

US EPA ARCHIVE DOCUMENT



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# 1996 Food Quality Protection Act

## Implementation Plan

**FOOD QUALITY PROTECTION ACT  
DRAFT IMPLEMENTATION PLAN**

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## **PART ONE**

### **BACKGROUND AND OVERVIEW**

#### **1.1 Introduction**

The U.S. Environmental Protection Agency (EPA) plays a major role in the lives of all Americans through its work to protect human health and the environment from unreasonable risks of pesticides and to ensure that pesticide residues in food are safe.

On August 3, 1996, President Clinton signed into law the most significant piece of pesticide and food safety legislation enacted in many years, the Food Quality Protection Act (FQPA) of 1996. The new law requires major changes in pesticide regulation and affords EPA unprecedented opportunities to provide greater health and environmental protection, particularly for infants and children. Major provisions, once fully implemented, will strengthen health and environmental protection in a number of ways. FQPA will:

- o Establish a single, health-based standard for all pesticide residues in food, eliminating past inconsistencies in the law which treated residues in some processed foods differently from residues in raw and other processed foods
- o Provide for a more complete assessment of potential risks, with special protections for potentially sensitive groups, such as infants and children
- o Require a reassessment of all existing pesticide residue limits in accordance with the new standard of safety
- o Place stringent conditions on the consideration of benefits in setting pesticide residue limits
- o Expand consumers' "right to know" about pesticide risks and benefits; requires preparation of a new brochure on pesticide residues in food for display in supermarkets and grocery stores
- o Ensure that all pesticides are periodically re-evaluated for adherence to current safety standards and are supported by up-to-date scientific data
- o Expedite the approval of safer, reduced risk pesticides
- o Encourage the development of safer, effective crop protection tools for American farmers
- o Establish a more consistent, protective regulatory process, grounded in sound science and adaptable to future advances in scientific understanding.

FQPA has presented EPA with many new directions, assignments and deadlines. The new law did not, however, provide an explicit transition period for implementation. Nevertheless, a transition period or interim approach is needed -- one that allows EPA to increase protection, make efficient use of its resources, and preserve the ability to revisit decisions as the Agency's knowledge expands. 1997 will be a transition year as the Agency implements the new provisions of FQPA. One of the early challenges for EPA has been to put together, with stakeholder participation, a practical and protective approach to decision-making for now and the future.

This document provides an overview of EPA's pesticide regulation responsibilities and summarizes EPA's strategy for implementing the key provisions of FQPA. EPA intends to review its implementation activities on a continuing basis, assess their effectiveness and modify them as necessary. The Agency will issue periodic updates on the status of implementation activities described in this document.

## **1.2 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 approximately 675 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 (OPP), approximately 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.

### **1.3 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. As of March 1, 1997, 148 of 380 pesticide reviews have been completed.

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.

FQPA amends both FIFRA and FFDCA and significantly strengthens the U.S. pesticide regulatory system. Most provisions became effective upon enactment in August 1996. The following sections of this document describe the guiding principles of EPA's implementation of the law, summarize the Agency's approach to implementation of key FQPA provisions, and outline the schedule for major implementation milestones, .

## **PART TWO**

### **GUIDING PRINCIPLES**

EPA is committed to implementing FQPA quickly, effectively and openly. To meet this goal, EPA has developed five key implementation principles to guide the Agency in turning the new law's promise of enhanced food safety into reality:

#### **1. Sound Science**

EPA implementation policies will be based on the best of current science. EPA will expand research on new risk assessment methods and will continue to update the science base underlying regulatory decision-making. Science policies and decisions will be adapted to take advantage of new findings and EPA will subject all new and revised science policies and methodologies to open and vigorous internal and external peer review.

#### **2. Health-Based Approaches to Food Safety**

EPA will take a health-based approach to implementing the new law, especially with respect to establishing safety factors for potentially sensitive populations, such as infants and children. In the absence of complete information, EPA will base its decisions on health protective scientific judgements.

#### **3. Promoting Safer, Effective Pest Control Methods**

As part of its pollution prevention orientation and ethic, EPA will encourage wider adoption of integrated pest management strategies that take advantage of conservation practices to minimize the use of pesticides. The Agency will also continue to work to replace older, high-risk pesticides with safer pesticides that present lower risks to human health, non-target organisms and ground and surface water resources.

#### **4. Openness**

In implementing FQPA provisions and making decisions under the new statute, EPA will employ an open, fair, and consistent process. Public access to information and consultation with stakeholders will be an integral part of policy and program development.

#### **5. Accountability**

EPA is committed to a public accounting of its actions under FQPA and careful management of its resources to achieve the public health and environmental protection goals of the new law. EPA will issue periodic reports on implementation, and will respond in a timely fashion to inquiries regarding progress.



## **PART THREE**

### **IMPLEMENTATION PROCESS:** **COMMUNICATIONS AND STAKEHOLDER INVOLVEMENT**

Consistent with its guiding principles, EPA has widely expanded communications relating to the new law, and is actively soliciting advice and comments on implementation from key stakeholders and the public. EPA is committed to involving all affected parties who wish to participate in the implementation process.

#### **3.1 Communications**

The first step has been to educate the public about pesticide regulation and the new statutory requirements. EPA is working with other government officials, the regulated industry, agricultural and other user groups, food processors, academia, environmental and public interest groups, the international community and the media to reach all interested audiences.

To keep public information up-to-date and easily accessible, EPA has established a special docket which contains materials on FQPA including interim updates on the progress of implementation. This information is also posted on the Internet.

☞ The public docket is open for document viewing and copying Monday through Friday from 8:00 am to 4:30 pm. The Office of Pesticide Programs public docket is located at 1921 Jefferson Davis Highway, Arlington, Virginia, Room 1132; Telephone: (703) 305-5805; Fax: (703) 305-4646.

☞ The FQPA home page can be accessed directly at <http://www.epa.gov/pesticides/lawsregs.htm>

EPA has also mailed information on issues of interest directly to constituents. Publicly available information includes:

- o "Reader's Guides" which discuss, section by section, the FQPA amendments to FFDCA and FIFRA;
- o Public fact sheets which briefly summarize key provisions and discuss major issues of the new law, including comparisons with existing law and practice;
- o Reports on the Food Safety Advisory Committee meetings held between September and December 1996;
- o Speeches given by EPA officials on the implications of FQPA;
- o EPA letters to interested parties (registrants, state lead agencies) concerning implementation plans and handling of registration and emergency pesticide use requests (FIFRA section 18 applications) in light of FQPA requirements;

- o Issue papers on the effect of the new law on registration, reregistration, and risk assessment practices and procedures and;
- o Science policy papers prepared for EPA's Scientific Advisory Panel peer review;
- o Meeting summaries and background issue papers for Pesticide Program Dialogue Committee meetings held every three to four months.

### **3.2 Stakeholder Involvement**

To implement FQPA promptly and effectively, EPA has consulted with key constituencies on a wide range of critical issues. Standing committees providing advice to EPA include:

- o The Food Safety Advisory Committee (FSAC), which concluded its work in December, was a broadly representative committee chaired by Deputy Administrator Fred Hansen and co-chaired by Assistant Administrator Lynn Goldman. It was established to advise EPA on broad strategies for implementing FQPA. The Committee met in open session on several occasions from September through December 1996, and a report of their work is expected in March 1997.
- o The EPA Science Advisory Board (SAB) and the FIFRA Scientific Advisory Panel (SAP) are scientific peer review groups that advise EPA on major scientific issues. They include experts in key scientific and public health disciplines.
- o The Pesticide Program Dialogue Committee (PPDC) is a broadly representative, permanently chartered federal advisory committee that provides advice and guidance to EPA on regulatory development and reform initiatives as well as public policy and regulatory issues associated with evaluating and reducing risks from pesticide use. The PPDC will play an ongoing role in advising EPA on FQPA implementation.
- o The Endocrine Disruptors Screening and Testing Advisory Committee (EDSTAC), established in December 1996, is working to develop a screening and testing program for potential estrogenic and other endocrine disrupting effects under FQPA and the Safe Drinking Water Act Amendments of 1996.
- o The State FIFRA Research and Evaluation Group (SFIREG) and other EPA state and regional stakeholder groups are also participating in FQPA discussions.

The FSAC has been instrumental in helping EPA devise an interim approach to risk management under FQPA. In essence, this high level partnership provided EPA an excellent public forum in which to test ideas, debate issues and develop the basis of an interim approach. EPA will continue to engage in public discussion of the issues through the PPDC, EDSTAC, SAP, SAB and SFIREG. In addition to these more formal groups, EPA is providing opportunity for involvement through a number of public meetings and workshops on specific provisions of the new law. EPA is also consulting other government agencies including the Departments of Agriculture (USDA), Health and Human Services (DHHS) and Justice (DOJ) on a range of issues relevant to improving food safety as directed by the new law.

## **PART FOUR**

### **TOLERANCES - NEW STANDARDS AND FACTORS TO BE CONSIDERED**

#### **4.1 Introduction**

The most significant reforms of FQPA are the broad changes to the tolerance setting procedures. The new law represents a major breakthrough, establishing a consistent, more protective scheme grounded in sound science. It establishes a single health-based safety standard for pesticide tolerances and directs EPA to upgrade its risk assessment process as part of the tolerance setting procedures. Provisions mandating improvements to risk assessment originated in recommendations from a 1993 report, "Pesticides in the Diets of Infants and Children," from the National Academy of Sciences. The report expressed concern that children may be particularly susceptible to pesticide exposure, and should have special protections. Specifically, FQPA requires EPA to:

- o use an extra 10-fold safety factor to take into account potential pre- and post-natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children. A different safety factor may be used only if, on the basis of reliable data, such a factor will be safe for infants and children;

and to consider available information on:

- o aggregate exposure from all non-occupational sources (i.e., dietary and nondietary routes of exposure, such as through drinking water or as a result of household pesticide use);
- o effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity;
- o effects of in utero exposure; and
- o potential for endocrine disrupting effects.

Incorporating these factors into the tolerance setting process poses a challenge, in light of the many scientific uncertainties about how best to address them in risk assessment. While EPA had begun to deal with these issues, many had not been a routine part of past risk assessments and call for new scientific policies and evaluation methods.

EPA has adopted an interim strategy to meet the new risk assessment requirements of FQPA. EPA will use public health protective scientific judgements and interim assessment practices when complete data are lacking. It is important to note that when reliable, specific data are submitted to support an evaluation, this information will take precedence over these scientific judgements. Further, as implementation progresses, EPA will replace interim evaluation procedures with methodologies that have been reviewed by the Science Advisory Panel.

In developing strategies for addressing the FQPA science provisions, EPA has consulted closely with the FIFRA Scientific Advisory Panel and other experts including the members of the FSAC and the PPDC. These groups have provided EPA with expert scientific and policy review and advice on interim approaches to the risk assessment provisions. EPA is continuing to consult with the SAP and the PPDC in updating scientific policies. The Agency is bringing additional scientific issues before the SAP in March 1997 and at subsequent meetings.

The following sections provide more detailed information on EPA's strategies for implementing the new safety standard and risk assessment provisions.

## **4.2 Single Health-Based Safety Standard**

### Background

Under prior law, tolerances in raw foods and in some processed foods were regulated under different sections of the FFDCA. EPA established tolerances for pesticide residues remaining in raw foods under FFDCA section 408. If residues concentrated in processing to a level higher than the raw food tolerance, a separate "food additive" tolerance under section 409 of FFDCA was required to prevent the processed food from being adulterated. The two sections of FFDCA contained different standards for establishing tolerances.

The "Delaney Clause" of section 409 prohibited the establishment of tolerances in certain processed foods where evidence indicated that the pesticide caused cancer in humans or laboratory animals, no matter how low the risk. Section 408, on the other hand, allowed EPA to consider the level of risk and the benefits of pesticide use. A tolerance could be set in a raw food for a potentially carcinogenic pesticide if it did not exceed a "negligible" risk level or if the benefits of the pesticide's use greatly outweighed its risk. One result of the inconsistency between 408 and 409 was that the same pesticide residues which were legal on a raw food could render a processed food unacceptable under the law.

The single, health-based safety standard for pesticide residues in food established by FQPA eliminates the longstanding problems posed by differing standards for pesticides in raw and processed foods under the previous law. FQPA removes the pesticides from Section 409 of the FFDCA, and establishes a single, new standard for all pesticide residues in food under FFDCA Section 408.

Once a tolerance is set under section 408 for a raw agricultural commodity (or an exemption from a requirement for a tolerance is granted by EPA), it applies to residues present at or below that level in any food made from that commodity. If residue levels are higher in a processed food, then a separate tolerance must be set under the same provision. Residue levels in all food must be determined by EPA to be "safe," which under FQPA means "a reasonable certainty that no harm will result from aggregate exposure" to the pesticide, including all exposure through the diet and other non-occupational exposures for which reliable information is available.

### Approach to Implementation:

Prior to passage of FQPA, EPA had revoked or had proposed to revoke a number of pesticide tolerances for processed foods that were subject to the Delaney Clause under FFDCA section 409. As of August 3, 1996, pesticides were no longer subject to the Delaney Clause and it became unnecessary to complete the proposed revocations. Therefore, all proposed revocations and final revocations which had not taken effect were withdrawn, as explained in a notice published in the Federal Register on September 26, 1996.

Also as of August 3, 1996, EPA began issuing all tolerances, both for raw and processed foods, according to the new health-based standard. Further, the Agency will reevaluate all existing tolerances and is establishing tolerances for emergency exemptions according to the new standard, as the law directs. Guidance on how to address the new tolerance requirements was issued in a Pesticide Registration Notice (PR Notice 97-1) in January 1997, to registrants and others who submit tolerance petitions and emergency use requests under FIFRA Section 18.

### **4.3 Special Provisions to Protect Children**

#### **Background**

EPA routinely assesses pesticide risks to a number of human subpopulations, including infants and children, as part of its registration and reregistration decisions. For threshold (generally non-cancer) effects, the Agency takes the lowest level of a substance that produces no observable adverse effects in test animals, and divides it by an uncertainty factor to set a safe level for humans. Historically, EPA has generally applied an uncertainty factor of 100 to the results of animal toxicity studies, to account for the fact that humans may be more sensitive than test animals and certain human subpopulations may be especially sensitive. In addition to the factor of 100, another uncertainty factor sometimes has been added to account for incomplete test data, including, but not limited to insufficient information about risks to infants and children. EPA has used scientific judgement to determine whether such an additional uncertainty factor is needed and if so, what the factor should be; the range typically has been between 3 and 10.

FQPA reflects a national commitment to provide greater assurance that infants and children are protected against pesticide risks. The new law requires an explicit finding that tolerances are safe for children. EPA is directed to use an additional uncertainty or "safety" factor of 10 to protect infants and children against threshold effects unless EPA determines based on reliable data that a different margin will be safe.

In addition to the safety factor, FQPA mandates consideration of available information relating to a number of other factors that are particularly relevant to risk assessment for children. These factors are discussed in later sections of this document.

### Approach to Implementation:

EPA will continue to apply best scientific judgement to interpretations of animal toxicity data to evaluate risks for children. To meet the requirement of the new law, EPA will require an additional tenfold margin of safety if the Agency does not have complete and reliable data to assess pre- or post-natal toxicity relating to infants and children, or if the data indicate pre- or post-natal effects of concern. When data are incomplete, EPA will use an additional safety factor between three and ten based on how much information is incomplete. Where reproductive and developmental data have been found acceptable by EPA, and the data do not indicate potential pre- or post-natal effects of concern, the additional tenfold margin of safety will not be applied. This approach is consistent with the recommendation of the FIFRA Scientific Advisory Panel resulting from a meeting on this issue in October 1996.

Each tolerance decision issued after August 3, 1996 will contain a specific safety finding for children. Each decision will clearly address hazards and exposure estimates for children as well as the application of any additional safety factor. EPA issued guidance in PR Notice 97-1 on 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.

EPA will continue to refine the process for assessing risks to infants and children. Even before passage of FQPA, EPA had begun updating its pesticide toxicity testing guidelines to enable the Agency to better assess risks to infants and children. In 1996, the Agency proposed updated testing guidelines for animal studies on prenatal development and reproduction and new guidelines on effects to the immune system. The SAP reviewed all three guidelines, concurred with the improved guidelines and made recommendations on revisions to the proposed immunotoxicity guideline.

#### **4.4 Aggregate Exposure**

##### Background

In assessing the risk of a food-use pesticide, EPA traditionally estimated total dietary exposure from all foods containing residues of the pesticide (if it was registered for use on more than one crop). While the Agency might examine several exposure pathways in addition to food (drinking water, residential sources or other exposures), the exposures and resultant risks were expressed individually, not as a combined risk.

One of the recommendations in the report "Pesticides in the Diets of Infants and Children" stated that the total exposure to pesticides from all sources should be combined. In response to this report, EPA began to examine the appropriateness of combining exposures from multiple sources. Since the report was issued in 1993, EPA has conducted risk assessments for some pesticides that take into account non-food exposures in addition to food exposures. For most pesticides, however, EPA has lacked data to characterize other, non-food sources of exposure including drinking water, residential uses and other sources.

FQPA mandates regular consideration of aggregate exposures from food **and** non-occupational sources as part of EPA's evaluation of whether a tolerance can be set that meets the



standards of the law. The law directs EPA to account for sources of exposure such as drinking water, residential uses and lawn care use.

### Approach to Implementation

EPA must develop new data and exposure models to estimate specific pesticide exposures from non-food sources. Until such information is generated and validated, EPA will estimate aggregate risk using an interim approach that relies upon health protective scientific judgements to estimate the relative contributions of food and sources other than food and occupational to total exposure.

EPA has developed an interim decision logic which it believes will adequately protect public health and allow timely decisions to be made while additional information is under development. The decision logic is designed to be workable with available data and methodologies. It is applicable to decisions to grant or deny tolerances for emergency exemptions (section 18s), new active ingredients including safer chemical registrations, new uses including minor uses, and reregistrations. When adequate data and modeling information are available, these will be used in place of scientific judgements. Further, as new exposure data and improved estimation methods are developed reflecting the FQPA requirements, decisions based on the interim logic will be revisited and modified as appropriate.

### **“The Risk Cup”**

EPA's interim decision logic is based on the concept that the total level of acceptable risk of a pesticide is represented by the pesticide's Reference Dose (RfD). For a chronic health hazard, this is the level of exposure to a specific pesticide that a person could receive every day over a seventy-year period without experiencing appreciable risk. For a risk from an acute exposure (e.g., acute poisoning or developmental effects) this is the level of exposure to a specific pesticide that a person could receive in one day with no appreciable risk.

The analogy of a “risk cup” is being used to describe aggregate exposure estimates. The full cup represents the total RfD or corresponding acute toxicity level: each use of the pesticide contributes a specific amount of exposure that adds a finite amount of risk to the cup. As long as the cup is not full, meaning that the combined total of all sources of estimated exposure to the pesticide has not reached 100% of the RfD or acceptable acute toxicity value, EPA can consider registering additional uses and setting new tolerances. If it is shown that the risk cup is full or exceeded, no new uses could be approved until the risk level is lowered. New uses could be granted if the registrant provides new data indicating lower exposures or hazards or if EPA takes measures to reduce the total risk level.

An important issue for making interim decisions which take aggregate exposure into account is how much of the “risk cup” should be set aside or reserved for sources of exposure for which the Agency has limited or no data. It is expected that over the ten-year tolerance assessment program these data will become available. Unless actual exposure data are available for these sources of exposure, (e.g., residential and drinking water), the size of the “reserve” portion will be based on various characteristics of the pesticide, such as toxicity, mobility and persistence in soils, and use pattern. In the interim, a portion of the risk cup will be set aside for non-dietary exposures for most pesticides for which there is likely to be some exposure from these sources. The remainder of the risk cup will be left for risk from residues in food for which reliable data are

available. However, for pesticides with particularly high toxicity or exposure, the registrant will be asked to provide data or explain why actual exposures to pesticides from food, drinking water and residential uses are lower than predicted. (This description is based on chronic threshold risk; but the same process will be applied to both short-term and intermediate effects risk assessments).

The interim decision logic for risk, as described above, applies when EPA lacks data to estimate specific exposures from the various routes. If data are available which permit a more precise estimate of exposure from a particular route, that information will be used to assign the appropriate portion of the risk cup for that route rather than the more general scientific judgements. The decision logic will be revised and updated as new exposure data are generated and as methodologies are developed. The Agency's proposed approach to aggregate exposure will be reviewed by the FIFRA SAP in March 1997.

For the long-term, EPA will devote resources to developing new exposure assessment methods and information to more precisely evaluate aggregate exposure and, specifically, the contributions from drinking water, lawn care and other residential uses of pesticides. Registrants will need to develop and submit to EPA data on these sources of exposure. Guidance on the types of information the Agency needs to evaluate aggregate exposure is contained in PR Notice 97-1.

EPA expects to collect new sophisticated information on pesticide exposures from home and lawn care uses through a formal call for data, issued in March 1995. The Outdoor Residential Exposure Data Call-In, or OREDCI is a project sponsored by EPA, the California Department of Pesticide Regulation (CDPR) and the Pest Management Regulatory Agency (PMRA), the Canadian government agency responsible for regulating pesticides. The three agencies put together a data call-in program designed to overhaul and upgrade the existing residential exposure data base which is limited. The OREDCI required data on exposure to professionals and homeowners from mixing and applying pesticides to home lawn uses. It will also generate data on pesticide exposures to homeowners when re-entering their lawns after a pesticide treatment.

To respond to OREDCI, industry established a task force which is working with the regulatory agencies to provide accurate, reproducible, comprehensive data on a wide range of residential exposures. From the results of the studies submitted by the task force, EPA will develop a data base with detailed information on the routes, duration and frequency of exposures from outdoor residential applications. EPA expects to be able to develop specific exposure profiles on professionals and homeowners and their families including adults, children and adolescents, that are reflective of the unique exposure patterns of each group. Data on mixing and application exposures are expected to be submitted to EPA beginning in 1998, and from 1999 to 2000, data on re-entry exposures will be submitted. As the information comes in and is evaluated, EPA will develop a state-of-the-art electronic data base on residential exposures for use in risk assessments.

Data on residential exposures to pesticides will be further improved as a result of research underway in EPA's Office of Research and Development (ORD) to support the development of testing guidelines on exposure. EPA is developing guidelines on monitoring and assessing exposures to pesticides and consumer use products following residential applications. These guidelines will improve data generation on lawn and garden exposures from skin contact and non-dietary ingestion (e.g., hand-to-mouth contact) and other residential exposures. ORD's research



will also support the development of exposure assessment models, with a special emphasis on children's exposures.

EPA expects to complete interim guidelines by the end of 1997 and to take these guidelines to the SAP in 1998.

#### **4.5 Common Mechanism of Toxicity**

##### **Background**

EPA has long recognized that two or more chemicals may cause adverse health effects through the same major pathway or "common mechanism of toxicity." Concurrent exposure to multiple chemicals with common mechanisms of toxicity may increase risk due to additive or "cumulative" effects. In the past, EPA has not routinely factored cumulative effects into pesticide risk assessments on related pesticides, because the Agency has usually lacked data and scientifically validated methods for determining which chemicals share common mechanisms of toxicity.

Under the new law, EPA is directed, when considering whether to establish, modify or revoke a tolerance, to take into account available information concerning the cumulative effects of a pesticide and other substances that have common mechanisms of toxicity.

##### **Approach to Implementation**

EPA is developing a policy for assessing the cumulative effects of pesticides and other substances sharing common mechanisms of toxicity. Agency scientists are preparing proposed guidance that will define the meaning of the term "common mechanism of toxicity," describe the kinds of data needed to infer that a group of pesticides and other substances act by common mechanisms of toxicity, and discuss ways to group chemicals based on similarities in their chemical properties. EPA will take this guidance to the SAP for review and comment in March 1997.

At the March SAP meeting, EPA will also present a case study on a specific group of pesticides that applies the proposed principles for determining whether a group of pesticide chemicals share common mechanisms of toxicity. A candidate series of chloroacetanilide pesticides was chosen, based upon structural similarity, for evaluation as chemicals that may cause toxic effects through the same pathways. EPA is evaluating which toxic effects are common to more than one chemical in the group, mechanisms that indicate how these effects may be caused, and other biological data that provide evidence on which chemicals may act similarly to one another. Using a weight-of-the-evidence approach, the Agency will draw conclusions on how the candidate pesticides can be clustered with regard to common mechanisms of toxicity. EPA is asking the SAP to provide comments and guidance on the proposed approach.

The next step is to develop proposals on how to combine exposures from chemicals with common mechanisms of toxicity. EPA will then need to determine how to quantify cumulative risk for a group of chemicals that act by common mechanisms of toxicity and share exposure

pathways. EPA plans to discuss these issues with the SAP at a meeting in June 1997 and at subsequent meetings.

EPA is further considering common mechanism of toxicity issues through a cooperative agreement with the International Life Sciences Institute's (ILSI) Risk Science Institute (RSI). RSI has organized a work group to address common mechanism of toxicity questions, using organophosphate pesticides as a case study. The work group includes scientists with expertise in organophosphate mechanisms and in general toxicology and risk assessment. This group will identify organophosphate chemicals that can be assessed together based on common mechanisms of toxicity. They will also develop methods to quantify the risks from multiple sources of exposures to these chemicals. Between March 1997 and September 1997, the work group intends to meet at least three times to draft a paper on the case study. RSI is sponsoring a workshop in September 1997 to discuss the workgroup's findings and recommendations. Based on discussions at the workshop, the work group will revise their paper and submit it for publication in a peer-reviewed journal.

Based on the conclusions of the ILSI RSI paper, EPA will develop a process for evaluating cumulative exposures to organophosphate pesticides that exert toxic effects through common mechanisms. The SAP will be asked to comment on EPA's proposed process at a meeting by the Fall of 1997. The Agency intends to initiate comprehensive cumulative risk assessments for selected groups of organophosphate pesticides in January 1998.

While this work is underway, EPA is using an interim approach to implementing the common mechanism of toxicity provision of FQPA. EPA's intention is to continue to make timely regulatory decisions that are protective of public health and the environment. In making tolerance decisions associated with registration and reregistration, the Agency will determine whether:

- 1) sufficient information exists to determine that a pesticide does not appear to share a common mechanism of toxicity with other substances; or
- 2) information is not sufficient to conclude that a pesticide does not share a common mechanism of toxicity with other substances.
- 3) information is sufficient to conclude that a pesticide does share a common mechanism of toxicity with other substances.

For a pesticide falling into the first category, EPA will explain its reasoning and make a tolerance decision for the chemical. For a pesticide falling into the second category, the Agency will conclude that available information on common mechanism of action is not sufficient to factor it into the tolerance decision at this time. The tolerance decision will be based upon the risk assessment of the individual chemical, and will not consider cumulative effects. A tolerance established for a pesticide in category two may be revisited, however, if later information clearly indicate that the pesticide does share common mechanisms of toxicity with other chemicals. For a pesticide falling into the third category, EPA will perform a cumulative risk assessment upon which the Agency will base a regulatory decision.

#### **4.6 In Utero Testing for Carcinogenic Effects**

## Background

The National Academy of Sciences 1993 report, "Pesticides in the Diets of Infants and Children," recommended that EPA develop toxicity testing procedures that specifically evaluate the vulnerability of infants and children, including to carcinogenic pesticides. EPA had long given careful consideration to the carcinogenic potential of pesticides to infants and children using the results of standard carcinogenic bioassays. The Agency determined on a case-by-case basis, based on a weight-of-the-evidence assessment of all of the available information, whether to require additional testing that would focus on the effects of pre- and peri-natal exposure to carcinogenic pesticides.

The new law requires EPA, when evaluating the special susceptibility of infants and children to pesticide exposure, to give specific consideration to available information on "the effects of in utero exposure to pesticide chemicals." The law enhanced the importance of examining the value of cancer testing that includes pre- and peri-natal exposures.

## Approach to Implementation

EPA has evaluated whether or not the Agency should routinely require as part of its carcinogenicity assessments a pre- and peri-natal study to adequately determine a pesticide's carcinogenic potential for children. A perinatal study includes exposure of the maternal animals to the test chemical prior to mating, during gestation and through weaning of the offspring: the offspring are also exposed to the chemical until 8 weeks old and are the animals used for the 2-year cancer study.

To help decide the matter, EPA reviewed the results of other scientific investigations on the issue of carcinogenic responses as a function of age at first exposure and conducted an independent evaluation of relevant cancer studies obtained from the Food and Drug Administration and the National Toxicology Program. EPA concluded that the currently available data do not support routine incorporation of perinatal exposure into standard cancer testing. The available data base for drawing conclusions was not large, however.

Therefore, to address the NAS concerns and the requirements of FQPA, EPA plans to develop criteria on when to include perinatal exposure as part of the cancer testing requirement and will apply these criteria on a case-by-case basis. EPA's conclusion is consistent with FDA's approach. FDA has developed a set of criteria for determining candidates for perinatal carcinogenesis studies based on use, exposure and toxicity observed in developmental and reproduction studies.

EPA's evaluation is further supported by the FIFRA Scientific Advisory Panel. At the October 1996 SAP Meeting, the Panel supported the Agency's proposal to require perinatal testing on an as-needed basis. EPA will continue using a weight-of-the-evidence approach based on all available toxicity studies including studies from the new testing guidelines on prenatal effects. The Panel encouraged the Agency to develop explicit criteria for when to require perinatal testing and to use the FDA criteria as a starting point. EPA is now developing these criteria and expects to take a proposal to the SAP later this year.

## 4.7 Endocrine Disruptors

## Background

In recent years, concern has increased about the possibility that synthetic chemicals, including pesticides, may pose significant risks to humans and other animals by disrupting the endocrine system. Proper functioning of the endocrine system is important in regulating growth, development, and reproduction. Endocrine disruptors may be linked to a variety of sexual development, behavioral, and reproductive problems. In response to this concern, EPA began to research the issue, and consulted with scientific experts on the subject to begin the development of appropriate testing strategies.

FQPA requires EPA to: (1) develop a peer reviewed screening and testing program for pesticides that may have estrogenic or other endocrine effects within two years; (2) implement the program within three years of enactment; and, (3) report progress to Congress within four years. Similar requirements were included in the Safe Drinking Water Act (SDWA) that was reauthorized in 1996. SDWA directs EPA's Office of Drinking Water to include some but not all drinking water contaminants in an endocrine effects evaluation program. The amended SDWA defers to the FQPA provisions in the Federal Food Drug and Cosmetic Act for developing and managing the endocrine disruptor program. The schedule set by FQPA is ambitious, given the complex scientific issues that must be addressed.

## Approach to Implementation

To formalize the work on endocrine disruptors and assist the Agency in fulfilling its FQPA mandates, the Office of Prevention, Pesticides and Toxic Substances working with the Office of Drinking Water, established a federally-chartered expert committee--the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) in November 1996. The EDSTAC is charged with providing direction to the Agency on the establishment of a comprehensive screening and testing program for pesticides and chemicals for estrogenic and other endocrine effects. The EDSTAC will meet frequently during 1997 and will form several working groups to more fully develop scientific, policy, and communication and outreach issues necessary to formulate its final recommendations. The broad objectives of the EDSTAC are to:

1. Design and validate initial screens to begin the endocrine disruptor screening and testing program;
2. Establish criteria for determining when more thorough endocrine disruptor testing, beyond initial screening, is needed;
3. Select validated tests that should be used subsequent to, or in lieu of, the initial screens; and
4. Develop a flexible process to select and prioritize the pesticides and chemicals that will be subjected to initial screening and, where appropriate, subsequent testing.

The EDSTAC held its first meeting in December 1996 to decide the scope of its work. The Committee agreed to investigate a broad range of hormonal effects (including those from estrogens, androgens and their anti-effects, and thyroid hormones) and to develop principles for looking at effects beyond these. The Committee also agreed that screening and testing should go beyond the scope set out in FQPA (pesticide active ingredients and inerts) to include all

environmental agents and that assessments should evaluate both human health and ecological hazards. At a second meeting in February 1997, the EDSTAC reviewed the basic principles of endocrinology and the state of science on endocrinology including structure activity relationships and existing screening and testing programs. The Committee discussed a set of principles to guide the screening and testing program. A third meeting is planned for April 1997 to discuss the design of an initial screen.

The EDSTAC will take a consensus approach to its findings and recommendations. The Committee expects to summarize its recommendations on the design of a screening and testing program in a report by March 1998. The report will be peer reviewed by the Agency's Science Advisory Board and the FIFRA Scientific Advisory Panel, followed by solicitation of public comments. The peer review process will also include a consultation with the National Academy of Sciences to occur in 1998, allowing time for the Agency to finalize a screening and testing plan for implementation in 1999. The Agency will issue a report to Congress in the year 2000 which describes the results of the screening program, and makes recommendations for further testing to evaluate the impact on human health of the substances tested, and for further action. The long-term goal of the program is to assess and manage the risks of endocrine disruptors, based on appropriate testing.

While the EDSTAC proceeds with its work, EPA will continue to regulate pesticides based on all available data. Until new, more specific testing is developed, EPA will use the results of toxicity studies including studies done according to the new developmental and reproductive testing guidelines proposed in 1996 to evaluate the potential for endocrine effects. While these studies do not provide specific information on endocrine related mechanisms, they do provide data on reproductive and developmental effects that may be the expression of damage to the endocrine system. EPA has completed a review of the existing literature on endocrine effects to provide support for its interim policy. The literature review and an interim policy statement were issued on March 13, 1997.

## **PART FIVE**

### **TOLERANCES-THE REGULATORY PROCESS**

#### **5.1 Consideration of Pesticide Benefits in Tolerance-Setting**

##### **Background**

Previous law required EPA to give appropriate consideration "to the necessity for the production of an adequate, wholesome, and economical food supply" when setting tolerances to protect the public health. EPA has traditionally assessed both the risks and benefits of a pesticide's use as part of the tolerance setting process. For certain pesticides that appeared to present significant risks, EPA carefully weighed the risks against the benefits to evaluate tolerances. A benefits evaluation provides information on the way a pesticide is used, the economic and consumer impacts of discontinuing a use and on the availability and practicality of alternative pesticides or treatment methods. Benefits assessments allowed EPA to determine whether a certain risk could be justified in light of the serious economic consequences or disruption to the food supply that would occur if a use were denied or discontinued because a tolerance could not be set. In practice, tolerance decisions have not been driven by economic considerations.

FQPA places strict limits on the use of benefits in establishing or maintaining tolerances under the FFDCA:

- o Benefits only apply to decisions on existing tolerances; they may not be used in deciding whether to establish a new tolerance.
- o Benefits may only be considered for "eligible" pesticides, as follows:
  - > Benefits may only be considered for non-threshold effect pesticides (which are typically, although not exclusively, carcinogenic pesticides); they do not apply to evaluations of threshold effects (which are generally non-carcinogenic effects).
  - > For carcinogenic pesticides, benefits may be considered only if the pesticide's threshold effects meet the new safety standard.
- o Existing tolerances of "eligible" pesticides may be retained if one of two separate benefits showings can be made:
  - > continued use of the pesticide will result in fewer adverse effects on human health than if the use were not allowed (i.e., the risk from the pesticide residue in food is less than the public health consequence of discontinuing the pesticide's use)



- > the pesticide use is necessary to avoid a significant disruption in the domestic production of an adequate, economical, and wholesome food supply.
- o Further, the tolerances may only be retained where:
  - > the yearly cancer risk does not exceed ten times the yearly level permitted under the negligible risk (i.e., one-in-a-million) standard; and
  - > the cumulative lifetime cancer risk will never be greater than twice the one-in-a-million level. To the extent that the cumulative lifetime risk would exceed this level, EPA is authorized to remove tolerances after specific phase-out periods.
- o The law also specifically prohibits the consideration of benefits to override the health-based standard for children.

### Approach to Implementation

In accordance with the requirements of FQPA, EPA will not establish tolerances based on a benefits finding except in the very narrow circumstances permitted by FQPA, as described above. EPA expects that, in practice, benefits very rarely will be used to approve tolerances for pesticides that exceed a negligible risk level, given that very few pesticides will meet the “eligible” criteria and other circumstances set out by the new law.

Benefits considerations still have a role to play in making decisions on pesticide use, however. For a pesticide with multiple uses (e.g., use on more than one crop and/or non-food uses) that collectively do not meet the safety standard, EPA must make a decision about how to reduce the risk to the pesticide. It may be possible to reduce the risk level sufficiently to meet the safety standard without removing all of the uses from the market. A benefits assessment on each use can provide information on which ones are most critical, which ones can be replaced by alternative pest control methods, and how applications rates and use patterns may be changed to reduce exposure. This type of information can assist EPA to make decisions about which uses should be retained and which ones should be canceled or modified. Similarly, benefits assessments also will be valuable in decisions on a group of chemicals that share common mechanisms of toxicity. Information on use and benefits will indicate which pesticide/crop combinations in the group are the least essential from an economic standpoint.

When EPA must reduce dietary risk posed by a certain pesticide or a group of pesticides with common mechanisms of toxicity, many stakeholders including pesticide users, commodity groups, states, registrants, consumers and others may be affected by the decision. EPA is committed an open process of deciding which uses to retain versus which ones to cancel or restrict.

EPA is working closely with the USDA National Agricultural Pesticides Impact Assessment Program (NAPIAP) to collect better information on pesticide use, efficacy and economic benefits. EPA and NAPIAP are working over the next six months to review existing economic models and design new ones that will provide new insights into the effect of a pesticide and its alternatives on commodity yield and quality. The information from such models will be applied to future benefits assessments.

## 5.2 Section 18 Emergency Exemptions

### Background

Section 18 of FIFRA authorizes EPA to allow states to use a pesticide for an unregistered use for a limited time if EPA determines that emergency pest conditions exist. Growers in particular regions identify a pest situation which registered pesticides will not control. The growers contact their state department of agriculture or other state lead agency and request the state to apply to EPA for a section 18 emergency exemption for a particular pesticide. Requests are most often made for pesticides that have food use registrations but not for the food use in question. The state agency evaluates the requests and submits petitions to EPA for emergency exemptions they believe are warranted. To be as responsive as possible to the states and growers, EPA attempts to make section 18 decisions within 50 days of receiving a request.

During this short period of time, EPA must perform a multi-disciplinary risk assessment of the requested use relying largely on data that already have been reviewed for the pesticide. In addition to evaluating potential health and environmental effects of the use, EPA also evaluates the validity of the emergency. EPA will deny a section 18 request if the pesticide may cause unreasonable adverse effects to health or the environment, or if emergency criteria are not met. For the past several years, EPA has approved exemptions for about 200 different pesticide/crop combinations per year.

Under FQPA, EPA retains the authority to allow the unregistered use of a pesticide in an emergency situation. What is new is that the Agency must now establish formal tolerances to cover all pesticides residues in food, even residues resulting from emergency uses. Previous to FQPA, EPA identified an "enforcement level." The enforcement level was EPA's best estimate of the maximum residue that would be found on food treated during a section 18 use. The enforcement level would be communicated in writing to FDA. Now, in establishing a tolerance, EPA must make the finding that aggregate and cumulative exposure to the pesticide is "safe," as required by the new FQPA health-based standard.



## Approach to Implementation

EPA has worked quickly to implement the new FQPA provisions on section 18 chemicals, recognizing the time-sensitive nature and economic importance of section 18 decisions. The Agency is engaged in an intensive process, including consultation with registrants, states and other interested stakeholders to develop new policies and procedures for granting emergency exemption requests according to the new provisions. As these policies and procedures are worked out, EPA is continuing to process section 18 applications for food uses which are consistent with the new safety standard and with FIFRA section 18 regulations.

Within a few weeks of passage of FQPA, EPA established a process for screening incoming section 18 requests to determine preliminarily whether a tolerance could be established to cover the proposed use. Under FQPA, EPA must consider several factors (see sections 4.3-4.7 of this document) when setting tolerances for section 18 applications. These factors were explained in interim guidance sent to the States and registrants in October 1996. Applicants were encouraged to include information relevant to the factors in their applications to assist the decision-making process.

EPA is applying the interim decision logic on aggregate exposure (described in section 4.3) to section 18 chemicals to make decisions as quickly as possible, giving due consideration to the new FQPA requirements. To compensate for incomplete data, the interim logic uses scientific judgements to estimate risk from aggregate pesticide exposures. The resulting assessments are protective but give essentially a "worst case" estimate of exposure. In non-emergency situations, EPA is generally able to acquire and evaluate additional data to more accurately estimate exposure. It often takes substantial time to develop and evaluate these data and refine risk estimates. For emergency exemptions, there is usually insufficient time to do this. EPA is taking a case-by-case approach to interpreting the results of risk estimates for proposed section 18 uses. The Agency is using professional judgement to draw reasonable inferences from the data that are in hand and from risk evaluations of established uses that are similar to the proposed uses.

The first tolerance for a section 18 emergency exemption was issued in September 1996. Subsequent to passage of FQPA and through March 1997, EPA has granted 60 section 18 requests and established 14 tolerances covering 31 of the requests. EPA is working quickly to establish tolerances to cover the remaining requests that have been granted; the Agency is committed to establishing tolerances to cover these uses before harvest times for the affected crops. In addition, EPA has denied an exemption for one pesticide and states have chosen to withdraw five section 18 requests following EPA's risk assessment outlining dietary concerns.

On November 21-22, 1996, EPA held a workshop to provide stakeholders with an opportunity to ask questions and offer comments on the section 18 process and implementation of the new FQPA provisions. State agencies, industry, trade associations, academia and environmental groups discussed, among other issues, ways to improve the efficiency of the emergency exemption process and the new data required to support the establishment of a tolerance under FQPA. EPA will take these discussions into account in developing policies to improve the section 18 process. A report of the workshop is available in the Office of Pesticide Program's public docket (see section 3.1).

In April 1997, EPA will publish a proposed regulation in the Federal Register summarizing the requirements of FQPA relating to section 18, indicating how the Agency intends to meet those requirements. EPA will promulgate the final procedural rule FQPA requires by August 3, 1997. Appropriate section 18 emergency exemptions will continue to be granted according to the strategy described above pending promulgation of that rule.

### **5.3 Tolerance Reassessment**

#### Background

Amendments to FIFRA enacted in 1988 require EPA to reregister existing pesticides that originally were registered years ago when the standards for government approval were less stringent than they are today. As part of reregistration, associated tolerances must be reviewed, as well. The reregistration program applies to each registered pesticide product containing an active ingredient initially registered before November 1, 1984. The 1988 amendments required a one-time only review.

The goal of reregistration is to bring the science base supporting registrations and tolerances up to modern standards. EPA makes a reregistration decision on a pesticide only after conducting a comprehensive review of all studies submitted in support of the active ingredient. This decision and a summary of the complete review are presented in a Reregistration Eligibility Decision document, or "RED."

Under the new law, EPA is required to reassess **all** existing tolerances and exemptions from tolerances for both active ingredients and inerts, not only those associated with older pesticides, within ten years to ensure they meet the new FQPA safety standard. EPA is directed to give priority review to pesticides that appear to present risk concerns, based on current data. This is a monumental undertaking: more than 9000 tolerances are now in effect.

#### Approach to Implementation

In order to accomplish tolerance reassessment and still meet requirements to complete the reregistration of older pesticides, EPA plans to use the reregistration process and the registration renewal process, once it is established, to reevaluate tolerances. EPA will give priority review to pesticides that raise risk concerns under the new safety standards (e.g., possible and probable carcinogens, and groups of related pesticides that may present adverse health effects). The Food Safety Advisory Committee reviewed and approved EPA's approach to tolerance reassessment in their November and December 1996 meetings.

By August 1997, EPA will publish in the Federal Register a schedule for the review of tolerances and exemptions enacted prior to FQPA. To develop this schedule, the Agency has organized the universe of pesticides and tolerances that are subject to reassessment into groups to determine which reviews should occur early in the reassessment process. Tolerances associated with these groups must be re-evaluated to consider the new FQPA factors. EPA is looking at five groups:

- Group 1: Pesticides subject to the current reregistration program for which Reregistration Eligibility Decisions (REDs) have been issued (150).
- Group 2: Pesticides subject to the current reregistration program for which REDs have not been issued (221).
- Group 3: Pesticides first registered after November 1984 and therefore not subject to the current reregistration program (180).
- Group 4: Registered inert pesticide ingredients which have tolerances or exemptions (about 1000).
- Group 5: Pesticide registrations and uses which have been canceled or which are not being supported for reregistration.

In developing the schedule, EPA has begun with the chemicals that must still go through re-registration (Group 2 above) to determine which of these should be reviewed first. During the first three years of reassessment, as FQPA directs, EPA plans to focus on the riskiest chemicals such as possible and probable carcinogens and other chemicals that appear to present concerns in light of the new standard. When reviewing a Group 2 chemical, EPA intends to review it together with other pesticides, including those from other groups, that may share common mechanisms of toxicity. For example, EPA will look at a carcinogen that has not been through reregistration and will review it together with other carcinogens in the same class that have already been through reregistration or are not subject to reregistration. The cumulative effects from exposure to all of these pesticides will have to be considered, not only to determine the registration eligibility of the Group 2 pesticide but also to reassess the tolerances for each pesticide.

During the first few years of reassessment, EPA also plans to deal with a number of largely administrative types of actions. For example, the Agency will propose to revoke tolerances which are no longer needed such as those for pesticides which have been canceled (over 500) and tolerances which are no longer being supported unless someone provides the necessary data to support those tolerances.

After the first three years, EPA plans to begin work on reregistration and tolerance reassessment for the remaining pesticides that present less of a risk concern. Reregistration is scheduled to be completed by the year 2002 for chemical pesticides and by the end of 1997 for biopesticides. Once reregistration is complete, registration renewal will replace the RED process as the regulatory program to reassess all remaining tolerances that were not included in reregistration (see registration renewal section 10.1).

EPA will develop a specific schedule for reregistration and tolerance reassessment according to the general outline given above; the Agency intends to meet the FQPA requirement to reassess 33% of all tolerances by 1999, 66% of all tolerances by 2002 and all tolerances by 2006.

#### **5.4 Summary of New Regulatory Decision Process for Pesticides**

The attached chart summarizes the decision process the Office of Pesticide Programs will apply to pesticides that require regulatory decisions including new use registrations, reregistration decisions for chemicals registered before 1984, emergency exemptions, and tolerances or tolerance reassessments. The chart illustrates the point that EPA's regulatory decisions on pesticides must meet the standard and new requirements of FQPA (if the product has food uses) as well as the standard of FIFRA.

For example, if EPA's risk assessment indicates that a particular pesticide use may pose an unreasonable adverse effect on the environment, FIFRA requires the Agency to mitigate that risk before making a regulatory decision to allow the use. If a food use were in question, FQPA would require EPA to consider all possible routes of human exposure (aggregate exposure) before deciding whether the use in question meets the standard of "reasonable certainty of no harm." A use posing risks to the environment may or may not also be a source of human exposure, but if it is, then that exposure must be factored in with food exposure before EPA can determine that the FQPA standard is met.

If the aggregate exposure to a specific pesticide meets the FQPA standard, EPA must then consider whether there is also exposure to chemicals that exert toxic effects by the same pathway as that pesticide. Again, if the standard is not met under this consideration, the Agency cannot proceed to a regulatory decision that allows use of the pesticide unless the risks can be reduced.

As the chart illustrates, the FQPA does provide for possible exemptions to the FQPA standard in extremely limited circumstances involving non-threshold (generally carcinogenic) risks. As described in part 5.1 of this document, the exemptions are available only in cases where the estimated risks are within specific limits and the benefits of the pesticide to public health or the nation's food supply are substantial.

## **PART SIX**

### **MINOR USE PESTICIDES**

#### **6.1 Minor Use Pesticides**

##### **Background**

Minor uses of pesticides are generally defined as uses for which pesticide product sales are low enough to make it difficult for a manufacturer to justify the costs of developing and maintaining EPA registrations. Collectively, such “minor” crops are very important to a healthy diet, and include many fruits and vegetables. Minor uses also include use on commercially grown flowers, trees and shrubs, certain applications to major crops such as wheat or corn where the pest problem is not widespread, and many public health applications. Since many of these uses produce smaller revenues for pesticide registrants than do major uses, the registrants are sometimes reluctant to support and maintain registrations and associated tolerances. Some minor uses have been lost through lack of registrant support during the reregistration process, resulting in grower concerns that adequate pest control tools will no longer be available for many minor crops. Pesticide minor uses are worth preserving because they are of major significance in agricultural production and public health protection.

Both USDA and EPA have long recognized and worked to alleviate minor use problems. EPA has full-time staff dedicated to minor use registrations and the Agency works closely with USDA’s ongoing research program, the Inter-Regional Research Project No. 4 (IR-4), to generate residue data for tolerances on minor crops. Careful consideration is given to the data requirements to support minor uses to minimize the burden of data generation. EPA and USDA operate early alert systems to notify growers when a pesticide use for a minor crop is about to be canceled. EPA also provides advance public notice of a proposed cancellation to allow time for another registrant to consider maintaining the pesticide use.

FQPA includes a number of provisions intended to help preserve the availability of minor use pesticides. The new law gives registrants a variety of incentives for maintaining existing minor use registrations and developing new ones. These incentives include expediting the review of data submitted in support of minor uses, granting time extensions for submitting data on minor uses, and giving those who invest in data development for minor uses additional exclusive rights to use of the data to support registration.

FQPA also formally establishes minor use programs at EPA and USDA to foster coordination on minor use issues and consultation with growers. A revolving grant fund is authorized at USDA to fund the generation of data necessary to support minor use registration. The Department of Health and Human Services is authorized to fund studies in support of registration or reregistration of minor use pesticides that are important for public health purposes.

#### Approach to Implementation

EPA is giving high priority to implementing the Minor Use Provisions of FQPA. The Agency will create a new program by September 1997 dedicated solely to coordinating minor use issues within the Office of Pesticide Programs. By April, 1997 EPA will publish a PR Notice providing information to registrants on:

- o The definition of a minor use (use on less than 300,000 acres). USDA, in consultation with EPA, has developed a list of "major agricultural crops." Pesticide uses on all other crops can automatically be considered minor uses. EPA will include criteria for the economic definition of a "minor use" on a "major crop" or non-crop site.
- o Criteria for assigning priority ranking to science reviews of minor uses and designing new procedures to expedite registrations.

EPA also plans to publish in 1997 and 1998 PR Notices on:

- o Policies and tracking systems to give special consideration to minor uses and public health pesticides during reregistration. These include policies on time extensions for the development and submission of residue and other minor use data, and modifying procedures for waiving minor use data requirements.
- o Interim procedures to identify, validate, and track exclusive use of data for minor uses.

EPA is working in partnership with an ad hoc work group formed by the Minor Crop Farmer Alliance (MCFA), National Food Processors Association, and the Agricultural Crop Protection Association (ACPA) to exchange information on issues relevant to new minor use registrations and maintaining existing registrations under FQPA. The objectives of the group are to identify areas of common interest among user groups, the food industry and manufacturers; improve communication and cooperation between users and registrants; develop information on pesticide use and pest management needs; develop processes to provide non-occupational exposure data; and improve involvement of the user community in the regulatory process.

EPA is also consulting with the USDA and DHHS on a number of issues regarding minor uses. EPA, USDA and DHHS are establishing a work group to address registration issues on public health pesticides. USDA and DHHS are authorized by law to develop data in support of



minor use public health pesticides. The work group will explore ways to expand data generation programs in USDA and DHHS to support the registration of critical public health pesticides. Further, the work group will develop information on the uses of public health pesticides, focusing on which pesticides are the most critical to public health protection. EPA has developed a comprehensive list of registered pesticides with public health uses for discussion by the work group.

In addition, EPA, USDA and DHHS are talking with the regulated community to develop new ideas for mitigating risks from pesticide use while still retaining critical minor uses. For a pesticide that presents a high risk from multiple minor and major uses, EPA may lower risk by limiting use in various ways. For example, certain important uses could be limited to once every two years (or another appropriate interval) to address pest resistance problems. Similarly, certain uses could be limited to targeted applications only in conjunction with an IPM program. EPA is exploring these and other ideas for allocating uses to reduce risks; the Agency is considering pilot projects to test the effectiveness and practicality of these approaches.

EPA will work closely with its advisory committee, the PPDC, to keep a broad range of stakeholders involved in minor use issues. The Agency will bring new ideas to the PPDC for discussion and will solicit comment on new policies as they are developed.

EPA will issue an interim report on the progress of implementing the FQPA minor use provisions by August 1998, as well as the comprehensive August 1999 report required by the law.

## PART SEVEN

### COMMUNICATIONS/RIGHT-TO-KNOW

#### Background

EPA maintains an active and varied pesticide communications program, producing press announcements on major decisions and important issues, background papers, and publications for general and specialized audiences, such as health professionals and workers who may be exposed to pesticides. Recognizing that many pesticide communications involve complex science or technical issues, a special effort is made by the Agency to prepare documents that are easy for the public to understand. Over 500,000 publications were distributed in 1995 alone.

Increasingly, pesticide information is available electronically. In 1996, the Pesticide Program redesigned its Internet home page to increase its user friendliness and make information easier to obtain. The Pesticide Program also supports a toll-free information hotline that handles an average of 21,000 calls per year.

FQPA encourages open communication on pesticide issues and contains a provision that requires EPA to make certain kinds of information more accessible to the public. The new "right-to-know" provision requires EPA to produce, in consultation with DHHS and USDA, consumer information on pesticide residues in food for distribution to large retail grocers for public display. FQPA directs EPA to include in the information a discussion of the risks and benefits of pesticides; recommendations to consumers to reduce exposure to pesticide residues in a manner consistent with maintaining a healthy diet; and a listing of any tolerances that EPA has set based on benefits considerations (that would not otherwise meet the safety standards of the law), the foods that may contain residues of such pesticides, and reasonable substitutes for those foods. EPA must produce and distribute this information within two years and must update it annually thereafter.

#### Approach to Implementation

EPA is planning a number of publications on implementation including periodic reports, Federal Register Notices, guidance documents and other more general information including a pamphlet containing highlights of FQPA. EPA has already placed a number of fact sheets and other documents on the Internet and in a public docket (see section 3.1 of this document).

Developing the new "right-to-know" consumer brochure for grocery store display represents a major new challenge for the program. As part of the development process, EPA will be working with the Pesticide Program Dialogue Committee, through a work group, to obtain their advice on public outreach products including the brochure. In addition, EPA will seek advice from consumer information groups, magazine editors and other media experts, USDA, DHHS, nutritionists, food producers and food retail industry representatives, and public health education organizations during the development process. The consumer/right-to-know work group of the PPDC will provide its initial thoughts on the consumer brochure to the full PPDC at the next meeting in March 1997.



EPA will also use focus groups and other research to help the Agency determine what information is most useful to consumers and how best to communicate that information. EPA's Office of Research and Development has begun the process by inviting research grant applications exploring communications outreach issues. Specifically, the research was solicited to: (1) identify the best way to disseminate information to consumers, and (2) determine what kinds of information consumers respond to. Factors to be explored include: (1) how to present information in a way that will be easily understood, (2) how best to discuss ways to reduce potential exposures, and (3) how best to reach minorities and potentially susceptible subpopulations. The research grant recipients will be chosen in September 1997, after peer review and rating on scientific merit.

EPA plans to make a draft of the consumer brochure available for public comment in January 1998. The final brochure is expected to be printed and distributed to large retail stores by August 1998, and updated every year thereafter. EPA will also make the document available via the Internet using EPA's web page.

Although not required by FQPA, EPA intends to make copies of the brochure available to small neighborhood markets, as well. The Agency will work in partnership with various organizations including food producers, nutritionists, environmental/public interest groups, state and national public health offices and other interested organizations to distribute materials to a broad audience.

The new right-to-know brochure represents only one piece of the larger Agency outreach and education strategy for FQPA. During 1997, EPA will seek comments from key constituent groups regarding other tools that can help increase public awareness about FQPA issues.

## PART EIGHT

### REDUCED RISK PESTICIDES

#### Background

In 1993, EPA launched its Reduced-Risk Pesticide Initiative and set the basic requirements that must be met in order for a pesticide to be considered “reduced risk.” The goal of the Initiative is to encourage the development, registration, and use of new pesticide chemicals which would result in reduced risks to human health and the environment compared to existing alternatives.

The major regulatory advantage of qualifying as a reduced risk pesticide is expedited registration review. In 1995, the average amount of time it took to register a new conventional pesticide was 38 months; the new reduced risk pesticides take, on average, only 14 months. Since 1993, 29 new chemical submissions have been received by EPA as reduced risk pesticide candidates. Of the 29, 17 met the reduced risk criteria for expedited review. Nine of those 17 have been registered.

In November 1994, EPA established a separate Division in the Office of Pesticide Programs, the Biopesticides and Pollution Prevention Division (BPPD), to encourage the development of reduced risk pesticides and to manage the registration and reregistration of biopesticides. Biopesticides include: (1) naturally occurring and genetically engineered microorganisms, (2) genetically engineered plants that produce their own pesticides (such as crops that produce the insecticidal proteins from the bacteria called "Bt"), and (3) naturally occurring compounds, or compounds essentially identical to naturally occurring compounds, that are not toxic to the target pest (such as pheromones). EPA approved 14 new biopesticide active ingredients in fiscal year 1995 and 10 in fiscal year 1996 -- representing well over one-third of new active ingredients registered in those years. EPA also issued Reregistration Eligibility Decision (RED) documents for 8 biopesticides.

FQPA recognizes the importance of safer or “reduced-risk pesticides” and supports expedited review to help these pesticides reach the market sooner and replace older and potentially riskier chemicals. The new law defines a reduced risk pesticide as one which "may reasonably be expected to accomplish one or more of the following: (1) reduces pesticide risks to human health; (2) reduces pesticide risks to non-target organisms; (3) reduces the potential for contamination of valued, environmental resources, or (4) broadens adoption of IPM or makes it more effective.”

Within one year of enactment of FQPA, EPA must develop procedures and guidelines on expedited review of applications for registration or amendments for a reduced risk pesticide. Both biological and conventional pesticides are eligible for designation as reduced risk.

### Approach to Implementation

FQPA provides a firm mandate and gives renewed impetus to EPA's reduced risk efforts. The Agency interprets FQPA as requiring the current program to expand to include consideration of new active ingredients, new uses of active ingredients already deemed to be reduced risk, and amendments to all uses deemed to be reduced risk. EPA will continue to give priority review to reduced risk pesticides and work with the regulated community and user groups to refine review and registration procedures.

In February 1997, EPA registered two new reduced-risk conventional pesticides and a new use of an existing reduced-risk conventional pesticide. These are the first reduced-risk pesticides registered under the new law. 10 biopesticides also have been registered following passage of FQPA through March 1997.

In April 1997, EPA will issue a PR Notice that outlines the Agency's plans for implementing the FQPA requirements on reduced risk pesticides. The PR Notice will: 1) announce EPA's expansion of the reduced risk program; 2) explain EPA's interpretation of the FQPA requirements with respect to criteria for determining reduced risk pesticides (EPA will continue to use a weight-of-the evidence approach to determine which pesticides qualify as reduced risk); and 3) inform registrants that applications qualifying for reduced risk review must meet all new FQPA requirements for registration as specified in PR Notice 97-1 in addition to the reduced risk criteria.

## **8.2 Integrated Pest Management**

### Background

In 1993, the Clinton Administration announced that reducing the use and risk of pesticides was a high priority. As part of that policy initiative, the Administration announced as a goal that 75% of all U.S. cropland would adopt Integrated Pest Management (IPM) before the year 2000. IPM programs mix a range of pest control methods including prevention, monitoring, mechanical trapping devices, and natural predators, as well as biological pesticides and, if appropriate, chemical pesticides. USDA was given the lead for ensuring that this goal is met.

In response to this initiative, EPA joined with USDA to begin a new program, the Pesticide Environmental Stewardship Program (PESP), to reduce pesticide use and risk. PESP promotes innovative means of reducing the risk of pesticide use through voluntary partnerships between EPA and pesticide user groups, both agricultural and non-agricultural. PESP partners commit to developing, with EPA's assistance, formal strategies that tailor a user group's pesticide use to specific sites, crops and regions of the country. These strategies typically include reliance on biological pesticides and IPM practices. To ensure that PESP participants receive current information on strategies to reduce use and risk, including IPM information, EPA assigns staff to work with each with PESP partner. Over 60 partners and supporting organizations currently participate in the PESP program.

FQPA requires USDA, in cooperation with EPA, to conduct research and education programs to support the adoption of IPM. FQPA also directs Federal agencies to use IPM techniques when controlling pests and to promote IPM through procurement and regulatory policies and other activities.

### Approach to Implementation

The FQPA requirements on IPM are in keeping with the principles of the EPA/USDA PESP Program. Through PESP, EPA has provided over the last two years a number of small, incentive and implementation grants to appropriate partners to encourage pesticide risk reduction and the use of IPM. EPA and USDA will continue to encourage pesticide user groups to develop and apply IPM practices and will explore the expansion of grants programs established within USDA to support additional research on IPM practices.

Further, in response to the FQPA provisions, EPA has established a committee to plan a conference for Federal agencies on using IPM practices. The planning committee includes representatives from the Department of Defense (DOD), the Government Services Administration (GSA), the National Park Service (NPS), the Department of Fish and Wildlife and USDA. The committee intends to meet monthly during 1997 to agree on the goals, agenda and logistics of the conference which will be held in early 1998.

As part of its work on IPM, EPA will continue to work closely through PESP and other activities, with pesticide user groups who rely upon chemical pesticides. It is important for these groups to be made aware of integrated pest management practices that can be used in place of these chemical pesticides that will not be reregistered because insufficient data are available to support them or because of risk concerns. Minor use groups can provide critical information to EPA in return. These groups can keep EPA informed on which chemical pesticides are a critical component of the IPM programs they have developed. EPA will consider such information when making regulatory decisions on these pesticides consistent with Agency's policy to encourage measures that reduce the overall risk of pesticide use.

## PART NINE

### ANTIMICROBIAL PESTICIDES

#### Background

Antimicrobial pesticides are substances used to control harmful microorganisms including bacteria, viruses or fungi on inanimate objects and surfaces. Types of antimicrobial products have traditionally included disinfectants, sanitizers, sterilizers, and antiseptics and germicides. To obtain registrations for antimicrobial products, manufacturers have been required to meet the general standards of FIFRA and to submit to EPA detailed information concerning their products including effectiveness data to document their claims against specific microorganisms. 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 products.

Under FQPA, EPA must continue to revise the antimicrobial registration process to reduce review times for all types of antimicrobial registration actions. After EPA receives a complete application, the goals for review are:

- > 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 an already registered product (“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 also amends the definition of “pesticide” to exclude certain liquid chemical sterilants, which are to be regulated exclusively by FDA. Some wood preservatives, some antifouling paints, agricultural fungicides, and aquatic herbicides are also excluded from the new FQPA definition of “antimicrobial pesticide” but will continue to be included within the definition of “pesticide” and subject to regulation by EPA.

## Approach to Implementation

While the review goals set out in the new law will be difficult to achieve, EPA is developing a program aimed at meeting them. EPA's plan for improving the efficiency of its regulation of antimicrobial pesticides has four general stages:

### 1. Establish a New Antimicrobial Division

In February 1997, EPA created a new organizational unit, the Antimicrobial Division, to address the many challenging policy and managerial tasks that must be accomplished to meet the deadlines of FQPA and other mandates. Organizational work within the Division is underway and is expected to be completed by May 1997.

### 2. Develop New Policies

EPA is moving quickly to resolve several urgent issues affecting the regulation of antimicrobial products, particularly as they involve the jurisdiction of the Food and Drug Administration (FDA) and EPA. The Agency has:

- o established policies for evaluating the risks of non-food use pesticides whose use may involve significant exposure to children. Guidance on this issue was included in PR Notice 97-1 issued in January.
- o clarified the types of pesticide products that will be assigned to the Antimicrobial Division. Letters were sent to registrants in January 1996 explaining which products would be reviewed in the new Division.

EPA is also working to:

- o clarify jurisdiction over liquid chemical sterilants used on critical and semi-critical medical devices and the establishment of tolerances for food contact sanitizers. A PR Notice on this matter will be issued by April 1997.
- o establish procedures and publish policies for revising antimicrobial pesticide product labeling as envisioned in the new law. EPA expects to issue a PR Notice in April 1997.

### 3. Address the Backlog of Pending Applications

The Agency is developing a plan to eliminate the backlog of pending antimicrobial application actions and to meet the FQPA deadlines. Elements of the plan may call for EPA to take the following steps:

- o group actions which can be acted on together, e.g., all applications which involve the same product or which depend on the resolution of a common policy or scientific issue.
- o establish review priorities, taking into consideration applications identified by companies as their highest priorities.
- o return applications which are incomplete.

### 4. Establish a Streamlined Antimicrobial Regulatory Process

FQPA requires EPA to publish regulations to improve the efficiency of its decision-making on antimicrobial pesticides. The law requires a proposed Antimicrobial Reform Regulation to be published in the Federal Register by May 1997 and a final regulation to be published no later than 240 days after the comment period ends. Because the regulations required by the law are quite complex, it may not be possible to publish a proposed regulation in the FR by the May date. EPA intends to informally circulate a draft proposal to stakeholders for comment in April and to publish a proposal in the Federal Register by July 1997. The Agency is discussing reforms to the antimicrobial regulatory process with stakeholders and will keep them informed of progress on a regular basis. The proposal for a streamlined process will address:

- o procedures for submission of applications;
- o data requirements for registration;
- o standards for evaluating the efficacy of public health antimicrobial products;  
and
- o requirements for labeling public health antimicrobial pesticides.

EPA will publish the final Antimicrobial Reform Regulation in the Federal Register in May 1998, as FQPA requires.



Under the new law, EPA also must submit annual progress reports to Congress until the review goals for antimicrobials are met. The reports are due annually by March 1. EPA is working to complete its first annual report which will explain the Agency's intensive effort to set up a new division and develop new policies and review procedures for antimicrobial products. The report of the first six months of accomplishments will be submitted to Congress by May 1997.

For the long-term, EPA is exploring a number of additional ideas for improving efficiency. While no time frames have been set, EPA will consider:

- o improved tracking systems for monitoring the status of application actions.
- o initiatives to streamline the regulation of entire classes of products, e.g., swimming pool chemicals.
- o use of a laboratory certification program to strengthen the reliability and reproducibility of efficacy studies.

EPA will keep the regulated community and other stakeholders informed of progress on antimicrobial implementation activities through press releases, policy statements, Federal Register publications, workshops, and regular meetings. The Agency held its first workshop on the new antimicrobial provisions in January 1997. At the workshop, EPA discussed the future direction of antimicrobial regulation and solicited comments from the regulated community and other stakeholders in attendance on specific issues such as labeling, data requirements and review priorities. EPA will consider the recommendations that emerged from the workshop during the preparation of the Agency's proposed Antimicrobial Reform Regulation. A report on the workshop will be available in the public docket in March 1997.



## PART TEN

### OTHER AMENDMENTS-FIFRA

#### 10.1 Registration Renewal

##### Background

Under EPA's reregistration program mandated by the 1988 Amendments to FIFRA, EPA has been re-evaluating tolerances associated with pesticides undergoing reregistration, although tolerance reviews were not specifically required by the law. The reregistration review was established as a one-time only re-evaluation to bring registrations and tolerances up to modern standards. No further periodic reviews were required.

In addition to requiring tolerance reassessments, the new law requires EPA to establish a system for periodic review of all pesticide registrations. The law requires periodic review to ensure a pesticide meets then-current standards every 15 years. If new data are needed for these reviews, EPA may require them at any time under the "data call-in" authority in Section 3(c)(2)(B) of FIFRA.

##### Approach to Implementation

EPA will phase-in a registration renewal program as the reregistration program is completed. Tolerance reassessment will be accomplished through reregistration as described in section 5.3 of this document until the year 2002 at which time reregistration is expected to be completed. All tolerances not reassessed through reregistration will then be evaluated as part of a registration renewal program. In 1998, EPA will begin establishing a program that continuously updates all tolerances on a periodic cycle including the tolerances reassessed as part of the reregistration program. EPA intends to establish a 15-year cycle to meet the goal set by FQPA. This periodic review will ensure that tolerances are supported by up-to-date scientific studies and residue data.

#### 10.2 Extension of Reregistration Fee Authority

##### Background

The 1988 Amendments to FIFRA authorized EPA to collect fees until September 30, 1997 to support the accelerated reregistration program (covering pesticides first registered before November 1984). The limit on the fee authority was based on the assumption that the reregistration program would be completed within the nine years dictated by the '88 amendments. Because of the complexity of reregistering several hundred active ingredient pesticides, it was not possible for EPA to complete reregistration in nine years, however.

The new law extends fee collection authority through September 30, 2001. It continues to provide for the collection of \$14 million per year to support the current reregistration program and the expedited processing of applications for pesticides that are substantially similar to pesticides

that are already registered. An additional \$2 million per year are to be collected in 1998, 1999, and 2000.

FQPA contains a number of requirements to ensure that fees collected under the new authority are used properly and that systems are established to track the expenditures. First, effective October 1, 1997, EPA must adopt cost accounting rules and procedures, approved by the General Accounting Office, to guarantee that fee revenues are dedicated to reregistration and expedited registration (fast track) actions. Also, the Inspector General must annually audit the collection and disbursement of fees and prepare a report for the House and Senate Committees on Agriculture. Third, EPA must establish and publish annually in the Federal Register, performance measures and goals for reregistration, tolerance reassessment, and expedited registrations.

#### Approach to Implementation

If fee authority had been allowed to expire in 1997, EPA would have been unable to complete its ongoing reregistration program. Many of the pesticides for which review would have been delayed are chemicals used on the foods most often eaten by infants and children. EPA will use the extended fee collection authority to apply additional resources to the current reregistration program to keep it on track. In January 1997, EPA announced in the Federal Register that the Agency has begun depositing fees related to tolerance activities into the Reregistration and Expedited Processing Fund.

As required by FQPA, the Agency will also publish in the Federal Register an annual FIFRA Fund Expenditures Report which will give an accounting of fee money and relate progress on reregistration including the schedule for all remaining reviews, tolerance reassessment and expedited registrations. EPA intends to publish this report soon after the close of the fiscal year each year. The first report will be published in the Federal Register in November 1997. The Office of the Inspector General will audit the fee expenditures and will report to Congress each year, as well.

### **10.3 Emergency Suspension Authority**

#### Background

Under previous law, EPA could not suspend a pesticide's registration unless a proposed notice of intent to cancel the registration had been issued previously or was issued simultaneously with the emergency suspension notice. This meant that a pesticide suspension could be delayed many months while a notice of intent to cancel was prepared even if the Agency determined that the pesticide presented an imminent threat to public health or the environment.

The new law allows EPA to suspend a pesticide registration immediately upon determining that an emergency exists. A notice of intent to cancel must be issued within 90 days, or the emergency suspension will expire.

#### Approach to Implementation

The new provisions do not change the substantive standard for issuing emergency suspensions. The sole purpose of the change is to allow EPA to move more quickly in situations that warrant immediate and decisive action to prevent serious risks to human health and the

environment. At the same time the rights of registrants in the cancellation process are preserved by the requirement for EPA to file a notice of intent to cancel within a reasonable period of time.

## **PART ELEVEN**

### **OTHER AMENDMENTS - FFDCA**

#### **11.1 National Uniformity of Tolerances**

##### Background

Prior to passage of FQPA, states were allowed to set tolerances for pesticide residues in food that were stricter than tolerances set by EPA. Although in practice states rarely set their own tolerances, there was the potential for disruption of interstate commerce in food products resulting from inconsistent federal and state tolerances.

Generally, the new law preempts states from establishing tolerances that differ from EPA tolerances first established or reassessed after August 3, 1996. States may petition EPA for exemptions to this provision if there are compelling local conditions that justify the exemption.

##### Approach to Implementation

States will continue to have authority to establish tolerances that differ from EPA tolerances if they petition EPA based on exceptional circumstances as indicated above. States may also require local warnings or other statements about the presence of pesticide residues (such as those required under California's Proposition 65). The protective safety standards in the new law are likely to decrease the possibility that a state will need to establish a tolerance that is different from a federal tolerance. EPA has informed states and the public of these new provisions in background materials on FQPA and will work with states to ensure these provisions are understood.

#### **11.2 International Standards for Pesticide Residues**

##### Background

As a matter of policy, EPA has routinely considered whether U.S. tolerances and international MRLs were consistent. Whenever possible, EPA has established national tolerances consistent with MRLs set by the Codex Alimentarius Commission, a United Nations organization that establishes international food standards for the protection of consumers and facilitation of trade. EPA risk assessments or U.S. pesticide use patterns have sometimes indicated, however, that a national tolerance should differ from a Codex MRL. EPA has not always explained publicly why the Agency has set a U.S. tolerance that differs from the Codex MRL.

FQPA requires EPA to publish a notice for public comment whenever the Agency proposes a tolerance that differs from an established Codex MRL. EPA remains free to set tolerances in accordance with the stringent standards in U.S. law and is required only to explain differences.

##### Approach to Implementation

EPA will incorporate the new FQPA requirement into its routine tolerance procedures. In its interim guidance (PR Notice 97-1), the Agency has requested that tolerance petitions include information on relevant Codex MRLs. If the Agency proposes that a tolerance be set at a different level, EPA will issue a notice asking for public comment.

### **11.3 Monitoring and Civil Penalties for Illegal Residues**

#### **Background**

Previous pesticide law contained no provisions authorizing civil penalties for pesticide residue violations in food. Neither did previous law authorize funds specifically to programs for monitoring pesticide residues in food entering commerce. Such monitoring is the responsibility of the Food and Drug Administration which has conducted their monitoring program in accordance with available resources.

FQPA established new, substantial civil penalties for introducing foods with violative pesticide residues into interstate commerce. These penalties do not apply to growers. The new law also authorizes \$12 million for increased monitoring by FDA in fiscal years 1997-1999.

#### **Approach to Implementation**

These provisions will be implemented by FDA. EPA will work with FDA to address issues involved in establishing civil penalties for residue violations. With respect to monitoring, Congressional appropriation of the funds authorized by FQPA would permit FDA to substantially increase its monitoring program. FDA plans to work with Congress on appropriation issues.

## APPENDIX

### ***FQPA IMPLEMENTATION HIGHLIGHTS***

<i>Stakeholder Involvement</i>	August - December 1996	Food Safety Advisory Committee (FSAC) and Pesticide Program Dialogue Committee (PPDC) Meetings on interim strategies for implementing FQPA provisions.
	March 1997	Pesticide Program Dialogue Committee meeting to discuss minor uses, section 18 emergency exemptions, and communications workgroup activities
<i>Tolerances: New Standard and Factors to be Considered</i>	September 1996	<u>Federal Register</u> Notice issued withdrawing proposed and final tolerances revocations not yet in effect that had been subject to the Delaney clause of the Federal Food, Drug and Cosmetic Act, section 409. These revocations are no longer necessary due to FQPA changes to FFDCFA section 409.
	September 1996	EPA discussions with stakeholders on development of strategy to screen and test pesticides for estrogenic effects
	October 1996	Scientific Advisory Panel (SAP) review of EPA's positions on: <ol style="list-style-type: none"> <li>1) use of an extra 10-fold safety factor to account for the potential enhanced susceptibility of infants and children to pesticide exposures, and</li> <li>2) <u>in utero</u> cancer studies</li> </ol>
	December 1996	Endocrine Disruptor Screening and Testing Committee (EDSTAC) established; first meeting decided scope of Committee's work
	February 1997	EDSTAC meeting discussed principles to guide screening and testing program; workgroups formed
	March 1997	Interim Policy Statement on Endocrine Disruption issued
	March - September 1997	Workgroup meetings sponsored by the International Life Sciences Institute's Risk Science Institute (RSI) to address common mechanism of toxicity issues through a case study on organophosphate pesticides
	March 1997	SAP to review EPA's approach to aggregate exposure and common mechanism of toxicity
	April 1997	EDSTAC meeting to discuss initial screen designs for potential endocrine disruptors
	June 1997	SAP to review EPA's proposal on common mechanism of toxicity evaluation



	September 1997	RSI public workshop on common mechanism of toxicity evaluation and organophosphate pesticides
	Fall 1997	SAP meeting to review EPA's approach to evaluating cumulative exposures to organophosphate pesticides with a common mechanism of toxicity
	January 1998	EPA to begin comprehensive cumulative risk assessments for selected groups of organophosphate pesticides
	March 1998	SAP and Science Advisory Board (SAB) to review EDSTAC report recommending design of screening process
	<b>August 1998*</b>	Endocrine disruptor screening and testing strategy must be completed
	<b>August 1999*</b>	Process to screen and test pesticides for estrogenic effects must be implemented
	<b>August 2000*</b>	Report to Congress on endocrine disruptor screening program due
<i>Tolerances: The Regulatory Process</i>	September 1996	First tolerance for an emergency exemption issued
	October 1996	Pending registration and reregistration actions inventoried for decision-making according to FQPA requirements
	November 1996	EPA workshop on section 18 emergency exemption issues conducted for stakeholders
	December 1996	FSAC reviewed EPA's approach to tolerance reassessment
	January 1997	EPA began depositing fees related to tolerance activities into Reregistration and Expedited Processing Fund; announced in Federal Register
	January 1997	PR Notice 97-1 issued to provide guidance to registrants on amending registration applications/tolerance petitions to comply with FQPA requirements
	March 1997	Fourteen section 18 emergency exemption tolerances (total) established between September 1996 and March 1997
	April 1997	Proposed regulation governing the establishment of tolerances for section 18 emergency exemptions to be published in <u>Federal Register</u>
	<b>August 1997*</b>	Final regulation outlining process for establishing tolerances for emergency exemptions must be published in <u>Federal Register</u>

	<b>August 1997*</b>	Schedule of pesticide tolerances to be reassessed within next 10 years must be published in <u>Federal Register</u>
	December 1997	EPA to make decision on extent to which changes in EPA's tolerance assessment program require change in current tolerance fee structure
<i>Minor Use</i>	January 1997	Minor Use Workshop conducted for stakeholders
	April 1997	PR Notice outlining priority ranking procedures for assigning minor uses to be issued; will include list of 25 major crops not considered minor use crops
	September 1997	Minor use program will be established within Office of Pesticide Programs
	August 1998	Interim progress report on implementation of minor use provisions to be published in <u>Federal Register</u>
	<b>August 1999*</b>	Progress report on registration of minor uses must be published in <u>Federal Register</u>
<i>Consumer Right-to-Know</i>	March 1997	Pesticide Program Dialogue Committee subgroup to coordinate development of consumer brochure on health effects of pesticide residues on food, and system for effective distribution
	January 1998	Draft consumer brochure to be issued for public comment
	<b>August 1998*</b>	Consumer brochure to be distributed to large retail grocery stores
<i>Reduced Risk Pesticides</i>	April 1997	PR Notice to be issued on EPA's plans for implementing FQPA reduced risk provisions
	<b>August 1997*</b>	Procedures and guidelines for implementing expedited processing and review of reduced risk pesticides (both biological and conventional) must be developed
<i>Integrated Pest Management</i>	Early 1998	Conference for Federal agencies on use of Integrated Pest Management (IPM) practices
<i>Antimicrobial Reform</i>	January 1997	Workshop on antimicrobial issues conducted for stakeholders
	February 1997	Antimicrobials Division established within the Office of Pesticide Programs

	<b>March 1997*</b>	First annual report on antimicrobial regulatory reform progress due to Congress; report to Congress expected in May on accomplishments of first six months
	<b>May 1997*</b>	Proposed Antimicrobial Reform Regulation must be published <u>Federal Register</u> ; may not be published until July
	<b>May 1998*</b>	Final Antimicrobial Reform Regulation must be published in the <u>Federal Register</u>
<i>Registration Renewal</i>	December 1998	Procedures for registration renewal program to be established
<i>FIFRA Fund Expenditures Performance Report</i>	<b>Annually* (Beginning November 1997)]</b>	Report containing the status of reregistration progress and projected years of completion must be published in <u>Federal Register</u>
<i>Coordination of Data Requirements</i>	March 1997	Initiated process to coordinate Federal and State data requirements
	<b>August 1997*</b>	Process to coordinate Federal and State data requirements must be developed
<i>Research and Development</i>	Ongoing	EPA research to support the development of guidelines for testing and assessing aggregate exposure, including dermal and hand-to-mouth pathways in a residential setting, with an emphasis on children
	Ongoing	EPA research aimed at better understanding children's unique susceptibilities to specific chemicals and across different toxicological endpoints
	Fiscal Year 1998	Consumer Right-to-Know research grants to be awarded to study risk communication to the public
	Fiscal Years 1998/1999	Research to develop new methods for assessing cumulative risk from multiple chemical exposures
<i>Enforcement</i>	Ongoing	Continue enforcement of antimicrobial violations with emphasis on efficacy of hospital disinfectants and unregistered products
	Ongoing	Continue enforcement of misbranded pesticides
	Ongoing	Continue to provide guidance to states on monitoring and enforcement of pesticide misuse violations