



Resolving the “Delaney Paradox”

Congress Resets the Table for Pesticides on Food

by James D. Wilson

New legislation should enable the federal government to ensure greater food safety while assuring the availability of favorite fruit and vegetables. The cost? Higher prices.

Just before escaping Washington last August, Congress suddenly enacted the “Food Quality Protection Act of 1996” (FQPA). In doing so, Congress partially resolved a forty-year-old regulatory problem—the “Delaney Clause” and its paradox. The paradox arose from food safety law, which had treated carcinogenic pesticide residues on raw and processed foods differently (see “Food Safety Laws at a Glance,” page 15), and from EPA’s unsuccessful attempt to erase the difference (see “Making the World Safe for Strawberries,” pages 16 and 17).

Policy Changes and Some Consequences

The 1996 legislation includes some interesting policy features. First FQPA recognizes that, unlike such food additives as coloring, flavor enhancers, and preservatives, pesticide residues are not intentionally added to achieve some useful purpose in processed food. Rather, such residues are like “indirect additives” and “contaminants.” They appear in food as an inescapable consequence of their use—adjacent, as it were, to food. Under food law, contaminants can be tolerated if requiring their removal would harm the “quality and abundance of the food supply”; pesticide residues certainly meet this test. The new legislation defines

conditions under which the presence of these particular “contaminants” may be approved.

Second, the new statute replaces the Delaney Clause’s scientifically obsolete distinction between “carcinogen” and “noncarcinogen” with a distinction between “threshold” and “nonthreshold” toxicants. In the process, Congress has reopened a science policy debate that long ago was abandoned as unprofitable. That debate concerns the meaning of “threshold”: does it mark the boundary between “some risk” and “zero risk,” or the transition between “discernable” and “insignificant” risk? If the risk involved in exposure to, say, a pesticide residue is too small to measure, biologists and other experimentalists consider the risk to be zero for all practical purposes. Mathematicians, however, beg to differ, asserting that there is an important difference between a substance’s immeasurability and its absence. From their point of view, the absence of risk equals “absolute zero,” that is, the total absence of the toxic substance. Such precision leads them to a much more stringent interpretation of what level of risk is then acceptable.

For purposes of standard setting, the Environmental Protection Agency will now have to decide which interpretation of “threshold” should

prevail. Over the past two decades, most government policy concerning exposure to substances labeled “carcinogenic” has been based on the experimentalists’ theory that, if exposure to a carcinogenic substance is very small, the risk is negligible, if not truly zero. EPA’s assertion that this theory was consistent with the Delaney Clause was struck down by the courts; it will be interesting to see what happens to the theory now. Meanwhile, the change in law creates an impetus for scientists to develop new lines of evidence that address the threshold question; they will very likely persuade their fellows and EPA that experimental criteria to determine these thresholds can be attained.

The 1996 FQPA also includes a concept that is new in food safety legislation. Pesticides for which it has not been possible to show the point or “threshold” at which they begin to have adverse health effects may be permitted on food at slightly higher levels than usual, if their use confers certain limited benefits (beyond those provided by all pesticides). Such benefits could include an overall reduction in risk to human health (as, for instance, might occur if a fungicide reduced occurrence of a dangerous fungus such as the rust that produces ergot). Another benefit might be production value to growers.

Yet to take advantage of this provision and obtain approval to leave a pesticide residue at a concentration not normally accepted, the producer must meet rather stringent requirements. The “lifetime” risk posed by the pesticide can be no more than ten times the risk level considered “safe.” Further, in any one year the risk may be only twice what is considered safe. Typically, the data used to estimate pesticide intakes are not precise enough to allow such fine distinctions, so any pesticide producer seeking to make use of this new provision will have to invest in special studies to make calculations that scientists have been used to regarding as meaningless.

Pesticide manufacturers can choose to invest in research to show that their products act by a “threshold” process. That is, they can attempt to show that the points at which the ill effects of their products occur can be pinpointed at a certain level of intake. Alternatively, they can invest in research to greatly refine the estimated amount of pesticide a consumer might take in through their products.

If they opt for the first type of research and succeed, manufacturers stand to receive approval from

Food Safety Laws at a Glance

Food Quality Protection Act of 1996 (FPQA)

- The acceptability of noncarcinogenic pesticide residues on food were and are judged by the food additive standard, “reasonable certainty of no harm when used as intended.” Under the new law, this standard now applies to all pesticide residues, whether carcinogenic or not.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Regulates pesticides
- Before passage of the 1996 act FIFRA also governed pesticide residues on raw foods, since they were not considered food additives. Such residues were judged by the FIFRA standard that is intended to maintain “an adequate, wholesome, and balanced food supply.”

Food, Drug, and Cosmetic Act (FDCA)

- Regulates foreign substances—“adulterants”—in foods
- Provides means to exempt some substances, including food additives and pesticide residues, from regulation as adulterants
 - Processed food.* Before passage of FPQA pesticide residues on processed foods were treated as “direct food additives” subject to the Delaney Clause ban on carcinogens.
 - Raw food.* Before passage of FPQA pesticide residues at safe levels on raw foods were exempt from further regulation under FDCA. If a “tolerance” existed for a residue on raw produce, no separate tolerance was needed on derived processed foods unless the residue concentrated during processing.

Tolerances

- FIFRA and FDCA are enforced by means of “tolerances”—acceptable concentrations of additives or residues measurable in foods. In general, foods containing permitted substances at levels less than or equal to the tolerance are legal; those found at levels greater than the tolerance are “adulterated” and subject to recall, seizure, and destruction.

EPA for a pesticide concentration up to forty times above what they would receive for a product whose ill effects cannot be pinpointed above or below a certain “threshold.” If they opt instead for the second type they can expect to gain no more than a twofold increase in their products’ acceptable concentration. Manufacturers will almost always choose the first option. Thus it seems likely that this benefits-based “escape clause” in the law will seldom, if ever, be used.

New Protections for Infants?

Another new feature of the FQPA may have more

impact. The statute requires that an additional tenfold safety factor be added to provide more certainty that infants will be protected, absent information demonstrating it is not necessary. This provision derives from speculation in a National Research Council report, "Pesticides in the Diets of Infants and Children," that the very young may sometimes be exceptionally sensitive to pesticides. Its incorporation into the 1996 law is reported to have been a concession in exchange for the willingness of some members of Congress to support the exemption of pesticides from the Delaney Clause. Yet the scientific foundation for this requirement is weak. Testimony and evidence assembled by an EPA-sponsored study group (see "Similarities and Differences Between Children and Adults," ILSI Press, 1992) suggest that few substances will be sufficiently more dangerous to infants than to other segments of the population to justify any deviation from standard practice. Furthermore, even before FQPA's passage EPA had the authority to require the testing needed to ensure children's safety, and had required it. Thus the added safety provision would appear to be a symbolic victory rather than a real change.

Depending on how EPA interprets and implements this provision, however, we could find a truly paradoxical result: pesticides once regarded (by some) as unreasonably dangerous because they were

associated with tumors in animal tests may now be accepted as quite safe. And, conversely, noncarcinogenic pesticides formerly regarded as quite safe may now be considered unreasonably dangerous because of the adverse effects they may have on the very young.

Winners and Losers

The biggest winner under the new law is EPA. It now has an unambiguous and unified statute to administer. A heavy burden has been lifted from the agency's senior management no longer forced to operate under conflicting federal laws. Further, EPA's Office of Pesticides Programs will grow, funded by the increased licensing fees on pesticides also authorized by this bill. FQPA requires pesticide regulators to review all existing pesticide tolerances within ten years, something not possible with EPA's current scientific resources.

Other clear winners will be animal-testing and research labs and scientific consultants. Now there will be a very high value attached to being able to show that pesticides exert their effects on animals through a "threshold" mode of action, that is, that their ill effects occur only after some critical level of exposure is reached. The new law will greatly stimulate demand for the tests that provide requisite data on this subject.

Other winners will be pesticide manufacturers

Making the World Safe for Strawberries

When Congress passed the Food Quality Protection Act of 1996, strawberries were due to become rare, seasonal, and very expensive. EPA was poised to cancel all food-use applications for pesticides that left residues shown to be animal carcinogens, including the fungicides that growers of fresh fruit depend on. Corn and soybean farmers also would have seen a steep decrease in their yields, since they depend on "pre-emer-

gent" herbicides—almost all of which are carcinogens—to increase their harvest fourfold. EPA was ready to take this drastic action in its ongoing effort to put to rest a legal conundrum blocking acceptance of improved—though not risk-free—food.

Fortunately for the strawberry, FQPA eliminated the problem before EPA made its move.

Until FQPA passed, pesticide residues on processed food—applesauce and baby food, for instance—were treated by law as food additives. As such, these residues were subject to the Delaney

Clause, a 1958 amendment to the Food, Drug, and Cosmetic Act (FDCA) that banned carcinogenic additives. Within the legal maze, however, pesticides on processed food could duck Delaney if they passed muster on raw food, such as fruits and vegetables.

Avoidance was possible for two reasons. First, pesticide residues on raw foods were not considered food additives, so Delaney did not apply to them. Second, if EPA had granted approval—what is known as a "tolerance"—for a certain residue concentration on a raw food such as apples,

it was not necessary under FDCA for an applicant to obtain a separate tolerance for the processed applesauce. The only caveat was that the residue on the apples could not become more concentrated during processing. For most food-residue combinations that is the case. Thus, until very recently, trace residues of many carcinogenic pesticides appeared in processed foods quite legally, coming in on piggyback through the back door of the FDCA.

Reflecting the state of the science over the years, EPA

whose most profitable products are carcinogenic in animals only beyond some threshold concentration. Common fungicides seem likely to fall into this set. Ironically, manufacturers of pesticides that are not carcinogenic may be losers under FQPA if product use levels approach the limits of safe exposure. At best, they will have to invest in research to show that infants are not especially susceptible to residues of their products in processed foods.

Farmers and food processors will win by having staved off a big loss: the chemicals on which they will depend will remain available. Any changes in their costs that result from the increased testing requirements will be incremental and probably passed along in higher prices.

Then there are the rest of us. We can be a bit more confident that the food supply is safe; newer, probably safer pesticides will replace some existing ones. We gain also by not suffering the disruption in our food supply that would have resulted if EPA had canceled licenses for all carcinogenic pesticides. Some of us will even appreciate the fact that the kerfuffle over pesticides will start to settle down.

On the other hand, food prices are likely to increase somewhat because of FQPA. The increase directly attributable to the costs of testing and analyzing for pesticide residues will not mean much to those

willing to treat themselves to Oregon blackberries at \$3.99 the half-pint, but to the poor it will matter. Many are already unable to afford the fruit and vegetables needed for a healthy diet; higher costs will just add to that burden. As a result, their health may suffer further. 🏠

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had granted quite a number of tolerances to pesticides mistakenly thought not to leave residues on raw food or not to be carcinogenic. As time went by and science advanced, many of these approved pesticides were found to cause cancer in animal tests and to leave small but detectable residues in foods. Similarly, as time went by, EPA began receiving applications to approve new pesticides that were ostensibly safer and often left smaller residues than the older products they were intended to replace. Their drawback,

however, was their detection as possible carcinogens.

The agency was caught in a Catch-22. If it approved the new pesticides, EPA would increase confidence in food safety, but because of the contradictory law, some carcinogens would end up in processed food. EPA decided it could not violate the spirit of Delaney by approving tolerances for these new pesticides, even though it could do so legally for raw foods. The paradox sprang from the fact that EPA could not cancel pesticide residues whose dangers had surfaced after

their approval unless they posed an "unreasonable risk," something very difficult to prove. Thus the seeming contradiction: apparently safer alternatives could not be registered while less safe pesticides remained on the market. Along with the paradox came an irony: in championing Delaney, EPA could be accused of shortchanging food safety.

In late 1988, EPA announced a new "negligible risk" policy, under which it would treat processed-food and raw-food pesticide residues alike, approving

those that posed an insignificant cancer risk.

Environmentalists promptly sued EPA, asserting that the proposed policy violated the Delaney Clause's total ban on carcinogens in processed food. The court agreed.

Believing it had no other choice, EPA then announced it would cancel all food-use applications for pesticides that left residues shown to be animal carcinogens in toxicology tests. The agency was moving with all deliberate speed to carry out this policy when FQPA passed. 🏠