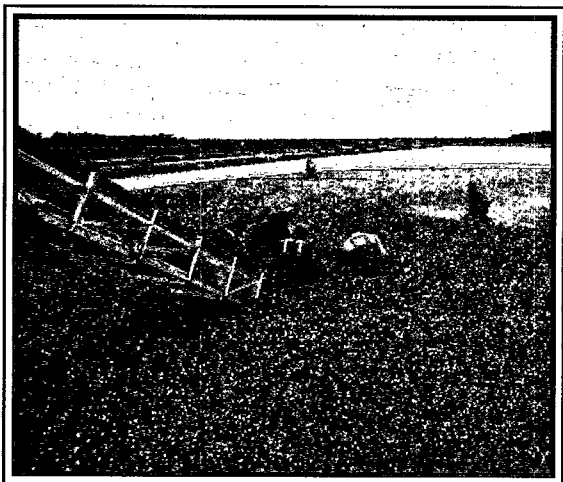
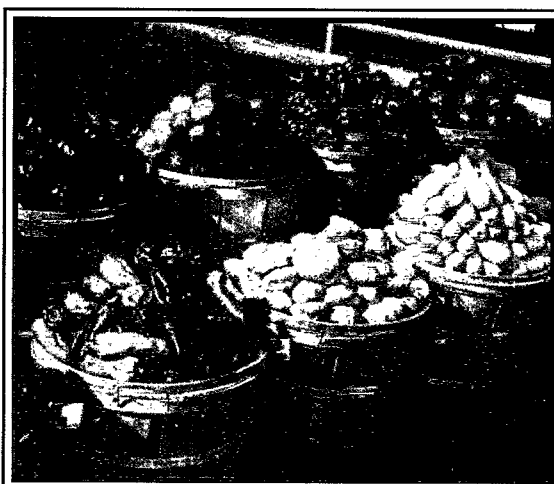




# Report on Minor Use Pesticides



**THE UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY**

**REPORT on MINOR USES of PESTICIDES**

Mandated by Section 31 of the Federal Insecticide, Fungicide,  
and Rodenticide Act (FIFRA) as Amended by  
the Food Quality Protection Act (FQPA) of August 3, 1996

Prepared by

EPA's Minor Use Team and Public Health Steering Committee  
in cooperation with  
the United States Department of Agriculture

## TABLE OF CONTENTS

Executive Summary .....	3
Background	
The Importance of Minor Use Pesticides.....	6
Definition of Minor Use.....	7
EPA Minor Use Activities	
Priorities for Minor Uses .....	9
EPA's Minor Use Team and Public Health Steering Committee.....	9
Registration Activities for Minor Uses .....	10
FQPA Exclusive Use Provisions for Minor Use Pesticides and Other Incentives to Register Minor Uses .....	11
Retaining Critically Needed Pesticide Uses.....	12
Relying on Sound Science and Real World Data.....	12
Maintaining a Level Playing Field in World Markets.....	13
Outreach and Communication .....	16
EPA/USDA Partnerships .....	18
EPA/DHHS Partnership.....	21
EPA/FDA Partnership.....	23
Conclusions.....	24
APPENDIX 1: Pesticides Registered Recently for Minor Use Crops .....	26
APPENDIX 2: Commonly used Acronyms.....	30

## EXECUTIVE SUMMARY

The Food Quality Protection Act (FQPA) of 1996 mandated a more coordinated approach for managing minor crop pesticides. One of the first steps taken by EPA to help improve its responsiveness to minor use concerns was the establishment of a full-time minor crop advisor reporting directly to the Director of the Office of Pesticide Programs. Through this mechanism, growers and others who are impacted by minor use issues are able to raise concerns and consult with senior program officials in a timely and coordinated fashion regarding minor use registrations, reregistrations and policy issues. To address public health minor use issues, EPA also designated a public health coordinator. EPA also created a minor use team to focus coordination of minor crop issues and a public health steering committee for vector pest control issues. These teams include representatives from the U.S. Department of Agriculture (USDA), from the Department of Health and Human Services (DHHS) and from various programs involved with pesticide issues throughout EPA.

### *Background*

Minor use pesticides are of 'major' significance in agricultural production and for protecting public health from disease vectors such as mosquitos, ticks, cockroaches, rats and disease-causing organisms. Without these comparatively small-scale but vital pesticide uses, many of the fruits, vegetables and ornamentals enjoyed in the U.S. and valued at billions of dollars could not be grown successfully. Minor uses of pesticides are those for which the total U.S. acreage for a particular crop is less than 300,000 acres or those for which the use does not provide sufficient economic incentive to support its registration. Thus, minor uses are not always economically attractive to the pesticide industry because the amount of pesticides sold for these uses is limited and revenues may be low, while the costs to obtain and maintain registration are substantial. However, EPA working cooperatively with USDA recognizes that a variety of pest management tools are needed in order to: 1) produce and maintain a safe, dependable supply of fruits and vegetables; 2) implement integrated pest management (IPM) programs; 3) manage pest resistance; 4) allow U.S. crop producers to compete effectively in a global food market; and 5) minimize global spread of pest-vectored public health diseases.

### *Priorities for Minor Uses*

EPA priorities for minor uses include expedited registration of minor use pesticides. Nearly 84 percent of all uses approved by EPA's pesticide registration program in 1998 and 1999 were for minor uses. And for 2000, the numbers are equally impressive with more than 80 percent of these chemical-crop combinations in a reduced-risk category. Importantly, many of these minor use crops are the fruits and vegetables consumed daily by children.

In response to concerns expressed by the minor use community, EPA is addressing the following issues:

**Maintaining an Adequate Supply of Effective Pesticides:** In fiscal year 1999, EPA registered 814 new pesticide uses for minor crops and 901 were registered in fiscal year 2000. In addition, over 550 emergency or crisis exemptions were granted in 1999 in record turn-around times and the same performance has continued in 2000. The majority of these actions were for reduced-risk pesticides.

**Retaining Critically Needed Pesticide Uses:** The Agency is working with USDA and DHHS to identify critical pesticide uses and is providing growers, public health program coordinators and other stakeholders opportunities to identify critical uses and discuss regulatory actions before they become final. In addition, provisions are being considered to permit selective use of critically needed pesticides while alternatives are being developed.

**Relying on Sound Science and Real World Data:** FQPA raised the standard of protection to pesticide exposure and has changed the way EPA conducts risk assessments. EPA is using real world data, state-of-the art risk assessment methods and extensive studies for risk assessments and relies on advice from the Scientific Advisory Panel, input from USDA and DHHS, internal and external peer review and public notice and comment periods to help develop sound science policies.

**Maintaining a Level Playing Field in World Markets:** EPA is harmonizing pesticide regulatory activities with Canada and Mexico through the North American Free Trade Agreement's (NAFTA's) Technical Working Group and with Europe and many other industrialized countries through the Organization for Economic Cooperation and Development (OECD). One of the primary goals of harmonization is to reduce barriers.

**Developing Partnerships between EPA, USDA and DHHS:** EPA has a long and productive history of working with USDA's Inter-regional Project #4 (IR-4) on pesticide registration for minor crops and is working with USDA's Office of Pest Management Policy (OPMP) on science policies, tolerance reassessment, reregistration and other pest management issues. EPA and DHHS's Center for Disease Control (CDC) signed a memorandum of understanding in July 2000 that outlines how the agencies will collaborate on implementing the FQPA public health pesticide provisions.

**Increasing Outreach and Communication by EPA:** Greater public participation and increased transparency are integral to the process used by EPA and USDA for tolerance reassessment. Based on recommendations from the Tolerance Reassessment Advisory Committee (TRAC) to improve outreach and communication for the FQPA-mandated tolerance reassessments, a pilot process was successfully developed. In March 2000, EPA proposed a public participation process for pesticide risk assessment that would apply to all tolerance reassessments. Building on the pilot process developed with the TRAC, this allows for greater public participation at important stages, including an opportunity for EPA, USDA and other agencies to meet with interested stakeholders to discuss

pesticide use and usage and to share available information. EPA will also inform the public well in advance about pesticides scheduled for the public participation process to allow registrants to inform the Agency about studies that have begun and the public to anticipate upcoming activities on pesticides of particular interest to them.

## BACKGROUND

### *The Importance of Minor Use Pesticides*

Minor crop producers and public health program administrators typically have fewer pesticide options for pest management due to lack of economic return to registrants to develop and register and/or support reregistration of pesticides for minor uses. However, a variety of pest management tools are needed to: 1) produce and maintain a safe, nutritious and dependable food supply and effectively control public health pests in the United States; 2) implement integrated pest management (IPM) programs; 3) manage pest resistance; 4) allow United States growers to compete effectively in a global food market; and 5) minimize global spread of pest-vectorized public health diseases.

The Food Quality Protection Act (FQPA) called for a new, better coordinated approach to managing issues involving minor uses of pesticides. This coordinated approach builds on existing efforts at both the EPA and USDA and increases the role of stakeholders in providing information crucial to sound regulatory decisions. The authors of FQPA recognized that in addition to strengthening protection of children and other sensitive populations in the United States from pesticide risks, that the Agency must consider other policy goals, such as maintaining a safe, dependable, and affordable supply of fruits, vegetables and other foods along with the protection of the public health from pest-vectorized diseases. Most fruit and vegetable uses and public health uses, such as mosquito control programs, are considered by EPA and USDA as minor uses for pesticides. The FQPA directs EPA, working together with USDA and DHHS, to give special consideration to minor uses for pesticides.

FQPA raises the standard of protection for children and other sensitive populations from pesticide risks and prescribes a time-line for reassessing all pre-existing pesticide residue tolerances. Minor use stakeholders are concerned that minor uses will be lost as EPA implements the tolerance reassessment/reregistration requirements of the FQPA. Prior to enactment of the FQPA in August 1996 and in response to reregistration changes in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) mandated in 1988, approximately 1,000 minor uses were voluntarily canceled by registrants during the reregistration process. Minor uses do not offer economic returns to registrants comparable to major crop uses, and have historically been the first uses dropped by registrants negotiating risk reductions for reregistration with EPA. In addition, many of these pesticides have outstanding data requirements that must be met before reregistration can be completed. Sometimes the cost of providing these data can be too high for the registrants, particularly in cases where the chemicals have a small or declining market share and profit margin. In these cases, the registrants may seek to voluntarily cancel part or all the uses of the pesticide.

### *Definition of 'Minor Use'*

FIFRA section 2(l), as amended by FQPA, defines 'minor use' as follows: "The term 'minor use' means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where--

- 1) The total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or
- 2) The Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for use and---
  - A) There are insufficient efficacious alternative registered pesticides available for the use; or
  - B) The alternatives to the pesticide use pose greater risks to the environment or human health; or
  - C) The minor use pesticide plays or will play a significant part in managing pest resistance; or
  - D) The minor use pesticide plays or will play a significant part in an integrated pest management program."

Several hundred crops, including most fruits and vegetables, meet the acreage criterion in this definition. The easiest way to identify them is by listing what is not a minor crop under the acreage portion of the definition. The following crops are grown on more than 300,000 acres, and thus do not meet the acreage definition of a minor crop: almonds, apples, barley, beans (snap and dry), canola, corn (field, sweet and pop), cotton, grapes, hay (alfalfa and other), oats, oranges, peanuts, pecans, potatoes, rice, rye, sorghum, soybeans, sugar beets, sugarcane, sunflower, tobacco, tomatoes, turf and wheat.

These 'major crops', however, can have minor protection needs, for certain pests or in certain regions. In such cases, a crop meeting the economic definition is eligible for treatment as a minor use. The Agency and IR-4 routinely undertake regional/pest specific requests for apples, grapes, snap and dry beans, pecans, potatoes, sugar beets and tomatoes that meet the economic definition of a minor crop.

FQPA defines public health pesticides as a sub-category of minor use pesticides. Specifically, section 2(nn) of FIFRA defines a "public health pesticide" as:

[A]ny minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the mitigation of viruses, bacteria or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.



FIFRA section 2(oo) defines the term "vector" as--

"any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats".

These definitions taken together contain the three mandatory conditions for a pesticide product to qualify as a "public health pesticide":

- 1) The public health use of the pesticide product must be a minor use, meeting the economic criterion under section 2(11) of FIFRA.
- 2) The pesticide must be registered for use and used predominantly in public health programs.
- 3) The use of the pesticide in the public health program must be for vector control or for other recognized health protection purposes.

## **EPA MINOR USE ACTIVITIES**

### ***Priorities for Minor Uses***

Priorities for minor uses include expediting minor use pesticide registrations. EPA gives high priority to minor use registrations that: replace uses canceled during tolerance reassessment and reregistration; avoid reissuance of FIFRA section 18 emergency exemptions; offer alternatives to methyl bromide, organophosphates, carbamates and class B2 carcinogens; fill critical use needs; will play a significant part in managing pest resistance; or will play a significant part in integrated pest management programs.

Minor use priorities for reregistration and tolerance reassessment are guided by recommendations from the Tolerance Reassessment Advisory Committee (TRAC) and the recently formed Committee to Advise on Reassessment and Transition (CARAT). In a response to a request to enhance stakeholder input on FQPA implementation, EPA and USDA established the TRAC to consult with, and make recommendations to the Administrator of EPA and the Secretary of Agriculture on how best to reassess tolerances, including those for organophosphate pesticides, as required by FQPA. The four implementation principles that direct EPA's priorities for reassessment of minor uses of pesticides are:

- Use of sound science in decision-making.
- Establishing a transparent regulatory process.
- Ensuring a reasonable transition for agriculture to new methods and alternatives.
- Fostering the involvement of stakeholders.

EPA and USDA have made considerable headway towards these goals with the development of key science policies for decision-making, use of the internet to post risk assessments and policies that increase transparency in real time, use of interactive processes for increasing stakeholder involvement, expedited registration of reduced-risk minor use pesticides, and implementation of grant programs for pest management strategies that reduce risk.

Obtaining real world pesticide use and residue data for refined risk assessments is a priority for EPA. These data are more readily available for major uses of pesticides than minor uses. EPA is working with USDA, minor crop growers, public health program administrators and other stakeholders to obtain real world data for minor uses.

### ***EPA's Minor Use Team and Public Health Steering Committee***

FQPA calls for coordinated action on minor use issues by EPA, USDA and DHHS and an increase in stakeholder involvement in actions affecting minor uses. As a focus for coordination, EPA created the multi-disciplinary Minor Use Team and the Public Health Steering Committee to facilitate minor use activities. These groups include members from USDA and DHHS. The goals of the Minor Use Team and Public Health Steering Committee are:

- Ensure that growers and public health program administrators have an opportunity to discuss their needs and concerns with EPA before EPA finalizes regulatory actions;
- Work with USDA, IR-4, DHHS, industry, growers, public health agencies and other stakeholders to promote registration and use of reduced-risk pesticides for minor uses;
- Encourage development of real world pesticide use and residue data by growers, public health agencies, USDA, DHHS and other stakeholders for use in refined risk assessments.

### ***Registration Activities for Minor Uses***

EPA's efforts to respond to minor crop growers' needs are evidenced by progress made on new registration decisions for minor crops. In fiscal year 1999, EPA registered new pesticides and approved new uses of existing pesticides, which provided growers with 814 additional new uses for minor crops. In fiscal year 2000, 901 new minor crop pesticide uses were registered. Of these, over three quarters involved biopesticides or reduced-risk pesticides. Examples of some of the recently registered minor uses are listed in Appendix 1.

EPA's Registration Division (RD) uses a priority planning system to manage conventional pesticide registration actions and gives high priority to minor use and reduced-risk pesticide registrations. IR-4 shares EPA's commitment to prioritizing registration of reduced-risk pesticides, and as a result over 80 percent of IR-4 projects for fiscal year 2000 supported registration of reduced-risk pesticides. RD has increased its efficiency in registering minor uses with IR-4 and industry registrants through developing new crop groupings for tropical fruits and other minor crops, discussing needs with grower groups and registrants and consolidating reviews. In addition, at the request of IR-4, RD has streamlined the requirements needed to support reduced-risk classification for minor use pesticide applications. Through hard work by both partners, productivity has increased and many new reduced-risk pesticides are being made available to minor crop producers. EPA and IR-4 are exploring additional ways to increase productivity.

The Fiscal year's FIFRA section 18 emergency response program granted over 550 emergency use or crisis exemptions in fiscal year 1999 with record turn-around times that have continued. Quick response to FIFRA section 18 emergency and crisis requests are a priority for EPA's Office of Pesticide Programs (OPP), and the majority of emergency exemption and crisis requests are for minor uses of pesticides. Prior to FQPA, EPA did not establish pesticide tolerances for crops in conjunction with Section 18 exemptions or crises, but advised the Food and Drug Administration (FDA) of acceptable pesticide levels for residues resulting from use under an exemption or crisis. FDA used the action levels for enforcement when monitoring foods for pesticide residues. FQPA specifically requires EPA to establish tolerances for FIFRA section 18 emergency exemptions. Obtaining required tolerances quickly has been a major concern for minor crop producers. EPA is evaluating these tolerance actions quickly, often relying on residue data provided by IR-4, and is also working with state lead agencies and grower groups to mitigate risks or find effective alternatives for requested pesticides that do not meet FQPA safety standards. Prescriptive-use programs have been developed for some section 18 requests, requiring growers,

state lead agencies and university extension specialists to work together to mitigate risks from pesticides and reduce the development of pest resistance to pesticides.

Biopesticides are registered by EPA's Biopesticides and Pollution Prevention Division (BPPD). Biopesticides are generally reduced-risk materials that have fewer human health and ecological toxicity concerns than most conventional pesticides. BPPD works together with IR-4, USDA-Agricultural Research Service (ARS) and USDA-Forest Service (FS) to facilitate registration of biological pesticides. USDA IR-4, ARS and FS have biopesticide research and/or development programs and have detailed some of their scientists to BPPD to learn about data requirements and the registration process. Biopesticides generally are not as broad spectrum or as quick acting as conventional pesticides and therefore require more field development and testing to determine how to use them most effectively. IR-4 is working with the biopesticide industry to develop the field testing and grower demonstrations vital to successful use of these products.

EPA and USDA are working together with stakeholders to find alternatives for organophosphate, carbamate, and class B2 carcinogen pesticides. Both EPA and USDA recognize that pest management products must be field tested, economically feasible and compatible with other integrated crop management practices in order to be accepted as viable alternatives. EPA is determining how to streamline experimental testing of reduced-risk pesticides, and USDA is gearing up to support new research and development proposals through IR-4 and with their competitive grants programs: 'Pesticide Management Alternatives Program' (PMAP), 'Crops at Risk' (CAR), and 'Risk Mitigation Program for Major Crops System' (RAMP). EPA relies on USDA to help minor crop producers develop viable alternatives.

#### ***FQPA Exclusive Use Provisions for Minor Use Pesticides and Other Incentives to Register Minor Uses***

FQPA provides for extension of exclusive use rights to rely on supporting data when a registrant applies for new minor uses. This was intended to be an incentive for registering more minor uses. FQPA directs EPA to give priority to registration submissions that request three or more 'significant minor uses' for every major use. Significant minor use is defined by FQPA as a minor use that would, in the judgment of the Administrator, serve as a replacement for any use that has been canceled in the five years preceding the receipt of the application, or a minor use that, in the opinion of the Administrator, would avoid the reissuance of an emergency exemption under FIFRA section 18 for that minor use. There have only been several specific requests by registrants to use this incentive. The American Crop Protection Association (ACPA) suggested, however, that an even greater incentive is EPA giving priority to any submission, which combines minor use applications with major uses.

RD has incorporated ACPA's suggestion into their priority system and also gives priority to submissions for minor and major uses, which are organophosphate pesticide alternatives. EPA is responsive to minor use concerns and routinely meets with IR-4, industry and minor use groups to prioritize needs and seek registration efficiencies.

### ***Retaining Critically Needed Pesticide Uses***

There is concern that critical uses of old pesticides, such as the organophosphates, carbamates and B2 carcinogens, will be lost as EPA reassesses tolerances under the new requirements of FQPA. Critical uses of pesticides are those that have few or no alternatives to pesticide uses undergoing tolerance reassessment or reregistration review. The transparent, highly interactive pilot process for reassessing organophosphate pesticide tolerances, developed by EPA and USDA with recommendations from TRAC, provides opportunities for stakeholders to identify critical uses and supply practical information for mitigating risks before regulatory actions become final.

As an illustrative example, the TRAC pilot process was used to assess the risks associated with the use of formetanate hydrochloride (Trade name Carzol), a carbamate insecticide/miticide. Acute dietary risk assessments for Carzol indicated that currently registered use patterns of the pesticide exceeded the allowable dietary intake by children. Risk mitigation would be required to achieve acceptable dietary levels. As part of the risk assessment process, EPA called on USDA's Office of Pest Management Policy (OPMP) to help identify critical uses and practical risk mitigation methods. USDA-OPMP arranged conference calls with growers, the registrant of Carzol, IR-4, state lead agricultural agencies, university extension specialists and others to discuss the risk assessment and identify critical uses. The calls helped identify practical risk mitigation practices for critical uses, and surfaced information crucial to the registrant's decision to support or abandon specific uses. In this case, based on input from affected grower groups, the registrant decided to support several critical minor uses that it had intended to drop. Other, non-critical uses were dropped to reduce risks from dietary exposure. In addition, prescriptive-use programs, similar to those used to mitigate risks for FIFRA section 18 emergency exemptions, are being developed to mitigate risks to acceptable levels and preserve critical uses until effective alternatives are developed.

### ***Relying on Sound Science and Real World Data***

Requirements of FQPA are changing the way EPA does risk assessments and new methods and policies have been developed to implement the law. EPA worked with TRAC to identify nine science policy issues that are key to the implementation of the FQPA and tolerance reassessment. Although EPA has sought independent review and public participation on a wide variety of issues, EPA agreed that the implementation process would benefit from a more thorough process of public notice and comment. In October 1998, EPA published a framework to describe these issues and a preliminary schedule for the release of the policy and guidance documents associated with each issue. In addition to the nine policy areas initially identified, EPA is seeking public comment on several related issues, such as policy on early assessments. To date, 19 science policy papers have been released for comment. EPA relies on the advice of the Scientific Advisory Panel, input from USDA and DHHS, public notice and comment and internal and external peer review to help develop sound science policies.

EPA is using real world data and state-of-the art risk assessment methods to develop quantitative risk assessments that meet the new requirements of FQPA. EPA works with USDA-

OPMP on science policies and relies on real world data generated by various USDA programs. The statistically valid, nationally representative residue data generated by USDA's Pesticide Data Program (PDP), crop-specific pesticide use data collected by the National Agricultural Statistics Service (NASS) and USDA food consumption surveys have played vital roles in EPA's FQPA risk assessments, and their importance cannot be overemphasized.

In addition, efforts by the Minor Crop Farmer Alliance and the American Mosquito Control Association to collect and submit real world pesticide use data for validation by EPA's Biological and Economic Analysis Division (BEAD) have provided critically important data for refined risk assessments and well-informed risk management decisions. Some grower and food processor groups have also voluntarily provided real world residue data, which EPA has validated and used for tolerance reassessments.

BEAD is taking a new approach to providing real world use and usage data for risk assessments, benefiting EPA's understanding of minor crop pest management issues and risk management possibilities. Instead of evaluating use and usage from a single-chemical perspective, BEAD is providing crop-based evaluations, which include validated use and usage information from stakeholders. These evaluations report regional variations and comparative efficacy of the various pest management tools available for the crop. To complement and supplement BEAD's crop evaluations, USDA is developing over 500 crop profiles and is piloting projects with USDA-NASS and USDA-PDP to provide EPA with data representing pesticide levels in foods resulting from growers' prevailing pesticide use practices. The EPA's Health Effects Division (HED) and BEAD have developed statistical models to translate USDA's PDP composite residue sampling data to single serving residue data, a form of data much more useful and more refined than currently available data for use in EPA's probabilistic acute dietary risk assessment model. HED also worked with USDA to develop a protocol for pesticide residue sampling for single servings, and PDP is using this method for its monitoring program.

### ***Maintaining a Level Playing Field in World Markets***

The North American Free Trade Agreement (NAFTA) and the General Agreement on Trade and Tariffs (GATT) have increased trade opportunities and challenges for U.S. growers and level playing field issues are becoming more critical than ever in an increasingly global food market. Minor crop producers want assurances that pesticides, which are severely restricted or banned from use in the United States, are similarly restricted or banned for use on imported food. They suggest that analytical methods that can detect pesticides banned or restricted in the U.S. at very low levels are required, and enforcement surveillance must be increased.

EPA has entered into an interagency agreement to begin purchasing analytical instruments for some FDA laboratories. The new instruments will allow for detection of pesticides at levels far below what is currently possible. EPA is developing methodologies for laboratory use and will provide FDA with a list of pesticides and crops for priority monitoring. The pesticides will be mainly organophosphates and the crops will consist of many domestically grown and imported children's foods. This improved monitoring will serve two purposes. First, it will allow detection of low levels of pesticides for which there are no tolerances. Second, where tolerances already

exist, it will provide better information on actual organophosphate residue levels for use in EPA's risk assessments.

EPA-OPP is active in a number of scientific harmonization and regulatory coordination efforts through international and regional organizations and directly with other countries. One of the primary goals of harmonization is to reduce trade problems and level the playing field in the world marketplace. In addition to reducing trade problems, harmonization also improves food safety, reduces regulatory burden on national governments and strengthens scientific procedures.

OPP is involved in cooperative work on pesticide issues with the Organization for Economic Cooperation and Development (OECD), an intergovernmental organization consisting of 29 industrialized countries in Europe, North America, Asia and the Pacific. OPP works with OECD through the OECD Working Group on Pesticides to explore ways to harmonize pesticide data requirements, focus test guidelines on pesticide regulatory needs, and harmonize industry data submissions and government data review formats and content. The Working Group on Pesticides is the only established international forum for OECD member countries to meet regularly to discuss pesticide regulatory issues of common interest. This group meets approximately every nine months in conjunction with OECD Joint Meetings to discuss and make decisions about the program of work agreed to by the member countries.

Common data requirements are an important building block for harmonizing countries' regulatory reviews. OECD member countries have developed proposals for similar core data requirements for biological pesticides, pheromones and microbials. OECD has built a database containing information on national pesticide registration evaluations and encourages the ad hoc exchange of data reviews. OPP keeps the United States' entries current and uses the database to determine which countries have pesticide reviews that could be of use in the United States. As a result, EPA has been able to use some of these reviews to support regulatory decisions. OECD member countries would like a common approach to testing pesticides and are working on achieving this by developing standardized test guidelines. Some testing guidelines have been harmonized and OECD is revising their test guideline program next year to increase responsiveness to member country's needs. OECD developed harmonized formats for industry data submissions and regulatory reviews. Standardizing the content and structure of submissions and reviews makes them more easily understood and potentially interchangeable between country's regulatory agencies.

Cooperative U.S./Canada bilateral efforts on pesticide regulatory harmonization were expanded in 1996 to include Mexico through the NAFTA Technical Working Group (TWG). The TWG is developing a coordinated pesticides regulatory framework among NAFTA partners to address trade irritants, build national regulatory/scientific capacity, share review burden and coordinate scientific and regulatory decisions on pesticides. This work has already begun to pay dividends by addressing specific trade irritants, developing a better understanding of each regulatory agency's risk assessment practices, working to harmonize each country's procedures and requirements and encouraging pesticide registrants to make coordinated data submissions to the three NAFTA countries to facilitate joint reviews.

The NAFTA TWG started doing joint reviews in 1998 and has completed reviews for cyprodonil fungicide on fruit, diflufenzopyr herbicide on field corn, fenhexamid fungicide on grapes, strawberries and ornamentals, Virosoft CP4 bio-insecticide for codling moth control in apples and Eastern Pine Shoot Borer pheromone. Eleven other joint reviews are in progress for an assortment of conventional and biological pesticides.

In an effort to support pesticide registration in all three NAFTA countries and to facilitate data development in support of minor crops, the NAFTA Food Residues Subcommittee completed the North America Crop Field Trial Zone Maps for Canada and the United States. Zones for Mexico have been provided to stakeholders for comment. Ten pesticide/crop combinations between Canada and the U.S. and one combination between Mexico and the U.S. were identified for field trials for minor use pesticide registrations in 2000 through the IR-4 program. The Food Residues Subcommittee will be working on residue zone validation and coordinating data waiver policy in the coming year.

The NAFTA TWG finalized a Geographic Information System (GIS)-based decision support system that registrants can use to select field dissipation study sites to address requirements of both Canadian and U.S. regulators. A new project will address harmonization of dissipation field study protocols including the number of sites that need to be tested for specific uses. In addition, the groundwork to allow full work sharing for occupational and residential exposure assessments is complete. Guidelines have been developed to use the EPA Pesticide Handlers Exposure Data Base for these reviews. Estimates of exposure conducted according to these guidelines can be used to address the requirements of Canada's Pest Management Regulatory Agency (PMRA), EPA and the California Department of Pesticide Regulation.

EPA supports the Codex Alimentarius Commission, a joint program of the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) whose goal is to protect the health of consumers and to ensure fair trade practices in food trade. It develops international food safety standards, including pesticide Maximum Residue Limit (MRL) recommendations. National governments can decide whether or not to accept and use the Codex MRL recommendations as national standards. Many developing countries depend upon Codex MRLs to set acceptable pesticide residue levels in their own countries. Industrialized countries with long-established programs review the Codex MRL recommendations and usually accept them when they are consistent with their national standards. In addition to governmental representation from 165 member countries, other international organizations and consumer, environmental and industry non-governmental groups participate as observers in Codex activities. EPA contributes technical expertise to the development of these international standards and tries to ensure that they are compatible with the U.S. levels. The FQPA placed increased emphasis on using Codex MRLs in setting U.S. tolerances for pesticide residues, to the extent feasible.

U.S. minor crop stakeholders indicate that they are having trouble exporting commodities treated with newly registered pesticides because MRLs have not been established for the new pesticides and importing countries will not accept the treated food commodities without an established MRL. Many of the newly registered pesticides are reduced-risk pesticides that U.S. producers would like to use, but may not be able to use on food commodities for export until MRLs



are established. It takes four to eight years to establish Codex MRLs under current MRL procedures. U.S. Codex Alimentarius Commission members are attempting to alleviate this concern by developing a process to quickly establish time-limited, temporary MRLs for newly registered reduced-risk pesticides.

Level playing field issues also affect public health programs. Global travel increases the potential for spread of pest-vectored diseases. Travelers carrying vector-borne pathogens and accidental introduction of pest vectors can result in epidemics of previously unseen diseases. The Agency tracks pest-vectored disease outbreaks in the United States and works with affected states and public health pesticide program administrators to ensure that effective pesticides are available and are used with minimal impact to the surrounding environment.

### ***Outreach and Communication***

Increased outreach, communication and transparency to all stakeholders guided development of the pilot process for reassessing the organophosphate pesticide tolerances by EPA and USDA with recommendations from TRAC. The pilot process has provided the public the opportunity to review and comment on risk assessments before they are finalized. The public process has encouraged sharing of information reflecting actual field practices for refining risk assessments and working with EPA and USDA on risk mitigation strategies. The pilot process includes the following activities: 1) risk assessments are posted on EPA's internet site and public docket, and comment periods are provided to obtain stakeholder input; 2) for many chemicals, EPA's Special Review and Reregistration Division (SRRD) provides technical briefings to the public on how risk assessments were done and on the calculated risks; 3) USDA arranges meetings and/or conference calls for EPA with grower groups, registrants, extension specialists, independent crop consultants and others to identify critical pest uses and provide a better understanding of actual use patterns; and 4) stakeholders, including environmental groups, industry, public interest groups, grower groups, regional EPA and state regulatory agencies, are contacted by EPA and USDA before the end of the tolerance reassessment or reregistration process to ensure that sound final regulatory decisions are made.

The EPA Minor Use Team and Public Health Steering Committee work with USDA and DHHS to ensure that the best available data are obtained and used in risk assessments. USDA is meeting with growers to develop Pest Management Strategy Programs and to identify critical pest control needs. EPA and IR-4 are using the critical pest needs identified at these meetings to channel and prioritize development and registration of alternatives for critical uses. This information also helps USDA to prioritize needs for their pest management competitive grants programs. These programs are discussed in more detail below under 'EPA/USDA Partnerships'.

EPA's Pesticide Environmental Stewardship Program (PESP) facilitates communications with grower and other pesticide user groups. The PESP program has over 30 minor use crop and public health partners. PESP works with their partners to develop practical, cost effective reduced-risk pesticide strategies and facilitates education and information sharing between pesticide user groups. PESP has provided seed money to support education about reduced-risk and IPM programs for both minor and major uses. In addition, PESP coordinates and catalyzes activity

between regional EPA, USDA and private enterprise IPM programs, which is resulting in real world pesticide risk reductions.

Other EPA outreach efforts include publication and Internet posting of RD's annual work plan to better inform all stakeholders of registration actions planned for the year and to increase predictability and timeliness of registration actions. EPA meets regularly with grower groups to discuss their priority needs and to provide information about the registration process. EPA's Minor Use Team and IR-4 are working with registrants and grower groups to facilitate development and testing of new biopesticides and reduced-risk pesticides for minor crops.

OPP initiated four pilot Agricultural Initiative projects in four of its ten regions in 1998. The four regions represent the areas of the country where the largest percentage of minor crops are produced including California (EPA Region 9), Florida and the southeast (EPA Region 4), Michigan and portions of the mid-west (EPA Region 5), and the Pacific Northwest (EPA Region 10). Each of the four regions hired an agricultural initiative specialist to facilitate communication and implement pollution prevention programs with the pesticide user community. The agricultural initiative programs are promoting understanding of FQPA and cultivating partnerships that draw affected regulatory agencies, industry and agricultural communities together to develop a clear understanding of regional pest management concerns and priorities and to develop pest management strategies that address these concerns. Agricultural initiative projects range from on-farm testing and demonstrations of reduced-risk pest control practices to collecting pesticide use information on minor crops. The regional agricultural initiative specialists are also working with USDA-OPMP on crop and region specific Pest Management Strategy Plans (PMSP).

## EPA/USDA PARTNERSHIPS

### *Cooperative Efforts with IR-4*

EPA's Office of Pesticide Programs and IR-4 have a long history of working together to register pesticides for minor crops. IR-4 shares EPA's commitment to prioritizing registration of reduced-risk pesticides, and as a result, over 80 percent of IR-4 projects for fiscal year 2001 support registration of reduced-risk pesticides. EPA gives high priority to minor use and reduced-risk pesticide registration submissions and expedites reviews for these submissions. EPA and IR-4 are working together to streamline processes and procedures for minor use pesticide registrations. The effectiveness of this streamlining was apparent in EPA's quick registration of IR-4's bifenthrin insecticide/miticide submission for snap beans and sweet corn; this product is proving to be an effective alternative to organophosphates on over 50,000 acres of beans and sweet corn. EPA and IR-4 are also working with USDA's Agricultural Research Service (ARS) to seek and register methyl bromide alternatives for minor crops. As a result, EPA expedited registration of halosulfuron-methyl, an herbicide alternative to methyl bromide, for control of nutsedge in cucumbers and squash.

Several EPA/IR-4 partnership projects are worthy of note:

- Streamlining the reduced-risk justification format for minor uses, making it less resource intensive for IR-4 to request reduced-risk classification.
- Developing 'blanket' tolerances for selected reduced-risk chemicals, reducing EPA review time.
- Improving the tolerance petition format, reducing EPA review time by two to three months.
- IR-4 assigning one of its minor crop experts to the Director's office in OPP to aid the program with minor crop issues.
- Sharing work plans, allowing EPA to predict arrival of IR-4 petitions and IR-4 to group submissions for the same pesticide, contributing further to a streamlined review.
- Harmonizing generation and review of data to support simultaneous registration of both conventional and biological pesticides with Canada's Pest Management Regulatory Agency (PMRA). Efforts are underway to do the same with Mexico and Europe.
- Creating new crop groupings resulting in fewer data requirements and substantial savings to both IR-4 and registrants. Crop groups combine similar commodities that are closely related botanically and have similar cultural practices and pest problems. By developing residue data on the representative crops within a crop group, a crop group tolerance applicable to all crops within that group can be obtained. This results in fewer field trials and less laboratory work than would be necessary to obtain tolerances on a crop-by-crop

basis. The use of crop groupings has had significant positive impact on both IR-4's and the industry's efficiency in obtaining tolerances. Five new commodity definitions for tropical fruits have been approved recently. In this example, residue data developed for papaya will be used to support the registration of pesticides for black sapote, canistel, mamey sapote, mango, and star apple. The potential research savings from reducing duplicate testing for all the tropical fruits could amount to \$2.5 million on a yearly basis.

EPA processing of IR-4 minor crop tolerance petitions was delayed the year immediately following the passage of FQPA (August, 1996 - August, 1997) like all other tolerance setting while EPA developed new methods of risk assessment required by FQPA. EPA has now developed many of the needed science policies and procedures to evaluate risk under FQPA's stricter safety standards, and the tolerance setting process is improved. IR-4 actions, on average, are processed by EPA in 18 months compared with 31 months for all new use actions submitted. Through hard work by both partners, productivity has increased and many new reduced-risk pesticides are being made available to minor crop producers. EPA and IR-4 are exploring additional ways to increase productivity and are building partnerships with California Department of Pesticide Regulation, Canada's PMRA and OECD for work sharing.

### *Cooperative Efforts with USDA-Office of Pest Management Policy (OPMP)*

USDA's OPMP consolidates pest management issues in USDA and includes members from all sectors of USDA with pesticide or pest management missions. EPA works closely with USDA-OPMP to obtain statistically valid, real world data for risk assessments and to identify critical pest management needs for tolerance reassessments and pest management strategies. This allows both EPA and USDA to focus efforts on working with those growers who need effective, viable alternatives to organophosphate, carbamate and class B2 carcinogen pesticides. OPMP is facilitating development of crop profiles for minor and major crops and has more than 300 such profiles to date, and expects to develop over 200 more. The crop profiles are state- and region-specific, and provide useful information for EPA risk management decisions. OPMP also facilitates development of Pest Management Strategy Programs (PMSP) by growers to address critical pest control needs. In addition, newly created USDA regional centers will be designated to further streamline and focus efforts on PMSP plans and regional pesticide issues.

EPA's Minor Use Team and Public Health Steering Committee keep the pesticide registration divisions and IR-4 informed on critical pesticide use needs identified during the tolerance reassessment process in order to focus registration efforts on those pesticide uses that need alternatives most. The EPA Minor Use Team Leader is a member of the USDA-OPMP core management team. Examples of the benefits of EPA and USDA coordination include:

**USDA Pesticide Data Program (PDP):** EPA relies on PDP for statistically valid, reliable, real world residue data on children's foods. This is the best source of refined residue data available to EPA and covers both United States and foreign produced crops consumed in the United States. PDP data have been essential for refining the risk assessments for the organophosphates and for non-organophosphate reregistration eligibility decisions. EPA meets regularly with USDA-PDP to discuss data needed by EPA for risk assessments. EPA and PDP developed a protocol for pesticide

residue sampling for single servings statistical models, a form of data needed for EPA's probabilistic acute dietary risk assessment model.

**USDA National Agricultural Statistics Service (NASS):** USDA-NASS provides statistically reliable, real world nationwide data on pesticide use for major and selected minor crops. EPA relies on these data to refine risk assessments. USDA-NASS also meets routinely with EPA and will custom design data collection for use by EPA.

**USDA Cooperative State Research, Education and Extension Service (CSREES):** CSREES is home to many programs that can provide alternative pest management practices for those growers who may lose pesticide uses through FQPA implementation. The IR-4 program is primarily funded by CSREES and the national Integrated Pest Management (IPM) and Pesticide Applicator Training (PAT) programs reside in CSREES. USDA has several competitive grant programs, administered by CSREES, designed to develop alternatives for critical uses of pesticides as follows: the 'Pest Management Alternatives Program' (PMAP), and recently funded 'Crops at Risk' (CAR), and 'Risk Management for Major Crop Systems' (RAMP). Lists of critical pest/pesticide uses that need alternatives are co-developed by EPA and USDA and USDA has given EPA voting rights on awarding the grants. Grower participation in programs like these is essential for changing real world pest management practices.

**USDA Agricultural Research Service (ARS):** USDA-ARS research is responsible for many insect pheromone and microbial pesticide discoveries and innovative ways to use parasites and predators for effective pest control. Many of the currently registered biopesticides owe their origins to USDA-ARS work. ARS has successfully transferred some of its technology to growers using area wide pest control programs. The USDA-ARS Pacific Northwest area wide codling moth pheromone control program for apples and pears is a good example of this. This program has allowed growers and researchers to develop effective and practical applications of pheromone technology for western apple and pear production areas. It has good potential to provide these apple and pear producers with sustainable, affordable alternatives to season-long conventional chemical controls. This technology has also been adopted by California pear growers who are developing novel application techniques for their growing areas. EPA supports these and similar programs through their PESP and regional grant programs. USDA-ARS also partially funds the IR-4 program and has detailed scientists to EPA's BPPD to facilitate development and registration of biopesticides.

**USDA Forest Service (FS):** USDA-FS has a productive biopesticide development program and has also detailed scientists to EPA's BPPD to facilitate development and registration of biopesticides. The USDA-FS is developing pesticide use profiles for forest uses, similar to crop profiles and has provided useful information for risk mitigation and identification of critical uses.

## EPA/DHHS PARTNERSHIP

In July 2000, EPA and DHHS's CDC signed a Memorandum of Understanding (MOU) that provides a framework for joint efforts and coordination of FQPA implementation between EPA and CDC. EPA/DHHS coordinated efforts required for FQPA implementation include:

- EPA, in coordination with DHHS and USDA, shall identify pests of significant public health importance.
- EPA shall consult with DHHS, upon a timely request to do so, prior to taking final action to suspend registration under Section 3(c)(2)(B), or cancel a registration under Sections 4, 6(e) or 6(f).
- EPA, in coordination with DHHS, shall implement programs to improve and facilitate the safe and necessary use of chemical, biological and other methods to combat and control such pests of public health importance.
- EPA shall exempt any public health pesticide from the payment of a reregistration fee or registration maintenance fee if EPA determines, in consultation with DHHS, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.
- EPA shall assure the expedited processing review of any application that proposes the initial or amended registration of an end use pesticide that, if registered as proposed, would be used as a public health pesticide.
- If necessary and appropriate DHHS shall make arrangements for the conduct of studies if EPA, in consultation with DHHS, determines that the benefits of continued use warrant a commitment by DHHS to conduct the studies for reregistration or continued registration. EPA shall amend the 3(c)(2)(B) notice to allow for reasonable time periods for submission of data by DHHS before taking final action.

EPA's Public Health Steering Committee worked with DHHS and USDA to identify significant public health pests and published the FQPA mandated public health pest list in April 2000 for review and comment. The Public Health Steering Committee works with stakeholders, such as the American Mosquito Control Association, to obtain real world pesticide use information, and has actively solicited input from DHHS on organophosphates used in mosquito control and other important public health programs.

EPA facilitates the safe and necessary use of pesticides to control pests of public health importance with CDC through PESP and Public Health Steering Committee membership on CDC's Federal West Nile Virus Coordinating Committee. EPA's PESP promotes IPM and reduced-risk pest management programs and both CDC and the American Mosquito Control Association are PESP partners.

EPA has not received any reregistration fee exemption requests to date and has had two requests for registration maintenance fee waivers: one that was granted and one that was denied. There have been no requests for registration of end use products for public health pest control to date.

EPA has provided DHHS with potential data gap information and estimated costs for conducting studies. EPA has not yet been faced with a case warranting a commitment by DHHS to conduct studies, but an EPA/CDC consultative process has been developed in case of need. EPA also arranged for discussions between DHHS and USDA IR-4, who has a well-established program in place to generate data for minor crops.

## **EPA/FDA PARTNERSHIP**

EPA and FDA are working on ways to assure safe harbor through channels of trade for food commodities containing legal residues of a pesticide whose pesticide tolerance has been revoked after legal treatment. Certain processed commodities have long shelf lives and can remain in channels of trade for four years or more. It is not illegal to have residues of pesticides whose tolerances have been revoked in food commodities if the pesticide was applied before revocation and use was lawful at the time under FIFRA. However, it is difficult for FDA to know which commodities that have residues of pesticides with revoked tolerances were legally treated. It is also difficult for food processors to gather the documentation required to prove that the foods were legally treated years after the foods were introduced into channels of trade. EPA and FDA have recently published proposals for review and comment on EPA tolerance revocation and FDA enforcement processes that provide for safe harbor and minimize burden on food processors.



## CONCLUSIONS

### *What is Working Well*

EPA and IR-4 have an effective, productive relationship. This partnership is solid and continues to yield new efficiencies and better ways to do business. It is a fine example of a successful strategic collaboration between EPA and USDA.

Harmonization of pesticide issues and data requirements between NAFTA and OECD pesticide working groups has provided workload efficiencies and avenues to pursue level playing field policies. EPA partnerships have been expanding to include harmonization and work sharing with the California Department of Pesticide Regulation and IR-4 is facilitating even greater work sharing for minor crops with all of these organizations.

Minor use stakeholders indicate that they like the pilot process for the FQPA organophosphate pesticide tolerance reassessments. It provides them with an opportunity to comment on the risk assessments before they become final. As part of the pilot process, EPA has been providing clearly articulated, highly refined risk assessments in public technical briefings. These briefings help stakeholders to understand EPA's concerns and allow time for further refinements, comments and risk mitigation discussions. Adequate time to develop the refined risk assessment and consider risk management options is a critical issue for minor use stakeholders.

### *Other Issues*

Real world pesticide use and residue data are necessary to refine risk assessments to reflect actual exposure scenarios for tolerance reassessment, reregistration and registration actions. EPA is encouraging generation and submission of these types of data. However, potential submitters should ask EPA to review their protocols for generating these data before they start data generation. EPA can help potential submitters determine how to provide data, which can be used to refine exposure assessments.

It is common practice to rotate short season vegetable crops like cucumbers, tomatoes, snap beans and cole crops (cabbage, broccoli, cauliflower). Rotational crop residue data are required by EPA to determine if residues from pesticides applied to one crop will occur in a different crop planted after the first crop is harvested. If these data are not available, restrictions on rotation are necessary and may preclude the use of the product. Registrants often do not find it cost effective to generate these data for minor crops, which can severely limit the applicability of the pesticide in areas where crop rotations are used. EPA is working on practical ways to work through this issue, including consideration of establishing tolerances on rotational crops by bridging data from other crops if the additional rotational crop uses do not exceed EPA's levels of concern and the registrant supports the additional uses.

A number of new insecticides and fungicides show real promise for minor crop uses. Many of these products are biopesticides and reduced-risk pesticides and represent new classes of

chemistry or biology, which makes them potentially effective new tools to manage pesticide resistance. However, most of these new compounds are not drop-in, one-for-one replacements for widely used older chemicals, and field efficacy testing and experimentation will be essential before growers will be prepared to risk relying on them. Efficacy testing is rarely performed anymore on minor crops that registrants do not actively seek registration. Most USDA and university researchers cannot justify the time and effort to do field research with minor crops, and there is little incentive or support for others to do this work. Registrants will not support registration of new products without efficacy and crop safety data due to liability concerns. In addition, the lack of field research showing efficacy is a major barrier to grower adoption of alternatives. Supporting programs or grants that lead to grower testing of promising alternative pest management practices is crucial for successful adoption of new technologies for pest management.

Efficacy testing and field demonstrations are just the first hurdle to be overcome for these products to be successfully adopted by growers. The second and probably more critical hurdle is the availability of trained professionals (consultants, extension agents, scouts, pest control advisors) to provide the education, monitoring and damage threshold evaluations required to use these products effectively and economically. Biopesticides and many of the reduced-risk pesticides tend to be very pest specific and most do not have the quick knock-down features that older, conventional pesticides have. In addition, they may be more expensive and labor intensive to use initially. Their long term benefits to cropping systems, such as increased populations of beneficial parasites and predators and pesticide resistance management, are difficult, at best, to convince growers about if trained professionals are not available to carefully monitor fields for optimal application timings and to develop economically feasible, integrated approaches for their use.

## **APPENDIX 1: Pesticides Registered Recently for Minor Use Crops**

In fiscal year 1998, EPA registered new pesticides and new uses, which provided growers with over 750 additional pesticide uses for minor crops. In 1999, 814 additional minor crop pesticide uses were registered and 901 more were registered in fiscal year 2000. Some highlights of minor use registration actions on reduced-risk pesticides include:

### **Acibenzolar-s-methyl (Trade name Actigard)**

Acibenzolar is a selective, systemic compound, which induces host plant resistance. This mode of action mimics the natural defense system in plants, referred to as systemic acquired resistance (SAR). It has no direct effect on the target pest. Actigard was registered in August 2000 for control of downy mildew on leafy vegetables, including Brassica leafy vegetables, bacterial spot and spec on tomatoes, blue mold on tobacco and diseases of banana. These are particularly difficult diseases to control and have few alternatives for control. The SAR-enhancing types of pesticides like Actigard are expected to revolutionize pest management disease control and reduce risks from pesticides.

### **Azoxystrobin Fungicide (Trade names Heritage, Abound, Quadris)**

In March 1999, EPA approved the registration of the reduced-risk fungicide azoxystrobin for use on almonds, grain, bananas, canola, cucurbits (examples include cucumbers, melons, squash), peanuts, pistachios, potatoes, rice, stone fruits (examples include peaches and cherries), tree nuts (examples include walnuts and pecans) and wheat. These new, mostly minor uses fill only a small percentage of the overall risk allowance for this chemical. The establishment of these additional tolerances allowed the withdrawal of five Emergency Exemption (Section 18) applications: two for cucurbits on watermelons and cantaloupes and three for rice. Azoxystrobin has also been approved for use on a wide variety of ornamental plants against a number of fungal pests that cause foliar and root diseases, where it offers a low-risk alternative to some other fungicides. IR-4 has received approval from EPA to submit a "blanket" tolerance petition for azoxystrobin, which will establish tolerances for all crop uses of this chemical.

### **Bifenazate Miticide (Trade name Floramite)**

In June 1999, this new reduced-risk miticide was registered for use on ornamental crops. This selective miticide has minimal impact on beneficial insects and IR-4 is pursuing additional registrations for minor crops.

**Bifenthrin Insecticide** (Trade names Capture, Brigade, Talstar, Biflex)

EPA registered new uses for the insecticide bifenthrin on cabbage, cucurbits (examples include cucumbers, squash and melons), edible-podded legume vegetable subgroup (examples include sugar snap peas and snowpeas), eggplant; globe artichoke, head and stem Brassica subgroup - except cabbage (examples include broccoli and cauliflower), rapeseed (canola), succulent shelled pea and bean subgroup (includes green, wax, lima and snap beans), and sweet corn. Tolerances for the last two crop groupings were jointly requested by IR-4 and FMC Corporation, the manufacturer of bifenthrin. Reports from the field indicate that this product is effective and is expected to replace organophosphate use on 50,000 acres of beans and sweet corn.

**Buprofezine** (Trade name Applaud)

Applaud insect growth regulator is a reduced-risk pesticide with a novel mode of action that was registered in August 2000 for control of sweet potato whitefly and other pests on various melons, cucumbers and lettuce. Sweet potato whiteflies have the potential to quickly develop resistance to pesticides and are responsible for millions of dollars of damage to susceptible crops. The registration of Applaud provides an effective tool for resistance management for this difficult to control pest.

**Codling Moth Granulosis Virus**

This biological pesticide was registered in July 2000 for control of codling moths. Codling moth is a primary pest of western apples, pears and walnuts. This product can support biointensive IPM programs and offers an alternative for codling moth pesticide resistance. The active ingredient is specific to control of codling moth and has minimal impact on the environment and human health. No risk to pesticide applicators or workers is expected and minimum levels of personal protective equipment are required.

**Diiflubenzuron Insect Growth Regulator Insecticide** (Trade name Dimilin)

In April 1999, EPA registered the insect growth regulator, diiflubenzuron, for use on rice. This action facilitated the use of this product for control of the rice water weevil, designated a critical crop/pest use (one that has few or no alternatives to a pesticide use undergoing tolerance reassessment or reregistration) by EPA and USDA's Pest Management Alternatives Program. Growers in California, Texas, Arkansas, Louisiana, Mississippi and Missouri will now have a replacement for carbofuran (Trade name Furadan), which is being phased out because of high avian toxicity.

**Fenhexamid Fungicide** (Trade name Elevate)

In May 1999, following joint U.S./Canada review, the new reduced-risk fungicide fenhexamid was registered for use on grapes, strawberries and ornamentals to control botrytis gray mold. Its use is expected to reduce dependency on older fungicides classed as

B2 carcinogens, such as captan, benomyl, iprodione, ziram, thiophanate-methyl and chlorothalonil and provide a resistance management alternative for producers. IR-4 is generating data to support registration of this product for many minor crops.

#### **Fludioxonil Fungicide** (Trade names Maxim, Medallion)

This reduced-risk fungicide has been registered on over 200 crops (both major and minor crops) for seed treatment use over the past several years. It is a resistance management alternative for producers.

#### **Halosulfuron-methyl Herbicide** (Trade names Permit, Semptra)

Halosulfuron-methyl was recently identified as a methyl bromide alternative by IR-4 and USDA's ARS for control of nutsedge in cucumbers and related crops and as a result received expedited registration this year by EPA.

#### **Harpin Protein**

Harpin protein is a biopesticide that works by activating natural defense mechanisms in host plants, referred to as systemic acquired resistance (SAR). Harpin elicits a protective action in plants that make them resistant to a wide range of fungal, bacterial, and virus diseases. In addition, it can also reduce infestation of selected insect pests. This product has a tolerance exemption and can be used on all food commodities as well as trees, turf and ornamentals. Harpin is not expected to cause any harm to the environment and also has minimal human health risks. Risks to pesticide applicators and workers are not expected and the minimum level of personal protective equipment is required. Harpin has been used effectively in tomato IPM programs, decreasing usage of conventional fungicides and insecticides by an average of 70%, while controlling diseases as well as or better than conventional fungicides. The SAR-enhancing types of pesticides like Harpin are expected to revolutionize pest management control and reduce risks from pesticides.

#### **Methoxyfenozone** (Trade name Intrepid)

Intrepid insect growth regulator was registered for use on pears, apples and other pome fruits in July 2000. Field testing indicates that it is effective for control of various leaf rollers and other lepidopterous pests and potentially fits well into orchard IPM systems. The product has reduced-risk characteristics and is an organophosphate alternative.

#### **Naval Orangeworm Pheromone**

Navel orangeworm pheromone is a biopesticide that works by disrupting the mating patterns of the navel orangeworm, a serious pest of almonds in California. A tolerance exemption has been established for this pheromone and minimal environmental or human health effects are expected. Mating disruption pheromones have been useful in IPM programs, reducing pesticide resistance development and risks to agricultural workers.

### **Prohexadione Calcium** (Trade name Apogee plant growth regulator)

Apogee plant growth regulator was registered in May 2000 for use on apples and peaches. This reduced-risk active ingredient is used on apples to aid in control of fireblight, a devastating bacterial disease of apples with few alternatives for control. Apogee does not directly affect the pest. Instead, it limits the amount of succulent apple growth that is particularly susceptible to the disease. This product will be used in conjunction with cultural practices and conventional and biopesticides to control the disease.

### **Pyriproxyfen Insect Growth Regulator Insecticide** (Trade names Knack, Esteem and Distance)

In April 1999, the reduced-risk insecticide, pyriproxyfen, was registered for use on pome fruits (apples, pears) and walnuts. Pyriproxyfen is a potential organophosphate and carbamate insecticide alternative. In 1998, it was registered for use on cotton, providing a much-needed alternative for control of sweet potato whitefly, a relatively new pest that has developed resistance to most older pesticides. IR-4 is generating data to support the registration of this product on several minor use crops.

### **Spinosad Insecticide** (Trade names Spintor, Tracer, Success, and Conserve)

In May 1999, the reduced-risk insecticide spinosad was registered for use on sweet corn, potatoes and other tuberous and corm vegetables (includes sweet potatoes and ginger). IR-4 has received approval from EPA to submit a "blanket" tolerance petition for spinosad, which will establish tolerances for all crop uses of this chemical.

### **Tebufenozide Insect Growth Regulator Insecticide** (Trade names Confirm and Mimic)

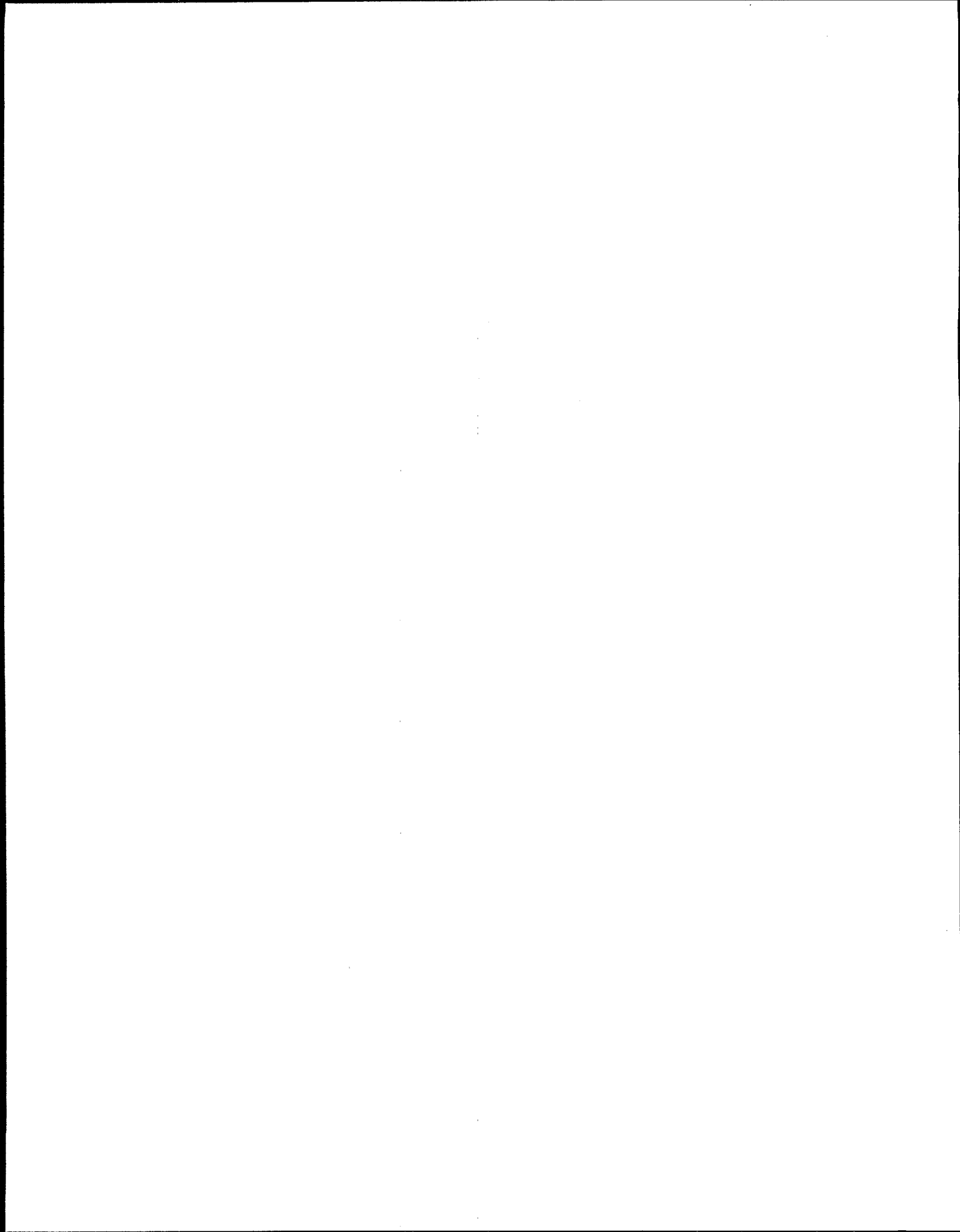
In April 1999, the reduced-risk insecticide tebufenozide was registered for use on 70 new crops including: the berry crop group (examples include strawberry, blueberry and raspberry), cranberries, peppermint, spearmint, fruiting vegetables - except cucurbits (examples of this crop group include tomato, peppers and eggplant), head and stem brassica subgroup (examples include cabbage, broccoli and cauliflower), leafy brassica subgroup (examples include collards and kale), leafy greens subgroup (examples include spinach and lettuce) and leafy petioles subgroup (examples include celery and chard). These registrations were supported by IR-4 generated data. This product is also registered for use on walnuts, pome fruits (examples include apples and pears) and cotton. Tebufenozide is a highly specific insecticide, which controls lepidopterous pests (such as armyworms and cabbage worms). It tends to fit well into IPM and resistance management programs and may be an alternative for some organophosphate and carbamate insecticides.

## **APPENDIX 2: Commonly Used Acronyms**

EPA	Environmental Protection Agency
OPP	Office of Pesticide Programs
USDA	United States Department of Agriculture
DHHS	Department of Health and Human Services
FQPA	Food Quality Protection Act
TRAC	Tolerance Reassessment Advisory Committee
IR-4	Interregional Research Project 4
OPMP	Office of Pest Management Policy
PMRA	Pest Management Regulatory Agency
OECD	Organization for Economic Cooperation and Development
NAFTA	North American Free Trade Agreement
FAO	United Nations Food and Agricultural Organization
OP	Organophosphate pesticides
PESP	Pesticide Environmental Stewardship Program
PDP	Pesticide Data Program
NASS	National Agricultural Statistics Service
CSREES	Cooperative State Research Education and Extension Service
ARS	Agricultural Research Service
MRL	Maximum Residue Level

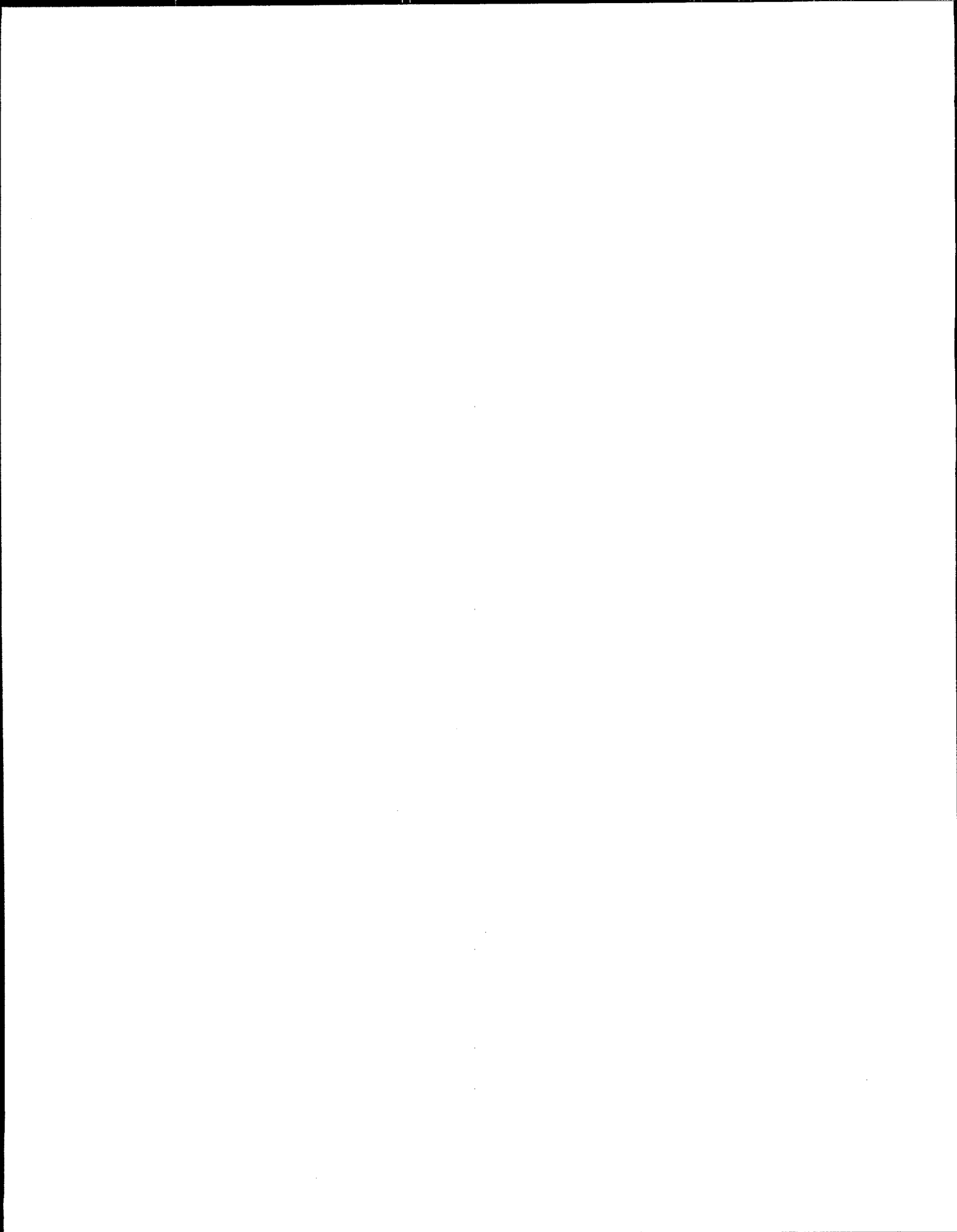
### **OPP DIVISIONS**

RD	Registration Division
SRRD	Special Review and Reregistration Division
BEAD	Biological and Economic Analysis Division
HED	Health Effects Division
BPPD	Biopesticides and Pollution Prevention Division
EFED	Environmental Fate and Effects Division
FEAD	Field and External Affairs Division
IRSD	Information Resources and Services Division













United States  
Environmental Protection Agency  
(7501C)  
Washington, DC 20460

Official Business  
Penalty for Private Use \$300