Tight deadlines and data gaps fan fight on pesticide safety

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Farmers and chemical manufacturers are bracing themselves for a bitter fight with environmentalists in the coming months over new pesticide regulations. Both sides claim that science is on their side.

[WASHINGTON] Moves by the US Environmental Protection Agency (EPA) to implement the Food Quality and Protection Act (FQPA), passed by Congress in 1996, are expected to reopen a battle about how much pesticide residue should be allowed in foods. The debate highlights the difficulty of setting public health policy in the absence of conclusive data about environmental threats.

The FQPA was meant to improve on the long-disputed Delaney clause, which had flatly banned any food additive found to cause cancer in animals. The new law substitutes a more flexible standard for food safety, demanding "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue".

Based largely on recommendations contained in a 1993 report of the National Academy of Sciences, the FQPA also added an extra layer of protection for children. Pesticide 'tolerances' — the maximum amount of residue allowed in food — should be ten times lower for children than the levels deemed safe for adults, unless data show that children are not more susceptible.

The FQPA came with tight deadlines. One third of the nearly 10,000 uses for hundreds of pesticides had to be reassessed by August 1999, with another third reassessed by 2002, and the remaining third by 2006. The EPA has assigned priority to the 40 organophosphates, including malathion, diazinon and Dursban (chlorpyrifos), which are widely used pesticides that target an insect's nervous system.

In the past three months, the EPA has published preliminary risk assessments for nearly half the pesticides in this group, but has not yet issued any revised tolerances. Preliminary analysis indicates that about half of the 40 organophosphates will require the additional three- to ten-fold safety factor to protect children.

Lack of exposure data

Research on animals shows that organophosphates have harmful neurotoxic effects. But, although these toxicological data are strong, exposure data — the amount of pesticide residue present in food — are sketchy. Lacking reliable information, the EPA has assumed in the past that an entire field of crops is treated with the maximum legal amount of a pesticide, but farmers and pesticide manufacturers say this greatly exaggerates the amount of chemical applied.

The US Department of Agriculture, which collects information on pesticide usage, has so far been unable to produce a comprehensive, reliable database to settle the matter conclusively. Data on pesticide exposures in the home and in drinking water are even scantier, yet the FQPA requires the EPA to come up with a single 'aggregate' risk from all different routes. Methods for producing this aggregate risk have yet to be developed.

The EPA has begun publishing guidelines as to how it will handle these and other issues related to the FQPA. These include: where to set safety thresholds when residue amounts are below the level of detection; what constitutes a "complete and reliable" database for assessing risks to children; and whether pesticides with a common method of toxicity might have cumulative effects.

Worried that the EPA will ban or restrict the use of pesticides based on assumptions rather than real-world data, farm groups and chemical manufacturers have lobbied for the agency to use its data 'call-in' authority to gather more information.

In a letter sent last month to Carol Browner, the head of the EPA, the American Farm Bureau Federation and American Crop Protection Association, which represents pesticide manufacturers, charged that, by not using this authority, the EPA is "needlessly jeopardizing tolerances for… products which could be proved to be safe if the necessary data were generated".

Environmentalists say the request for a data 'call-in' is a stalling tactic. An EPA official responsible for implementing the FQPA says only that "we'll look at all the information that is available to us", adding that industry-supplied data are of varying quality and relevance, and cannot always be accepted.

A 'horrendous task'

Farmers and pesticide manufacturers counter that the law requires the use of real data, not models or estimates, and that piling one worst-case assumption onto another overestimates the threat to public health.

For example, the EPA sets its regulatory threshold for pesticides at a level 100 times below the dose at which no effect occurs in animals. Some pesticide companies have pushed for testing pesticides on humans because they believe that this uniformly applied safety margin is too conservative (see *Nature* **394,** 515; 1998).

Faced with so many uncertainties, the EPA should slow down, say pesticide and farm groups. But, although acknowledging that there are holes in the data, environmental groups say the potential threat to children's health justifies action now.

More research could help to answer some important questions. But federal money for pesticide research has been scarce, and manufacturers rarely generate large amounts of data themselves unless forced to do so by regulatory deadlines.

The FQPA may provide that stimulus. Both sides agree that the law's vagueness — using terms like "reliable" information and "reasonable" harm — has left the EPA in a quandary, as it must write specific regulations based on that language. The time constraints alone, says one scientist, have created a "horrendous task" for the agency. □

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Fine line: arguments still rage about how much pesticide can be safely applied to food crops.