

The Delaney Clause

The Delaney Clause is a part of the 1958 Food Additives Amendment (section 409) to the 1954 Federal Food, Drug and Cosmetic Act (FFDCA). This clause governs regulation of pesticide residues in processed foods. It establishes that no residues from pesticides found to cause cancer in animals will be allowed as a food additive. This means that tolerance levels must be based only on the risk of carcinogenicity and that the benefits of the pesticide may not be considered.

The Pesticide Residue Amendment (section 408) of the FFDCA governs the regulation of residues in raw commodities. It states that tolerances should be set at levels that balance the need to protect the consumer's health against the need for "an adequate, wholesome and economical food supply." As the agency in charge of regulating safety and registration of pesticides the Environmental Protection Agency (EPA) must conduct risk/benefit analysis of pesticide use on raw food.

Section 402 of the FFDCA states that pesticide residues on processed foods may not be greater than the tolerance established under section 408 for the raw food. If they are, or if no tolerances have been set, the product will be considered adulterated according to the FFDCA and is no longer legal.

The consequences of the three laws, sections 402, 408 and 409 are inconsistent for raw and processed foods. Section 408 bases tolerances on a risk/benefit analysis, while section 409 establishes a no-risk standard. Under section 408 a pesticide may be regulated on a risk/benefit basis at the time of registration. Under section 409, the pesticide may later be subject to the Delaney Clause if it is used on food to be processed and could be concentrated in the processing. Also, dairy, meat and poultry do not have any recognized processed food form, thus are exempted from the Delaney Clause.

In February, 1985, the National Research Council's (NRC) Board on Agriculture was asked by the EPA to study its' methods of setting tolerances for pesticide residues in food. Specifically, the EPA was interested in how the Delaney Clause affected the process of setting tolerances.

The NRC committee made four recommendations to the Environmental Protection Agency. First, regulate both new and old pesticides on raw and processed foods by the same standards. Second, set a "negligible risk" standard of one in one million for all possible carcinogenic pesticides applied to food crops. The committee reported this would

reduce dietary exposure with only a moderate reduction of benefits. Third, develop a plan to reduce risk from the most suspect pesticides on the most consumed crops, and make all pesticide registration and tolerances comply with the law, including the Delaney Clause. Fourth, improve tools and methods for risk/benefit analysis "of prospective regulatory action on health, the environment, and food production."

In response to these recommendations, the EPA declared in October, 1988, that pesticide uses which posed a "de minimis" risk would be exempted from the Delaney Clause.

In May, 1989, the state of California, the Natural Resources Defense Council, Public Citizen, the AFL-CIO and several individuals petitioned the EPA to revoke the food additive registration of seven potentially carcinogenic pesticides. The petitioners claimed the registrations and the EPA's "de minimis" risk policy violated the Delaney Clause.

In July, 1992, the Ninth Circuit Court of Appeals upheld the petition against the EPA's "de minimis" food pesticide residue policy. The unanimous opinion of the court stated, "The language is clear and mandatory. The Delaney Clause provides that no additive shall be deemed safe if it induces cancer . . . The statute provides that once the finding of carcinogenicity is made, the EPA has no discretion . . ."

The Environmental Protection Agency is presently enforcing the Delaney Clause, but is encouraging Congress to enact legislation recognizing the "de minimis" standard as an approved approach to food safety.

Source: Rodney L. Holloway and Melissa Rowell, Texas Agricultural Extension Service.