committee report, and that members support all of its conclusions.

While the report itself may be very good, and may be an excellent base upon which we can conduct hearings in the future, I don't feel as an individual Member that I have had sufficient input into the material that is contained herein to in any way have it represent my views. That is the only concern I have. Whatever we are working on here, it ought to be made very clear that this is only staff investigative work, and not the work of the subcommittee in terms of a final report.

Mr. BROWN. I don't know of any committee of the Congress, Mr. Panetta, that doesn't depend upon staff investigative reports for its action or actions, and this will be clearly labeled staff investigative report.

Mr. THOMAS. Mr. Chairman, I do not fully understand the workings of this subcommittee historically or other subcommittees of the Congress. It has been my experience in the past, however, that at least on the basis of the general direction and a specific overall charge that the members of the subcommittee have an opportunity to initially determine the direction of an investigation. I certainly stand to be corrected. It does bother me that I am presented with a finished product that I am asked to either accept or reject or on which I can at most make some minor corrections without ever having approved the general thrust or direction of that investigation in the first place.

Mr. BROWN. Mr. Thomas, I don't want to become pedantic or sardonic or anything of that sort, but it is the prerogative of the chairman of this subcommittee to initiate an investigation. All the members were notified by letter.

At any point, if they wished to cancel it, they probably could have done so at a meeting of the subcommittee, but it would have been very unwise of them to do so, and we have followed meticulously the provisions of the rules.

You are not being asked to approve, disapprove or even comment on this report today if you don't feel like it. You have 10 days to do so, to comment.

As far as approval or disapproval, that will be handled in the normal way of any subcommittee at the appropriate time.

Mr. THOMAS. Thank you, Mr. Chairman.

On the basis of the comment then, although Mr. Benbrook indicated that the Environmental Protection Agency had made comments in written and verbal form, if there is anyone here from the Agency who wants to make some comments at this time, I think that would be appropriate if the chairman will so allow.

Mr. BROWN. The chairman will allow first the staff director to make a very brief review; then the Agency, if they wish; the minority, if they wish; or anyone else, if they wish, because we intend to pursue the processes of democracy to their ultimate ludicrousness.

Mr. Benbrook.

Mr. BENBROOK. Mr. Chairman, the report that has been in evolution since last June and has been circulated to the members early this month is now in actually a third draft. The report addresses three major issues. It tries to lay out the statutory and administrative authorities under which the Agency operates the pesticide regulatory program. The first three chapters are largely descriptive in nature.

Mr. THOMAS. Excuse me. The third draft is the one we have before us?

Mr. BENBROOK. Yes, sir.

Mr. THOMAS. Including?

Mr. BENBROOK. The memorandum that is before you contains about 22 pages, which are to be substituted into the draft circulated on Tuesday, which will make that draft current.

Mr. THOMAS. This portion with the one that you sent us would be labeled the third draft?

Mr. BENBROOK. Yes; it could be.

Mr. HOGAN. Excuse me, Mr. Chairman, could I be heard a moment?

In the table of contents there is indicated an appendix. I just received my copy of this today, but I do not have a copy of the appendix nor do I believe a copy of the appendix has been provided to any of the minority members or the minority staff members, but I am told that it is an appendix of substantial length. I wonder if Mr. Benbrook could cover that.

Mr. BENBROOK. I will cover that when I get through the report.

The first three chapters deal largely with the statutory authority under which EPA operates the pesticide program. The organization of the Office of Pesticide Programs is described, as are the various types of registrations and processes that pesticides are registered under. The report also explains the various processes through which pesticides are reviewed, including the registration standards program, the data call-in program, and the RPAR program.

The next three chapters of the report deal largely with the scientific procedures and concepts which enter into the regulation of pesticides. The fourth chapter deals with the tolerance system, and again is largely descriptive with respect to how the Agency establishes tolerances and evaluates tolerances and the authorities under which they carry out that task.

The fifth chapter describes the pesticide data base and how EPA manages the safety and health data that we dealt with at such great length during our legislative hearings. The chapter contains information on the extent of the data base, what it covers, its vintage, and also sections describing some of the issues and problems that come about as the Agency tries to evaluate what that data shows. The chapter discusses both the adequacy of the Agency's reviews, as well as the material that is originally submitted. The last section of the chapter discusses at some length the laboratory audit program, and includes another letter that the Agency recently sent to Chairman Brown in response to some questions included in his June 28 letter to the Agency.

The sixth chapter is on the scientific principles and concepts the Agency employs in evaluating the oncogenicity of pesticides. The first 30 or so pages of that chapter again is largely descriptive in that it lays out the statutory authority and the administrative rules which govern how the Agency evaluates and then establishes regulatory actions on the basis of a pesticide's oncogenicity, and then goes through and quotes very extensively from various international scientific groups and other scientific experts about some of the scientific issues that come into play when trying to evaluate a pesticide's oncogenicity. The last two sections of that chapter address some emerging efforts in this administration to develop a new cancer policy as well as some of the decisions and actions taken in the Office of Pesticide Programs.

The seventh chapter deals largely with information and program coordination issues dealing with how the different divisions of the Office of Pesticide Programs interact, and the critical role of information management in the overall efficiency of the program.

The eighth chapter discusses the changes in budgets that have occurred in the last few years, and tries to document the level of resources available to the program in contrast to the number of accomplishments that OPP has been able to complete. It also discusses several of the regulatory reform initiatives that have been undertaken, many of which are now complete, and briefly explains how they have impacted the program.

The ninth chapter is a very short conclusions chapter, which tries to draw out and describe themes that are common to several of the chapters.

The appendix which Mr. Hogan referred to contains several excerpts from the statute, from the Code of Federal Regulations, laying out the detailed regulations pertaining to the program. Also included are several standard operating procedures which are documents guiding how the Agency implements the statute in processing applications, and several memoranda and papers done by the Agency. This material is descriptive in nature, and has generally been prepared either for other congressional oversight activities, for the GAO, for other scientific meetings. These items explain in

more detail the Agency's procedures and criteria for carrying out regulatory actions and reaching scientific decisions described elsewhere in the report.

Most of the material in the appendix is referenced specifically in the text. In the report there is often a paragraph or a page excerpted out of a longer document, and the text will note that the balance of the report or memorandum is included in the appendix.

There was circulated with the earlier draft a table of contents of the appendix, which includes reference to the vast majority of the items that are to be included in it. However, in the last several meetings that I have had with the Agency in discussing the draft, the Agency has suggested that several other items, some of them more recent versions of documents, be included, in the appendix. The exact content of the appendix will not be established in concrete for a few days while the Agency has an opportunity to help make sure that the most up-to-date and appropriate items are included.

Mr. THOMAS. How much do you have in the appendix now excluding that which the EPA may wish to add?

Mr. BENBROOK. About 150 pages.

Mr. THOMAS. So the appendix may well exceed the pagination of the document?

Mr. BENBROOK. Assuming that the EPA letter is counted as part of the report, I don't think so. If one were to count the EPA's 39-page letter, and Mr. Brown's 7-page letter as part of the appendix, then it is quite probable that the appendix would exceed the length of the report.

Mr. PANETTA. Mr. Chairman.

Mr. BROWN. Mr. Panetta.

Mr. PANETTA. Could you in a few brief words summarize the purpose of this report?

Mr. BENBROOK. The purpose of the report is to try to pull together in one document the legislative and administrative material that governs the various registration actions that EPA undertakes.

The report can act as a reference guide in a single document, so if a member is faced with a situation where he needs to evaluate a section 18 emergency exemption or some other registration action, either in the course of dealing with a constituent inquiry or with a potential amendment, the pertinent statute and registrations and other material is together in one place, so one doesn't have to go and find certain Federal Register inserts et cetera. It turned out to be a very time-consuming job, to pull together the major descriptive material.

The second major goal of the report is to try to explain how the Agency deals with uncertain science, and how the Agency reaches regulatory decisions when the scientific knowledge underlying the situation is unavoidably equivocal.

Regulating in the face of uncertainty is an issue that obviously has been discussed at great length and came up in several different ways during the legislative hearings. The investigation attempted to develop and gather information describing how the Agency proceeds in several representative cases where scientific uncertainty commonly exists. The tolerance system and the regulation of oncogenic pesticides emerged as two areas which I think very clearly

demonstrate the type of dilemmas that the Agency occasionally faces when they have to make a regulatory decision which is either yes or no, based on very uncertain science.

Mr. PANETTA. Regarding the first part, this is basically an accumulation of legislative and administrative material?

Mr. BENBROOK. Yes, sir.

Mr. PANETTA. And that is included in the report?

Mr. BENBROOK. Yes, sir.

Mr. PANETTA. Basically background material?

Mr. BENBROOK. Yes.

Mr. PANETTA. On the law?

Mr. THOMAS. Will the gentleman yield on that point?

Mr. PANETTA. Yes.

Mr. THOMAS. How much of that is in the body of the report and how much of that would be in the appendix?

Mr. BENBROOK. The first three chapters fall almost entirely into that category.

The majority of both the tolerance chapter and say the first third of the cancer chapter are also that way, where the first sections, as you see, if you will look at the table of contents, the first subsection in several of the chapters involves statutory basis for the tolerance system.

Mr. THOMAS. But you mentioned that in the text often there was simply a paragraph?

Mr. BENBROOK. Right.

Mr. THOMAS. Or a notation with reference to the appendix.

Mr. BENBROOK. Right, and then in the appendix the full part from the Code of Federal Regulations, where the paragraphs were drawn, would be included.

In addition, one of the things that we found most useful in trying to understand the details of some of the regulations is to put in the appendix the proposed rule, where the Agency included as a preamble to the rule an explanation of what they were trying to accomplish with the rule. We then also include in the appendix the final rule as published in the Federal Register. In the preamble statement to final rules, the Agency responds to the comments that various people and organizations made to the proposed rule. By putting those two together you can see the logic and the issues that the Agency considered and how they resolved them in coming to a final rule. On several of the most difficult issues, it is really the best way to obtain a complete appreciation of how the rules came into the form that they are now in.

Mr. THOMAS. I thank the gentleman.

Mr. PANETTA. The second part which concerns me more, discusses, as I understand it, the question of how the Agency then reaches its regulatory decisions. There is no question that in this part you have made subjective conclusions as to how the Agency has operated, whether they have operated well, poorly, or indifferently.

I believe you have made judgments here as to whether the Agency is effectively or not effectively implementing these conclusions, is that correct?

Mr. BENBROOK. Yes.

Mr. PANETTA. So to that extent, the report, while one part of it may be an accumulation of documentation, the second part is really an investigative summary of what you as a staff member have concluded as to how the Agency has operated in this area?

Mr. BENBROOK. Yes.

Mr. PANETTA. Thank you, Mr. Chairman.

Mr. BROWN. Would you describe for the subcommittee the degree, if any, to which the report has been subjected to external review?

Mr. BENBROOK. The first draft of the report, as I explained earlier, was provided to the Agency, and I am not entirely sure of the exact process the Agency used to review it internally, but I met several times with different Agency officials and received a lengthy list of changes that the Agency felt were required. I think there were 14 items on it, all of which have been addressed in one way or another.

I am aware that the Agency still takes exception to certain of the conclusions reached largely in the cancer chapter.

I am not aware of any other parts of the report that they feel deviates substantially from their position or the responses that were given to your questions by Dr. Todhunter in his recent letter.

The report also was obtained by the National Agricultural Chemicals Association. They are in the process of reviewing it. Several different pieces of the report have been looked at by other people. A copy has been sent to the National Audubon Society, at your direction, but only partial reviews have been obtained at this time. However, in developing the discussion and framing the issues, the subcommittee consulted with scientists and regulatory officials and former regulatory officials, and people in the industry very extensively, reflected by the diversity of sources that are quoted and cited in the report.

I don't think that there is much original subjective judgment voiced in the report. All of the conclusions in the cancer chapter, for example, could be extracted in quotes from Science magazine, the New York Times, and other reputable publications reporting the results of other analyses where people have reached comparable conclusions.

Mr. PANETTA. But do you do that?

Mr. BENBROOK. We certainly could.

Mr. PANETTA. Do you do that in the report? It seems to me if there are subjective conclusions that you say can be substantiated, then I think they ought to be substantiated by citing the actual sources you are referring to.

Mr. BENBROOK. This brings out one of the dilemmas that we are faced with in drafting the report. In briefings and staff discussions on the report, counsel from both the majority and minority sides suggested that no names of pesticides and no specific cases be included in the report. Accordingly, conclusions and findings had to be stated in a fashion where it was quite clear that there was a subjective nature to them.

However, if I had been at liberty to explain substantive cases, the facts would have spoken for themselves, and the subjective nature of many of the statements would not have been necessary.

In the appendix there is a lengthy Science magazine article describing the cancer policy changes which will be included as well as several other shorter pieces that I think would be very appropriate to include, and could in fact be worked into the text. However, no references of that nature are included in the text at this time.

Mr. BROWN. That was because you did not wish to cite specific companies or chemical products?

Mr. BENBROOK. That is correct. The Science magazine article, for example, describes several specific cases. A decision was made not to discuss any pesticide by name in a manner which might raise any doubts concerning its safety.

I recognize that creates a difficulty in the report and I am afraid we can't have it both ways. We either talk about them or not.

Mr. PANETTA. My concern is that if this is an investigative report which raises implications about decisions in these areas, while you may not want to offend anybody, the fact is, you are going to offend somebody and you ought to have substantiation for what you are saying in here, even if it refers to specific cases. Those companies may come back and say this is being drawn by implication from a particular instance. I don't think you avoid the problem by not naming the source.

Mr. BENBROOK. If the subcommittee would reach agreement that that would be the basis to proceed, the report could be revised to do that without any problem. There is not a single conclusion in the report that can't be substantiated with multiple cases, and I am prepared to do that.

Mr. BROWN. I find this discussion very illuminating. Are there any further questions?

Mr. Fithian?

REMARKS OF HON. FLOYD J. FITHIAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. FITHIAN. Thank you, Mr. Chairman.

First, let me say that this obviously represents a prodigious amount of effort on the part of Dr. Benbrook. Despite our efforts here to clarify the purpose of this, I am still at sea.

I take it that since there were no hearings on this, where you would have the Agency here to be cross-examined, or authors of the articles which you cite to be queried or industry to defend or environmental groups to get their nickel's worth in, the arguments of some pretty sweeping judgmental conclusions toward the end, then I am not quite sure what the document is.

At least in the years I have been on the committee, as well as on an oversight committee, this is not the procedure that I have ever seen done before, in either this or other subcommittees of which I have been a member.

I am just a little puzzled as to how we might proceed.

Certainly we should not proceed in such a way as to lose the value of your work, nor I think could we reasonably proceed as though this is the product of the subcommittee, with hearings and all the things that go along with a subcommittee report.

It is kind of neither fish nor fowl. At this point it seems to me that maybe proper use of the disposition of this tremendous