The Food Quality Protection Act

Implications for Missouri Agriculture

G.S. Smith, S.A. Becker, and F.M. Fishel
Missouri NAPIAP Program
University of Missouri
Columbia, Missouri

J.R. Lea and P. Bailey
Missouri Department of Agriculture
Jefferson City, Missouri

Agricultural Experiment Station
College of Agriculture, Food, and Natural Resources
University of Missouri - Columbia

Special Report 513

Revised
November 1998

Major Provisions of FQPA

New safety standard for all pesticide residues in food

- "Reasonable certainty of no harm" from exposure to pesticide residues
- Aggregate assessment of pesticide exposure ("Risk Cup" concept)
- Assessment of cumulative exposure to pesticides

Special protection for infants and children

- Consideration of children's special sensitivity and exposure to pesticides
- Use of extra tenfold safety factor
- Explicit determination that a tolerance is safe for children

Endocrine disruptors screening and testing program

- Screen and test chemicals which could potentially disrupt endocrine process

Tolerance assessment and reassessment

- Apply new safety standards to tolerances issued after Aug. 3, 1996
- Reassess tolerances within 10 years to ensure they meet new safety standard
- Establish tolerances for emergency exemptions (Section 18)

Minor use pesticides

- Incentives to maintain existing minor uses and develop new ones

Right-to-know

- Develop consumer brochure on pesticide residues for distribution to large retail grocers for display

Reduced-risk pesticides

- Streamline registration of reduced-risk pesticides
- Adopt integrated pest management (IPM) techniques

Pesticide registration and registration renewal

- Authorize a 15-year registration renewal requirement

Anti-microbial pesticides

- Reform anti-microbial registration process to meet shortened review period

Impacts of FQPA

- Potential loss of an entire class of compounds
- Loss of minor uses
- Changes in labeling and usage
- Lowering of tolerances

The Food Quality Protection Act
Implications for Missouri Agriculture

Table of Contents

The Food Quality Protection Act

What is the Food Quality Protection Act?

The Food Quality Protection Act (FQPA) became law in August 1996 and it will profoundly affect the way pesticide tolerances are set by EPA. It established a new standard of safety for pesticide residues in food with an emphasis on protecting the health of infants and children. Under this legislation, all pesticide exposures from food, drinking water, and home and garden use must be considered when determining allowable levels of pesticide residues in food. In reassessing tolerances, EPA must conclude with "reasonable certainty" that "no harm" will come to infants and children or other sensitive individuals exposed to pesticides.

To ensure the safety of the U.S. food supply, EPA sets "tolerances" or limits in the amount of pesticide residue that can lawfully remain in or on each raw food commodity. In establishing tolerances, EPA considers the toxicity of each pesticide, how much is applied and how often, and how much residue remains in or on the commodity. A wide margin of safety ensures residues remaining in foods are many times lower than the amounts that could actually cause adverse health effects.

Tolerance:
Maximum permissible levels for pesticide residues allowed in or on commodities for human food and animal feed. EPA is responsible for establishing residue tolerances. Tolerances are enforced by FDA and USDA.

Once residue tolerances are established, they are enforced by various state and federal agencies. Food commodities traveling in commerce, including domestically grown and imported produce, are monitored by FDA and USDA who work closely with the states. Food crops must be within tolerances set by EPA, or they are subject to seizure and destruction.

The implementation of FQPA will occur during a 10-year period. By August 2006, EPA must reassess more than 9,700 existing tolerances (maximum pesticide residue limits for foods), giving priority to those pesticides that appear to pose the greatest risks. One-third of these tolerances must be reviewed by August 1999.

EPA has separated the 469 pesticides with existing tolerances into three priority groups:

Group 1 consists of 228 pesticides that appear to pose the greatest risk to human health. These include:

- the organophosphate (OP), carbamate, and organochlorine chemical classes;
- probable and possible human carcinogens;
- high-hazard inert ingredients;
- any pesticides that exceed their reference dose (RfD), the amount believed not to cause adverse effects if consumed daily during a 70-year lifetime.

Because protection of infants and children is a high priority under FQPA, approximately 1,800 OP tolerances will receive a priority review. Of these, over 300 are for residues on crops that are among the top 20 foods consumed by children.

Group 2 contains 93 pesticides that are possible human carcinogens not included in Group 1 and all remaining pesticides subject to reregistration.

Group 3 contains 148 pesticides, including most of the biological pesticides, inert ingredients, and more recently registered pesticides with tolerances that are not subject to reregistration (pesticide active ingredients registered after 1984).

Risk Assessment: Changes Under FQPA

FQPA will profoundly change the way pesticide tolerances are determined by EPA. Previously when setting a residue tolerance, EPA examined each pesticide individually, one crop or use at a time and added a safety factor to ensure the tolerance level was safe for adults.

Under FQPA, risk assessment must consider three major factors in reassessing tolerances:

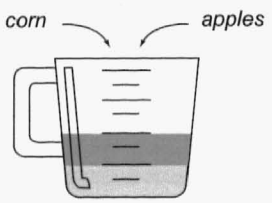
1. EPA must examine groups of pesticides based on common mechanisms of toxicity, i.e., pesticides

that act in a similar way in the human body. For example, all OP insecticides act as cholinesterase inhibitors in humans so risk assessment under FQPA will consider all OPs together instead of individually.

2. EPA must consider aggregate exposure when setting tolerances. This includes exposure through dietary and non-dietary sources including occupational exposure, drinking water, and home and garden exposure.
3. EPA can add an additional safety factor which reduces tolerances by up to tenfold to protect children.

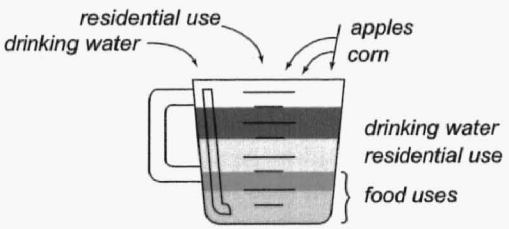
The "Risk Cup" Concept

The risk cup is an analogy used to describe aggregate exposure estimates. Each use of the pesticide contributes a specific amount of exposure that adds a finite amount of risk to the cup. If it is shown that the risk cup is full or exceeded, no new uses for the pesticide can be approved until the risk level is lowered.



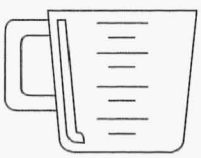
Pre-FQPA Risk Cup

Before FQPA was enacted, each pesticide had its own risk cup that held only the risks associated with pesticide use on food crops, for example corn and apples. Under FQPA, human exposure to a pesticide that can be safely allowed is visualized as filling a "risk" cup. This cup contains the amount of pesticide residue that a person can be exposed to daily without adverse health effects.



Aggregate Risk Cup

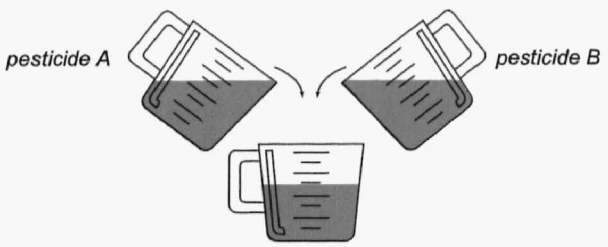
Under FQPA, the risk cup must now include, in addition to residues on food, residues associated with drinking water, and residues from pesticide uses in and around homes, lawns, gardens, parks, rights-of-way, and golf courses. Human exposure to pesticides from these multiple sources are combined as an "aggregate" risk.



Pre-10x Safety Factor Risk Cup

Extra 10x Safety Factor Risk Cup

When data pertaining to a pesticide's effects on children's health are required, EPA also may add an additional tenfold margin of safety. In these cases, the risk cup for a pesticide or group of pesticides becomes smaller.



Cumulative Risk Cup

Under a concept known as "cumulative" risk, if two or more pesticides act on human health in the same manner, FQPA provisions require the pesticides to share a common risk cup.

Crop Profiles and Benefits Assessments: Research Data Needs for EPA

FQPA instructs USDA and EPA to obtain pesticide use and usage data on major and minor crops. Of particular importance at this time are use and usage data for the OPs, carbamates, and possible carcinogens (B1 and B2). These classes of pesticides have been identified as top priority at EPA for the tolerance reassessment process. These same pesticides are also vital to the production of many of our crops. Because some of these uses may be canceled, it is important to identify where we stand now, where we need to be in the future, and what research efforts are needed to get us there as far as pest management practices are concerned. In order to better understand where future research efforts should lead it is necessary to first identify areas of critical need (i.e., those crops or situations where few if any alternative control measures are available to producers).

Crop profiles are intended to provide the complete production story for a commodity, including current pest management practices, and look at current research activities directed at finding replacement strategies for the pesticides of concern (see Benefits assessments). Crop profiles are being requested from each state to help USDA and EPA obtain this information. To date, 387 profiles on 120 commodities are being prepared in the U.S. In Missouri, crop profiles on apples, corn, cotton, grapes, peaches, rice, sorghum, soybeans, watermelon, and wheat are being prepared.

Crop profiles should include **typical** pesticide information (not simply what appears on pesticide labels). They will play a major role in risk mitigation and risk assessment during FQPA implementation. Each crop profile should address three main points:

1. Critical pesticide uses.
2. Interactions of a pesticide(s) with an IPM program.
3. The involvement of the pesticide(s) in a resistance management program.

Other minor roles of crop profiles include Section 18 applications, registration of new uses for older chemistries, registration of new chemistries, and transition pest management strategies. For consistency, crop profiles should be presented in the requested format (see box).

Benefits assessments involve the collection of accurate data on target pests, pesticide use information, identification of alternative practices, and accurate estimates of yield, quality, and the costs of using alternatives. This information is usually collected through questionnaires, but in some instances expert opinion must be used. When information originates from expert opinion, the source(s) should be identified.

Experience has shown the biggest single factor affecting the timeliness of an assessment is in the data collection phase. One major problem is the difficulty of estimating crop yield and/or quality results of replacing a pesticide with an alternative practice. In many cases, field trial data comparing alternative practices are unavailable or outdated (more than 5 years old). In other cases, field trials measure changes in pest populations (e.g., product A provided 70% control compared to product B that provided 90% control), but don't measure crop yield or quality. In such cases, scientists rely on their expert opinion based on research or extension experience. However, many scientists are reluctant and some are unable to make expert estimates.

While the format for a benefits assessment is flexible, there are certain components that enhance the quality and usefulness of the report. Keep in mind that the intended audience is USDA, EPA, research institutions, politicians, commodity groups, state departments of agriculture, environmental groups and agri-chemical companies. Also, text should be kept to a minimum; tables and figures are preferred.

Crop Profile Format

- Production facts
- Production regions
- Cultural practices
- Insect and mite control
- Weed control
- Disease and nematode control
- Chemical controls (identify any uses of pesticide(s) in IPM or resistance management programs)
- Alternatives
- Cultural control practices
- Biological controls
- Post-harvest control practices
- Other issues
- Key contacts
- Cite references

Assessment Components

- Background information on the crop/pest system
- Use and biological impact data

- Economic analysis
- Executive summary

Background information on the crop/pest system. This section consists of information on major pesticides and non-chemical practices, specific regional problems, and pest information.

Use and biological impact data. Data should be collected from appropriate experts in the field. Two categories of information are required: use and impact. The use category includes information on pests of economic importance, current chemical usage, chemical alternatives, non-chemical alternatives, pesticide resistance, integrated pest management practices, and the impact on beneficial organisms.

The impact category (resulting from loss of important pesticides) includes information that identifies alternative pesticides, identifies alternative practices, and determines the yield, quality (price deduction), and cost changes that occur when using alternative practices.

These data are best acquired through field trials that test comparative product performance. The following types of information should be recorded in field trials so the data are useful to EPA: yield and quality impacts; alternative products and practices; paired comparisons; replications in time and location; the level of pest pressure; list races or strains of pest; host variety or hybrid; pesticide residues at harvest; variety preferences for end uses; weather and climate variables that may have affected results.

Economic analysis. This component is based on the biological data and determines the economic impacts of various pest control approaches. The purpose of the analysis is to estimate important economic effects of a potential regulatory action.

Executive summary. A concise one- to four-page summary of the assessment at the beginning of the publication.

The Role of USDA in FQPA Implementation

(excerpts from an April 1998 memorandum)

Realizing the challenges that lie ahead regarding implementation of FQPA, Dan Glickman, Secretary of Agriculture, said "American agriculture can respond to the challenges of FQPA by developing and delivering safer pest management technology to ensure that Americans in the 21st century will continue to have the safest food supply in the world."

The USDA established the Office of Pest Management Policy to coordinate USDA's response to FQPA issues. Office of Pest Management Policy will work closely with EPA to ensure FQPA implementation decisions are based on sound science, transparency, consultation with the public, and a reasonable transition period for agriculture. Office of Pest Management Policy is also working with other USDA agencies, land grant institutions, farmers, and chemical producers to identify crops most vulnerable to potential cancellations under FQPA. This effort will result in crop profiles that identify major pests, their current controls, and alternative pest management strategies, thus forming the basis for crop-specific transition strategies.

For some crop/pest combinations, transition to new pest management tools may be possible in a short time period. In many cases, however, the transition will take several years and require additional research, applicator education and training, and a commitment from EPA to issue timely regulatory decisions on new and alternative pesticide products. USDA will work closely with EPA to reduce barriers to the development, testing, and registration of new pest management products.

The Role of Minor Crops in FQPA Implementation

(March 1998)

The Inter-regional committee (IR-4) of the National Agricultural Program is charged with aiding the development of pest management technologies in minor crops. As pesticide regulatory changes under FQPA become apparent, IR-4 may provide some help in developing alternative tactics. The greatest challenge faced by IR-4 is identifying high priority projects and then gaining concurrence from all stakeholders that IR-4 should expend resources to address these priorities.

In 1998, the major thrust by IR-4 will be selecting EPA Group I tolerance reassessment alternatives. Highest priority will be given to crop protection products that qualify by EPA definition as reduced-risk products. Products that do not qualify as reduced-risk products but are generally considered to be safer-use pesticides, will also be given priority by IR-4.

Minimal efforts by IR-4 will be given to mitigate risk for EPA's Group I FQPA-vulnerable pesticide products. However, in certain cases it appears that risk mitigation is the most plausible approach to assure pest control needs are met for minor crop producers. Risk mitigation strategy is pursued only in cases where measurable residues exist at the preharvest intervals (PHIs) that were established by EPA for the crop at the time the pesticide was registered.

FQPA and its Impacts for Missouri

Implications for Missouri Agriculture

The requirements under FQPA that will affect the reassessment of pesticide tolerances may have significant effects on the availability of pesticides for many Missouri crops. The IR-4 program has listed 25 insecticide/nematicide, nine fungicide, and four herbicide tolerances considered at risk (Table 1). Minor crop registrations for these at-risk pesticides are listed in Tables 2, 3 and 4.

Because EPA will reassess tolerances for the OP and carbamate insecticides first, the impact of the loss of either class of insecticide in Missouri was assessed based on use data and the percentage of crop acreage treated with each insecticide class (Table 5). Total use of OP and carbamate insecticides is estimated at 703,410 and 332,000 pounds of active ingredients, respectively. Three crops: corn, alfalfa, and cotton account for 85% of OP and 76% of carbamate insecticides applied to 16 crops in Missouri. Corn, alfalfa and cotton account for 45%, 21%, and 16% of OP use and 27%, 22% and 27% of carbamate use, respectively.

Some major crops grown in Missouri (soybeans, corn, wheat) may 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, loss of the OP insecticides would have a large economic impact on seven of the crops, including alfalfa, cotton, rice, and wheat. Missouri's minor crops: apples, peaches, tobacco, and nursery crops would be crippled by the loss of the OP insecticides.

Loss of the carbamate insecticides would have a major economic impact on eight of the crops, including cotton, rice, and sorghum. Missouri's minor crops: cucurbits, fresh beans, grapes, nursery, and tomato crops would be crippled by the loss of the carbamate insecticides.

Table 1. Current pesticide tolerances considered to be at-risk for minor crop uses.

Pesticide	Trade name
Insecticides and Nematicides:	
Acephate	Orthene
Aldicarb	Temik
Azinphos-methyl	Guthion, Sniper
Carbaryl	Sevin
Carbofuran	Furadan
Chlorpyrifos	Lorsban
Diazinon	Diazinon, D-Z-N
Dichloropropene	Telone II
Dimethoate	Dimethoate, Cygon
Disulfoton	Di-Syston
Ethoprop	Mocap
Fenamiphos	Nemacur
Fonofos	Dyfonate
Formetanate HCl	Carzol
Malathion	Cythion, Malathion
Metam	Vapam
Methamidophos	Monitor
Methidathion	Supracide
Methomyl	Lannate
Naled	Legion, Dibrom
Oxamyl	Vydate
Oxydemeton-methyl	Metasystox-R
Parathion-methyl	Methyl parathion
Phosmet	Imidan
Thiodicarb	Larvin
Fungicides:	
Benomyl	Benlate
Captan	Captan, Captec
Chlorothalonil	Bravo
Iprodione	Rovral
Mancozeb	Dithane, Manzate, Penncozeb
Maneb	Maneb
Orthophenylphenol	PostHar
Thiophanate-methyl	Topsin
Vinclozolin	Ronilan
Herbicides:	
Alachlor	Lasso
Bensulide	Prefar
Phenmedipham	Spin-Aid
Pronamide	Kerb

Table 2. Current fungicide tolerances considered to be at-risk, including trade name and minor use crops affected.

Fungicide	Trade name	Minor use crops with current labels for fungicide
Benomyl	Benlate	blackberry, blueberry, cabbage, cherry, cucumber, eggplant, melons, mustard greens, peach, pear, plum, pumpkin, spinach, squash (summer and winter), strawberry, sweet potato, tree nuts
Captan	Captan, Captec	blackberry, blueberry, cabbage, cherry, eggplant, mustard greens, peach, pear, pepper, plum, spinach, strawberry, watermelon
Chlorothalonil	Bravo	cabbage, cherry, cucumber, melons, peach, plum, pumpkin, squash (summer and winter)
Iprodione	Rovral	blackberry, blueberry, cherry, peach, plum, strawberry
Mancozeb	Dithane, Manzate, Penncozeb	asparagus, cucumber, melons, pear, squash (summer squash only), watermelon
Maneb	Maneb	cabbage, cucumber, eggplant, melons, pepper, pumpkin, squash (summer and winter), watermelon
Orthophenylphenol	PostHar	pear
Thiophanate-methyl	Topsin	cherry, cucumber, melons, peach, plum, pumpkin, squash (summer and winter), strawberry
Vinclozolin	Ronilan	cherry, peach, pepper (bell only), plum, strawberry

Table 3. Current herbicide tolerances considered to be at-risk, including trade name and minor crops affected.

Herbicide	Trade name	Minor use crops with current labels for herbicide
Alachlor	Lasso	bean (lima)
Bensulide	Prefar	cabbage, cucumber, eggplant, melons, pepper (bell and chili only), pumpkin, spinach, squash, water-melon
Phenmedipham	Spin-Aid	spinach
Pronamide	Kerb	birdsfoot trefoil, blackberry, blueberry, cherry, peach, pear, plum

Table 4. Current insecticide and nematicide tolerances considered to be at-risk, including trade name and minor use crops affected.

Insecticide / Nematicide	Trade name	Minor use crops with current labels for the insecticide or nematicide
Acephate	Orthene	pepper
Aldicarb	Temik	sweet potato
Azinphos-methyl	Guthion, Sniper	birdsfoot trefoil, blackberry, blueberry, cabbage, cherry, cucumber, eggplant, melons, peach, pear, plum, spinach, strawberry, watermelon
Carbaryl	Sevin	asparagus, bean (lima), birdsfoot trefoil, blackberry, blueberry, cabbage, cherry, cucumber, eggplant, melons, mustard greens, okra, peach, pear, pepper, plum, pumpkin, spinach, squash (summer and winter), strawberry, sweet potato, watermelon
Carbofuran	Furadan	cucumber, melons, pepper, pumpkin, squash (summer and winter), strawberry, watermelon
Chlorpyrifos	Lorsban	asparagus, bean (lima), blackberry, blueberry, cabbage, cherry, cucumber, mustard greens, peach, pear, pepper, plum, pumpkin, spinach, strawberry, sweet potato, tree nuts
Diazinon	Diazinon, D-Z-N	bean (lima), blackberry, blueberry, cabbage, cherry, cucumber, melons, mustard greens, peach, pear, pepper, plum, spinach, squash (summer and winter), strawberry, sweet potato, watermelon
Dichloropropene	Telone II	asparagus, birdsfoot trefoil, blackberry, blueberry, cabbage, cherry, cucumber, eggplant, melons, mustard greens, okra, peach, pear, pepper, plum, pumpkin, spinach, squash (summer and winter), strawberry, sweet potato, tree nuts, watermelon
Dimethoate	Dimethoate, Cygon	asparagus, bean (lima), cabbage, cherry, melons, mustard greens, pear, pepper, spinach, watermelon
Disulfoton	Di-Syston	asparagus, bean (lima), cabbage, pepper
Ethoprop	Mocap	bean (lima), cabbage, cucumber, okra, sweet potato
Fenamiphos	Nemacur	asparagus, cabbage, cherry, eggplant, okra, peach, pepper (non-bell only), strawberry
Fonofos	Dyfonate	asparagus, bean (lima), cabbage, pepper, strawberry

(table continued on next page)

Table 4 (continued). Current insecticide and nematicide tolerances considered to be at-risk, including trade name and minor use crops affected.

Insecticide / Nematicide	Trade name	Minor use crops with current labels for the insecticide or nematicide
	(continued)	
Formetanate HCl	Carzol	peach, pear, plum
Malathion	Cythion, Malathion	asparagus, birdsfoot trefoil, blackberry, blueberry, cabbage, cherry, cucumber, eggplant, melons, mustard greens, okra, peach, pear, pepper, pumpkin, spinach, squash (summer and winter), strawberry, sweet potato, watermelon
Metam	Vapam	blackberry, blueberry, cabbage, cucumber, eggplant, melons, mustard greens, pepper, spinach, squash (summer and winter), strawberry
Methamidophos	Monitor	cabbage, cucumber, eggplant, melons, pepper
Methidathion	Supracide	peach, pear, plum, tree nuts
Methomyl	Lannate	asparagus, blueberry, cabbage, cucumber, eggplant, melons, mustard greens, peach, pear, pepper, spinach, squash (summer only), strawberry
Naled	Legion, Dibrom	bean (lima), cabbage, eggplant, melons, peach, pepper, pumpkin, spinach, squash (summer and winter), strawberry, watermelon
Oxamyl	Vydate	cucumber, eggplant, melons, pear, pepper, pumpkin, squash (summer and winter), sweet potato, watermelon
Oxydemeton-methyl	Metasystox-R	bean (lima), cabbage, cucumber, eggplant, melons, pepper, pumpkin, squash (summer and winter), watermelon
Parathion-methyl	Methyl parathion	birdsfoot trefoil, blackberry, blueberry, cabbage, mustard greens, peach, pepper, spinach, squash (summer and winter)
Phosmet	Imidan	blueberry, cherry, peach, pear, plum, sweet potato, tree nuts
Thiodicarb	Larvin	cabbage, spinach

Table 5. Use and importance of organophosphate (OP) and carbamate insecticides on selected major and minor crops in Missouri.

Crop and state acres	% acres treated w/ insecticides	Percentage treated acres		Pounds active ingredient applied		Number of applications per season	Relative impact on crop due to loss of OPs or carbamates [1]
		-OPs-	-Carbamates-	-OPs-	-Carbamates-		
Alfalfa: 480,000 A	53%	66%	3%	147,750	74,000	1.1	OPs = high Carbamates = mod.
Apples: 4,800 A	95%	92%	2%	6,750	255	5.5	OPs = high Carbamates = low
Corn: 2,650,000 A	31%	48%	11%	315,000	91,000	1.1	OPs =low to mod. Carbamates = low
Cotton: 385,000 A	85%	39%	36%	110,000	90,000	2.7	OPs = high Carbamates = high
Cucurbits: 12,800 A	63%	3%	71%	350	5,700	1.8	OPs = low Carbamates = high
Fresh beans: 800 A	36%	15%	77%	60	550	2.8	OPs = low to mod. Carbamates = high
Grapes: 800 A	100%	66%	34%	1,400	1,400 [2]	2.1	OPs = moderate Carbamates = high
Greenhouse: 5,300,000 sq. ft.	67%	13%	3%	200	13	1.9	OPs = moderate Carbamates = low
Nursery: 11,250 A	56%	60%	32%	NA	NA	4.7	OPs = high Carbamates = high
Peaches: 2,200 A	96%	39%	16%	1,200	1,400 [3]	5.6	OPs = high Carbamates = mod.
Pecans: 12,000 A	25-40%	95%	1%	NA	NA	1.0	OPs = moderate Carbamates = low
Potatoes: 7,100 A	100%	32%	14%	1,000	945	1.3	OPs = moderate Carbamates = mod.
Rice: 90,000 A	18%	3.5% [4]	97%	600	16,000	2.2	OPs = low Carbamates = high
Sorghum: 80,000 A	11%	47%	51%	30,000	35,000	1.0	OPs = high Carbamates = high
Tobacco: 2,700 A	98%	93%	5%	8,400	1,074	3.6	OPs = high Carbamates = low
Tomatoes: 400 A	70%	22%	39%	100	378	2.9	OPs = low to mod. Carbamates = high
Wheat: 1,300,000 A	12% [5]	84%	15%	75,000	22,000	1.0	OPs = high [5] Carbamates = mod.

1 Qualitative impacts based on assumption that insecticide registrations of other class are maintained.
2 On grapes, carbaryl (Sevin) use alone accounts for 50% of use.
3 On peaches, carbaryl (Sevin) use alone accounts for 40% of use.
4 On rice, carbofuran (Furadan) use alone accounts for 96% of use.
5 On wheat, OP use is high only in certain years. In 1992, OP use was to control a true armyworm outbreak.

What can you do to protect Missouri agriculture under FQPA?

FQPA instructed EPA to reassess pesticide tolerances based on "reasonable certainty of no harm." In addition to traditional dietary residue data that EPA relied on to set tolerances, they must now include drinking water and non-occupational (residential) exposure, and a tenfold added safety factor for children. Also, tolerances will be based on cumulative exposure to pesticides with the same mode of action rather than assessing pesticides individually. *Where actual use data are not available to assess exposure and risk, EPA will rely on "default assumptions." This assumes a product is used at 100% of its labeled rate and is applied the maximum number of times allowed on the label.* Actual use data indicates this is rarely the case.

Agricultural industries can contribute by assisting with the collection of pesticide use data, conducting research on alternative pest management strategies and products, formatting research protocols to meet the requirements of benefits assessments, and assisting commodity groups with completion of Section 18 and 24C applications when needed. In addition, become familiar with state agencies (Missouri Department of Agriculture, IR-4, NAPIAP) that assist EPA and USDA with FQPA requirements. These agencies are valuable resources as we all work together to ensure that Missouri agriculture remains economically viable.

Section 18s and Section 24Cs: What they are and how to file

Section 18s

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) allows the EPA Administrator to exempt State and Federal agencies from any provision of the Act, if he (she) determines that emergency conditions exist that require an exemption.

An emergency condition is defined as *an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when:*

1. No effective pesticides are available under the Act that have labeled uses registered for control of the pest under the conditions of the emergency; **and**
2. No economically or environmentally feasible alternative practices which provide adequate control are available; **and**
3. The situation
   - involves the introduction or dissemination of a pest new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; **or**
   - will present significant risks to human health; **or**
   - will present significant risks to threatened or endangered species, beneficial organisms, to the environment; **or**
   - will cause significant economic loss due to an outbreak or an expected outbreak of a pest; or a change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).

Types of emergency exemptions

There are four types of emergency exemptions: specific, quarantine, public health, and crisis.

Specific exemptions are the most common emergency exemptions applied for. Specific exemptions may be authorized in an emergency condition to avert

The FQPA Debate:

Safer Food versus Economically Viable Agriculture

"Pesticide usage has increased by 70 million pounds since 1993 and is still increasing. Their report states that during the first 5 years of a child's life, they have already been exposed to their lifetime risk from pesticides."

Environmental Working Group

"Pesticide usage has declined since 1979, in large part through adoption of integrated pest management (IPM) programs and the introduction of targeted, environmentally sensitive, crop-protecting products."

American Crop Protection Association

either a significant economic loss or a significant risk to endangered species, threatened species, beneficial organisms, or the environment.

Quarantine exemptions are most usually applied for through the Animal Plant Health Inspection Service (APHIS). This exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not theretofore known to be widely prevalent or distributed within and throughout the U.S. and its territories.

Public health exemptions may be authorized in an emergency condition to control a pest that will cause a significant risk to human health.

Crisis exemptions may be used in an emergency condition when time restrictions prohibit applying for the other exemptions mentioned. Crisis exemptions are approved for a period of 15 consecutive days which generally allows only one or two pesticide applications.

Prior to FQPA, a tolerance was not required to be established before the harvested crop could enter the trade channels. Since the inception of FQPA, emergency exemptions may be approved by EPA; however, a time-limited or temporary tolerance must be established by EPA before the harvested crop can enter the trade channels.

How to apply for a Section 18

There are two steps required to obtain a Section 18 emergency exemption. Note, it takes EPA an average of 90 to 120 days to review a Section 18 request.

Step 1: Contact the Missouri Department of Agriculture. Inform them of your need to ensure that your situation meets the requirements of a Section 18.

Step 2. Coordinate with appropriate Land Grant personnel (University of Missouri, University Extension, Lincoln University) to obtain the required information.

Information required for a Section 18 application

1. Identify knowledgeable experts who can comment on the scientific, technical, and economic aspects of the request. Include the name, address, telephone number and fax number of these experts.
2. Identify the active ingredient, using the accepted American National Standards Institute name or the most accurate chemical name. This information can be obtained from the Missouri NAPIAP program.
3. Specify the number of acres to be treated, including the specific location(s) within the state. If the request is not a statewide request, then specify the names of counties where applications will occur. Include as much detail as possible (e.g., proximity to bodies of water, urban areas, etc.) to aid EPA review.

   Specify the method of application, rate of application (pounds a.i./acre), and duration of treatment period, particularly if an innovative method for reducing pesticide exposure will be used.
4. Estimate residue levels if the requested use is for a food or feed crop. Residue levels must be estimated for all the food commodities, even if residues in a processed food are expected to be lower than those in a treated commodity.
5. Include a detailed discussion of the potential risks from the proposed use. This discussion must address the potential risk to human health, endangered or threatened species, beneficial organisms, and the environment.
6. Provide a letter from the pesticide registrant or manufacturer indicating their awareness and support for the request. This letter might also include the progress toward registration of the proposed use.
7. List any year(s) in which an emergency exemption was granted previously for the requested use.
8. Include a discussion of the progress being made toward registration of the proposed use. Also include in this discussion a summary of deficiencies and gaps in data and the registrant's timetable for correcting the deficiencies.
9. Discuss the anticipated economic loss(es) associated with the emergency condition. EPA requires 5 years of yield and price data along with the cost of production data (either 5 years of production cost data or a crop budget) to complete an economic analysis. This information should include the cost of pesticides or other pest control practices used during the last 5 years and the cost of the pesticide requested under the exemption. Alternative methods of control should address whether other products are available, whether

alternative products are as effective, any problems with alternative products, and the effectiveness of the proposed product. Supportive research data are required.

Section 24C (SLN)

Under Section 24C, Special Local Need (SLN) Registration of FIFRA, a state may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that state to meet SLNs in accordance with the purposes of the Act and if registration for such use has not been denied, disapproved, or canceled by EPA. Such registration shall be deemed registered under Section 3 of FIFRA for all purposes, but shall authorize distribution and use only within the state of registration.

SLN is defined as: an existing or imminent pest problem within a state for which the state lead agency (Missouri Department of Agriculture), based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available. SLN registrations are particularly useful in providing pest control materials for minor crops.

To register a new end-use or an additional-use pesticide product, the following conditions must exist:

1. There is a SLN for the use within the state.
2. The use is covered by necessary tolerances, exceptions or other clearances under the FFDCA if the use is a food or feed use.
3. Registration for the same use has not previously been denied, disapproved, suspended, or canceled by EPA, or voluntarily canceled by the registrant subsequent to issuance by EPA of a notice of intent to cancel that registration because of health or environmental concerns.
4. The registration is in accordance with the purposes of FIFRA.

Steps to follow to obtain a Section 24C - SLN registration

Step 1: Contact the pesticide registrant and request their support of the proposed use.
Step 2: Contact your local or state extension specialist.

Once this has been accomplished the pesticide registrant, extension specialist, and Missouri Department of Agriculture personnel will work in cooperation to develop the 24C - SLN label and register the product.

Section 18 *or* 24C- Which One Do I Need?

Section 18 scenario:

My apple crop has been affected by a new insect pest the past 3 years. Current registered insecticides have not provided adequate control. There is an insecticide on the market that controls this insect but it does not yet have a federal label for apples. An interim tolerance has been established for this product on apples. I would contact an extension specialist on apples and request that a specific Section 18 be submitted for the next growing season.

Section 24C scenario:

My apple crop has just experienced an outbreak of mites that occurs only once every 10 years. I need a miticide *now* to control this outbreak. There is a miticide available and it has a tolerance established but does not have a federal label on apples. I would contact an extension specialist on apples and request a Section 24C to immediately use this product.

Conclusion

FQPA is the law and in the process of being implemented. Some pesticides and/or pesticide uses will be lost during the tolerance reassessment process. The next 2 to 3 years will focus on pesticides that pose the highest risks - the B1 and B2 carcinogens, which include many OPs and carbamates. Therefore, some or all uses of pesticides in this group may be lost. The definition of which pesticides are in a group with a common mode of action may determine the extent of the losses, i.e., how many chemicals are considered in the same "risk cup." Many minor crop insecticides and fungicides are considered to be at risk.

FQPA Terminology

Aggregate risk: The combined risk from all exposures to a pesticide from food and non-occupational sources, including drinking water, residential uses and lawn care use. The FQPA requires EPA to consider aggregate exposure when setting a tolerance for a pesticide.

Common mechanism of toxicity: Two or more chemicals that cause adverse health through the same major pathway (or mechanism). Under FQPA, EPA is directed, when considering whether to establish, modify or revoke a tolerance, to take into account available information concerning the cumulative effects of pesticide and other substances that have common mechanisms of toxicity.

Cumulative effects: The combined effects of concurrent exposure to multiple chemicals. Under FQPA, EPA is directed, when considering whether to establish, modify or revoke a tolerance, to take into account available information concerning the cumulative effects of a pesticide and other substances that have common mechanisms of toxicity.

Delaney clause: Found in Section 409(c)(3)(A) of the Federal Food, Drug and Cosmetic Act (FFDCA), the Delaney clause prohibits food additive or drug tolerances for any substance that causes cancer in test animals or humans, if the substance is added to or concentrates in processed food or feed. The FQPA amends the Delaney Clause by removing pesticides from being included in Section 409 of FFDCA.

Endocrine disruptors: Synthetic chemicals, including pesticides, that may pose significant risks to humans and other animals by disrupting the endocrine system. Proper functioning of the endocrine system is important in regulating growth, development, and reproduction. Endocrine disruptors may be linked to a variety of sexual development, behavioral, and reproduction problems.

Group A, B1, B2, C, D, E carcinogens: Qualitative classification of chemicals for human carcinogenic potential based on EPA's Carcinogen Assessment Guidelines. *Group A* includes known human carcinogens. *Group B*, which is subdivided into categories *B1* and *B2*, contains probable human carcinogens. B1 is reserved for agents that have limited evidence of carcinogenicity from epidemiologic studies and sufficient evidence from animal studies; B2 is for agents for which there is sufficient evidence from animal studies and inadequate or no data from epidemiologic studies. *Group C* contains possible human carcinogens for which there is limited animal evidence; *Group D* includes chemicals that have no carcinogenic information or insufficient information to classify the chemicals; and *Group E* consists of chemicals that are not expected to be human carcinogens.

Kid's safety factor: One of the special provisions in FQPA is designed to protect infants and children. FQPA requires that an additional tenfold safety factor be employed (for computation of RfDs or MOEs) to protect infants and children. EPA may use a different safety factor (i.e., it may dispense with all or part of the additional tenfold safety factor) on the basis of reliable data. See also Uncertainty factor (UF).

Margin of exposure (MOE): A numerical value that characterizes the amount of safety to a toxic chemical – a ratio of exposure to a toxicological endpoint, usually the no observable effect level NOEL. Formerly referred to as the Margin of safety (MOS).

Margin of safety (MOS): Maximum amount of exposure producing no measurable effect (NOEL) in animals or studied humans divided by the estimated amount of human exposure in a population. See Margin of exposure (MOE).

Minor use: Under FIFRA, the term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where –

1. the total U.S. acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; **or**
2. the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing

registration of a pesticide for such use **and** –

A. there are insufficient effective alternative registered pesticides available for the use;

B. the alternatives to the pesticide use pose greater risks to the environment or human health;

C. the minor use pesticide plays or will play a significant part in managing pest resistance; **or**

D. the minor use pesticide plays or will play a significant part in an integrated pest management (IPM) program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

The following is a list of U.S. agricultural crops exceeding 300,000 acres. Minor use crops would be any agricultural crop not on this list. This list was generated from statistics on crop production provided by the National Agricultural Statistics Service of USDA. Categories of crops like dry beans or grass seeds were excluded from this list because the crops would be considered individually.

Crops Exceeding 300,000 Acres in U.S.

Almonds	Pecans
Apples	Popcorn
Barley	Potatoes
Beans, snap	Rice
Canola	Rye
Corn (sweet, field)	Soybeans
Cotton	Sugarbeets
Cottonseed	Sugarcane
Grapes	Sunflower
Hay (alfalfa & other)	Tobacco
Oats	Tomatoes
Oranges	Wheat
Peanuts	

Monte Carlo analysis (MCA): A mathematical model for determining the probable distribution of possible outcomes for dietary risk assessment. MCA is performed by random pairing of pesticide residue and food consumption values. Pesticide residue values are derived from field trials or monitoring data. When field trial data are used, the percent of crop not treated is fed into the model as zeros. Food consumption values are from a USDA survey which documents 31,000 subjects' meals over a 3-day period. Currently, EPA's Office of Pesticide Programs policy is to use the 99.9th percentile of exposure (i.e., your worst meal out of 1,000 meals) when calculating MOE for acute dietary risk assessments. For chronic assessments, average or 50th percentile exposures are adequate.

No observed effect level (NOEL): The dosage or exposure level at which no toxicologically significant adverse effect(s) can be detected. It is the highest dose level (quantity) of a substance administered to a group of experimental animals that demonstrates the absence of effects observed or measured at higher dose levels. The NOEL should produce no biologically significant differences between the group of treated animals and a control group of unexposed animals maintained under identical conditions.

Q star, Q*, Q1 star, Q1*: Also called Oncogenic potency. The potency factor is derived from a mathematical model that extrapolates from data derived from animal experiments to estimate human cancer risk. The Q* value is a probabilistic estimate of the upper bound on incidence of extra instances of tumor formation in humans that can be expected following dietary ingestion, or exposure by other routes, of a given level of a particular chemical during a 70-year human lifetime. A high Q* value indicates that the chemical has a high oncogenic potential. Q1* represents potency of effect. It is expressed as: $(\text{mg of chemical/kg of body weight/day})^{-1}$. The Q1* is multiplied by an exposure value to give an estimate of excess cancer risk. Q1* also is used in conjunction with lifetime average daily dose (LADD).

Reduced-risk pesticide: A pesticide which poses a reduced risk to human health and the environment compared to existing alternatives. Under FQPA, a reduced-risk pesticide is one which "may reasonably be expected to accomplish one or more of the following:

1. reduces pesticide risks to human health;
2. reduces pesticide risks to nontarget organisms;

3. reduces the potential for contamination of valued, environmental resources; or
4. broadens adoption of integrated pest management (IPM) or makes it more effective."

Reference dose (RfD): An estimate of the level of daily exposure to a pesticide residue which, during a 70-year human life span, is believed to have no significant deleterious effects. RfDs are based upon data for noncarcinogenic effects of substances, even those which also may be carcinogenic. Formerly called the acceptable daily intake (ADI). The RfD is operationally derived from the NOEL (from animal and human studies) by a consistent application of uncertainty factors that reflect various types of data used to estimate RfDs and an additional modifying factor, which is based on a professional judgment of the entire database on the chemical. The RfDs are not applicable to nonthreshold effects such as cancer.

Registration renewal: An EPA system for review of all pesticide registrations every 15 years to ensure pesticides meet current standards. Registration renewal is required by FQPA.

SMART meeting: A meeting between EPA and registrants which takes place early in the reregistration process to ensure that EPA is using accurate use and usage information in their assessment of the pesticide. At a SMART meeting the registrant would present information on the crops on which its product is used, typical and maximum rates, pests controlled, overall amounts used, etc. This avoids an EPA assessment on outdated information which is only caught once the registrant reviews the Reregistration Eligibility Decisions chapters.

Tolerance: Maximum permissible levels for pesticide residues allowed in or on commodities for human food and animal feed. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is responsible for establishing residue tolerances. Whenever a pesticide is registered for use on a food or feed crop, a tolerance or exemption from the requirement of a tolerance must be established. Established tolerances and exemptions for pesticide chemicals in or on raw agricultural commodities are listed at 40 CFR 180. Tolerances for pesticides in processed food are at 40 CFR 185; and tolerances for pesticides in processed animal feed are listed at 40 CFR 186. Tolerances are enforced by FDA and USDA. FQPA precludes states from establishing separate tolerances.

Tolerance reassessment: Under FQPA, EPA is required to reassess all existing tolerances and exemptions from tolerances for both active ingredients and inert ingredients within 10 years to ensure they meet the new FQPA safety standard. EPA is directed to give priority review to pesticides that appear to present risk concerns, based on current data. Organophosphates (OPs), carbamates, and Group B carcinogens (probable human carcinogens) will be the first tolerances reassessed under FQPA.

Uncertainty factor (UF) (a.k.a. Safety factor): A factor used in operationally deriving the RfD from experimental data. UFs are intended to account for (1) the variation in sensitivity among members of the human population, (2) uncertainty in extrapolating animal data to the case of humans, (3) the uncertainty in extrapolating from data obtained in a study that is of less than lifetime exposure, and (4) the uncertainty in using LOEL data rather than NOEL data. Usually each of these factors is set equal to 10.

Resources for FQPA Information

Resource Agencies and Personnel for Data Collection

Crop budget data can be obtained from:

Department of Agricultural Economics
200 Mumford Hall
University of Missouri, Columbia, MO 65211
Phone: 573-882-6533

Data on alternatives, costs of control, etc. can be obtained through:

Missouri NAPIAP Program
George S. Smith, NAPIAP State Liaison Rep.
Anastasia Becker, NAPIAP Associate
45 Agriculture Bldg.
University of Missouri, Columbia, MO 65211
Phone: 573-882-4314

Submit completed Section 18 or 24C application(s) to:

James R. Lea, Supervisor,
Bureau of Pesticide Control
Division of Plant Industries
P. O. Box 630
Jefferson City, MO 65102-0630
Phone: 573-751-5504

Missouri contact for the IR-4 Program is:

Chris Starbuck
Horticulture Department
1-87 Agriculture Building
University of Missouri, Columbia, MO 65211
Phone: 573-882-9630

Electronic Information Sources: FQPA on the Web

EPA's FQPA site:
http://www.epa.gov/oppfead1/fqpa/index.html

EPA's Office of Pesticide Programs (OPP):
http://www.epa.gov/pesticides

EPA's OPP site on organophosphate pesticides:
http://www.epa.gov/oppsrrd1/op/

EPA's Tolerance Reassessment Advisory Committee:
http://www.epa.gov/oppfead1/trac/

EPA's Science Advisory Board:
http://www.epa.gov/science1

PICOL (Pesticide Information Center On-Line):
http://picol.cahe.wsu.edu/

EWG (Environmental Working Group):
http://www.ewg.org

MDA (Missouri Department of Agriculture):
http://www.state.mo.us/

NAPIAP (National Pesticide Impact Assessment Program):
http://ipmwww.ncsu.edu/usdanapiap

MOPIAP (Missouri Pesticide Impact Assessment Program):
http://www.missouri.edu/~moipm/

CAPIAP (California Pesticide Impact Assessment Program):
http://www.capiap.ucdavis.edu

Funding for this publication was provided by
The National Agricultural Pesticide Impact Assessment Program (NAPIAP).

SR 513

Revised 11/98/750