

Pressure Building to Stop Implementation of the *Food Quality Protection Act*

Additional Margin of Safety for Children and Consideration of Multiple Chemical Exposure Attacked

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With industry breathing down the Administration's neck and pressure from the leadership on Capitol Hill, Vice President Gore sent a directive to Environmental Protection Agency (EPA) Administrator, Carol Browner, and Agriculture Secretary Dan Glickman, on April 8, 1998 signaling possible delays in the implementation of the *Food Quality Protection Act* (FQPA). In response, the agencies established a 45-member Tolerance Reassessment Advisory Committee (TRAC) which is predominantly industry and industry-supported groups, thus raising serious concerns about the further politicizing of EPA science. At issue is implementation of key FQPA provisions: the 10-fold extra margin of safety for children (in cases where EPA does not have complete health data), the so-called "common mechanism of effect" clause (which requires that EPA calculate the multiple effects of pesticides with similar toxic properties), and the definition of "reliable" science. These issues were raised in a letter from industry to EPA in March, which voiced concern about imminent agency action to remove numerous pesticides (priority is organophosphates) from the market by revoking their food tolerances. To ensure a "transparent" process, Gore called for the creation of the advisory committee which would meet four times over the summer.

"Sound Science," "Safety" Factors, and Risk Assessment

The recurring problem is that EPA must make decisions about protecting human health without the benefit of extensive data.

The law requires EPA to use "reliable" and "available" data, but often these do not exist. Industry stresses the need for "sound science," but setting an "acceptable" level of harm or risk is a *policy* not a *science* question.

This is where risk assessment comes in. Risk assessments are mathematical calculations, based on certain exposure assumptions, used to calculate human risk from toxic materials. A

10x factor (10-fold additional margin of "safety") is required when existing data are insufficient to determine risk levels for children. However, in a



failure to properly implement *FQPA*, only nine out of 91 tolerances set since the passage of the *Act* have included this ten-fold safety factor. Industry says that this 10x factor is unnecessary because exposure estimates are conservative enough to protect both children and adults.

EPA Preliminary Assessments Show Organophosphates Exceed Acceptable Levels

The four TRAC meetings in June and July were productive but frustrating. In the second meeting, EPA released summary preliminary assessments on 40 organophosphate pesticides, showing that at least 20 exceed EPA's current threshold for either acute or chronic effects from dietary exposure. At that time, EPA failed to release the names of the chemicals associated with the preliminary assessment, though the information is discloseable through the *Freedom*

of Information Act. Industry representatives say broad disclosure will blacklist their products before EPA reaches its final determinations. The industry is pushing hard to force more "refined" risk assessments, dramatically reducing risks on paper by getting EPA to use lower public exposure assumptions, e.g. a smaller percentage of crops treated. The third TRAC meeting focused on when to release information during the risk assessment process. Should agencies allow the chemical registrants prior access to agency decisions before the public is allowed to comment? After much discussion and debate, the agency proposed a compromise in which the registrants would have first review and be allowed to make only technical corrections before public disclosure, subjecting questions of reformulating underlying assumptions in evaluating human risk to a public comment period.

EVER PLAYED MONTE CARLO?

EPA plays gambling games with our lives every day. Monte Carlo is a statistical tool used by EPA in performing its risk assessments on pesticide chemicals when setting acceptable pesticide residues on food ("tolerances"). It is an attempt to methodically deal with lack of scientific data. Basically, the agency will create a plot of points on a graph, which shows percent of population on the Y axis and likelihood of exposure on the X axis. Most likely, estimates about food residues, for example, would show a curve sloping downward to the right, showing many people with low exposure and a minority of people with high exposure. For example, EPA may make the assumption that the average American eats 5-15 avocados per year, while a few people may eat 50 or more per year. The basic equation for calculating risk from residue exposure is HAZARD x EXPOSURE = RISK. The hazard of a chemical may be known or estimated, and is represented as a numerical figure. The agency must attempt to achieve a numerically quantifiable exposure level and plug it into the equation to calculate risk. This is where many assumptions come into play. A computer chooses 1000 points off the original graph (it will often choose the more common points, thus eliminating the extreme cases), plug these numbers into the risk equation, and run it 1000 times. Then the results are plotted on a second

graph. From this graph, the agency attempts to regulate the chemical in a way that will protect the 99.9th percentile, or 99.9 percent of the people at risk. For a nation of roughly 270 million people, the small percentage left out is still 270,000 people. The policy reasons for using this percentile, rather than the 95th or 90th percentile are now being subjected to intense lobbying by those in industry seeking to allow an even greater degree of harm/risk.

Sound good? Convinced that you're safe?

Monte Carlo is basically a method of being more precise and objective about imprecision and possibly false or inaccurate assumptions. It is a fancy way of expressing the uncertainty that is unavoidable until more chemical evaluations and exposure assessments are completed. The underlying problem is that risk assessment policy accepts that certain people will be at risk, though risk may be defined as low. It also does not account for multiple, additive, and synergistic exposure. It allows chemicals on the market assuming innocence until proof of guilt. It rejects the notion of prevention and the precautionary public health principle. Unfortunately, human suffering is the price to pay for this policy.

Congress Prepares To Step In

On June 25, 1998, the Department Operations, Nutrition, and Foreign Agriculture Subcommittee of the U.S. House of Representatives Agriculture Committee held a hearing to challenge the agencies on the implementation of the *FQPA*. The hearing opened with Deputy EPA Administrator Fred Hansen and Deputy Secretary of Agriculture Richard Rominger fielding often hostile questions from members of Congress concerned about *FQPA*'s impact on chemical intensive agriculture, then continued on to a full day of testimony from pro-chemical constituents. The House Agriculture Subcommittee did not allow any representatives of the public interest community the opportunity to speak, though requests to do so had been submitted. It is believed that the Senate Agriculture Committee will also hold a hearing soon. Hearing speakers raised concern about other countries having economic advantages over the U.S. because they may continue to use pesticides banned in the U.S.

Chemical Industry Coalition Releases "Road Map" for Implementing Law

Industry hearing testimony was a re-vocalization of the concerns listed in its recently released "Road Map" or *Science-Based, Workable Framework for Implementing the Food Quality Protection Act*. This document was produced by the Implementation Working Group (IWG), made up of pesticide industry and agribusiness representatives, in early June 1998.

IWG urges EPA to:

- reduce delay in the registration of new "safer" pesticides;
- allow adequate transition time to adjust to new practices, and;
- ensure availability of realistic alternatives to phased-out chemicals.

The "Road Map" cites concern that sudden loss of pesticides will cause devastating crop loss, and is critical of what is perceived as a lack of comment opportunities afforded the industry during the decision making process. IWG does not believe that all organophosphates should be treated as a group although they all inhibit cholinesterase in nerve function, because there is no established methodology by which EPA determines how a group of chemicals displays a "common mechanism of toxicity" (language in the law).

TRAC Meets in September, Public Comment Sought on Preliminary Risk Assessments

There are many more issues that need to be addressed by the TRAC. For this reason TRAC members added a fifth meeting, scheduled for September 15-16, 1998 at the Ramada Inn, New Carrollton, MD. Until then, work will continue with two "working groups" formed to address some of the technical issues; one group focuses on risk assessment and the other on risk management. There are nine separate science-policy issues being addressed by the risk assessment group. They are: the ten-fold safety factor, dietary exposure assessment, interpreting "no residue detected," dietary exposure estimates, drinking water exposure, assessing residential exposure, aggregating exposure from non-occupational sources, cumulative risk assessment for common method of toxicity, and selection of toxicity endpoints (or critical effects). These nine separate issues will be compiled into a single paper with a target completion date of February 1999. The risk management group faces the task of creating a realistic phaseout process for the high-risk chemicals. Public comments can be submitted on the work group issues.

NCAMP points out the need for attention to issues regarding drift, frequency of chemical toxicity misclassification, training of applicators, impact of inert ingredients, reliance on information extrapolated from animal tests to humans, and other real world use problems that impact on risk assessments. Though EPA was supposed to have disclosed by name in early July the forty priority organophosphates for which preliminary risk assessments are being done, it finally released the names of the first nine in the August 12, 1998 *Federal Register* (63FR43175). Public comment is being solicited on each until October 13, 1998. A report on the final outcome of the TRAC meetings will be printed in the next issue of PAY.

Submit comments on risk assessments to Information Resources and Services Division (7502C), Office of Pesticide Programs, EPA, 401 M Street SW, WDC 20460. For more details and background on TRAC meetings, including the preliminary risk assessments (available in September), go to the EPA website at www.epa.pesticides/trac.htm. General TRAC questions should be directed to Marjorie Fehrenbach, EPA, fehrehbach.margie@epamail.epa.gov, 703-308-4775, fax 703-308-4776. Organophosphate questions should be directed to Karen Angulo, EPA, angulo.karen@epamail.epa.gov, 703-305-5805. For a copy of the industry "Road Map" (133pp), send \$16.00ppd to NCAMP.

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