New Uniform Standards for Pesticide Residues in Food

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The longstanding debate concerning pesticide regulation made one thing evident to advocates on all sides of the controversy—the laws regulating pesticide use and pesticide residues in food had to be reformed. Congress responded with the passage of the Food Quality Protection Act of 1996, amending the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). This bipartisan effort, which passed unanimously in both the House and Senate, will enable pesticide regulation to keep pace with scientific advancements.

The Act includes many provisions that pesticide manufacturers, growers, and the food industry sought—notably the application of a uniform safety standard to residues in raw and processed foods. In addition, the new law generally prohibits States from setting residue standards that differ from Federal standards, and it facilitates the registration process for pesticides used on specialty, or minor, crops, including many fruit and vegetable crops in the United States. The new law also makes it easier to register public-health pesticides—those used to protect the public from diseases carried by insects or animals.

On the other hand, the Act also includes provisions championed by environmental and public health groups. For example, the new law contains directives to improve consumers' access to information about possible dietary exposure to pesticides. It also seeks greater protection for infants and children by requiring the U.S. Environmental Protection Agency (EPA) to consider the risks from pesticide residues to infants and children and for the U.S. Department of Agriculture (USDA) to collect improved data on their consumption patterns. In addition, the Act contains other provisions which some experts expect will lower allowable levels of pesticide residues.

The impetus for much of the Act stems from a pair of influential and widely cited reports by the National Academy of Sciences (NAS), a private, nonprofit organization of scientists dedicated to using science and technology to improve human welfare. In a 1987 study titled *Regulating Pesticides in Food: The Delaney Paradox*, NAS recommended the adoption of a single, negligible risk standard for all pesticide residues in foods. A subsequent study, *Pesticides in the Diets of Infants and Children*, published in 1993, highlighted the unique sensitivity of children to possible health risks from pesticide residues in food.

Delaney Clause Became Anachronistic

In 1957, U.S. Representative James J. Delaney introduced amendments to the FFDCA—the law that, among other things, regulates pesticide residue levels on raw commodities and processed food. Included among the amendments, and adopted in 1958, was the Delaney Clause, which stated that no food additive will "be deemed safe if it is found to induce cancer when ingested by man or animal." The FFDCA defined as food additives residues from pesticides legally applied to raw commodities that appear in processed food products in concentrations above levels approved in raw commodities. Pesticides used on processed foods, such as fumigants used to protect flour or raisins in storage, were also subject to the Delaney Clause. As a result, because the Delaney Clause did not apply to pesticides residues on raw commodities, pesticide residues in raw and processed foods were judged by different standards.

Tolerances, or maximum allowable pesticide residue levels, are set for specific pesticides on specific commodities. Prior to the passage of

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the Food Quality Protection Act, EPA set tolerances for residues on raw commodities at levels necessary to protect public health while considering the need for "an adequate, wholesome, and economical food supply." Under the Delaney clause, pesticide residues in processed foods were subject to a zero-cancer risk standard—yet the same pesticide residues were evaluated under a more lenient "public health" standard if found on raw commodities. In the case of a pesticide used on a raw commodity, no residue was permitted on a resulting processed food product if the pesticide was a possible carcinogen and its concentration exceeded the level sanctioned on the raw commodity.

EPA began a review of tolerances after a 1992 Federal court decision mandated that the agency strictly apply and enforce the Delaney Clause. As a result, EPA wrote rules to revoke some pesticide residue tolerances on some food and feed products. The registrations of those pesticides on the food crops ultimately would have been canceled under FIFRA, making their use on those crops illegal. The inconsistency between raw and processed foods invited challenges to the regulation of pesticide residues. There was general agreement that the standard for these two food groups should be the same. Groups differed, however, as to the direction in which this uniformity should go—a zero-cancer risk or a standard that permitted a small, but negligible, risk. Negligible risk is currently interpreted as an increased cancer risk of less than 1 in 1 million over a 70-year lifetime.

In its 1987 report, NAS estimated, using pesticide use data from 1978 to 1986, that 60 percent of herbicide, 90 percent of fungicide, and 30 percent of insecticide use, by weight (pounds active ingredient), consisted of materials classified by EPA as carcinogenic to lab animals or potentially so to humans. Without many of these chemicals, several major fruit and vegetable crops could be left without adequate pest control options. NAS believed banning these chemicals could present serious disease-control problems for certain crops in major production regions.

NAS also argued that a rigorous application of the Delaney Clause would reduce EPA's flexibility to reduce dietary cancer risks over time. It would not allow EPA to grant tolerances for new chemicals that might pose a slight cancer risk even if use of such pesticides would displace more hazardous materials currently used. It would also constrain EPA's ability to discriminate between relatively significant and insignificant risks and focus on the more significant ones. The NAS report contended that a uniform standard for raw and processed food would eliminate most existing dietary carcinogenic risk, while allowing certain low risk chemicals to be used.

The old law forced EPA to apply different standards not only to raw and processed foods, but also to carcinogens and noncarcinogens. Despite the health risk presented from a noncarcinogenic residue, such as potential to cause, for example, birth defects or problems to one's immune system, noncarcinogens were not subject to the strict Delaney test.

Proponents of reform of the Delaney clause argued that a modification of the law would enable EPA and others to devote resources consumed by Delaney-related activities to higher priority public-health and environmental protection issues.

New Law Applies Uniform Health-Based Standard

The Food Quality Protection Act amends the FFDCA by applying a new safety standard to residues in both raw and processed foods. The Act removes pesticide residues in processed food from the definition of a "food additive," taking processed food residues outside of the Delaney Clause's regulation.

The general rule now applied to all pesticide residues—in raw or processed foods, whether carcinogens or not—is that these residues are unsafe, and the food containing them is adulterated, unless the residue is within the tolerance limit, or a tolerance exemption is in effect. Tolerance limits are set at "safe" levels, defined as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

Under the new safety standard, EPA must consider dietary exposures from all food uses of the pesticide, dietary exposure from drinking water, and nonoccupational exposure, such as use of the pesticide for lawn care. In addition, EPA must consider exposure from pesticides with a common mechanism of toxicity. As a result, the exposure from one use of a pesticide will affect whether or not the exposure from another use can be permitted. If risk from all currently registered uses just meets the safety standard, no new uses of the pesticide can be registered unless one or more other uses are canceled or residue tolerances reduced to allow the risk from the new uses, or new data show that risk from current uses are lower than currently estimated. If the total risk from all currently registered uses exceeds the safety standard, one or more uses will have to be canceled or residue tolerances reduced unless new information shows the risks to be within the overall standard. If other substances have a common mechanism of toxicity, the risks from these substances would in effect reduce the allowable risk for the pesticide.

While it is currently uncertain how EPA will implement the new

safety standard, the implications for the availability of pesticides are potentially profound. The pesticide industry and grower groups are concerned that many uses of pesticides will be canceled and that new uses will not be registered. In particular, there will be incentives for registrants to cancel uses for small-market crops, such as fruits, nuts, or vegetables, in order to minimize the impacts on sales of the pesticides.

EPA will continue to look at two types of effects on humans when setting tolerances for pesticide residues in food: threshold and nonthreshold effects. Threshold effects are effects for which EPA scientists can identify a level at which the residue will not cause or contribute to known or anticipated harm to human health. In its report accompanying the Act, the House Commerce Committee said that it expects tolerance limits for the threshold effects to be set so that the aggregate exposure to the pesticide chemical residue will be 100 times lower than the maximum level determined not to cause a known or anticipated harm to human health. (As discussed later, an additional 10-fold safety factor can be added to protect infants and children.)

Nonthreshold effects are those for which EPA is not able to identify such a level because there is no known safe level, such as with some carcinogens. In the case of nonthreshold effects, the new Act requires that tolerance limits be set so that any increase in lifetime cancer risk will be no greater than negligible.

The Act does not preclude EPA from changing its risk assessment methodology or levels of risk considered to be safe. But if EPA does change its methodology, the change must be made through a regulation, the new method must be scientifically based, and the new method must be shown to be equally protective of the public health.

EPA Must Review All Tolerances

There are more than 9,000 tolerances currently in place for pesticides. Legislation adopted in 1988 required EPA to evaluate and reregister by 1997 all pesticides initially registered before 1984. As part of this process, EPA evaluated the residue tolerances associated with food uses of these pesticides. As of September 30, 1996, EPA had completed about 148 Reregistration Eligibility Decisions (RED's), accounting for about 40 percent of the 382 cases supported by registrants. (An additional 232 cases were not supported and were suspended or voluntarily canceled.) The new law presents EPA with an ambitious undertaking. Since the law establishes new criteria, all residue tolerances must be reviewed, giving priority to those that may pose the greatest risk, according to the following schedule: 33 percent in 3 years, 66 percent in 6 years, and 100 percent in 10 years. The new law also changes reregistration from a one-time review required under the old law to an ongoing process, with periodic reviews of registered pesticides and their uses. Regulations are required to implement this new registration renewal process. EPA will coordinate the review of residue tolerances with the review of pesticide registrations to the extent possible.

The Act requires EPA to abandon those actions revoking residue tolerances under the Delaney Clause, if they were not final as of August 3, 1996—the day the Act was signed into law. On September 20, 1996, EPA announced that it was withdrawing all final and proposed rules revoking tolerances for processed and raw commodities resulting from its implementation of the Delaney Clause (all the final revocations were not yet in effect). EPA will assess these tolerances under the new tolerance review process. Pesticides that had not been reviewed by EPA will currently remain available for agricultural use, and continue to be available if EPA determines they are "safe."

Benefits Play a Limited Role in Setting Tolerances

The new law significantly narrows those instances in which benefits of use (including economic factors, such as changes in production, production costs, and consumer prices) may be considered in decisions about tolerances for raw agricultural commodities, but enlarges the scope of circumstances under which benefits may be considered in decisions about tolerances for processed foods. Under the previous law, benefits, including production of an adequate, wholesome, and economical food supply, were considered for pesticide tolerances on raw commodities, but benefits were never considered for pesticide tolerances on processed foods. The effects on registration approval for raw commodities should be minimal, for EPA rarely considered benefits when setting new tolerances.

New tolerances, whether for new chemicals, or simply newly issued tolerances, must meet the "safe" standard; benefits are not considered in setting that level. However, the new law permits benefits of use to be considered when evaluating existing tolerances: certain tolerances may remain in effect or be modified to levels slightly higher than "safe," if use of the pesticide protects consumers from greater health risks or prevents a significant disruption in domestic production of food. This exemption applies only to residues for which there are no known "safe" level of exposures (nonthreshold effects, generally carcinogens). The residues also must be safe with respect to any threshold effects associated with them. Many people expect that few, if any, existing tolerances will be justified or modified based on the anticipated

benefits, because these less strict tolerances would be identified in consumer brochures to be distributed to major retail grocers. Expectations are that grower concern over public reaction to this information may limit the use of these pesticides. However, benefits, including economic impacts, may serve a role in evaluating how to cost-effectively meet a safety standard.

When benefits are considered in maintaining a tolerance, the Act limits the maximum risk allowed. The yearly risk from aggregate exposure cannot exceed 10 times the yearly risk that is considered "safe," and cumulative lifetime risk cannot be greater than twice the lifetime risk allowed under the general standard (thus, going from 1 in 1 million to 2 in 1 million). If necessary, the tolerance will have to be time-limited (terminated or phased-out by some date) to ensure that the lifetime risk standard is not exceeded. Also, all such tolerances must be safe for children. EPA will re-evaluate pesticide tolerances registered under this exemption standard after 5 years to determine whether the benefit findings are still valid and the lifetime risk criteria are still satisfied. If the determining criteria no longer apply, the tolerance must be revoked or modified within 180 days of such determination.

The Act lists several factors, many advocated by health groups, that EPA should consider when evaluating tolerances for pesticide residue levels. These include reliability and completeness of data, nature of any toxic effect, information on dietary consumption patterns of consumers and major identifiable subgroups, information concerning cumulative effects, information concerning the aggregate exposure levels of consumers and subgroups to the pesticide and to other related substances, and effects similar to a naturally occurring estrogen or other endocrine effects. It is not clear how all of these factors will be incorporated into the evaluation of "safety." Particularly unclear is the incorporation of aggregate and cumulative exposures to multiple substances.

Uniform Tolerances

Many industry representatives voiced concerns over the ability of States to impose stricter regulatory standards than those imposed federally. Proponents of this argument claimed that in addition to burdening interstate commerce, such variations in standards could drive production to more lenient States or countries. They also argued that a lack of uniformity burdens manufacturers with compliance costs, such as scientific testing, product reformulation, and exposure to expensive litigation, that result in higher prices for consumers. In addition, one industry trade group argued that a lack of uniformity served as international trade barriers.

States' rights advocates led the other side of the debate. This group argued that because of the unique demographic or consumption characteristics of certain States, flexibility should be encouraged. Although States rarely set stricter standards, certain States—notably California—do. California's adoption of proposition 65 in 1986 requires the Governor to publish a list of chemicals that pose a risk of cancer or reproductive toxicity that is greater than 1 in 100,000 people. If the public is exposed to a chemical on the list, that chemical must carry a warning label.

The new Federal law generally prohibits States from setting tolerances that differ from EPA tolerances, except if the State petitions EPA for an exemption to this provision. EPA may allow a State to establish its own pesticide residue standard if the State's standard is justified by compelling local conditions and would not cause any food to be in violation of Federal law. States still may require that foods containing a pesticide residue carry a warning.

The international Codex Alimentarius Commission, sponsored by the United Nations Food and Agriculture Organization and the World Health Organization, establishes maximum residue levels for many chemicals on foods. To avoid unnecessary restraints on international food trade, the new law requires EPA to consider these levels when determining U.S. tolerances. If EPA decides to depart from an established Codex standard, EPA must publish for public comment a notice explaining the deviation.

Risks to Infants and Children Considered

"Children are not little adults" summarizes the NAS findings regarding the effects of pesticides in children's diets. In its 1993 report, NAS concluded that "estimates of expected total exposure to pesticide residues should reflect the unique characteristics of the diets of infants and children and should also account for all nondietary intake of pesticides." NAS asserted that "an uncertainty factor up to the 10-fold factor traditionally used for fetal development toxicity should also be considered when there is evidence of post-natal developmental toxicity and when data from toxicity testing relative to children are incomplete."

Heeding this advice, Congress now requires that EPA consider the risks to infants and children, and publish a specific finding before a tolerance can be issued. EPA must ensure, with reasonable certainty, that no harm will result to infants and children from aggregate exposure. When assessing pesticide risks, EPA must consider the following:

(1) Consumption patterns among infants and children;

(2) The special susceptibility of infants and children, including the effects of in utero exposure to

Table 1
Highlights of the Food Quality Protection Act

Issue	Old provision
Treatment of pesticide residues	Treatment differed for carcinogenic residues in raw and processed foods. Treatment of cancer and noncancer risks differed.
General tolerance standard	Required EPA to establish tolerances that will "protect the public health."
Consideration of the diets of infants and children	No analogous section.
Consideration of benefits for pesticide tolerances	Required EPA to set tolerances giving appropriate consideration to the production of a wholesome and economical food supply. Thus, a risk-benefit analysis could be applied.
Uniform national standard	States could set stricter tolerances than those set by EPA.
International standards	No analogous section. However, international treaties oblige the United States to explain the need to set standards stricter than those of Codex.
Suspension	EPA could suspend a registration only after issuing a notice of intent to cancel the registration.
Minor-use pesticides	Previous law and practices included efforts to facilitate registration.

Changes made by new law	Economic implications of the changes
Pesticide residues no longer fall under the Delaney Clause. Thus, a uniform health-based standard will be applied to all foods and all risks.	EPA no longer forced to review/revoke tolerances that triggered the Delaney Clause. Producers and farmers do not have to seek substitutes for pesticides threatened by Delaney. Thus, food production costs are not increased, and consumer prices should not be affected adversely.
Tolerances must be "safe"—that is, a reasonable certainty that no harm will result from aggregate exposure.	The consideration of aggregate exposure could result in the revocation of tolerances and cancellation of registrations. Food production costs and consumer prices, especially for fruits and vegetables, could increase.
Requires EPA to address the risks to infants and children, and publish a specific finding before issuing a tolerance.	Could disproportionately affect certain crops, subjecting them to stricter standards, thus increasing costs of production and consumer prices.
EPA may permit tolerances for some carcinogens to remain in effect despite a failure to meet the "safe" standard, if the use of the pesticide protects consumers from greater health risks or prevents a significant disruption in domestic food production. Limits additional annual and lifetime cancer risks.	The probability of tolerance revocation could increase where benefits cannot be considered. The effects should be minimal in practice, because economic considerations did not play a big part in EPA tolerance decisions.
Pre-empts States, with some exceptions, from setting tolerances that differ from EPA tolerances.	Reduces costs to registrants. Many States did not set stricter standards.
If EPA departs from a Codex standard, the agency must publish a notice explaining the deviation.	Many U.S. standards may be stricter than international standards, thus international trade is affected.
EPA may issue emergency orders of suspension prior to issuing a notice of intent to cancel. EPA must issue a notice of intent to cancel within 90 days or the emergency order will expire.	Allows EPA to more quickly address an imminent hazard without changing the substantive standard for issuing a suspension.
Defines minor use as the use of a pesticide on an animal, on a commercial crop or site, or for protection of public health, where crop is grown on less than 300,000 U.S. acres, or use provides insufficient financial incentives for registration. In the case of insufficient incentive, the pesticide must play a significant role in managing pest resistance or in an IPM program, the alternatives must pose greater health or environmental risks, or there must be insufficient effective alternatives.	Lowers the cost of registering minor-use pesticides and lessens the possibility that important uses will not be registered. Could help to maintain or lower food production costs, but might offset the loss of registered uses due to the "aggregate exposure" provision of the new safety standard and other risk assessment considerations.
Provides additional time for the submission of data, or in some cases, waives data requirements; extends, in some cases, the period of exclusive use of data. Requires EPA to expedite review. Directs USDA to establish a matching fund to develop data supporting these pesticides.	

Continued—

Table 1
Highlights of the Food Quality Protection Act—*continued*

Issue	Old provision
Petition for tolerances	Petitions could be initiated only by applicants.
Estrogenic screening program	No analogous provision.
Re-evaluation of existing tolerances	EPA had been reassessing tolerances for pesticides registered before November 1984 as part of reregistration.
Existing stocks of suspended or cancelled pesticides	Without statutory authority, EPA permitted the continued use and sale of existing stocks.
Right-to-know provision	No analogous provision.

the effects of in utero exposure to pesticide chemicals; and

(3) The cumulative effects on infants and children of such residues, and the cumulative effects of "other substances that have a common mechanism of toxicity."

USDA, in consultation with the Department of Health and Human Services (HHS) and EPA, must conduct surveys to document dietary exposure among infants and children. In the case of threshold effects, an additional 10-fold margin of safety for the pesticide chemical residues and other sources of exposure will be applied for infants and children. EPA may use a different margin of safety only if, on the basis of reliable data, such a margin will fully protect infants and children.

The new risk assessment requirements for infants and children could focus regulatory concerns on certain fruits and vegetables—such as apples, grapes, and corn—common in children's diets, disproportionately reducing the number of registered materials for such crops.

In addition to the data collection requirements regarding the diets of infants and children, the Act directs USDA to collect State or regional pesticide use data for all the major crops and crops of dietary significance. The new law also directs USDA to work with EPA on research, demonstration, and education programs to support adoption of integrated pest management—an ecologically based approach to managing insects, diseases, weeds, and other pests by combining biological, cultural, physical, and chemical tools. Federal agencies are directed to promote integrated pest management techniques.

Retailers Will Provide Information for Consumers

The Act includes provisions meant to ensure consumer access to information on dietary exposure to pesticides. The Act requires EPA to publish, in laypersons' terms, a discussion of risks and benefits of pesticide chemicals in or on food, including:

(1) Recommendations to consumers for reducing exposure to pesticide chemical residues while maintaining a healthy diet;

Changes made by new law	Economic implications of the changes
Anyone may petition to establish, modify, or revoke a tolerance. A registrant must now include a summary of data with an authorization to publish the summary. In addition, the registrant must provide additional health-based information.	Easier for environmental, public interest, and grower groups to initiate proceedings. Economic consequences are unclear.
Requires EPA to develop and implement a comprehensive screening program for estrogenic and other endocrine effects.	Increases monitoring costs for EPA. New data requirements could increase costs for registrants, crop production costs, and possibly food prices for consumers.
Requires EPA to review all tolerances within 10 years.	Increases EPA's administrative costs. The "aggregate exposure" provision of the new safety standard could result in more pesticide uses being cancelled than under the old law. Some tolerances retained because the Delaney Clause no longer affects pesticides. Economic consequences unclear.
Grants EPA statutory authority to continue its practice.	No effect, as existing practice is continued.
Includes directives to improve consumer access to dietary information (including a list of substitute foods for higher risk products) through an EPA-developed pamphlet distributed to supermarkets.	Could shift demand away from "high-risk" products, lowering the price of those commodities, and raising prices for substitutes. EPA will incur costs of producing the pamphlet.

(2) Actions taken by EPA that may result in higher residue risks from certain foods; and

(3) A list of foods that may reasonably substitute for these foods.

The information must be published and distributed within 2 years, and annually thereafter.

EPA, in consultation with USDA and HHS, will develop and distribute this information to large retail grocers. Grocers will determine the manner of displaying the pamphlets. The Act does not prescribe any civil or criminal liability to grocers who fail to display the information. If a store runs out of the EPA pamphlet, the store would not be held liable for any civil or criminal penalties.

Minor-Use Pesticides Get Special Treatment

For cost, not safety, reasons, the registrations of pesticides for some minor uses have been voluntarily canceled. The cost of meeting EPA's data requirements made it uneconomical for some manufacturers to reregister existing minor uses or to pursue new minor-use registrations.

To avoid the disruption of production for some crops, the new law streamlines regulatory procedures for minor-use pesticides. A minor use is defined as the use of a pesticide on a crop whose total acreage is fewer than 300,000 acres, the use of a pesticide on an animal or crop that protects public health from diseases carried by insects or animals, or the use provides insufficient financial incentives for a company to seek registration. To qualify as a minor-use pesticide in the case of insufficient financial incentive, the pesticide must also play a significant role in managing pest resistance or in an integrated pest management program, or there must be insufficient effective alternatives for the pesticide.

The new law extends the deadline for producing data to support a minor-use registration until the final deadline for submission of data for registrants of all other uses of the pesticide. In some cases, EPA can waive the data requirements, if such a waiver does not prevent a risk determination or adversely affect the environment. USDA is directed to establish a grant program to develop data underlying registration and re-registration of minor-use pes-

ticides. Grant recipients have to match the funds provided by USDA.

Other Provisions of the Act

Estrogenic Screening Program

The Act requires EPA, in consultation with HHS, to develop a screening program within 2 years to determine whether certain substances may have an effect in humans similar to one produced by naturally occurring estrogen or other endocrine effects. If a substance is found to have such effect, EPA must take action necessary to protect the public health. The program must be implemented within 3 years, and EPA must report its findings to Congress within 4 years.

Petition for Tolerances

Under the new law, any person may petition EPA to establish, modify, or revoke a tolerance. Previously, such petitions could only be initiated by the applicant for registration. Now, public-interest and industry groups may exercise this option. The new Act also requires that a registrant include various data and information to support the petition and allow the data to be made public. The required data and information include the following: how to use the pesticide; tests relating to human health effects, such as endocrine effects and effects on infants and children; residues in food; and methods of detecting residues.

Penalties

The new law adds civil penalties that may be imposed against any person who introduces or delivers food adulterated by a pesticide chemical into interstate commerce. This monetary penalty can be imposed instead of, not in addition to, seizures, injunctions, or criminal prosecutions that were already available.

By passing the Food Quality Protection Act, Congress made clear its paramount concern of reducing the myriad health risks associated with pesticides. This is evident in the "safe" standard under which all existing tolerances will be evaluated, the provision regarding the diets of infants and children, and the effort to facilitate registration of public-health pesticides. Moreover, by eliminating pesticide residues from the purview of the Delaney Clause, tolerances that pose negligible cancer risks yet reduce other risks, or pose less of a health risk than certain non-carcinogens, can be maintained.

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