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Agency

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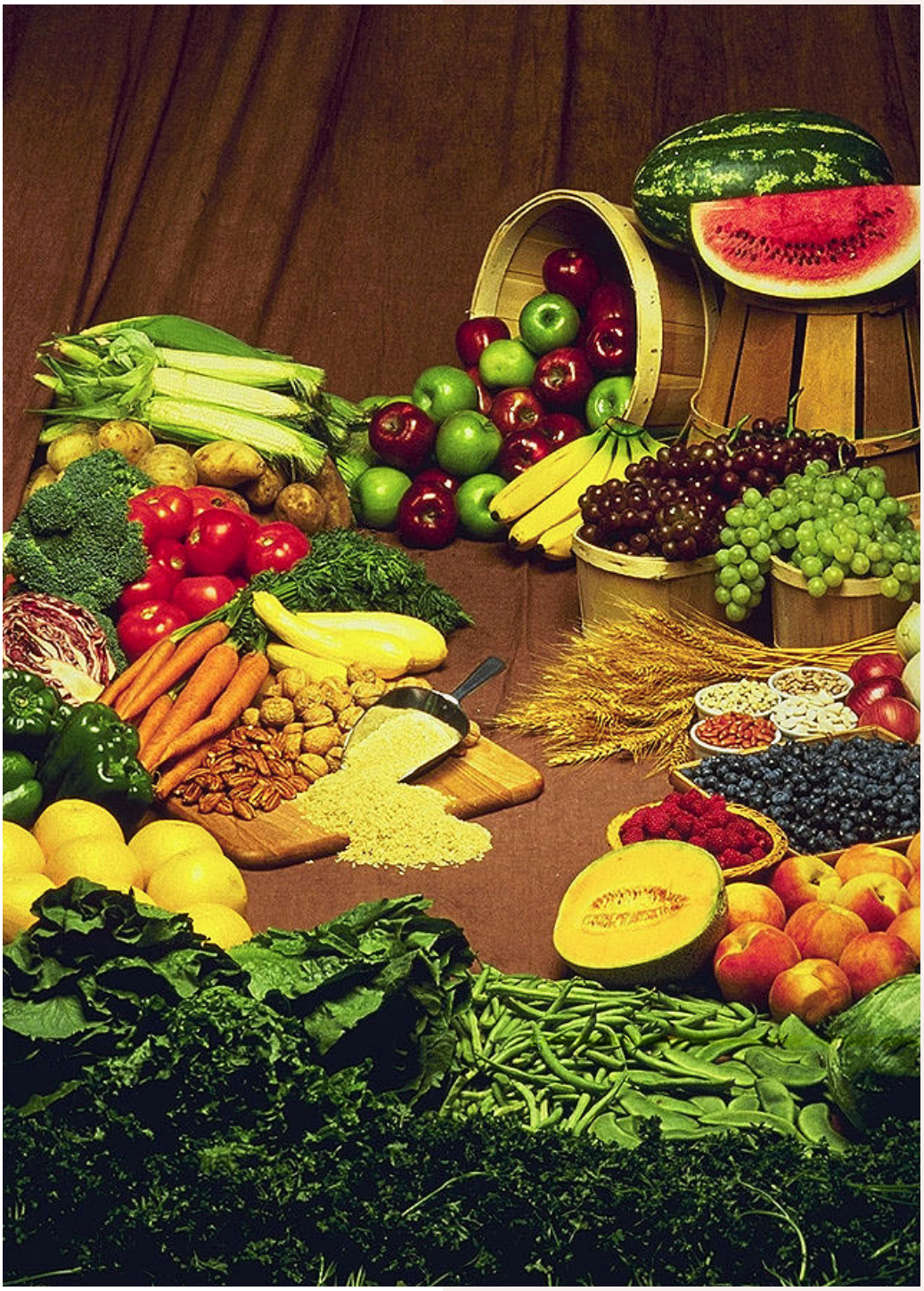
Implementing the Food Quality Protection Act

Progress Report



Progress Report: Implementing FQPA

Executive Summary

This report details the U.S. Environmental Protection Agency's (EPA) progress in implementing the requirements of the Food Quality Protection Act (FQPA). It reflects how implementation furthers EPA's mission to protect human health and the environment and assures all Americans access to safe and affordable foods.

President Clinton signed FQPA into law on August 3, 1996, representing a major step forward in the regulation of pesticide use in the United States. 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
- created an environment favorable for the development and adoption of lower risk, effective crop protection tools for U.S. agriculture.

Most importantly, the law presented a strong challenge to regulators and regulated alike to move beyond traditional methods and ways of thinking. FQPA's authors appreciated the need to maintain a strong agricultural sector, but recognized that greater protections for the public needed to be provided, and newer technologies introduced, without jeopardizing that strength.

Principles of Implementation

EPA's activities have been guided by four principles outlined in an April 8, 1998, memo from Vice President Gore to EPA Administrator Browner and U.S. Department of Agriculture (USDA) Secretary 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 public and other agencies. With these principles as the foundation, EPA and USDA have made significant progress in:

- using the regulatory process to lower the risks of pesticide use,
- ensuring that all new and previously registered pesticides meet the FQPA standard,
- promoting public participation and transparency in the process,
- providing special protections for those who are most vulnerable, especially infants and children,
- developing the tools needed to implement FQPA's innovative scientific approaches, and
- working with our partners and diverse stakeholders.

Lowering the Risks

FQPA enhanced EPA's responsibility to promote the development of safer pest control options. We also have a responsibility to provide registrants with reasonable review times for applications for pesticide registrations. This became a much greater challenge with the signing of FQPA and the immediate effectiveness of most of the law's provisions. Nevertheless, we have been very successful in instituting the reduced risk provisions codified by FQPA and in maintaining the registration process, including the review of emergency exemption requests from states.

Since FQPA passed, we have continued to reach historically high numbers of new registered active ingredients -- 77 during the last three years. Of these, more than half are biologicals or reduced risk pesticides. In addition, we have improved the review time for biological pesticides, which are generally regarded as posing less risk than traditional pesticides. According to many pesticide manufacturers, the emphasis on reduced risk pesticides has fundamentally altered their research and development processes, placing a premium on the identification and development of these types of products.

Ensuring the Safety of Existing Pesticides

While we move forward to assure that all new pesticides meet the stringent FQPA safety standard, we also must reassess existing pesticide uses to assure that they are protective of public health. This comprehensive effort involves completion of the Reregistration Program, begun in 1988 for all chemicals registered before November 1984, as well as the reassessment of existing pesticide tolerances (allowable residue limits) required by FQPA. The law sets a ten year schedule for review of the 9721 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 is August 3, 1999, when 33% (approximately 3207) of the total must be done.

During the past three years since passage of FQPA, we have completed reevaluation of 48 pesticides (or groups of similar pesticides) and determined whether they can continue to be used or whether they should be restricted or canceled. Of these 48 pesticides, 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. For tolerance reassessment, as of July 30, 1999, we have reassessed 3290 tolerances, thereby surpassing the 33% requirement. We are continuing our focus first and aggressively on organophosphates, carbamates, and others identified for priority review. Of the reassessments completed, 66% are for pesticides the Agency identified for priority review because they appear to pose the greatest risk to human health.

Transparency and Public Participation

The challenge of FQPA requires greater public participation and processes which lead to an understanding of EPA's regulatory approach. As soon as the law passed, EPA established a Food Safety Advisory Committee. This diverse group of stakeholders provided the Agency with guidance on prioritizing implementation activities. We have also taken advantage of existing advisory bodies such as the Pesticide Program Dialogue Committee (PPDC) and the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) to help the Agency sort through the multitude of issues resulting from FQPA. Since May 1998, the Tolerance Reassessment Advisory Committee (TRAC), co-chaired by EPA and USDA, has provided a forum for the exchange of ideas and opinions on implementation issues such as: key science policies; ways to increase the transparency of and public participation in our regulatory process; and transition strategies for agriculture.

In addition to advisory committees, EPA has sought to improve public participation in other aspects of its regulatory program. The Agency is using a strong consultative process to address risk concerns about the fumigants, aluminum and magnesium phosphide, and about products used to control rodents. Through this process, EPA hopes to develop practical, effective methods of risk mitigation. The Agency also relied heavily on the use of public focus groups as well as consultation with the PPDC in developing the FQPA-required consumer brochure on pesticide risks, which was distributed early in 1999.

Special Protection for Vulnerable Populations

We know that some people may be more vulnerable to pesticide exposures than others. For example, we have strong evidence to indicate that some pesticides can pose greater risk to children than adults because children's internal organs and bodily processes are still developing and maturing, their eating patterns are different, and their behavior patterns may increase exposure. Consequently, all tolerances established since FQPA have been set to be protective of children. Likewise, because of the length of exposure and the possible exposure to stronger formulations of pesticides used commercially, agricultural workers are particularly vulnerable. We are reviewing our worker protection activities, including the methods for risk assessment, to determine if agricultural workers are receiving adequate protection or if more stringent requirements are necessary to assure their safety.

To further increase protections for infants and children, EPA is requiring registrants to conduct acute, subchronic, and developmental neurotoxicity studies for at least 140 pesticides. We have also issued an updated set of test guidelines for development of data on reproductive and developmental effects. EPA's Office of Research and Development currently is conducting and supporting research on the evaluation of age-related differences in sensitivity to pesticides and the development of toxicity testing procedures for immature animals that will further our knowledge of any differences between children and adults. Other EPA efforts include conducting research on appropriate techniques to measure residential exposure to pesticides, increased research on

exposure to children in farming areas, particularly the children of migrant workers, and working with USDA on the collection of better data on the food consumption patterns of infants and children and residues in foods children eat. Where risks to children or agricultural workers are of concern, the Agency may take action on specific pesticides, such as the recent modification and elimination of uses for azinphos methyl and methyl parathion.

On the Forefront of Sound Science

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). This work is strengthening the U.S. regulatory system making it one of the most scientifically advanced in the world. Proper development of this cutting edge science requires consultation with independent, respected scientists both internal and external to the government. For instance, the Endocrine Disruptors Screening and Testing Advisory Committee (EDSTAC) was formed to help us develop a process for determining which chemicals might potentially disrupt the hormone (endocrine) systems of humans and wildlife. EDSTAC reached consensus on recommendations in August 1998 and those recommendations, considered in combination with public comments, are helping EPA develop a final endocrine disruptor effects screening program.

Key to implementing FQPA's science provisions is the development of science policies. Immediately after passage of FQPA, we established interim policies to allow for the continuation of regulatory activities while revised policies were developed. With the help of TRAC, the Agency 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.

Partners and Other Stakeholders

FQPA created momentum for fuller participation by all stakeholders in the regulation of pesticides. The complexities of the law have led us to increase our efforts to coordinate with other regulatory authorities, both in the U.S. and abroad. USDA is an important partner in gathering data on pesticide use and residues, developing and evaluating alternative pest control tools, and reaching out to the agricultural community and ensuring that their concerns are adequately addressed. We are also working with USDA and groups such as the Inter-regional Research Project #4 (IR-4) to coordinate efforts on minor use pesticides. EPA works with the Department of Health and Human Services (DHHS) in an effort to develop broad policies on food safety and to consult on public health pesticides. Under international agreements, such as the North American Free Trade Agreement, we are harmonizing standards and data requirements. This work allows greater regulatory coordination, improving health and environmental protection, saving time and resources for governments and registrants, and helping to speed the availability of newer pest control methods to users.

Improved coordination with partners helps assure that our decisions are scientifically sound, protective, and practical: USDA has reviewed 14 organophosphate risk assessments; based on the work of the IR-4 and others, we have approved over 1300 new minor uses, more than 80% of which are for reduced risk pesticides; we have consulted DHHS on 5 organophosphates with public health uses; and, the U.S. and Canada have jointly reviewed and registered 3 new reduced risk pesticides and 1 pheromone. These results are indicative of the future impacts of these strengthened relationships.

Conclusion

The passage of FQPA brought comprehensive reform to our nation's pesticide and food safety laws--setting in motion many fundamental changes in our approach to protecting human health and the environment from risks associated with pesticide use. Meeting the law's immediate and more stringent requirements for a single, health-based safety standard for new and existing pesticides, while also maintaining momentum for bringing new biologicals and safer products to market, has been an extraordinary challenge. We will continue to work closely with our federal, state and tribal partners, as well as with our many public stakeholders to seek guidance and meaningful public involvement in FQPA implementation activities and in the development and refinement of science policies.

www.epa.gov/oppfead1/fqpa

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Appendices

I. FQPA - The Basics

In the three years since FQPA passed, EPA, the U.S. Department of Agriculture (USDA), and our many stakeholders have done much to realize its potential and make its provisions standard practice. We have prepared this report to showcase many of these accomplishments. Since these accomplishments derive from this landmark legislation, its major provisions are outlined below for reference For background on pesticide regulation in general, see Appendix 1. Appendix 2 outlines the statutory deadlines for FQPA major provisions.

New Safety Standard for all Pesticide Residues in Food

- "Reasonable Certainty of No Harm" from exposure to residues;
- Aggregate assessment of all non-occupational sources of exposure, including drinking water, residential, and dietary exposure;
- Assessment of cumulative exposure to a pesticide and other substances with common mechanisms of toxicity.

Reduced Risk Pesticides

- Streamlined the registration process of reduced risk pesticides, including new active ingredients, new uses of existing active ingredients already found to be reduced risk, and amendments to all uses deemed to reduce risk;
- Adoption of Integrated Pest Management (IPM) techniques through research, education, and procurement and regulatory policies.

Tolerance Assessment and Reassessment

- Application of the new safety standard to all tolerances issued after August 3, 1996;
- Reassessment, within 10 years, of all tolerances issued prior to enactment of FQPA to ensure they meet the new safety standard;
- Establishment of tolerances for emergency exemptions issued under Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);
- Authorization to charge fees for performance of tolerance functions.

Pesticide Reregistration and Periodic Registration Review

- Reauthorization and increase of maintenance fees to complete review of older pesticides first registered prior to November 1984;
- Authorization for a 15-year registration review program.

Right-to-Know

- Development of a simple, understandable consumer brochure on pesticide residues to be distributed to large, retail grocers for public display;
- Publication of an informative statement about the data relating to a tolerance.

Special Protections for Infants and Children

- Consideration of children's special sensitivity and exposure to pesticides;
- Use of an extra 10-fold safety factor in addition to the traditional 100-fold safety factor, unless, on the basis of reliable data, a different factor is determined to be safe for children;
- Explicit determination that a tolerance is safe for children.

Endocrine Disruptors Screening and Testing Program

- Development and application of a screening and testing program for chemicals with the potential to disrupt the endocrine process;
- Progress report to Congress by August 2000.

Antimicrobial Pesticides

- Reform of the antimicrobial registration process to meet shortened review period goals while still ensuring efficacy and safety;
- Annual report to two Congressional Committees on progress in meeting the reform goals.

Minor Use Pesticides

- Incentives to maintain existing minor uses and to develop new ones;Establishment of minor use offices within EPA and the U.S. Department of Agriculture.

II. Lowering the Risks

With the introduction of a new, single health-based standard, FQPA significantly advanced the protection of human health and the environment from the risks posed by pesticides. This landmark legislation introduced several more protective factors that we must take into account in registering pesticides and setting tolerances.

FQPA formalized the expedited review for reduced risk pesticides, which are considered to pose even less risk than conventional pesticides registered under the FQPA safety standard. (EPA began this program in 1993.) The reduced risk program, together with a streamlined registration process for biopesticides, has resulted in dozens of new "safer" products being introduced into the marketplace, providing greater protections to human health and the environment, and clear benefits to growers and homeowners.

REDUCING RISK: An Alternative to Using Some of the Organophosphates

In a recent action, EPA set new tolerances for the reduced-risk insecticide tebufenozide for use on pome fruit and cotton. Tebufenozide has been identified as a potential alternative to some of the more toxic organophosphate pesticides--azinphos-methyl, phosmet, chlorpyrifos, and chlorpyrifos and dimilin in cotton. (See Section III for details on the organophosphates.)

Since 1996, every new tolerance established for new uses and products has met the new safety standard. We have reviewed other ingredients used in pesticide formulations (formerly known as inert ingredients) against the FQPA safety standard, and registered new products for important minor crop and public health uses.

Safer Pesticides

FQPA mandates 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:

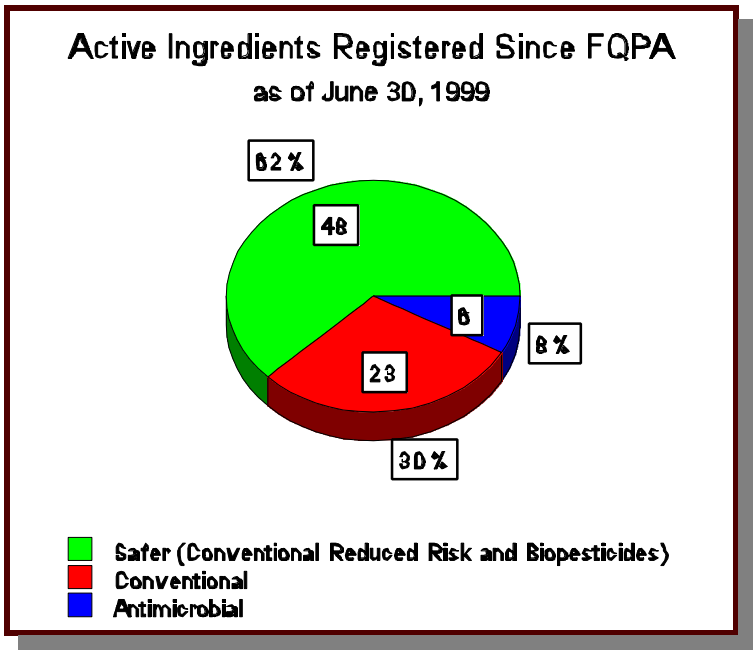
- lower impact on human health,
- lower toxicity to non-target organisms (e.g., birds, fish, and plants),
- lower potential for groundwater contamination,
- lower use rates, low pest resistance potential, and
- compatibility with Integrated Pest Management.

There are two types of safer pesticides: conventional reduced risk pesticides (which we screen in our reduced risk program) and biopesticides, which are generally distinguished from conventional chemical pesticides by their unique modes of action, low use volume, lower toxicity, target species specificity or natural occurrence. Two ways to measure the success of the expedited registration program for safer pesticides is by (1) the number of registrations for new safer active ingredients and (2) by the number of new uses of pesticides considered safer.

II. Lowering the Risks *continued*

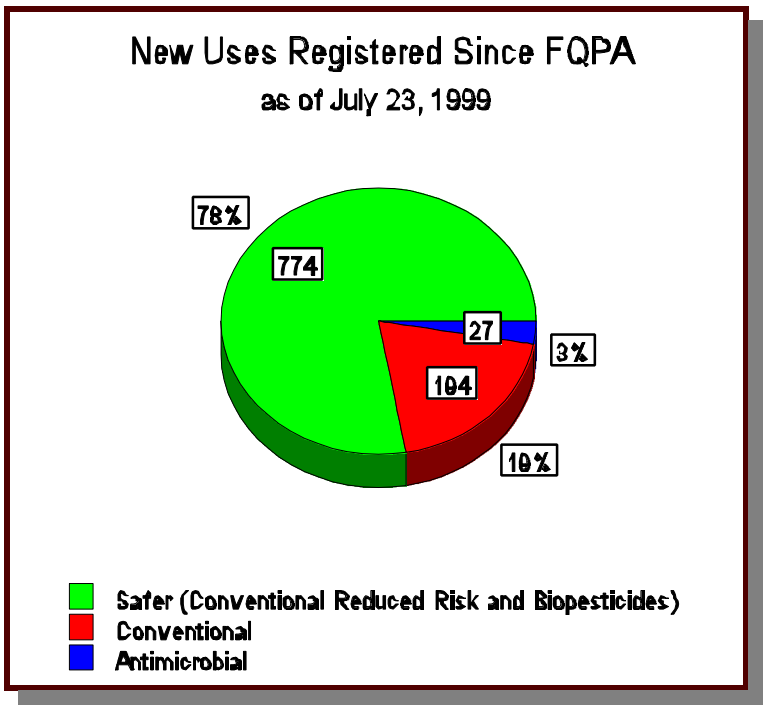
(1) Safer active ingredients

Active ingredients are the substances in a pesticide that prevent, destroy, repel or mitigate a pest. Since FQPA was enacted, we have registered 48 active ingredients which are considered "safer" than conventional pesticides, representing 62% of the total number of active ingredients registered.



(2) Safer New Uses

"Uses" are the specific crop(s) or other site(s) where a pesticide product can be used. One active ingredient can have many different uses. Since FQPA was enacted, EPA has approved 774 new uses that are considered "safer," representing 77% of the total new uses approved.



II. Lowering the Risks *continued*

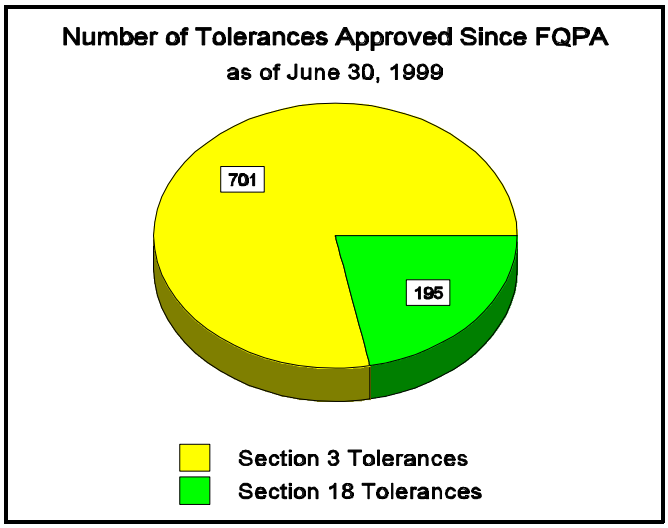
In addition to providing risk reduction through the registration of safer pesticides, EPA has also registered six new active ingredients that provide for lower-risk alternatives to several organophosphates. The organophosphates are among the first group of pesticides for which EPA is reassessing tolerances (see Section III for details).

Organophosphate Alternatives

Chemical	Alternative for...	On...
bifenazate	chlorpyrifos	ornamentals
diflubenzuron	chlorpyrifos	homes (below ground bait stations)
hexaflumeron	chlorpyrifos, isofenfos	homes (below and above ground bait stations)
pyriproxyfen	azinphos methyl, chlorpyrifos, phosmet, methidathion, acephate	apples, pears, walnuts
	acephate	cotton
spinosad	profenfos	cotton
	chlorpyrifos	sweet corn
	diazinon, chlorpyrifos, methidathion, naled, phosmet, azinphos methyl	almonds
	diazinon, chlorpyrifos, naled, phosmet, azinphos methyl	apples
	malathion, methamidophos, dibrom, diazinon,	brassica (cole) leafy vegetable
	dimethoate, chlorpyrifos, naled	citrus
	malathion, methamidophos, dibrom, diazinon, acephate, methyl parathion	fruiting vegetable (except cucurbits)
	azinphos methyl, malathion, dibrom, diazinon, acephate	leafy vegetables (except brassica)
tebufenozide	chlorpyrifos	cotton, leafy and cole vegetables, pecans,
	acephate, chlorpyrifos, diazinon	forestry
	azinphos methyl, chlorpyrifos, phosment	pome fruit
	azinphos methyl, chlorpyrifos	walnut
	acephate, diazinon, azinphos methyl, chlorpyrifos	cranberry
	diazinon, azinphos methyl, malathion	berry crop group
	acephate	mint

New Tolerances Since FQPA

Since FQPA, we have set 701 tolerances in conjunction with registrations under Section 3 of FIFRA. Every new tolerance has met the new safety standard.



Tolerances for Other Ingredients in Pesticide Products

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 used to make the product formulation. Generally, these other ingredients are not "pesticidally" active themselves and are exempted from the need for a tolerance so long as they do not present a hazard to the public health.

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 the Agency's 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.

Emergency Exemptions and FQPA

FQPA requires EPA to establish pesticide tolerances for all food and feed uses, including for uses of pesticides under emergency conditions, based on the new safety standard. Before FQPA, we did not establish tolerances for pesticides used under emergency exemptions. We moved quickly to implement the new FQPA provisions, recognizing the time-sensitive nature and economic importance of these decisions. The Agency has worked with states, growers, and other interested stakeholders to develop new policies and procedures for considering emergency exemption requests according to the new statutory provisions.

Since August 1996, 1154 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. In June of this year, we proposed a rule that provides criteria and procedures for tolerance-setting for emergency exemptions. We also solicited comments on several measures to further improve the emergency exemption program.

EMERGENCY EXEMPTIONS AND FQPA

Section 18 of FIFRA authorizes EPA to allow state and federal agencies to permit the unregistered use of a pesticide for a limited time if EPA determines that emergency pest conditions exist and there is no registered pesticide available that would be effective. When this occurs, a state or federal agency applies to EPA on behalf of growers for an "emergency exemption."

Reducing the Risks of Medfly Control Pesticides

Medfly quarantine programs are vitally important to the citrus industry in Florida and California. In the past, when emergencies arise, the states have used the organophosphate malathion. Recently, EPA and USDA have worked with the states, local authorities, and concerned citizens to find creative solutions. As a result:

- Florida will be using the reduced risk pesticide spinosad to address medfly infestation under this year's quarantine program;
- EPA and California are working together to integrate spinosad into its approach as well, and the state has initiated the internal process to analyze spinosad in the hopes of moving to its use next season;
- Both California and Florida have extensive prevention and monitoring programs which should greatly diminish the need for a large-scale eradication program;
- Both states are also using sterile medfly releases as a non-chemical control mechanism.

III. Ensuring the Safety of Existing Pesticides

Promoting Safer Pesticides for Minor Uses

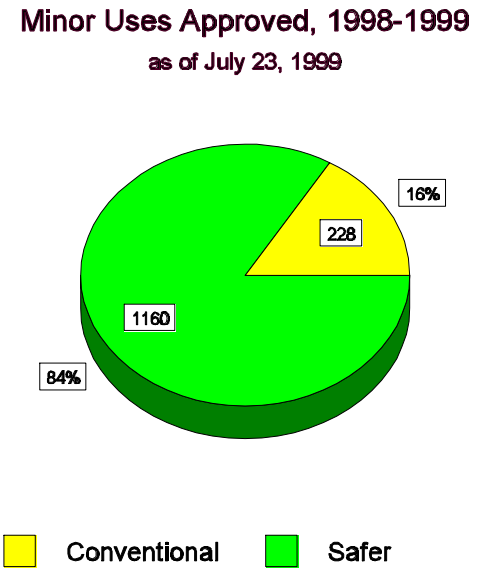
EPA is working closely with USDA's research program (IR-4) that generates residue data needed for tolerances to streamline the data development and review process for reduced risk pesticides used on minor use crops. Measures taken include:

- Issued Pesticide Registration Notice 97-2 in April 1997, defining minor crops and providing guidance on submission of minor use, and emphasized that the Agency would give priority review for minor uses;
- Improved the petition format, reducing the review time by 2-3 months;
- Streamlined the reduced risk justification form, making it less resource intensive for IR-4 to request reduced risk consideration;
- Identified with USDA potential vulnerable crop and pest combinations to facilitate development and approval of alternative controls.

Nearly 84 percent of uses approved in 1998 and 1999 were for minor use. These efforts are particularly important because many of the fruits and vegetables children eat daily are considered minor use crops.

What are Minor Uses?

A "minor use" of a pesticide can be any use on a commercial agricultural crop or site, livestock, or for the protection of public health where: 1) the total U.S. acreage for the crop is less than 300,000 acres or 2) the use does not provide sufficient economic incentive to registrants to provide data for supporting initial or continuing registration. Minor use pesticides are of major significance in agricultural production, to farmers as well as to consumers. Without these small scale but vital pesticide uses, farmers would not grow many of the fruits, vegetables, and ornamentals that we enjoy in the U.S., worth billions of dollars. Minor uses are also important in protecting public health from disease vectors such as mosquitoes, ticks, cockroaches, and rats, and disease-causing microorganisms.

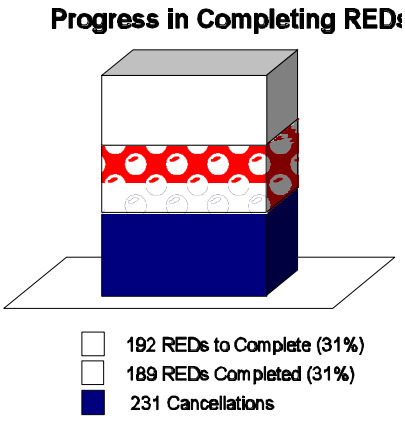


Registration of Pesticide for Potentially Vulnerable Crops

Recently, EPA set a permanent tolerance for the synthetic pyrethroid, cyfluthrin, on potatoes (a potentially vulnerable crop) and removed the time limitations for tolerances on sweet corn, field corn, and pop corn (including forage and fodder). Potentially vulnerable crop/pest combinations are those for which producers have only one or a limited number of effective alternatives, where pest resistance limits effective pest management, or where regulatory action would result in pest management problems.

III. Ensuring the Safety of Existing Pesticides *continued*

EPA has been reviewing older pesticides during the past 10 years to make sure that they meet current scientific and regulatory standards. FQPA mandates completion of this review, called reregistration, by 2002. In completing each review of a registered pesticide's human health and environmental effects, the Agency makes changes to the pesticide's registration where necessary to reduce risks. Our evaluation and regulatory changes are summarized in a Reregistration Eligibility Decision (RED). Of the 612 pesticide cases (or groups of related active ingredients) subject to reregistration, EPA has issued a total of 189 REDs to date. In addition, all the pesticide products in 231 cases were voluntarily canceled; 192 more REDs must be completed by 2002. (To obtain REDs and fact sheets, see www.epa.gov/REDs)



Reregistration Accomplishments Since FQPA

Since FQPA was enacted, we have completed 48 post-FQPA REDs, 33 for pesticides with food uses. Seven of these were voluntary cancellations, and all include measures to reduce risks and improve the safety of the uses that were allowed to continue. With some required modifications, the tolerances for the chemicals that are eligible for reregistration have been found to meet the FQPA safety standard.

48 Post-FQPA REDs

FY 96 REDs (7)
+ Bromacil
+ Colletotrichum gloeosporioides
+ Mepiquat Chloride
+ Paraquat Dichloride
+ Polyhedral Inclusion Bodies
S-Kinoprene
+ Virelure

FY 97 REDs, Rodenticide Cluster (6)
Brodifacoum
Bromethalin
Bromadiolone
Chlorophacinone
Diphacinone
Pival

Other FY 97 REDs (17)
+ Bt
Butralin
+ Dichlobenil
+ Diflubenzuron
+ Diphenylamine
IPBC
Methylene bis-thiocyanate (MBT)
+ Metribuzin
* Paranitrophenol (PNP)
+ Pendimethalin
+ Propoxur
+*Sulprofos
+ Terbacil
+ Thiobencarb
+ Triclopyr
Triethylhexahydro-s-triazine
+ Zinc Phosphide

FY 98 REDs (13)
+ Alachlor
+ Aluminum Phosphide
+ Magnesium Phosphide
+ Bromoxynil
+ Chlorothalonil
DEET
1,3-Dichloropropene
+ Dicofol
+ Hydramethylnon
+ Iprodione
+ Methomyl
+ Propachlor
+ Thiodicarb

FY 99 REDs (thru July '99) (5)
+*Fonofos
+*Isofenphos
* Oxythioquinox
+*Ryanodine
+*Vernolate

+ Includes Food Uses
*** Voluntary Cancellation**

Reducing Risks through Post-FQPA REDs

During the reregistration process, EPA may identify risks that must be reduced to ensure safety before a pesticide can be eligible for reregistration. A wide range of remedies are available to reduce those risks. EPA works with registrants and others to develop voluntary measures or regulatory controls that are both practical and effective to reduce risks of concern. The table below shows the types of risk mitigation measures EPA has required for the 48 post-FQPA REDS. Three examples of risk reduction through REDs are provided in Appendix 3b.

Risk Reduction Through Post-FQPA REDs	# of REDs
Canceled, deleted, or declared not eligible for reregistration	in 21 REDs
Restricted to use only by trained & certified applicators	in 14 REDs
Limited the amount, frequency, or timing of use	in 14 REDs
Other application restrictions	in 38 REDs
Personal Protective Equipment (PPE) or Restricted Entry Intervals (REI)	in 32 REDs
User safety measures	in 35 REDs
Engineering controls/special packaging	in 14 REDs
Ground water or surface water safeguards	in 13 REDs
Spray drift labeling	in 19 REDs
Other environmental safeguards	in 17 REDs
Other significant measures	in 13 REDs
Reduction of residential/children's risks	in 17 REDs

Meeting FQPA Tolerance Reassessment Goals

FQPA requires EPA to reassess all 9721 tolerances and tolerance exemptions that were in effect when the law was passed in August 1996. EPA must complete reassessment of 33% of these tolerances by August 1999, 66% by August 2002, and the remaining tolerances by August 2006.

As required by FQPA, we reassessed 3290 tolerances by July 30, 1999, surpassing the 33% goal for August 1999. Of the reassessments completed, 66% (2178) are in our first priority group. These reassessments represent over 39% of the 5546 tolerances in this highest priority group. (See box below detailing the three priority groups.) We have 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.

OP Replacement Registered for 1999 Growing Season

EPA registered new uses for the insecticide, bifenthrin, an organophosphate alternative for cabbage, the cucurbit vegetable crop group, edible-podded legume vegetable subgroup, eggplant, globe artichoke, head and stem Brassica subgroup (except cabbage), rapeseed (canola), succulent shelled pea and bean subgroup (includes green, wax, lima and snap beans); and sweet corn. Tolerances for the last two crop groupings were jointly requested by the Interregional Research Project (IR-4) and FMC Corporation, the manufacturer of bifenthrin. The registration of bifenthrin was expedited to meet targeted organophosphate reduction efforts by the food processing industry for the 1999 crop season. EPA understands that this action occurred in time for Del Monte Foods and other processors of peas, beans and sweet corn to begin replacing methyl parathion, dimethoate and acephate with bifenthrin. Del Monte expects that, if commercial control is as successful as their trials have suggested, bifenthrin will

Priority Groups for Tolerance Reassessment

In August 1997, EPA published a Federal Register notice dividing the pesticides with tolerances that must be reassessed into three priority groups. FQPA requires EPA to give highest priority to pesticides that appear to pose the greatest risk.

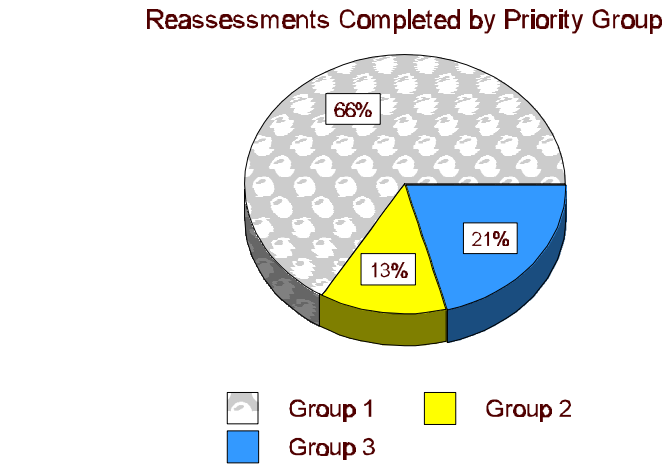
- **Group 1** (228 pesticides/5546 tolerances) includes
  -Organophosphates
  -Carbamates
  -Organochlorines
  -Probable carcinogens
  -Reference dose exceeders*****
  -High-hazard inerts

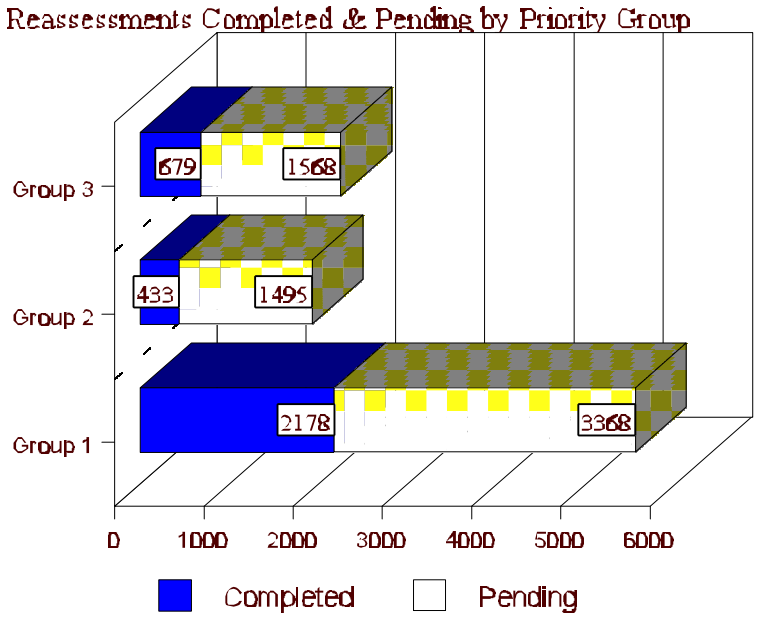
- **Group 2** *(93 pesticides/1928 tolerances)*
  -Possible carcinogens
  -All remaining reregistration chemicals (those that were first registered before 1984)

- **Group 3** *(148 pesticides/2247 tolerances)*
  -Remaining pre-FQPA pesticides with reregistration eligibility decisions
  -Remaining post-1984 pesticides
  -Biological pesticides
  -Remaining inerts

***Dietary exposure at levels above the amount that is believed to be safe for life-long, daily consumption**

Among the reassessed tolerances are 1493 tolerance revocations, of which 1258 are for pesticides in priority Group 1, and 796 are for organophosphates, carbamates, organochlorines, and carcinogens. Revoking tolerances for these pesticides helps ensure that foods exported to the U.S. do not have residues of these pesticides.





Tolerance Fees

FQPA requires EPA to collect fees that will be sufficient to cover the costs of evaluating tolerances for pesticide products. It expanded the number of regulatory actions that fall under the heading of tolerance processing. The largest category of new actions is tolerance reassessment. Factors such as more comprehensive data requirements, scientific advancements in risk assessment, improvements in data base management and tracking systems, and the increasing complexity of scientific review of petitions have resulted in costs substantially exceeding the fees currently charged.

On June 9, 1999, EPA published a proposed rule regarding the collection of fees for establishing and reassessing pesticide tolerances and exemptions. The proposed fees for tolerances are based on the actual resources needed for each type of tolerance action and are designed to fully recover costs. The rule proposes several exemptions from fees for tolerance actions that in the public interest, as well as a continuation of current practice of granting fee waivers on a case-by-case basis, according to criteria and procedures in the proposed rule. The proposed automatic waiver categories are:

- Petitions submitted by IR-4 (a research program sponsored by the U.S. Department of Agriculture to help establish tolerances for pesticide uses on minor crops)
- Minor use tolerances, unless the minor use is the first or only food use of a pesticide
- Tolerances for emergency exemptions
- Tolerance revocations
- Biopesticide tolerance actions, except plant-pesticides
- Other ingredients generally regarded as safe (List 4A inerts)
- Tolerance exemptions for chemicals exempted from FIFRA regulations under section 25(b)

The fees in the rule, when final and implemented, will be the first major increase in tolerance fees in almost 15 years.

IV. Public Participation and Transparency

Public consultation improves the quality of decisions. Sharing information and involving the publc are important commitments for EPA. Sharing information and involving the public are important commitments for us. It is essential that the public play a major role in environmental decision making today, and pesticide decisions are no exception. By including stakeholders and other members of the public to an unprecedented extent, we hope to arrive at the fairest, most realistic and informed decisions possible for these pesticides. Our expanded stakeholder involvement is reflected in the examples below.

The Tolerance Reassessment Advisory Committee (TRAC) Meetings and the OP Tolerance Reassessment Process

In April 1998, in response to a request from Vice President Gore to enhance stakeholder input on FQPA implementation, EPA and USDA formed the Tolerance Reassessment Advisory Committee (TRAC) to help the two agencies establish a framework for making tolerance reassessment decisions. TRAC has been co-chaired by the Deputy Administrator of EPA and the Deputy Secretary of Agriculture and was established as a subcommittee under EPA's National Advisory Council for Environmental Policy and Technology. The TRAC provides 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 organophosphate pesticides (*see box*).

TRAC has met six times, with one additional meeting planned for later in 1999. The group has helped EPA and USDA make significant progress in several areas critical to the successful implementation of FQPA. For example, with the assistance of TRAC, EPA and USDA have:

Organophosphate Pesticides

Acephate
Azinphos-methyl
Bensulide
Cadusafos*
Chlorethoxyfos
Chlorpyrifos
Chlorpyrifos methyl
Chlorthiophos**
Coumaphos
Dialiflor**
Diazinon
Dichlorvos (DDVP)
Dicrotophos
Dimethoate
Dioxathion**
Disulfoton
Ethion
Ethoprop
Ethyl parathion
Fenamiphos
Fenitrothion
Fenthion
Fonofos**
Isazophos **
Isofenphos**
Malathion
Methamidophos
Methidathion
Methyl parathion
Mevinphos**
Monocrotophos**
Naled
Oxydemeton methyl
Phorate
Phosalone**
Phosmet
Phosphamidon**
Phostebupirim
Pirimiphos methyl
Profenofos
Propetamphos
Sulfotepp
Sulprofos**
Temephos
Terbufos
Tetrachlorvinphos
Tribufos (DEF)
Trichlorfon

*Import tolerances only; no U.S. registrations for use
**These chemicals have been canceled or proposed for cancellation. They will be included in the organophosphate risk assessment if import tolerances remain after other tolerances are revoked.

- Initiated a pilot approach for obtaining public comment on preliminary risk assessments for the organophosphate pesticides improving transparency of decisionmaking; and

- Increased focus on transition issues to prepare growers for possible changes in pesticide use patterns.

Risk Assessment/Risk Management Pilot for the Organophosphate Pesticides

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. In the first step of the process, EPA releases preliminary risk assessments for the organophosphate pesticides for public comment. EPA placed the first nine preliminary risk assessments in the docket and on the internet (http://www.epa.gov/pesticides/op/) in August 1998. In September 1998, EPA released seven more preliminary risk assessments. As of July 1999, EPA has released a total of 29 preliminary risk assessments for public comment with 11 preliminary risk assessments remaining to be released.

Following completion of the public comment period on each preliminary risk assessment, EPA reviews the comments and revises the risk assessment, as appropriate. USDA then reviews the revised risk assessment to identify opportunities for risk management and the potential need for transition strategies. In many cases, EPA and USDA present a technical briefing on the revised risk assessment to provide an opportunity for the public to learn about the data, information, and methods used to develop and revise the risk assessments. 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. Five organophosphates have entered the risk management consultation phase and two are in the risk management strategy stage. Appendix 3 briefly describes the risk assessment/risk management pilot phases.

Aluminum and Magnesium Phosphide Stakeholder Process

EPA initiated an extensive public and stakeholder process to obtain input and ideas about ways to reduce the risks associated with aluminum and magnesium phosphide, two fumigants used to control insects and rodents where agricultural commodities are stored. In issuing the Reregistration Eligibility Decision for these two pesticides in December 1998, EPA identified risks of concern to bystanders and pesticide applicators from exposure to phosphine, a highly toxic gas created when these fumigants are used.

The Agency proposed 15 risk reduction measures to increase the level of protection to bystanders and pesticide applicators from exposure to phosphine. We received many comments questioning the feasibility of the proposed measures. Since few, if any, viable alternatives exist for fumigation to control pests in stored products, we are continuing to seek extensive stakeholder and public involvement in developing workable ways to reduce risks.

EPA has extended its schedule for completing the ongoing reregistration review of aluminum and magnesium phosphide. This extension will allow more time for stakeholder involvement, public input, and complete consideration of alternative ways to reduce risks from these important pesticides. We are considering all comments received so far and attended fumigant demonstrations from May to July. According to the recently revised schedule, the Agency plans to:

- issue a revised set of proposed risk mitigation measures in September 1999;
- hold stakeholder meetings in several U.S. cities in October, November, and December 1999; and
- issue final risk mitigation measures needed for reregistration, in late 1999 or early 2000.

To identify feasible risk mitigation measures before releasing a new proposal, EPA is working with the U.S. Department of Agriculture, the National Institute of Occupational Safety and Health, the Occupational Safety and Health Administration, and a coalition of industry groups and user organizations. In addition, EPA is consulting with the Phosphine Task Force, a group of experts from Land Grant Universities and USDA Agricultural Research Service scientists with expertise in commodity storage pest management systems who are investigating possible alternative risk mitigation measures. EPA recognizes the importance of phosphine to agriculture, the lack of viable alternatives, and the potential impacts of the initial set of risk mitigation measures on the continued use of the chemicals. Final decisions will be based on sound science and a full understanding of agricultural needs. With the full participation of stakeholders EPA will be able to develop improved risk mitigation measures that are both protective and practical.

Rodenticide Cluster Stakeholder Process

In completing the Reregistration Eligibility Decision (RED) for a cluster of six rodenticide pesticides in September 1998, EPA announced its plans to assemble a stakeholder workgroup to explore and recommend ways to reduce the risk of exposure to rodent control products, especially accidental exposures experienced by young children. Six months later, in March 1999, the Rodenticide Stakeholder Workgroup, established under the Pesticide Program Dialogue Committee, held its first open meeting. Members of the workgroup represent public health and environmental organizations, industry groups, government agencies, and the general public. Through an ongoing series of public meetings this spring and summer, the workgroup is discussing and analyzing options and proposals for reducing risks. So far, the workgroup has developed an initial recommendation on product labeling and a plan for continued progress, including a meeting this fall to discuss additional options and consider ways to communicate with rodenticide product users. EPA will use the workgroup's recommendations in developing a strategy to reduce the risks of exposure to rodenticides while preserving their public health benefits. Meanwhile, EPA is requiring rodenticide registrants to incorporate an indicator dye and a bittering agent into their product formulations; the timing of these changes is under discussion.
(www.epa.gov/pesticides/ppdc/rodent)

Right-to-Know Brochure and Website

With advice from the Pesticide Program Dialogue Committee and consumers, and consultation with USDA and FDA, EPA developed a brochure, *Pesticides and Food*, to inform consumers about pesticide use on food, government programs that protect them from pesticide risks, and ways they can reduce their exposure to pesticides. The brochure also explains how the Food Quality Protection Act (FQPA) increases protection of infants and children from exposure to pesticides.

EPA distributed copies to 30,000 grocery stores during the Winter of 1999. Copies have also been distributed to public health officials, libraries, and the medical community. Over 4 million copies have been distributed to date. In addition to the brochure, EPA designed a website, also called *Pesticides and Food.* This website, which is referenced in the printed brochure, provides consumers with more detailed information. (www.epa.gov/pesticides/food)

About the Pesticides and National Strategies for Health Care Providers

Last year, an EPA-led interagency initiative began that includes the support of the U.S. Department of Agriculture, U.S. Department of Health and Human Services, and the U.S. Department of Labor. The interagency group sponsored a workshop to identify strategies to improve the ability of health care providers to recognize, diagnose, manage and prevent adverse health effects due to pesticide exposure. Based on the proceeding of the workshop , EPA published a report, "Pesticides and National Strategies for Health Care Providers", which outlines a series of recommendations for improving the training that health care providers receive on health concerns related to pesticide exposures. Among the recommendations included are the need to:

- specify competencies that providers should demonstrate upon completion of their education and other specialty training;
- develop educational tools and training materials that will motivate students and health care providers to acquire an understanding and knowledge of possible health effects resulting from pesticide exposure; and
- raise awareness and make more information available to providers on health complaints and illnesses that may be related to pesticide exposure through materials and resource development, professional meetings, marketing and outreach programs, and other activities.

To carry forward this initiative and further develop the 4 broad strategies, workgroups were created in three core areas: Formal Education of Health Care Providers, Health Care Provider Practice and Resources for Health Care Providers.

In May 1999, EPA and several other federal agencies convened the Education and Practice workgroups to further develop components of an implementation plan for raising knowledge and awareness of pesticide issues in the educational and practice settings of primary care providers. Workgroup members came from academic faculty; professional associations for physicians, nurses and physician assistants; farmworker and community interest groups, federal and state agencies, and pesticide experts. A third workgroup on resources will convene in August 1999. A draft national implementation plan will be published which will serve as working document for the next year of activity on this initiative, culminating in a National Forum in 2000.

V. Special Protection for Vulnerable Populations

FQPA includes several provisions that increase protection for vulnerable populations. EPA has vigorously implemented these provisions when making regulatory decisions based on the safety standard of "reasonable certainty of no harm" and in considering the appropriate FQPA safety factor for each pesticide.

Special Protection for Infants and Children

FQPA emphasizes the potential for infants and children to be especially sensitive to pesticides and the need to ensure that they are afforded adequate protection. This issue received significant attention in the 1993 National Academy of Sciences (NAS) report, *Pesticides in the Diets of Infants and Children.* Many of FQPA's provisions are based on that report's recommendations (which are discussed in more detail in Appendix 4).

New Data will Help Ensure Protection of Children

In an effort to further increase protections for infants and children, EPA is requiring registrants of many food use pesticides to conduct acute, subchronic, and developmental neurotoxicity studies and submit the results to EPA This program to call in data will apply to at least 140 pesticides and will be completed in phases over the next several months. EPA expects to receive the first studies within two years. This data call-in program was developed in part following advice from the FIFRA Scientific Advisory Panel.

Among the NAS recommendations codified by FQPA are the need to specifically determine that tolerances are protective of infants and children and the use of a safety factor during risk assessment to account for special sensitivities. In keeping with FQPA, each tolerance decision issued after August 3, 1996, contains a specific finding that the tolerance levels are appropriately protective of children. FQPA requires EPA to apply an additional safety factor of 10 during its risk assessment to account for the potential for pre- and post-natal toxicity, as well as for the completeness of the toxicology and exposure database, unless the Agency determines that another factor is adequately protective. EPA uses available, reliable data when considering the need to raise, retain, modify, or remove the 10-fold additional safety factor.

EPA, recognizing the importance of the 10-fold safety factor, began developing policy and implementation procedures soon after passage of FQPA to ensure consistent and defensible decisions. Within three months, we sought advice from the FIFRA Scientific Advisory Panel (SAP) regarding the Agency's approach to this issue. In January 1997, we issued guidance in Pesticide Registration Notice 97-1, which describes generally the types of information needed to determine whether infants and children are especially sensitive to a chemical and whether an additional safety factor is needed for their protection. More recently, an EPA task force has considered policy issues

related to the FQPA safety factor, and we submitted our revised draft policy and operational practices for making decisions on the 10-fold FQPA safety factor to the SAP for review in May 1999. These documents also have been released (in July 1999) for public review and comment, based on a process established in conjunction with the TRAC.

We have also updated our pesticide toxicity testing guidelines to enable the Agency to better assess risks to infants and children. The proposed revisions to guidelines for animal studies on prenatal development and reproduction and new guidelines on effects to the immune system were reviewed by the SAP. EPA incorporated recommendations from the SAP and published the guidelines for use by registrants in conducting such studies in July 1998.

Reducing Organophosphate Risks to Children and Workers - Two Case Studies

Methyl Parathion Uses Eliminated

Methyl parathion is a very acutely toxic organophosphate insecticide and is widely used on crops. Like azinphos methyl, 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, certain peas and beans, and tomatoes), eaten frequently by children. These actions will help protect children as well as adults. In addition, worker risks are unreasonable for many use scenarios, and EPA is modifying product labels to increase worker protection. This decision protects two of our most vulnerable populations, children and workers. It is based on a thorough, sound, and refined analysis of all the available data. In particular, it will help ensure that our food is safe by providing a greater margin of protection to the foods we and our children eat. A diet rich in fruits and vegetables is important for children and adults.

Azinphos Methyl Uses Modified and Reduced

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.

National Agenda to Protect Children's Health from Environmental Threats

EPA has initiated a "National Agenda to Protect Children's Health from Environmental Threats." This agenda is helping to focus additional attention on this important sub-population in all of our regulatory actions. The Children's Health Protection Advisory Committee published several recommendations related to the pesticide program:

- Reevaluate the atrazine pesticide tolerances;
- Reevaluate pesticide tolerances for methyl parathion, dimethoate, and chlorpyrifos; and
- Reevaluate the Worker Protection Standard.

We have included atrazine, methyl parathion, dimethoate, and chlorpyrifos in the first priority group of tolerances for reassessment. All of these tolerances will be reviewed in the coming months. The preliminary risk assessments for methyl parathion and dimethoate have been completed. The preliminary risk assessment has been revised for methyl parathion. We announced risk management actions for methyl parathion on August 2 and held a technical briefing on the revised risk assessment the same day. The preliminary risk assessment for dimethoate is currently being revised based on comments received during the public comment period. The review of atrazine will be completed by next summer. Future efforts also will increase protection of children of workers based on reexamination of risk assessment methods and research that will identify areas of vulnerability.

Special Protection for Agricultural Workers

We place a strong emphasis on assuring the health of agricultural workers whose jobs require mixing, loading, or applying pesticides and are committed to strengthening national efforts to safeguard upwards of 3.5 million farm workers and their families. EPA's Worker Protection Standard, first implemented in 1992, has resulted in pesticide safety education and training efforts across the country.

Since the passage of FQPA, our Worker Protection Program to implement the standard has devoted significant resources to producing and distributing bilingual or multi-lingual and educational materials. Our communication efforts include a new Pesticide Workers Website, publication of over 1 million grower compliance manuals, over 2.7 million safety training manuals, over 680,000 safety posters, and more than 11,000 safety training videos.

Finally, the EPA is conducting a review of its worker protection activities, including the methods for risk assessment, to determine if workers are receiving adequate protection. Last year, the EPA initiated a national assessment of implementation and enforcement of the worker protection regulation. This effort includes a worker protection assessment group composed of the EPA, the USDA, the Department of Labor, the Department of Health and Human Services, state regulators, state extension service safety educators, farm worker advocacy groups, farm worker service/training associations, agricultural employer associations, farm worker clinicians networks, and others. The goals of the group are to:

- assess the current program's status;
- generate stakeholder interest that can effect change in the programs;
- provide a means to foster the partnerships essential to make the program work;
- and most importantly, provide a continuing forum to focus and resolve worker protection issues.

The worker protection assessment group will develop a strategic plan for the national worker protection program and issue annual reports detailing accomplishments and progress towards achieving its goals.

Applicator Certification and Training

Over one million applicators are currently certified nationwide, including over 900,000 private applicators and about 350,000 commercial applicators. For the past three years, approximately 243,000 private and 198,000 commercial applicators received their initial certification. EPA has recertified approximately 129,000 private and 121,000 commercial applicators each year for the past three years. Several hundred thousand applicators attended training sessions to learn or review the appropriate methods for applying pesticides.

As noted above, the Agency is currently conducting a national assessment of the applicator certification and training program. A certification and training assessment group of representatives from EPA, USDA, state pesticide agencies, tribes and pesticide safety educators was formed to draft

About Pesticide Certification and Training Programs

EPA may designate some or all uses of a pesticide as "restricted." Restricted use pesticides may only be used by or under the direct supervision of specially trained and certified applicators. Certification programs are conducted by states, territories, and tribes in accordance with national standards set by the EPA. All states require commercial applicators to be recertified, generally every three to five years, to maintain their certification.

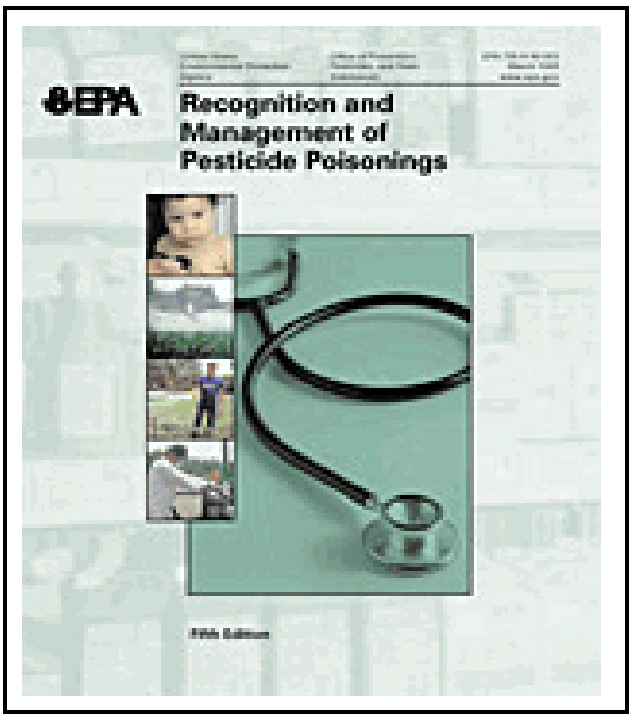
proposals to guide the program's future. The proposals for review by the nation's program partners are grouped under five program goals:

- Reduce the risks to the public from pesticide use;
- Provide high quality pesticide education and safety training programs;
- Maintain the consistency, integrity and validity of the certification and recertification programs and processes;
- Ensure that adequate and equitable funding is available to education and training programs,
- Improve the efficiency of program organization and operations and;

Response from the program partners and the program stakeholders will help frame a national strategy for the future of the applicator certification and training program.

Pesticide Workers Website

Just recently, the EPA began a new pesticide safety programs website (www.epa.gov/pesticides/safety) to inform farm workers, certified applicators, and health care providers about the Agency's pesticide safety programs. This site, which provides easy access to information in both English and Spanish, marks an important step in the Agency's pesticide worker safety outreach efforts. It provides specific information on applicator certification and training requirements and the EPA's Worker Protection Standard, including pesticide safety training, notification of pesticide application, use of personal protective equipment, and emergency medical assistance.



The site also provides information on the EPA's Pesticides and National Strategies for Health Care Providers initiative aimed at helping health care providers become better aware and trained in diagnosing and preventing pesticide related illnesses. 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 pesticide poisonings, is also available at this site.

VI. On the Forefront of Sound Science

Implementing the new FQPA safety standard is driving changes in risk assessment methods and the science policies that support regulatory decisions. FQPA requires EPA to consider the combined or aggregate effects of pesticide exposure from food, drinking water, and other non-occupational uses (such as in the home), as well as the cumulative effects of pesticides that act in the same way. EPA is developing new aggregate and cumulative exposure and risk assessment methods. In addition, FQPA directs EPA to explore the potential of chemicals to disrupt the functioning of the human hormonal or endocrine system, by developing an extensive new screening and testing program. In leading these changes, EPA is consulting with a wide array of outside experts in many scientific disciplines.

EPA also has worked to increase the transparency of its scientific work both during the development of methods and policies and by inviting review of draft documents such as risk assessments on various chemicals. Public comment is informing our science policies as well as providing access to data that can be used in refining chemical-specific risk assessments.

Development of Science Policies

Shortly after passage of FQPA, EPA began using a set of interim guidance (developed with input from the Food Safety Advisory Committee) in making various pesticide-related decisions. In response to subsequent advice from the Tolerance Reassessment Advisory Committee, EPA identified nine science policy issues that needed to be resolved in updating the interim guidance. On October 29, 1998, EPA published a Federal Register notice summarizing the science issues and outlining a schedule for publication of the related documents. Since then, EPA has issued several of the documents for public comment and is revising them and reissuing them based on comments received. The documents are posted on the Internet as they are completed. (http://www.epa.gov/pesticides/trac/science/)

What are the nine science policies?

1. Applying the FQPA 10-Fold Safety Factor
2. Dietary Exposure Assessment - Whether and How to Use "Monte Carlo" Analyses
3. Exposure Assessment - Interpreting "No Residues Detected"
4. Dietary (Food) Exposure Estimates
5. Dietary (Drinking Water) Exposure Estimates
6. Assessing Residential Exposure
7. Aggregating Exposures from all Non-occupational Sources
8. How to Conduct a Cumulative Risk Assessment for Organophosphate Insecticides or Other Pesticides With a Common Mechanism of Toxicity
9. Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates

Among the issues included in this science policy discussion are application of the FQPA 10-fold safety factor ("10X"), how to conduct a cumulative risk assessment, several exposure assessment issues (dietary, drinking water, residential, aggregate), selection of toxicity endpoints, and use of probabilistic exposure assessment techniques. In addition, we have released for public comment several other policy documents that were not part of the original discussion, such as *The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management* (published July 14 1999). There are 19 planned science policy papers associated with the nine policy areas; of the 19, 14 have been published. Appendix 5 includes a list of the planned papers and current status. These science policies represent a major advance in the methodology of risk assessment, and will ensure that the Agency is using the most appropriate and protective standards in its pesticide regulatory program.

Pesticide Use Information

In 1998, EPA began collecting available information about current pesticide usage (starting with the organophosphates) and organized it into tables or Crop Matrices to improve accessibility and ease of use by analysts, decision-makers, and stakeholders. Crop matrices present, on a crop basis, best available information on actual use of organophosphates. The information, largely quantitative, describes the percent of crop treated, average and maximum rates of pesticide use, and number of applications. They also identify target pests, alternatives to the organophosphates (*OPs*), and their constraints. We use data from the matrices to assess risks and to make decisions about regulatory actions. Draft OP matrices for 10 crops were posted on the Internet at (http://www.epa.gov/oppbead1/matrices). Matrices for other crops will be posted as they are complete.

Sources of Pesticide Use Information

Most of the available data about pesticide usage is on agricultural crops, but some limited data are available for non-agricultural uses. The use data are obtained through various sources:

- Agreements with other government agencies for data that are generally publicaly available (e.g., USDA National Agricultural Statistics Service, USDA National Agricultural Pesticide Impact Assessment Program, and the California Department of Pesticide Regulation);

- Purchases from firms who are in the business of collecting and selling pesticide use data. Such data must be bought under proprietary agreements, and data are not available to those who have not entered into agreements with the provider;

- State recommendations for pest control and crop and livestock management for farmers and ranchers generated by each state's agricultural extension office. These publications present the views of the agricultural science community in each state about which pesticide products are most likely to work in their area;

- USDA crop profiles generated by USDA's State Liaison Representatives and other entities. They capture information in narrative format about crop production, cultural practices, and pesticide use. (ipmwww.ncsu.edu/opmppiap) ; and

- The Label Use Information System (LUIS), an EPA database of use patterns found on the labels of currently registered pesticide products--in other words, the legal limits on how the product may be used. It contains detailed information on registered sites, application methods (type, timing, and equipment), application rates, and limitations on the use of pesticides (e.g., preharvest intervals, reentry intervals). LUIS captures only information specified on the approved label for a pesticide product.

Another category of pesticide use information is the Quantitative Usage Analysis (QUA) and the Quantitative Usage Analysis Plus (QUA+). The QUA summarizes from the sources listed above estimates of use of individual pesticides on both crop and non-crop sites. The QUA+ contains supplementary data received from growers and registrants on typical usage rates, descriptions of alternatives and their limitations, as well as expanded information about application methods and pest pressures. For those crops where this information is available, it has been included in the matrices described above.

Endocrine Disruptors

In recent years, evidence has arisen to suggest that chemicals may disrupt the hormone (endocrine) systems of humans and wildlife and cause reproductive disorders, birth defects, immune dysfunction, and other harmful effects. A variety of chemicals, including pesticides, have been found to disrupt the endocrine systems of animals in laboratory and field studies, and compelling evidence has accumulated that endocrine systems of fish and other wildlife have been altered by chemicals that contaminate their habitats. With few exceptions, however, such effects have not been conclusively demonstrated in human beings to date.

Because of the potentially serious consequences of human exposure to endocrine disrupting chemicals, Congress included a mandate to EPA in the FQPA and the 1996 amendments to the Safe Drinking Water Act (SDWA) to develop an endocrine disruptor screening program. FQPA requires EPA to:

- develop a screening program for pesticides that may have estrogenic or other endocrine effects within two years of enactment;

- implement the program within three years of enactment; and
- report progress to Congress within four years of enactment.

Since receiving the statutory authority, EPA has moved quickly to set up a screening program that can be used to gather data on the endocrine disrupting potential of pesticides and other chemicals.

VI. On the Forefront of Sound Science *continued*

To help inform the implementation of the screening program provisions of FQPA, EPA formed an advisory committee, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC). This committee provided recommendations on how to develop the screening program. EDSTAC reached consensus on its recommendations and presented them to EPA in August 1998.

EPA used the EDSTAC recommendations as the primary basis of a proposal for an Endocrine Disruptor Screening Program (EDSP). This proposal was published in the Federal Register on December 28, 1998. EPA's proposed screening program has the following characteristics:

- A two-tiered screening program for chemicals, pesticides, and environmental contaminants to detect effects on the estrogen, androgen, and thyroid hormone systems;
- Inclusion of evaluation of potential for effects on human health and wildlife;
- Potential use of high-volume, automated technology to screen large numbers of chemicals to help set priorities (under research and development);
- Development of a relational database to help set priorities and track data; and
- Standardization and validation of all assays before regulatory use.

EPA is beginning to implement the Endocrine Disruptor Screening Program using a tiered approach. This approach appears to be the most effective way to use available resources to detect endocrine disrupting chemicals and quantify their effects. The core elements of the approach include initial sorting, priority setting, tier one screening, and tier two testing. The final step is hazard assessment.

The Agency is establishing the priority setting process for selecting the initial chemicals for the screening program, developing methods for endocrine disruptor screening and testing, and standardizing and validating the screening and testing methods for regulatory programs. For more details on the endocrine disruptor screening program, see Appendix 6.

In order to improve its regulation of pesticides, EPA has created partnerships with other federal agencies, international organizations, states, tribes, and directly with stakeholders. These partnerships generate consortia of interest that can effect change to reduce pesticide risk.

VII. Partners and Other Stakeholders

Other Federal Agencies

Pesticide regulatory authority resides with several U.S. government agencies, making coordination at the federal level essential. FQPA contains specific provisions for cooperative activities between EPA, USDA, and the Department of Health and Human Services (DHHS).

U.S. Department of Agriculture

USDA, a particularly important partner given its relationship with the grower community, has:

- served as co-chair of the TRAC;
- created an Office of Pest Management Policy to serve as liaison to EPA and the agricultural community on FQPA issues;
- provided data through food consumption surveys and the Pesticide Data Program which help refine risk estimates and ensure that they reflect actual pesticide use;
- reviewed EPA's preliminary and revised organophosphate risk assessments to determine how pesticide use and food consumption data are considered, to validate assumptions, and to consult on risk management strategies where necessary;
- worked with growers and registrants to identify crop/pesticide combinations where limited crop protection alternatives exist, and supported minor use registrations through its IR-4 program.
- through the extension service, conducted certification and training for pesticide applicators.

Health and Human Services

EPA is actively consulting with USDA and DHHS on pesticides with public health uses, such as mosquito or cockroach control. For food use pesticides which also have public health uses, FQPA requires EPA to factor exposure from the public health use into its aggregate exposure assessments. There is concern by some public health professionals that this provision may lead to limits on some public health pesticide uses because registrants may choose to support more profitable food uses at the expense of the public health uses. When evaluating tolerances, consideration of the benefits of public health uses are limited to special circumstances, subject to the same restrictions in FQPA as all other pesticide uses. The important benefits of public health pesticides, however, would be considered by the Agency in determining how best to mitigate any unacceptable risks in order to bring aggregate exposures within safe levels.

For example, if the aggregate risk of a pesticide were found to be unacceptable, EPA would consider the benefits associated with all the uses, and the availability of alternatives, when determining how to bring the risk down to an acceptable level. FQPA requires that EPA consult with DHHS and USDA if the Agency were to conclude that a non-food public health use may need to be limited or eliminated. Rather than relying solely on this requirement to ensure that public health uses are given appropriate consideration, EPA is sharing with DHHS all risk assessments for pesticides with public health uses at a stage well before any regulatory decisions are to be made. To date, EPA has requested DHHS comment on risk assessments for five organophosphates with public health uses.

Food and Drug Administration

EPA also is coordinating with HHS' Food and Drug Administration (FDA) on improved pesticide residue detection. While EPA sets tolerances, it is the responsibility of FDA to monitor domestic and imported fruits and vegetable for residue levels. In order to improve the quality of monitoring data, the Agency has begun to purchase analytical instruments for FDA laboratories which will allow for detection of pesticides at levels far below what is currently possible. EPA is developing methodologies for laboratory use and will provide FDA with a list of pesticides and crops which should be a monitoring priority. The pesticides will be mainly organophosphates and the crops will consist of many children's foods. This improved monitoring will serve two purposes. First, it will allow detection of low levels of pesticides for which there are no tolerances. Second, where there are tolerances, it will provide better information on actual organophosphate residue levels for use during EPA's risk assessments.

President's Council on Food Safety

EPA is an active participant in the President's Council on Food Safety. This council, co-chaired by the Secretary of Agriculture, the Secretary of Health and Human Services, and the Chairman of the White House's Office of Science Technology and Policy, is examining the current structure for regulating food safety at the federal level. While the Council's initial focus was bacterial and microbial contamination of food, it has expanded its work to include pesticides. The Council is holding a series of public meetings to allow interested parties to provide their suggestions for improving food safety regulation in the U.S. Member agencies have established a website (http://www.foodsafety.gov) containing information on the Council's activities and are developing a comprehensive Federal food safety plan which will guide cooperative efforts at the national level and between the U.S. government and state and local regulatory authorities.

International: The NAFTA Technical Working Group on Pesticides

EPA, under statutory requirements and international agreements, works with other countries and international organizations on a wide array of pesticide issues. For example, in 1996 the U.S., Canada, and Mexico established a Technical Working Group on Pesticides (TWG) under the North American Free Trade Agreement (NAFTA). Many TWG activities build on work previously being conducted by the U.S. and Canada, with Mexico continually becoming more active.

The TWG's primary objective is to facilitate cost effective pesticide regulation and trade among the three countries through harmonization and work sharing. These activities will improve food safety, help ensure environmental protection, assist in the resolution of trade problems, and streamline regulatory processes.

Through the TWG, EPA and its Canadian counterpart, the Pesticide Management Regulatory Agency (PMRA), have already jointly reviewed and registered three reduced-risk chemical pesticides and one pheromone. The next step in the joint review process is for Canada, Mexico, and the U.S. to conduct tri-national review of a new chemical pesticide. This review will also give all three countries experience with the new submission format developed by the Pesticide Working Group of the Organization for Economic Cooperation and Development (OECD). The TWG is considering potential organophosphate alternatives as candidates for joint review, since reevaluation of organophosphates under FQPA may result in changes in the uses and associated tolerances of these chemicals, potentially affecting trade with NAFTA partners. (http://www.epa.gov/oppfead1/international/).

Joint U.S./Canadian Reviews

Cyprodinil (Vangard) - Reduced risk fungicide for field and nut crops. Registered by Novartis.

Fenhexamid (Elevate) - Reduced risk fungicide to control grey mold on grapes, strawberries, and ornamentals. Registered by Tomen Agro.

Diflufenzopyr (Distinct) - Reduced risk herbicide for use on field corn. Registered by BASF.

Eastern Pine Shoot Borer (9-dodecenyl acetate) - Pheromone for use in forests and wood lands. Registered by 3M.

PMRA has been working closely with EPA to ensure that Canada fully understands the scientific issues raised by FQPA. Canada supports the new safety standard and is incorporating these new approaches into its review processes and methodologies. EPA and PMRA are also coordinating their efforts to reevaluate older pesticides, focusing on the priority chemicals under FQPA. In June 1999, PMRA announced their intent to conduct a re-evaluation of the uses of all organophosphates, similar to the reregistration process in the U.S. PMRA will be using EPA reviews as much as possible and will assess risk from food, occupational, and bystander exposure, plus drinking water exposure relevant to Canadian conditions. PMRA anticipates completing its review in December 2000 and will not accept submissions for major new uses of organophosphates until the review is finished.

EPA and Canada have recently taken a critical step towards practical implementation of harmonization goals. In June 1999, EPA and PMRA agreed upon a formal memorandum of understanding (MOU) on good laboratory practices (GLP) providing a framework for mutual acceptance of reviews of pesticide studies that are used to support pesticide registration in both countries. GLP is an internationally-recognized quality system which covers the organizational processes and conditions under which non-clinical human health and environmental safety studies are conducted. In keeping with international standards for mutual acceptance of data and GLP compliance monitoring, the MOU establishes mutual recognition of each country's GLP requirements and associated compliance program. The agreement will be fully implemented after the joint inspection and program evaluation activities are completed to confirm the compatibility of U.S. and Canadian programs.

States, Tribes, and Regional Coordination

Since EPA delegates authority to enforce pesticide regulations to states and some tribes, they are very much our regulatory partners and have an integral role in FQPA implementation. State and tribal regulators interact directly with pesticide dealers and commercial applicators, as well as farmers and others who use pesticide products. Thus, they are in a unique position to help collect information on pest control needs, current pesticide use practices, and the potential impacts of changes in pesticide availability that may result from decisions taken to meet FQPA mandates. State and tribal agencies also have the role of communicating regulatory decisions to the user community, and in providing information and training in the use of alternative pest control methods to replace highly toxic products that may not meet the new safety standards of FQPA. Much of the routine exchange of information and coordination between states, tribes and EPA occurs within the Agency's 10 regional offices.

Dialogue with states is important for providing feedback on the field impact of pesticide regulations, policies, and product registration and labeling decisions. EPA interacts with states in a number of different forums. Regular meetings are held with organizations consisting solely of state representatives, such as the State FIFRA Issues Research and Evaluation Group, and states are represented on the Agency's broad stakeholder advisory groups, such as the Tolerance Reassessment Advisory Committee and the Pesticide Program Dialogue Committee.

EPA headquarters and regional offices work closely with states on pesticide field programs such as groundwater and endangered species protection, worker protection, and certification and training of pesticide applicators. EPA and States also work together on special efforts such as the emergency response to the misuse of methyl parathion, which began in 1994. EPA is investigating ways states can play a more active role in supporting minor use pesticides and facilitating the emergency exemption process under Section 18 of FIFRA. Since FQPA amended FIFRA to require tolerances for uses granted an emergency exemption, EPA issued guidance to states and increased efforts to discuss potential applications with states prior to submission. This allows the Agency to provide a preliminary indication as to the likelihood that a tolerance can be established, possibly avoiding situations where crops treated under an emergency exemption are not allowed to be marketed.

EPA maintains an active partnership with over 25 tribes that have pesticide programs. Like states, tribes have primary responsibility for enforcing federal pesticide laws on tribal lands. With help from states, EPA provides support to tribes wishing to identify and monitor pesticide use and develop programs to educate pesticide users on proper techniques and available pest control methods. EPA and tribes are developing a national Tribal Pesticide Program Council that will work to address tribal pesticide program needs and technical issues. The agency also assists tribes with specific issues through activities such as workshops on the Pesticide Management Plan rule, which is scheduled to be promulgated in 2000.

A new approach, being used in EPA's Region 10 (San Francisco) office, involves a "circuit rider" staff position. The circuit rider travels among reservations in the region and provides technical assistance on pesticide regulatory issues. The circuit rider concept is one that EPA is considering expanding and is a possible mechanism to ensure that tribes are familiar with, and will properly implement, FQPA requirements.

EPA's regional offices serve as a link between the Agency, states, and tribes. They establish and manage cooperative agreements, participate in enforcement activities, and promote community based programs and pollution prevention activities. Regions also play an active role in tracking pesticide imports and assisting with international technical assistance activities. Regional offices help connect EPA with activities undertaken at the state and local level which might be beneficial if conducted on a broader basis. Through grants, regional offices are allowed to reward these activities by providing support and attention not always available on the national program level. In addition, particularly for FQPA and other agricultural issues, EPA regions can help determine the unique effects of a national regulation in an individual state or group of states within the same geographical region.

In Fiscal Year 1998, EPA initiated funding for the Regional Agricultural Initiative. Under this initiative,

Regional Agricultural Initiative

There are currently four pilot projects being conducted by EPA regional offices with the support of headquarters. The objective of the Regional Agricultural Initiative is to increase communication between EPA and stakeholders related to implementation of FQPA. Highlights of the four pilots include:

Region 4 (Atlanta) - enrollment of more than 163 thousand acres of farmland in the Delta F.A.R.M. project (Mississippi), designed to increase the acceptance of best environmental practices, and development of crop profiles in Florida, which will provide better data on current pesticide use.

Region 5 (Chicago) - a pesticide residue study conducted by Michigan State University and the Michigan Department of Agriculture, which will result in more accurate risk assessments for minor use crops.

Region 9 (San Francisco) - a joint project between the California grape industry, the University of California, USDA, and others to develop a comprehensive overview and analysis of the problems faced by grape growers, current pesticide use, and available alternatives.

Region 10 (Seattle) - a cooperative agreement with Washington State University to study biological controls, alternative cropping systems, precision pesticide application, and other mechanical and cultural practices which might mitigate pesticide risk.

regions are provided with money to be used to work with and support state projects specific to FQPA implementation. Four pilot projects were undertaken in 1998 and EPA hopes to expand the effort in the year 2000.

Unique Stakeholders

FQPA contains specific provisions recognizing the uniqueness, and importance, of two segments of the regulated community. Antimicrobial pesticides are used in a variety of settings such as hospitals, around the home, and recreational areas. These pesticides may have important public health uses and generally pose less risk than agricultural chemicals. Some agricultural uses of pesticides are termed "minor use" because they are used on limited acreage or they do not provide the registrant with as much economic return as other pesticides. These uses, while termed minor, are often of major significance to consumers and growers. Without these small scale but vital pesticide uses, many of the fruits, vegetables, and ornamentals that we enjoy in the U.S. could not be grown successfully.

Antimicrobial Pesticides

Antimicrobial pesticides are used to control harmful microorganisms including bacteria, viruses or fungi in/on inanimate objects and hard surfaces. Antimicrobial products include sterilants, disinfectants, and sanitizers, as well as swimming pool chemicals, wood preservatives, and antifoulant paints. Antimicrobial products also include public health pesticides. To obtain registration for antimicrobial products, manufacturers are required to meet general standards of FIFRA. For public health pesticides, registrants must also submit detailed efficacy data to document their claims against specific microorganisms. Prior to FQPA, FIFRA contained no separate provisions for regulating antimicrobial products. EPA shared regulatory responsibilities with FDA for some products, and gave no particular review priority to antimicrobial products over other types of pesticide products.

Antimicrobial Review Timeframes

- 540 days for a new antimicrobial active ingredient
- 270 days for a new antimicrobial use of a registered active ingredient
- 120 days for any other new antimicrobial product
- 90 days for a product that is substantially similar or identical to a previously registered product (a "me-too" product)
- 90 days for an amendment to an antimicrobial product registration requiring no scientific review
- 90 to 180 days for any other antimicrobial product amendment requiring scientific review.

FQPA required that EPA revise the antimicrobial registration processes to reduce review times for antimicrobial products to less than that of other types of pesticide products. Specific review-time goals for different regulatory actions on antimicrobials are detailed in the law (see Appendix 5). To help

implement FQPA's requirements, an Antimicrobial Division was formed within EPA's Office of Pesticide Programs. This Division has made significant progress towards meeting the FQPA requirements for antimicrobials, including:

- Streamlining the regulatory review process, enabling the Agency to meet all registration deadlines for submissions filed since November 1996;
- Reducing the backlog of registration actions by 98% since the beginning of 1997;
- Clarifying the roles of EPA and the Food and Drug Administration concerning regulation of antimicrobial pesticides that come in contact with food, and the use of liquid chemical sterilants;
- Issuing draft guidance to help prevent the public from being misled that certain products (e.g., paint treated with a pesticide to protect the paint coating) actually protect consumers from germs and bacteria.

Minor Use Pesticides

In response to FQPA, and the needs of the minor use growers, EPA established a Minor Use Team which is drawn from throughout the Pesticide Program and is headed by a Minor Use Officer. The Minor Use Team has three primary goals:

- obtaining and using the best available data to support minor use tolerances;
- working more closely with the minor use grower community early in the regulatory process; and;
- promoting the use of safer pesticides for minor uses by urging manufacturers to research and expedite registrations for lower risk pesticides.

With the help of the Minor Use Officer, EPA has strengthened its communication with minor use growers and has helped bring growers and registrants together earlier in the registration process. In addition, by including minor use representatives on the TRAC, the Agency has helped bring the issues surrounding these important uses to the attention of other stakeholders.

Pesticide Environmental Stewardship Program

Although the Pesticide Environmental Stewardship Program (PESP) was initiated in 1994 before FQPA was enacted, the goals of program are consistent with those of FQPA. The PESP is a partnership between EPA and pesticide user groups to reduce pesticide risk in agricultural and nonagricultural settings. The guiding principle for PESP is reduction of pesticide risk through various means. Organizations who elect to become PESP members develop strategies for their organization that use Integrated Pest Management (IPM), grower education, use reduction, improved application techniques, and other methods to reduce risks from the use of pesticides. PESP Partners (pesticide user groups) and Supporters (organizations who work with pesticide user groups) number over 100 at this time (see Appendix 7). Each organization has an EPA Liaison who works with the Partner or Supporter to enhance communication between the user community and EPA.

EPA has small incentives grant programs to assist Partners and Supporters in implementing their risk reduction strategies. These grants, for example, may help a Partner learn to use a new alternative pesticide which would replace a more toxic pest control. These grants support both laboratory and field research as well as a number of training programs. PESP is committed to helping its members protect public health, the environment, and the food supply in the US through the use of efficient, cost effective pest control practices.

FQPA Progress Report Appendices

Appendix 1

The Scope of Pesticide Regulation

Pesticides subject to EPA regulation include insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators and other substances intended to control pests. Pesticides have many uses: in agriculture, greenhouses, and on lawns; in swimming pools, industrial buildings and households; and in hospitals and food service establishments. Overall, there are about 20,000 registered pesticide product formulations, containing over 900 active ingredients and 1,835 inert 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. Within EPA's Office of Pesticide Programs (EPA), over 800 people in nine divisions carry out activities relating to pesticide regulation and management. In addition, a large number of people in other EPA offices, including regional offices, provide administrative, legal, enforcement, and research support to the pesticide program.

Statutory Framework: EPA's Role in Food Safety

EPA regulates pesticides under two major statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA requires that pesticides be registered (licensed) by EPA before they may be sold or distributed for use in the United States, and that they perform their intended functions without causing unreasonable adverse effects on people or the environment when used according to EPA-approved label directions.

FFDCA authorizes EPA 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. Due in no small measure to EPA's work under these two laws, Americans enjoy one of the safest, most abundant, and most affordable food supplies in the world.

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. Study requirements are tiered to the intended use and certain properties of the pesticide. 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, the Agency may take action to suspend or cancel its registration and revoke the associated tolerances. EPA may also undertake an extensive special review of a pesticide's risks and benefits or work with manufacturers and users to implement changes in a pesticide's use (such as eliminating use on some crops, reducing application rates, or cancellation of a pesticide’s uses). As part of its ongoing

reregistration program, EPA is systematically reviewing all older pesticides registered before November 1984, to ensure that they meet current testing and safety standards.

While EPA is responsible for making registration and tolerance decisions, the Agency relies on others to carry out enforcement activities. Registration-related requirements under FIFRA are enforced by the states. Tolerances are enforced by the Department of Health and Human Services/Food and Drug Administration for most foods, and by the U.S. Department of Agriculture/Food Safety and Inspection Service for meat, poultry, and some egg products.

Appendix 2

Status of FQPA Statutory Deadlines

Endocrine Disruptors Screening and Testing Program

Develop an Endocrine Disruptor screening program [FFDCA 408(p)(1)]	August 3, 1998	Endocrine Disruptors Screening and Testing Advisory Committee final recommendations submitted August 1998. EPA used these as the basis for its proposed program, beginning in 1998.
Implement program to screen and test endocrine disruptors [FFDCA 408(p)(2)]	August 3, 1999	Validation program underway
Report to Congress on screening and testing program [FFDCA 408(p)(7)]	August 3, 2000	EPA will meet this deadline

FIFRA Section 18 (Emergency Exemption) Tolerances

Publish final regulation outlining process for establishing Section 18 tolerances [FFDCA 408(l)(6)]	August 3, 1998	Proposal published on June 3, 1999; comment period runs through August 2, 1999. Final rule in 2000.

Tolerance Reassessment

Publish general schedule for tolerance reassessment [FFDCA 408(q)(3)]	August 1997	Completed August 1997
Complete 33% of reassessments [FFDCA 408(q)(1)(A)]	August 1999	Agency has met this deadline; 3290 tolerances reassessed by August 2, 1999.
Complete 66% of reassessments [FFDCA 408(q)(1)(B)]	August 2002	Agency will meet this deadline
Complete 100% of reassessments [FFDCA 408(q)(1)(C)]	August 2006	Agency will meet this deadline

Tolerance Fees

Require fees sufficient to cover costs of processing tolerance petitions [FFDCA 408(m)(1)]	No set time	Proposed rule published on June 9, 1999; comment period runs through September 9, 1999. Final rule in 2000.

Consumer Right-to-Know

Publish Consumer Brochure [FFDCA 408(o)]	August 1998	Final Brochure published and distributed in February 1999

Minor Uses

Publish progress report on the registration of minor uses in Federal Register [FIFRA 31(b)]	August 1999	EPA is working with USDA, IR-4, and minor use stakeholders to prepare the report

Reduced Risk Pesticides

Develop procedures/ guidelines for implementing expedited processing/review of reduced risk and biological pesticides [FIFRA 3(c)(10)(B)]	August 1997	Published as Pesticide Registration Notice 97-3 on September 4, 1997

Antimicrobial Pesticides

Submit first annual report on antimicrobial regulatory reform progress to Congress [FIFRA 3(h)(4)(A)]	No later than March 1 of each year, beginning in 1997	First report submitted in October 1997. The second report will be submitted October 1999.
Publish proposed Antimicrobial Reform Regulation [FIFRA 3(h)(3)(A)]	May 1997 (not later than 270 days after enactment of the law)	Publication of Proposal expected September 1999
Final Antimicrobial Reform Regulation [FIFRA 3(h)(3)(B)]	Not later than 240 days after close of comment period for the proposed rule	Final rule planned within eight months of the proposed regulation.

Reregistration

Adopt accounting rules, approved by GAO and the IG, to ensure that fee money is allocated to reregistration and fast track actions [FIFRA 4(k)(2)(A)(i)]	Effective October 1, 1997	Cost accounting standards have been adopted. Procedures are reviewed in detail by the IG each year as part of the formal audit mandated by the CFO Act of 1990.
Publish report on progress of reregistration and projected completion for remaining cases [FIFRA 4(l)]	No set time - language calls for EPA to "...establish and publish annually"	Report for FY `97 was published in the Federal Register on October 7, 1998; report for FY `98 is under review and is expected to be published in September 1999.

Data Coordination

Develop process to address disparities between state and federal data requirements [FIFRA 3(c)(2)(b)(viii)(III)]	August 1997	Workgroup was formed with SFIREG and registrants; severity of problem was evaluated and all agreed that no formal action was needed; if future problems arise, workgroup will act as mechanism for addressing them.

Periodic Registration Review

Establish a process for the periodic review of pesticide registrations, with a goal of review every 15 years [FIFRA 3(g)(1)(A)]	No specific deadline for development	Advanced Notice of Proposed Rulemaking, covering procedural issues, is under development; We have begun pilot projects using current authority to determine if construct of review process is practical.

Appendix 3a

Review Process for the Organophosphates

Phase 1 (30 days) -- **Registrant "Error Only" Review:** EPA sends its preliminary human health and ecological risk assessments to registrant(s) of the pesticide and the U.S. Department of Agriculture (USDA) for a 30-day review. They are asked to identify any computational or other errors that EPA may have made in developing its preliminary assessment of the pesticide's risks.

Phase 2 (up to 30 days) -- **EPA Considers Registrants' and USDA's Comments:** EPA summarizes and considers comments from registrants and USDA. If necessary, EPA incorporates comments or makes changes in the preliminary risk assessment to correct any errors identified. By the end of this phase, EPA opens a Public Docket for the pesticide.

Phase 3 (60 days) -- **Public Comment on Preliminary Risk Assessment:** EPA publishes a Federal Register (FR) Notice of Availability announcing its preliminary risk assessment, opening a 60-day public review and comment period. Registrants, grower groups, other stakeholders, and the public are encouraged to submit data and other information to revise EPA's preliminary risk assessment. They also may begin submitting proposals to address any risk concerns identified in the document. EPA may meet with registrants and other stakeholders to discuss risk related data, use information, and risk assessment / risk mitigation alternatives.

Phase 4 (90 days + USDA review and public meetings/briefings) -- **EPA Revises Risk Assessments, Holds Public Meetings/Technical Briefings:** EPA summarizes and considers comments, data and risk mitigation proposals received during Phase 3, develops a revised risk assessment, and sends it to USDA for review. EPA and USDA host public meetings or technical briefings to share the revised risk assessment with stakeholders and the public and to discuss risk management ideas.

Phase 5 (60 days) -- **EPA Solicits Risk Management Ideas:** EPA releases the revised risk assessment to the public for viewing via the OP Public Docket. EPA publishes an FR Notice of Availability opening a 60-day public consultation period during which risk management proposals are solicited. Registrants, grower groups, other stakeholders and the public are encouraged to participate and submit their risk management proposals. EPA and USDA may meet with registrants and other stakeholders to discuss risk management alternatives and strategies. Meeting minutes are included in the Public Docket.

Phase 6 (up to 60 days) -- **EPA Develops Risk Management Strategies:** EPA considers all risk management proposals received. With input from USDA, EPA develops risk management strategies that ultimately will contribute to the Agency's risk management decisions for the OPs.

Appendix 3b

Examples of Risk Reduction through REDs

The following examples illustrate the ways in which risks, especially risks to children, are being reduced through post-FQPA REDs (Reregistration Eligibility Decisions).

Chlorothalonil - Used to control foliar diseases of vegetable, field, and ornamental crops and to control mildew in paint. Homeowner uses include paint additive, ornamental plant, and turf uses. Cholorothalonil poses a cancer risk to occupational and residential handlers, and to toddlers exposed through home lawns. To protect toddlers and residential handlers, the home lawn use was deleted through the RED; all chlorothalonil products are prohibited for use on home lawns. In addition, paint additive products containing chlorothalonil must be labeled to prohibit over-the-counter and retail sale, and in-container preservative products are prohibited. An impurity limit for technical and manufacturing use products must be met by January 2003 or registrations will be canceled. To protect workers, engineering controls (water soluble bags or closed systems), increased Personal Protective Equipment (PPE) and Reentry intervals (REIs), and application restrictions are imposed. To protect wildlife, many application rates are reduced and buffers are required, as are surface water, ground water, and aerial drift reduction advisories.

DEET - Widely used among the U.S. population, including children, DEET is one of the few residential-use pesticides applied directly to the skin. It is an insect repellent used in households, on the human body and on clothes being worn, and on cats, dogs, horses, and pet living and sleeping quarters. DEET has been implicated with seizures in children but data are insufficient to establish DEET as the cause. DEET does not appear to pose a significant health risk to the general U.S. population. To protect children and others vulnerable populations, however, EPA believes it is prudent to require improved label warnings and use restrictions, including 14 statements informing users/consumers about safe methods of application, special precautions for children, and directions for medical attention. Products that contain DEET and sunscreen together are not eligible for reregistration pending consultation with outside agencies and groups.

Iprodione - A fungicide used on a variety of field, fruit and vegetable crops, ornamentals, lawns and golf courses, iprodione is a Group B2 carcinogen and causes developmental and reproductive effects. All residential uses were voluntarily canceled through the reregistration process due to cancer risk concerns. Acute dietary risk and aggregate cancer risk from dietary, residential, and water exposure are acceptable with risk mitigation measures identified in the RED, including increased pre-harvest intervals and reduced tolerances for strawberries and stone fruit. The belly grinder application method is prohibited to protect handlers. Other handler risks are acceptable with engineering controls, enhanced PPE, extended REIs, limiting the number of applications per season, and other application restrictions. The herbaceous ornamental seed treatment use was voluntarily canceled to mitigate risks to birds. With risk mitigation, including a vegetative buffer strip requirement, other ecological risks are acceptable.

Appendix 4

National Academy of Sciences Recommendations

In 1988, the U.S. Congress requested that the National Academy of Sciences establish a committee within the National Research Council to study scientific and policy issues concerning pesticides in the diets of infants and children. The committee on Pesticide Residues in the Diets of Infants and Children was charged with examining what is known about exposures to pesticide residues in the diets of infants and children, the adequacy of current risk assessment methods and policies, and toxicological issues of greatest concern.

In 1993, the National Academy of Sciences published the committee's report entitled, "Pesticides in the Diets of Infants and Children." The committee concluded that estimates of expected total exposure to pesticide residues should reflect the unique characteristics of the diets of infants and children and should account also for all non-dietary intake of pesticides. A progress report on the committee's specific recommendations follows.

NAS Recommendation #1: Tolerances

EPA should modify its decision-making process for setting tolerances so that it is based more on health considerations than on agricultural practices. These changes should incorporate the use of improved estimates of exposure and more relevant toxicology, along with continued consideration of the requirements of agricultural production. As a result, human health considerations would be more fully reflected in tolerance levels. Children should be able to eat a healthful diet containing legal residues without encroaching on safety margins. This goal should be kept clear.

> ***EPA Implementation:*** Beginning in 1994 and increasingly since the enactment of the Food Quality Protection Act of 1996 (FQPA), EPA has made numerous changes to its tolerance setting process that strengthen the protections for infants and children. FQPA amended the food safety laws to establish a single, health-based safety standard for all pesticide residues in food. Under FQPA, EPA must specifically determine that each newly established tolerance is safe for infants and children. In addition, FQPA requires the Agency to reexamine all existing tolerances against its new safety standard, and bring them into compliance if they are not safe. EPA has changed many aspects of its risk assessment process to improve its ability to assess exposure more accurately and to strengthen its capacity for understanding the potential for chemicals to pose greater toxicity to children. As a result of these new approaches, EPA is confident that its decisions fully protect infants and children from risks due to pesticide use on food.

NAS Recommendation #2: Toxicity Testing

Toxicity testing procedures must be developed that specifically evaluate the vulnerability of infants and children. Testing must be performed during the developmental period in appropriate animal models, and the adverse effects that may become evident must be monitored over a lifetime. Of particular importance are tests for neurotoxicity and toxicity to the developing immune and reproductive systems. Careful attention to interspecies differences in pharmacokinetics and metabolism of pesticides and the relative ages at which organ systems mature is essential. It is also important to enhance understanding of

developmental toxicity, especially in humans, during critical periods of postnatal development, including infancy and puberty.

> ***EPA Implementation:*** EPA has developed and published new guidelines for conducting studies to evaluate the potential of pesticides to cause neurotoxicity (effects on the nervous system), immunotoxictiy (effects on the immune system), and developmental neurotoxicity (effects on the nervous system of newborns and the young). EPA has begun a data call-in program to require acute, subchronic and developmental neurotoxicity data for at least 140 pesticides. We wil aslo revise our current rule on data requirements to reflect these test guidelines. In addition, EPA is making greater use of information on the pharmacokinetics and metabolism of pesticides in its risk assessments.

NAS Recommendation #3: Uncertainty Factors

Because there exist specific periods of vulnerability during postnatal development, an uncertainty factor up to the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete.

> ***EPA Implementation:*** FQPA requires EPA to apply an additional safety factor of 10 in its risk assessments to account for potential for pre- and post-natal toxicity, as well as for the completeness of the toxicity and exposure databases, unless based on reliable, available data EPA determines that a different factor would be safe for infants and children. EPA's approach to implementing this provision, which became effective on enactment, is described in a series of science policy documents that have undergone peer review by the FIFRA Scientific Advisory Panel and that have been recently been made available for comment by the general public.

NAS Recommendation #4: Food Consumption Data

Additional data on the food consumption patterns of infants and children should be collected within narrow age groups because available data indicate that infants and children consume much more of certain foods on a body weight basis than do adults.

> ***EPA Implementation:*** EPA's risk assessments have long taken into account that infants and children typically consume a different blend of foods and more food per body weight than adults do. The food consumption data EPA uses in risk assessment come primarily from surveys conducted by the USDA. Since the 1993 NAS Report, USDA has updated the food consumption data with new studies, and EPA is using the updated information. In addition, USDA is actively working on completion of a survey that provides a significantly larger amount of information on the eating habits of infants and children. The most recent survey data on food consumption will be incorporated into EPA's risk assessments beginning this fall.

NAS Recommendation #5: Pesticide Residue Data

To maximize the utility of pesticide residue data collected by various laboratories, comparable analytical methods and standardized reporting procedures should be used, and a computerized data base should be established to collate data on pesticide residues generated by different laboratories.

-FDA should increase the frequence of sampling of the commodities most likely to be consumed by infants and children, including metabolites and degradates.

-Food residue monitoring should target a special "market basket survey" focused toward the diets of infants and children.

-Pesticide field trial data should be consulted to provide a basis for estimating potential maximum residue levels.

-More information should be gathered on the effects of food processing on levels of pesticides in specific food-chemical combinations potentially present in the diets of infants and children.

EPA Implementation: EPA, working with USDA, FDA, food processors, and chemical companies, have agreed to establish a comprehensive National Pesticide Residue Database. This Database will include information from a variety of sources and will be available for use in pesticide risk assessments.

-Most of the pesticide residue data used in risk assessment come either from field trials performed by chemical companies or from the Pesticide Data Program administered by USDA. In recent years, EPA and USDA have agreed that PDP sampling will focus on commodities that are most likely to be consumed by infants and children. The resulting PDP data have been used extensively in risk assessments for a number of organophosphate insecticides.

-In addition to PDP monitoring, which resembles a "market basket survey" in many respects, EPA is working with individual chemical companies on the design of specialized market basket surveys for specific pesticides or groups of pesticides.

-For over twenty-five years EPA has used pesticide field trial data to estimate the maximum residues likely to remain in treated commodities when they enter commerce. EPA has issued guidelines for collecting, reporting, and analyzing such data; these guidelines are widely followed by chemical companies and others, not only in the United States but also around the world.

-EPA routinely requires studies to determine whether various types of processing will increase or decrease the concentration of pesticides, compared to levels in the raw commodities. Recently, chemical companies, grower organizations, and food processors have been providing additional studies on the impacts of processing on residues. The Agency uses this information in its risk assessments for pesticides.

NAS Recommendation #6: Risk Assessment

All exposures to pesticides – dietary and non-dietary – should be considered when evaluating the potential risks to infants and children. Non-dietary environmental sources of exposure include air, dirt, indoor surfaces, and pets.

-Estimates of total dietary exposure should be refined to consider intake of multiple pesticides with a common toxic effect.

-Risk assessment should include estimates of exposure to pesticides in drinking water and in water as a component of processed foods.

-Given adequate data on food consumption and residues, exposure distributions should be used, rather than single point data to characterize the likelihood of exposure to different concentrations of pesticide residues.

EPA Implementation: FQPA requires EPA to consider both dietary and non-dietary and non-occupational sources of exposure in making decisions regarding the safety of pesticide residues in food. To this end, EPA has expanded the scope of its risk assessments to take into account not only the exposures that occur from residues in food, but also residues in drinking water. Further, EPA aggregates these exposures with exposure that occurs when pesticides are used in and around homes, offices, schools, parks, or other similar sites. In evaluating the risks from these different uses, EPA examines each pathway and route by which people may be exposed: for example, by inhalation of vapor or mist; absorption through the skin following contact with pets, dirt, or treated surfaces; and ingestion of drinking water or treated food.

-In addition, FQPA requires that EPA consider the cumulative effects of pesticides which have a "common mechanism of toxicity," since such chemicals may have a combined impact greater than the risks from exposure to only one compound. EPA expects to have guidance on cumulative risk assessment during the summer of 2000.

-The new food consumption data from USDA which EPA will begin to use this fall, provides information on individual consumption of water, both as drinking water and as a result of use in processing. EPA will be able to combine this information with data on pesticide residues in water to produce more realistic exposure estimates.

- EPA has implemented new risk assessment techniques which provide a description of the distribution of exposure to pesticide residues in food. These "probabilistic" techniques take into account the variability in both food consumption from individual to individual and the variation in the levels of pesticide residues found in food.

Appendix 5

FQPA TRAC SCIENCE POLICY ISSUES AND RELATED PAPERS

FQPA TRAC Science Policy Papers	Status of Draft for Public Comment	Status of Revision after Public Comment
1. Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity	Issued 8/6/98	Issued 2/5/99
2. Office of Pesticide Programs' Science Policy on the Use of Data on Cholinesterase Inhibition for Risk Assessments	Issued 11/5/98 Went to SAP several times.	Expected 10/99
3. Guidance for the Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs	Issued 11/5/98 Went to SAP 3/98	Expected 6/00
4. Proposed Threshold of Regulation Policy When a Food Use Does Not Require a Tolerance	Issued 12/4/98	Expected 8/99
5. Assigning Values to Nondetected/ Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments	Issued 12/4/98	Expected 3/00
6. A Statistical Method for Incorporating Nondetected Pesticide Residues into Human Health Dietary Exposure Assessments	Issued 12/4/98	Merged with #5
7. A User's Guide to Available OPP Information on Assessing Dietary (Food) Exposure to Pesticides	Issued 1/4/99	Expected 3/00
8. Dietary (Drinking Water) Exposure Estimates	Issued 1/4/99 Went to SAP 5/99	Expected 10/99
9. Framework for Assessing Non-Occupational/Non-Dietary (Residential) Exposure to Pesticides	Issued 1/4/99	Expected 12/99
10. Standard Operating Procedures (SOPs) for Residential Exposure Assessment	Issued 1/4/99	Expected 12/99 To SAP 9/99
11. Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern (99.9th percentile)	Issued 4/7/99 Went to SAP as part of #3.	Expected 12/99
12. 10X Task Force and OPP Guidance Documents (three draft documents; one final)	Issued 7/8/99 Went to SAP 5/99	Expected 3/00
13. Standard Operating Procedures (SOPs) for Use of the FQPA Factor	Issued 7/8/99 Went to SAP 5/99	Expected 3/00
14. Guidance for Performing Aggregate Exposure and Risk Assessment	Expected 10/99	Expected 5/00

15. SOP: Interim Guidance for Conducting Aggregate Exposure and Risk Assessment	Merge with #14	Merge with #14
16. Use of the Pesticide Data Program (PDP) in Acute Dietary Assessment	Went to SAP 5/99	Expected 1/00
17. Cumulative Risk Assessment Guidance	Expected 1/00. Hazard part to SAP 9/99; Exposure part to SAP 12/99	Expected 8/00
18. Drinking Water Screening Level Assessment	(Merge with paper #8)	N/A
19. SOP for Drinking Water Assessments, including Reservoir Model	(Merge with paper #8)	N/A
Additional Related Papers		
20. Data for Refining Anticipated Residue Estimates Used in Dietary Risk Assessments for Organophosphate Pesticides	Issued 4/7/99	Expected 3/00
21. Interim Early Assessment Policy for Organosphosphate Pesticides	To Be Determined	To Be Determined
22. The Role of Use-Related Data in Pesticide Risk Assessment and Risk Management	Issued 7/14/99	Expected 2/00
23. Interim Human Studies Policy Guidance	To Be Determined	To Be Determined
24. Guidelines for the Conduct of Bridging Studies for Use in Probabilistic Risk Assessment	Expected 8/99	Merge with #20
25. Guidelines for the Conduct of Residue Decline Studies for Use in Prob. Risk Assess.	Expected 8/99	Merge with #20
26. Quantitative Assessment of Uses of Concern for Drinking Water	Expected 12/99 To SAP 5/00	Expected 7/00
27. Factoring Drinking Water Treatment into Drinking Water Assessments for Pesticides	Expected 2/00 To SAP 5/00	Expected 9/00

(7/21/99)

Appendix 6

EPA's Proposed Endocrine Disruptor Screening Program

EPA outlined its Endocrine Disruptor Screening Program (EDSP) on August 11,1998, and provided greater detail in a proposed policy statement on December 28, 1998. The Agency's proposed EDSP closely follows consensus recommendations provided by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC). The EDSP involves four discrete stages: initial sorting of chemicals; establishment of screening priorities; Tier 1 analysis; and Tier 2 analysis. The proposed EDSP is summarized below, followed by a status report of implementation activities within the Agency.

Initial sorting

Chemicals to be sorted include approximately 900 pesticide active ingredients; 2,500 pesticide formulation inert ingredients; 75,500 industrial chemicals; and 8,000 cosmetics, food additives, and nutritional supplements. EPA may not have regulatory purview over the latter three chemical groups; it will focus its efforts on pesticides, industrialchemicals, and environmental contaminants. In keeping with the EDSTAC recommendations, EPA will continue to collaborate with other appropriate federal agencies (e.g., Food and Drug Administration, National Institute of Environmental Health Sciences) to facilitate examination of the remaining groups of chemicals.

The initial sorting stage will separate chemicals into four categories based upon a review of all existing relevant scientific information. Category 1 includes those chemicals that are unlikely to exhibit endocrine activity and should not be screened (e.g., strong mineral acids and bases, amino acids, sugars, certain polymers, etc.). Category 2 consists of chemicals with insufficient data to determine their potential for endocrine activity. Category 3 includes those chemicals that have sufficient data to bypass screening, but need testing. Finally, Category 4 consists of substances with adequate data which willbe referred to the appropriate agency for hazard assessment.

Priority setting

The Category 2 chemicals (those with insufficient information and data to determine if they are endocrine active) may constitute the largest category, and are therefore of the greatest interest to EPA for priority setting. EPA is presently developing a relational database to consolidate existing databases and information for chemicals. The database will also be used to establish sets of chemicals to be ranked for priority setting.

Tier 1 Screening

No single assay system can presently be used to detect estrogenic and other closely related types of hormonal activity. Therefore a battery of eight assays was proposed as necessary to evaluate endocrine disruption potential. Chemicals that are negative in Tier 1 would be considered to have a low potential for estrogen, androgen, or thyroid activity. Chemicals with positive Tier 1 results move to Tier 2 for a more comprehensive evaluation.

Tier 2 Testing

Tier 2 testing is intended to identify effects due to endocrine disruption and establish dose-response relationships. The Tier 2 tests include the most sensitive developmental life stages and multi-generational effects for mammals, birds, fish, amphibians, and invertebrates.

Implementation of the Endocrine Disruptor Screening Program

EPA has begun to implement its Endocrine Disruptor Screening Program (EDSP) under the deadlines mandated by FQPA. The Agency is focusing its implementation priorities on the explicit statutory mandates of the

FQPA, and will phase in broader discretionary aspects of the program as allowed by available resources. The Agency has already accomplished key implementation steps for its EDSP:

• Convened the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) under the Federal Advisory Committee Act to obtain recommendations from federal and state governments, industry, environmental groups, public health groups, worker protection groups and academic scientists concerning how the Agency should proceed with endocrine disruptor screening and testing (August 1996 to August 1998).

• Accepted EDSTAC's final report of 71 recommendation regarding the development of an endocrine disruptor screening program (October, 1998).

• Consulted with a joint committee of the U.S. EPA Science Advisory Board and the FIFRA Scientific Advisory Panel regarding the scientific merits of the EDSTAC draft recommendations (May,1998).

• Proposed the Endocrine Disruptor Screening Program (August, 1998)

• Published a proposed statement of policy concerning the EDSP and requested public comments (December, 1998).

• Held a workshop to provide public input into the development of the Endocrine Disruptor Priority Setting Database and priority setting approach (January 1999).

• Completed a high-throughput pre-screening (HTPS) feasibility demonstration study (March, 1999). The study indicated that the technology requires additional development prior to regulatory use.

• Convened a formal scientific peer review of the proposed statement of policy concerning the EDSP by a joint committee of the U.S. EPA Science Advisory Board and the FIFRA Scientific Advisory Panel (April, 1999).

• The Agency is engaged in numerous ongoing implementation activities. These include:

-- continuing to develop the Endocrine disruptor Priority Setting Database;

-- working with the international community to validate and harmonize endocrine screening tests;

-- convening an Endocrine Disruptor Standardization and Validation Task Force to accomplish appropriate scientific validation of screening assays;

-- conducting demonstration studies of several screening assays proposed for use in the EDSP.

Appendix 7

Pesticide Environmental Stewardship Program (PESP) Partners

All Service Pest Management, Inc. (FL)
Almond Board of California (CA)
American Electric Power Service Corporation (OH)
American Mosquito Control Association (FL)
American Nursery and Landscape Association (DC)
American Peanut Council (VA)
American Pest Management, Inc. (MD)
Arizona Public Service (AZ)
Artichoke Research Association (CA)
California Citrus Research Board (CA)
California Cling Peach Growers Advisory Board (CA)
California Floral Council (CA)
California Fresh Carrot Advisory Board (CA)
California Lettuce Research Board (CA)
California Pear Advisory Board (CA)
California Pear Growers (CA)
California Pistachio Commission (CA)
California Prune Board (CA)
California Tomato Commission (CA)
Carolina Power & Light (NC)
Central Maine Power Company (ME)
Chevy Chase Village (MD)
City of Davis (CA)
City/County of San Francisco Department of Agriculture (CA)
Connectiv (DE)
Cranberry Institute (MA)
Creative Technology, Inc. (AL)
Daystar Termite Control Inc. (CA)
Delta Pest Control (FL)
Duke Power Company (NC)
Eastern Utilities (MA)
Eden Advanced Pest Technologies (WA)
Edison Electric Institute (DC)
Enviroguard Pest Control (TX)
Environ "Pest Elimination" Inc. (TN)
Fillmore Citrus Protective District (CA)
Florida Fruit & Vegetable Association (FL)
Florida Pest Control Association (FL)
Florida Turfgrass Association (FL)
Georgia Peach Council (GA)
Global Integrated Pest Management (MD)
Golf Course Superintendents Association of America (KS)
Griggs County, ND 319 Water Quality Project (ND)
Hawaii Agriculture Research Center (HI)
Hawaii Banana Industry Association (HI)
Hawaiian Electric Company (HI)
Hood River Grower-Shipper Association (OR)
Kansas Corn Growers Association (KS)
Kansas Grain Sorghum Producers Association (KS)
Lodi-Woodbridge Winegrape Commission (CA)
Massey Services, Inc. (FL)
Michigan Cherry Committee (MI)
Mint Industry Research Council (WA)
Monroe County School Corporation (IN)
National Pest Control Association (VA)
National Potato Council (CO)
Nature's Safeway Pest Control (FL)
New England Vegetable & Berry Growers Association (MA)
New Orleans Mosquito Control Board (LA)
New York Berry Growers Association (NY)
New York City Board of Education (NY)
New York State Gas & Electric (NY)
Northeast Utilities (CT)
Northern Indiana Public Service Corporation (IN)
Northwest Alfalfa Seed Grower Association (WA)
Oregon Wheat Growers League (OR)
Owen Specialty Services, Inc. (MI)
Pacific Coast Producers (CA)
Pear Pest Management Research Fund (CA)
Pebble Beach Company (CA)
Pennsylvania Electric (PA)
Pennsylvania Power & Light (PA)
Pennsylvania Rural Electric Association (PA)
Pest Birds, Inc. (OK)
Pest Police Pest Control (ME)
Pineapple Growers Association of Hawaii (HI)
Processed Tomato Foundation (CA)
Professional Lawn Care Association of America (GA)
Reliable Pest Control (WI)
Roses Inc. (MI)
Sanitary Pest Control Company (NV)
South Dakota Cattlemen's Association (SD)
South Texas Cotton and Grain Association, Inc. (TX)
Sprague Pest Solutions (WA)
Steritech Group, Inc. (MD)
Sunkist Growers (CA)
Sun-Maid Growers of California (CA)
Tennessee Valley Authority (TN)
Texas Association of Nurserymen, Inc. (TX)
Texas Pest Management Association (TX)
U.S. Apple Association (VA)
U.S. Canola Association (DC)
U.S. Department of Defense (DC)
U.S. Hop Industry Plant Protection Committee (WA)
U.S. Public Health Service - Centers for Disease Control and Prevention (GA)

University of Georgia-College of Agriculture & Environmental Sciences (GA)
Utilicorp United (CO)
VA, MD & DE Association of Electric Cooperatives (VA)
Vegetation Managers, Inc. (PA)
Walnut Marketing Board (CA)
Washington State Department of Transportation (WA)
West Virginia Power (WV)
Winter Pear Control Committee (WA)
Wisconsin Ginseng Growers Association (WI)
Wisconsin Public Service Corporation (WI)

Pesticide Environmental Stewardship Program (PESP) Supporters

Agricultural Conservation Innovation Center (SC)
American Association of Pesticide Safety Educators (HI)
Aqumix, Inc. (VA)
Association of Applied Insect Ecologists (CA)
Audubon International (NY)
Bay Area Stormwater Management Agencies Assoc. (CA)
Bio-Integral Resource Center (CA)
Campbell Soup Company (CA)
Claymont Center for Continuous Education (WV)
Del Monte (CA)
Farm*A*Syst / Home*A*Syst (WI)
Gempler's Inc. (WI)
General Mills, Inc. (MN)
Gerber Products Company (MI)
Glades Crop Care, Inc. (FL)
Institute for Agriculture and Trade Policy (MN)
IPM Institute of North America, Inc. (WI)
Maryland Department of Agriculture (MD)
Miami Tribe of Oklahoma (OK)
National Council of Farmer Cooperatives (DC)
Northeast Research, Extension & Academic Program Committee for IPM (NY)
Rainforest Alliance - ECO O.K. Program (NY)
United States Golf Association (NJ)
University of Wisconsin Center for Integrated Agricultural Systems (WI)