Is FQPA Ag’s Y2K?

History and current status of Food Quality Protection Act provisions shows a smoother transition and implementation than predicted.

The agricultural community has been living under the shadow of the Food Quality Protection Act (FQPA) of 1996 and its deadlines much like the rest of the world has been living under the shadow of Y2K. No one was positive what would happen, but we all know nothing will be the same. This issue of From the Ground Up: agronomy news provides background information on FQPA’s provisions and discusses some of the specific issues raised by FQPA, as well as the status of implementation.

Background and goals

FQPA amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food Drug, and Cosmetic Act (FFDCA), fundamentally changing how the Environmental Protection Agency (EPA) regulates pesticides. President Clinton signed FQPA into law on August 3, 1996 as the strongest law ever enacted to protect the public from the potential risks posed by pesticide residues in food. Among other things, FQPA:
• established a single, health-based standard for pesticide residues in raw and processed food;
• provided tools for enhancing the protection of all consumers, particularly infants and children; and
• encouraged the development and adoption of lower risk, effective...
crop protection tools for U.S. agriculture.

In addition, FQPA set a ten-year schedule for review of the 9,721 tolerances in existence when the law was signed, to bring them into compliance with the new standard. The first milestone for this ten-year reassessment effort was August 3, 1999, when 33% (approximately 3,207) were to be completed.

Overall, there are about 20,000 registered pesticide product formulations, containing more than 900 active ingredients and 1,835 other ingredients. About 470 pesticide active ingredients are used in agriculture, and EPA has established more than 9,000 residue limits (tolerances) for pesticides in food. EPA’s pesticide regulations directly affect approximately 30 major pesticide producers, another 100 smaller producers, 2,500 formulators, 29,000 distributors and other retail establishments, 40,000 commercial pest control firms, one million farms, three and a half million farm workers, several million industry and government users, and all households.

EPA is authorized under FFDCA to set tolerances, or maximum legal limits, for pesticide residues in food. Tolerance requirements apply equally to domestically-produced and imported food, and any food with residues not covered by a tolerance (or in amounts that exceed an established tolerance) may not be legally marketed in the United States. EPA requires extensive data as part of its pesticide review and approval process, requiring more than 120 studies before granting a registration for most pesticides used in food production. These studies allow EPA to assess risks to human health, domestic animals, wildlife, plants, groundwater, beneficial insects and other environmental effects. When new evidence arises to challenge the safety of a registered pesticide, EPA may take action to mitigate risk or suspend or cancel its registration and revoke the associated tolerances. To mitigate risk EPA undertakes an extensive special review of a pesticide’s risks or works with manufacturers and users to implement changes in a pesticide’s use (such as eliminating use on some crops, reducing application rates, increasing reentry intervals, or cancellation of a pesticide’s uses).

FQPA’s guiding memo

EPA’s FQPA activities have been guided by four principles outlined in an April 8, 1998 memo from Vice President Gore to EPA Administrator Carol Browner and U.S. Department of Agriculture (USDA) Secretary Dan Glickman. Specifically, the Vice President stated the importance of using sound science in protecting public health, developing a sufficiently transparent implementation process, providing a process for the reasonable transition of agriculture to new pest management strategies, and maintaining open consultation with the

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public and other agencies. EPA and USDA were instructed to work more closely together to implement FQPA.

EPA and USDA are coordinating efforts to ensure that risk assessment and transition strategies balance the need for safety standards with adequate pest control options for producers. USDA is providing data on what people eat, on what residues are actually found in the real world, on what pesticides farmers use and how they are used and is working to identify risk management and transition opportunities.

EPA and USDA have been involving stakeholders in a whole range of ways -- probably the most visible was the Tolerance Reassessment Advisory Committee (TRAC).

TRAC

TRAC was co-chaired by EPA Acting Deputy Administrator Peter Robertson and USDA Deputy Secretary Richard Rominger, and included pesticide registrants, state regulatory officials, growers, food processors, environmental and consumer groups, and public health professionals. TRAC provided a forum for a diverse group of individuals representing a broad range of interests and backgrounds from across the country to consult with and make recommendations to EPA and USDA on how best to reassess tolerances, particularly those for organophosphates. TRAC met eight times and helped EPA and USDA make significant progress in several areas critical to the successful implementation of FQPA.

FQPA requires EPA to address a number of new scientific areas related to pesticide regulation, such as aggregate exposure (from all non-occupational routes) and cumulative risk (consideration of effects and exposures from pesticides and other substances that act by a common mechanism of toxicity). Key to implementing FQPA’s science provisions is the development of science policies. With the help of TRAC, EPA identified nine areas where revised science policies were needed:

1. applying FQPA’s 10-fold safety factor,
2. conducting dietary exposure risk assessment [Monte Carlo analyses],
3. interpreting cases where no pesticide residues are detected,
4. conducting dietary (food) exposure assessment,
5. conducting dietary (drinking water) exposure estimates,
6. assessing non-occupational/non-dietary (residential) exposure,
7. aggregating exposure from all non-occupational sources,
8. conducting cumulative risk assessments for pesticides with a common mechanism of toxicity, and
9. selecting appropriate toxicity endpoints for risk assessments of organophosphate pesticides.

Papers have been, or are being, prepared in each of the nine areas and are being released for public comment. To learn more visit: http://www.epa.gov/opfed1/trac/.

An era of reduced risk

FQPA mandated expedited registration of reduced risk pesticides, which can be expected to pose even less risk to human health and the environment than other pesticides that meet the FQPA safety standard. These pesticides typically have one or more of the following advantages over existing products:

• lower impact on human health,
• lower toxicity to non-target organisms (e.g., birds, fish, and plants),
• lower potential for groundwater contamination,
• lower use rates,
• low pest resistance potential, and
• compatibility with Integrated Pest Management.

There are two types of reduced risk pesticides: conventional reduced risk pesticides and biopesticides.

There are two ways to measure the success of the expedited registration program for reduced risk pesticides: (1) by the number of registrations for new reduced risk
active ingredients and (2) by the number of new uses. Since FQPA was enacted, EPA has registered 48 active ingredients which are considered reduced risk, representing 62% of the total number of active ingredients registered and has approved 774 new uses for reduced risk, representing 77% of the total new uses approved.

Inert ingredients

EPA is required to set tolerances or grant exemptions based on the new FQPA safety standard for all ingredients in a pesticide product for use on food, both the active and the other ingredients (formerly referred to as inert) used to make the product formulation. For these other ingredients, EPA has set one tolerance and exempted 17 from the requirements of a tolerance based on the FQPA standard.

EPA is developing a new risk assessment methodology for the other ingredients that will help streamline assessment of aggregate exposure. Aggregate exposures for these ingredients can include exposure from food, drinking water and residences as a result of pesticide use as well as other consumer exposures resulting from their nonpesticidal uses as components of laundry detergents and food additives, for example.

Public involvement a must

The challenge of FQPA requires greater public participation. Since May 1998, EPA has sought to improve public participation in its regulatory program. Through this process, EPA hopes to develop practical, effective methods of risk mitigation.

In July 1998, in consultation with TRAC, EPA and USDA started a process that allows all stakeholders to review preliminary risk assessments and contribute to their improvement, as well as to provide risk management ideas later in the process. The organophosphates are being piloted in the process.

In the first step of the process, EPA releases preliminary risk assessments for the pesticides for public comment. The preliminary risk assessments can be found on the internet at: http://www.epa.gov/pesticides.op/.

Following completion of the public comment period on each preliminary risk assessment, EPA reviews the comments and revises the risk assessment, as appropriate. USDA, in consultation with Land Grant Universities and commodity groups, then reviews the revised risk assessment to identify opportunities for risk management and the potential need for transition strategies. (To date, 14 organophosphate risk assessments have been reviewed. Colorado State University’s participation is coordinated through the Colorado Environmental Pesticide Education Program.)

EPA then publishes the revised risk assessment and a comment period on risk management follows during which the public is invited to submit risk management ideas and proposals. Final decisions are published in the Federal Register: http://www.access.gpo.gov/su_docs/aces/aces140.html.

Did EPA meet the deadline?

FQPA required EPA to reassess all 9,721 tolerances and tolerance exemptions that were in effect when the law was passed in August 1996 within ten years. In August 1997, EPA published a Federal Register notice dividing the pesticides with tolerances with that must be reassessed into three priority groups. FQPA requires EPA to give highest priority to pesticides that appear to pose the greatest risk.

- Group 1 (228 pesticides/5,546 tolerances) includes: organophosphates, carbamates, organochlorines, probable carcinogens, high-hazard inerts, and reference dose (RfD) exceeders (those with dietary exposure at levels above the amount that is believed to be safe for life-long, daily consumption)
- Group 2 (93 pesticides/1,928 tolerances) includes: possible carcinogens, all remaining reregistration chemicals (those that were first registered before 1984)
- Group 3 (148 pesticides/2,247 tolerances) includes: remaining pre-FQPA pesticides with reregistration eligibility decisions, remaining post-1984 pesticides, biological pesticides.

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Remaining inert

EPA had to complete reassessment of 33% (3,240) of these tolerances by August 1999. EPA reassessed 3,290 tolerances by August, 1999, surpassing the 33% goal. Of the reassessments completed, 66% (2,178) are in the first priority group. These reassessments represent over 39% of the 5,546 tolerances in this highest priority group. EPA has reassessed 28% of the organophosphate tolerances, 31% of the carbamate tolerances, and 20% of the organochlorine tolerances, as well as 29% of the tolerances for pesticides classified as “probable” human carcinogens.

EPA has completed reevaluation of 48 pesticides, of these 33 are for pesticides with food uses. This brings the total count to 189 pesticides which, coupled with 231 voluntary cancellations of potential reregistration candidates, leaves 192 pesticides to be reevaluated.

Since August 1996, 1,154 Section 18 emergency exemptions were authorized, with 195 tolerances set, each meeting the FQPA safety standard. The average turn-around time for emergency exemptions is under 60 days. Nearly 84% of uses approved in 1998 and 1999 were for minor use. EPA has approved more than 1,300 new minor uses, more than 80% of which are for reduced risk pesticides.

Organophosphates review

The first organophosphates (OP) are through their review. Some uses of methyl parathion are eliminated, and aziniphos methyl uses are modified and reduced.

Methyl parathion is an acutely toxic organophosphate insecticide and is widely used on crops. It is one of the early organophosphates in the public review process. EPA is canceling the use of the pesticide methyl parathion on all fruits and many vegetables (including apples, peaches, pears, grapes, nectarines, cherries, plums, carrots, cauliflower, celery, certain peas and beans, collards, lettuce, mustard greens, spinach, and tomatoes) many of which are eaten frequently by children. EPA is taking these action to help protect children as well as adults.

In addition, worker risks were found to be unreasonable for many use scenarios, and EPA is modifying product labels to increase worker protection. Closed mixing/loading systems and enclosed cabs/cockpits for all uses and formulations will be required by the 2001 growing season. Airblast application of methyl parathion will only be allowed on tree nut crops. And EPA is requiring that more than 80% of total methyl parathion be applied by professional aerial applicators.

Methyl parathion was registered for food use in 1954 and was listed as a restricted use pesticide in 1978. Approximately 4.2 million pounds of methyl parathion were applied last year, but 75 percent of that was applied to cotton, corn and wheat, which are not affected by the new regulations.

Azinphos methyl is an organophosphate pesticide used on many fruits eaten by children and is one of the first pesticides to enter the final stage of the pilot review process. EPA is requiring changes to the use patterns for the pesticide to reduce dietary risks that exceed the margins of safety deemed acceptable under FQPA. These use changes (for example, lengthening the pre-harvest interval to reduce residues on foods) are important to ensure adequate protections for both children and workers. EPA is canceling use of azinphos methyl on sugarcane nationwide and cotton in areas of surface water vulnerability to prevent unreasonable risks to wildlife and contamination of water. EPA is also imposing a cap on sales of azinphos methyl.

Other organophosphates

EPA also announced an 18 month schedule for completing its review of all 39 organophosphates. There are 35 OPs left to reassess, covering at least 1,129 tolerances. To
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**FQPA**

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see the list go to http://www.epa.gov/pesticides/op/status.htm.

**More restrictions**

Growers, be on the alert: If you haven’t been following EPA’s recent actions concerning FQPA, now is the time to begin. Stay informed. Be involved. Growers should be concerned how soon alternatives to pesticides cancelled due to FQPA will be available. Researchers and growers need time to figure out how to best use any alternative. This is where the discussion regarding “transition’ must focus.

It is critical that growers know which pesticides are essential to their production systems and that this information can be communicated to EPA. It is also important that how growers mitigate the potential risk of exposure to individual pesticides be communicated to EPA. Data-based information can be sent to Neil Anderson at EPA via e-mail at: Anderson.Neil@epa.gov.

**Worker Protection Standard**

EPA’s Worker Protection Standard (WPS), first implemented in 1992, has resulted in pesticide safety education and training efforts across the country. Since the passage of FQPA, EPA’s Worker Protection Program to implement the standard has devoted significant resources to producing and distributing bilingual or multi-lingual educational materials.

The EPA began a new pesticide safety programs website, http://www.epa.gov/pesticides.safety, to inform farm workers, certified applicators, and health care providers about the EPA’s pesticide safety programs. This site provides easy access to both English and Spanish versions of information about pesticide topics including pesticide safety training, notification of pesticide application, use of personal protective equipment, and emergency medical assistance. EPA’s new publication, the 5th Edition of Recognition and Management of Pesticide Poisonings, a manual that assists health care providers in the diagnoses and management of treatment for pesticide poisonings, is also available at this site.

Some new issues are arising such as WPS training for specific chemicals. New restrictions and more training may be the only way these materials can be retained for use. Many of the worker protection restrictions discussed in regards to methyl parathion are proposed for all organophosphates. These include closed mixing and loading systems, enclosed cab/cockpit equipment, increased protective clothing and increased reentry intervals.

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Hot Topics For 2000

Specialists look ahead and cite these issues for the next year: GMOs, water, urbanization, economics, and environmental concerns.

Looking forward to the new year, I asked the extension specialists in Soil and Crop Sciences and Bioagricultural Sciences and Pest Management what hot topics and emerging issues we all needed to be aware of in 2000. The “Man of the Month”, Frank Pearis said, “Entomologists are loath to make predictions -- we’re resigned to being surprised by our worthy opponents,” but others took a stab at the topics we will need to learn more about this next year.

The Genetically Modified Organism debate was the most frequently mentioned topic. One specialist went so far as to predict that while most “official” trade barriers to GMO crops will be removed, public acceptance and marketability will remain an issue, and overall acreage will decrease (short term) due to producer disenchantment. In any case, development of GMO corn and other crops will continue.

Water was the second most commonly mentioned topic. One person said that drought resistant dryland crops would be necessary if the current dry weather continues. Water quality issues mentioned included salinity problems and regulatory programs such as Total Maximum Daily Loads (TMDLs) and Source Water Protection.

Water was frequently linked to growth issues. Water quantity and quality will be impacted by increased urbanization along the Front Range. This growth also means loss of productive farmland, and reduced tolerance for agricultural odors and dust. In addition, growth adds to pressures on agriculture by reducing habitat for plants and animals being considered for endangered species designation such as prairie dogs.

Several economic issues were mentioned for 2000. They included: future of the royalty system for wheat and bean varieties; demise of the farm bill and subsequent free market economy; the pressures between food and fiber versus industrial crops; crop diversification; expanding markets for environmental products which are renewable and recyclable; and the future of organic farming without premiums.

Pest management – the perennial economic agriculture topic – has several manifestations this year, according to the specialists. Invasive species, reemerging diseases (Goss’s wilt, for example), new diseases like corn red root rot and small grain viruses were mentioned, along with the economic

and other impacts of Food Quality Protection Act implementation. Managing host plant resistance will be important, as well as education for producers and agents on pesticides and dryland cropping systems.

Precision agriculture was mentioned both as a tool and a challenge. As a tool, precision ag can help manage resources, for example locating herbicide resistant wheat within fields. As a challenge, it provides Colorado State an opportunity to contribute in terms of education, technologies, and collaborative efforts.

Some topics don’t just go away, and manure is one of those. We will continue to hear debate and see the need for more education as feeding operations develop their waste/nutrient management plans.

As we enter a new millennium, we face issues both new and familiar. Staying informed and delivering relevant programs on topics pertinent to our various clientele will remain our biggest challenge.

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http://www.epa.gov/pesticides/trac/
Background information on TRAC, mission statement, and meeting agendas.

http://www.epa.gov.pesticides/op/
Organophosphate review process, schedule, and more

http://www.epa.gov.pesticides/op/status.htm
Alphabetical listing of organophosphates and their current review process status.

http://www.access.gop.gov/su_docs/aces/aces140.html
Federal Register Online. Search by date or subject to find notices about your topic.

http://www.epa.gov/pesticides/safety
EPA worker safety page (English or Spanish) includes standards, training programs, and more.

http://www.ace.orst.edu/info/nptn/
Science-based information on pesticide products, toxicology, and environmental chemistry.