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CHEMICALS AND FOOD CROPS

HEARING

BEFORE THE

SUBCOMMITTEE ON TOXIC SUBSTANCES, ENVIRONMENTAL OVERSIGHT, RESEARCH AND DEVELOPMENT

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

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Mr. CARBAUGH. They will be registered. It's just a difference in terminology. We call that registration of product—we've been doing that since 1948. We will continue to do that.

What the new law does, is allow the new board to take into consideration whether there are any adverse effects on health or environment as it relates to Virginia.

Senator LIEBERMAN. Of a particular pesticide?

Mr. CARBAUGH. Of a particular pesticide, yes.

Senator LIEBERMAN. And, do I understand that in coming to that finding that the burden is on the commercial applicator or on the manufacturer to prove the safety?

Mr. CARBAUGH. That's right.

Senator LIEBERMAN. And that would include so-called old pesticides as well as new pesticides?

Mr. CARBAUGH. It could. We, I guess, have that bridge yet to cross, but it could.

Senator LIEBERMAN. And the question of safety is not just for the workers, but for the consumers of products on which that pesticide is placed?

Mr. CARBAUGH. That's correct.

Senator LIEBERMAN. Okay, I appreciate your answers because that may suggest some trend or direction in which we might move as we alter the Federal system.

Thank you. I have no further questions.

Senator REID. Thank you very much, gentlemen.

Mr. Hind, we appreciate your being here also and recognize your contribution to this whole area.

The people that will be on our next panel will be Dr. Charles Benbrook from the National Research Council and Mr. Peter Guerrero from the General Accounting Office.

Gentlemen, would you, while you're there, raise your right hands and be sworn?

[Whereupon, the witnesses were sworn.]

Senator REID. Dr. Benbrook, would you proceed, please? We'd ask that you'd summarize your statement because the written statement is more than the five minutes allotted.

STATEMENT OF CHARLES M. BENBROOK, EXECUTIVE DIRECTOR, BOARD ON AGRICULTURE, THE NATIONAL RESEARCH COUNCIL

Mr. BENBROOK. Yes, Mr. Chairman, I'd be delighted to.

I'm Charles Benbrook, the executive director of the Board on Agriculture, in the National Research Council.

Over the years we've conducted a number of studies on pesticide regulatory issues, the science of pest control. One of our studies, released in 1987, I hope the Senators have seen. It was entitled, "Regulating Pesticides in Food, the Delaney Paradox." This is the report that documented the dimensions of the problem that has now erupted into a full-scale national issue and led to these hearings.

What I would like to try to do today is trace with you what's wrong with our Federal statutes governing pesticide regulation and point you in the direction of where some legislative and administrative solutions might be found.

I'd very much like to try to help you understand the dilemma that EPA finds itself in. We are embarking down a course in this country which I think is very inefficient in dealing with this problem. I think it's important to understand its dimensions.

The problem that EPA faces in regulating cancer-causing chemicals is that it must deal with two statutes. One statute, the Food, Drug and Cosmetic Act, includes the infamous Delaney clause. The Delaney clause applies to certain pesticide tolerances and would impose a zero risk standard for cancer risk from any residues on foods.

This Food, Drug and Cosmetic Act Delaney clause applies only in cases when a pesticide residue concentrates on processed foods and when the pesticide has been shown to be an oncogen. Our report documented and analyzed the frequency of this instance in the food supply and tried to understand how EPA can reconcile this zero risk standard in the Food, Drug and Cosmetic Act with the risk-benefit standard in the FIFRA statute which governs the registration of pesticides and the establishment of tolerances in raw foods.

The dilemma that EPA faces is that one statute tells it to do one thing and another statute in certain instances tells it to do something else. It's really placed in a position of having to break one law or another.

Dr. Moore, later this morning in his testimony, will no doubt explain to you what the agency has tried to do to reconcile these conflicting standards.

But, ultimately, for the Nation to regain control over the safety of its food supply in a reasonably efficient regulatory process, fundamental inconsistencies between these two statutes have to be resolved; the fundamental conflicts between the FDA and the EPA have to be resolved, and some common sense has to be restored to the pesticide regulatory process.

I'd like to go directly, if I may, to the major findings of our report because I think they are helpful in putting into perspective the dimensions of this problem.

EPA has set about 8,500 distinct tolerances for the use of a pesticide on an individual crop. That is sort of the universe of food uses of pesticides that have to be evaluated for their risks and benefits.

About 80 percent of the total estimated worst case oncogenic risk stems from residues in fresh foods and about 20 percent from processed foods. One category of pesticides, used principally for the control of plant diseases, fungicides, accounts for over half of the risk in fresh fruits and vegetables, and almost 80 percent of the risk in processed foods.

Let me have a chart put up now that's drawn from our report, if I could, right here. I'd like to walk the panel through some of this information through use of this chart.

This is a table drawn directly from this report. It contains a list of many of the common active ingredients that have a number of food use registrations. The first column of numbers has the number of food uses or tolerances. You'll see 83, 83, 50 uses. One is down at 11; benemyl is up at 101. Obviously, these chemicals are registered for use on a wide range of crops.

You'll note that these chemicals are ranked according to the total estimated risk, the worst-case risk, if they were used on all crops and if residues appeared at the tolerance level.

Now you'll also notice that, of the top ten, all of them are fungicides except for one insecticide. You'll also notice that several of them have received a weight-of-the-evidence ranking by EPA for human carcinogenicity of B2, which means that EPA considers these to be probable human carcinogens.

A "C" ranking indicates that there is some evidence of carcinogenicity in humans, but it's certainly not as firm or convincing as in the case of the B2 ranking.

You'll also note here the year of the first tolerance, which is a good indicator of the year of introduction or how old the chemicals are. Our top ten, 1955, 55, 57, 78—the most modern of the newer chemicals—62, 55, 61, 67, 72, 55, on and on and on.

Mr. Chairman, we have an old chemical problem when we talk about pesticide risk in the food supply. If EPA is going to do anything serious to reduce risks in the diet, they can draw a line right here and forget everything else. This is where the risk is. It so overwhelms the risks from all other pesticides that, if they don't deal with these, they will have virtually no impact on risk in the food supply. This is what our report documents.

The distribution of risk in the food supply is not even. We have 8,500 tolerances, and a handful of them account for virtually all the risk. EPA has, to the extent that we can detect a carcinogenic potential of a pesticide, to the extent that we can measure these things, EPA has a pretty good idea of where that risk is.

The problem is it doesn't have a statute that allows it to go directly to those risky uses of chemicals and take action to reduce the risk. Alar is a perfect case in point. Captan is a perfect case in point.

If this problem is to be resolved, the limitations in the statute that make it very difficult for EPA to take actions to reduce risk—perhaps not to zero, but substantially reduce it—must be dealt with.

Mr. Chairman, my time is up. I'll be glad to respond to any questions.

Senator REID. Mr. Guerrero.

STATEMENT OF PETER F. GUERRERO, ASSOCIATE DIRECTOR, ENVIRONMENTAL PROTECTION ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, GENERAL ACCOUNTING OFFICE

Mr. GUERRERO. Thank you, Mr. Chairman and members of the subcommittee.

Rachel Carson in "Silent Spring" said, "if we are going to live so intimately with these chemicals, eating and drinking them, taking them into the very marrow of our bones, we had better know something about their nature and their power."

Since her words in 1960, our production of pesticides has increased fivefold. Recognizing that, indeed, we did need to know more about these substances, EPA undertook, beginning in 1972, a program to reassess existing pesticides and their tolerances. This

COPING WITH DELANEY'S PARADOX

Invited Testimony by
Charles M. Benbrook, Ph.D.
May 15, 1989

Before the
Subcommittee on Toxic Substances,
Environmental Oversight, Research and Development
Senate Committee on Environment and Public Works

I appreciate this opportunity to testify before the subcommittee. My name is Charles M. Benbrook. I am the Executive Director of the Board on Agriculture of the National Research Council. The NRC is the working arm of the National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine.

The Board on Agriculture and NRC have a long history of studies on pesticide and agricultural policy. In 1987, the board completed a major EPA funded project on a particularly vexsome aspect of the pesticide regulatory system. Our report, entitled Regulating Pesticides in Food: The Delaney Paradox, assessed the regulatory and legal dilemma facing EPA as it tries to reconcile the conflicting standards that govern setting certain pesticide tolerances. In 1986 we released a report, Pesticides and Groundwater Quality: Issues and Problems in Four States. A major report was released in 1985 on pesticide resistance. In the late 1970s, the NRC undertook a comprehensive assessment of the pesticide regulatory process, and helped the EPA establish many of the scientific principles now incorporated in pesticide risk-benefit decision-making.

Our work is ongoing, as well. We will release this fall a comprehensive study on alternative agriculture, which examines options to pesticides and how some public policies have increased farmers' dependence on chemical control technologies. Incidentally, many of the key issues addressed in our forthcoming report were raised in last week's Wall Street Journal piece, "A Movement to Farm Without Chemicals Makes Surprising Gains." (A copy of this article is attached.) In partnership with the NRC's Board on Environmental Sciences and Toxicology, we also have under way a very important study examining the adequacy of current risk assessment methodologies in predicting the risks faced by infants and children from exposure to pesticides through food and water. I attach for the record a brief description of our ongoing study, "Scientific and Policy Issues Surrounding the Regulation of Dietary Exposure to Pesticides for Infants and Children". A report summarizing the results of this study will be released in the fall, 1990.

The Delaney Paradox

I would like to describe the issues analyzed in our 1987 report Regulating Pesticides in Food: The Delaney Paradox. I attach for the

record the report's table of contents and Executive Summary, and a list of the committee which carried out the study.

This report presented the first comprehensive analysis of the pesticide tolerance setting process and its impacts on the distribution of pesticide residues and "worst case" oncogenic risks in the diet. Chapter 3, "Estimates of Oncogenic Risks," contains a number of striking findings relevant to the policy issues and options before the agency, and under review this morning. I should note that legislation drafted by Congressman Henry Waxman and recently introduced in both houses ("The Food Safety Amendments of 1989," S. 722, Senator Kennedy; HR 1725, Congressman Waxman) rests largely upon the report's findings, and attempts to incorporate in legislation the report's principal recommendations.

The charge given in 1984 to the Delaney committee by EPA was to develop an analytical framework to assess the public health and agricultural impact of different approaches to setting food tolerances. We were asked, in particular, to focus on resolving the inconsistency between the zero-risk standard set by the Delaney Clause of the Food, Drug and Cosmetic Act and the risk-benefit balancing standard in the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA.

Congressional oversight committees and EPA had by 1983 identified a number of specific pesticide regulatory cases in which the requirements of the two statutes appeared in conflict; and in which EPA felt compelled to take action (or, more commonly inaction) which either violated the standards and procedures of one statute or the other.

Delaney's Paradox first arose as EPA denied in the mid-1980s registrations for safer, new pesticides that posed very minute oncogenic risk (say 10^{-8}), yet left on the market other pesticides for the same use posing more risk (say 10^{-5} or higher).

The zero risk standard of the Delaney Clause would seemingly allow no food tolerance to be set for certain pesticides shown to cause tumors in laboratory animals. More by legislative construction than design, the zero-risk standard applies only to oncogenic pesticides for which residues concentrate in processed food above the level allowed in raw food. The Delaney Clause, an amendment to section 409 of the FDCA, does not have any practical impact on the residues of oncogenic pesticides on or in raw food unless the residues concentrate to higher levels in processed food. Tolerances to cover residues in fresh foods are set by EPA using a risk-benefit standard, under authority specified in section 408 of the FDCA. When residues concentrate and a pesticide is found to be an oncogen, then presumably the Delaney Clause would apply.

This obscure legal point has exacerbated controversies over EPA's regulation of several pesticides including daminozide, captan, the EBDC's, and benomyl. This is because the EPA is caught between a legal "rock" and a public health "hard place." While prudent public health policy would seem to warrant tolerance reductions for major food uses for pesticides like daminozide and captan, such actions would create difficult legal problems for the Agency. The legal problem would arise because lowering section 408 raw agricultural product tolerances will routinely -- but not

always -- create the need to establish some higher section 409 tolerance to cover concentrating residues in some processed foods. Alas, the Agency would be blocked by the Delaney clause from doing so when a pesticide has been found to cause cancer in man or animals. Accordingly, EPA has never used or seriously explored tolerance reductions as a separate administrative action. In the view of some legal experts, EPA lacks clear authority to lower -- as opposed to cancel -- tolerances. The legality of such actions has, in any event, never been tested by the Agency outside the context of a special review or cancellation action, accompanied by a complete dataset and risk-benefit finding that risks indeed exceed benefits. It takes years and tens of millions of dollars per pesticide in public and private costs to conduct a contested special review or cancellation action. In some cases like daminozide, the results are far from satisfying to all parties even after enormous investments in trying to determine the true magnitude of risk.

The committee which authored our Delaney Paradox report assembled a unique and powerful data base. It covers all pesticides registered for use on foods, and each crop use of each pesticide. It includes EPA data on food consumption, legal tolerances, and the carcinogenic potency of 28 pesticides. As new data on oncogenicity or reliable actual residue data become available, they can be incorporated into the data base. The data base is <u>not</u> appropriate, by itself, to conduct highly refined risk-benefit assessments on all pesticides and foods, a task which would have required much more detailed analysis than time allowed, and years to generate still missing data. Rather, the committee's goal was to gain understanding of the distribution of risk among pesticides and foods, and across types of tolerances and pesticides, based on the best information then available to EPA. The committee designed the data base as an analytical tool to assess the impact of different regulatory options or scenarios on the risks and benefits of pesticides. It was, and remains a powerful and reliable tool to estimate the consequences of alternative risk reduction strategies, including alternative definitions of negligible risk.

Using this data base the committee arrived at several important conclusions regarding the distribution of pesticide risk in the food supply, as well as insights into the most efficient way to reduce this risk. (Efficient in terms of minimizing the loss of benefits to agricultural producers in achieving a given degree of risk reduction.) Many of these observations seem relatively basic; however, they are very important in understanding where EPA can focus it's efforts in reducing potential oncogenic risk from pesticide residues in the diet. Although a few pesticides have been removed from the market since 1987, and several additional pesticides have been determined by EPA to pose oncogenic risks, the policy-related conclusions reached by our committee remain valid.

Major Findings in the Delaney Paradox Report

The most important overall finding of the committee is that most of the potential oncogenic risk from pesticides in the diet is accounted for by a relatively small number of pesticides and foods. The committee estimated that between 80 to 90 percent of all dietary oncogenic risk from pesticides arise from residues of about 10 pesticides in about 15 foods.

Not surprisingly, the committee also concluded that most crops, and most uses of oncogenic pesticides pose "worst case" dietary cancer risks far less than one-in-one million, the common benchmark used in quantifying a "negligible risk" standard. Accordingly, meeting a negligible risk standard will not cause the wholesale disruption of American agriculture feared by some individuals and organizations. Adjustments in cropping patterns and agricultural production practices necessary to reduce dietary pesticide risk to negligible levels will impact relatively few producers growing a small number of crops, and then only in certain regions where these crops are grown. Regardless of the pesticide regulatory strategy the nation opts for, negligible risk levels will be most difficult to meet in generally hot, humid fruit and vegetable producing regions where pest pressures, soil conditions, and climate result in the need for much higher than average reliance on pesticides.

In addition the committee found that:

- EPA has set about 8,500 distinct tolerances, each covering use of a specific pesticide on a single crop (or crop grouping, like different kinds of lettuce). (See Table 2-1, page 35, Regulating Pesticides in Food: The Delaney Paradox.)

- About 80 percent of total estimated "worst case" risk stems from residues in fresh foods, and about 20 percent from processed foods. Fungicides account for 55 percent of risk in fresh foods, and 78 percent of risk in processed foods. (See Table 3-10, page 69.)

- For 53 oncogenic pesticides, there were over 800 food uses with a corresponding processed food form, yet there were only 31 section 409 tolerances for these uses -- far below the number that could ultimately be needed to cover concentrating residues. (See Table 3-8, page 64.)

- About 90 percent of the total estimated "worst case" dietary oncogenic risk is from tolerances granted before 1978. (See Table 3-28, and Figure 3-4, pages 86-87.)

- In terms of volume applied, 90 percent of all fungicide applications, 60 percent of all herbicide applications, and 30 percent of all insecticide applications are made with oncogenic compounds.

The committee then analyzed four regulatory scenarios to judge their effectiveness in reducing risk. A detailed description of these scenarios is contained in the attached pages from the report that I have submitted for the record.

The principal findings of the committee's scenario analyses are that:

- A one-in-one million risk standard would reduce dietary oncogenic risk by well over 90 percent, and revoke or modify only about one-third of all current tolerances for oncogenic pesticides, if consistently applied to residues in raw and processed foods, new and old pesticides, and each type of pesticide.

- The Delaney Clause, because of its selective impact on processed foods, could at best, if strictly enforced as written, reduce risk by about 55 percent. This assumes EPA would also cancel all section 408 tolerances associated with crop uses on which residues concentrate, a practical necessity since there is rarely a full-proof way to separate out that portion of a crop grown for the fresh market from crops destined for processing. Moreover, in the process of achieving a 55 percent reduction in potential risk, the Agency would have to revoke many more tolerances on more crops than necessary through consistent adherence to a negligible risk standard.

Key Conclusions

The committee reached several other important conclusions. One of the most important is that current laws and regulations, and the way they are implemented, have resulted in glaring inconsistencies in the way residues -- and hence risks -- of old and new pesticides are regulated.

Most troubling is the new versus old pesticide problem: under current policy, a new pesticide is guilty until proven innocent, an old pesticide is innocent until proven guilty. In the case of trade-offs between new and old oncogenic pesticides this arises because EPA has applied the Delaney Clause only to new pesticides.

The EPA has deferred applying the Delaney Clause to old pesticides because of the burdensome standard under FIFRA and process which must be followed to cancel a pesticide use. The Delaney Clause may appear to compel action, but it provides EPA no tools to get the job done. EPA is forced to change pesticide registrations through the provisions of FIFRA. It cannot grant a registration until a tolerance is set; it cannot revoke a tolerance without canceling a corresponding registration. Ironically, the EPA has used the Delaney Clause to deny tolerances and registration of some very weakly oncogenic new pesticides that present risks as low as 1 in 100,000,000, while not using the same Delaney Clause to revoke tolerances of other oncogenic compounds with dietary risks over 1,000 times higher. In some cases studied by the committee the new, safer pesticides would have been direct substitutes for the more hazardous pesticides, and would have provided farmers with an opportunity to reduce risks to themselves and consumers. In light of these facts, it is hard to escape the conclusion that the Delaney Clause has fallen short of accomplishing its objectives in the regulation of pesticides.

Another significant but indirect result of this study was the realization on the part of EPA, FDA, farmers, and the food industry that very little good data existed on actual levels of pesticide residues in the food supply. The recent flap over daminozide (Alar), and the NRDC report

on pesticide risks faced by children shows how far we have to go in generating better data on food residues of pesticides, and how weak our data is on the actual extent and consequences of use of potentially worrisome pesticides. The whole issue of pesticide benefit assessment is, I am sorry to say, a jumbo size can of worms.

The response to our 1987 report was immediate and significant. It was, in many respects, surprising. Perhaps the most surprising result of our report was the almost immediate emergence of private residue testing services now used by thousands of food retailers across the country. The popularity of such programs indicates the willingness of retailers and consumers to pay for increased certainty in the safety of the food they eat. NRDC would, no doubt, acknowledge that the most surprising, and clearly unwarranted and unintended result of their 1989 report was action by several school districts to halt distribution of apples, until their safety could be verified.

EPA Implementation Activities

We would like to take this opportunity to comment on EPA's efforts to date in implementing our report's recommendations. On October 19, 1988 the EPA issued a notice in the Federal Register describing a detailed plan to implement the committee's recommendations. In general the Agency proposed to grant food tolerances for new oncogenic pesticides that meet a negligible risk standard, as recommended in our report. The agency was not as clear, however, about the application of this standard to current food tolerances for older oncogenic pesticides. No doubt Dr. Moore will update the subcommittee later this morning on when and how the EPA will amend existing registrations and tolerances on older pesticides that pose risks above a negligible level.

This is clearly significant because most oncogenic risk is from old pesticides. By only addressing the establishment of <u>new</u> tolerances and not clearly articulating a plan to reduce risk from <u>current</u> tolerances the agency has not demonstrated a convincing commitment to risk reduction. Leaving risk reduction to a re-registration process likely to last well into the next century continues to erode public confidence in the Agency. This is regrettable, and largely undeserved, since EPA is making steady progress in filling key data gaps, and could accelerate risk reduction through re-registration if it had new authority to conditionally reduce risks to negligible levels when and as necessary, pending receipt of complete datasets and final re-registration or cancellation actions.

An example may help the subcommittee understand this point. The first pesticide to which EPA applied its new Delaney policy is the widely used fungicide captan. Our report contains a brief case study of captan on pages 201-203. In 1985 EPA proposed to cancel most uses of captan based on worst case risk estimates, which were far above negligible levels. It deferred action, pending the receipt of more accurate data on actual food residue levels, data on how widely the chemical is used, and other aspects of the risk and benefit assessment. Data has since been gathered showing that actual food residues are, in fact, far below tolerance levels, and that actual risks are far less that indicated by a worst case analysis. In

February of this year, EPA issued its final decision to cancel some captan uses and retain other uses, based on this new data. I would like to note that without rendering judgment, serious questions can be raised about the analytical methods and assumptions EPA used in reaching the judgment that risks associated with the major uses of captan are not above a negligible level. These questions will no doubt be debated in the scientific community -- with a little prodding from lawyers -- as the EPA and/or Congress defines new policy for regulating pesticides in food.

EPA's final decision on captan proposes to cancel 42 uses of captan, while retaining 24 others. While reducing potential risk substantially, a closer look raises many questions about the outcome of this decision.

First, nearly all of the canceled uses of captan were on crops where the agency had little evidence of captan use. In general between 0 and 10 percent of the acres of these crops were treated in any given year with captan. Canceling uses of a pesticide on crops where it is not used is not likely to result in significant actual risk reduction.

This decision may also have the unintended effect of increasing the oncogenic risk from fungicide residues on certain crops. In the absence of captan, other more hazardous fungicides may be used in the years when a disease outbreak warrants treatment. In fact, for many of the canceled uses, other oncogenic fungicides of greater oncogenic potency are listed as likely substitutes by EPA, and are still registered. Further, while the residues of captan are reduced with washing, some of the more potent oncogenic alternatives and their breakdown products are not removed with washing.

Second, none of the major uses of captan were canceled, nor were any of the tolerances covering these uses lowered toward a negligible risk level. EPA based this decision on estimates that no individual crop presents a greater than negligible risk when risk is calculated using a new methodology reliant on FDA monitoring data as the basis for exposure estimates. Moreover, because EPA generally calculates risk and exposure on a nationwide basis the method used in this case to calculate exposure may actually underestimate exposure and risk to regional subpopulations living in areas where fresh fruits and vegetables are often treated with captan.

Summary

The EPA faces a daunting task in regulating pesticides. Public concerns are clearly rising and are likely to continue growing as more is learned about the presence of pesticide residues in the food supply. The science of toxicology is advancing, particularly in new areas like immunotoxicity and neurotoxicity, and in estimating risks faced by special population. groups like infants, the elderly, and chronically ill individuals. A new generation of pest control technologies is emerging, which pose new challenges for EPA.

It is increasingly evident that the nation's pesticide regulatory laws and programs are not up to the task. Solutions that deal with fundamental issues and concerns will be politically contentious, will pose high short-run costs on some farmers and chemical companies, but if crafted wisely need not increase consumer food costs, nor adversely affect the availability of produce. I hope this Subcommittee will use the record of this hearing in the search for sound solutions. Thank you for the invitation to appear before the Subcommittee this morning.