Office of Pesticides
and Toxic Substances
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EPA

Environmental Fact Sheet

THE DELANEY PARADOX AND NEGLIGIBLE RISK

INTRODUCTION

The U.S. Environmental Protection Agency (EPA) regulates pesticides under two statutes, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Under FIFRA, EPA may license or "register" pesticide products for sale and use in the United States if the benefits of these uses outweigh the risks. Under the FFDCA, EPA sets legally enforceable limits, or "tolerances", for pesticide residues that are expected to remain in or on foods treated with pesticides. Tolerances are set for pesticide residues remaining in raw agricultural commodities under the provisions of section 408 of the FFDCA, while "food additive tolerances" are set for residues remaining in certain processed foods under section 409 of the FFDCA.

For many years, EPA's program to regulate pesticides used on food has been complicated by the differing statutory standards of FIFRA and the FFDCA. Section 409 of the FFDCA contains the "Delaney Clause", which has been especially problematic. While EPA may make other pesticide registration and tolerance-setting decisions taking into account both risks and benefits of pesticides, the Delaney Clause bars EPA from establishing a food additive tolerance for pesticide residues in certain processed food if there is evidence that the pesticide may cause cancer in man or animals, no matter how small the risk or how large the benefits. The conflicting "zero risk" standard embodied in the Delaney Clause has hindered the overall progress of EPA's pesticide reregistration and food safety programs, as explained further below.

Based on recommendations of the National Academy of Sciences, EPA has adopted a new approach to setting food additive tolerances which partly overcomes the inconsistency between the scientifically obsolete Delaney Clause and both FIFRA and the rest of the FFDCA. As described in a policy statement issued by EPA in October 1988, whenever possible, the Agency will use a "negligible risk" standard rather than the zero risk standard set forth in the Delaney Clause. EPA plans to apply this approach as it proceeds with its reregistration and tolerance reassessment

programs, and is developing legislative initiatives to make clear, consistent standards explicit in our pesticide and food safety laws.

BACKGROUND

The inconsistent standards in our current laws--what the National Academy of Sciences has called the "Delaney paradox"--have been a source of difficulty and confusion for pesticide regulators and the general public alike for many years. The paradox occurs because the regulatory standard which EPA is required to apply in establishing pesticide tolerances under section 409 of the FFDCA is different from the standards that apply under FIFRA and section 408 of the FFDCA. FIFRA specifically directs the Agency to balance pesticide risks and benefits in making registration and other regulatory decisions. Similarly, under section 408 of the FFDCA, EPA gives appropriate consideration to the necessity for the production of an adequate, wholesome and economical food supply in setting tolerances for raw agricultural commodities. Thus, both FIFRA and section 408 of the FFDCA require consideration of the benefits of pesticide use as well as the risks.

By contrast, the Delaney Clause set forth in section 409 of the FFDCA, which applies when setting tolerances for pesticide residues that concentrate in processed food products (often called "food additive tolerances") says that, "no additive shall be deemed safe [and therefore no food additive tolerance may be set] if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal..." Literally interpreted, the Delaney Clause sets a "zero risk" standard for pesticides that induce cancer responses in test animals, even if the risk to humans is inconsequential because the oncogenic potential of the pesticide is weak and/or human exposure is very low.

The Delaney Clause became increasingly problematic for EPA in cases where pesticides were found to meet the risk/benefit test of FIFRA, but not the Delaney standard. In reviewing existing pesticides, questions about applying the Delaney Clause arose in two types of instances. First, in some cases, new risk data have indicated that a pesticide with previously approved registrations and food additive tolerances induces tumors in test animals. Second, in other instances, newer, more sophisticated testing techniques have allowed EPA to detect low levels of pesticide residues that previous analytical methods could not detect. These new residue data have indicated a need for food additive tolerances for certain uses of pesticides that are known to induce some degree of tumor response in laboratory animals.

EPA has questioned the appropriateness of a strict application of the Delaney Clause for a number of reasons. For example, pesticide uses that result in residues requiring food additive tolerances (for example, in tomato paste) do not necessarily pose risks that are greater than pesticide uses that result in residues requiring only regular section 408 tolerances (for example, on fresh tomatoes). Also, when a pesticide has shown only a marginal carcinogenic effect in a high dose animal study, or when study results conflict, EPA has questioned whether a strict, retroactive application of the Delaney Clause would in fact serve to promote the overall safety of the food supply.

In reviewing new pesticides and new uses of "old" pesticides, EPA has in the past consistently applied a rigorous interpretation of the Delaney Clause. However, in instances such as those described above, where new test data required by EPA on older pesticides have raised questions about the retroactive application of the Delaney Clause, the Agency has deferred making chemical-specific decisions, to date. The effect overall is to seriously hamper the Agency's ability to make sound decisions in conducting the pesticide reregistration and tolerance reassessment programs.

NAS REPORT AND RECOMMENDATIONS

In 1985, EPA commissioned the National Academy of Sciences (NAS), an expert, non-governmental body, to examine the scientific and regulatory implications of the varying food safety standards contained in FIFRA and the Delaney Clause of the FFDCA. The NAS report, Regulating Pesticides in Food: The Delaney Paradox, issued on May 20, 1987, was the result of this study. The NAS study report reached four principal conclusions:

1. All pesticides should be regulated on the basis of a consistent standard, so that there is no "double standard" for raw vs. processed foods or for old vs. new pesticides.

2. A uniform "negligible risk" rather than a "zero risk" standard for carcinogens in food, consistently applied, would best enable EPA to improve the overall safety of the food supply, and would result in only modest reductions in the benefits of pesticide use to farmers.

3. EPA should set its regulatory priorities by focusing first on the most worrisome pesticides used on the most-consumed crops.

4. The Agency should adopt a comprehensive analytical framework for forecasting the broad-scale impact of its pesticide-specific regulatory actions on the overall safety of the food supply.

EPA POLICY STATEMENT

In response to the NAS report, EPA published in the Federal Register on October 19, 1988, the policy statement, "Regulation of Pesticides in Food: Addressing the Delaney Paradox." A point-by-point summary follows.

EPA Response to NAS Conclusions 1 and 2

Ideally, in the absence of Delaney Clause constraints, EPA would evaluate and reevaluate all pesticides, old and new, according to a uniform risk/benefit standard. Pesticide residues in food would be considered in terms of the risks they present--based on their toxicity and anticipated dietary exposures--rather than according to the form of the food bearing them.

However, due to the specific language of the Delaney Clause, EPA cannot take the ideal approach in regulating pesticide uses that come under the purview of FFDCA section 409. Only a legislative change would allow EPA to implement fully its favored approach and the recommendations of the NAS.

As a matter of policy, however, EPA no longer considers the Delaney Clause an absolute bar to issuance of food additive tolerances under section 409 of the FFDCA. The Agency is now interpreting the Delaney Clause according to the de minimis principle of law, which holds that an administrative agency ordinarily has the inherent authority to avoid applying the terms of a statute literally when to do so would yield pointless or absurd results. EPA's position is that the Delaney Clause is subject to a de minimis interpretation when the human dietary risk from residues of a pesticide is at most negligible.

NAS recommends such use of a uniform negligible risk standard rather than a zero risk standard for carcinogens in food, but does not define "negligible risk". However, the NAS report does refer to past practice of both the Food and Drug Administration (FDA) and EPA. In cases where a quantitative risk estimate has been made, both agencies have generally used an upper-bound incremental lifetime risk on the order to 10^{-6} (0.000001 or 1 in a million), calculated using conservative risk assessment techniques as a benchmark. EPA's October 1988 notice therefore stated that its negligible risk policy would generally apply to risks of 10^{-6} or less, allowing for some variability in risk levels depending on the quality and strength of the data underlying the risk assessment.

EPA's use of negligible risk standard will affect different categories of pesticides, as follows. (See also Table I attached.)

1. Pesticides Posing No Cancer Risk - EPA will continue to issue registrations under FIFRA and set tolerances under sections 408 and 409 of the FFDCA, provided that these pesticides meet all other FIFRA criteria. EPA generally will not scrutinize the benefits of these pesticides, consistent with current practice; benefits will be assumed from the applicant's willingness to bear the cost of supporting the registration.

2. Pesticides Posing Negligible Cancer Risk - EPA will treat negligible risk as essentially no risk, proceeding as in 1 above to issue registrations under FIFRA and to set both section 408 and section 409 tolerances under the FFDCA. This represents a change in policy in that EPA will now use a negligible risk standard rather than a literal zero risk standard to set food additive tolerances under section 409 of the FFDCA.

3. Pesticides Posing Greater than Negligible Risk - EPA will continue to register such pesticides and issue relevant section 408 raw agricultural commodity tolerances if the benefits of these uses exceed their risks. However, under current law, EPA cannot and will not issue section 409 food additive tolerances for these pesticides, regardless of the benefits they afford.

EPA Response to NAS Conclusion 3

NAS' recommendation that EPA focus its energies on reducing risk from the most worrisome pesticides used on the most-consumed crops is reflected in the Agency's priority system for reviewing old pesticides. Priorities for reregistration review have been set according to a scheme which groups pesticides that are used on similar crops. This scheme is designed to address first those high volume uses which present the greatest potential risks. Therefore, reregistration reviews for most of the major food use pesticides in the U.S. are already underway.

EPA Response to NAS Conclusion 4

EPA is also taking steps to develop new analytical tools that will help us implement the fourth NAS recommendation--that EPA should develop improved tools and methods to estimate more systematically the overall impact of prospective regulatory actions on the safety of the food supply.

For example, EPA has laid the groundwork for tolerance reassessment by requiring pesticide registrants to submit up-to-date test data where studies are missing or inadequate. In addition, the Agency has developed a computerized Dietary Residue Exposure System (DRES), which enables EPA to assess the dietary risks of pesticides with much more sophistication than has previously been possible. As resources permit, EPA hopes to obtain more and better data on actual pesticide residues in food and on food consumption patterns. Using these data, EPA will be able to improve its pesticide risk assessments.

LEGISLATIVE INITIATIVES

Working with the Department of Health and Human Services/Food and Drug Administration and the Department of Agriculture, EPA is developing concrete legislative proposals to implement the President's Food Safety Plan, a set of needed, far-reaching pesticide regulatory reforms announced by President Bush in October 1989. A key element of this plan is harmonization of the legal standards that EPA uses in evaluating the safety of pesticide residues in food. The plan calls for use of a consistent negligible risk standard in evaluating the safety of pesticide residues in both raw and processed foods. Appropriate changes in the FFDCA and FIFRA currently are being drafted to implement these and other provisions of the President's plan, including enhanced EPA suspension and enforcement authorities and streamlined cancellation procedures.

Additional information is available from EPA on the provisions of the Bush Food Safety Plan and on the current status of relevant legislation.

TABLE I - REGULATORY OUTCOMES
OUTCOMES UNDER OLD AND NEW POLICIES

CANCER RISK LEVEL	NEED 409 CLEARANCE?	ACTION UNDER FFDCA (NEW POLICY)	ACTION UNDER FIFRA (NEW POLICY)	COMPARISON TO PRIOR POLICY
No risk	No	Issue 408 tolerance	Register	Same
	Yes	Issue 408, 409 tolerances	Register	Same
Negligible cancer risk	No	Issue 408 tolerance	Register	Same
	Yes	Issue 408, 409 tolerances	Register	Changed: Under old policy, EPA would have refused to issue 408, issue 409, or register
Greater than negligible cancer risk	No	Issue 408 tolerance if benefit outweighs risk	Register if benefit outweighs risk	Same
	Yes	Refuse to issue 409 because of Delaney; refuse to issue 408 because 409 barred	Refuse to register because of lack of needed FFDCA clearances	Same