

ISSUES FOR THE 1990's

Environment



Registration of Pesticides Used To Produce Food

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Issue. Regulation of pesticide products by the Environmental Protection Agency (EPA) is governed by two statutes: the Federal Food, Drug, and Cosmetic Act (FFDCA), which establishes tolerances for pesticide residues on food and feeds, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which regulates the sale and use of pesticides through its registration process to prevent unsafe health and environmental risks. Several issues have unified consumer interest groups, environmentalists, agribusiness, and farmers in calling for changes in the registration process, although solutions offered by each group differ significantly. These issues include (1) the application of the Delaney, or zero-risk, standard in judging the safety of pesticide products, (2) the different regulatory treatment received by old and new pesticide products, (3) the lengthy time lag and high costs associated with the registration process, (4) research and development (R&D) incentives to develop safer pesticides, and (5) the registration of pesticides for minor uses.

Context. EPA, in granting a pesticide registration, specifies how a pesticide may be used. The specification takes into consideration exposure levels for farmworkers and consumers (human health issues include cancer and other illnesses) as well as environmental damage and wildlife protection. One of the most contentious elements of FFDCA is the Delaney, or zero-risk, clause that prohibits use of a pesticide if there is scientific evidence that it causes cancer and concentrates in processed foods. Since 1988, the EPA has chosen to implement a *de minimis* risk standard that permits the use of a potentially carcinogenic pesticide product if the risk is negligible. Negligible risk is expressed in terms of probability that an individual will experience cancer from exposure to a substance over a lifetime. For example, accepting a risk estimate of one in a million indicates that one out of a million individuals exposed daily over a 70-year lifetime will develop cancer.

In 1988, Congress required the EPA to reregister pesticides registered before November 1984 to ensure compliance with current health and environmental risk standards. Advances in technology have generated problems with the registration process itself. New products are scrutinized more than older pesticides because regulators demand state-of-the-art testing. Over time, testing has increased scientists' ability to measure residues and the biological functions most affected. Improved testing techniques in conjunction with the zero-risk standard raises the possibility of a regulatory paradox: that a new and weakly carcinogenic pesticide product could be denied a registration, while pesticide products already registered and potentially posing higher health risks remain on the market, at least in the short term. Other consequences of the more data-intensive registration process revolve around the high cost imposed on pesticide manufacturers and time lag during which society cannot realize the benefits of possibly safer and more effective pesticides.

At Stake. The reregistration of pesticides will potentially have far-reaching, but currently unmeasured, effects on production and marketing systems as well as on the environment, worker safety, and food residues. These effects will be manifested in the cost, availability, and physical appearance of a wide variety of food products. The elimination of currently registered products or the introduction of new products could result in significant changes in the type, amount, and timing of pesticide applications as well as changes in producer and consumer costs. Benefits and costs from changing the registration process will not likely apply evenly throughout the agricultural sector. If farmers with the worst pest problems become much less productive and total agricultural production

declines, farmers with modest pest problems may benefit from commodity price increases. Consumers who are willing to trade off higher prices for less pesticide exposure may benefit at the expense of consumers who care only about prices. An industry that develops alternatives to pesticides may benefit at the expense of the pesticide industry.

Consumer and environmental groups supporting the implementation of the Delaney standard argue that the negative human health and environmental effects are still not clearly understood or accurately measured. The food and agribusiness sector supports negligible risk standards, arguing that existing standards are excessive given the level of risk and that the pesticides generate better quality food in larger quantities. And, some argue that imposing strict health and environmental standards on American producers hurts U.S. export competitiveness when farmers in competing nations are subject to less stringent controls.

Fruit, vegetable, and specialty crop producers argue that their productivity is especially at risk. Some predict that the zero-risk standard and registration process costs would force chemical manufacturers to drop registrations for fruits and vegetables, which are considered minor-use crops. Fruit and vegetable growers claim they have few good substitutes for existing chemicals. The increasing data demands for registration may create deterrents for chemical manufacturers to carry out R&D. If pesticide manufacturers consider the costs of registration to be fixed costs, a large fixed cost could make the business of developing low-volume products unprofitable.

Alternatives. Several changes to the EPA's current registration process are being debated. Some consumer and environmental interest groups favor the Delaney clause in the registering of pesticide products even if meeting this standard disrupts current production practices. They believe that all cancer risk from synthetic chemical use on food products should be eliminated to protect consumer health and the environment. Many farm and pesticide interest groups favor replacing the Delaney zero-risk standard for pesticide residue with a *de minimis* or negligible risk standard. Using some form of a negligible risk standard would allow the EPA to concentrate on higher risk products which may potentially represent the greatest threat to health and environment and allow those products which pose a negligible risk to remain on the market. Some consumer groups oppose the negligible risk standard because it permits the use of pesticides with a known, albeit small, health risk. Government agencies have discussed, with no agreement so far, incentives for companies to develop lower risk pesticide products. Incentives proposed by the EPA include changing labeling standards to permit producers of lower risk products to indicate this in their advertising, streamlining the registration process for targeted products, waiving fees, reducing data needs, and giving higher priority to lower risk pesticide products. The USDA and pesticide producers favor changing the methodology used to estimate risk in establishing tolerance levels; instead of estimating pesticide risk to humans from laboratory tests, the EPA would use data measuring residues found on food products.

Agenda. A challenge by consumer groups to the EPA's application of the *de minimis* exception to the Delaney clause was upheld in the U.S. Court of Appeals in July 1992. A Justice Department petition to the Court of Appeals for a rehearing was denied in October 1992. This ruling could force the EPA to impose the Delaney standard in registration decisions. Doing that, EPA stated, would affect 35 chemicals used on 80 crops. Several alternative bills proposing changes in the existing registration process are pending before Congress.

Information Sources. National Academy Press, *Regulating Pesticides in Food: The Delaney Paradox*, Committee on Scientific and Regulatory Issues Underlying Pesticide Use Patterns and Agricultural Innovation, Board on Agriculture, National Research Council, 1987. Also, three Congressional Research Service publications: Donna U. Vogt, *The Delaney Clause: The Dilemma of Regulating Health Risk for Pesticide Residues*, 92-800 SPR, 1992; Vogt, *Proposed Changes to Policies Governing Pesticide Residues in Foods*, 92-179 SPR, 1992; and Jasper Womach, *Pesticide Policy Issues: Debating FIFRA in the 102d Congress*, IB91055, 1992.