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The Delaney Clause: New Interpretations

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Responding to concern over food safety and questions about chemical residues in the food supply, the Environmental Protection Agency (EPA) has changed the method by which it will consider granting registrations to new pesticides, and reviewing both new and old uses of established pesticide products.

In order to be more consistent in the manner in which pesticide products are registered for sale and use, the EPA is attempting to reconcile the often conflicting stipulations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with the Delaney Clause portion of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Under FIFRA, EPA registers pesticide products and their uses after determining that the pesticides will cause no unreasonable adverse effects to man or the environment. Under the FFDCA, the Delaney Clause applies to processed food and indirectly to raw foods that have a processed form. The Delaney Clause ensures that none of the additives in processed foods are carcinogenic (interpreted to be tumor causing). For FFDCA purposes, pesticides are considered food additives. The Delaney Clause applies only to pesticides that concentrate in food processing. Therefore, if a carcinogenic pesticide concentrates in processed food and is detectable (Delaney Clause), the pesticide could not be issued a registration under FIFRA.

Under EPA's new policy, the agency applies a uniform set of criteria to all FIFRA registration, tolerance, and food additive regulation decisions. EPA shifts from zero tolerance for carcinogenic

pesticides under the Delaney Clause to negligible risk (generally defined as one additional incidence of cancer per 1 million people over a 70-year life span). If the residues of a pesticide on a particular food pose no carcinogenic risk or only a negligible risk, the pesticide's use on that food is approved under both acts provided they meet the other requirements of FIFRA and the FFDCA.

Tolerance Setting Methods Studied

In 1985, the National Academy of Sciences (NAS) was provided a grant to study EPA's methods for setting pesticide tolerance levels and to examine the current and likely effects of the Delaney Clause on the tolerance-setting process.

The NAS study determined that about 55 percent of total dietary carcinogenic risk arises from pesticide residues on specific crops that have raw and processed food forms. Of this 55 percent, 20 percent stems from the consumption of the processed form of these crops, and 35 percent derives from the consumption of the raw form. However, 45 percent of estimated dietary carcinogenic risk arises from foods considered by EPA to have no processed forms, such as all red meat, milk, and poultry products as well as fruits and vegetables which have no processed form.

These foods without any processed form are not under the Delaney Clause. Therefore, strict application of the Delaney Clause would eliminate only about 55 percent of the estimated dietary carcinogenic risk from consumption of pesticide residues in foods. The remaining 45 percent would be beyond the scope of the Delaney Clause. By applying the new negligible risk approach in pesticide registration decisions rather



The Delaney Clause of the Food, Drug, and Cosmetic Act assures that none of the additives in processed food, or raw foods that have a processed form, are carcinogenic. Pesticides are considered food additives.

than the zero risk Delaney Clause method, NAS estimated that total dietary risk from the carcinogenic pesticides included in their study would be reduced by 98 percent.

There is at least "limited evidence" of carcinogenicity (virtually all from animal studies) for 66 or more of the approximately 350 pesticides already approved for food use. EPA expects this number to become somewhat larger as it receives and evaluates more studies on pesticides used in food production.

Economic Implications

EPA's new interpretation of the Delaney Clause could have considerable economic implications for growers and consumers. By shifting from zero tolerance to negligible risk, many new pesti-

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cide products would potentially be able to be registered and subsequently marketed. At the same time, older product registrations not able to meet the negligible-risk standard would be canceled.

The new interpretation also could allow some of the "old" materials to remain, which, from an economic standpoint, would be significant. For instance, older pesticide products are generally much less expensive than newly patented products and farmers are comfortable with using products that are familiar to them. In addition, maintaining a large complement of diversified pesticide products helps prevent the buildup of resistance by pests to any single pesticide product or pest control method.

To register a pesticide use, pesticide manufacturers must provide the EPA with information describing the acute and chronic effects of human exposure and toxicity, as well as environmental fate studies. Exposure means the level to which people are subjected to the pesticide products' residues in air, water, and food. Toxicity information details the health effects of a given level of exposure. An assessment of the level of risk associated with a particular pesticide is the combined effects of exposure and toxicity.

FIFRA takes into account the economic, social, and environmental costs, and also the benefits of pesticide use when considering registration. The act allows specific uses of a pesticide, with explicit terms and conditions for effective and safe handling and application. The terms and conditions of use must be on the container or package label, and the label must include precautionary statements such as the restriction of use to trained applicators, and the time interval after which farm workers may reenter fields after a pesticide application. Other conditions of registration may require modification of product use or formulations, and packaging limitations.

Under FFDCA, the EPA establishes pesticide tolerance levels defining the maximum amounts of pesticide residues that may be legally present in raw and processed food and animal feed sold in interstate commerce. Before the "negligible risk" allowance, a pesticide could not be granted a tolerance if concentrated residues of the carcinogenic pesticide

appeared in foods after they had been processed. The benefits of pesticide use were not considered. Without FFDCA approval, a tolerance cannot be granted for use of the pesticide in producing that food under FIFRA, regardless of the possible benefits that particular use of the chemical would have.

An important problem is that sequential tolerance revocations or denials for one active ingredient at a time could, in some cases, actually increase human dietary carcinogenic risk by possibly increasing the use of a more hazardous compound after tolerances for a less toxic compound are revoked.

The Delaney Clause applies only to processed foods. For raw foods, such as fresh market fruits and vegetables, the FFDCA implicitly recognizes that pesticides can be both beneficial and risky and that both should be weighed when setting tolerances in produce. If a food crop is not processed in any form, the potential benefits of a carcinogenic pesticide that may be used in producing that crop are included in making a pesticide registration determination.

EPA's current pesticide reregistration procedure, which aims to make all pesticide products conform to modern safety and environmental standards, is thorough and time consuming. Older pesticide products remain in use pending the outcome of the reregistration evaluation.

Ironically, the Delaney Clause bars new pesticides from registration that are shown by pesticide manufacturers or EPA data to pose comparable or lower risks than older pesticide products currently in use. Given the high costs of data development, there is little incentive to develop a new pesticide that shows carcinogenic potential, even if the risk is minimal, and even if the new pesticide could replace an old product that poses a higher risk. Thus, EPA's past implementation of the Delaney Clause retarded the development of new, lower risk pesticides.

EPA's policies toward the uses of older pesticides may likely change as technology continues to become increasingly sophisticated in detecting pesticide residues in processed food. Compelling questions that must be addressed include what level of determined risk will ensure sufficient food and the economic viability

of the agricultural sector, and are any pesticide residues acceptable in the food supply that could be carcinogenic to humans?

Government Studies Continue

The issue of pesticide residues in food and acceptable levels of exposure remains the object of efforts to amend the FIFRA and FFDCA in Congress. In addition, the USDA has launched, for fiscal 1991, a Pesticide Data Initiative that will provide funding for the collection and analysis of data describing pesticide use, residue levels, and potential exposure levels from selected commodities in the Nation's food supply. This program is designed to develop information which will improve regulatory decisions substantially.

Some consumer and environmental groups have mounted or announced their intention to mount a judicial challenge to EPA's decision to adopt a negligible-risk approach in determining pesticide registration potential. They argue that the intent of Delaney was and continues to be the prohibition of carcinogenic food additives in processed food, and therefore EPA's de facto abrogation of Delaney is in violation of the FFDCA. The issue is not settled and may not be for some time.

Lacking any change in the governing Federal codes or improvement in the information base describing the present food residue and exposure situation, EPA must make regulatory decisions based on current interpretations of the law. EPA's recent changes in interpretation of the Delaney Clause afford the regulatory decisionmaking process greater efficiency with little or no increase in health risk. Increased efficiency allows the EPA to speed the reevaluation of older pesticide products and remove only those that pose greater than negligible health risks, which benefits both consumers and producers of agricultural products. ■

Reference

National Research Council, National Academy of Science, Board on Agriculture. *Regulating Pesticides in Food: The Delaney Paradox*. National Academy Press, Washington, DC, 1987.