Hearing: Food Safety Amendments of 1989

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ADDITIONAL MATERIAL

Senator HATCH. That is agreeable.

The CHAIRMAN. We can file additional questions and I do think it is helpful to all of the members of our committee to hear all the witnesses. As I say, I am reluctant to do it, but we will hear from each.

STATEMENTS OF CHARLES BENBROOK, BOARD ON AGRICULTURE, NATIONAL ACADEMY OF SCIENCES, WASHINGTON, DC; DAVID ROE, SENIOR ATTORNEY, ENVIRONMENTAL DEFENSE FUND, OAKLAND, CA; AND GARY M. BOOTH, DIRECTOR, TOXICOLOGY RESEARCH LABORATORY AND PROFESSOR OF ZOOLOGY, BRIGHAM YOUNG UNIVERSITY, PROVO, UT

Mr. BENBROOK. Thank you, Mr. Chairman. I am delighted to have three minutes to explain a problem I have been studying for 8 years. [Laughter.]

The CHAIRMAN. No. You get five.

Mr. BENBROOK. First of all, Mr. Chairman, Senator Hatch, I would like to commend you for your past efforts to try to deal with this problem. It is a very complicated problem. Very few people understand the full implications of the legislation that has to be drafted to deal with the inconsistency between the Food, Drug and Cosmetic Act and FIFRA statute. The legislation, Mr. Chairman, that you have drafted with Congressman Waxman goes a very long way toward doing just that. It is long. Very few people understand it. There is much behind it, including this whole report of ours. In my statement, I go through a number of factors that need to be assessed in perfecting the impact of that legislation.

I would like to not spend the time addressing what is in the testimony and go directly to what I think are the two dominant political problems that the committee faces if you are going to be able to perfect and pass this legislation. First of all, the bill can be faulted because it is somewhat overly aggressive. You have been dealing with this problem for eight, ten years, this problem of public concern about pesticide residues in the diet, and recent events have brought public concern to such a fevered pitch that in crafting the current bill, it really has tried in a very short amount of time to wring virtually all the risk out of the food supply, not just from pesticide active ingredients but also from inert ingredients.

This fact has created a great deal of concern in the food industry and in the agricultural industry, concern that too many pesticides will be lost to production agriculture too fast. They are not sure if that is going to happen. No one really understands what the bill will do, but particularly the four-year and the six-year stand risk reduction goals in the bill are very difficult to estimate what they will do. There is rather wide agreement that the two-year goal, the first goal of lowering all tolerances to a negligible risk level is both appropriate public policy and do-able. And Commissioner Young acknowledged that.

The food industry and the agri-chemical industry and food processors are raising the issue of benefits because they view that as perhaps the only way to stop several hundred tolerances being lowered to a point where the product cannot be used. So from that side

of the aisle, you are going to hear a lot of talk about benefits, and perhaps an overly aggressive standard.

On the other side of the issue are public interest and environmental groups that have looked at a record of EPA, which is not as strong as it could be in dealing with documented risks in the food supply. They have been dealing with ALAR for eight years, and it is still not resolved. All the fungicides that Senator Harkin noted, most of them have been under review for most of the 1980's and still essentially no steps have been taken to reduce the risks. So the public says EPA obviously must not be too concerned about these risks.

Their current program of re-registration and special review, as GAO and others have testified, will not come to closure until some time into the next century, which obviously is not acceptable. So these individuals look at the Delaney clause, the simple club of the Delaney clause, as about the only statutory provision with any hope of bringing about substantial reduction from pesticides in the food supply. And so they are very concerned about seeing this statutory tool compromised or weakened. When they hear a regulatory agency say, "We need more flexibility," they hear "No action." So you have got these two concerns working on both sides of the issue, and somehow in crafting legislation you are going to have to come up with a formulation that brings about, with a high degree of certainty, a large portion of risk reduction.

Our report estimated that you could eliminate 98 percent of the risk from the food supply with rather modest impacts on agriculture. And I would say that if you look at EPA's most recent analyses of those older pesticides, 90 percent is clearly within reach. This could be achieved in a year without legislation if they were to take action. With some modest amendments, the Kennedy bill could be crafted to force those actions, and we can get on with this problem.

The big concern and the problem that is going to, I think, pose the most difficulty for the committee is what to do about perhaps the last ten percent of risk, how strict a standard to use. I hope that the committee working with the agency can figure out a way to resolve this problem, and let us get the 90 percent that everyone agrees is there—we know what pesticides they are, and it is do-able within a very short amount of time—to eliminate that risk while additional statutory authority, better science, better enforcement is developed to deal with the remainder.

Thank you.

[The prepared statement of Mr. Benbrook along with responses to questions asked by Senator Kennedy follows:]

WILL S. 722 UNRAVEL DELANEY'S PARADOX?

PREPARED STATEMENT OF CHARLES M. BENBROOK, PH.D.

Mr. Chairman, I am delighted to have an opportunity to present testimony on S. 722, "Food Safety Amendments of 1989." My name is Charles M. Benbrook. I am the Executive Director of the Board on Agriculture of the National Research Council (NRC), National Academy of Sciences (NAS). I am accompanied today by my colleague, Mr. Richard Wiles, the staff officer in the NRC responsible for overseeing our work on pesticide regulatory issues, sustainable agriculture, and related matters.

In May of 1987 the NRC released a major report Regulating Pesticides in Food: The Delaney Paradox. We are pleased to note that several of the key provisions in S. 722 are based on our report's recommendations, and commend the Committee for taking action to resolve this perplexing and increasingly costly food safety dilemma. This morning I would like to highlight some of the major findings, conclusions, and recommendations of our report; identify provisions of S. 722 consistent with the report; note some aspects of the legislation that warrant further assessment, clarification, and possibly change; and, highlight a few critical food safety and pesticide regulatory policy issues that deserve the Committee's consideration.

Major Findings of the 1987 NRC Report

The principal findings of our committee were:

- There are about 8,500 separate tolerances covering a residue of a distinct pesticide used on a distinct food crop--for example, captan residues in grapes.

- For 53 pesticides the Environmental Protection Agency (EPA) identified as of July 1986 as suspect oncogens, there are about 2,500 tolerances set under section 408 of the Food, Drug, and Cosmetic Act (FDCA) covering residues in raw agricultural commodities; and 31 tolerances for residues in processed foods set under section 409 of the FDCA.

- There are about 3,180 distinct processed food forms, each derived from a raw agricultural commodity on which a distinct pesticide may be used.

- The universe of pesticide uses possibly effected by the Delaney Clause includes over 800 processed food forms, each derived from a distinct crop on which one of some 55 oncogenic pesticides is registered for use.

- There are just over 30 section 409 tolerances covering concentrating residues of oncogenic pesticides in processed foods. These 30 plus tolerances all appear to violate the Delaney Clause. Moreover, these 30 tolerances are only a small fraction of the number that will be needed once more complete residue chemistry data is submitted to the EPA, particularly given how the Agency currently measures whether residues concentrate.

- Ten fungicides account for over half the estimated worst-case dietary cancer risk from residues on or in fresh food. Across all three major types of pesticides (herbicides, insecticides, fungicides), fresh foods account for about 80 percent of total worst-case risk, and processed foods about 20 percent.

- Residues of a dozen or so pesticides in or on 15 or 20 crops accounted for at least 90 percent of the total estimated worst-case risk.

- EPA has applied the Delaney Clause only to newer pesticides, even though older pesticides (those first registered before 1978) account for well over 90 percent of total worst-case dietary risk.

- EPA cites the Delaney Clause as the reason for denying registration of new pesticides posing worst-case cancer risks on the order of 10^{-7} to 10^{-8}, even though these new products would provide farmers a clearly safer alternative pesticide posing risks one hundredfold or more below the risk levels associated with currently registered products.

- Consistent adherence to a 10^{-6} negligible risk standard--applied to new and old products, all types of pesticides, and to the combination of residues in raw and processed foods derived from a particular use of a pesticide--would eliminate the vast majority (more than 90 percent) of worst-case estimated risk. To achieve this level of risk reduction, only 32 percent of all tolerances covering use of oncogenic pesticides--or about 750 tolerances--would need to be revoked. To eliminate the remaining 2 percent of risk, an additional 1,500 tolerances would have to be revoked.

- Strict and immediate adherence to the Delaney Clause would eliminate, at most, a little over half the current level of worst-case risk in the diet, through revocation of nearly 2,000 tolerances covering use of oncogenic pesticides on 38 different crops.

These findings and the committee's extensive deliberations on the challenges facing EPA in moving through the re-registration process on some 200 or more older pesticides used on food crops, led the committee to reassess the current statutory scheme and regulatory approach governing

pesticide residues in food. Based on the committee's analysis, four major recommendations were offered. I attach the Executive Summary of our 1987 report, Regulating Pesticides in Food: The Delaney Paradox, which explains in more detail the analytical foundation of these findings and the committee's principal recommendations.

Recommendations of the 1987 NRC Report

Our four principal recommendations are:

- A consistent standard should be applied to pesticide residues in raw and processed foods, to new and old pesticides, and to all types of pesticides.
- A negligible risk standard, applied consistently, could dramatically reduce risk with modest reduction of the benefits from the use of pesticides.
- "Logic argues that the EPA should focus its energies on reducing risk from the most worrisome pesticides on the most consumed crops, and compelling reasons support such a strategy." (page 14, Regulating Pesticides in Food: The Delaney Paradox)
- EPA should develop and apply improved analytical tools and a systematic approach to assessing dietary risks from pesticides.

Major Provisions of S. 722

S. 722 is a complex, comprehensive bill that goes well beyond the recommendations in our 1987 report. It is an ambitious bill in that it strives in a relatively short period of time to remove nearly all dietary risk both from pesticide active ingredients and pesticide product inert ingredients. (Under the provisions of S. 722, the task of dealing with inert ingredients could pose considerable drain on Agency resources, and would direct attention away from other challenges such as pesticides in ground water and developing scientifically sound regulatory principles to assess the safety of pest control technologies evolving from recombinant DNA techniques.)

As the Committee considers amendments to S. 722, attention should be directed to the administrative feasibility and cost of the bill's major provisions, with a special focus on perfecting and passing those sections of the bill that would bring about substantial risk reduction without posing potentially large costs on farmers, the regulated industry, EPA, and society as a whole.

Two key provisions of S. 722 are consistent with the NRC report's recommendations:

- The existing statutory inconsistency is resolved between the tolerance-setting standards established in section 408 and section 409 in a direct, and common sense approach.

- A negligible risk standard is proposed, and applied consistently to all pesticides.

While conceptually consistent with several key aspects of the 1987 NRC report, S. 722 would bring about an even more rapid and dramatic reduction in risk than a regulatory strategy patterned after the committee's basic recommendations. Recall that our recommendations, if fully adhered to, would eliminate 95 percent or more of the oncogenic risk posed by pesticide residues in the diet. Two central features of S. 722 warrant further consideration.

- When setting tolerances consistent with a negligible risk standard, the bill requires EPA to consider unique risks faced by vulnerable population groups (infants, children, pregnant women, the ill), and people who may consume relatively larger quantities of particular pesticides because of unusual dietary patterns.

A possible problem in requiring EPA to consider risks faced by infants and children is that EPA lacks the scientific knowledge base to do so. As written, S. 722 can be interpreted to require EPA to postpone tolerance adjustments until new scientific methods are developed and new toxicology data is generated by registrants. As an alternative, the Committee might direct EPA to set tolerances at levels consistent with a negligible risk standard, based on currently available data and prudent risk assessment methods.

Developing sound risk assessments methods for special population groups will take several years, since EPA still is uncertain about what new studies to require. Indeed, the NRC is currently undertaking a major study, mandated by Congress and supported by EPA, on how to incorporate in the pesticide regulatory process the unique consumption patterns and toxicological susceptibility of infants, children, and pregnant women. (See attached description of this committee's mandate and activities.) Our ongoing study is a first step in a process bound to take at least a decade.

- The bill requires that the combined risk from all uses of a pesticide meet the negligible risk standard in four years. Our committee found that a crop-wide approach (e.g., all fungicides registered on a given crop) to regulation is a more effective, reliable way to reduce risk. Accordingly, the committee recommended to EPA that pesticide risks and benefits should be estimated for each distinct crop, across all pesticides of the same type registered for use on the crop (for example, fungicides registered for use on peaches, herbicides used on soybeans).

Several problems could arise as a result of the four-year goal under S. 722. It would be administratively difficult to determine how to meet

the goal. It would place the Agency in an awkward position where it would have to choose which crop uses to spare and which to cancel. It could conceivably penalize chemicals with many uses, and might exacerbate the loss of minor use registrations under re-registration. It could set back efforts toward Integrated Pest Management (IPM), an approach to pest control that can dramatically reduce overall reliance on pesticides, but does so in part through judicious, occasional use of a wide range of pesticide products. Attempts to slow the emergence of pesticide-resistant pest populations would be made more difficult in some instances. To meet the four-year goal, EPA would, in all likelihood, have to cancel many additional tolerances for at best marginal additional gain in public health protection. The bill's six-year risk reduction goal would exacerbate many of these potential problems.

Critical Questions Before the Congress and the Public

Several key policy issues should be addressed thoughtfully as food safety reform legislation is developed by the Committee. Some questions reflect the role of benefits in regulatory decisionmaking, others arise from the imperfect art of risk assessment--most regulatory actions are now based upon very crude estimates of human risk. In most instances, current models and data over-estimate human risk, but in other cases, possibly significant sources of risk may be missed. In addition, significant data gaps persist, and science is just beginning to consider additional biological endpoints--neurotoxicity, and immological effects are two examples.

The Appropriate Standard and How to Apply It to Both New and Old Pesticides.

The effectiveness and cost of S. 722 will be determined, in large part, by how it defines and applies negligible risk, at what level a negligible risk standard is set, and what EPA is required to do (and how fast) to reduce existing tolerances that currently could pose risks above a negligible level.

Pesticide residues in the diet are often the most worrisome result of a pesticide's use. In other cases, worker exposure, wildlife impacts, or groundwater contamination may be the Agency's greatest concern. By tightening down aggressively and exclusively on dietary risks, full implementation of the provisions of S. 722 as written will lead to the cancellation of many pesticide uses, some of which may pose rather marginal dietary risks. As a result, farmers will have to switch to other products or technologies, which may pose other, more serious risks. The loss of several hundred major uses of the 10 registered oncogenic fungicides could prove particularly worrisome, since it is unclear how quickly farmers could adapt, or whether the public would face greatly elevated risks from natural molds, fungi, and toxicants which would be more difficult to keep in check.

Procedural Inconsistency With the FIFRA Statue

Our 1987 report addresses the need to eliminate inconsistency between the standard governing the setting of tolerances under FIFRA (risk-benefit) and section 409 (Delaney Clause zero-risk). S. 722 would resolve this inconsistency, but inadvertently creates a possibly significant procedural inconsistency. Tolerance reductions mandated by S. 722 will clearly have to be accompanied by changes in some pesticide product labels. Labels are what govern lawful pesticide use, and are the critical link between farmers and applicators, and attainment of public health and environmental protection goals.

Label changes that involve restricting the number of applications, rates of application, or pre-harvest intervals, however, must be made following the administrative procedures and risk-benefit standards in FIFRA. Through amendments to the FDCA, S. 722 will compel EPA to reduce tolerance levels in several hundred cases as a necessary step to save a registration. In some of these cases, accompanying label changes will be essential in order to keep actual residues on or in food below the now lowered tolerance levels. Yet, EPA must base such label changes on a risk-benefit determination, thereby triggering the complex, time-consuming procedures inherent in the FIFRA statute. Regrettably, EPA lacks statutory authority under FIFRA to reduce tolerances in an administratively expeditious fashion. The obvious remedy to this situation, possibly as a companion bill or amendment to S. 722, is a new section in FIFRA providing EPA conditional risk reduction authority, patterned after the Agency's current authority to grant conditional registrations. (Conditional registration authority allows EPA to grant a registration "conditionally," pending receipt of additional data. Congress granted EPA this authority to lessen the time period needed to gain new product registrations.)

The need for conditional registration in the late 1970s is matched in the late 1980s by the need for conditional risk reduction authority, coupled with a more expeditious suspension/cancellation process. To resolve potential procedural problems following passage of S. 722, Congress must somehow work around or overcome long-standing jurisdictional tensions that arise when Congress attempts to harmonize and/or modernize environmental and public health protection policies in the FIFRA and FDCA statutes.

The Role of Benefits and How to Calculate Them

Events in recent months highlight the difficult public policy issues that arise in the context of considering benefits in pesticide regulatory decisionmaking. S. 722 would eliminate consideration of benefits when risks are above a negligible level. This change in policy would greatly simplify the regulatory process, and provide EPA new authority to act decisively in reducing tolerances when data shows a pesticide might pose risks above a negligible level. It is important to note that S. 722 does not eliminate consideration of benefits in all cases, an erroneous claim that arose repeatedly in hearings before Congressman Henry Waxman's subcommittee.

If the negligible risk standard is defined and applied as proposed in S. 722, the lack of any consideration of benefits becomes more worrisome to farmers and the food industry, who fear the prospect of losing many, perhaps most uses of the approximately one-third of currently registered food use pesticides that pose some level of oncogenic risk. This may not sound threatening to the Committee or the public, since there would still be many products available. The problem, however, is the prospect of major changes in our ability to produce several major fruit and vegetable crops, foods that we all need to eat more of to meet dietary goals (see the recently released NRC report Diet and Health). Production of these crops in humid regions in the southeast, mid-Atlantic, and northeastern states would become difficult to sustain, unless there are dramatic and unanticipated developments in application of genetic engineering and biological pest control.

The impact of S. 722 on other farmers' ability to control pests would be, for most of American agriculture, modest. But for a few crops, in a few regions, in certain years, the impact would clearly be of major concern. In some cases, crop yields would decline, raising per unit costs. In other cases, farmers would be unable to protect produce and fruit from certain diseases and pests that blemish or scar the surface of fruit or vegetables. This loss of quality would drive down prices, unless consumer attitudes change, and could increase natural sources of risk in the diet.

These considerations raise the need to revisit the role and definition of benefits in pesticide regulation. What sorts of benefits should be taken into account? How should they be measured?

The 1987 NRC report did not speak directly to this issue. If and when benefits are considered, many people argue that they should be defined more broadly. Ideally, the assessment of benefits should not stop at the farmgate, as is currently the case for all intents and purposes. The net benefits of alternative pest control strategies--chemical and non-chemical--should be estimated, taking into account the cost and availability of food, the ability to supply fresh fruits and vegetables year-round (a key factor in building consumer acceptance), the potential risks of pesticides and natural toxicants from food produced overseas or grown in this country without effective control measures, the cost of public and private efforts to assure and monitor the safety of the food supply (already several hundred million annually, growing fast with no end in sight), and the prospective direct and indirect costs of human health problems likely to result from registered uses of pesticides (both acute and chronic problems in manufacturing plants, on the farm, among farmworkers, people drinking contaminated water in certain farming regions, and the general public).

In defining the role for benefits in pesticide regulatory decisionmaking, the Congress should assess realistically the cost and feasibility of carrying out benefits assessments. Given current methodologies and data for making such estimates, it could be both contentious, and certainly will be costly to estimate pesticide use benefits in a way which is analytically sound. Does it make sense to invest more heavily in learning how to estimate pesticide benefits for

several thousand uses of old pesticides in an era when funding is almost non-existent for research on the biological control of pests, the adoption of proven Integrated Pest Management systems, and non-chemical alternatives to pesticides? I hope Congress will ponder this key question of priorities and public policy.

In closing, I would like to stress that S. 722 is ambitious, comprehensive, and carefully drafted legislation. While a number of potential problem areas have been noted, rather modest changes in S. 722 could largely alleviate these problems. It is assuredly far more important for the Congress to perfect and pass this legislation than proceed toward passage of legislation banning Alar, the latest but not last pesticide to gain national attention. The decision last week by the manufacturer of Alar to suspend sales until safety issues are resolved lessens the need for Congress to ban this product through legislation. Hopefully, the Congress will now focus its attention on S. 722.

Thank you for the opportunity to speak before the committee this morning. I commend you and the Committee for taking on this politically contentious task.

REGULATING PESTICIDES IN FOOD

Executive Summary

In February 1985, the Environmental Protection Agency (EPA) asked the Board on Agriculture of the National Research Council to study the EPA's methods for setting tolerances for pesticide residues in food. Specifically, the EPA asked the board to examine the impact of the Delaney Clause on the tolerance-setting process. Although the Delaney Clause appears on its face to be a minor feature of the complex statutory scheme governing the regulation of pesticides and pesticide residues in food, its potential impact on the EPA's future decision making is great.

The EPA establishes tolerances for pesticide residues on raw commodities under section 408 of the Federal Food, Drug and Cosmetic (FDC) Act. Enacted in 1954, this law stipulates that tolerances are to be set at levels deemed necessary to protect the public health, while taking into account the need for "an adequate, wholesome, and economical food supply." Section 408 thus explicitly recognizes that pesticides confer benefits and risks and that both should be taken into account in setting raw commodity tolerances.

Pesticide residues that concentrate in processed food above the level authorized to be present in or on their parent raw commodities are governed by the FDC Act's section 409, the law governing food additives. Under section 409, such residues must be proven safe, which is defined as a "reasonable certainty" that "no harm" to consumers will result when the additive is put to its intended use. Consideration of benefits is not authorized. Moreover, section 409 contains the Delaney Clause. This clause prohibits the approval of a food additive that has been found to

"induce cancer" (or, under the EPA's interpretation, to induce either benign or malignant tumors—i.e., is oncogenic) in humans or animals.

The dichotomous statutory standards applicable to tolerance setting inspired this study. A pesticide regulated on a risk/benefit basis at the time of registration and in the setting of tolerances for residues in or on raw agricultural commodities becomes, solely because it concentrates in processed food, subject to the Delaney Clause's ostensible zero-risk standard. This shift in criteria has potentially far-reaching effects. If any portion of a crop to which an oncogenic pesticide has been applied is processed in a way that will concentrate residues, the EPA's current policy is to deny not only a section 409 tolerance for the processed food but also a section 408 tolerance for residues of the pesticide in or on the raw commodity. Further, if required section 408 tolerances cannot be granted for a food-use pesticide, the EPA must also deny registration of the pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The EPA's policy concerning application of the Delaney Clause to new pesticides and new uses is fairly clear. The EPA's policies are currently less settled regarding the large number of already-registered pesticides, however, and are expected to come under intense pressure in coming years. The sources of this pressure are the following:

- The EPA has instituted programs to expand substantially the data on the toxicological properties of pesticides and the tendency of individual pesticides to concentrate in processed foods.
- Once tested in accordance with contemporary standards, many older pesticides are likely to be identified as oncogenic or potentially oncogenic, inviting regulatory action by the EPA.
- As more data on the tendency of pesticides to concentrate in processed food become available, many more currently registered pesticides will be shown to need section 409 tolerances and thus will become subject to the Delaney Clause.

It is unlikely that the EPA will be able to avoid applying the Delaney Clause to registered pesticides. Thus, as the agency proceeds through the reregistration process, it must determine how to apply the zero-risk standard of the Delaney Clause to a significant number of currently registered, commercially important pesticides. Because of the potential magnitude and complexity of this task, the EPA asked the Board on Agriculture to undertake this study.

The committee undertook three principal tasks. First, it examined the statutory basis of tolerance setting for pesticide residues in food and the operation of the tolerance-setting process at the EPA. Second, it developed a computerized data base to estimate the potential dietary oncogenic

risk associated with pesticides determined or suspected by the EPA to be oncogenic. Third, using the data base it had developed, the committee analyzed the impact of alternative approaches to tolerance setting on estimated cancer risks and pesticide use and development.

THE COMMITTEE'S ESTIMATES OF ONCOGENIC RISK

The analytical methods involved in estimating oncogenic risks from pesticide residues in food contain many areas of scientific and technical uncertainty. The assumptions made to account for these uncertainties can have profound implications for the resulting risk estimates. For example, the calculation of exposure to pesticide residues in a given foodstuff can yield risk estimates that vary by an order of magnitude. The committee assumes all residues are at the tolerance level, although actual residues may be different. Likewise, assumptions regarding how and when to aggregate risks from a pesticide used on a variety of crops can significantly alter risk estimates. The quantification of a pesticide's oncogenicity potency, called a Q star or Q^*, can also vary by orders of magnitude, depending on such factors as whether a surface area or body weight correction is made in extrapolating risks from rodents to humans, the choice of extrapolation model, or whether malignant and benign tumors are combined when calculating the response to a given dose. The Q^*'s used by the committee were calculated by EPA scientists and have not been formally peer reviewed.

The EPA generally follows a conservative policy in estimating risk. Whenever assumptions must be made, the agency attempts to make them in a way that minimizes the chance of underestimating risks. The cumulative result of these assumptions is an upper-bound estimate of additional oncogenic risk above the background cancer risk of 1 in 4 or 0.25 (2.5×10^{-1}). For perspective, it is worth noting that an additional dietary oncogenic risk of 1 in 1 million or 1×10^{-6} would raise this background risk of 0.25 to 0.250001. In developing the risk estimates contained in this report, the committee adopted what it understood to be the EPA's current methodology for quantitative risk assessment, recognizing that many key elements of the agency's risk assessment procedures are under review. This report only notes the importance of these assumptions and underlying issues; it does not offer resolutions.

In arriving at a regulatory position on an oncogenic pesticide, the EPA considers the relative significance of all the evidence of oncogenicity for a compound. This "weight-of-the-evidence" approach involves considering many qualitative factors such as the tumor type, results of mutagenicity bioassays for the compound, and negative oncogenicity test results. In calculating the distribution of dietary oncogenic risk and the conse-

quences of regulatory scenarios examined in this report, the committee did not use weight-of-the-evidence techniques. Instead, it relied entirely on the quantitative risk assessment methods that the EPA uses. Risk estimates are generally shown with the EPA's oncogenic classification for the compound, however. This classification system is designed to characterize a pesticide's oncogenicity in humans (see Chapter 3).

The reader should understand that a wide margin of uncertainty surrounds nearly all of these numbers. With this in mind, the reader should focus on general patterns of risk distribution and how key parameters change when policy alternatives are assessed, not on specific point estimates of risk.

The committee further emphasizes that all risk estimates in this report are limited to oncogenic risk from pesticide residues in food. This does not imply, however, that other risks presented by pesticides or other routes of exposure are less important. Indeed, the regulation of pesticides involves a consideration of many health and environmental risks, only one of which involves residues of oncogenic pesticides in food.

ESTIMATED ONCOGENIC RISK AND ITS DISTRIBUTION IN THE FOOD SUPPLY

To characterize the universe of oncogenic pesticides, the committee adopted the list of 53 suspected oncogenic compounds that the EPA transmitted to Congressman Henry Waxman (D-Calif.) in October 1985. Of these compounds, the committee limited its analysis to three types of pesticides—herbicides, fungicides, and insecticides. The risk estimates discussed in this report are derived from only 28 of these 53 active ingredients (see Chapter 3). To roughly characterize the benefits associated with the use of these oncogenic compounds, the committee assembled crop use and farm-level expenditure estimates averaged over three years on all 53 compounds.

Findings

The committee's analysis indicates that the Delaney Clause will be central to the EPA's decision making in future years.

First, the EPA considers a substantial fraction of all herbicides, fungicides, and insecticides to be oncogenic or potentially oncogenic in animal studies. On the basis of pounds of pesticide applied, 60 percent of all herbicides are oncogenic or potentially oncogenic. (This number includes two compounds not on the "Waxman list" that have since been found to be suspect oncogens, raising the percentage from around 40 percent to just over 60 percent.) By volume, 90 percent of all fungicides fall into this category, as do about 30 percent of all insecticides.

Second, for the 53 oncogenic compounds, the committee has identified 31 processed foods with approved section 409 tolerances. All of these appear to conflict with the Delaney Clause. Moreover, the committee has identified an additional 778 processed foods *with no 409 tolerances* for which oncogenic pesticides are registered. Residues of these pesticides are expected to concentrate in many of these processed foods. Hence, over the next few years, the EPA will face bringing several hundred additional pesticide uses into compliance with section 409 of the FDC Act and the Delaney Clause.

Third, over the next five years, the EPA is scheduled to complete regulatory actions that will force decisions on compliance with the Delaney Clause for 10 currently registered oncogenic pesticides. These pesticides account for between 80 and 90 percent of the total estimated dietary oncogenic risk from residues of the 28 compounds that comprise the committee's risk estimate (see Chapter 3).

Fourth, the committee explored the distribution of dietary oncogenic risk from residues of these 28 pesticides. Fungicides account for about 60 percent of all currently estimated dietary oncogenic risk from these 28 compounds. Of the remaining risk, 27 percent stems from crop uses of herbicides and 13 percent from insecticides. Fungicides, however, account for only about 7 percent of all pesticide sales and less than 10 percent of all pounds applied. Further insights derived from the committee's analyses of these 28 pesticides include the following:

- About 55 percent of the total estimated dietary oncogenic risk stems from residues on crops that have raw and processed food forms.
- About 20 percent is associated with consumption of the processed forms of these crops. Approximately 35 percent is from consumption of the raw form of the same crops.
- About 45 percent of estimated dietary oncogenic risk is from foods that the EPA considers to have no processed form. These foods include many fruits and vegetables and *all* meat, milk, and poultry products.

These figures lead to several observations:

- At most, the Delaney Clause could apply to processed-food residues responsible for only one-fifth of the estimated dietary oncogenic risk from pesticides. However, its implementation could eliminate another 35 percent of the estimated risk from residues on the raw forms of these processed foods because it is the EPA's policy to deny section 408 raw food tolerances when section 409 tolerances cannot be established for the processed forms of the same crop.

• Foods accounting for nearly one-half of the total estimated dietary risk (all meat, milk, poultry, and pork products and many fruits and vegetables) are ostensibly beyond the scope of the Delaney Clause, because under current EPA guidelines they have no processed form.

Fifth, dietary oncogenic risk appears to be concentrated in a relatively small number of pesticides and crops. Nearly 80 percent of the estimated dietary oncogenic risk (from all 178 food uses of the 28 compounds that comprise the committee's risk estimate) is from residues of 10 pesticides on only 15 different foods.

IMPACTS OF FOUR ALTERNATIVE WAYS TO REGULATE ONCOGENIC RESIDUES

The committee studied the implications of four theoretical policy scenarios, or frameworks, for regulating residues of oncogenic pesticides in food. The committee emphasizes that these scenarios are artificial constructs chosen not because they reflect any current regulatory approach but rather because they represent a plausible range of approaches. Further, the committee does not offer a legal opinion on the compatability of any of these scenarios with current law or interpretation. These tasks were not in the committee's charge.

Scenario 1 applies a zero-risk standard for oncogenic risk to all pesticide residues on both raw and processed foods. If the EPA determined that a pesticide was oncogenic, all food tolerances for that pesticide would be revoked.

Scenario 2 applies a zero-risk standard for oncogenic risk to all pesticide residues in *processed* foods: any residue of an oncogenic pesticide in a processed food would be disallowed. This scenario further assumes that when residues of an oncogenic pesticide are present in the processed portion of a crop, tolerances for both raw and processed forms would be revoked.

Scenario 3 would revoke all tolerances for a pesticide on a crop when the combined estimated cancer risk from the residues of that pesticide on both the raw and processed forms of a crop exceeds 1 in 1 million or 1×10^{-6}.

Scenario 4 would revoke all tolerances for a pesticide on a crop when the total risk from residues of a pesticide on all *processed* forms of a crop exceeds 1×10^{-6}. As under scenario 2, when residues on the processed form of the crop trigger revocation, both raw and processed food tolerances would be revoked.

Results of the Scenarios

Scenario 1 would revoke all tolerances for all oncogenic pesticides and eliminate all estimated dietary oncogenic risk.

Scenario 2 would revoke tolerances that would reduce dietary oncogenic risk (from the 28 pesticides that constitute the committee's estimate of dietary oncogenic risk) by 55 percent, ignoring about 45 percent of total estimated dietary risk from foods with no processed form.

Scenario 3 would reduce total estimated risk from these 28 compounds by 98 percent, while revoking only 32 percent of all tolerances for the 28 oncogenic pesticides.

Scenario 4 would eliminate just 35 percent of the estimated dietary oncogenic risk, while revoking the smallest percentage of all tolerances.

The most significant finding from the committee's crop level analyses is that under a "negligible risk" standard applicable to residues on both raw and processed food—illustrated by scenario 3—a high percentage of total risk is eliminated while a low percentage of "benefits" (as measured here by acre treatments and expenditures) are lost. For certain crops, scenario 4 would also eliminate a high percentage of total risk while affecting a low percentage of benefits. Scenario 4 would be less effective at reducing overall risk, however, by not addressing tolerances on three of eight crops.

Scenarios 1 and 2 have the same effect on all crop-pesticide combinations examined except peanut fungicides; all oncogenic risk from residues on these crops would be eliminated. In most cases, tolerances associated with a significant percentage of current pesticide expenditures and acre treatments on these crops would be lost. For certain crops in certain regions, the loss of all oncogenic compounds—particularly fungicides—would cause severe short-term adjustments in pest control practices because of the lack of economically viable alternatives.

Findings

The four scenario analyses suggest that progress toward risk reduction could be the greatest and most uniform when raw and processed foods are subject to a consistent risk standard. The potential advantages of a negligible risk standard, with no consideration of benefits, are also highlighted. Such a standard, consistently applied, could eliminate most existing dietary oncogenic risk while allowing continued use of—and benefits from—certain low-risk compounds.

AN ANALYSIS OF THE FUNGICIDES: A SPECIAL CASE

Fungicides present a unique problem. The EPA needs to establish hundreds of new processed-food tolerances for these compounds, but about 90 percent by weight of all fungicides now applied are considered potential oncogens. All but 1 of the 14 oncogenic fungicides were

registered more than 15 years ago. These older pesticides are relatively inexpensive, remain effective in various applications, and provide significant benefits to agricultural producers and consumers. These fungicides are important in the production of many high-value fruit and vegetable crops, particularly in the eastern and southeastern regions of the country. The eleven fungicides in the committee's total risk estimate represent less than 10 percent of all acre treatments with pesticides, but are responsible for about 60 percent of the total estimated dietary oncogenic risk.

The mode of action of fungicides makes it difficult to develop compounds that are nontoxic to genetic material. As a result, few effective non-oncogenic new fungicides are being developed. Only four fungicides registered since 1972 have gained greater than 5 percent of the market share for any food crop. Data on several of these compounds indicate oncogenicity and other chronic effects, however.

The combination of the above factors makes the regulation of oncogenic risk from fungicide residues extremely complex. It is the committee's view that literal application of the Delaney Clause will significantly complicate the EPA's efforts to reduce dietary oncogenic risks from fungicides. The committee performed several simple analyses (see Chapter 5) showing that sequential tolerance revocations or denials for one active ingredient at a time could in some cases actually *increase* human dietary oncogenic risk and in many other cases only lower it slightly. These results would occur when the use of a fungicide presenting an equal or greater risk *increased* after tolerances for a less-hazardous compound were revoked.

In response to this dilemma, the committee examined the effect of cropwide tolerance reductions as a means for reducing estimated dietary risk from fungicides. Even a cursory analysis suggests that this and other new regulatory strategies warrant detailed study in terms of their potential to bring about significant reduction in dietary oncogenic risk while preserving beneficial fungicide uses. Cropwide tolerance reductions could reduce the total estimated dietary oncogenic risk from fungicides by up to 50 percent with only modest enforcement effort and minor adjustments in the agricultural sector.

PESTICIDE INNOVATION AND ALTERNATIVE PEST-CONTROL METHODS

Despite the development of pest resistance to chemical pesticides, environmental damage, applicator risk, and fears of cancer associated with pesticide use, most farmers believe that pesticides are a critical part of a reliable and cost-effective pest control strategy. If a large number of tolerances for oncogenic pesticides are revoked over the next five years,

adequate replacement pesticides, particularly fungicides, probably would not be available for several major fruit and vegetable crops. For herbicides, however, the prospects are more optimistic. Considering all alternatives being developed, it appears that the loss of several major oncogenic herbicides would not pose a serious threat to agriculture. The outlook for insecticides lies somewhere between that for herbicides and fungicides.

The simultaneous loss of several oncogenic fungicides as described above could present serious disease control problems in certain crops in major production regions. Further, the rate of successful new product development within the three major categories of pesticides is almost inversely proportional to dietary risk; innovation has not been occurring to address the problem of oncogenicity.

Alternative Technologies

Advances in classical plant breeding, innovation in biological and cultural pest control systems, and progress in genetic engineering offer some promise for nonchemical pest control in the future. Nonchemical approaches will be encouraged by tolerance revocations if more profitable chemical controls are not available. For many crops, especially fruits and vegetables, there are few equally effective technologic alternatives to chemical pest control. More important, as with synthetic chemical pesticides, R&D efforts in alternative technologies do not appear directed toward the pest problems most likely to be affected by Delaney Clause–driven tolerance revocations; breeding for disease resistance is an important exception.

Because of the time needed to further develop plant genetic engineering techniques, new technologies involving or derived from biotechnology will not be available to reduce the impact of the next five years of regulatory actions. Although plant breeding offers the promise of more pest-resistant crop varieties, these new varieties will probably lower rather than eliminate the need for pesticides. The objective of biocontrol techniques is to establish a more stable pest control situation in the long run, but these methods are often complex and do not always provide the certainty that chemical pesticides provide. The problems with these alternative technologies will delay the adoption of nonchemical techniques in the absence of incentives.

The Effect of the Delaney Clause on R&D

In the long term, a rigorous application of the Delaney Clause to both existing and new pesticides is likely to shift the focus of public and private

R&D away from oncogenic compounds and reduce the total investment in chemical pesticides. This shift and reduction of investments will depend on factors that the committee was not able to examine quantitatively, including the structure of the industry (corporate mergers), regulatory developments, and scientific breakthroughs. If gross sales of agricultural chemical companies are reduced or if net returns become more variable as a result of tolerance revocations, however, revenues available for these R&D activities will decline and overall innovation is likely to fall. These declines in R&D investments are more likely if revocations lead to increased use of nonchemical controls—developments that provide no profit for pesticide companies.

The Minor Use Issue

All fruit and vegetable crops grown in the United States are considered "minor" crops in terms of pesticide use. Most minor crops have no recognized processed forms under EPA regulations. Most minor crops also present relatively small oncogenic risks. The important issue with these crops is whether pesticides currently vital to their production will remain available when the tolerances for oncogenic pesticides on other crops are revoked pursuant to the Delaney Clause.

Certain minor crops with processed forms *do* present potentially significant risk, however. Apples, tomatoes, grapes, potatoes, and citrus are directly vulnerable to tolerance revocations under any version of the Delaney Clause. In contrast to most minor crops, these crops represent intermediate markets for pesticide producers and therefore provide an incentive for product development. In this fashion, the continued availability of pesticides for small minor crops is linked to the continued availability of pesticides on "minor" crops representing larger markets.

Liability for crop failures or crop injury is another potential obstacle to future pesticide availability for small minor crops. This results from the limited acreage of these minor crops and hence the limited pesticide market they provide, relative to potential liability for control failures. Liability is high because these crops have high per acre value and must meet high-quality standards.

The Delaney Clause and Pest Resistance

A distinct value of many widely applied, suspect oncogenic fungicides is that even after years of use, pests show little if any resistance to them. In contrast, a number of pests have developed some degree of resistance to many of the new, non-oncogenic or more weakly oncogenic fungicides and insecticides. The viability of many of these newer compounds is often

linked to their simultaneous use with the older oncogenic compounds. Given the large number of tolerances for older fungicides that may be revoked under the Delaney Clause, there is a critical need to develop non-oncogenic fungicides as well as resistance management programs for these fungicides in the next five years.

MAJOR CONCLUSIONS AND RECOMMENDATIONS

The committee's analysis and findings support four basic conclusions. The first deals with the legal and institutional base for regulating oncogenic pesticide residues in food. The second addresses the possible roles of other than zero oncogenic risk criteria in targeting regulation on pesticide uses that pose potentially significant human health hazards. The third involves the need for and structure of an overall strategy for the EPA as it moves ahead with the task of bringing all existing pesticide registrations and tolerances into compliance with the law, including the Delaney Clause. The fourth describes the adoption of an analytical framework to facilitate a more systematic examination of the risks and benefits associated with pesticides.

Legal Basis for Regulation

Pesticide residues in food, whether marketed in raw or processed form or governed by old or new tolerances, should be regulated on the basis of consistent standards. Current law and regulations governing residues in raw and processed food are inconsistent with this goal.

First, the committee can discover no scientific reason for the law's different treatment of raw and processed food tolerances. Because the committee could find no scientific reason for this disparity, it recommends the consistency and simplification of treating them alike.

Second, residues stemming from the use of older pesticides should be subject to the same scrutiny and standards as those applied to residues from new pesticides. Although concentrating on new pesticides that might present new dangers was a reasonable policy when the regulation of pesticides began, new analyses, data, and criteria provide compelling reasons for uniform treatment of old and new compounds. Neither the FDC Act nor FIFRA provides a clear basis for treating residues of new pesticides differently from those of old pesticides. Subjecting old tolerances to contemporary safety criteria is essential.

The committee's analysis demonstrates that about 90 percent of estimated dietary oncogenic risks from pesticides stems from uses sanctioned by tolerances granted before 1978. The only way for the EPA to reduce

dietary risk substantially is to subject old pesticides to the same regulatory scrutiny it applies to new agents. Doing so in the context of reregistration will provide the EPA with an opportunity to reduce public exposure to at least some of the oncogenic pesticides that now are routinely present in food.

Third, the two agencies charged with implementing and interpreting the Delaney Clause—the EPA and the Food and Drug Administration (FDA)—should continue to work to achieve consistent legal interpretations of their common statute and compatible regulatory policies based on the best contemporary science. As long as the Delaney Clause is a part of the FDC Act, better cooperation and communication between EPA and FDA scientists and policy-level officials will be increasingly important as the two agencies work to develop policies for implementing this provision. The effective functioning of both agencies depends on the development of consistent policies for achieving the widely supported goal of eliminating added carcinogens from the food supply whenever feasible and prudent.

A Nonzero Standard for Oncogenic Risk

A negligible risk standard for carcinogens in food, applied consistently to all pesticides and to all forms of food, could dramatically reduce total dietary exposure to oncogenic pesticides with modest reduction of benefits.

The committee believes that the elimination of oncogenic pesticide residues from human food is an appropriate aspiration of regulation. The committee recognizes, however, that residues of several dozen oncogenic pesticides may be found in hundreds of different foods. Many such residues pose little risk to humans, whereas some clearly warrant attention and, quite probably, regulatory action. The problem of implementing action against many pesticides with limited personnel and resources should be minimized. Moreover, the challenge for regulators grows increasingly complex as science and technology advance. Improvements in analytical chemistry and residue detection capabilities, new toxicological data, changing pesticide use practices, and the development of new pesticides and foods establish an urgency *and* the feasibility to devise a strategy for attaining a safer food supply.

One option for regulators is to adopt a negligible risk standard in setting and revising tolerances for all oncogenic pesticides found in food. The committee sees merit in such a standard if its adoption can speed up progress toward risk reduction and help the EPA focus its limited resources on pesticides and crops that pose significant oncogenic risks.

The committee notes with concern that current EPA policy has allowed continued use of pesticides that pose estimated dietary oncogenic risks as high as 1 in 10,000 (1×10^{-4}). The adoption of a negligible-risk standard would provide added justification for the agency to reduce relatively high risks while deferring actions on relatively low or perhaps even zero risks. The committee would not endorse the adoption of such a standard if it were not consistently applied to all pesticides and all forms of human food.

The committee is aware that a zero-risk standard applied to pesticide residues in all foods would eliminate that source of oncogenic risk in the diet. The committee believes, however, that in certain regions and on certain crops, the implementation of such a policy would cause severe adjustments in agricultural practices, particularly in control of plant diseases. This policy could impede agency discretion necessary to achieve significant risk reduction over the next 5 to 10 years while maintaining viable disease control alternatives.

The committee's analysis highlights several advantages of a consistently applied negligible-risk standard over even strict adherence to the traditional zero-risk interpretation of the Delaney Clause, which applies a zero-risk standard only to processed foods and their parent raw commodities:

- The committee found that, if consistently applied, a negligible-risk standard applied to raw and processed foods (assuming no consideration of benefits) could lead to the elimination of 98 percent of existing dietary risk from exposure to the 28 pesticides comprising the committee's estimate of dietary oncogenic risk. In contrast, a zero-risk standard applied only to oncogenic residues in processed foods and their parent raw commodities would reduce estimated risk by just 55 percent. In reality, however, benefits must be considered, and not all residues will concentrate. Also, the risk reduction achieved under both scenarios will probably be less than suggested. Nonetheless, the committee believes that the relative effectiveness of these two scenarios will remain constant and that any plausible negligible-risk standard that treats section 408 and 409 tolerances consistently will lead to greater risk reduction than a zero-risk standard applied only to section 409 tolerances.
- A uniform negligible-risk standard could give the EPA the flexibility needed to reduce dietary oncogenic risks over time. One important option would be the ability to grant tolerances for new chemicals that might pose a slight oncogenic risk (currently prohibited by the Delaney Clause), if use of such pesticides would displace more hazardous products now routinely used. In the past, the EPA has applied the Delaney Clause to deny tolerances for weak oncogens on certain crops. To date, the agency has not invoked the clause to revoke any existing tolerances (in most cases

citing lack of acceptable data on oncogenicity and residue concentration). This application of the Delaney Clause has had the effect of preserving the market share for, and continuous dietary exposure to, pesticides that present relatively greater dietary oncogenic risks.

- A negligible-risk standard for tolerance setting would aid the EPA in focusing regulatory resources on the crop and pesticide combinations presenting the greatest oncogenic risk. On the other hand, a zero-risk standard does not encourage and may not allow the EPA to discriminate between relatively significant and relatively insignificant oncogenic risks. Indeed, the Delaney Clause has focused considerable agency resources on protracted scientific assessments designed to determine whether a pesticide is an "oncogen" per se and whether the risk associated with a particular use of that pesticide is zero, or some very small level that is well beyond the predictive power of currently available toxicological tests and risk assessment methods.

The advantages of a consistently applied negligible-risk standard will depend on how fast the EPA will reregister old chemicals, the sequence that will be followed, and perhaps most important, how the benefits will be taken into account. Risk reductions of the magnitude that the committee's analyses suggest are not guaranteed because the analyses did not incorporate benefit considerations. The benefits of some pesticide uses may justify greater risks. The level of risk reduction achieved through the adoption of such a negligible-risk standard will depend on the importance the EPA places on the benefits of specific pesticide uses.

Targeting High-Risk Pesticide and Crop Uses

The committee's analysis (described on pages 50–66) suggests that about 80 percent of oncogenic risk from the 28 pesticides that constitute the committee's risk estimates is associated with the residues of 10 compounds in 15 foods. Logic argues that the EPA should focus its energies on reducing risk from the most worrisome pesticides on the most-consumed crops, and compelling reasons support such a strategy.

First, if the EPA developed a regulatory position on all oncogenic pesticides used on a given crop, the agency would have a realistic chance of dealing with the special problems that arise when there is more than one oncogenic pesticide used on a particular crop. As a class, the fungicides present special difficulties because nine oncogenic compounds account for about 90 percent of all fungicide sales. Further, these nine compounds present comparable risks and generally are viable substitutes for one another. In this situation the agency's historical approach—regulating one pesticide at a time across all of its uses—is not well suited

to ensuring real risk reductions. This approach could even *increase* oncogenic risk when revocation of one agent allows a more potent oncogen to gain wider use.

The recommended strategy would also help preserve the benefits of pesticide uses that pose very low, but possibly not zero, risks. For example, most suspect oncogenic pesticides used on corn, soybeans, and cotton present very low dietary oncogenic risks. Further, the committee's analysis indicates that when estimated dietary oncogenic risks from herbicides or insecticides on these crops are deemed high, they can generally be substantially reduced through actions affecting one or two compounds. Most pesticides used on these crops would probably be passed over if a policy were in effect that targeted pesticide uses presenting relatively high dietary oncogenic risk. Such pesticide uses could come under scrutiny for other reasons, however, such as other health effects, ecological problems, or groundwater contamination.

The Adoption of an Analytical Framework

The EPA should develop improved tools and methods to more systematically estimate the overall impact of prospective regulatory actions on health, the environment, and food production. Rapid advances in computer technology, as well as the EPA's successful efforts to computerize major data sets like the Tolerance Assessment System (TAS) make such progress readily attainable.

The EPA's current approach to pesticide regulation focuses on the risks and benefits of one active ingredient at a time across all its uses. Much of the committee's analysis rested on new analytical manipulations of EPA data sets. Insights gained on the distribution and relative magnitude of risks and benefits associated with pesticide use are the foundation of the committee's recommendations. The analytical framework and data base that the committee developed on a prototype basis are described in detail in Chapters 3–5 and Appendix B. The framework the EPA might develop and utilize could be more thorough and precise. The committee's preliminary work provided intriguing new insights, however. The data base that the committee developed is extremely valuable in comparing the effectiveness of different regulatory policies that reduce dietary oncogenic risks from pesticides.

Use of new analytical tools and data bases could help the EPA get ahead of its growing work load. The refinement of such a system would allow the EPA to project with increased confidence a wide range of impacts associated with its regulatory actions. For example, the committee's rudimentary analysis demonstrates that certain strategies for

implementing the Delaney Clause could increase dietary risk, and vigorous application of the Delaney Clause to tolerances for residues in processed foods may not be the most effective strategy for minimizing dietary exposure to oncogenic pesticides.

It is important to note that this study's preoccupation with oncogenic hazards simplifies the challenges that the EPA actually faces. In developing regulatory decisions, the EPA must take into account trade-offs between oncogenic risks and other sorts of health and environmental hazards among all pesticides registered for a particular use. Nonetheless, this more complicated task would be aided by the analytical tools discussed in this report.

NATIONAL RESEARCH COUNCIL
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Committee on Pesticides in the Diets of Infants and Children

At the request of the Congress and with the support of the U.S. Environmental Protection Agency, the National Academy of Sciences initiated a study in 1988 to examine risk assessment methods for pesticides in the diet, focusing on infants and children. To conduct the study, the Academy created the Committee on Risk Assessment Methods for Pesticides in the Diets of Infants and Children. This committee is established jointly under the Commission on Life Sciences, Board on Environmental Studies and Toxicology, and the Board on Agriculture.

The study will evaluate current risk assessment methods, and their use of average lifetime exposure estimates, in light of the potential sensitivities and increased exposure of infants and children. The exposure and potential sensitivity of infants and children to pesticides and other toxic chemicals has been the subject of scientific examination for several decades.

This study derives from the general consensus in the scientific community that new methods may be available to improve risk assessment methods and better protect the public health. It is important to note, however, that this study does not arise from the documented increase in any disease or adverse health condition in infants, children, or adults resulting from exposure to legal levels of pesticides in the diet.

The committee has only begun to study this issue. It plans to thoroughly examine each step of the risk assessment process, focusing on the scientific assumptions currently used. Critical review will be made of food consumption survey methods, pesticide residue detection methods and sampling procedures, and available information on the actual levels of pesticides to which infants and children are exposed. The usefulness of animal testing and extrapolation models, sensitivities of children to toxic substances, and the ultimate effect of these factors on methods used to project lifetime risk will also be examined. The committee will look for improvements in the risk assessment process that will (1) better protect infants and children from effects that may occur in childhood and (2) better protect children from effects that may occur later in life as a result of childhood exposures to pesticides in the diet.

A report on pesticides in the diets of infants and children was released earlier this week by the Natural Resources Defense Council. The committee will analyze this report and other pertinent documents as a part of its examination of the issues.

The committee's report is scheduled for completion in the fall of 1990. A list of committee members and staff is attached.

RESPONSES OF CHARLES M. BENBROOK TO QUESTIONS ASKED BY SENATOR KENNEDY

1. "It is imperative that good science be the foundation of regulatory decision-making. In testimony that has been given before this Committee, it is my understanding that the science of risk assessment is a discipline with several unknowns. When we talk about assuring the public that consuming foods treated with chemicals will not present more than a negligible risk of harm, what does that mean and how good is that assurance?"

   A risk is termed "negligible" when there is credible evidence available to judge that the risk is so small (generally, less than one-in-one million) and so unlikely to occur (at least a 95 per cent chance that the risk is less than one-in-one million) that it is the "functional equivalent of zero."

   Over the last decade the Food and Drug Administration has used quantitative risk assessment techniques to determine whether a potential risk exceeds a negligible level, the point at which appropriate regulatory actions are then taken under the general food safety clause of the Food, Drug, and Cosmetic Act. A principle recommendation of the 1987 NAS report "Regulatory Pesticides in Food: The Delaney Paradox" called for EPA to apply a similar negligible risk standard in setting pesticide tolerance levels. If such a standard were consistently applied in setting or adjusting tolerances, the committee concluded that the vast majority of the current potential dietary risk in the food supply would be eliminated, and that the remaining risk would be so small that it would almost certainly pose no real risk to consumers. In a word, it would be "negligible."

   It is important to note, however, that the public has reason to question whether some current pesticide uses pose a greater than negligible risk. Indeed, the Agency acknowledges that several hundred pesticide uses pose risks well above a negligible level, if residues are present on or in foods at current tolerance levels. Such levels would be legal, yet are clearly above what the EPA--or any government agency--would consider acceptable. Whether these uses of pesticides are actually causing cancer, birth defects, and other diseases, cannot be proven or disproven conclusively at the present time. By lowering exposure to these chemicals, however, risks can be lowered to negligible levels.

   As more complete toxicological data is generated and more prudent exposure estimates are made by EPA, the EPA should act quickly to utilize this improved

information in adjusting tolerances downward when needed so that risks--even to the most susceptible population subgroup--are surely no more than negligible. Then the public can place greater confidence that all reasonable and prudent steps have been taken to protect public health from potential dietary risks from pesticides.

It is also important to recognize that there are a number of uncertainties in the risk assessment process which are rarely totally eliminated. When regulatory scientists reach a judgement that a chemical poses no more than a negligible risk, two key factors are taken into account.

First, an estimate is made of exposure to the chemical. In general, it is possible for regulatory scientists to develop reasonably accurate exposure assessments, particularly for chemicals that pose no unique difficulties for analytical chemists. An important, common problem, however, arises from the great diversity in potential exposure profiles for individuals across the population.

In developing exposure estimates resulting from a registered use of a pesticide, it is important to consider, among other factors, regional patterns of food distribution, whether the crop is processed or consumed fresh, how much of the crop is sprayed, at what rates and with what methods, and how often. In estimating exposure for individuals and certain key population sub-groups, like infants, other unique characteristics must be taken into account: the high rate of consumption of relatively few foods by children (in relation to body weight); dietary patterns that often include large portions of a few favored foods; ethnic food consumption patterns; where foods consumed are grown; food preparation and cooking habits; etc.

Until recently, the EPA has calculated "average" dietary exposure estimates for pesticides based on the assumption that each person is average in size, and consumes very small portions of some 350 distinct foods each day. Also, EPA still assumes that residues of pesticides that are likely to occur in food are distributed evenly throughout the national food supply. This assumption ignores the fact that many seasonal fruits and vegetables are grown, sprayed, and consumed in certain regions of the country, and hence consumers in that region will be exposed to residues reflecting

regional pesticide use patterns, not national average use patterns. Meat and milk consumption patterns are also clearly not random across the nation.

The EPA is exploring new ways to more accurately and realistically estimate exposure by population subgroup. The goal is to develop dietary exposure estimates for the most "at risk" group of the population. High exposure population subgroups may receive as much as 100 times the residue that EPA currently estimates using "average" food consumption data. When regulations are based on protecting this group, the public can rest assured that a regulatory action posing no more than a negligible risk truly protects public health, indeed overprotects the majority of the population. Despite complexities in estimating exposure, the scientific tools are now available to eliminate much of the uncertainty in this process.

The second step in the risk assessment process must consider the toxic potential of the chemical. Estimating human toxicity from toxicological data derived in animal studies also involves many uncertainties. As a result, the standard methods used by government agencies include conservative assumptions designed to minimize the chance of substantially underestimating risk. Even with these assumptions, recent progress in toxicity testing suggests that certain pesticides may pose significant risks at levels of exposure once regarded as of no practical concern. (For example, data from the California Department of Health and the U.S. EPA suggest that routine food residues of the pesticide aldicarb may be far more toxic to infants and sensitive individuals than previously thought.)

While uncertainties abound in risk assessment, they can be lessened somewhat through a number of other scientific assessments involving new kinds of toxicity tests and epidemiological analysis of real world events. Much progress is underway in developing new sorts of disease markers, which will in turn help clarify whether pesticide exposure is or is not a cause of disease.

2. "In making decisions about which chemicals are to be permitted in the market place, benefits in formulation has traditionally been an important parameter to consider. In most cases the decision to use or not use a pesticide is not so clear cut. For example, risk calculations, which have

several scientific unknowns may indicate that a chemical is just over the negligible risk line. This chemical could be essential to a crop. How much variance should we include around the negligible risk value?"

Most pesticides regulated by EPA have at least 5 and often 20 or more major food uses. Some chemicals have 50 or more minor crop uses. A review of recent EPA actions suggests that an assessment of benefits plays a role in determining the regulatory fate of relatively few uses--those that pose more than negligible risks, but are of unique value to producers in at least some regions.

The 1987 NAS report "Regulating Pesticides in Food: The Delaney Paradox" contemplated a regulatory system in which benefits would play a limited role in certain cases.

*Benefits would generally not play a role when risks are less than a negligible level--registrations should be granted or retained without regard to benefits.

*When risks are clearly well-above negligible levels, no amount of benefits would justify continued use of a pesticide--registrations would be denied or suspended.

The committee that authored our 1987 report recognized that circumstances will inevitably arise when benefits should be taken into account in the regulatory process. But this was not a major point of the committee's deliberations, and no conclusions were reached on the role of benefits, nor how benefits should be defined and estimated. The committee also did not resolve the difficult question of how a regulatory agency should weigh an estimate of human health risks, measured as additional cases of some disease, against pesticide benefits expressed as additional dollar profits to farmers, or gains to consumers in the form of lower food costs.

The role of benefits, and their definition in pesticide regulation is surely one of the most challenging policy and analytical challenges facing the Congress and EPA. I hope the committee will return to this issue for a more in-depth discussion since a consensus is growing that change is needed in how, and when, benefits are considered, yet there has been inadequate reflection, and virtually no solid analysis, of alternative ways to take benefits into account in the regulatory process.

RESPONSE TO FOLLOW-UP QUESTIONS
FROM EDWARD M. KENNEDY

1) *S. 722 would establish a requirement that within four years of enactment, the combined risk from all uses of a pesticide must meet the negligible risk standard. The National Academy of Sciences committee recommended that all pesticide residues on a single crop must meet the negligible risk standard. Could you provide us with more detail on the pros and cons of the two approaches?*

The report, Regulating Pesticides in Food: The Delaney Paradox, made two findings that appear to form the basis of language found in S. 722. The first and most important is that a consistently applied regulatory risk standard of one-in-one-million additional cancers over the lifetime of a population would reduce dietary cancer risk from pesticides by 98 percent and eliminate only 32 percent of all tolerances. (Consistently applied means that it would be applied evenly to both old and new pesticides, and to the sum of residues in raw and processed foods from each registered crop use of a pesticide.) This finding is particularly striking in contrast to the level of risk reduction expected following strict application of the Delaney clause, which would apply a zero risk standard to only a part of the food supply--and thus achieve significantly less risk reduction (about 45 percent less). The second relevant finding is that in certain cases a cropwide approach to risk reduction would more effectively reduce risk than EPA's current procedure of regulating the sum total of a pesticide's dietary risk one pesticide at a time. This is particularly true in the case of fungicides since 8 major pesticides pose oncogenic risks of roughly comparable magnitude, and these pesticides are often substitutes for one another.

It is important to note that the 98 percent risk reduction achieved under the committee's theoretical analysis required that all pesticide tolerances on a crop that exceeded the one-in-one-million risk standard were automatically revoked. S. 722 does not require this automatic revocation of tolerances that present greater than one-in-one-million risk but rather allows tolerances to be lowered to meet the risk standard. This is a key difference between S. 722 and the policy scenario the committee studied. By lowering tolerances rather than eliminating tolerances, the risk reduction achieved under S. 722 will be somewhat less that the 98 percent achieved under the committee's analysis. Still, the degree of risk reduction would clearly be sizable, possibly approaching 85 to 90 percent.

Strengths of Cropwide Regulation

In contrast to current EPA risk assessment procedures and standards that assess all uses of one pesticide, the principal argument for a cropwide regulatory approach is to avoid increasing risk by canceling a pesticide that proves to actually be less hazardous than other pesticides, but which is restricted or cancelled purely because EPA had complete data on it before other pesticides, or scheduled its data reviews earlier. This scenario is most likely to occur for fungicides; about 8 fungicides of roughly equivalent toxicity account for about 90 percent of all fungicide use and a majority of all dietary cancer risk from pesticides. Similar but

not so serious problems could also arise in the corn-soybean herbicide area.

Regulatory actions that paradoxically increase risk are most likely when pesticides are regulated one at a time. For example, it is very complicated to ensure net risk reduction following decisions on captan in 1989, benomyl in 1990, and the EBDC's in 1991. In contrast, under S. 722 all pesticides will meet a one-in-one-million risk standard at the same time. The problem of increasing risk through wider use of more hazardous pesticides following regulatory actions would thus be largely eliminated.

An additional strength of cropwide regulation is that it more effectively meets the needs of growers. In fact, agricultural needs for certain groups of pesticides are so compelling that, even though S. 722 does not formally require cropwide regulation until six years after passage, cropwide analyses will begin at the four-year stage. This is because effective implementation of the four-year phase of S. 722 (risk reduction across all uses of a single pesticide to a combined negligible risk level) will require EPA to analyze growers' needs and the effectiveness of each pesticide on each crop in order to determine, for each pesticide, which tolerances to keep, which to lower and by how much, and which to revoke. Thus, one could argue for amending the bill to require cropwide regulation at the four-year stage to avoid confusion in implementation.

Strengths of a Chemical Approach to Regulation

An important advantage of the chemical-wide approach (regulating based on total exposure and estimated risk from all registered uses of one pesticide) is that it is consistent with and, in many ways, identical to current EPA practice. EPA currently regulates dietary exposure to a pesticide by adding up the risks from all of its food uses to determine if the risks outweigh the benefits. The important differences between S. 722 and current EPA practice are that S. 722 requires that all pesticides meet a prescribed risk standard at the same time, and that the risks from all uses of a pesticide have not less than a 100-fold margin of safety or cause no more than a one-in-one-million additional cancer risk over the lifetime of the exposed population. Historic EPA policy and procedure is different from S. 722 principally because it allows a pesticide's summed cancer risks to be greater than one-in-one-million when justified by benefits.

It is noteworthy, however, that in the October 19, 1988 Federal Register EPA proposed to adopt procedures based on the recommendations of the committee that would, in the agency's view, apply a one-in-one-million risk standard to dietary risks from pesticides, except in cases when extraordinary benefits were present. While some would argue with the methods EPA apparently intends to use in implementing this policy, it is important to note that EPA is on record in favor of a negligible risk standard, despite its opposition to this bill.

In Sum

The conclusion in Regulating Pesticides in Food: The Delaney Paradox supporting a cropwide approach to pesticide regulation is proposed as an alternative to current EPA practice of regulating pesticides one at a time. The report points out cases in which this alternative approach is particularly necessary to avoid regulatory decisions that paradoxically increase risks. Because S. 722 would require that all pesticides meet a negligible risk standard at the same time, it is unlikely under S. 722 that risk could markedly increase as farmers switch to riskier pesticides. Nonetheless, a principal advantage of cropwide risk reduction remains. That is, it is more suited to the needs of agricultural producers and researchers in developing alternative pest control practices consistent with risk reduction strategies and producer needs.

In contrast, a chemical approach to risk reduction is more suited to and is, in many ways, nearly identical to current regulatory programs and policies. However, bringing all pesticides in line with one standard simultaneously will likely change chemical regulation into cropwide risk management out of practical need.

2) *In addition S. 722 would revise the way EPA sets tolerances on pesticide residues. EPA could only assess risks from particular pesticides, as opposed to their current risk-benefit determination. What is your opinion of only assessing the risk of adverse health effects in considering tolerances for pesticide residues?*

The committee made no specific recommendations or evaluation of the benefits assessment process for pesticides at EPA. They did note, however, that benefits would likely need to be considered when risk reductions of this magnitude were attempted. The nature of an appropriate benefits assessment process was not specified, however, nor was EPA's current method of assessing benefits endorsed as appropriate.

My opinion--and that echoed by the Administration witnesses at the hearing--is that pesticides, like other chemicals added to food, should meet basic public health standards applied to the food supply. The two standards most commonly applied to food are a one-in-one-million additional cancer risk standard for oncogens, and a 100-fold margin of safety for non-cancer risks. S. 722 contains these standards. To some, it is noteworthy and objectionable that the one-in-one-million cancer risk standard in S. 722 weakens current law applicable to concentrating residues of pesticides found to cause cancer in humans or animals in processed foods. These residues are currently regulated as food additives and are thus presumably prohibited by the Delaney clause. A principal justification for allowing a negligible increase in allowable levels of exposure to residues of cancer causing pesticides in food, as called for in S. 722, is the general

recognition that pesticides confer distinct benefits to food production that other food additives do not, and that consistent adherence to a negligible risk standard can very efficiently eliminate most of the potential risk from pesticides in the diet. (Another pivotal justification for negligible risk is that a consistently applied negligible risk standard would achieve greater risk reduction than the Delaney clause's zero risk standard applied only to processed food.)

Nonetheless, for certain foods grown in some areas, production costs may increase and production levels may fall under the four- and six-year implementation phases of S. 722. In certain cases, therefore, the consumer benefits of a somewhat less strict standard may need to be weighed in light of any significant and well-documented disruptions in food supply that may result from S. 722. It is essential, however, that the agency (and probably law) more clearly and explicitly define what benefits are to be taken into account, and how they are to be measured. Benefits are now measured in terms of the cost of alternative pesticides and any yield or quality losses. Benefits are not currently expressed in terms of their effects on those who bear the risk (food consumers). A critical policy issue at the heart of the benefits debate is whether the food consuming public should be asked to bear greater than negligible risks if they do not receive direct benefits in the form of a more nutritious and affordable food supply.

3) *You indicate that establishment of a one-in-a-million negligible risk standard would eliminate the vast majority of dangerous pesticides, and only 32 percent of all the tolerances covering cancer-causing pesticides would need to be revoked. The food industry argues that revoking pesticides under this standard would be disruptive to agriculture. To your knowledge, are their* [sic] *safer pesticides that could be substituted, such that agriculture productivity would not be reduced?*

Under the committee's analysis, a one-in-one-million risk standard would revoke 32 percent of all tolerances for carcinogenic pesticides, thereby reducing dietary cancer risk from pesticides by 98 percent. Unlike S. 722, however, the committee's analysis required that all pesticide tolerances on a crop that exceeded the one-in-one-million risk standard were automatically revoked. S. 722 does not require this automatic revocation of tolerances that present greater than one-in-one-million risk but rather allows tolerances to be lowered to meet the risk standard. This flexibility to lower tolerances to acceptable levels is an important attribute of S. 722, and would accord producers and the agrichemical industry an opportunity to develop modified formulations and use patterns for many products that would bring risks down below a negligible level.

It is difficult to predict what percent of current tolerances might be lost under S. 722. It is certain, however, that the claim cited above is unfounded, and exaggerates the impact of S. 722. It is also important to

acknowledge that under current EPA policy and the ongoing re-registration process (and without S. 722) a large number of the riskiest pesticide uses will be abandoned by registrants and cancelled by EPA. Based on recent agency experience, perhaps 15 to 20 percent of the riskiest uses are likely to be cancelled as a result of the data generation costs required to gain re-registration. To meet the two-year risk reduction goals of S. 722, at most another 5 to 10 percent of published tolerances may need to be revoked. Others will be adjusted downwards but not require major changes in current use patterns.

In contrast to exaggerated claims of the impact of S. 722, what appears to be true is that for many major commodities (corn, cotton, wheat, soybeans, barley, and rice) few or no revocations in tolerances for any pesticides used on these crops would be necessary. In fact, there are no data to support the claim that under S. 722 any tolerances for widely used pesticides would have to be revoked for any of the major field crops listed above. Tolerances may have to be reduced for two or three important compounds, but this appears feasible since tolerances are currently set well above actual residue levels, a point repeatedly made during the hearing.

Tolerance reduction, as an alternative to revocation, is a feasible and effective means to reduce risk on the above crops because the majority of the dietary risk for these crops is derived from residues of fungicides used to protect seeds and pre-plant herbicides. Most of this risk as currently measured is theoretical, actual risk is far lower. Tolerances for these uses could easily be reduced without affecting the use or availability of nearly all compounds. In addition, for many major field crops farmers have numerous non-pesticide control alternatives to control certain insects, diseases, and many weeds in these crops, or technologic and agronomic systems which markedly increase the efficiency of pesticide use so that an adequate degree of control is attained with much less pesticide.

The situation with fresh fruit and vegetable production in some regions is more problematic. Nonetheless, the claim that S. 722 would result in a 32 percent reduction in available uses and tolerances is an inaccurate application of the committee's findings to S. 722. While some important pesticides used on a few crops in certain regions may not meet the negligible risk standards even when tolerances are reduced to their lowest effective level, the ability of farmers to develop alternative control strategies has always been underestimated by EPA in assessing the potential loss of benefits when a pesticide is cancelled. Necessity is the mother of invention on the farm, and biotechnology, bio-control, integrated pest management (IPM), and safer pesticide alternatives to reduce risk are available or within reach. More aggressive regulatory policies--as envisioned in S. 722--will clearly increase the importance of a timely, strategic response by federal and state agricultural research and education institutions to producers' needs for effective alternative control options. Congressman George E. Brown has, in recent months, aggressively pushed the USDA to play a more proactive role in accelerating and targeting research and development efforts. I hope this committee will also lend its support to this effort as it continues to work toward passage of S. 722.