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Options to Achieve a Single Regulatory Standard

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Different standards in the two key federal pesticide laws—the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA)—have led to differences in the way pesticides used on foods are regulated. These differences, which have their basis in law rather than science, are often characterized as the "Delaney dilemma," after the so-called Delaney clause in FFDCA. As a result of the Delaney dilemma, pesticides that have been found to cause cancer may be used on some foods but not on others, and the benefits of using pesticides, such as increased crop yields, may be considered in some but not all regulatory decisions.

In previous legislative sessions, amendments to reconcile the differences between these two laws have been debated in the Congress but not enacted. During the current session, several Members of Congress have also sponsored bills designed to establish a single regulatory standard. Most recently, in April 1994, the administration proposed legislation that would, among other things, attempt to establish a single standard. This report, which we prepared to assist the Congress in its deliberations on pesticide issues, discusses (1) the federal pesticide laws and the administrative policies that the Environmental Protection Agency (EPA) developed to implement them and (2) legislative options for establishing a single standard for regulating the use of pesticides on foods.

Background

EPA regulates the use of pesticides under two federal laws—FIFRA and FFDCA. Appendix I sets forth the relevant provisions of these laws.

FIFRA requires that a pesticide be registered (in effect, licensed) by EPA before it can be sold or distributed in the United States. To qualify for registration, the pesticide must perform its intended function without causing "unreasonable adverse effects on the environment."[1]

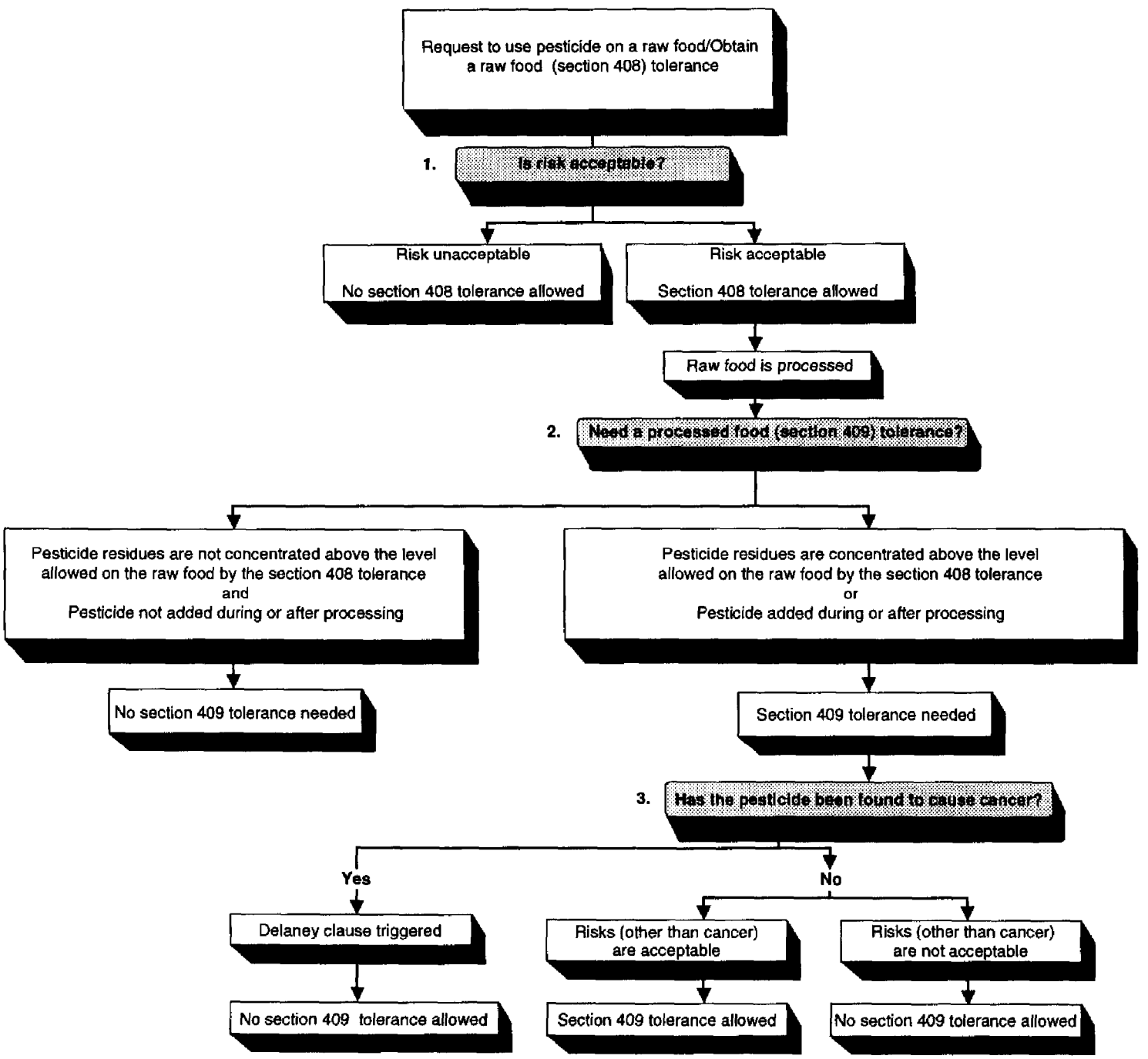
Different sections of FFDCA authorize EPA to set limits, or tolerances, on the amount of pesticide residue that can legally remain in or on raw and processed foods. Under section 408, EPA sets tolerances (called section 408 tolerances or raw food tolerances) for pesticide residues in or on raw agricultural commodities. Under section 409, it sets food additive

[1]7 U.S.C. 136a(c)(5).

regulations (called section 409 tolerances) for residues in certain processed foods. A section 409 tolerance is required (1) when a pesticide's residues are found in higher concentrations in a processed food that is ready to eat than are allowed on the raw food or (2) when a pesticide is added during or after processing. However, according to the Delaney clause in section 409, with limited exceptions for animal feed, a pesticide that requires a section 409 tolerance cannot obtain that tolerance if the pesticide has been found to induce cancer in humans or animals.

Under section 402 of FFDCA, a section 409 tolerance is not required when a pesticide's residues are not concentrated in a processed food above the raw food tolerance or the pesticide is not added during or after processing. Section 402 is commonly known as the "flow-through" provision because it allows the raw food tolerance to "flow through" and apply to residues in the processed food. Thus, a pesticide that has received a raw food tolerance can be used in processed food even if it has been found to induce cancer in humans or animals—as long as its residues have not been concentrated during processing or it has not been added during or after processing. Figure 1 outlines the process for granting food-use tolerances under FFDCA.

Figure 1: Process for Granting a Food-Use Tolerance Under FFDCA



Results in Brief

Because of differences between FIFRA and FFDCA—and even between sections of FFDCA—EPA applies different standards of risk in different situations and considers the benefits of using pesticides in some instances but not in others. Specifically, in setting tolerances, or allowable limits, for pesticide residues in or on food, EPA may allow the use of a carcinogenic (cancer-causing) pesticide on raw foods or in certain processed foods when it has determined that the risk of cancer is negligible.[2] However, under the Delaney clause, EPA may not allow the presence of a carcinogenic pesticide in other processed foods, no matter how negligible the risk.

For example, EPA may issue a tolerance for a carcinogenic pesticide on raw tomatoes if the risk of cancer is negligible. It may also issue a tolerance for the pesticide in canned tomatoes if the pesticide's residues are not concentrated during processing above the level allowed on the raw tomatoes (the raw food tolerance). But, under the Delaney clause, EPA may not issue a tolerance for the same pesticide in tomato paste if the pesticide's residues are concentrated during processing above the raw food tolerance—even though tomato paste is ordinarily diluted before it is consumed. Similarly, EPA may consider benefits in regulating a carcinogenic pesticide except when that pesticide's residues are concentrated during processing above the raw food tolerance.

To address these differences in risk and benefit standards, EPA issued a statement in October 1988 outlining several administrative policies. One of these policies, called the de minimis policy, allowed the presence in processed food of pesticide residues that were prohibited under the Delaney clause but that, according to EPA, posed a negligible risk of cancer. This policy allowed EPA to grant tolerances for pesticides that could not otherwise have received tolerances. Another policy, called the coordination policy, required EPA to cancel the raw food tolerance for any pesticide that could not receive a tolerance for use in processed food.

In 1993, in Les v. Reilly,[3] the Ninth Circuit Court of Appeals determined that the de minimis policy was incompatible with the Delaney clause. Following this decision, EPA proposed the revocation of the processed food tolerances for the pesticide uses named in the court case, but it has not yet revoked the raw food tolerances for these pesticides in accordance with the coordination policy. If EPA retains the coordination and other

[2]In practice, EPA has generally defined negligible risk as an incremental increase in lifetime risk of 1 in 1 million or lower, as calculated according to a conservative risk-assessment methodology.

[3]Les v. Reilly, 968 F.2d 985 (9th Cir. 1992), cert. denied, 113 S. Ct. 1361 (1993).

remaining administrative policies, it could cancel the tolerances for approximately 100 pesticide uses in or on food. The impact of these cancellations on public health and the economy is widely debated by EPA, environmental groups, public health organizations, pesticide manufacturers, and food processors. According to preliminary estimates from EPA and industry groups, the cancellations could diminish crop yields and increase food prices, as well as discourage the development of some safer pesticides. In addition, representatives of pesticide manufacturers and food processors say that the loss of some pesticides could increase risks to public health. However, according to some environmental groups and public health organizations, the cancellations would not cause such serious economic effects and could accelerate the development of safer pesticides and benefit public health. Industry groups have said that EPA could mitigate the effect of the court's ruling by revising or revoking the coordination policy. Nevertheless, the differences in the federal standards for regulating pesticides would remain. An amendment to the existing federal pesticide laws could provide a single standard for regulating pesticide residues in or on all foods.

Options for legislative change that would establish a single regulatory standard for pesticides in raw commodities and processed food include (1) allowing zero risk of cancer[4] (providing for a phaseout of the most hazardous pesticides) with no consideration of benefits, (2) allowing negligible dietary risks with no consideration of benefits, and (3) allowing negligible dietary risks with some consideration of benefits. The administration is currently advocating the use of a negligible-risk standard with very limited consideration of benefits. Because scientific data are not always adequate to quantify risks and benefits, the choice of an appropriate regulatory standard entails value judgments and is, ultimately, a policy decision.

The Federal Pesticide Laws Contain Different Standards

Section 409 of FFDCA—and particularly the Delaney clause—differs from both FIFRA and the other sections of FFDCA. As a result, EPA regulates pesticide residues in or on some processed foods differently from pesticide residues in or on raw foods and other processed foods. Appendix II sets forth the differences in the federal laws regulating pesticides.

Because the Delaney clause prohibits the presence in processed food of any pesticide that has been found to cause cancer in humans or animals (if that pesticide's residues have been concentrated in a processed food

[4]As used in this report, "zero risk" means no intentional addition of carcinogens to food.

above the raw food tolerance or the pesticide has been added during or after processing), EPA may not grant a section 409 tolerance for that pesticide, no matter how low a risk it poses to humans.[5] According to EPA, no pesticides known to induce cancer in humans are currently registered for food use. Under the Delaney clause, EPA may not consider benefits in setting a section 409 tolerance for potentially carcinogenic pesticide residues. In contrast, EPA may grant a section 408 tolerance for a carcinogenic pesticide in raw foods and allow the tolerance for a carcinogenic pesticide to flow through to processed foods under section 402 if the agency has weighed the dietary risks posed by the pesticide against the benefits of using the pesticide and found that the benefits outweigh the risks. Thus, potentially carcinogenic residues may be on raw food or in processed food if the residues are not concentrated in the processed food above the level approved for the raw food or if the pesticide was not added during or after processing. Ironically, EPA has approved tolerances under section 408 for some pesticides that it has found to be potentially more carcinogenic to humans than other pesticides for which it has not been able to issue a tolerance under section 409.

In regulating pesticides under FIFRA and provisions of FFDCA other than the Delaney clause, EPA must assess multiple health risks, including the risk of birth defects or of reproductive or nervous disorders, as well as the risk of cancer. Because the Delaney clause requires EPA to avoid only the risk of cancer, the agency may issue section 409 tolerances for pesticides that pose other risks to human health or the environment.

In addition to the Delaney clause, section 409 of FFDCA contains a general safety clause that requires EPA to determine whether the use of a pesticide "will be safe." EPA and the Food and Drug Administration (FDA) disagree over whether this clause allows for the balancing of risks and benefits. EPA has interpreted the clause as allowing the balancing of risks and benefits when the Delaney clause does not apply (i.e., when the pesticide is not carcinogenic). Thus, EPA believes that it may consider benefits as well as risks when setting tolerances for pesticide residues. In contrast, FDA applies a risk-only standard when approving and setting tolerances for food additives other than pesticides, such as artificial sweeteners and animal drug residues.[6]

[5]EPA may, however, grant section 409 tolerances for certain pesticide residues in animal feed.

[6]Section 409 of FFDCA governs the regulation of food additives. FDA has primary responsibility for implementing section 409, but EPA has been assigned responsibility for regulating pesticide residues that are food additives.

Both FIFRA and section 408 of FFDCA require EPA to consider both risks and benefits in making regulatory decisions. FIFRA states that a pesticide may not cause "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[7] Similarly, FFDCA calls upon EPA both to protect public health and to consider the need for producing "an adequate, wholesome, and economical food supply."[8]

In practice, EPA bases tolerance decisions primarily on perceived risks and presumes that benefits will be determined by the marketplace. As we previously reported,[9] the principal role of benefit analysis is to supply EPA decisionmakers with information about the benefits associated with a pesticide's use during special review—EPA's administrative process for reviewing already-registered pesticides in the light of new data indicating health or environmental concerns. EPA uses this process to determine which uses to cancel and which to retain.

EPA Developed Policies to Reconcile Differences in the Pesticide Laws

To implement the federal pesticide laws and address the differences posed by section 409 of FFDCA—and particularly by the Delaney clause—EPA established several policies, including a coordination policy, a concentration policy, a ready-to-eat policy, and a de minimis policy. In establishing these policies, EPA sought to ensure that farmers and food processors could produce foods that were reliably in compliance with the federal pesticide laws and were not adulterated. The policies were intended both to protect consumers and to alleviate farmers' and food processors' concerns that legally treated raw commodities could yield adulterated processed foods.

Through the coordination policy, EPA endeavored to establish more consistent standards for regulating pesticides in or on raw and processed food. According to the agency, consistent standards were needed because it is often difficult for growers to predict whether a treated crop will be eaten raw or processed. EPA determined that it would generally not establish or maintain a section 408 tolerance for a pesticide's use on a raw commodity if a section 409 tolerance would be required for some processed form of that commodity and the agency could not issue a

[7] 7 U.S.C. 136(bb).

[8] 21 U.S.C. 346a(b).

[9] Pesticides: EPA's Use of Benefit Assessments in Regulating Pesticides (GAO/RCED-91-52, Mar. 7, 1991) and Pesticides: Better Data Can Improve the Usefulness of EPA's Benefit Assessments (GAO/RCED-92-32, Dec. 31, 1991).

section 409 tolerance because of the Delaney clause. Thus, for example, EPA would not establish or maintain a section 408 tolerance for a pesticide's residues on raw apples if (1) the pesticide had been found to cause cancer in humans or animals and (2) the pesticide's residues were more concentrated in apple pomace (a processed apple product) than on raw apples. (In such a case, EPA would not grant a registration under FIFRA either.)

Through the concentration policy, according to an EPA official, EPA established a standard for determining whether concentration occurs during food processing and a section 409 tolerance is therefore needed for the pesticide's residues in processed food. While EPA has not set a strict numerical standard, EPA has concluded in the past that concentration in the range of 10 percent is just cause to require a section 409 tolerance. In other words, if EPA determines that a food may contain approximately 10 percent more residue when it is processed than when it is raw, then EPA concludes that concentration has occurred and a section 409 tolerance is needed.

According to section 402 of FFDCA, a section 409 tolerance is not necessary when the level of residue in a processed food "when ready to eat" is no greater than the level allowed by the section 408 tolerance. The federal pesticide laws do not define the term "ready to eat," and it is not always clear what "ready to eat" means. According to EPA, it would often not be practical to enforce tolerances for the forms of food that are actually served to people. Hence, through its ready-to-eat policy, EPA sets tolerances for pesticide residues in processed foods—such as apple juice, instant potatoes, flour, and tomato paste—as these products are available to the consumer or the food processor. In setting these tolerances, EPA assumes conservatively that the foods will be eaten as purchased, not washed, peeled, cooked, or combined with other ingredients. According to an EPA official, besides protecting the consumer, this approach is practicable: It does not require EPA to estimate how and in what concentrations consumers may combine these foods with other foods—an enormously complicated and virtually impossible task.

In 1988, EPA established a de minimis policy for setting section 409 tolerances for pesticides subject to the Delaney clause. The agency took this action to partially resolve the inconsistency between the Delaney clause's absolute prohibition of carcinogenic residues and the toleration, under other federal pesticide provisions, of minimal risks in exchange for benefits. Responding to a recommendation made by the National Academy

of Sciences in 1987 that EPA adopt a "negligible-risk" rather than a "zero-risk" standard in setting tolerances,[10] EPA announced that it would treat the Delaney clause as subject to a de minimis exception[11] when the human dietary risk from a pesticide's residues was, at most, negligible. In practice, as previously noted, EPA has generally defined negligible risk as an incremental increase in lifetime risk of 1 in 1 million or lower, as calculated according to a conservative risk-assessment methodology.[12] This methodology estimates theoretical rather than actual risk.

The Court Overruled EPA's De Minimis Policy

In attempting to implement the de minimis policy, EPA encountered resistance from environmentalists, labor organizations, and certain state officials. In May 1989, several parties filed a petition requesting EPA to revoke 14 section 409 tolerances for seven pesticides[13] on the grounds that these pesticides were carcinogenic to animals and therefore their uses violated the Delaney clause. The agency agreed to revoke a few of the section 409 tolerances, reserved judgment on some, and denied the petition for others on the basis of the de minimis policy.

In July 1992, the Ninth Circuit Court of Appeals overturned EPA's de minimis interpretation, concluding that, under the Delaney clause, once evidence of carcinogenicity is found, EPA has no discretion to apply a de minimis interpretation and therefore cannot allow a section 409 tolerance. In February 1993, the Supreme Court declined to review this case; hence, the court of appeals' ruling stands. Unless the Congress amends section 409 of FFDCA, EPA will implement the court of appeals' decision on the Delaney clause.

[10]The National Academy of Sciences committee concluded that a negligible-risk standard consistently applied to raw and processed foods "could give EPA the flexibility needed to reduce dietary oncogenic risks over time [and] . . . (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." Regulating Pesticides in Food: The Delaney Paradox, National Academy of Sciences (Washington, D.C.: 1987), p. 13.

[11]The legal doctrine of de minimis means that the law does not care for or take notice of very small or trifling matters.

[12]To calculate potential risk, EPA multiplies estimated exposure levels by estimated hazard levels. To estimate dietary risk, EPA evaluates data on the nature and amount of pesticide residue that can be expected to remain in food, the types and amounts of foods in the diet (exposure), and the toxic effects of the residue (hazard). In assessing dietary risk, EPA considers each pesticide separately and considers only exposure from food (and not from other sources, such as air and water). EPA often incorporates several worst-case assumptions—that, for example—pesticide residues are present at the published tolerance level (maximum legal level) and 100 percent of the acreage of a crop that could be treated with a pesticide will be treated. Some people believe that the uncertainties in risk-assessment methodology and the pesticide-by-pesticide assessment significantly underestimate risk. Others believe that this methodology substantially overestimates risk.

[13]Trifluralin, benomyl, phosmet, mancozeb, dicofol, dichlorvos (DDVP), and chlordimeform.

EPA Expects the Court's Decision to Prove Costly

While environmental, labor, and consumer groups view the Les decision as a victory for public health, EPA anticipates that its effects will prove costly. In July 1993, EPA issued a revocation notice for the section 409 tolerances cited in the court's decision, but the effective date of these revocations was automatically delayed by requests for administrative hearings and stays. As of March 1994, the agency had not applied its own coordination policy and proposed the revocation of the section 408 tolerances for the associated raw foods. According to the agency, the Les decision will ultimately require it to revoke tolerances for about 30 pesticides—with approximately 100 raw and processed food uses—unless it revises its remaining administrative policies. These pesticides include benomyl, which is used on apples, and triadimefon, which is used on barley. Appendix III lists the pesticides and uses that may be revoked.

In EPA's view, a literal implementation of the court's decision could hinder the agency's ability to ensure the safety and affordability of the food supply. In addition, placing so much emphasis on the relatively small dietary risk of cancer tends to obscure potentially more serious risks, such as risks to workers and the environment. The total impact of the Les decision will depend greatly on how EPA applies its administrative policies. According to the agency, the loss of the affected, currently registered pesticides could decrease the volume, quality, and variety of the agricultural crops grown in the United States. How long these effects might last is unknown. The production of minor crops[14]—such as apples and grapes—which now depends heavily on the use of pesticides subject to the Delaney clause (i.e., benomyl and dicofol), is expected to suffer the most, since alternatives to these pesticides may be limited. Hence, the loss of these pesticides could increase the prices of some foods and decrease the availability of a nutritional and varied food supply for consumers.

At the same time, according to EPA, the revocation of existing pesticide uses could affect incomes in the agricultural community, causing economic dislocations in certain parts of the country as well as geographical shifts in the production of certain crops, as the following example shows: A crop grown in several regions of the United States may be exposed to different pests in different regions. If a pesticide used to control pests in one region is eliminated, then production of the crop in that region may suffer. As a result, production of the crop may increase in other regions to overcome this shortfall.

[14]Minor crops are generally considered to be those crops for which the sales of a pesticide may not be judged to warrant the expense of maintaining an existing registration or establishing a new registration, and they include specialty crops, such as fruits and vegetables. In 1990, U.S. agricultural sales for minor crops totaled approximately $30 billion.

Although EPA has not formally estimated the economic costs to consumers and the agricultural community of losing these pesticides, it has stated preliminarily that the costs could be significant. EPA officials suggest that, in almost all cases, the economic effects on users of losing a specific pesticide are minimized within 3 to 5 years.

According to representatives of pesticide manufacturers and food processors, the loss of some pesticides could increase risks to public health by increasing consumers' exposure to (1) naturally occurring toxins whose growth is currently inhibited by certain fungicides for which weak evidence of human carcinogenicity has been found and (2) noncarcinogenic alternatives that pose other—sometimes greater—risks, such as the risk of birth defects or neurological damage. Furthermore, according to EPA, strict interpretation of the Delaney clause—which applies only to carcinogenic pesticide residues that are concentrated in or added to processed foods—could discourage the development, registration, and use of safer new pesticides. For example, if pesticide X posed a lower risk of cancer in raw foods than pesticide Y but pesticide X was concentrated in processing, pesticide X would not receive a section 409 tolerance—no matter how negligible the potential risk of cancer it posed. Although pesticide Y might pose a greater potential risk of cancer, it would not require a section 409 tolerance because it was not concentrated during processing. Thus, if pesticide Y met the standards in FIFRA and FFDCA section 408, it could be registered for food use, while, under the Delaney clause, the lower-risk pesticide, pesticide X, could not.[15]

According to consumer, labor, environmental, and public health organizations, which argue that the use of pesticides can jeopardize public health, the loss of carcinogenic pesticides would reduce consumers' exposure to harmful chemicals and thereby improve food safety and public health. In addition, these organizations believe that the cancellation of hazardous pesticides could accelerate the development of safer pesticides. According to these organizations, adopting safer methods of pest management, such as alternative agricultural practices, could reduce the use of pesticides and further decrease consumers' exposure to

[15]Similarly, if pesticide Z posed small, yet greater noncarcinogenic risks (of, for example, reproductive effects or birth defects) than pesticide X and if pesticide Z was not concentrated in food processing and met the standards in FIFRA and FFDCA section 408, then pesticide Z could be registered for food use. Under the Delaney clause, the safer pesticide, pesticide X, could not be registered for use in a processed food in which the pesticide's residues were concentrated above the level allowed on the raw food.

carcinogens. Furthermore, they contend that the economic impacts of cancelling these pesticides are overstated.

Modifying Administrative Policies Would Not Resolve Differences

To mitigate what it sees as the negative effects of the Les decision, EPA could modify its remaining administrative policies, but such modification could not resolve the legal differences that first led the agency to develop the policies. For instance, if EPA abandoned its coordination policy, it would not have to revoke the section 408 tolerances for those pesticide uses whose section 409 tolerances the court found in violation of the Delaney clause. Thus, for example, if EPA abandoned the coordination policy, it could retain the section 408 tolerance for the use of a pesticide on raw apples even after it had revoked the section 409 tolerance for the use of the same pesticide in apple pomace.[16]

Similarly, EPA could modify its concentration and ready-to-eat policies by altering the threshold for concentration and thereby relaxing or tightening regulatory standards. For example, EPA could decide that concentration in the range of 5 percent—or of 15 percent—was just cause for requiring a section 409 tolerance. Or it could set higher tolerances for pesticide residues in foods that it assumed would be combined in specified proportions with other ingredients. But changes in the standard of concentration—from a flexible range to a single numerical standard—would be arbitrary, and changes in the ready-to-eat policy could not cover all contingencies and, according to EPA, would be virtually impossible to administer and enforce. Moreover, such changes could not alter the fact that, under the "flow-through" provision of FFDCA (section 402), comparison with a raw food tolerance (which could have been established through a consideration of risks and benefits), rather than evaluation based on a uniform standard of risk, drives the regulation of pesticide residues in processed foods.

Even though administrative changes will not resolve the varying requirements in the federal pesticide laws, the Les decision has fueled the demand for EPA to modify its remaining administrative policies. In September 1992, for example, the National Food Processors Association

[16]The economic impact of abandoning the coordination policy is not clear. Such a change in EPA's policy might reduce the economic impact of the court's decision on pesticide manufacturers, growers, and consumers because it would continue to allow the use of the affected pesticides on raw food. However, it could increase the likelihood that food processors would unknowingly produce adulterated food. According to an EPA official, the market might create some rough equivalent of the coordination policy if farmers and processors reacted to the possibility that processed food might be adulterated by simply refusing to accept foods containing pesticides for which section 409 tolerances had been denied or revoked.

filed a petition with the agency, asking it to reassess its coordination policy in order to forestall the perceived negative effects of implementing the court's decision. The petition seeks recision of EPA's concentration and coordination policies on the grounds that these policies are inconsistent with the flow-through provision of FFDCA. According to the association, FDA and industry data demonstrate that actual pesticide residue levels in agricultural commodities and in processed food are well below the levels set in section 408 tolerances. Furthermore, according to the association, food processors employ good manufacturing practices that ensure the compliance of finished products with the flow-through provision.

Similarly, although EPA has argued that changes in its ready-to-eat policy would be difficult to administer, the National Food Processors Association filed a petition in May 1993 with FDA, which is responsible for enforcing pesticide tolerances, to provide for what the association believes is the proper application of the flow-through provision. The petition asks FDA to recognize that a concentrated processed food that is not ready to eat is legal so long as ready-to-eat foods made from the concentrated product contain lower levels of a pesticide's residues than are specified in the applicable section 408 tolerance. The petition requests FDA to prescribe appropriate concentrations for reconstituted processed ingredients on the basis of the ingredients' customary use in finished foods. It also requests FDA to issue a tolerance or action level under section 406 of FFDCA for a pesticide's residues in a ready-to-eat processed food that exceed the tolerance for the raw product but pose an acceptable health risk.

Meanwhile, environmental, labor, consumer, and public health groups have opposed any weakening of the remaining policies. They contend that EPA's policy of denying section 408 tolerances for pesticides that cannot receive section 409 tolerances is sound public policy consistent with federal statutes. According to an EPA official, as of March 1994, EPA had not determined whether it would revise its administrative policies in light of the Les decision.

The Congress Could Amend the Federal Pesticide Laws

The Congress alone has the authority to amend the federal pesticide laws to establish a single regulatory standard for pesticide residues on or in raw commodities and processed foods. Policy options considered by the Congress range from taking no legislative action to amending the laws to both resolve their differences and extend their scope. In broad terms, options for amending the laws include (1) allowing zero risk of cancer (providing for a phaseout of the most dangerous pesticides) with no

consideration of benefits, (2) allowing negligible dietary risks with no consideration of benefits, and (3) allowing negligible dietary risks with limited consideration of benefits. If the Congress decides to amend the laws, its choice of a regulatory standard will depend on its determination of (1) how much risk, if any, is appropriate and (2) whether and how benefits, and which benefits, should be considered and for what time period. The legislation proposed by the administration in April 1994 would allow only negligible risks, with limited consideration of benefits during a transitional period after the law's enactment. The proposed legislation would also mandate consideration of some factors that the current laws do not specifically address, such as risks to infants and children.

Taking No Legislative Action Would Perpetuate EPA's Regulatory Dilemma

If the Congress takes no action, differences in the federal pesticide laws will remain, and EPA will have to implement different standards. Since the Les decision, EPA has not been able to invoke the de minimis approach, and it may find that the recent industry petition asking it to reassess its coordination policy is followed by lawsuits, no matter how it rules on the petition. Furthermore, if both the laws and EPA's remaining administrative policies stay the same, reductions in the quality and variety of the available food supply and increases in food prices could occur, as EPA has indicated.

A Zero-Risk Standard Would Eliminate All Carcinogenic Uses

To create a zero-risk standard[17] for pesticide residues on or in both raw and processed foods, the Congress could amend sections 408 and 409 of FFDCA to be consistent with the Delaney clause. Under this option, EPA would have to phase out all food tolerances for any pesticide found to cause cancer in animals. For consistency, the Congress could also amend FIFRA to require the cancellation of all food uses of all carcinogenic pesticides.

Proponents of this approach argue that scientific knowledge of the risks posed by carcinogens is too uncertain to justify allowing any potential risk. Although science can determine that a chemical is a carcinogen, it cannot determine how much exposure to that chemical is necessary to trigger carcinogenic effects in humans. Neither can it definitively determine how that chemical will interact with other chemicals in the body. Nor can it measure delayed or long-term effects with sufficient accuracy to determine how much exposure to a chemical poses no risk of cancer. Therefore, according to advocates of a zero-risk standard or

[17]As previously noted, the term "zero risk," as used in this report, means no intentional addition of carcinogens to food.

carcinogenic phaseout, there is no scientific basis for categorizing any carcinogenic exposure as a "trivial" or "negligible" risk, and there is no justification for intentionally adding any carcinogen to food. According to proponents of the zero-risk standard, the current regulatory system's admission of "negligible" or "acceptable" levels of risk may permit the use in food of chemicals that cause thousands of extra cases of cancer per year. Until more is known about the carcinogenic effects of chemicals on humans, proponents believe, a zero-risk standard is necessary to protect public health.

Opponents argue that implementing a zero-risk standard would create the same negative effects as implementing the Les decision in conjunction with EPA's administrative policies. Such a standard would negatively affect the cost and availability of foods, afford no opportunity for considering the benefits of pesticides to public health, and could create international trade difficulties. Opponents further argue that a zero-risk standard would be impracticable and costly to implement. The term "zero risk" is itself misleading, they believe, because the results of scientific tests are too uncertain to prove definitively that no risk exists. Furthermore, the meaning of the term shifts constantly as testing methods improve. Today, tests are far more sensitive than they were in 1958 when the Delaney clause was written, and scientists are now able to detect traces of residue in concentrations of parts per billion and smaller. Although, according to opponents, these traces pose virtually no threat to public health, EPA is obliged to prohibit the presence of carcinogenic residues, regardless of risk, when the Delaney clause applies. According to the National Academy of Sciences, EPA has focused considerable resources on assessing carcinogenic risk.

A Negligible-Risk Standard Would Allow EPA to Evaluate Carcinogenic Risks

To create a single negligible-risk standard for carcinogens, the Congress could amend FFDCA so that the same standards would be applied to both raw and processed commodities. According to the National Academy of Sciences, the application of such a standard to all pesticides and all forms of food could dramatically reduce the total dietary exposure to carcinogenic pesticides and only marginally reduce benefits.

Proponents contend that the consistent application of a negligible-risk standard to raw and processed foods would allow the United States to continue producing a safe, economical, and abundant food supply. It would improve the federal regulation, and reduce the risks, of pesticide use by focusing limited regulatory resources on the crop and pesticide

combinations presenting the greatest risks. A negligible-risk standard applied to all uses would allow EPA to discriminate between relatively significant and relatively insignificant carcinogenic risks, and it would give the agency the flexibility to replace more carcinogenic with less carcinogenic pesticides, thereby enabling it to reduce consumers' overall exposure to carcinogens in the diet. In addition, pesticides posing minimal carcinogenic risks could replace other pesticides that pose higher risks to health and the environment but are not carcinogenic.

The term "negligible risk" could be defined in strictly numerical or in narrative terms. A numerical, or "bright line," definition would require EPA to apply a specific measure—such as a theoretical incremental increase in the lifetime risk of cancer of 1 in 1 million people—to all pesticide uses on all commodities and could require EPA to use a specific methodology. A narrative, or "fuzzy line," definition would give EPA the flexibility, in setting tolerances, to use the most up-to-date methods of assessing risk as these evolve with changes in scientists' understanding of carcinogenic risk.

Proponents of a bright line standard believe that it would give consumers the best assurance that food is safe. Since a bright line standard would require the agency to reevaluate existing pesticide uses against a numerical legal standard, proponents argue, it would provide a consistent basis for measuring carcinogenic risk and would help to protect EPA against litigation, manipulation, and political pressure. According to proponents, the adoption of a bright line standard would not deny EPA the right to choose the methodology for conducting risk assessments, nor would it prevent the agency from modifying the assumptions it used to conduct risk assessments in keeping with scientific developments.

Proponents of a narrative definition of negligible risk believe that regulators should be given the flexibility to set tolerances on the basis of evolving science, not on the basis of a number—considered arbitrary by some—codified into law at a specific time. Furthermore, they argue, setting a numerical standard would suggest that risk assessment is a more exact science than it is. According to proponents, a fuzzy line would be more consistent with the actual variation in the quality of the data that are available to EPA in assessing risks. For example, existing data may not adequately demonstrate the quantities and toxicological effects of pesticide residues. Moreover, according to proponents, a narrative standard would give EPA the discretion to use the most up-to-date risk-assessment procedures and to take into account the fact that

scientists believe, in some cases, that quantitative risk assessment is not appropriate.

Opponents of a negligible-risk standard support a zero-risk standard, or an ultimate phaseout of carcinogens. They contend that a negligible-risk standard unnecessarily exposes people to cancer-causing substances and fails to create incentives for developing safer alternatives. As previously noted, opponents argue that no risk can be deemed "acceptable" or "negligible" because too little is known about when or in what dosage a carcinogen causes cancer. Hence, opponents believe that carcinogens should not intentionally be added to the food supply.

Considering Benefits in Conjunction With a Negligible-Risk Standard Would Give EPA Greater Flexibility

To allow EPA to consider benefits in conjunction with a negligible-risk standard, the Congress could amend section 409 of FFDCA to be consistent with section 408 and FIFRA, both of which require EPA to consider specified types of benefits. This policy option could give EPA the flexibility to consider the economic as well as the health and ecological effects of its regulatory decisions.

Proponents of considering benefits argue that, by killing weeds and insects, pesticides help farmers produce a varied, abundant, affordable, and dependable food supply. Thus, pesticides provide nutritional and economic benefits to consumers. It is these benefits, as distinct from industry profits, that should be considered in regulating pesticides, proponents maintain.

Opponents of considering benefits argue that the practice allows economic rather than health concerns to dominate the regulatory process.[18] They believe that, under the current system, benefit assessments create a "loophole" that could permit the use of pesticides whose tolerances exceed negligible-risk standards. For example, if removing a pesticide from the market would create an economic loss, then a benefit assessment might provide a rationale for keeping the risky pesticide on the market. Thus, according to opponents, consumers' health

[18]For example, the National Academy of Sciences argued in 1993 that, to "ensure that infants and children are not exposed to unsafe levels of pesticide residues . . . EPA [should] modify its decision-making process for setting tolerances so that it is based more on health considerations than on agricultural practices. These changes should incorporate the use of improved estimates of exposure and more relevant toxicology, along with continued consideration of the requirements of agricultural production. As a result, human health considerations would be more fully reflected in tolerance levels." Pesticides in the Diets of Infants and Children, National Academy of Sciences (Washington, D.C.: 1993), p. 8.

could receive lower priority than agricultural practices when benefits were assessed.

The Administration Has Proposed Legislation to Reform the Federal Pesticide Laws

In April 1994, the administration proposed legislation outlining legislative reforms and administrative initiatives to improve food safety, protect human health and the environment, and establish a consistent framework for making timely regulatory decisions. The proposed legislation calls for, among other things, amending FFDCA to require EPA to set tolerances for pesticide residues in all types of food in accordance with a strong, health-based safety standard. This standard would require reasonable certainty of no harm to consumers and negligible risk for carcinogens. According to an EPA official, EPA does not want legislation to specify a bright line numerical standard for negligible risk in the statute because such a standard could, like the Delaney clause, become outdated as science evolves. Under the administration's proposal, benefits could be considered in some instances when existing tolerances exceeded the negligible-risk standard. However, these tolerances could be continued for a limited time (up to 5 years, or 10 years after the law's enactment, whichever is earlier) when needed to avoid a significant disruption in the food supply or the loss to consumers of direct health benefits.

However, an EPA official told us that although the administration's proposal would allow EPA to consider benefits in determining whether pesticides could be registered under FIFRA, it would limit the agency's consideration of benefits in setting tolerances for pesticide residues under FFDCA. According to EPA, benefits are and would be considered under FIFRA mainly for pesticides that were not used on foods. Regulatory decisions for food-use pesticides would be made primarily under FFDCA. EPA officials acknowledged that any legislative reform would need to clearly link actions under FFDCA and FIFRA to avoid any differences between the two statutes.

Besides seeking to resolve differences in the existing federal pesticide legislation, the administration's proposal addresses a number of issues related to establishing pesticide tolerances. The proposal would direct EPA to

- consider the impact of exposure to pesticides from multiple sources, such as food, air, and water;
- publish specific findings showing that tolerances protect infants and children;

- assess the impact of exposure to multiple pesticides that cause the same health effect;
- consider food distribution patterns and risks to potentially sensitive subpopulations;
- encourage the development and use of less toxic pesticides, methods of pest control, and agricultural practices; and
- review all existing tolerances to ensure that they meet the new health-based safety standard.

The Choice of a Regulatory Standard Will Depend on Values

If the Congress decides to amend the federal pesticide laws, its choice of a policy option is likely to depend ultimately as much on policy judgments and decisions as it does on science. As we have demonstrated in other reports,[19] both risk and benefit assessments rely on uncertain data and assumptions, and efforts to balance risks and benefits require weighing public health and economic interests as well as evaluating data. Hence, the Congress's choice of a policy option—and of an appropriate standard for regulating pesticides—will require agreement on policy as well as scientific issues.

Conclusions

The administrative policies that EPA developed to reconcile differences in the federal pesticide laws have been and may again be challenged in court. If these laws remain unchanged and if EPA retains the coordination policy and other remaining policies, the Les decision may compel the revocation of tolerances for a large number of pesticide uses. If the laws remain unchanged and if EPA revokes its remaining policies, fewer tolerances would have to be revoked.

Amending the federal pesticide laws to establish a single standard for regulating pesticide residues in or on all foods would give EPA a coherent basis for setting tolerances and would allay controversy over the agency's implementation of the pesticide laws. What that standard should be—how much risk it should allow and whether it should permit the consideration of benefits—is a question that science cannot yet answer definitively. Although scientists have improved their ability to detect pesticide residues and assess risks, they cannot determine exactly how much risk these

[19]For information on risk assessments, see Pesticides: Pesticide Reregistration May Not Be Completed Until 2006 (GAO/RCED-93-94, May 21, 1993) and Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125, Apr. 18, 1986). For information on benefit assessments, see Pesticides: Better Data Can Improve the Usefulness of EPA's Benefit Assessments (GAO/RCED-92-32, Dec. 31, 1991). See also Food Safety: Difficulties in Assessing Pesticide Risks and Benefits (GAO/T-RCED-92-33, Feb. 26, 1992).

residues pose, either alone or in combination with other environmental effects. Therefore, at this time, decisions about whether to allow residues of carcinogenic pesticides in food are, ultimately, policy judgments—judgments that the Congress may be called upon to make in reauthorizing FIFRA and amending FFDCA. A clear resolution of the differences in the federal pesticide laws would help to avoid recurring regulatory difficulties and disputes.

Agency Comments

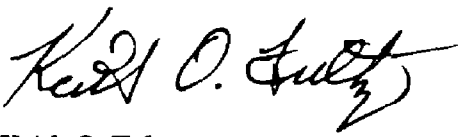
In written comments on a draft of this report, which appear in appendix IV, EPA concurred with our conclusions. Under separate cover, EPA provided technical clarifications that we incorporated into this report where appropriate. We also incorporated comments from panelists who participated in a symposium on pesticide issues that we sponsored on July 20, 1993.

Scope and Methodology

We conducted our review from June 1993 to April 1994. To accomplish our objectives, we collected and reviewed data from federal agencies and from industrial, environmental, and other nonprofit organizations. We interviewed officials from EPA. Also, as noted, we sponsored a symposium on July 20, 1993, for experts on pesticide issues from federal agencies, environmental groups, and industry groups to discuss options for resolving differences in the federal pesticide laws. The five panelists were Jay Feldman, Executive Director, National Coalition Against the Misuse of Pesticides; Rick Jarman, Director, Technical Regulatory Affairs-EPA, National Food Processors Association; William L. Jordan, Deputy Director, Policy and Special Projects Staff, Office of Pesticide Programs, Environmental Protection Agency; John McCarthy, Vice President, Global Scientific and Regulatory Affairs, National Agricultural Chemicals Association; and Erik D. Olson, Senior Attorney, Natural Resources Defense Council.

We are sending copies of this report to interested congressional committees and to the Administrator, EPA. We will make copies available to others on request.

This work was performed under the direction of Peter F. Guerrero, Director, Environmental Protection Issues, who can be reached at (202) 512-6111. Other major contributors to this report are listed in appendix V.



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The Honorable Carlos J. Moorhead
Ranking Minority Member
Committee on Energy
and Commerce
House of Representatives

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Abbreviations

EPA	Environmental Protection Agency
DDVP	Dichlorvos
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act

Provisions of Federal Laws Regulating Pesticides

Law/provision	Regulates	Purpose/effect
FIFRA	Pesticide uses	Register specified uses of pesticide products on the basis of both risks and benefits. Pesticide may not cause any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide.
FFDCA (specified sections)	Pesticide residues in or on foods	Limit the amount of pesticide residue in or on raw agricultural commodities, processed foods, or animal feed.
Section 408	Pesticide residues on raw agricultural commodities (raw foods). Requires a tolerance (legal limit on the amount of pesticide residue allowed) or tolerance exemption.	Protect human health while allowing for the production of an adequate, wholesome, and economical food supply.
Section 409 (includes Delaney clause, sec. 409(c)(3)(A))	Pesticide residues (classified as food additives) in processed foods. Requires a tolerance when the level of residue exceeds that prescribed in the section 408 tolerance for the raw agricultural commodity. Under the Delaney clause, no food additive tolerance may be granted for a pesticide found to induce cancer in humans or animals. (Certain exceptions are made for animal feed.) Also regulates pesticides applied during or after processing.	Protect human health by requiring that proposed use will be safe. Delaney clause establishes a strict "zero-risk" standard for carcinogenic pesticide residues in processed food.
Section 402	Adulterated food. Provides that a raw food is adulterated if it contains a pesticide whose residues are not authorized by a section 408 tolerance or exemption. Requires a section 409 tolerance for a pesticide (1) whose residues are concentrated above the section 408 tolerance in processed food that is "ready to eat" or (2) that is added to the processed food during or after processing. (Without a tolerance, the processed food is considered adulterated.) The "flow-through" provision, section 402(a)(2)(C), exempts a pesticide from the requirement for a section 409 tolerance when the pesticide's residues in a processed food that is "ready-to-eat" are not concentrated above the tolerance prescribed in section 408 for the same raw food.	Permit the use of certain products for which a section 409 tolerance could not be obtained. Under the flow-through provision of section 402(a)(2)(C), the use of a pesticide containing a minute quantity of a carcinogenic ingredient could be allowed, whereas, under the Delaney clause, this use would be prohibited. Since the term "ready to eat" has not been defined, the concentration requiring a section 409 tolerance is uncertain.

Differences in Federal Laws Regulating Pesticides

Legal provision	Regulates	Balances risks and benefits	Permits controlled use of carcinogens
FIFRA	Pesticide uses	Yes	Yes
FFDCA (specified sections)	Pesticide residues on or in foods	Under some conditions	Under some conditions
Section 408	Pesticide residues on raw agricultural products	Yes	Yes
Section 409 (excluding Delaney clause)	Pesticide residues in processed food that are concentrated above the section 408 tolerance	Yes (according to EPA's interpretation)	Not applicable
Section 409 - Delaney clause	Carcinogenic pesticide residues	No	No
Section 402(a)(2)(C) - flow-through provision	Pesticide residues in ready-to-eat processed food that are not concentrated above the section 408 tolerance	Yes	Yes

Pesticide Uses Potentially Affected by Revocation of Section 409 and Corresponding Section 408 Tolerances

According to EPA, the registrations for the pesticides and the tolerances for their uses listed in tables III.1 and III.2 may be revoked if EPA holds to a strict interpretation of the Delaney clause. EPA has not determined that these pesticides "induce cancer" within the meaning of the Delaney clause but has found, under its cancer classification guidelines, that the pesticides are potentially carcinogenic. As EPA acquires new data through its reregistration program from tests of pesticides' carcinogenicity and from food-processing studies, it may include some other pesticides or uses in these tables, or it may exclude others. Hence, the tables should not be considered definitive or final. The information in the tables is frequently updated.

The publication of these tables does not affect the regulatory status of any of the pesticides or uses cited. If EPA proposes to revoke tolerances under FFDCA, it will announce its intention to do so through regulatory channels, providing notice and seeking comment as appropriate.

Table III.1: Pesticides With Established Section 409 Food Additive Tolerances

Registered pesticide	Raw crop (408 tolerances)	Processed food/feed with 409 tolerance(s)
Acephate	Cotton	Seed hulls, meal
	Soybeans	Meal
	Not applicable	Food handling establishments
Benomyl[a]	Apples	Pomace
	Citrus	Pulp
	Grapes[a]	Pomace
		Raisins[a] (proposed for revocation)
		Raisin waste
	Rice	Hulls
	Tomatoes[a]	Puree or catsup[a] (proposed for revocation)
Captan	Grapes	Raisins
Dichlorvos (DDVP)[a]		Packaged nonperishable food[a,b] (proposed for revocation)
Dicofol[a]		Dried tea[a,b] (revoked)
Diflubenzuron	Soybeans	Hulls, soapstock
Dimethipin	Cotton	Seed hulls
Dimethoate	Citrus	Pulp
Ethylene oxide	Whole spices	Ground spices

(continued)

Registered pesticide	Raw crop (408 tolerances)	Processed food/feed with 409 tolerance(s)
Mancozeb[a]	Barley[a]	Bran[a]
		Flour
		Milled fractions
	Grapes[a]	Raisins[a] (proposed for revocation)
	Oats[a]	Bran[a]
		Flour
		Milled fractions
	Rye	Bran[a]
		Flour
		Milled fractions
	Wheat[a]	Bran[a] (proposed for revocation)
		Flour (proposed for revocation)
		Milled fractions
Norflurazon	Citrus	Pulp, molasses
Oxyfluorfen	Cotton	Cottonseed oil
	Peppermint	Oil
	Spearmint	Oil
	Soybean	Oil
Phosmet[a]	Cotton[a]	Cottonseed oil[a] (proposed for revocation)
Propargite	Apples	Pomace
	Grapes	Raisins
		Dried pomace
	Figs	Dried figs
	Citrus	Pulp
	Tea	Dried tea
Propylene oxide		Cocoa[b]
		Glace fruit[b]
		Edible gums[b]
		Processed nutmeat (except peanuts)[b]
		Prunes[b]
		Processed spices[b]
		Starch[b]
Simazine	Sugarcane	Molasses, syrup
		Potable water[b]

(continued)

Registered pesticide	Raw crop (408 tolerances)	Processed food/feed with 409 tolerance(s)
Tetrachlorvinphos		Feed items[b]
Thiophanate-methyl	Apples	Pomace
Triadimefon	Apples	Pomace
	Barley	Milled fractions
	Grapes	Pomace
		Raisin waste
	Wheat	Milled fractions
Trifluralin[a]	Peppermint[a]	Oil[a] (proposed for revocation)
	Spearmint[a]	Oil[a] (proposed for revocation)

[a]Identifies pesticides and uses that have been challenged in the Les v. Reilly case.

[b]Identifies commodities that do not have corresponding section 408 tolerances because the pesticide is used only on the processed commodity.

Source: GAO's presentation of information from EPA.

Table III.2: Pesticides That Do Not Have Established Section 409 Food Additive Tolerances but Would Require Them Under EPA's Current Policies

Registered pesticide	Crop(s) with section 408 tolerance(s)	Processed food(s) with no section 409 tolerance(s)
Acephate[a]	Soybeans[a]	Hulls
Alachlor	Peanuts	Meal
	Soybeans	Hulls, meal
	Sunflower seed	Meal
Asulam	Sugarcane	Bagasse, molasses
Atrazine	Sugarcane	Bagasse, molasses
Benomyl[a]	Rice[a]	Bran
	Soybeans	Hulls
Captan[a]	Apples	Dry pomace
	Grapes[a]	Raisin waste, juice, dry pomace
	Plums	Prunes
	Tomatoes	Dry pomace
Chlorothalonil	Soybeans	Hulls
	Potatoes	Wet peel
Dichlorvos (DDVP)[a]	Not applicable	Food handling establishments
Dicofol[a]	Apples	Dry pomace
	Citrus	Oil

(continued)

Registered pesticide	Crop(s) with section 408 tolerance(s)	Processed food(s) with no section 409 tolerance(s)
	Grapes	Dry pomace, raisins, raisin waste
	Plums	Prunes
Dimethoate[a]	Apples	Juice
	Citrus[a]	Oil
Hexazinone	Alfalfa	Meal
	Pineapple	Bran, molasses
	Sugarcane	Bagasse, molasses
Lindane	Tomatoes	Dry pomace
Linuron	Potatoes	Dry and wet peel, dried granules, chips
	Soybeans	Meal
Mancozeb[a]	Apples	Dry pomace
	Grapes[a]	Raisin waste
	Sugar beets	Pulp
	Wheat[a]	Middlings
Maneb	Apples	Dry pomace
	Sugar beets	Pulp
	Grapes	Raisin waste
Methidathion	Citrus	Oil
Metiram	Apples	Dry pomace
	Sugar beets	Pulp
Metolachlor	Peanuts	Meal
Methomyl	Wheat	Bran
Norflurazon[a]	Citrus[a]	Oil
	Grapes	Raisin waste
Oxyfluorfen[a]	Apples	Dry pomace
PCNB	Potatoes	Wet and dry peel
	Tomatoes	Dry pomace
Permethrin	Tomatoes (limited to use on tomatoes to be sold fresh in the marketplace)	Dry pomace
Phosmet[a]	Citrus	Oil
Propargite[a]	Citrus[a]	Oil
	Plums	Prunes
	Grapes[a]	Raisin waste
Simazine[a]	Sugarcane[a]	Bagasse
Triadimefon[a]	Pineapple	Bran
Trifluralin[a]	Potatoes	Processed potato waste

(Table notes on next page)

[a]Identifies pesticides and uses that are also included in table III.1.

Source: GAO's presentation of information from EPA.

Comments From the Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 14 1994

OFFICE OF
ADMINISTRATION
AND RESOURCES
MANAGEMENT

Mr. Peter F. Guerrero, Director
Environmental Protection Issues
Resource, Community, and Economic Development Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Guerrero:

I appreciate the opportunity to review and comment on the GAO draft report entitled Pesticides: Options to Resolve Inconsistent Legislation (GAO/RCED-94-57). Under separate cover, EPA staff provided GAO with editorial comments for consideration when preparing the final report.

The report describes the inconsistencies in Federal statutes with respect to the regulation of potentially carcinogenic pesticides which are used in food production. In the report, GAO concludes that only Congress can resolve the inconsistencies between the Delaney clause of section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) and the general safety standard of the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). We concur with GAO's conclusions.

We have been working with the U.S. Department of Agriculture, the Food and Drug Administration and the White House to develop an Administration legislative proposal. The heart of the proposal is the establishment of a strong, health-based standard that would apply to all pesticide residues in food.

I appreciate the careful effort by GAO evaluators to understand this complex subject. I look forward to receiving the final report.

Sincerely,

David J. O'Connor

for Jonathan Z. Cannon
Assistant Administrator
and Chief Financial Officer

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