

# agronomy news

## FQPA: Balancing Business and Food Quality Issues

**Pesticide uses and consumer health concerns are major issues for agricultural concerns.**

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On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law, effective immediately. FQPA amended both the Federal Food, Drug and Cosmetic Act (FFDCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Congress unanimously passed the legislation. A broad coalition of environmental, public health, agricultural and industry groups supported it. FQPA was effective immediately with no transition or phase-in period.

Since this date FQPA has been the main topic of conversation and focus of the agricultural industry. Since there was no phase-in period, EPA, registrants, USDA and growers are all struggling with it's interpretation and

### ***Food Quality Protection Act of 1996***

#### ***Highlights***

- amends both major pesticide laws
- mandates a single, health-based standard for all pesticides in all foods, with a goal of protecting the public from pesticide residues in dietary and non-dietary sources
- provides special protections for infants and children by reducing residue tolerances
- expedites approval of safer pesticides
- requires periodic re-evaluation of pesticide registrations and tolerances
- establishes a new, uniform standard for setting pesticide residue tolerances in raw and processed food
- considers information on common mechanisms of toxicity and aggregate exposure when setting tolerances

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## Issues

(Continued from page 1)

implementation. In time FQPA will ensure a greater degree of food safety. Nevertheless, the short-term is going to be a bumpy ride. I have attempted to give an overview of the highlights and impacts of FQPA. If you are already familiar with FQPA, skim the highlights, read the updates on the various activities and, please read the section on what is and can be done. More than anything be aware that FQPA is changing and will continue to change the world of pesticides.

Some changes that are already apparent. . . FQPA is affecting the

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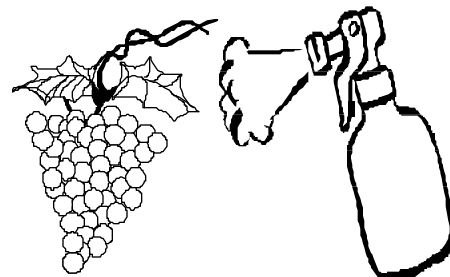
pesticide programs in the states. The definition of pesticide was changed in FQPA to include nitrogen stabilizers. While this definition was changed at the Federal level, many states, including Colorado do not have the authority under their Pesticide Act to regulate nitrogen stabilizers.

The enforcement of any mitigation measures implemented due to saving uses in the FQPA risk cup (see A Peek in the Risk Cup) will fall on State Departments of Agriculture. More Section 18 (Emergency Exemptions) and Section 24(c) (Special Local Needs) registrations are predicted, and each of these will add to the work load of the CDA.

Many label changes will occur. Many voluntary ones are occurring now. The ones that have the entire industry concerned are the ones that EPA will force due to the overflowing "risk cup."

It is important not only to be familiar with FQPA but to keep up with it as pesticide regulatory changes become apparent. Some potential impacts include: loss of pesticides or entire pesticide families, loss of minor uses, changes in labels and usage and lowering of tolerances.

The requirements under FQPA that will affect the reassessment of pesticide tolerances may have significant effects on the availability of pesticides for Colorado crops. Table 1 lists ?? OP and carbamate insecticide tolerances considered at-risk during the first



round of reassessments. Many nematicides, herbicides, fungicides and other insecticides will be at-risk during rounds two and three.

Some crops grown in Colorado will be largely unaffected by FQPA actions. This is due to the relatively small percentage of acres treated with pesticides considered at-risk and due to other efficacious pesticides or non-pesticide alternatives. However, production of other crops may be crippled by the loss of pesticides. Or, due to the percentage of a crop grown here, Colorado may be removed from the label to gain space in the "risk cup."

Health-Based Safety Standard for Pesticide Residues in Food – FQPA established a health-based safety standard for pesticide residues in all foods, using "a reasonable certainty of no harm" as the general safety standard.

Aggregate Exposure – EPA must consider all non-occupational sources of exposure, including drinking water, and exposure to other pesticides with a common mechanism of toxicity when setting tolerances.

(Continued on page 3)

# Is FQPA on TRAC?

## Advisory committee provides strategic guidelines for regulations and procedures.

Vice President Gore's April 8, 1998 Memorandum to EPA Administrator Browner and Secretary of Agriculture Glickman directed EPA and USDA to "... work together to ensure that implementation of the paramount public health goals of the new law is informed by a sound regulatory approach, by the expertise of the Department of Agriculture (USDA), by appropriate input from affected members of the public, and by due regard for the needs of our nation's agricultural producers." The EPA-USDA Tolerance Reassessment Advisory Committee (TRAC) was established on April 30, 1998, in response to this memo.

The TRAC is made up of a diverse group of individuals representing a broad range of interests and backgrounds from across the country, including registrants, Farm Bureau, commodity organizations, environmental organizations and medical professionals. TRAC provided policy guidance to the EPA regarding a strategic approach for organophosphate (OP) pesticide tolerance reassessment. The OPs are the first group of pesticides to be reevaluated under FQPA. This reassessment will be the framework for future reassessments.

The ag caucus decided that it was important for the TRAC to have additional meetings so that the work could be continued to further

ensure the transparency of EPA's decisions. Over the objections of the non-ag members of TRAC this suggestion passed and meetings are scheduled through the spring of 1999.

TRAC has improved transparency through the public release of preliminary risk assessments. And

enhanced EPA/USDA cooperation and increased public input. All of the participating groups have been made aware of the critical issues – transition, level playing fields, alternatives and concerns regarding imports. In addition, a "Plain English" guide on the risk assessment procedure is being drafted by one of the TRAC working groups.

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## Issues

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**Infants and Children (10X Factor)** – FQPA requires an explicit determination that tolerances are safe for children due to children's special sensitivity and exposure to pesticide chemicals. An additional safety factor of up to ten-fold can be added to account for uncertainty in data relative to children.

**Tolerance Reassessment** – All existing tolerances be reviewed within 10 years to make sure they meet the requirements of the new health-based safety standard. EPA's priority will be to review those pesticides that appear to present the greatest risk concerns based on current data. Through the reregistration process, EPA is ensuring that older pesticides meet contemporary health and safety standards, that their labeling is improved, and that their risks are reduced.

**Pesticide registration and registration renewal** – EPA will periodically review pesticide registrations, with a goal of establishing a 15-year cycle, to ensure that all pesticides meet updated safety standards. See AT RISK "Round One" for further details.

**Endocrine screening** – FQPA incorporates provisions for endocrine testing, and also provides new authority to require that chemical manufacturers provide data on their products, including data on potential endocrine effects. EPA must develop a screening program within two years of enactment, implement it within three years of enactment, and report to Congress within four years. This is a very ambitious schedule. Little is known about mechanisms of endocrine disruption and possible synergistic effects. See EDSTAC Report on Endocrine Disruptor Screening Accepted by EPA for further details.

# Insecticides At Risk: Round One

**Organophosphates and carbamates are the first pesticides to be reviewed.**

Under FQPA, EPA must reassess all existing tolerances (more than 9,700) for 469 pesticides according to the new requirements. They will give priority to pesticides that may pose the greatest risk to public health. Tolerances for organophosphate (OP) and carbamate insecticides will be reviewed first, by August of 1999. Then, EPA will review all remaining tolerances within 10 years:

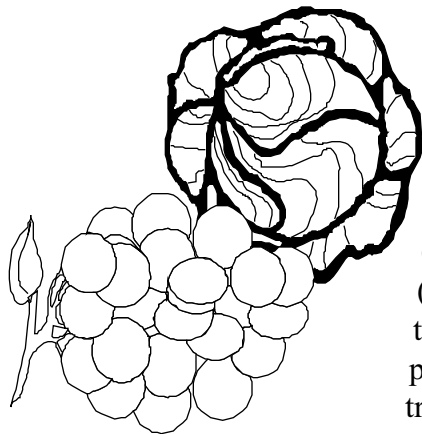
August 1999 – 33% (3,210) of tolerances reassessed

August 2002 – 66% (6,420) of tolerances reassessed

August 2006 – 100% (9,728) of tolerances reassessed

The International Life Sciences Institute concluded and advised EPA that all OPs and car-

bamates act by a common mechanism of toxicity. OPs and carbamates both inhibit acetylcholinesterase, although the biochemistry of the inhibition is very different between the two classes. If EPA uses this grouping to determine the cumulative risk the two classes will be combined into a single “risk cup” (see A Peek in the Risk Cup).



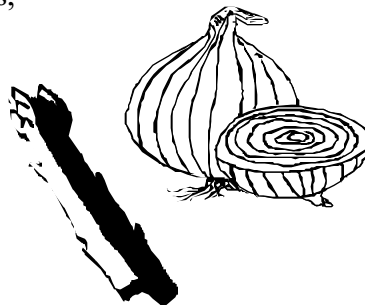
Thirty-five of the 39 OPs are subject to registration. Fifteen of the 39 have both food and non-food uses, 20 have only food uses, five have only non-food uses, 16 have residential uses and 19 have public health uses.

About 60 million pounds of OPS are applied to 38 million acres of US crops yearly. Field corn accounts for 19 million pounds, cotton for 15 million pounds and fruits, nuts and vegetables use a combined 16 million pounds.

Roughly 17 million pounds are used yearly to control termites and mosquitoes. Five OP products account for 60% of all OP uses: chlorpyrifos (Dursban/Lorsban), terbufos (Counter), profenofos (Curacron), tribuphos (Folex/Def), and malathion.

In August OPP released a report entitled “FQPA Safety Factor Recommendations for the Organophosphates” on the safety and hazards of the 39 OPs. The report contains recommendations on whether to retain, reduce or remove the additional 10X safety factor for the OPs. The preliminary conclu-

sion of the safety panel was the the 10X safety factor should be retained on six OPs, reduced to 3X on 10 OPs and removed on 18 OPs.



The OP and carbamate classes of insecticides are extremely important for insect con-

control for many crops grown in the U.S. For many small acreage fruit, nut and vegetable crops, the OP and carbamate insecticides have been the main means of controlling key pests for several decades. Although considerable research has been conducted to find alternatives, the OP and carbamate products remain the primary means of controlling key pests for many crops. If the OPs and carbamates are lost without a transition period, there are no or very few alternatives for many crops, especially minor crops. Identifying, developing and learning to use alternate pest management tools and practices will take time.

But FQPA is not limited to insecticides, herbicides, fungicides and all other pesticides will be reviewed for reregistration. This is just round one.

# Insecticides At Risk: Round One

<b>Trade Name Common Name</b>	<b>Crops Affected</b>
<b>Counter</b> / <i>terbufos</i>	sweet corn, field corn, sorghum, sugarbeets
<b>Cygon</b> / <i>dimethoate</i>	alfalfa, dry beans, small grains, sorghum, soybeans, lima beans, snap beans, cole crops, lettuce, melons, peas, peppers, potatoes, spinach, tomatoes, fruit trees
<b>Cythion</b> / <i>malathion</i>	alfalfa, dry beans, field corn, pasture range, small grains, soybeans, sugarbeets, asparagus, lima beans, snap beans, melons
<b>D-Z-N</b> / <i>diazinon</i>	sugarbeets, lima beans, snap beans, cole crops, onions, pumpkins, winter squash, spinach, summer squash, zucchini, sweet corn, tomato, fruit trees
<b>Di-syston</b> / <i>disulfoton</i>	alfalfa, dry beans, small grains, sorghum, cole crops, potatoes
<b>Dibrom</b> / <i>naled</i>	dry beans, pasture range
<b>Dyfonate</b> / <i>fonofos</i>	field corn, sorghum, potatoes, sugarbeets, sweet corn
<b>Furadan</b> / <i>carbofuran</i>	alfalfa, field corn, small grains, sunflowers, sweet corn
<b>Guthion</b> / <i>azinphos-methyl</i>	alfalfa, cucumbers, melons, onions, peppers, potatoes, tomatoes, fruit trees
<b>Lannate</b> / <i>methomyl</i>	alfalfa, dry beans, field corn, small grains, sorghum, soybeans, sugarbeets, asparagus, snap beans, lima beans, carrots, cole crops, lettuce, melons, onions, peas, peppers, spinach, summer squash, zucchini, sweet corn, tomatoes, fruit trees
<b>Larvin</b> / <i>thiodicarb</i>	cole crops, lettuce, spinach
<b>Lorsban</b> / <i>chlorpyrifos</i>	alfalfa, field corn, small grains, sorghum, soybeans, sugarbeets, sunflowers, lima beans, snap beans, onions, potatoes, sweet corn
<b>Mocap</b> / <i>ethoprop</i>	field corn, potatoes, sweet corn
<b>Metasystox R</b> / <i>oxdemeton-methyl</i>	sorghum, sugarbeets, cole crops, lettuce, sweet corn
<b>Monitor</b> / <i>methamidophos</i>	cole crops, potatoes
<b>Nemacur</b> / <i>fenamiphos</i>	soybeans
<b>Orthene</b> / <i>acephate</i>	dry beans, pasture range, soybeans, lima beans, snap beans, cole crops, lettuce, peppers
<b>Penncap M</b> / <i>methyl parathion</i>	alfalfa, dry beans, field corn, pasture range, small grains, sorghum, soybeans, sugarbeets, sunflowers, lima beans, snap beans, onions, peppers, potatoes, sweet corn, tomatoes
<b>Sevin</b> / <i>carbaryl</i>	alfalfa, dry beans, field corn, pasture range, small grains, sorghum, soybeans, sugarbeets, sunflowers, asparagus, lima beans, snap beans, carrots, cole crops, cucumber, eggplant, melons, peas, peppers, potatoes, pumpkins, winter squash, summer squash, zucchini, sweet corn, tomatoes
<b>Temik</b> / <i>aldicarb</i>	dry beans, sorghum, sugarbeets, lima beans, snap beans
<b>Thimet/Rampart</b> / <i>phorate</i>	dry beans, field corn, small grains, sorghum, soybeans, sugarbeets, potatoes, sweet corn
<b>Vydate</b> / <i>oxamyl</i>	eggplant, peppers, potatoes

# A Peek Inside the Risk Cup

**Tolerances and exposures must be determined for each chemical to determine acceptable uses.**

The risk cup is an analogy used to describe aggregate exposure estimates. Under FQPA, EPA must review and adjust all tolerances to assure the protection of all Americans, including vulnerable population groups like infants, children, and pregnant women. When assessing pesticide tolerances, EPA first determines the acceptable amount of exposure to a pesticide, in other words, the total amount of the pesticide that a person could be exposed to every day, for 70 years, without experiencing additional health risks. This acceptable amount of exposure is characterized as a “risk cup.” The amount of risk that will fit into the risk cup is a finite number.

In the absence of real data, EPA is relying on multiple default assumptions in an attempt to “guess” at what the dietary and non-dietary exposures might be. To protect the widest range of people EPA is using 99.9<sup>th</sup> percentile risk assumptions for exposure (i.e., worst case scenarios). EPA is reserving portions of the cup:

- 10% for drinking water exposure
- 5% for indoor residential exposure
- 5% for outdoor residential exposure

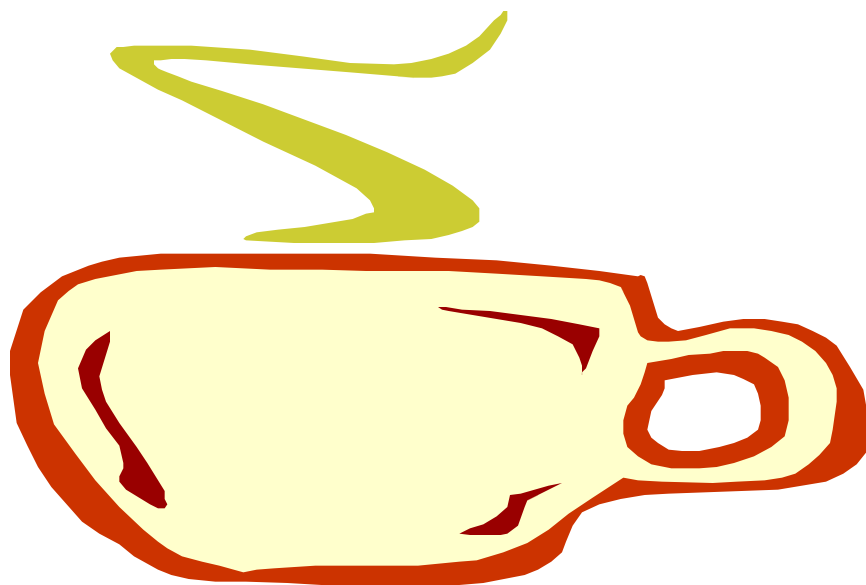
The remainder of the risk can be allocated to dietary (food source).

Previously when setting tolerances,

the EPA examined the dietary exposure to each pesticide individually, one crop use at a time, and added a safety factor to ensure the tolerance was safe. Under FQPA, EPA must consider aggregate exposure for each pesticide, meaning they must examine all non-dietary and all dietary exposures together. Drinking water will be included as a component of the acute dietary exposure.

Non-dietary exposures would include exposures through residential, lawn and garden uses. EPA can add an additional safety factor to protect children. EPA must also reassess groups of pesticides based on common mechanisms of toxicity. For example, insecticides in the organophosphate (OP) class are considered to have a common mechanism of toxicity (See At Risk - Round One). Using the worst case assumptions EPA reports that some OPs are already overflowing their risk cups.

When the cup is full or a registrant wants to add a new product, the registrant could: make label or formulation changes so the pesticide is safer, most likely an extension of the preharvest interval (phi) or drop pesticides or uses from the cup.



# A Glossary of Food Quality Protection Terms

**ACUTE EXPOSURE** – a single or one day exposure that is estimated using worst-case assumptions for the pesticide residues present in the food.

**AGGREGATE RISK** – the combined risk from all routes of exposure for a single pesticide, including food, drinking water, residential uses, lawncare and all other non-occupational uses.

**CHRONIC EXPOSURE** – occurs over a substantial portion of the individual's lifetime (i.e., long-term or continuous).

**COMMON MECHANISM OF TOXICITY** – where two or more chemicals have the same impact on the human body. In such cases, risks from these chemicals will be combined.

**CUMULATIVE RISK** – combined risk from all pesticides that have a common mechanism of toxicity.

**EDSTAC** – Endocrine Disruptor Screening and Testing Advisory Committee, an independent scientific advisory group charged with recommending to EPA an endocrine disruptor screening/testing program for pesticides and chemicals.

**ENDOCRINE DISRUPTOR** – chemicals that have been shown to result in developmental and reproductive abnormalities in wildlife and are suspected by some scientists of causing adverse health effects in humans, including birth defects, breast cancer, prostate cancer and infertility.

**EPA** – Environmental Protection Agency.

**FDA** – Food and Drug Administration.

**FFDCA** – Federal Food, Drug and Cosmetic Act regulates the establishment of pesticide tolerances.

**FIFRA** – Federal Insecticide, Fungicide, and Rodenticide Act requires EPA registration for all pesticides sold in U.S.

**FQPA** – Food Quality Protection Act became law August 3, 1996. It contains far-reaching provisions to revise the standards pesticides must meet to be registered by the EPA.

**MINOR USE CROPS** – Defined by FQPA as U.S. agricultural crops grown on less than 300,000 acres. It is easier to list the major crops and say that minor crops are any crop not on the list – U.S. major crops: almonds, apples, barley, canola, corn (field & sweet), cotton, cottonseed, grapes, hay (alfalfa & other), oats, oranges, peanuts, pecans, popcorn, potatoes, rice, rye, snap beans, soybeans, sugarbeets, sugarcane, sunflower, tobacco, tomatoes, and wheat.

**OPMP** – Office of Pest Management Policy was established within USDA to coordinate the response to FQPA.

**OPP** – Office of Pesticide Programs within EPA.

**REDUCED RISK PESTICIDE** – poses a reduced risk to human health and the environment compared to existing alternatives.

**RED** – Reregistration Eligibility Decision documents contain the results of EPA's regulatory reviews of pesticides initially registered before November 1, 1984. A reregistration eligibility decision is made after EPA has conducted a comprehensive review of all the studies submitted in support of an active ingredient. The culmination of the entire reregistration process is presented in the Reregistration Eligibility Decision document, or "RED."

**RISK CUP** – Under FQPA holds the total amount of a pesticide (or pesticides with common mechanism of toxicity) that a person (infant, child or adult) could be exposed to every day, for 70 years, without additional health risk.

**SAP** – Scientific Advisory Panel.

**TOLERANCE** – the maximum permissible level for pesticide residues allowed in or on commodities for human food and animal feed (i.e., the amount of pesticide residue legally allowed on a particular food). Tolerances are enforced by EPA and FDA.

**TRAC** – Tolerance Reassessment Advisory Committee.

# EPA Accepts Endocrine Disruptor Screening Strategy

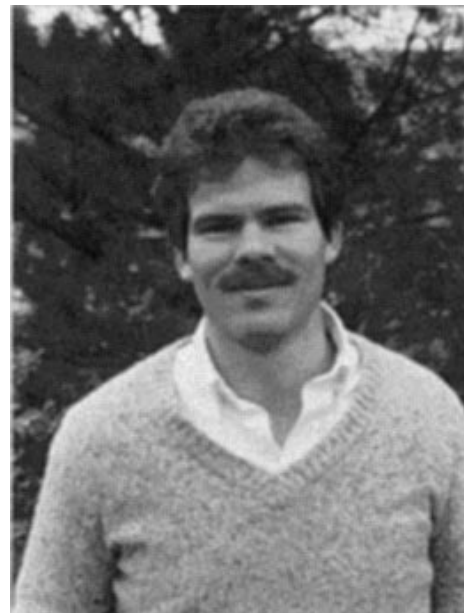
Testing to start in 1999, report on first 15,000 chemicals due August 2000.

EPA formally accepted the Endocrine Disruptor Screening and Testing Advisory Committee's report for an endocrine disruptor screening/testing program on October 5. Chemicals to be screened are in thousands of common products and range from pesticides to plastics. EPA promised to formally propose its screening and testing program based on the EDSTAC recommendations by the end of the year. Both FQPA and the amendments to the Safe Drinking Water Act, which Congress passed in the summer of 1996, require that the Agency develop a screening and testing strategy for endocrine disruptors by August 1998, start screening and testing by August 1999, and report

progress to Congress by August 2000.

Based on EDSTAC's recommendations, EPA plans to focus its initial screening program on 15,000 chemicals, which are produced in volumes exceeding 10,000 pounds per year and for which existing data is limited. Pesticides are not to be part of the initial screen because FIFRA and FQPA testing is for developmental/reproductive toxicity will provide an initial indication of whether a pesticide has endocrine disrupting potential. Chemicals that test positive in the initial screen would be subject to a series of additional tests, including specific tests to determine their reproductive, developmental and behavioral effects.

*meet. . .*



Greg L. Butters is an associate professor in the Department of Soil and Crop Sciences at Colorado State University. He teaches classes in soil physics and environmental soil science. His research program focuses on chemical and water movement in soils, and measurement of soil hydraulic properties. Dr. Butters would be a good resource for questions dealing with pesticide and nutrient mobility. Butters holds the B.S. in Chemistry, the M.S. in Environmental Science, and the Ph.D. in Soil Science from the University of California at Riverside.

## FQPA Listserves

The Food Quality Protection Act Discussion Group, sponsored by the National Pesticide Telecommunications Network (NPTN), is an open and free forum for anyone interested in FQPA and the challenges of implementing it. Subscribe by email ([fqpa@lists.ace.orst.edu](mailto:fqpa@lists.ace.orst.edu)) or at URL <http://ace.orst.edu/info/nptn/fqpalist/pfqalist.htm>. Once you visit the website, you can

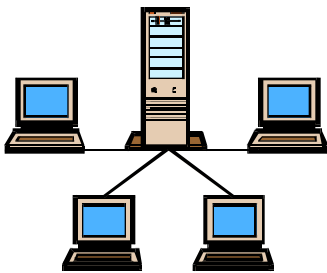
choose what you want to receive from the group – every message that comes to the group, a daily digest of the days messages in one e-mail, a daily index of subject headings in one e-mail, or receive no e-mail and view the messages through the web interface. You can also join by sending e-mail to subscribe-, but you will have to visit through the web to change your settings.



# Risk Assessment: How Is It Done?

**Data collection, database establishment, development of crop profiles and revision of pest management strategies will direct changes in pesticide use.**

Specific data collection efforts include pesticide use surveys, food consumption surveys and pesticide residue monitoring. These data are fundamental components of the Environmental Protection Agency's risk assessments. USDA will work with EPA to identify and develop improved risk assessment tools.



In cooperation with the USDA Office of Pest Management Policy, Colorado State University's Pesticide Program has begun developing state-level crop profiles. These profiles summarize basic agronomic information on each crop in Colorado and will focus on major pests and management practices. Crop profiles will provide much of the basic data needed for determining priorities and identifying vulnerable crops. USDA will use the crop-pest profiles to identify crop production issues, pest management alternatives, research needs and opportunities for risk mitigation.

Minor crops like fruits, vegetables, sugarbeets, and dry beans (small markets for pesticide manufacturers) are most at risk for label restrictions and pesticide losses. If you grow such crops, be aware that your pesticide options may change over the next few years. The new FQPA standard may result in registrants dropping minor uses to maintain more profit generating uses. Minor uses of pesticides are generally defined as uses for which pesticide product sales do not justify the costs of developing and maintaining EPA registrations.

Both short- and long-term pest management research programs are being examined and retooled to respond to FQPA-driven needs.

Databases are being developed to help guide EPA decision making. For each use of OP and carbamates, the key pests and control efficacies of available alternatives are being identified.

For some crop-pest combinations,

transition to new pest management tools may be possible in the short-term. Most often, however, the transition will take several years and require additional research, applicator education and training. The crop profiles will help identify major pests, their current controls and any alternative management strategies thus forming the basis for crop-specific transition strategies.

Growers can contribute by participating in the collection of pesticide use data. Thank you to everyone that participated in the Pesticide Use Surveys conducted by Colorado Agricultural Statistics Service in 1997. The data is being used currently in the development of crop profiles and is being incorporated into a national pesticide use database to counter EPA's default assumption of 100% application on 100% of the acreage. If you interested in participating in the development of the crop profiles please contact the Pesticide Program at CSU by calling us at 970-491-6027.



EPA Office of Pesticide Programs: <http://www.epa.gov/opppsp1/fqpa/>

Organophosphate Preliminary Risk Assessment Documents: Group 1:  
<http://www.epa.gov/oppsrd1/op.group1.htm>

Preliminary Risk Assessments of Organophosphate Pesticides:  
<http://www.epa.gov/oppsrd1/op/>

Organophosphate Preliminary Risk Assessment Documents: Group2:  
<http://www.epa.gov/oppsrd1/op/group2.htm>

The EXtension TOXicology NETwork provides a variety of pesticide information, including pesticide profiles.  
<http://ace.ace.orst.edu/info/extoxnet/>

National Pesticide Telecommunication Network provides information on pesticide products and pesticide ingredients. <http://ace.ace.orst.edu/info/nptn/>

Pesticide Reregistration Eligibility Decisions (REDs): <http://www.epa.gov/docs/oppsrd1/REDs/>

FQPA Roadmap Project – The Implementation Working Group Report.  
[http://www.nfpa-food.org/pubpol\\_fr.html](http://www.nfpa-food.org/pubpol_fr.html)



