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FOOD SAFETY

Difficulties in Assessing Pesticide Risks and Benefits

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Mr. Chairman and Members of the Subcommittee:

Good morning. We are pleased to be here today to discuss our observations on the difficulties in assessing the risks and benefits of pesticides used in or on food. Our testimony is based on a large body of work that we have done over the years on pesticide regulation, food safety, and risk and benefit assessment. (Attachment I contains a list of related reports.)

Three federal agencies--the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)--share responsibility for providing pesticide regulatory services to both food consumers and food providers. In brief, these services are designed to screen out pesticides that may present unreasonable risks and approve those that provide benefits.

In summary, three key points emerge from our work:

-- First, assessing the risks and benefits of pesticides used on food is uncertain. Limitations in scientific methodologies and relevant data preclude precise estimates of the hazards, exposures, and benefits of pesticide use and prevent the government from assessing food safety as reliably as possible. Although understanding of the risks and benefits of pesticides used on food is expanding, policymakers and the public need to recognize the inherent uncertainty surrounding the assessment and management of pesticide risks and benefits.

-- Second, persistent problems exist in collecting and managing the data needed to develop more precise estimates of pesticide risks and benefits. Despite recent progress, federal food safety agencies need to improve how they work together and overcome barriers presented by fundamental

differences in their missions. Moreover, ineffective agency planning and management of data needs and resources is jeopardizing the accessibility, reliability, and utility of the data that are collected.

-- Third, controversial policy issues continue to hamper pesticide regulation. For example, inconsistencies in the statutory provisions governing carcinogenic pesticide residues in food established under the major pesticide law and the major food safety law have not been resolved. Furthermore, EPA has been unable to establish policies or guidelines in several areas of risk management.

Before we discuss these points in more detail, let us explain how the federal government regulates pesticides used on food.

BACKGROUND

Pesticides are a mixed blessing: they contribute significantly to the variety, quality, and quantity of available foods, but they can adversely affect people and the environment. Because pesticides are substances designed to kill and control plant and animal pests, exposure to them can be hazardous. Some pesticides remain as residues on food and can be ingested along with the food. More importantly, some pesticides have been shown to cause adverse human health effects, such as cancer or birth defects.

The regulation of pesticides is governed principally by two statutes. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a pesticide product generally must be registered by EPA before it can be marketed. If EPA determines that a pesticide's benefits outweigh its risks, then a registration is granted. For food-use pesticides, EPA requires manufacturers to submit data on a pesticide's toxicity (its potential to cause

adverse human health and/or environmental effects) and residues (the amount that is likely to remain in or on food) as part of the registration process.

Under the Federal Food, Drug and Cosmetic Act (FFDCA), EPA must either establish a tolerance or grant an exemption for each registered use of a pesticide on a food product. A tolerance is the maximum amount of pesticide residue that is allowed by law to remain in or on raw agricultural commodities, processed foods, or animal feed. It is the amount of residue that is considered to impose no health hazard within a practical certainty over a lifetime of daily exposure. The dietary risk from pesticide residues depends on their toxicity and on the level of potential human exposure to residues in the diet (i.e., how much residue is likely to remain in or on foods and how much of these foods people eat).

Because most pesticides were registered and most tolerances were established with less information than is now required, the Congress has amended FIFRA several times since 1972, requiring EPA to reregister older pesticides according to current data requirements and scientific standards. As part of this effort, EPA plans to reassess tolerances for older food-use pesticides. Most recently, the Congress enacted the FIFRA Amendments of 1988 (known as FIFRA '88), which imposed mandatory time frames and provided authority to collect fees in order to help accelerate reregistration. Approximately 23,000 pesticide products will need to be reregistered in compliance with the provisions of FIFRA '88.

If, at any time, new evidence on a pesticide raises a concern about a significant human health or environmental risk, EPA may conduct a detailed analysis--called a special review--of the pesticide's risks and benefits to determine if regulatory action, such as canceling or restricting a pesticide's use(s) and revoking a tolerance, is needed. EPA typically analyzes benefits in detail

when new evidence suggests that a registered pesticide may pose an unreasonable risk to human health or the environment. Such evidence calls for a formal weighing of the risks and benefits of the pesticide's use(s). EPA's benefit assessments compare the economic impacts--on farmers, consumers, and food processors and distributors--of alternative pest control methods. The agency's benefit assessment includes a biological analysis and an economic analysis. A biological analysis estimates differences in crop yield resulting from the use of a number of pest control methods. An economic analysis assigns dollar values to these differences and includes the costs of alternative pesticides.

FDA and USDA are responsible for monitoring domestic and imported food products and enforcing tolerances, with assistance from the states. FDA is responsible for monitoring most of the nation's food supply through sampling and testing of fresh and processed commodities, such as fruits and vegetables. USDA monitors pesticide residues in meat, poultry, and egg products. USDA also studies pesticide usage and practices, pesticide residues remaining after crop treatment, and types and quantities of food products consumed by the American public.

Having completed this overview, we would now like to focus on the uncertainties surrounding estimates of the risks and benefits of pesticides used on food.

UNCERTAINTIES OF RISK/BENEFIT ASSESSMENTS

Assessing the risks and benefits of pesticides used on food is highly uncertain because of limitations in methodologies and gaps in knowledge. Uncertainty limits the precision of risk and benefit estimates, which are usually presented in numerical terms. Often, these numerical terms imply a level of precision that simply does not exist. Therefore, policymakers and the public need to recognize the range of uncertainty surrounding estimates of

pesticide risks and benefits and understand how such uncertainty might affect decisions concerning pesticide use and food safety. However, we have found that EPA has not consistently acknowledged these uncertainties.

Uncertainties Caused by Methodologies

Limitations exist in methodologies for assessing both risks and benefits. These limitations result in uncertain estimates, even when complete, accurate and reliable data are available. Our work has not specifically focused on EPA's scientific methodologies for assessing the risks of pesticides used on food. However, our work on pesticide issues has indicated that limitations exist in the following areas:

-- First, uncertainty exists because risks to humans are projected from animal studies. Uncertainty occurs because (1) there are biological differences between animals and humans, (2) higher doses are used in animal tests than humans are expected to ingest, and (3) susceptibility to toxic effects varies from one individual to another. As a result, EPA uses certain conservative assumptions in its toxicity analyses to compensate for these uncertainties.

-- Second, not considering synergistic effects contributes to uncertainty. Synergism occurs when the simultaneous action of separate substances--such as two or more active ingredients in a pesticide product--produces a greater total health effect than the sum of the individual ingredients. Generally, EPA does not assess synergistic effects because of scientific and cost limitations.

In addition, uncertainty arises from benefit assessment methodology. In its current methodological approach, EPA usually does not include all relevant alternatives, and it narrowly defines

benefits. This approach increases the uncertainty of the agency's benefit estimates and could impair its attempts to balance pesticide risks and benefits. In particular, we found that EPA's benefit assessments are typically based on differences between registered chemical alternatives. The assessments generally do not make comparisons to nonregistered chemical and nonchemical pest control options because of limitations in available data. In addition, EPA's benefit assessment methodology focuses on direct benefits to farmers and the food industry (food processors and distributors) while ignoring potential health and environmental benefits. (For example, pesticide use may increase the quantity and variety and decrease the costs of fruits and vegetables, thereby enhancing the nutritional value of consumers' diets.) Because EPA's benefit estimates are incomplete, they may overstate or understate the actual benefits of pesticide use.

Now, let us address gaps in the knowledge of risks and benefits.

Uncertainties Caused by Gaps in Knowledge

Gaps in knowledge of pesticide risks and benefits contribute substantially to uncertainty. As we have reported on several occasions, without acceptable studies of the quantities and toxicological effects of pesticide residues remaining in or on foods, the safety of many existing tolerances remains unknown. Enactment of FIFRA '88 was intended to address such concerns by accelerating the reregistration of about 23,000 older pesticide products. However, the reregistration task has proven more formidable than anticipated, and EPA will not meet the 1997 reregistration time frame established by FIFRA '88. In the interim, previously registered pesticide products may be used on food under their existing registrations and tolerances, despite EPA's incomplete knowledge of their human health and environmental effects. We are currently evaluating EPA's progress in

reregistering pesticides and expect to report on it later this year.

The need for accurate data to assess pesticide risks will not end with reregistration. As science advances and additional testing needs are identified, EPA must develop new test protocols and require additional data. For instance, many pesticides have not been tested for effects on the nervous system; however, EPA has now developed test protocols and will require such tests in the future. As we have previously reported, EPA lacks an efficient mechanism to keep regulatory assessments on pesticide food uses current with changes in science and uses.

Our recent work on EPA's use of USDA's Nationwide Food Consumption Survey illustrates how inadequate knowledge may affect pesticide risk estimates. To establish safe levels of pesticide residues in or on food, EPA estimates dietary exposure to pesticide residues using data from USDA's survey, which is conducted every 10 years. However, we found that EPA's estimate of potential human exposure to pesticide residues in food is uncertain because these surveys are flawed. For example, our review of USDA's 1987-88 survey found that it was not representative of the U.S. population because the response rate was too low. To compensate for this deficiency, EPA is using the older 1977-78 survey data to estimate food consumption, but this survey may not reflect the current eating habits of Americans. Moreover, neither the 1977-78, nor the 1987-88 Nationwide Food Consumption Survey sampled subpopulations, such as infants and pregnant females, in numbers large enough to permit precise estimates of their dietary exposure and, hence, of risks to them from pesticide residues.

Our recent review of EPA's benefit assessments also documented the effect of data limitations on the usefulness of these assessments. Although benefit assessments can be an important part of regulatory analysis, EPA's quantitative estimates of pesticides'

benefits are generally imprecise because some of the data on which they are based are poor in quality or missing altogether. Specifically, we found that EPA lacks reliable data on the quantity of pesticides used on food crops and, more importantly, the effect of various pest control alternatives on crop yields. In the absence of reliable data, the agency pieces together whatever information it can on a case-by-case basis from a variety of sources, including reports from USDA and state agriculture departments and pesticide manufacturers, scientific literature, commercial surveys, and estimates of experts and farmers. The problem is particularly acute for estimates of less frequently used pesticides or for pesticides used on smaller-volume crops, such as fruits and vegetables. We concluded that, currently, EPA's benefit assessments are not meeting their full potential to help refine the agency's regulatory decisions primarily because of limitations in the data used.

Need to Disclose Level of Uncertainty

Calculating and reporting the impact of uncertainty on risk and benefit estimates can help to prevent inappropriate interpretations of data. Our work has shown, however, that EPA has not consistently acknowledged the uncertainty inherent in its assessments of exposures to, and benefits of, pesticides used on food.

As our review of EPA's use of USDA's food consumption survey data has shown, the presentation of risk information in numerical terms implies a level of precision that does not exist. We found that EPA does not calculate and report the precision level (sampling error) of the exposure estimates that it derives from data in the 1977-78 USDA food consumption survey. Without this information, EPA officials cannot be sure whether the tolerances they establish partly on the basis of exposure estimates adequately protect all subpopulations from potentially unsafe pesticides.

Similarly, our analysis of EPA's benefit assessments showed that EPA's quantitative estimates of pesticides' benefits are potentially misleading because the analyses frequently do not acknowledge their limitations and, thus, can appear more precise than they really are. Although EPA's guidelines emphasize the importance of identifying the limitations of the data underlying benefit assessments, we found that EPA's analyses often do not acknowledge the uncertainties they contain. If benefit assessments misrepresent the cost-effectiveness of alternatives pesticides, EPA could make misguided regulatory decisions.

SYSTEMATIC SOLUTIONS NEEDED FOR IMPROVING PESTICIDE DATA COLLECTION AND MANAGEMENT

Our work has shown that federal food safety agencies lack a coordinated strategy for systematically identifying, collecting, and managing key data needed to reduce uncertainties in pesticide risk and benefit assessments. Fundamental differences in agency missions and responsibilities have hindered progress in reducing inefficiencies in the collection and management of these data. In addition, poor information resources management has prolonged inefficiencies in pesticide data accessibility, reliability, and utility.

Pesticide Data Collection Efforts Suffer From Inadequate Interagency Direction

Fragmented food safety responsibilities among EPA, USDA, and FDA require effective program coordination and information exchange to prevent wasteful duplication of effort, address gaps in recognized data needs, and ensure the safety of the nation's food supply. USDA, EPA, and FDA have begun to cooperate on interagency pesticide data needs. However, despite the recognized need to improve the quality and quantity of data supporting risk and benefits assessments, our reviews of USDA's Food Consumption Survey

and Pesticide Data Program indicate that data collection problems continue to jeopardize federal investment of resources in this area. For example, we found that EPA did not participate with USDA in designing the latest food consumption survey. In part because of this lack of participation, USDA's survey, which cost $7.6-million, produced data that did not fulfill all of EPA's needs.

In addition, our recent review of USDA's Pesticide Data Program illustrates how the absence of interagency agreements on program objectives and direction may prevent USDA from realizing its key objective: the collection of comprehensive, statistically valid, and scientifically based pesticide residue data. USDA intends to focus data collection on crop/pesticide combinations for which data gaps are prevalent (namely fresh fruits and vegetables) or where EPA has a need for data to support reregistration or a special review of a pesticide. For example, when estimating human exposures to calculate tolerances, EPA assumes residues occur at the maximum tolerance level allowed; USDA's data could provide more realistic estimates of the residue levels that consumers encounter.

However, USDA underestimated the complexities of implementing the residue data collection portion of the program, did not reach agreements with EPA or FDA on specific program direction, and is not collecting statistically defensible data--a key program objective. It is therefore unclear whether USDA's efforts to collect residue data will correspond to EPA's schedule of pesticide regulatory reviews, meet data needs, and provide the data quality originally assumed. Also unresolved is how USDA and FDA will coordinate their work to ensure that USDA's efforts under its Pesticide Data Program and FDA's plans to conduct statistically based residue enforcement sampling will not result in duplication of effort. As a result, USDA is spending $24 million in fiscal years 1991 and 1992 to collect residue data on a small number of crop/pesticide combinations that are not statistically reliable,

could duplicate some FDA data collection efforts, and may not meet EPA's program needs.

Information Management Weaknesses Persist

Work we have done at EPA and USDA indicates that in addition to problems with collecting better pesticide data, weak management of information resources and poor information system designs are adversely affecting pesticide data accessibility, reliability, and utility.

Our review of EPA's process for identifying, reviewing, and tracking studies on pesticides' adverse health and environmental effects illustrates how ineffective information management precludes the agency from effectively accessing and tracking information critical to pesticide registration reviews. Under Section 6(a)(2) of FIFRA, all registrants are required to submit to EPA additional factual information regarding unreasonable adverse effects of registered pesticides if registrants become aware of such information after registration. However, as the 1991 spill of the pesticide metam-sodium in California revealed, EPA has not regularly reviewed registrants' submissions of 6(a)(2) studies. After the spill occurred, EPA discovered that it had not reviewed 6(a)(2) studies received on metam-sodium in 1987. Our review indicated that similar studies may exist within EPA's files on other pesticides because, before 1988, EPA did not require registrants specifically to identify data reportable under section 6(a)(2).

Our reviews of the information systems that EPA uses to support FIFRA indicate that the agency's problems in managing, tracking, and controlling information on pesticides are related to how the information systems have been designed and implemented. Because information submitted by the registrants may be scattered across different nonintegrated systems or kept in paper files, EPA

is unable quickly to compile a comprehensive and reliable picture of the review status of a particular pesticide. Basic information on pesticide studies ends up being entered several times into different systems, or not at all. For example, our reviews of disinfectants[1] showed that EPA's data systems contained inaccurate and/or incomplete data or were missing data. In fact, as much as 60 percent of the disinfectants data in one system may be inaccurate or incomplete. Rather than designing information systems to provide timely and effective management support for its critical regulatory responsibilities, EPA has focused narrowly on automating specific processes that simply track the movement of paper files.

Similarly, our review of USDA's Pesticide Data Program found the absence of an overall information management strategy critical for program success. Data collection activities commenced without USDA's having determined the requirements for processing and disseminating the pesticide usage and residue data needed to (1) support pesticide exposure estimates and economic analyses of alternative pesticide policies within USDA, (2) provide input data for health risk and benefits assessments central to pesticide registration or special review decisions at EPA, and (3) alert FDA of potential residue tolerance violations or usage patterns that could help it target its surveillance activities. As a result, USDA cannot be sure that its information systems can provide the collected data to its own agencies or to EPA or FDA in a timely and cost-effective manner.

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[1]As defined by EPA, "disinfectant" refers to only one of several types of antimicrobial pesticides, which, with some exceptions, are substances intended to inhibit or destroy microorganisms (bacteria, fungi, viruses, and spores). Disinfectants are used extensively on food-contact surfaces (e.g., food-processing equipment and utensils) to reduce the likelihood that food may become contaminated.

This evidence suggests inadequate attention is being paid to planning and managing data systems to ensure better information access, sharing, and reliability. Because pesticide data are used across federal food safety agencies, data collection and management should be considered from an interagency perspective as well as from the perspective of an individual program. Pesticide data collection and management represent a significant federal investment in food safety that affects the soundness and completeness of analyses used to make key regulatory decisions. These activities require (1) clear understanding and agreement on the costs and benefits of collecting data to improve risk and benefits assessments and (2) sound information management strategies to ensure that data are accessible and reliable for those making pesticide safety decisions. Both elements are absent to some extent today.

Concerns About Data Integrity

As we noted earlier, EPA relies largely on data submitted by registrants to assess the risks of pesticides used on food. However, we are concerned about the effectiveness of EPA's controls over these data because of past and recurring incidents of registrants submitting falsified data. The EPA Inspector General is currently reviewing EPA's efforts to ensure the quality of laboratory data submitted by pesticide registrants. In addition, our work at EPA and our recently completed work on FDA's program for approving new animal drugs--which is similar in design to EPA's pesticide program--further contribute to our concerns. In our review of EPA's regulation of disinfectants, we found several weaknesses in EPA's data review, lab inspection, and data audit programs, which inhibited EPA's ability to ensure the quality and integrity of registrant-submitted data. Similarly, our January 1992 report on FDA's new animal drug approval process found that FDA cannot ensure the integrity and accuracy of animal drug data because of weaknesses in its controls over the data. For example,

we found that FDA did not conduct any inspections to verify the accuracy and integrity of data supporting over 50 percent of the new drugs for food-producing animals that it approved over a 6-year period.

POLICY LIMITATIONS NEED TO BE RESOLVED

Controversial policy issues continue to hamper pesticide regulation. For example, inconsistencies in the statutory provisions governing carcinogenic pesticide residues in food established under the major pesticide law and the major food safety law have not been resolved. Furthermore, EPA has been unable to establish policies or guidelines in several areas of risk management.

Differing Legal Requirements

The controversial Delaney Clause within FFDCA section 409 prohibits the establishment of tolerances for food additives found to cause cancer in humans or animals. EPA establishes tolerances under section 409 if a residue is concentrated in processed foods above the limit permitted on the raw commodity or if the pesticide is added to foods during processing. In addition, section 409 does not permit consideration of any benefits. In contrast, Section 408 of FFDCA--which applies to raw agricultural commodities--allows EPA to weigh human health risks against food production benefits when establishing tolerances for both carcinogenic and noncarcinogenic pesticides. Section 408 is consistent with the risk/benefit provisions of FIFRA. Consequently, FFDCA's provisions are inconsistent for regulating carcinogenic pesticide residues in raw and processed foods. Furthermore, since section 409 does not permit consideration of any benefits, it is inconsistent with the FIFRA standard requiring the weighing of risks and benefits.

Reconsidering the Delaney Clause

Since the Delaney Clause was added to FFDCA in 1958, scientific and legislative changes have necessitated congressional reconsideration of its appropriateness. In the scientific realm, analytical detection methods have advanced so that very low levels of substances can be detected, yet the risks to humans of low levels of carcinogens are unknown. In the legislative realm, since FIFRA was amended in 1972, EPA has been required to gather new data and reregister older pesticides. As a result, EPA expects to confront legal and regulatory problems posed by the Delaney Clause with increasing frequency as the agency reregisters pesticides and encounters inconsistencies between FFDCA section 409 on the one hand, and FFDCA section 408 and FIFRA on the other hand. In some situations, the risk-benefit standard in FIFRA would indicate that a pesticide registration should be retained, while the ban on carcinogens in FFDCA Section 409 would indicate that certain tolerances related to the same pesticide registration ought to be revoked. When we reported on this issue in 1981 and 1986 we concluded that the Congress should reconsider the appropriateness of the Delaney Clause.

In 1987, the National Academy of Sciences/National Research Council's Board on Agriculture published a report,[2] prepared at EPA's request, addressing impacts of current standards and possible different standards on dietary cancer risk and on pesticide use. According to the National Academy of Sciences study, the Delaney Clause will increasingly be a factor in future EPA decisions. Since EPA has never invoked the Delaney Clause to repeal an

[2]Regulating Pesticides in Food: The Delaney Paradox, Board on Agriculture, National Research Council, National Academy of Sciences (National Academy Press, Washington, D.C., 1987).

existing tolerance,[3] this issue will need to be resolved as EPA confronts a sizable number of cases where the clause may apply as reregistration proceeds. For the 53 pesticides identified as carcinogenic at the time of the Academy study, there were 31 foods with approved tolerances under section 409, and additional foods in which these pesticides are concentrated during processing were expected to be identified. As a result of reregistration, EPA will need to bring several hundred additional pesticide uses into compliance with the Delaney Clause, according to the Academy study. EPA has attempted to resolve this problem by proposing a negligible risk standard, but the proposal is involved in litigation.

Over the last few years several proposals have been made to resolve the inconsistencies between FIFRA and FFDCA; however, consensus on how the laws should be changed is proving hard to achieve. Three possible changes are establishing (1) a zero-risk standard for carcinogenic residues in both raw and processed food commodities, which would, in effect, extend the Delaney Clause to both sections 408 and 409 of FFDCA, (2) a negligible risk standard with no consideration of benefits, and (3) a weighing of risks and benefits, as can now be done under FFDCA section 408. Although we have not taken a position regarding these alternatives, we do have some observations about their advantages and disadvantages. The major advantages of choosing any of these alternatives would be to provide a consistent, clear direction for regulatory decisions, to end a debate that has sometimes sapped EPA resources as it makes and justifies its decisions about carcinogens, and to reassure a concerned public. As the pace of regulatory decisions accelerates with increased pesticide reregistration, it is particularly vital to resolve this issue promptly.

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[3]The agency has invoked the Delaney Clause to refuse tolerances for new pesticide active ingredients found to be carcinogenic.

Option 1--A Zero Risk Standard

Requiring EPA to ban all carcinogenic food-use pesticides would provide maximum protection to the public and be relatively simple to administer but could create adverse economic impacts to agriculture, the pesticide industry, and consumers. According to the National Academy of Sciences study, almost 200 crops--some 95 percent of all crops having tolerances--would lose certain tolerances. Effects would vary by crop and pesticide type; however, crops heavily dependent on fungicides, such as potatoes and peanuts, would suffer the most severe consequences because 90 percent of all fungicides (by weight) are carcinogenic or potentially carcinogenic.

Option 2--A Negligible Risk Standard

A negligible risk standard with no consideration of benefits has several advantages. First, certain lower-risk pesticides that might be banned under Delaney's no-risk standard could still be used. Second, if benefits are not considered, the public might not be as skeptical about economic interests interfering with food safety. Third, this option would significantly reduce risk, when compared to the current situation. A major finding of the National Academy of Sciences study was that a negligible risk standard for carcinogens in food, applied consistently to all pesticides and all forms of food, could dramatically reduce total dietary exposure to carcinogenic pesticides with modest reduction of benefits. The study's analyses were based on 28 of the 53 suspected carcinogenic pesticide active ingredients identified at that time. Specifically, consistent application of a negligible-risk standard could eliminate 98 percent of existing dietary risk from exposure to the 28 pesticides studied. In comparison, application of the Delaney Clause (as it applies to processed foods and their parent raw commodities) would reduce the estimated risk by only 55 percent.

This option also has some disadvantages. Because differing mathematical models for estimating human risk can produce widely varying estimates, assessments of cancer risk will continue to be controversial. As it considers this option, the Congress should be aware that the numeric risk estimates that EPA develops reflect a wide range of uncertainty. According to EPA officials, cancer risk estimates are rough estimates, representing 10-fold differences in risk. This is because mathematical models are used to extrapolate from the incidence of tumors observed at high doses in animal tests, to the incidence of tumors expected to occur at the relatively low doses in the human diet. Comparing an imprecise risk estimate to a precise numerical negligible risk standard can create an illusion of scientific certainty. The other disadvantage this has is that it might lead to banning a pesticide for which benefits outweigh risks.

Option 3--A Risk/Benefit Standard

Of the three options, balancing risks and benefits, as is currently done under FIFRA and FFDCA section 408, would allow the highest level of public exposure to carcinogenic pesticides, as well retain of the greatest number of pesticide uses. Within this option, some have proposed that the Congress place limits on the circumstances under which benefits could offset a degree of risk.

An advantage to the risk-benefit option is that it would increase EPA's flexibility in regulating pesticides. For instance, a pesticide with substantial benefits and no alternative could be retained. In another hypothetical example, if one pesticide presented little cancer risk and its alternative presented a different and significant health risk, such as a high probability of birth defects, regulatory flexibility could be advantageous.

With uncertainties--some of them unavoidable--existing in both risk and benefit assessment, such decisions would involve EPA in a

complex series of social judgments that could be controversial. Furthermore, a direct balance of risks and benefits is extremely difficult because the two are not directly comparable. If this option were adopted, strengthening EPA's internal policies and guidelines for assessing risks and benefits would be particularly critical.

Need for EPA Policies

In two reports issued in 1989 and 1991, we identified the following three areas in which EPA has been unable to set policies or guidelines for managing pesticide risks.

-- First, although EPA has the capability to assess risks to population subgroups (such as young children, ethnic groups, etc.), the agency has not established a policy as to whether, and in what circumstances, tolerance levels are to be based on the subgroup with the highest potential exposure to the pesticide.

-- Second, EPA has not established guidelines for performing anticipated residue studies and using such data in risk assessments, although such data have been used on a case-by-case basis for a substantial number of pesticides. EPA has recently made progress in this area and expects to issue guidelines soon.

-- Third, when EPA assesses risks from pesticide residues in food--in order to set tolerances--the agency is not routinely considering additional exposure that can result from pesticide-contaminated groundwater and has no plans to do so.

We believe that controversy over EPA's regulatory decisions has been exacerbated by the agency's lack of policies for risk and

benefit assessment. EPA has generally preferred to work on a case-by-case basis because of very real differences in pesticides' uses and risks to health and the environment. However, we believe that EPA could clarify its policies while still leaving room to account for these differences.

Establishing such policies would also have significant advantages for the agency. A case-by-case approach is resource-intensive. On the basis of our observations of EPA's regulatory efforts over many years, we believe that better policies and guidelines could streamline the processes for assessing risks and benefits and then making regulatory decisions. The "wheel" might need fine-tuning, but it would not have to be re-invented.

OBSERVATIONS

Long a contentious issue, the use of pesticides on food promises to remain controversial as EPA proceeds with reregistration and new information is brought to bear on established public policy positions and standards. Furthermore, fundamental differences in values and beliefs contribute to the controversy as much as limitations in data and methods and differences in scientific judgment. EPA is making some progress in pesticide reregistration, but the task will not be completed for years. In the interim, a number of issues need to be resolved. In particular, inconsistencies in legislative mandates for regulating carcinogenic pesticides used on food need to be resolved. Despite uncertainties arising from limitations in data and methods, as well as differences in regulatory philosophy--including whether and how pesticide benefits should be considered--this reconciliation is necessary to promote consistent pesticide regulation. In addition, it would enhance public and business confidence in federal pesticide regulation and in the safety of the nation's food supply.

Furthermore, EPA, USDA, and FDA need to resolve several long-standing management and policy issues that currently impede efficient pesticide regulation. For example, the agencies need to work together to improve the collection and management of data. In addition, EPA needs to set clearer internal policies or guidelines for managing pesticide risks--determining, for instance, whether tolerances should be set to protect the most vulnerable subpopulations.

Since, in some cases, it is unclear why the federal food safety agencies have not resolved several of these long-standing management and policy issues, we will continue to followup on our prior report recommendations during the course of our future work. However, although we have not specifically evaluated some of the reasons for inaction, we suspect, on the basis of other ongoing food safety work, that a combination of factors is contributing to federal agency inaction. At present, responsibility and accountability for pesticide and food safety are spread out over several departments and agencies with different legislative missions and mandates, and no strategic approach effectively bridges these differences and coordinates interagency concerns, such as data collection and management.

Lastly, our work raises several larger policy issues that the Subcommittee may wish to address, including (1) how much we, as a country, want to invest to reduce the uncertainty surrounding the assessment of the risks and benefits of pesticides used on food; and (2) whether the measurable gains of reducing the uncertainty will be worth the costs of reducing the uncertainty.

Mr. Chairman, this completes our prepared statement. We would be happy to respond to any questions.

LIST OF RELATED GAO PRODUCTS

Food Safety: USDA Data Program Not Supporting Critical Pesticide Decisions (Jan. 31, 1992, GAO/IMTEC-92-11)

Food Safety and Quality: FDA Needs Stronger Controls Over the Approval Process for New Animal Drugs (Jan. 17, 1992, GAO/RCED-92-63)

Pesticides: Better Data Can Improve the Usefulness of EPA's Benefit Assessments (Dec. 31, 1991, GAO/RCED-92-32)

Breast Cancer: Progress to Date and Directions for the Future (Dec. 11, 1991, GAO/T-PEMD-92-4)

Pesticides: EPA Lacks Assurance That All Adverse Effects Data Have Been Reviewed (Oct. 30, 1991, GAO/T-RCED-92-16)

Pesticides: EPA's Information Systems Provide Inadequate Support for Registration (Oct. 30, 1991, GAO/T-IMTEC-92-3)

Reproductive and Developmental Toxicants: Regulatory Actions Provide Uncertain Protection (Oct. 2, 1991, GAO/PEMD-92-3)

Reproductive and Developmental Hazards: Regulatory Actions Provide Uncertain Protection (Oct. 2, 1991, GAO/T-PEMD-92-1)

International Food Safety: Comparison of U.S. and Codex Pesticide Standards (Aug. 22, 1991, GAO/PEMD-91-22)

Nutrition Monitoring: Mismanagement of Nutrition Survey Has Resulted in Questionable Data (Jul. 26, 1991, GAO/RCED-91-117)

Environmental Protection: Meeting Public Expectations With Limited Resources (Jun. 18, 1991, GAO/RCED-91-97)

Pesticides: Food Consumption Data of Little Value to Estimate Some Exposures (May 22, 1991, GAO/RCED-91-125)

EPA Should Act Promptly to Minimize Contamination of Groundwater by Pesticides (May 8, 1991, GAO/T-RCED-91-46)

Pesticides: EPA could Do More to Minimize Groundwater Contamination (Apr. 29, 1991, GAO/RCED-91-75)

U.S. Department of Agriculture: Improving Management of Cross-Cutting Agricultural Issues (Mar. 12, 1991, GAO/RCED-91-41)

Pesticides: EPA's Use of Benefit Assessments in Regulating Pesticides (Mar. 7, 1991, GAO/RCED-91-52)

Food Safety and Quality: Who Does What in the Federal Government (Dec. 21, 1990, GAO/RCED-91-19A&B)

Disinfectants: Concerns Over the Integrity of EPA's Data Bases (Sep. 21, 1990, GAO/RCED-90-232)

Disinfectants: EPA Lacks Assurance They Work (Aug. 30, 1990, GAO/RCED-90-139)

FDA Resources: Comprehensive Assessment of Staffing, Facilities, and Equipment Needed (Sep. 15, 1989, GAO/HRD-89-142)

Guidelines Needed for EPA's Tolerance Assessments of Pesticide Residues in Food (May 17, 1989, GAO/T-RCED-89-35)

Reregistration and Tolerance Reassessments Remain Incomplete for Most Pesticides (May 15, 1989, GAO/T-RCED-89-40)

Pesticides: Economic Research Service's Analyses of Proposed EPA Actions (Mar. 14, 1989, GAO/RCED-89-75BR)

Health Risk Analysis: Technical Adequacy in Three Selected Cases (Sep. 30, 1987, GAO/PEMD-87-14)

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