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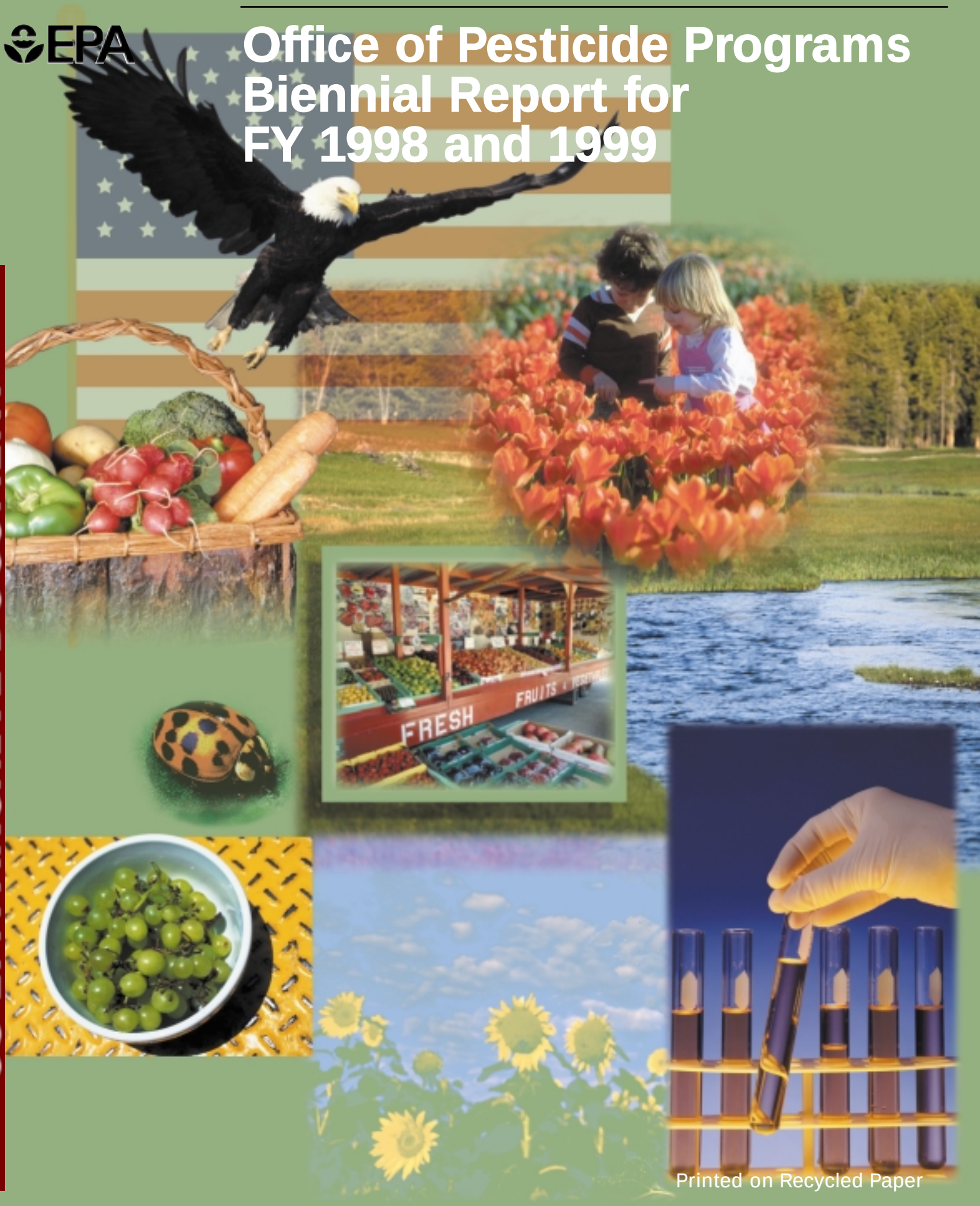
United States
Environmental Protection
Agency

Prevention, Pesticides,
And Toxic Substances
(7506C)

EPA 735-R-99-002
December 1999

Office of Pesticide Programs Biennial Report for FY 1998 and 1999



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Printed on Recycled Paper

Office of
Pesticide Programs
Biennial Report

Fiscal year 1998 and 1999

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EPA United States Environmental Protection Agency
Office of Pesticide Programs (7506C)

FOREWORD

by MARCIA E. MULKEY, Director
Office of Pesticide Programs

The Office of Pesticide Programs (OPP) is pleased to provide you with a summary report regarding many of the important activities carried out by the Program during 1998 and 1999. Clearly, the Food Quality Protection Act (FQPA) of 1996 has resulted in fundamental changes to the way pesticides are regulated in our country–providing the Agency with new tools and standards for assessing and reducing potential risks from pesticides, especially to children. This has been a remarkable period of time in OPP's history and one in which we've made tremendous progress not only in implementing FQPA but also in carrying out our many other important regulatory responsibilities.

...the Food Quality Protection Act of 1996 has resulted in fundamental changes to the way pesticides are regulated in our country...

Throughout the past two years, the program has made great strides in increasing transparency and stakeholder consultation in all of its activities, including, for example, developing and revamping many key science policies and working with the Tolerance Reassessment Advisory Committee (TRAC) to develop and implement the pilot process for public involvement in assessing and managing risk from organophosphates. Significantly, the program met the first tolerance reassessment deadline in FQPA by completing over 33% by August 3, 1999, with 3,430 tolerances reassessed.

Progress is not always about achieving higher numbers. While over the last two years, we exceeded our historic performance by registering 53 new active ingredients, it is important to note that we are continuing to bring to market higher numbers of "safer" or "reduced risk" conventional products. These products will continue to replace older, more toxic chemicals and thus help reduce potential risks from pesticides. Incorporating FQPA's new safety standard, we also completed 1,046 emergency exemption decisions and achieved significant risk reductions through the completion of 27 Reregistration Eligibility Decisions in 1998 and 1999. In virtually all areas involving routine registration actions, we substantially reduced or eliminated backlogs.

Working with our regional, state and tribal partners, OPP made progress in implementing worker protection programs, reassessing the applicator certification and training programs, and advancing many other field programs–all described more fully in this report. We also remain strongly committed to expanding the public's right to know through website development, communication activities and stakeholder involvement.

I hope you will take a few moments to review our Biennial Report for 1998 and 1999. Let's also look ahead with a commitment to make even more progress together in safeguarding public health and the environment from pesticide risks.

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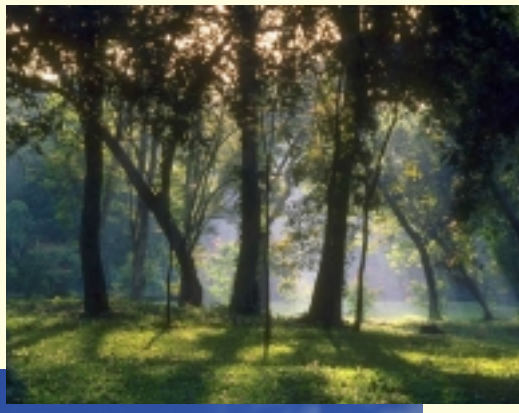
The mission of the Office of Pesticide Programs (OPP) is to protect human health and the environment from unreasonable adverse effects resulting from the use of pesticides and to assure that there is a reasonable certainty of no harm from pesticides in the diet of all Americans, especially children.



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OPP AT A GLANCE

THE MISSION OF THE OFFICE OF PESTICIDE PROGRAMS (OPP) IS TO PROTECT human health and the environment from unreasonable adverse effects resulting from the use of pesticides and to assure that there is a reasonable certainty of no harm from pesticides in the diet of all Americans, especially children. OPP regulates pesticides under two major federal statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), both significantly amended by the Food Quality Protection Act of 1996 (FQPA).

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

FIFRA is a product licensing statute. Many provisions of FIFRA provide regulatory tools for OPP to use to fulfill the intent of the law:

- Registration – pesticide products for use in the U.S. generally must be registered or licensed by EPA based on a scientific evaluation prior to manufacture, transport, and sale.
- Labeling – all pesticide products must have a label that describes, among other things, the content, directions for use, safety precautions, and disposal requirements.
- Data-Call-In – since 1978, FIFRA has provided strong authority to require data (results from pesticide testing) enabling OPP to evaluate the safety of pesticide products.
- Restrictions – certain high risk pesticides are restricted for use only by trained and state-certified applicators.
- Enforcement – FIFRA contains enforceable provisions on the manufacture, sale, distribution, and use of pesticides (Section 18's).
- Emergency exemption authority – in certain emergency cases, FIFRA permits approval of unregistered uses of registered products on a time-and geographically-limited basis.
- Reregistration – all pesticides registered before November 1, 1984, must be reevaluated to ensure that they meet today's more stringent safety standards.
- Registration review – after EPA completes the reregistration process, FIFRA requires the Agency to establish a registration review program through which all pesticide registrations will be reviewed periodically in light of new standards and information.
- Suspension or cancellation – through the appeals and adjudicatory processes, some or all of a pesticide product's uses can be suspended or canceled to prevent unreasonable adverse effects.
- Antimicrobials program – FIFRA requires OPP to review antimicrobial actions within prescribed time-frames. Antimicrobial products are used to control germs such as bacteria and fungi (molds and mildews) that can cause infections, food spoilage and odors.
- Minor use program – FIFRA requires EPA to establish a program that gives special consideration and support to minor uses of pesticides, which may be of low value to pesticide producers but high value to farmers. Most fruits and vegetables are grown with "minor use" pesticides.

Our regulatory decisions affect approximately:

30 major pesticide producers plus another 100 small producers

2,500 pesticide formulators

29,000 distributors

40,000 commercial pest control firms

1 million farms

3.5 million farm users

several million industry and government users

90 million households

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1906
the Pure Food Law (FFDCA) set labeling standards for truthful labeling

1910
the Insecticide Act (early FIFRA) was a consumer protection law intended to prevent the manufacture, sale, or transportation of products that do not work

1947
FIFRA enacted

1954
FDA gained the authority to establish pesticide tolerances

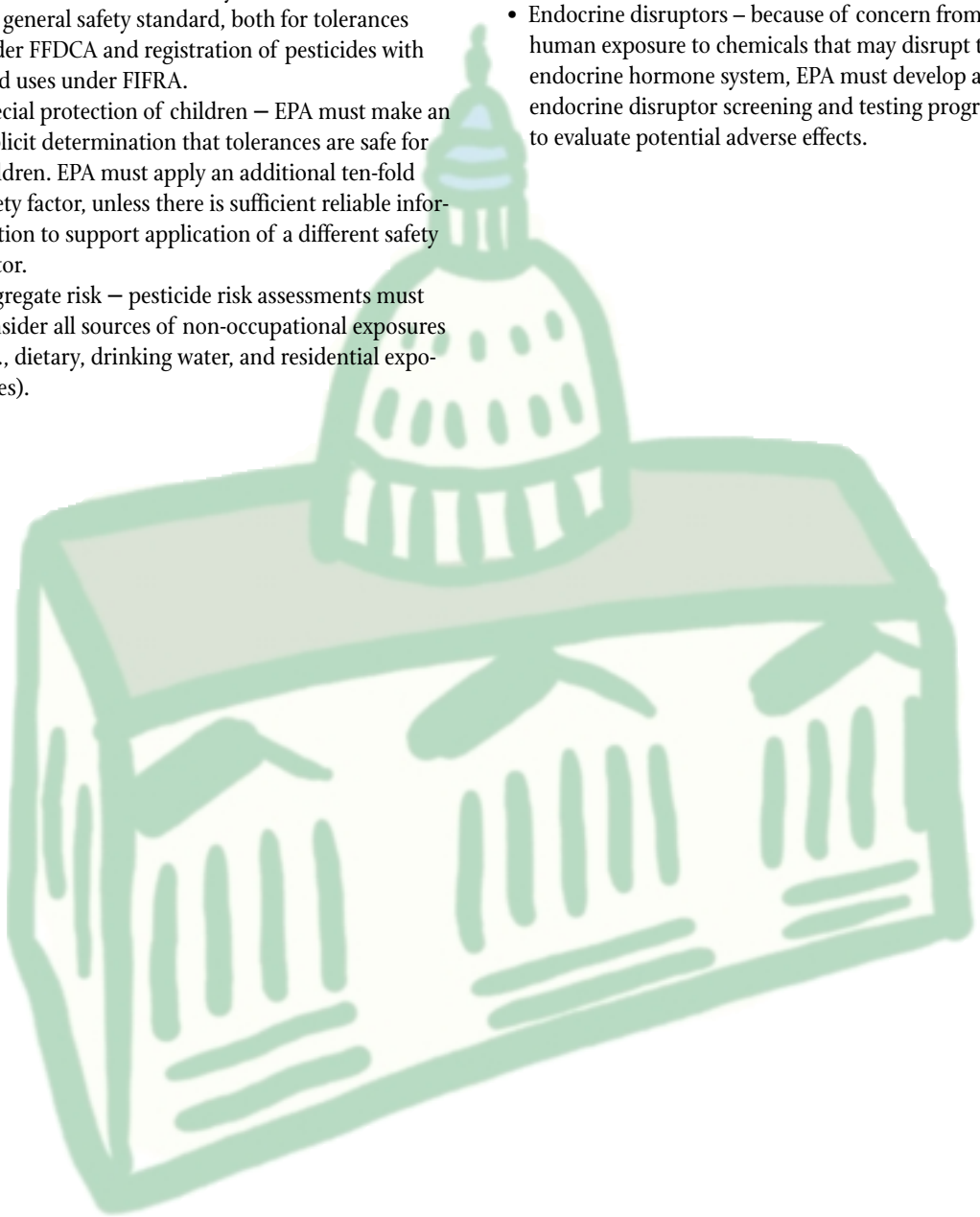
1958
Delaney clause added to FFDCA

1964
FIFRA amended to give USDA authority to refuse registration for unsafe as well as ineffective pesticides

The Federal Food, Drug, and Cosmetic Act (FFDCA)

FFDCA provides the Office of Pesticide Programs with the authority to set tolerances (maximum allowable residue levels) for pesticides in or on foods and animal feed. Key elements of FFDCA include:

- Tolerance reassessment – all tolerances that were in place as of August 1996 must be reassessed – 33% by August 1999; 66% are due by August 2002; and all must be completed by August 2006.
- Reasonable certainty of no harm safety standard – FFDCA now includes a health-based safety standard for pesticide residues in both raw and processed foods. "Reasonable certainty of no harm" is now the general safety standard, both for tolerances under FFDCA and registration of pesticides with food uses under FIFRA.
- Special protection of children – EPA must make an explicit determination that tolerances are safe for children. EPA must apply an additional ten-fold safety factor, unless there is sufficient reliable information to support application of a different safety factor.
- Aggregate risk – pesticide risk assessments must consider all sources of non-occupational exposures (i.e., dietary, drinking water, and residential exposures).
- Cumulative risk and common mechanisms of toxicity- EPA must consider the cumulative effects of related pesticides that share common mechanisms of toxicity.
- Benefit-based tolerances – under very limited conditions, EPA may retain a tolerance for a pesticide that does not meet the new safety standard if it is deemed to be in the public interest.
- Right To Know – the Agency must develop information to educate the public about the risks and benefits inherent in using pesticides on foods. EPA must also list any tolerances that are set based on benefits considerations, and explain ways consumers may reduce their exposure to pesticides in or on food.
- Endocrine disruptors – because of concern from human exposure to chemicals that may disrupt the endocrine hormone system, EPA must develop an endocrine disruptor screening and testing program to evaluate potential adverse effects.



OPP's Structure

The Office of Pesticide Programs (OPP) is divided into nine divisions and a resource management staff, employing nearly 900 scientists, administrative and regulatory personnel. For more information on OPP's structure, please refer to List 4 in the Appendix and visit our website at http://www.epa.gov/pesticides.

Office of the Director (OD)

Senior Science Advisor
Minor Use Officer
Deputy Director for Pesticide Programs
Deputy Director for Pesticide Program Management

Resource Management Staff (RMS)

Budget and Personnel

Antimicrobial Division (AD)

Risk Assessment and Management

Special Review and Reregistration Division (SRRD)

Risk Management

Registration Division (RD)

Risk Management

Biopesticides and Pollution Prevention Division (BPPD)

Risk Assessment and Management

Health Effects Division (HED)

Risk Assessment

Environmental Fate and Effects Division (EFED)

Risk Assessment

Biological and Economic Analysis Division (BEAD)

Usage Data
Benefits Analysis
Chemistry Labs

Field and External Affairs Division (FEAD)

Field Programs
Policy and Regulation Support
Communications

Information Resources and Services Division (IRSD)

Information Management and Systems Support

1970
pesticide regulation transferred from USDA to the newly established EPA

1972
FIFRA amended to consider risks and benefits of pesticides rather than efficacy

1974
EPA sets the first standard for worker reentry into treated fields

1978
FIFRA amended; allowed for conditional registration; gave manufacturers ten year rights to data

1984
EPA publishes extensive data testing requirements in 40 CFR Part 158–pesticide companies now have to perform numerous hazard and exposure testing studies prior to applying for a registration

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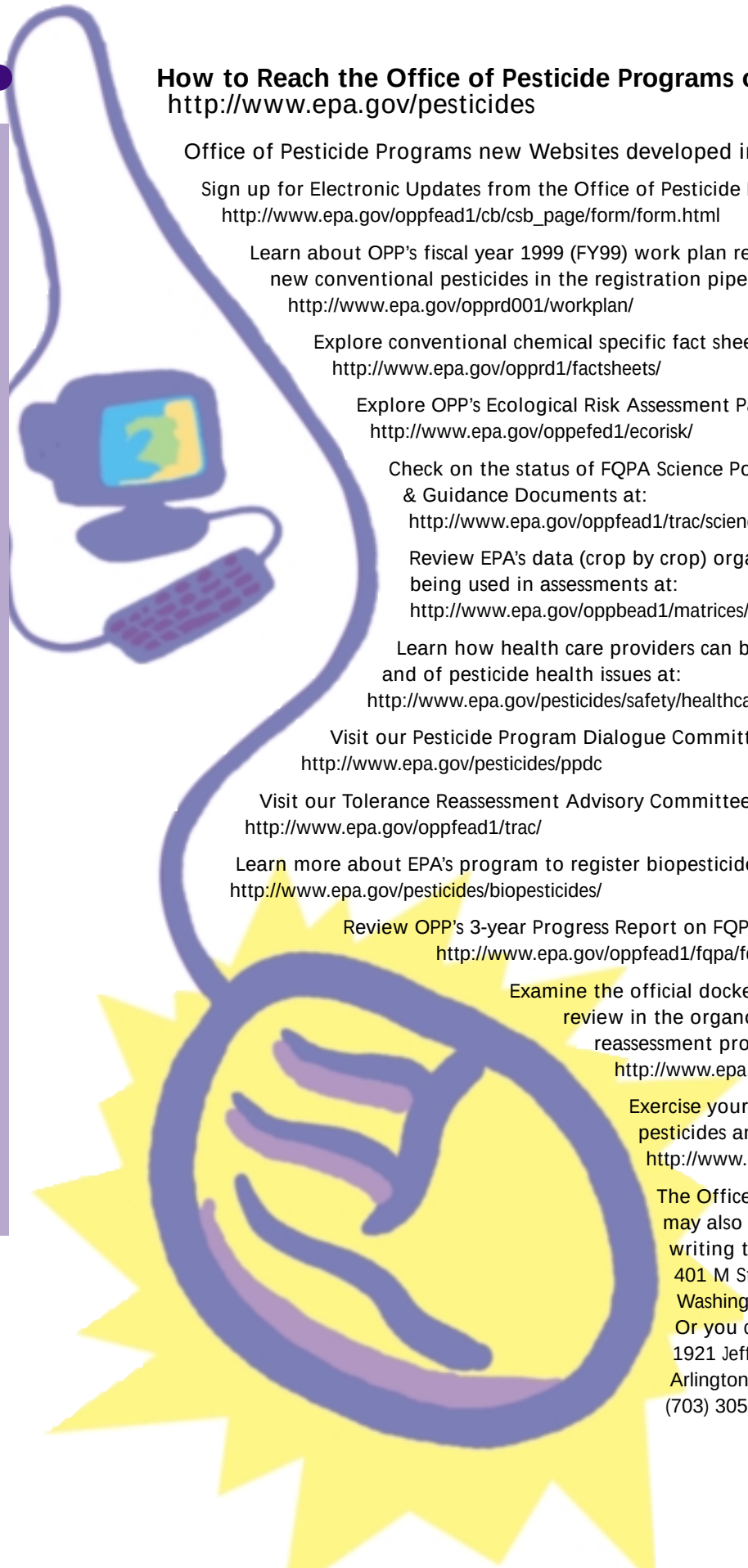
1988
FIFRA amended and required re-registration program be established to review chemicals registered prior to 11/84

1996
FQPA established a single, health-based standard for pesticides used on food crops; added protection for infants and children

1998
Pilot process for organophosphate risk assessments initiated

1999
Met first tolerance reassessment deadline and canceled significant food uses of two organophosphate pesticides



How to Reach the Office of Pesticide Programs on the Internet
http://www.epa.gov/pesticides

Office of Pesticide Programs new Websites developed in 1998 and 1999:

Sign up for Electronic Updates from the Office of Pesticide Programs at:
http://www.epa.gov/oppfead1/cb/csb_page/form/form.html

Learn about OPP's fiscal year 1999 (FY99) work plan registering new conventional pesticides in the registration pipeline at:
http://www.epa.gov/opprd001/workplan/

Explore conventional chemical specific fact sheets at:
http://www.epa.gov/opprd1/factsheets/

Explore OPP's Ecological Risk Assessment Page at:
http://www.epa.gov/oppefed1/ecorisk/

Check on the status of FQPA Science Policy Issues & Guidance Documents at:
http://www.epa.gov/oppfead1/trac/science/

Review EPA's data (crop by crop) organophosphate use being used in assessments at:
http://www.epa.gov/oppbead1/matrices/

Learn how health care providers can become more aware and of pesticide health issues at:
http://www.epa.gov/pesticides/safety/healthcare/healthcare.htm

Visit our Pesticide Program Dialogue Committee (PPDC) website at:
http://www.epa.gov/pesticides/ppdc

Visit our Tolerance Reassessment Advisory Committee (TRAC) website at:
http://www.epa.gov/oppfead1/trac/

Learn more about EPA's program to register biopesticides at:
http://www.epa.gov/pesticides/biopesticides/

Review OPP's 3-year Progress Report on FQPA implementation at:
http://www.epa.gov/oppfead1/fqpa/fqpareport.pdf

Examine the official docket for chemicals under review in the organophosphate tolerance reassessment process at:
http://www.epa.gov/pesticides/op/

Exercise your right to know about pesticides and your food at:
http://www.epa.gov/pesticides/food/

The Office of Pesticide Programs may also be reached by writing to:
401 M St., S.W. Mailcode 7506c
Washington, D.C. 20460
Or you can visit our offices at:
1921 Jefferson Davis Hwy., CM#2
Arlington, VA
(703) 305-5017

REGISTRATION

To move less risky pesticides into the marketplace quickly, we placed high priority on reviewing these applications.

APPROXIMATELY 20,000 PESTICIDE PRODUCTS ARE CURRENTLY REGISTERED or licensed for use in the U.S. Pesticide products are used in or on food, around homes, businesses, schools, hospitals, and in parks. Before EPA will register a pesticide product for sale and use, we evaluate test data on all of its ingredients. The test data, which include studies on the effects the product will have on humans, wildlife, fish, and plants (including endangered species), are provided by the registration applicant (known as the registrant). Depending on the type of pesticide, a registrant may be required to generate data from as many as 100 different tests in order for us to determine the product's safety. Pesticides which are crucial to public health, such as hospital disinfectants and tuberculocides, are tested in EPA's Office of Pesticide Program's Microbiology Laboratory to ensure that they work as claimed.

Registering New Active Ingredients in Pesticide Products

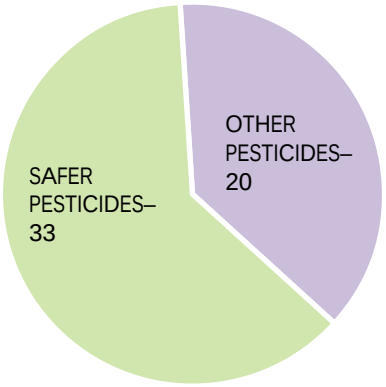
During the last two years, OPP made significant progress in registering new pesticides. In 1998, the Agency registered 27 new pesticide active ingredients and in 1999, we registered 26 new pesticide active ingredients. More than half of these new pesticide registrations were for biopesticides and "reduced risk" conventional pesticides which pose less risk than the more toxic conventional pesticides registered years ago.

Biopesticides include "microbial pesticides" (bacteria, viruses, or other microorganisms used to control pests); "biochemical pesticides," such as pheromones (compounds that disrupt the mating behavior of insects); and plant pesticides, substances that plants produce from genetic material that has been added to the plant. New conventional pesticides are considered for "reduced-risk" status if they have at least one or more of the following characteristics:

- low risk to human health;
- low toxicity to non-target organisms;
- low ground water contamination potential to contaminate ground water, surface water, or other valued environmental resources;
- broaden the adoption and effectiveness of integrated pest management strategies.

To move these less risky pesticides into the market-place more quickly, we placed high priority on reviewing these applications. Registration decisions for conventional "reduced risk" pesticides and

PROPORTION OF NEW ACTIVE INGREDIENTS CONSIDERED SAFER IN FY 1998-1999



EPA Sought Public and Scientific Comments on New Pesticide–Chlorfenapyr (Pirate)

OPP took groundbreaking steps in 1999 in order to inform OPP's registration decision-making process for the new chemical compound, chlorfenapyr. The Agency sought public comment and input on our risk and benefits assessments prior to making any regulatory decision through a *Federal Register* Notice and the Internet. Chlorfenapyr is a member of a new class of chemical compounds known as 'pyrroles'–a class which has a unique mode of action, clear economic benefits to the cotton industry, and data indicating avian reproductive effects. Chlorfenapyr is the first pyrrole submitted for U.S. registration. Chlorfenapyr has clear economic benefits to the cotton industry because it can play an important role in controlling several important cotton pests. However, chlorfenapyr appears to be persistent in the environment, and studies show a potential adverse impact to wildlife, particularly birds. For these reasons–and our limited experience with pyrroles–we believe this chemical presents special issues for pesticide regulation. Accordingly, in 1999 we took this extra step of seeking public comment, of a specific nature, on this chemical's human health and ecological risk and benefit assessments before any regulatory decision-making. The Agency also consulted with the U.S. Fish and Wildlife Service, solicited external scientific peer review on our ecological risk assessment, and will consider the alternatives and their effectiveness as part of the decision-making process.

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biopesticides were generally made in half the time that it takes for other conventional pesticides. We also expedited the introduction of organophosphate alternatives into the marketplace.

Approving "Other Ingredients" in Pesticide Products

Pesticide products contain "active" ingredients to prevent, destroy, repel or mitigate a pest. By law, the active ingredient must be identified by name on the label together with its percentage by weight. "Other ingredients" in pesticide products are not intended to affect a target pest, but are used to help, among other things, formulate, stabilize, or disperse the product. Before 1997, these other ingredients were known as "inert ingredients." The law does not require other ingredients in pesticides to be identified by name and percentage on the label unless they are of toxicological concern.

Over the past two years, OPP approved 210 of these kinds of "other ingredients" in pesticide products. These ingredients are safer than many of the older ingredients of this type. At the same time, the Agency continues to review existing "other ingredients." In the summer of 1998, EPA removed 249 chemicals which were no longer in use from the list of "other ingredients" permitted for use in pesticide products which were no longer in use. In June 1999, EPA removed 12 additional chemicals, all considered toxic and listed on the OPPT Toxics Release Inventory. As a result, registrants wishing to include these chemicals as "other ingredients" in pesticide formulations need to satisfy the data requirements for new other ingredients, as if the chemicals had never been used before.

EPA also took action to remove formaldehyde as an approved "other ingredient" in pesticide products. In response to this initiative, manufacturers of pesticide products that contained formaldehyde as an "other ingredient" agreed to cancel or reformulate their products, thereby eliminating this chemical as an "other ingredient."

Registering Antimicrobial Pesticide Products

In 1998 and 1999, we continued to improve our Antimicrobials Program. Antimicrobial pesticides are used to control harmful microorganisms including bacteria, viruses, or fungi in or on inanimate objects and hard surfaces. Antimicrobial products include sterilants, disinfectants, and sanitizers, as well as swimming pool chemicals, wood preservatives, and antifoulant paints. Approximately 1,000 antimicrobial pesticide products are registered for use on food and food contact surfaces as disinfectants, sanitizers, and preservatives.

The Agency has made substantial progress in fulfilling the antimicrobial provisions of FQPA. A backlog of pending actions has been reduced from a high of 388 in December 1996, to only 24 outstanding actions as of September 1999.

In September 1999, as required by FQPA, we published in the *Federal Register* a proposed rule detailing procedures and policies for reviewing antimicrobial applications for registration, including review time frames, a sunset provision for continued efficacy of public health products, and labeling standards for public health products, along with assorted definitions and exemptions. A number of other provisions were also proposed, including: a policy on nitrogen stabilizers;

EPA's Review of "Other Ingredients" in Pesticide Products

EPA announced its policy on toxic "other ingredients" in pesticide products in the *Federal Register* of April 22, 1987 (52 FR 13305). Through this policy, EPA encourages the use of the least toxic "other ingredients" available and requires the development of data necessary to determine the conditions of safe use of products that contain other ingredients which are toxic. In developing this policy EPA placed "other ingredients" in the following four lists according to toxicity:

List 1: "Other ingredients" of toxicological concern.
List 2: Potentially toxic "other ingredients," with high priority for testing.
List 3: "Other ingredients" of unknown toxicity.
List 4: "Other ingredients" of minimal concern.

The list of other pesticide product ingredients is revised as new data become available.

FY 1999 Registration Work Plan Made Public

In keeping with the Agency's efforts to improve transparency in the pesticide registration process, OPP published its fiscal year 1999 registration work plan in the *Federal Register* and posted it on the Internet. This work plan announced the quarter by which the Agency committed to make decisions on new active ingredients, new uses of previously-registered active ingredients, and food use "other ingredients." During 1999, OPP periodically published registration work plan updates via the Internet, including dates when decisions had been made. Many external customers encouraged the Agency to continue to provide this type of information to the public. The Agency is making annual registration work plans a routine part of its operations.

EPA Registers Alternative to Tributylin (TBT) Antifouling Paints

On March 20, 1998, OPP registered five new antifouling paint products containing the new active ingredient Irgarol, in combination with copper, to enhance efficacy. Antifoulant paints are used on marine vessels and structures to inhibit growth of fouling organisms, e.g., barnacles and algae. The new antifouling products are approved for vessels of any size, and appear to present minimal risks to the environment. After two years, the conditional registration of Irgarol and its products will expire unless the company provides additional ecological effects data. EPA issued the time-limited registration because the benefits of introducing Irgarol products quickly were deemed to outweigh any potential ecological risks.

Since 1988, the United States and other industrialized countries have prohibited the use of antifoulants containing tributyltin (TBT) on non-aluminum-hulled vessels shorter than 25 meters. Despite noticeable improvement, ten years after this and related restrictions took effect, TBT is still present in the aquatic environment at levels that harm organisms such as snails and oysters. The TBT phase-out target year is 2006. EPA is working with international organizations to address issues associated with the planned phase-out of TBT antifoulants and is reviewing data on additional new antifouling active ingredients and products. Having alternatives available is critical to meeting the phase-out date.

permission for single applications for identical non-data labeling changes affecting multiple products; and labeling revisions affecting the signal word, the "Keep Out of the Reach of Children" statement, use dilution and first aid statements. EPA expects to publish a final rule in 2000.

Focusing on Public Health Pesticides

During 1998 and 1999, EPA continued its efforts to coordinate with USDA and the Department of Health and Human Services (HHS) regarding the regulation of pesticides with public health uses, such as mosquito and cockroach control. For pesticides which have both food and public health uses, FQPA requires that the Agency consider exposure from the public health use when conducting an aggregate exposure assessment.

FQPA defines public health pesticides as any minor use pesticide product used predominantly in public health programs for vector control or other recognized public health protection uses. Public health pesticides are afforded the same considerations as other minor use pesticides, such as priority review and the waiving of some of the fees associated with registration. As with pesticide registrations in general, EPA is seeking low risk alternatives to traditional public health pesticides.

Supporting Minor Crops and Public Health Pesticides

The Food Quality Protection Act (FQPA) called for EPA to develop a new approach to managing minor crop and public health pesticides. In response, during 1998 OPP appointed a full-time Minor Use Crop Coordinator and an OPP Public Health coordinator, supported by a Minor Use Team and a Public Health Steering Committee. The teams share common members and coordinate activities with USDA and the Department of Health and Human Services (HHS). The primary goals of the Minor Use Team and Public

"Minor Uses" are pesticide uses for which the total United States treated acreage is less than 300,000 acres (minor crops) or uses for which the market does not provide sufficient economic incentive to support the initial or continuing registration. Minor uses of pesticides are often critical because they support many fruit and vegetable crops and public health pesticides.

Proposed Rule Published Outlining Procedures for Establishing Tolerances for Emergency Exemption Requests

On June 3, 1999, EPA published a proposed regulation outlining the suggested criteria for establishing tolerances under the emergency exemption requirements of FIFRA Section 18. The proposed regulation discusses the Agency's plan to use available data to determine the Agency's ability to establish time-limited tolerances for Section 18 uses on a case-by-case basis. These time-limited tolerances will cover both domestic commodities and those imported into the U.S. during the duration of the emergency exemption. The proposed rule also details provisions which ensure that food legally treated under the Section 18 may continue through the channels of trade after the tolerance expires, provided the levels are within acceptable limits.

In addition to EPA's proposed process, the proposal lists recommendations for changes to the Section 18 process developed by the National Association of State Departments of Agriculture and the Association of American Pesticide Control Officials. EPA will evaluate the comments on these recommendations separately from the comments on the rule. We expect to publish a final rule in 2000.

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EPA Takes Action Against Illegally Pesticide-Treated Articles

In recent years, the marketplace has seen a proliferation of new types of unregistered consumer products that are treated with pesticides. Among other things, these products have claimed to protect consumers against diseases caused by bacteria, fungi, and other microorganisms. Types of pesticide-impregnated products include food cutting boards, toys, kitchen sponges, cat litter, articles of clothing, and even writing pens. Their packaging often contains words and phrases such as "antibacterial," "germ-free," or "kills harmful E.coli." Any pesticidal product making public health claims must work as claimed and be registered with EPA as a pesticide. These products are unlawful if they make public health claims and are not registered with EPA.

EPA has taken major steps to address the proliferation of unregistered "treated articles," such as cutting boards and kitchenware, that make unlawful pesticidal health claims. Over 20 enforcement actions had been taken against non-complying companies as of September 30, 1999, and more than $1,000,000 in fines were collected to further assure compliance with the law. EPA expects to issue guidance in 2000 that will clarify acceptable claims.

Health Steering Committee are to:

- provide growers and public health program administrators an opportunity to discuss their needs and concerns with the Agency before the Agency finalizes regulatory actions;
- work with USDA, industry, growers, public health agencies and other stakeholders to promote registration and use of reduced-risk pesticides for minor uses;
- encourage development and submission of "real world" pesticide use, usage and residue data by growers, public health agencies, USDA and other stakeholders for use in refined risk assessments.

This increased focus has strengthened EPA's communication with the minor use community and has helped bring registrants and minor use stakeholders together early in the regulatory process.

Cooperative Efforts with USDA's IR-4

EPA's Office of Pesticide Programs and USDA's Interregional Research Project 4 (IR-4) have a long history of working together to register pesticides for minor crops. With input from affected grower groups, IR-4 and EPA are working together to accelerate registration of alternatives to organophosphates, carbamates and B2 carcinogens, with special emphasis on reduced-risk products. Beginning three years ago, IR-4 has focused heavily on reduced-risk products. Over 60% of their fiscal year 1999 projects are for reduced-risk products, and current projections are that this figure will exceed 70% for fiscal year 2000. Several current EPA/IR-4 partnership projects are worthy of note:

- developing blanket tolerances for selected reduced-risk chemicals, reducing review time potentially by years;
- improving the tolerance petition format and creating new crop groupings;
- streamlining the reduced risk justification format for minor uses;
- harmonizing registration data development with other countries.

These efforts are already providing benefits. Whereas the Agency established only one IR-4 sponsored tolerance in 1997, in 1999 the Agency established 32 tolerances for minor crops or minor crop groupings. Based on its review of the IR-4 work plan, EPA plans to review over 100 petitions on 40 active ingredients in FY 2000, which could result in 300 new registrations for minor crops.

Biopesticide Profile: Bacillus thuringiensis subspecies israelensisi (Bti)

In October 1998, the Agency registered Bacillus thuringiensis subspecies israelensisi, part of a large group of bacteria that occur naturally in soil. These bacteria are toxic to certain species of insects and can be used as insecticides. Called a microbial pesticide, Bti contains a bacterium as its active ingredient. Bti differs from plant-pesticides which are pesticides that plants produce from genetic material that has been added to the plant. Once ingested by insects, Bti bacteria release a toxic protein into the digestive system, which results in death. Primarily used to control mosquito larvae in aquatic habitats, other public health pests including, black flies, gnats, and filter flies are controlled that can transmit diseases such as malaria, dengue fever and encephalitis. Bti is a natural bacteria that kills insects by releasing toxins which bind to specific receptors in their digestive systems. It poses no risk to humans or other non-target organisms. An effective, low-risk, low-toxicity pesticide, Bti can be used instead of conventional public health pesticides, many of which are organophosphates which are toxic to humans and other non-target species.

REREGISTRATION

THE OBJECTIVE OF EPA'S REREGISTRATION PROGRAM IS TO ENSURE THAT OLDER pesticides meet contemporary standards of health, safety and product labeling and that their risks are adequately mitigated. As directed by amendments to FIFRA in 1988, EPA has been conducting a comprehensive review of pesticides initially registered before November 1, 1984. In 1996, FQPA added new dimensions to the pesticide reregistration program. It set a new, stricter safety standard for pesticide residues in or on food, and requires EPA to reassess all existing tolerances within 10 years to ensure that they meet the new standard. FQPA's requirements – to consider the special sensitivities of infants and children, aggregate exposure and cumulative effects of pesticides with a common mechanism of toxicity, and their possible endocrine disruptor effects – apply to reregistration decisions for all food use pesticides.

Through the reregistration program, significant improvements in pesticide safety and use are being made.

Achieving Risk Reduction through Reregistration

Through the reregistration program, significant improvements in pesticide safety and use are being made. EPA reviews and reregisters products, reassesses their tolerances and requires labeling changes to achieve risk reduction. These reassessed products can then be used more safely in the future, enhancing protection of users, the general public, and the environment. Some examples of risk reduction measures include:

- limits on amount, frequency or timing of applications;
- improved use directions and precautions;
- ground water and surface water safeguards;
- requirements for personal protective equipment to be worn when applying the pesticide;

Profile of Reregistration Eligibility Decision (RED): Captan

In 1999, EPA completed a Reregistration Eligibility Decision (RED) for captan. Because this fungicide has a wide array of agricultural and non-agricultural uses, our reevaluation included all of the major new FQPA factors and occupational and ecological risk assessments as well. We found it does not pose acute, chronic or cancer risks of concern through food or drinking water. Cancellation of lawn uses eliminates residential exposure. Worker risk is acceptable for most occupational scenarios. New requirements for water soluble bags, reductions in application rates, use of personal protective equipment (PPE), and revised reentry intervals will mitigate remaining occupational concerns. Revised labeling will reduce risks to non-target aquatic concerns.

Captan is used to control diseases in orchard crops, berries, seeds, turf, and ornamentals, and is also incorporated into paints and adhesives as an in-can preservative. The Agency has classified captan as a B2 (probable human) carcinogen; however, all dietary risk estimates are below 1 X 10^{-6}, and worker risks are below the level of concern. There is no evidence of special sensitivity to infants and children so the safety factor was removed. A potential common mechanism of toxicity exists for captan and another fungicide, folpet, because they have a common metabolite, thiophosgene. EPA conducted a conservative aggregate assessment for thiophosgene, assuming people may be exposed through use of both captan and folpet, and concluded that thiophosgene does not pose risks of concern. Because of toddlers' exposure to treated lawns, the technical registrants have agreed to voluntarily cancel captan's residential lawn uses and all other turf uses except sod farms and golf courses. Risks to mixers and loaders of wettable powder formulations for aerial applications will be mitigated by requiring the use of water soluble bags or a suitable reduction in application rate. Captan is also severely irritating to the eyes. Thus, the enhanced PPE required includes eye protection as well as chemical-resistant gloves, aprons/coveralls, and dust/mist respirators in various scenarios. Eye wash stations are required for occupational field workers entering treated fields as is repeated notification for workers entering treated fields. Updated reentry intervals, ranging from 12 hours for seed treatments to 4 days for ornamentals, also are required to protect reentry workers.

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- special programs to enhance protection of young children; and
- cancelling pesticide uses.

Establishing Stakeholder Process During Pesticide Reregistration Reviews

Aluminum and Magnesium Phosphide Stakeholder Process

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

The Agency originally proposed 15 risk reduction measures to increase the level of protection to bystanders and pesticide applicators from exposure to phosphine. The Agency received extensive comments on the risk reduction measures and decided to extend the schedule to allow more time for stakeholder involvement, public input and complete consideration of the alternative ways to reduce risks. The Agency plans to issue a revised set of proposed risk mitigation measures in late 1999 and final risk mitigation measures in 2000.

To identify feasible risk mitigation measures before releasing a new proposal, we have been working with the National Institute of Occupational Safety and Health, the Occupational Safety and Health Administration, and a coalition of industry groups and user organizations. In addition, we are consulting with the Phosphine Task Force, a group of experts from Land Grant Universities and USDA Agricultural Research Service scientists with expertise in commodity storage pest management systems who are investigating possible alternative risk mitigation measures.

EPA recognizes the importance of phosphine to agriculture, the lack of viable alternatives, and the potential impacts from the initial set of risk mitigation measures. Final decisions will be based on sound science and a full understanding of agricultural needs. With full participation from stakeholders, EPA will be able to develop improved risk mitigation measures that are both protective and practical.

Rodenticide Cluster Stakeholder Process

In March 1998, EPA assembled a stakeholder work group to explore and recommend ways to reduce the risk of exposure to rodent control products, especially accidental exposures experienced by young children.

The Rodenticide Stakeholder Workgroup was established under OPP's advisory committee, the Pesticide Program Dialogue Committee. Members of the work group represent public health and environmental organizations, industry groups, government agencies, and the general public. Through an ongoing series of public meetings in the spring and summer of 1999, the work group has developed an initial recommendation for improved product labeling. EPA will use all the workgroup's recommendations in developing a strategy to reduce the risks of exposure to rodenticides while preserving their public health benefits. Meanwhile, EPA is requiring rodenticide registrants to incorporate an indicator dye and a bittering agent into their product formulations.

Insect Repellent DEET: Reregistration Review and Outreach Materials

In 1998, OPP completed its review of DEET, a common insect repellent and an important public health pesticide. DEET repels biting pests such as mosquitoes and ticks, including ticks that may carry Lyme disease. Every year, approximately one-third of the U.S.population is expected to use DEET.

In a 1998 reevaluation, OPP concluded insect repellents containing DEET do not present significant health risks when they are used correctly, but it is important for consumers to follow label directions and take proper precautions. OPP required several changes to current product labels to ensure that DEET is applied safely, particularly on children. DEET products can no longer claim that their products are "child safe," and new labels will instruct parents not to allow children to handle these products. Labeling for insect repellency must be displayed prominently on any DEET products that also have cosmetic uses.

In partnership with the American Mosquito Control Association, OPP developed two fact sheets for consumers: *How to Use Insect Repellents Safely* , and *Mosquitoes: How to Control Them*. This consumer information was available for the summer use season in 1998 and 1999. During the late summer and fall of 1999, the fact sheet *Mosquitoes: How to Control Them* was in high demand on the East Coast due to mosquito-borne illnesses in the New York City metropolitan area.

Tolerance Reassessment

EPA SETS TOLERANCES (MAXIMUM RESIDUE LEVELS) FOR PESTICIDES USED TO grow food. By 2006, EPA must review the safety of all tolerances that were in effect when FQPA was passed in 1996. Each of these reassessments must ensure that the resulting tolerance level is safe for all consumers, particularly infants and children, and represents an affirmation of public health protection and the safety of the U.S. food supply. The law requires EPA to place the highest priority for tolerance reassessment on pesticides that appear to pose the greatest risk.

Reassessing Tolerances

Tolerance reassessment is being accomplished through the pesticide reregistration program. Through the tolerance reassessment process, we can make decisions to raise, lower, or maintain existing tolerance levels, or to revoke existing tolerances entirely to protect consumers from unsafe pesticides residues in or on food.

Tolerance reassessment is a large task:

- more than 450 pesticides and other ingredients have tolerances or exemptions from the requirement for a tolerance;
- there can be many tolerances associated with a given chemical, which contributes to the complexity of the review;
- 9,721 tolerances were in effect when FQPA was passed;
- EPA met (and surpassed) the first FQPA goal as we completed the reassessment of over 33% of all tolerances subject to reassessment by August 3, 1999.

By the end of 1999, EPA reassessed 3430 tolerances. Each of these tolerances are in conformity with the stringent new safety standard of FQPA and are based on the latest sound scientific methods, data, and policies. EPA placed all pesticides with tolerances that must be reassessed into one of three priority groups. Most (two-thirds) of the tolerances reassessed are for pesticides in our highest priority group–those that appear to pose the greatest risk to public health, including the organophosphates, carbamates, organochlorines, and carcinogens.

Many of these tolerances were for pesticides used on the top 20 raw agricultural commodities frequently eaten by kids. Almost 40% of "kids'" food tolerances have been reassessed. Many decisions were also for 'minor' uses, or pesticide uses on crops with less

EPA Reduces Pesticides Risks to Children

The U.S. Environmental Protection Agency announced on August 2, 1999, cancellation agreements and risk reduction strategies to increase protections for American families and their children from risks posed by two of the oldest, most widely used chemical compounds in use as pesticides today. Based on its concerns, EPA is eliminating the use of methyl parathion–one of the more potent organophosphates–on apples, peaches, pears, grapes, nectarines, cherries, plums, carrots, certain peas, certain beans, and tomatoes, among other fruits and vegetables. For azinphos methyl, also considered to be a pesticide of concern, the Agency is reducing application rates and requiring practices that will result in significant reductions in allowable residues on apples, pears and peaches. By the end of next year, EPA is scheduled to complete its reassessment of the organophosphates and several other older, more commonly used pesticides, and to meet the Food Quality Protection Act's food safety goals.

Priority Groups for Tolerance Reassessment

EPA placed all pesticides with tolerances that must be reassessed into three priority groups. FQPA requires EPA to give highest priority to pesticides that appear to pose the greatest risk.

Group 1 (228 pesticides/ 5546 tolerances) includes:

- Organophosphates
- Carbamates
- Organochlorines
- Probable carcinogens
- Reference dose exceeders*
- High-hazard "other ingredients"

Group 2 (93 pesticides/1928 tolerances)

- Possible carcinogens
- All remaining reregistration chemicals (those that were first registered before 1984)

Group 3 (148 pesticides/ 2247 tolerances)

- Remaining pre-FQPA pesticides with reregistration eligibility decisions
- Remaining post-1984 pesticides
- Biological pesticides
- Remaining "other ingredients"

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

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The law requires EPA to place the highest priority for tolerance reassessment on pesticides that appear to pose the greatest risk.

than 300,000 acres of total U.S. production, which include many fruits and vegetables. (See Appendix, Figure 2)

Establishing the Tolerance Reassessment Advisory Committee (TRAC)

On April 30, 1998, in a response to a request from Vice President Gore to enhance stakeholder input on FQPA implementation, EPA and USDA established the Tolerance Reassessment Advisory Committee (TRAC) as a subcommittee under the auspices of EPA's National Advisory Council for Environmental Policy and Technology. TRAC was established 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.

TRAC Accomplishments

TRAC has met seven times and followed the four implementation principles outlined by the Vice President: use of sound science in decision-making, establishing a transparent regulatory process, ensuring a reasonable transition for agriculture to new methods and alternatives, and fostering the involvement of stakeholders. The group helped the EPA and USDA make significant progress in several areas critical to the successful implementation of FQPA. For example, TRAC:

- fostered a broader understanding of the complexity of pesticide regulation, the special considerations that each sector brings to the table, and the rationale that EPA uses in making decisions;
- identified key science policy issues related to tolerance reassessment and defined an approach to refining these policies that includes substantial public and expert input;
- initiated a pilot approach for obtaining public comment on preliminary risk assessments for the organophosphate class of pesticides as part of OPP's effort to improve transparency of decision making;
- increased focus on transition issues to prepare growers for possible changes in pesticide use patterns.

In July 1998, in consultation with TRAC, EPA and USDA implemented a process that allows all stakeholders to review preliminary risk assessments and contribute to their improvement, as well as to provide risk management ideas later in the process. This pilot process was designed to increase transparency and improve opportunities for stakeholder involvement. It helps ensure that risk assessments are based on the best available and most realistic data. By October 1, 1999, EPA had released 31 preliminary risk assessments and 15 revised risk assessments through the pilot process.

TRAC Profile

TRAC was composed of approximately 50 members approved by the Deputy Administrator of EPA and the Deputy Secretary of the U.S. Department of Agriculture. Members were selected based on their relevant experience and diversity of perspectives on organophosphate pesticide/food safety issues from the following sectors: environmental and public interest groups; pesticide industry and trade associations; user, grower and commodity organizations; pediatric and public health organizations; federal agencies, tribal, state, and local governments; academia; and consumer groups. The Deputy Administrator of EPA and the Deputy Secretary of Agriculture served as Co-Chairs of TRAC.

Visits to the field help OPP officials identify the components of an effective federal program.

The final meeting of TRAC was held October 20 and 21, 1999. At the meeting, the Committee reviewed lessons learned from the pilot process. EPA and USDA received valuable feedback on how the process could be modified for reassessment of other chemicals in the future. This discussion included the role and involvement of growers and other pesticide users. The input from TRAC and other informal sources will be used to develop a proposed new process, which will be published for public comment by the end of 1999. This proposed process would be used for all pesticides subject to reregistration or tolerance reassessment.

Publishing Tolerance Processing Fees Rule Proposed

FQPA requires industry to cover the costs of setting tolerances for pesticide residues on food. EPA is revising the current fee structure to bring it in line with the new responsibilities mandated by FQPA, the increased complexities of science reviews, and more sophisticated data management systems. Estimates show that, to sufficiently recover costs, tolerance fees need to increase.

The Agency's proposed rule on Pesticide Tolerance Processing Fees was published in the *Federal Register* on June 9, 1999 for comment. We will be assessing these comments and working with our various stakeholders during 2000 to refine our approach.

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SOUND SCIENCE

WHAT ARE THE NINE SCIENCE POLICIES?

- Applying the FQPA 10-Fold Factor
- Dietary Exposure Assessment–Whether and How to Use 'Monte Carlo' Analysis
- Exposure Assessment –Interpreting 'No Residues Detected' Findings
- Dietary (Food) Exposure Estimates
- Drinking Water Exposures
- Assessing Residential Exposure
- Aggregating Exposures from All Non-Occupational Sources
- How to Conduct a Cumulative Risk Assessment for Organophosphate Insecticides or Other Pesticides with a Common Mechanism of Toxicity
- Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphates and Carbamates

SOUND SCIENCE IS A NECESSARY FOUNDATION FOR THE TOUGH DECISIONS OPP must make every day. Whether establishing new science policies to support FQPA implementation or improving our understanding of how pesticides interact with humans and the environment, OPP tackled a number of important issues in 1998 and 1999.

Developing New Science Policies

Shortly after passage of FQPA, EPA began using a set of guidance (developed with input from the Food Safety Advisory Committee) in making various pesticide-related decisions. In response to subsequent advice from the Tolerance Reassessment Advisory Committee (TRAC), EPA identified nine science policy issue areas important to the implementation of FQPA.

On October 29, 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. By the end of fiscal year 1999, EPA had released for comment 14 of the original 19 planned science policy papers and issued one science policy paper that had been revised in light of public comments. In addition to the nine policy areas initially identified, EPA issued four additional draft papers on related science issues for public comment. In late fall 1999, EPA released two additional draft science policy papers and two revised papers. The remaining science policy papers are scheduled for final publication during FY 2000. The documents are posted on the Internet when they are completed. (http://www.epa.gov/pesticides/trac/science/)

Improving Our Protection for Infants and Children

In 1998, we published updated testing guidelines for use by registrants in conducting studies to evaluate the prenatal, developmental and reproductive effects pesticides may have on infants and children. New guidelines on conducting studies to evaluate the effects of pesticides to their immune system were also published.

In May 1999, we submitted to the FIFRA Scientific Advisory Panel (SAP) for review our draft policy and operational practices for making decisions on the 10-fold safety factor required by FQPA to protect infants and children. The policy was released in July 1999 for public review and comment based on the process established in conjunction with the TRAC. FQPA requires that each pesticide tolerance be protective of infants and children, and that we use an appropriate safety factor during risk assessment to account for their special sensitivities.

New Partnerships with the Office of Science Coordination and Policy

During 1999, OPP collaborated with the Office of Science Coordination and Policy (OSCP), a new organization within the Office of Prevention, Pesticides, and Toxic Substances (OPPTS). Established in January 1999, the purpose of the new office is to coordinate the development and implementation of cross-cutting science policies and programs that underpin EPA's toxic chemical and pesticide programs. OSCP is helping OPP to identify and incorporate the latest scientific and technological information into its risk assessment and regulatory decisions. Through its management of the FIFRA Scientific Advisory Panel and Science Review Board, OSCP gives OPP access to top scientific and technical experts and peer reviewers. OSCP is coordinating the development of EPA's Endocrine Disruptor Screening Program, a program that will have an important impact on OPP-regulated chemicals. Working with the national and international scientific communities, OSCP coordinates OPPTS activities related to the updating and harmonization of national and international testing guidelines, standard scientific operating procedures, and Agency research objectives. Most importantly, OSCP will work to ensure that OPPTS's science-based methods and policies set the standard by which sound science is judged.

Specifically, EPA is required to apply an additional safety factor of 10 during its risk assessments to account for the potential pre-and post-natal toxicity, as well as for the completeness of the toxicology and exposure database, unless the Agency determines that another factor is adequately protective. Many of FQPA's provisions to protect children are based on recommendations in the 1993 National Academy of Sciences (NAS) report, *Pesticides in the Diets of Infants and Children*. In keeping with FQPA, each tolerance decision issued in 1998 and 1999 contained a specific finding that the tolerance levels are appropriately protective of children. EPA used available, reliable data when considering the need to retain or replace the 10-fold additional safety factor.

Expanding Our Understanding of Endocrine Disruptors

In recent years, evidence has arisen to suggest that chemicals may disrupt the hormone (endocrine) system of humans and wildlife and cause reproductive disorders, birth defects, immune dysfunction and other harmful effects. Because of the potential concern from human exposure to endocrine-disrupting chemicals, Congress included a mandate to EPA in the FQPA and the 1996 amendments to the Safe Drinking Water Act (SDWA) to develop an endocrine disruptor screening program.

Since receiving the statutory authority, EPA has moved quickly to set up a screening program that can be used to gather data on the endocrine-disrupting potential of pesticides and other chemicals. On December 28, 1998, we published in the *Federal Register* a proposal for an Endocrine Disruptor Screening Program (EDSP). EPA's proposed screening program has the following characteristics:

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

EPA is beginning to implement the Endocrine Disruptor Screening Program using a tiered approach.

The tiered approach uses a priority setting process for selecting the initial chemicals for the screening program, developing methods for endocrine disruptor screening and testing, and standardizing and validating the screening and testing methods for regulatory programs.

Protecting Human Test Subjects

EPA is concerned about the welfare of people who participate as test subjects in scientific research on human health or the environment, regardless of who conducts the research or how it comes to the Agency's attention.

EPA neither requires nor encourages human toxicity testing with pesticides, and will not rely on these data to make final decisions under FQPA until a policy is in place which can ensure that any such testing meets the highest ethical and scientific standards.

In December 1998, EPA convened a special joint subcommittee of its Science Advisory Board and the FIFRA Scientific Advisory Panel to discuss ethical and scientific issues surrounding human testing. The subcommittee met again in November 1999. EPA will develop its policy after the subcommittee submits their recommendations.

Understanding and Predicting Pesticide Spray Drift

OPP made significant progress during the last two years towards gaining a more comprehensive understanding of the science of pesticide spray drift and improving our ability to predict spray drift and the associated potential risks under a wide array of agricultural applications and weather conditions. We completed our assessment of the results of spray drift studies submitted by the registrants' Spray Drift Task Force and cooperated with EPA's Office of Research and

FIFRA Scientific Advisory Panel (SAP)

To help make decisions and policies based on sound scientific principles, OPP frequently consulted with the FIFRA Scientific Advisory Panel (SAP) on key issues. Managed by EPA's Office of Science Coordination and Policy (OSCP), the FIFRA Scientific Advisory Panel consists of independent outside scientific experts who provide scientific advice on health and environmental impacts of pesticides and pesticide related issues. The panel was created in 1975 through amendments to the Federal Insecticide, Fungicide, and Rodenticide Act, and modified by FQPA.

The SAP's role extends to peer-reviewing current scientific issues which may influence the direction of OPP's regulatory decisions. During 12 scheduled meetings in FY1998 and 1999, OPP consulted with the SAP on over 20 issues, including:

- human testing ethics,
- determination of the appropriate risk assessment safety factor for children,
- methods to estimate basin-scale pesticide concentrations in drinking reservoirs,
- residential exposure assessment procedures,
- assessment of risk from opportunistic human pathogens,
- assessment of cumulative risk from pesticides with a common mechanism of toxicity,
- the Endocrine Disruptor Screening Program.

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Acute Dietary Risk Assessments Using Monitoring Data:

In 1999, the Office of Pesticide Programs (OPP) continued the process of developing new and refined tools for estimating acute dietary exposure and risk to pesticides. Significant accomplishments include: development of proposed guidelines for conducting probabilistic, aggregate and cumulative risk assessments; development of proposed guidelines on regulating acute dietary risk at the 99.9th percentile of the exposed population; and the development of statistical models to expand the applicability of monitoring data to assess acute dietary exposure and risk by "decompositing" composited pesticide residue samples to better reflect pesticide residues on single-serving sized samples.

Development and the Task Force to develop predictive modeling for our risk assessment and management responsibilities for pesticides.

OPP sought outside expert opinions of these studies and the modeling by consulting with the SAP and other independent experts. Overall, these experts supported our conclusions of the studies and utility of the spray drift model. Data from these studies are superior to using the standard assumptions OPP previously used to assess drift from aerial and ground applications of agricultural pesticide sprays. These new data will enable OPP to better understand the risks from spray drift and will result in better informed decisions on how applicators can control spray drift. OPP plans to begin using these conclusions and the predictive model for its risk assessments and, where necessary, risk reduction strategies for applications of agricultural pesticide sprays will be implemented.

Identifying and Developing Ecological Risk Assessment Methods

In May 1996, the FIFRA Scientific Advisory Panel advised the Office of Pesticide Programs (OPP) to improve the ecological risk assessment process by moving from the currently used methods which are useful for screening purposes to more sophisticated, scientifically rigorous methods which could better support regulatory decisions. These new methods must be able to predict the magnitude of the expected impact of pesticide use on non-target organisms as well as the uncertainty and variability involved in these estimates. In response to this recommendation, OPP began a new initiative in 1997 to strengthen the core elements of the ecological assessment process by identifying, developing, and validating tools and methods to conduct probabilistic assessments and to improve the characterization of the risk by describing all attendant uncertainties in the assessment. EPA formed the Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM) to review current assessment methods and to develop new tools and approaches for terrestrial and aquatic assessments. This committee was composed of scientific experts drawn from government agencies, academia, industry, environmental advocacy groups and contract laboratories. Members represented the appropriate disciplines and represented a cross-section of affiliations.

In May 1999, the terrestrial and aquatic reports were issued. They contained detailed and thorough recommendations on risk assessment methodologies and data requirements needed to perform probabilistic risk assessments in these two areas. The reports received peer review and comments in June and an implementation team was organized in August. The team's goal is to prioritize the recommendations made by the committee, to set short term, intermediate and long term goals for the program, and to identify data and research needs that will provide the Agency with the ability to perform refined probabilistic risk assessments on those pesticides which most adversely affect ecosystems and the environment.

The program is enthusiastically moving forward and working with other offices within EPA, including the Office of Water and the Office of Research and Development, to develop new risk assessment tools, exposure models and appropriate test guidelines needed for probabilistic ecological risk assessment. By improving methods and the ability to refine ecological risk assessments for those chemicals which have the greatest potential to adversely impact the environment, the risk managers in OPP will possess the information required to make more informed regulatory decisions that are based on sound, defensible science and good public policy.

Improving Drinking Water Exposure Assessments

FQPA mandates EPA to add the contribution of pesticide residues in drinking water to the total dietary exposure to pesticide residues. In order to improve its methods of estimating pesticide concentrations in drinking water and to obtain actual occurrence data on these residues, OPP began working closely with the Office of Water, the U.S. Geological Survey (USGS) and industry to obtain occurrence data of pesticides in surface and ground waters which supply drinking water to the public. The ideal situation is to obtain monitoring data on finished water taken during high pesticide use seasons in agricultural areas throughout the United States, or to be able to reliably approximate concentrations using validated, predictive models. In addition:

- USGS and OPP have launched a reservoir pilot program which will monitor surface water and finished water in 12 reservoirs throughout the United States;
- The Office of Water (OW) and OPP have set up a coordination workgroup for the purpose of sharing data on occurrence of pesticides in drinking water monitored under the requirements of the Safe Drinking Water Act. OPP now has access to occurrence levels of regulated pesticide contaminants, pesticides considered as priorities for regulation and others that are unregulated but are being monitored due to production, release and physical properties. In addition, OPP and OW are working together on cross-cutting science policy issues and recommending research priorities to ORD for the development and validation of exposure models

which can estimate pesticides in drinking water human health risk assessments and for use in probabilistic ecological risk assessments;

- OPP has improved the screening level model by developing an index reservoir scenario to replace the small pond model which also considers the percentage of the acreage treated with the pesticide (s);
- OPP is working with the American Crop Protection Association (ACPA) to design a national survey with emphasis on surface water sources for drinking water;
- OPP is also developing a predictive model for and is studying the effects of water treatment methods on pesticide concentrations in drinking water.

Developing an Aggregate Exposure and Risk Assessment Tool: Hampshire Research Institute's (HRI) Lifeline Software Model

In June 1998, OPP entered into a co-operative agreement with the Hampshire Research Institute (HRI) to support the development of an aggregate and cumulative risk modeling tool to be made available to the general public. The computer-based modeling tool will allow professional and non-professional persons interested in risk assessment to better engage in a discussion of exposure and risks from pesticides in the environment. This effort is geared toward more effective protection of public health and the environment through fostering the dissemination of reliable information on risk, and by increasing the public's ability to analyze, understand and make decisions about environmental problems.

There are three main goals to this software modeling project. The first is to stimulate investigation and dissemination of aggregate risk assessment concepts. The project will develop literature and tools to help the public understand the concept and role of risk assessment in environmental decision making to allow for greater public involvement. This is especially relevant in light the new requirements of FQPA to investigate aggregate exposure (exposure to a pesticide from multiple sources and by multiple routes) and, in the future, cumulative risk (risk associated with concurrent exposure to multiple pesticides that act via a common mechanism of toxicity). The second goal is to support development of a flexible computer model which performs aggregate risk assessment by combining exposures to chemicals used as pesticides from the dietary, drinking water and residential routes of exposure through utilization of a flexible computer model. The tool uses new approaches to risk assessment evaluating multiple exposures (aggregate) in a computer-based platform that allows for input of currently available information (the U.S. Census) and user-specified information.

An additional goal of the project is to facilitate the availability of the aggregate risk modeling tool to the public at a cost that is not prohibitive. OPP believes it is important to encourage the distribution of aggregate risk assessment concepts and models to all interested members of the general public in an understandable format and at a cost that is affordable. OPP believes that support of this software development, addressing both aggregate exposure and cumulative risk, will help to make scientific advancements compatible with more effective public involvement in environmental decision making.

Collecting Pesticide Use Information

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

Opening of EPA's Environmental Science Center

In January 1999, laboratory staff from the Office of Pesticide Programs (OPP) and Region 3 moved into their new laboratory at Fort Meade, Maryland. The new lab replaces outdated laboratory facilities with state-of-the-art technology and consolidates six EPA facilities formerly located in Annapolis and Beltsville, Maryland; Cincinnati, Ohio; and Research Triangle Park, North Carolina; and is the first non-Department of Defense federal facility at Fort Meade. The new Environmental Science Center supports enforcement & monitoring for Region III and analytical chemistry and microbiology for the Office of Pesticide Programs. Its analytical capabilities include chemistry (organic, inorganic, and metals) analysis, biology, microbiology, and other scientific activities that further the mission and goals of the Agency.

EPA Region III Administrator, Mike McCabe, speaks during the dedication ceremony of the new Environmental Science Center in Fort Meade, MD.

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PARTNERSHIPS

OPP works with these partners, as well as the diverse stakeholder community, in developing and applying better, more consistent pesticide program policies and decisions.

BY MAINTAINING STRONG COMMUNICATIONS WITH EPA REGIONS, OTHER government agencies, states, and tribes, OPP promotes the Agency's mission of protecting public health and the environment from the risks pesticides may pose and promoting safer means of pest control. OPP works with these partners, as well as the diverse stakeholder community, in developing and applying better, more consistent pesticide program policies and decisions.

Providing Support for Regional Initiatives

Pesticide Urban Initiative

Misuse of pesticides in residential settings has been a recurring problem for many years, with a series of highly dangerous incidents sharply increasing OPP's level of concern. In several separate incidents a highly toxic agricultural pesticide, methyl parathion, was illegally used indoors to control cockroaches. EPA took action on two fronts: our Superfund program led a lengthy and expensive cleanup efforts in private homes; enforcement actions focused on stopping this extremely dangerous practice and developing ways to prevent future misuse incidents. Our enforcement partnership included pesticide and enforcement programs–especially in our EPA regional offices and our state lead agencies.

In response to our increased concern, EPA developed a strategy in 1999 called the Pesticide Urban Initiative, to help stop pesticide misuse. Key components of the strategy include increased regulatory and enforcement presence in urban communities to detect diversion of agricultural pesticides to urban areas, and enhanced outreach effort to educate the public on the dangers of misuse of pesticides. EPA is providing training and compliance assistance to states in implementing this program, such as workshops with state agriculture departments and cooperative extension services.

EPA issued a public service announcement providing information on how to hire an appropriate pest control service and about the dangers of pesticide misuse. Articles describing the consequences of pesticide misuse and pest control methods were published in various medical and consumer publications. EPA regional offices have developed a wide variety of outreach materials, often in cooperation with extension service and state agencies, and are actively conducting seminars and training sessions for state and local health department staff, homeowners and apartment residents.

Developing Stakeholder Partnerships

Pesticide Environmental Stewardship Program

The Pesticide Environmental Stewardship Program (PESP) is a voluntary partnership between EPA and the pesticide user community to reduce pesticide risk in agricultural and nonagricultural settings. Organizations with a commitment to reducing pesticide risk

Regional Agricultural Initiatives

To increase communications between EPA and stakeholders on issues relating to FQPA, four pilot projects were initiated. Highlights of the four pilots include:

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

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

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

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

OPP staff and pineapple farmers discuss integrated pest management (IPM) strategies under the PESP program

are eligible to join PESP either as Partners or Supporters. Partners are organizations that either use pesticides or represent pesticide users. Supporters are organizations that have an interest in pesticide issues. PESP's membership now includes over 100 Partners and 25 Supporters who have agreed to develop and implement strategies to reduce pesticide risk and to report regularly on their progress. OPP provides each Partner and Supporter with a liaison to help them obtain information not only about the partnership, but about other EPA programs, policies, and procedures.

PESP also works to reduce pesticide risk in non-agricultural settings. A PESP Supporter, the Bay Area Stormwater Management Agencies Association (BASMAA) reported that diazinon and chlorpyrifos, pesticides widely used in urban landscapes, were exceeding acceptable levels in the surface water runoff in the San Francisco Bay area. In this urban area (population of 4.7 million), homeowner use was identified as a major source of diazinon and chlopyrifos reaching the creeks. Using funds from OPP and the State of California, BASMAA developed a program to educate sales persons and the general public in pesticide retail outlets (landscape nurseries, hardware stores) about the use of less toxic pesticides and integrated pest management. In one hardware store, diazinon sales decreased 20% while the sales of less toxic pesticides increased 20%. The store personnel attributed these results to the educational program. BASMAA plans to expand this program from four pilot stores to more than 100 in the Bay area. Detailed information on PESP, its members and their activities, and funded projects is available on the Internet at www.pesp.org.

EPA Partnerships with Potato Grower Stakeholders

In October 1998, in a cooperative effort with the Wisconsin potato growers, University extension specialists, and Zeneca Ag Products, EPA issued an Experimental Use Permit (EUP) to test azoxystrobin, a "reduced risk" pesticide for use on potatoes in Wisconsin to control early and late blight. The Experimental Use Permit generated information that was useful for the preparation of the risk assessment for the registration of the use on potatoes. The latest health risk assessment including potatoes reinforced the benign nature of azoxystrobin, as determined during previous registration activities on this chemical. The tolerance on potatoes was established later in 1999.

The Consumer Labeling Initiative

The Consumer Labeling Initiative (CLI) is a voluntary, cooperative effort among OPP, the Office of Pollution Prevention and Toxics (OPPT), other federal and state agencies, industry, and the public, to foster pollution prevention and to improve consumer understanding of safe pesticide use and information on household consumer product labels. The CLI has been focusing on indoor insecticides, household hard surface cleaners, and outdoor pesticides.

In 1999, EPA approved most of the CLI Partner/Task Force recommendations, including label changes, ingredient information, and disposal instructions. OPP will issue Pesticide Registration Notices and/or *Federal Register* Notices, as appropriate, to implement the label changes. OPP continues to work with state and local and industry representatives to develop revised disposal label instructions; a draft proposal is planned for late in 1999. Outreach efforts included presentations to EPA staff and other interested organizations around the country, a CLI web site, and other program status updates. The CLI team, at management's direction, continued to develop educational materials, a logo, and an implementation strategy for the consumer education campaign. All of the research and work done under Phase II was included in the CLI Phase II Report. This report was peer reviewed and the CLI plans to publish the report in late 1999.

Coordination with Infection Control Specialists in Medical Facilities

One of OPP's successful outreach activities involved the Association for Professionals in Infection Control and Epidemiology (APIC). Members are infection control specialists who work primarily in health care settings. APIC has the formidable task of trying to reduce the number of hospital-acquired infections occurring in the United States, currently estimated at more than 2 million annually. Because approximately 1,000 out of 5,000 registered antimicrobials products are hospital disinfectants, OPP has opened a dialogue with APIC members to explore areas of mutual interest.

APIC members indicated a need to know which agency to call with specific questions about infection

Profile on PESP

As funds allow, OPP provides PESP with money to support pest management projects that reduce pesticide risk. The Texas Association of Nurserymen, with assistance from Texas A&M University and EPA, have succeeded in getting IPM information about horticultural crops into the hands of growers over the Internet. Their website at, http://www.hortipm.tamu.edu averages 1.5 million hits per month, 36% from growers, and 32% from extension agents who advise growers. The site provides detailed information on, and pictures of pest identification, scouting methods, and cultural, biological and chemical pest control methods. The site's users highly rate the advice they get from the site: 47% of users think the pest solutions provided are good or outstanding; and 100% say they will continue using the site. Quick, reliable access to this information will allow growers to make pest control decisions using the latest reduced-risk technologies.

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Working Closely with State and Federal Laboratories

OPP operates three laboratories which work closely with State FIFRA laboratories providing technical support for compliance monitoring and enforcement activities, as well as assistance with quality assurance and training. In 1998 and 1999, OPP and states cooperated to help develop critically needed methods for analyzing herbicides which require newer analytical and instrumental technologies.

More and better residue monitoring data for organophosphates (with emphasis on children's foods) will be the result of a new agreement between OPP and FDA. Our Analytical Chemistry Laboratory is working with FDA to develop multi-residue methods at least ten times as sensitive as the old methods. Using those methods, FDA through its existing network of field laboratories and compliance monitoring program, will analyze a thousand imported and domestic food samples in the coming year.

OPP's Microbiology Laboratory has begun a collaborative research project with the FDA's Engineering and Analytical Center to evaluate new procedures and equipment to improve the tuberculocidal test.

OPP laboratories include:

- a microbiology lab, which conducts efficacy testing of antimicrobial pesticide products of public health significance, such as hospital disinfectants;
- an analytical chemistry lab, which evaluates analytical methods to detect pesticides in foods and fibers to ensure that the methods are suitable for enforcement monitoring; and
- an environmental chemistry lab specializing in evaluating test methods for pesticides in soil and water to determine if they are suitable for generating reliable data to support pesticide registration and reregistration decisions.

control practices and products. OPP, with input from other agencies, prepared a document to answer APIC s most immediate questions. The document explains that EPA generally is responsible for products that control germs on inanimate surfaces and objects; such as walls and bedpans, and for some products that treat medical waste before disposal. (Liquid chemical sterilant products used on critical and semi-critical medical devices are FDA's responsibility.) APIC and OPP have exchanged drafts of various manuscripts to help ensure their accuracy and usefulness. Future activities may include: arranging site visits between OPP staff and APIC members, making APIC training courses available to OPP staff, working together to make labeling more user friendly; and discussing ways of treating medical waste before disposal.

Partnering with States and Other Agencies

EPA and Texas Aquatic Herbicide Workgroup

OPP and our Region 6 office in Dallas, Texas established an Aquatic Herbicide Workgroup to work with the Texas Department of Agriculture to negotiate risk mitigation measures that would allow Texas to use endothall and diquat dibromide. These efforts provided the necessary tools to the state to control of aquatic weeds, while ensuring that the use of these pesticides would not cause unreasonable adverse effects to humans and/or the environment.

OPP and the Association of American Pesticide Control Officials (AAPCO) Celebrate 20 Years of Partnership

In an effort to fulfill the need for information exchange between OPP and state regulatory officials regarding the implementation of the amended Federal Insecticide, Fungicide and Rodenticide Act, a cooperative agreement was entered into in 1978 by OPP and AAPCO. It created the State FIFRA Issues Research and Evaluation Group (SFIREG), which consists primarily of state pesticide regulatory officials. Reports that contain valuable information and recommendations on matters relating to pesticide registration, enforcement, training and certification, water quality, disposal, and other areas of environment concern are received from co-sponsored meetings with SFIREG. Both parties continue to work together to ensure the development, guidance and approval of state pesticide programs and policies.

Working with USDA to Bring Conventional Reduced Risk Pesticides to the Marketplace

As a result of a January 1999 meeting between the Environmental Protection Agency and the U.S. Department of Agriculture, the Interregional Research Project 4 (IR-4) has accelerated data development efforts to support tolerances for the pesticide spinosad for all crop groups. The expanded use of this pesticide is expected to provide alternatives to many organophosphates (OPs) used on a wide variety of fruits and vegetables. The IR-4 expects to complete all spinosad residue data requirements and submit tolerance petitions, covering major and minor crops, to the Agency early in the year 2000.

In 1999, the Agency approved an emergency exemption (Section 18) for the use of spinosad for the 1999 season's Medfly program of the Florida Department of Agriculture. The Agency is hopeful that with its approval, spinosad will become the principal pesticide used in Florida to address Medfly outbreaks. The availability of this lower risk pesticide will allow Florida to phase-down and/or phase-out the use of malathion in their Medfly programs.

Joint EPA/USDA Seminars on Pesticide Use

In a joint venture with USDA, OPP provides staff with in-service education by hosting approximately 22 seminars a year. Speakers come from universities and industries throughout the U.S. to discuss a variety of subjects, ranging from minor crops to non-agricultural uses of pesticides. Topics cover field experience in pest management in a variety of crops, such as sweet potatoes, apples, cotton, wheat, stored grains, corn and sorghum, canola, and wild rice, as well as regional crops in the northeast, mid-Atlantic, southeast and New Mexico. Seminars in the past year outlined production of California pistachios, northwest small berries, California carrots, wine grapes, and processed tomatoes in California. Alternative pesticides were discussed in various seminars, most notably for atrazine in corn and sorghum weed management and for synthetic fungicides. Even pesticide tracking and reporting systems were described in seminars on *The California Pesticide Use Reporting System* and *An Overview of Non-agricultural Uses of Insecticides in the U.S.* All seminars were well attended and provided excellent opportunities for meaningful dialogue.

Coordinating International Activities

The overall goals of OPP's international efforts are to promote improved health and environmental protection world-wide, and to ensure that international trade initiatives and other agreements are consistent with the high level of protection afforded by U.S. laws. With the expansion of international trade in agricultural and chemical products, it is no longer possible to separate domestic and international issues, and a global approach is often required. In 1998, we worked with a number of partners at the bilateral, regional, and global levels. These cooperative activities will result in reducing risks more quickly, promoting food safety, helping save resources by avoiding redundant efforts, and leading to better and more consistent program decisions grounded in sound science.

International Agreements

Regional Treaty on Persistent Organic Pollutants–In June 1998, the U.S., Canada, and European countries (including the Russian Federation and Newly Independent States), signed a legally binding protocol on persistent organic pollutants. Persistent organic pollutants are toxic chemicals that do not readily break down in the environment and that bioaccumulate through the food chain. Initially, the chemicals covered by the agreement include aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, mirex, toxaphene, hexachlorobenzene, PCBs, dioxins and furans. Other chemicals may be added as scientific evidence warrants. The protocol establishes obligations aimed at restricting or eliminating persistent organic pollutants and will inform ongoing efforts to develop a global persistent organic pollutant agreement.

Prior Informed Consent–In September 1998, the United States signed the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. This agreement governs trade in pesticides and other hazardous chemicals that have been banned or severely restricted in the U.S. or other countries based on health or environmental risk concerns, or which pose special risks in developing countries. Participating countries are obligated to provide information about regulatory actions and to prohibit the export of PIC chemicals when importing countries indicate that they do not want to receive shipments.

Working with the Organization for Economic Cooperation and Development

Harmonization and Work Sharing–The Organization for Economic Cooperation and Development's (OECD) Pesticide Working Group provides a forum where governments can express their points of view, share their experiences, and search for common answers on pesticide regulatory issues. One of the main objectives of the OECD Program is to make registration and re-registration evaluations more efficient by harmonizing the structure and content of pesticide review reports and sharing the work of reviews. In 1998-1999, OECD Member countries reached agreement on harmonized formats for dossiers (industry data submissions) and monographs (country review reports). Common formats are critical to sharing the work of pesticide registration successfully. Guidance documents on dossier and monograph formats were adopted in February 1998 and made available on the Internet. An expanded version of these documents will be published in 2000.

In 1998-1999, progress was made on harmonizing data requirements, including a workshop on common core data requirements for pheromones and an initial

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proposal for common core requirements for microbial pesticides. The outcome of a series of workshops held in 1999 to develop a proposal for common data requirements to establish Maximum Residue Limits (MRL) will be presented to the OECD Pesticide Working Group in 2000. Agreement on data requirements for MRLs is important not only to OECD Member countries, but also to the work of the Codex Alimentarius Commission, which sets international MRLs.

Classification, Labeling and Test Guidelines–The 1992 United Nations Conference on The Environment and Development endorsed the development of a globally harmonized system of chemical hazard classification and labeling, with a goal for completion by the end of the year 2000. Through OECD, international consensus was achieved in late September 1998 on classification criteria for eight health and environmental endpoints: acute toxicity; aquatic toxicity; carcinogenicity; eye and skin irritation/corrosivity; germ cell mutagenicity; reproductive and developmental toxicity; and sensitization. Criteria for physical hazards, such as flammability and explosivity, are also substantially complete. Efforts are ongoing to harmonize hazard labeling and approaches for dealing with chemical mixtures.

EPA completed work on a number of test guidelines, harmonizing EPA's requirements internationally through OECD. Among the guidelines published in 1998 were those governing testing for key reproductive and developmental endpoints.

Codex

OPP continued to support the Codex Alimentarius Commission, a joint program of the United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO) that sets international standards for pesticide residues in foods. The United States is working to improve the scientific basis and timeliness of Codex decisions, and to boost public participation.

North American Free Trade Agreement (NAFTA) Activities

Cooperative work with Canada and Mexico under the NAFTA Technical Working Group on Pesticides continued to grow in 1998 and 1999. The first joint review of the conventional "reduced risk" pesticide was successfully completed in 1998, with coordinated registrations issued in Canada and the United States. In 1999, the United States and Canada completed the joint reviews of two additional conventional "reduced risk" pesticides and one pheromone. NAFTA countries developed a procedure and priority scheme for handling agricultural impediments to trade (e.g., different registrations or tolerances) and are continuing to work with growers and pesticide producers to resolve them, particularly with respect to canola production and pesticide seed treatments. In 1999, OPP worked with the Office of Enforcement and Compliance Assurance to complete a United States-Canada Memorandum of Understanding (MOU) on Good Laboratory Practices, aimed at promoting reciprocal acceptance of high quality data to support pesticide registrations in both countries.

Under NAFTA, a cooperative project between OPP and its Canadian counterpart, the Pesticide Management Regulatory Agency (PMRA) was initiated to determine the distribution of landscapes in the northern tier states of the United States which are similar to the soil landscapes in the southern regions of several Canadian provinces.

Assuming pesticide dissipation is comparable among similar soil landscapes and climatic regions with corresponding management practices and cropping patterns, the identified landscapes could be used for conducting terrestrial field dissipation studies in support of pesticide registration in both countries. Field studies conducted in similar landscapes would reduce the costs associated with field dissipation studies and increase knowledge of pesticide dissipation under field conditions. Comparable soil landscapes will be identified using a customized Geographic Information System (GIS) application with crop distributions, ecological regions of North America, rainfall distribution, soil temperature regimes, and various soil attributes in the Canadian Soil Landscapes System and the U.S. State Soil Geographic Database (STATSGO).

OPP will further benefit from the project through increased access to geo-spatial data (e.g., crop distributions, soils information) to refine risk characterizations and improve guidance for evaluating terrestrial field dissipation studies.

Cooperating with Developing Countries

To enhance environmental protection world-wide, OPP and its Regional offices work with developing countries to improve pesticide regulation and promote the sound management of chemical production, distribution, use and disposal. Activities in 1998 included:

- training and consulting with the Pesticide Secretariat of the Indonesian Ministry of Agriculture as part of a capacity-building project funded by the World Bank;
- developing a Central American regional pesticide laboratory training seminar, in collaboration with international development agencies;
- working with the Choluteca community in Honduras on a community-based pesticide risk reduction plan which could serve as a model for other Central American communities; and
- initiating new pest/pesticide management project with Ukraine, under the leadership of Region 5 and in cooperation with the Agency for International Development and Virginia Tech.

Field Programs

THE EPA'S OFFICE OF PESTICIDE PROGRAMS (OPP) RELIES HEAVILY ON cooperative relationships with EPA regional offices, state pesticide regulatory agencies, and tribes, in addition to public and private organizations and other stakeholders to carry out its regulatory programs in the field.

The woodstork is protected by the Endangered Species Protection Program

Focusing on the Endangered Species Protection Program

The Endangered Species Protection Program relies on cooperation between the U.S. Fish and Wildlife Service (FWS), EPA Regions, states, and pesticide users. The goal of the Endangered Species Protection Program is to protect threatened and endangered species from potentially harmful effects of pesticides, while minimizing the impact of the program on pesticide users.

In 1998 and 1999, the Endangered Species Protection Program focused on improving the availability of public and technical information, and consultation with stakeholders. OPP upgraded its toll-free endangered species information line to include "fax-back" capability for county bulletins, which contain measures pesticide users can take to prevent harm to endangered species. OPP also upgraded the species-by-county database to include all species listed through June 1999, and made the database Internet-accessible. With development of a new Geographic Information System data for several states, OPP is overlaying crop, rangeland and forestry information with species locations and pesticide use data for two pilot states in the western United States. Preliminary results indicate that this will be a powerful tool in focusing our consultations with the FWS to include specific pesticides and species. Finally, the Endangered Species Protection Program continues to work with the pesticide industry's FIFRA Endangered Species Task Force, which was formed to address certain endangered species protection conditions on new registrations.

Highlighting a Success: The Peregrine Falcon and the American Bald Eagle

On August 20, 1999, the Department of the Interior announced final action removing the peregrine falcon from the Endangered Species List. A proposal to remove the American bald eagle from the list was announced in July 1999.

The removal of these birds from the Endangered Species list is the culmination of the good work of many people and agencies through the years. It is a reminder that laws, such as FIFRA and the Endangered Species Act, in combination with the will and skill to administer them, can make a profound difference in our environment.

Recovery of these birds began with, and would not have been possible without, the cancellation of DDT in the 1970's. The decision to cancel DDT was difficult and controversial, but the results have paid off manyfold for protecting human health and the environment.

Developing the Ground Water Pesticide Management Plan Program

The ground water Pesticide Management Plan (PMP) program continued to move forward in 1998-99. When final, the PMP program will provide states and tribes the opportunity to manage use of pesticides known to be found in ground water. The PMP program employs management measures that can be tailored by states or tribes to reflect their philosophy on ground water protection, pesticide use in their area, and the use, value, and vulnerability of ground water. The regulatory review team continued efforts to address public comments on the proposed regulation and to develop the final regulation, which is anticipated to be promulgated in the Spring of 2000.

The removal of these birds from the Endangered Species list is the culmination of the good work of many people and agencies through the years.

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New Regional Approach to Pesticide Education and Enforcement

In 1998, EPA Region 10 initiated a new "circuit rider" staff position to work with six tribes in the region. The new staff person travels among the six reservations and enforces tribal and federal pesticide regulations, while sharing information with the tribes that use pesticides or are impacted by pesticides.

The PMP program is unique in that it recognizes the local knowledge possessed by states and tribes regarding the ground water resource; the regulatory review team is unique in that all 10 EPA Regional Offices, plus 10 states and three tribes, are represented.

Two innovative PMP outreach activities began in 1998 and 1999. OPP designed a new approach to providing information and technology transfer in Indian Country. More than 5% of the nation's land base is located on tribal lands and over sixty tribes have been identified as having significant agricultural operations affected by the proposed PMP rule. The Agency's tribal outreach efforts were designed to improve the knowledge of tribal environmental agencies and staff about developing PMPs using training which considers Native American land-use and cultural beliefs and practices.

In 1998 and 1999, the regulatory review team conducted 22 training sessions or workshops in Indian Country. These included outreach sessions, rule-education workshops to guide participants through the essentials of OPP's rulemaking and chemical-specific management programs, and workshops for training interested tribes in developing a model or "shell" PMP. During the first six months of the program, more than 250 tribal officials and environmental professionals were introduced to the PMP concept of adopting management measures based on local natural conditions and levels of pesticide use.

Also in 1998, a team from EPA Headquarters and EPA Region 7, joined by state agencies from Missouri, Kansas, Iowa and Nebraska, and two grower organizations, developed, planned and executed a process to better inform growers of the provisions of the PMP rule.

Approximately 100 people representing growers, industry, natural resources protection agencies, public interest groups, universities, and federal agencies, attended a workshop that allowed participants to develop parts of a "mock" PMP and put it into practice based on several different scenarios of pesticide use and ground water contamination detections. According to evaluations from participants, the workshop was a success and can be used as a model to engage the grower community on a variety of issues in the future.

Preventing Pesticides in the Environment Through Container And Containment Standards and Support of Collection Programs

OPP continued developing final regulations for pesticide container standards and containment areas. While the regulations do not specifically address disposal of unwanted pesticides, OPP continues to support state efforts. States have taken the initiative to collect and dispose of unwanted pesticides to prevent these products from winding up in ditches, streams, and ground water.

These efforts, referred to as Clean Sweep Programs, play an important role in pollution prevention and, as funding allows, are supported by EPA Regional Offices through grants and technical assistance. While some programs are fully implemented and permanent operations for regular collection and disposal of unwanted products, many states face unpredictable funding and operate their programs on an occasional or one-time basis when funds are available.

During 1999, OPP began tabulating data on Clean Sweep Programs, and developing a clearinghouse for information on this topic. Information gathered by OPP shows these programs are increasing and are collecting greater volumes of unwanted pesticides. Between 1989 and 1998, over 13 million pounds of unwanted product were collected and disposed of safely.

OPP will compile the data and individual state information in a Clean Sweep Report during the year 2000. The report will publicize successes of Clean Sweep programs nationwide, and provide ideas and information for program managers wishing to initiate or improve a program. The report will also support EPA's integrated strategy on persistent and bioaccumulative toxic chemicals (PBTs), which includes both national programs, such as the Great Lakes National Program Office, and international treaty negotiations, such as the Persistent Organic Pollutants (POPs) Protocol.

In 1999, OPP issued a Call for Proposals to fund projects for states, tribes, or counties to monitor and report the amount of specific pesticides collected during Clean Sweep Programs and to estimate the cost of tracking this additional information. OPP is interested in data on amounts of all pesticides, but is focusing on those which support EPA's broad PBT Initiative and the POPs treaty negotiations.

Developing Tribal Initiatives and Programs

Like states, tribes have primary responsibility for enforcing pesticide regulations under FIFRA. A number of tribes provide this function under a grant agreement with EPA Regions and are in the process of developing programs for these areas as needed. OPP works with tribes, EPA Regions, states, other EPA program offices (e.g., the American Indian Environmental Office, Office of General Counsel) and other federal agencies coordinating efforts related to tribes and pesticides. It is OPP's goal to help tribes resolve pesticide issues regardless of their capacity or whether they have an established pesticide program.

Currently, OPP works with over 25 tribes that have pesticide programs, helping them develop ground water, certification and training, worker protection and endangered species components of their programs. Other activities relating to Tribal Initiatives and Programs include:

National Tribal Pesticide Council–In September 1999, EPA awarded a cooperative agreement to Native Ecology Initiative (NEI) to organize a national group–the Tribal Pesticide Program Council (TPPC). Membership will initially include 30 tribes that now have EPA pesticide programs and a number of tribes with pesticide interests. The TPPC will promote and enhance tribal pesticide program development, raise pesticide issues important to tribes and their people, and deal with policy at the national level. TPPC issues will include pesticide registration, training, enforcement, certification, ground water, disposal and spray drift. The national group give tribes a mechanism for communication and organization similar to that provided by the State FIFRA Issues Research and Evaluation Group (SFIREG) for the States.

Outreach to Tribes on Groundwater Management–During 1998 and 1999, through a grant with the Native Ecology Initiative, EPA provided tribes across the country with information on EPA's proposed Pesticide Management Plan rule, as well as technical and legal assistance for developing groundwater management plans. EPA also entered into an Interagency Agreement (IAG) with the U.S. Geological Survey (USGS) to support tribes and states in the development of PMP's. In this IAG, USGS assists tribes and states as they collect, integrate and interpret existing technical information and apply it to their lands of interest as they develop a PMP.

Tribal Pesticide Projects–In 1998, OPP solicited tribal pesticide project proposals through the Regions and awarded grants for the projects to tribes across the nation. The projects addressed various pesticide issues on tribal land. Six out of ten project proposals were chosen.

There was a significant increase in the submission of tribal project proposals in 1999. Eight out of 25 groundwater project proposals submitted were funded from Regions 6, 7, 8 and 9. Six out of 19 special pesticide project proposals submitted were funded from Regions 8, 9 and 10. The types of projects selected for funding ranged from the development of groundwater pesticide management plans to assessing the impact of pesticides on culturally significant plants and subsistence hunting and fishing.

Supporting Agricultural Workers

Special Protection for Agricultural Workers

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

During 1998 and 1999, our Worker Protection Program devoted significant resources to producing and distributing bilingual or multi-lingual educational materials. Communications include a new Pesticide Workers Website, publication of over 1 million grower compliance manuals, over 2.7 million safety training manuals, over 680,000 safety posters, and more than 11,000 safety training videos.

EPA began reviewing worker protection activities, including risk assessment methods, to determine if workers are receiving adequate protection. Last year, EPA initiated a national assessment of implementation and enforcement of the worker protection regulation. We are establishing a worker protection assessment group comprised of EPA, USDA, the Department of Labor, the Department of Health and Human Services, state regulators, state extension service safety educators, farm worker advocacy groups, farm worker service/training associations, agricultural employer associations, farm worker clinicians networks, and others. The group's goals are to:

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

Tribes and EPA lost a true environmental advocate with the October 1999 death of Conner Byestewa, Jr. of the Colorado River Indian Tribes in Parker, Arizona. He contributed significantly to the development of the Tribal Pesticide Program Council. Conner was well known for his ability to create change through personal involvement and positive relationships. We appreciated his gentle way, his humor, and his presence. He will be greatly missed.

Conner Byestewa, Jr., Colorado River Indian Tribes, shares news from Indian country with OPP staff.

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FIFRA Section 6(a)(2) Submissions

Section 6(a)(2) of FIFRA requires pesticide product registrants to submit adverse effects information about their products to OPP. OPP reviews these submissions and studies to see if there are risks associated with the product that were not anticipated at the time of registration. In late 1998, OPP's new adverse effects reporting requirements took effect. These regulations clarified and in many cases lowered the threshold for adverse incident reporting. As a result, 6(a)(2) submissions increased considerably during FY99. For additional information on 6(a)(2), please refer to the Appendix, Figure 3.

- In FY 1998, OPP received approximately 1,800 submissions containing reports of more than 22,000 incidents.
- In FY 1999, OPP received nearly 1,500 submissions containing reports of more than 46,000 incidents.

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

Applicator Certification and Training

More than 1.2 million applicators are currently certified nationwide, including over 800,000 private applicators and about 400,000 commercial applicators. Over the past two years, approximately 160,000 private and 170,000 commercial applicators received initial certification and more than 400,000 private and 380,000 commercial applicators were recertified.

EPA also conducted a national assessment of the applicator certification and training program. A certification and training assessment group, consisting of representatives from EPA, USDA, state pesticide agencies, tribes, and pesticide safety educators, was formed to draft proposals to guide the program's future. The proposals for review by the nation's program partners are grouped under five program goals:

- reduce risks to the public from exposure to pesticides;
- provide high quality pesticide use education and safety training programs;
- maintain the consistency, integrity and validity of the certification and recertification programs and processes;
- ensure adequate and equitable funding for education and training programs; and,
- improve the efficiency of program organization and operations.

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

Pesticide Worker Website

In 1999, EPA launched a new website (www.epa.gov/pesticides/safety) to inform farm workers, certified applicators, and health care providers about the Agency's pesticide safety programs. This site, which provides easy access to information in both English and Spanish, marks an important step in the Agency's pesticide worker safety outreach efforts. It provides specific information on applicator certification and training requirements and EPA's Worker Protection Standard, including pesticide safety training, notification of pesticide application, use of personal protective equipment, and emergency medical assistance. Finally, the web site contains the 5th Edition of *Recognition and Management of Pesticide Poisonings*, a manual that assists health care providers in diagnosing and managing pesticide poisonings, which was published in 1999.

Developing an Interagency Initiative: Pesticides and the National Strategies for Health Care Providers

In 1998, an EPA-led interagency initiative began with the support of the U.S. Department of Agriculture, the U.S. Department of Health and Human Services, and the U.S. Department of Labor. The interagency group sponsored a workshop to identify strategies to improve the ability of health care providers to recognize, diagnose, manage and prevent adverse health effects due to pesticide exposure.

Based on the proceedings of the workshop, EPA published a report, *Pesticides and National Strategies for Health Care Providers*, which outlines a series of recommendations for improving the training that health care providers receive on health concerns related to pesticide exposures. Among the recommendations are the need to:

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

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

In May 1999, EPA and several other federal agencies convened the Education and Practice workgroups to further develop components of an implementation plan for raising knowledge and awareness of pesticide issues in the educational and practice settings of primary care providers. Workgroup members came from academic faculty, professional associations for physicians, nurses and physician assistants, farmworker and community interest groups, federal and state agencies, and pesticide experts. A third workgroup on Resources began its deliberations in August 1999.

Once the workgroups have developed proposals, a draft national implementation plan will be published which will serve as a working document for the next year of activity on this initiative, culminating in a national forum in 2000.

Right to Know

PROVIDING ALL AMERICANS WITH ACCESS TO INFORMATION ABOUT PESTICIDES and involving them in our work are essential parts of the Agency's comprehensive approach to protecting public health and the environment. This goal is premised on the concept that all U.S. citizens have a right to know about the pesticides in their environment, as well as those used to grow food they consume.

Access to such information enables Americans and the international community to make informed decisions about their environment. In 1998 and 1999, the Office of Pesticide Programs expanded its pesticide education and outreach programs by disseminating information about pesticides to the public through fact sheets, brochures, other written correspondence and documents, the Internet, mass media, public meetings, press announcements, and other outreach tools. Highlights of some these documents are provided below.

Expanding Pesticide Education and Outreach Materials to the Public

Disseminating Fact Sheets and Brochures

Over the past two years, we developed over 30 fact sheets for the public on topics ranging from pesticides and mosquito control to Integrated Pest Management and food production. With advice from the Pesticide Program Dialogue Committee and consumers, and in consultation with USDA and FDA, EPA developed in English and Spanish, the brochure, "Pesticides and Food: What You and Your Family Need to Know." The brochure informs consumers about pesticide use on food, government programs that protect them from pesticide risks, and ways they can reduce their exposure to pesticides. The brochure also explains how the Food Quality Protection Act (FQPA) increases protection of infants and children from exposure to pesticides. Over six million copies have been distributed to 30,000 grocery stores, public health officials, libraries, and the medical community and it is also available on our website.

Responding to Written and Electronic Inquiries

OPP places great importance on listening and responding in a timely fashion to comments and inquiries from the general public on the various pesticide programs. In 1998 and 1999, OPP responded to over 2,700 inquiries from the public and their representatives in Congress. These inquiries came in the form of e-mails, postcards, letters, and phone calls and ranged from citizens seeking information on pesticide health issues to expressions of opinions regarding pesticide regulations.

Providing Pesticide Information on the Internet: www.epa.gov/pesticides

OPP's use of the Internet continued to grow during the past two years, offering information for consumers, businesses, researchers, states, and international partners. The Website has become an important resource to OPP's customers and is beginning to have a fundamental effect on the way OPP communicates.

The increase in Internet access has made it easier for the public and stakeholders to get the information they need and want, saving them time and natural

This goal is premised on the concept that all U.S. citizens have a right to know about the pesticides in their environment as well as those used to grow food they consume.

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resources. Highlights of new items added to OPP's website over the past two years include:

- the activities of the Pesticide Program Dialogue Committee and Tolerance Reassessment Advisory Committee;
- guidance for submitting pesticide registration documents electronically known as "CADDY";
- EPA's scientific reviews of the class of pesticides called organophosphates. This is the first time risk assessments have been published on the website, making them widely available for public comment. This effort to increase transparency has evolved into a comprehensive organophosphate homepage, providing updated schedules, risk assessments, and other information on the organophosphate pesticides as the information is placed in the Pesticides' Docket (an information collection and dissemination service that provides public access to proposed rules and regulations relating to pesticides);
- the Pesticide Management Resource Guide;
- the Label Review Manual, developed as a training and guidance tool for reviewing pesticide product labels;
- a FIFRA Section 18 database listing actions, by chemical name (FIFRA Section 18 allows states, under emergency conditions, to use a pesticide for an unregistered use for a limited time);
- various forms and guidance information required for pesticide registration;
- a regional, state and tribal web page, which includes information on OPP's field programs that help put pesticide laws and regulations into practice;
- extensive information about biopesticides;
- the "Pesticides and Food" website, which is referenced in the printed brochure, provides consumers with more detailed information on pesticide regulation (www.epa.gov/pesticides/food);
- "Sign up" through the Web site to a mailing list for electronic OPP Updates.

Finally, OPP made significant changes to the website's design, making it easier and quicker for people to find information. For example, at the home page, the browsing public now has access to enhanced search tools, as well as a "site map" which presents major categories of information and related documents.

Providing Toll-Free Access to Pesticide Information

Sometimes people want to pick up the telephone and communicate with a real person on a particular issue. To answer questions the public may have about pesticides, the Office of Pesticide Programs provided a grant to Oregon State University in Corvallis, Oregon, to operate two toll-free telephone services: the National Pesticide Telecommunications Network and the National Antimicrobial Information Network.

National Pesticide Telecommunications Network (NPTN)

NPTN provides objective, science-based information on a wide variety of pesticide-related subjects. The NPTN website is an increasingly popular source of information and can be accessed at http://ace.orst.edu/info/nptn. In 1998 and 1999, NPTN answered over 46,000 requests from the public, including over 36,800 calls received between March and October of both years. This coincides with the

time of year when most pest pressures are the highest. Over 20,000 calls were health-related inquiries. Approximately 10,000 calls were for information about pesticide usage, and nearly 5,000 calls were of a regulatory nature.

National Antimicrobial Information Network (NAIN)

Another toll-free service available to the public is the National Antimicrobial Information Network (NAIN), which provides a wide variety of information about antimicrobial pesticides. NAIN also has an Internet service. Organized as a cooperative effort between Oregon State University and EPA, NAIN maintains information on the toxicity, health effects, and safety of antimicrobial pesticides. It also maintains lists of antimicrobial products registered with EPA, including sterilants, disinfectants, tuberculocides, and products effective against HBV and HIV. NAIN also helps callers interpret product labels and EPA's antimicrobial policies and regulations. The website, which receives about 20,000 hits annually, contains regulatory and policy documents to help keep interested parties up-to-date about antimicrobial activities.

Within the last two years, NAIN has received an average of 2,000 telephone calls. More than half of the callers are from the medical community, with manufacturers and the general public accounting for most of the remainder. Most callers request information about specific products or types of products; the next largest set of calls covers regulation, registration, and complaints, including complaints about unregistered or ineffective antimicrobial products. Common questions include:

- can household bleach be used for cleaning blood spills in medical settings?
- is product X registered for use in nursing homes?
- should my restaurant install "antimicrobial" carpeting?

While continuing to respond to all inquiries, NAIN plans to maintain, expand, and publicize its antimicrobial website, and develop documents and fact sheets that answer frequently asked questions and that provide information on common antimicrobial products. NAIN operates toll free at 1-800-447-6349, Monday through Friday 7:30 a.m. to 4:30 p.m. Pacific time. The fax number is 541-737-0761; e-mail: nain@ace.orst.edu; website: http://ace.orst.edu/info/nain/

Staff from NPTN answer an average of 2,000 inquiries per month.

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APPENDICES

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TABLE 1

Registration of Safer Chemicals

The proportion of pesticide active ingredients that are considered to be safer (biological chemicals and reduced-risk conventional chemicals) than conventional chemical pesticides has steadily increased over the past several years, as the chart below indicates.

NUMBER OF PESTICIDE REGISTRATIONS BY CATEGORY

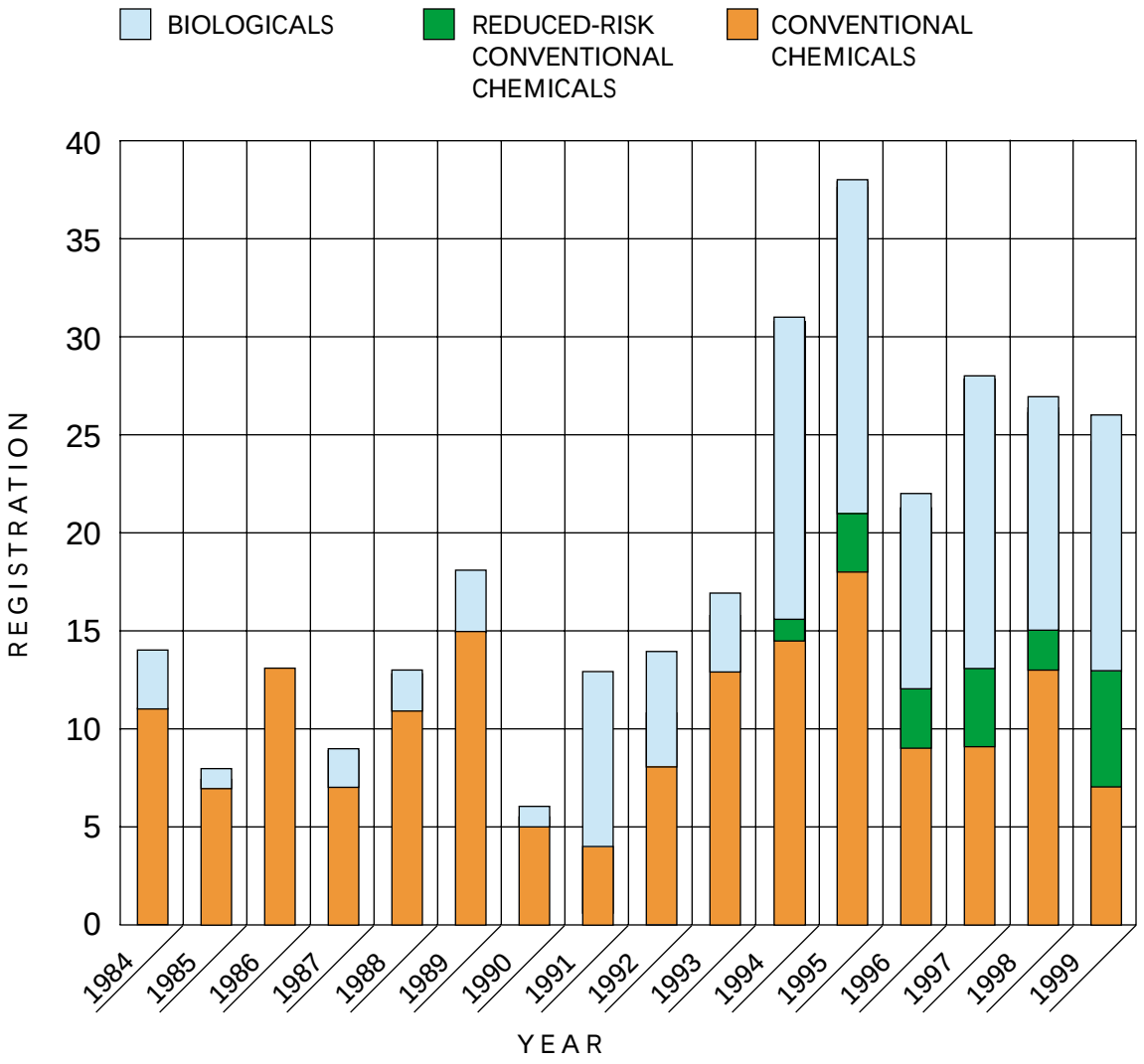

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TABLE 2

Pesticide Active Ingredients Registered in FY 1998

Of the 27 new active ingredients registered, 14 are safer pesticides. For the purpose of this chart, safer pesticides are those that have at least one or more of the following characteristics: they have low risk to human health; low toxicity to non-target organisms (birds, fish and plants); low ground water contamination potential; low use rates; low pest resistance potential; are compatible with integrated pest management (IPM); or are biopesticides. Non-reduced-risk pesticides do not pose unreasonable adverse affects, but may have the potential to cause greater harm than reduced risk pesticides if not properly used.

PESTICIDE	TYPE	CLASS	USES	SAFER
Bt Isrealensis Strain	insecticide	microbial	mosquito	yes
Canola oil	insecticide	biochemical	range of fruit, vegetables, ornamentals	yes
Carfentrazone-ethyl	herbicide	conventional	corn, soybeans, wheat	yes
Cloransulam-methyl	herbicide	conventional	soybeans	no
Cry9C Protein	insecticide	plant-pesticide	field corn	yes
Cuprous Chloride	fungicide	conventional	non-food	no
2-Cyclopenten-1-one, 2 hydroxy-3-methyl Maple lactone	insect attractant	biochemical	roach attractant-non food	yes
Cymoxanil	fungicide	conventional	potatoes	no
Cyprodinil	fungicide	conventional	stone fruit, pome fruit, grape, almond	yes
Dimethomorph	fungicide	conventional	potatoes	no
Fish oil	mammal repellent (deer, rabbits)	biochemical	ornamentals	yes
Flufenacet	herbicide	conventional	corn, soybeans	no
Fluroxypyr	herbicide	conventional	wheat, barley, oats	no
Gamma aminobutyric acid	plant regulator	biochemical	field crops, vegetables, ornamentals	yes
Gliocladium catenulatum strain J1446	fungicide	microbial	range of fruit, vegetables, ornamentals	yes
Hypochlorous acid	biocide	antimicrobial	indoor, non-food use	no
Imiprothrin	insecticide	conventional	indoor, non-food use	no
Isoxaflutole	herbicide	conventional	corn	no
Kaolin	insecticide, fungicide	biochemical	all ag crops	yes
Kresoxim-methyl	fungicide	conventional	non-food use	no
L-Glutamic acid	plant regulator	biochemical	field crops, vegetables, ornamentals	yes
Mono and di potassium salts of phosphorous acid	fungicide	biochemical	turf, ornamentals, bedding plants	yes
Monobasic potassium phosphate	fungicide	biochemical	apples, grapes, cucurbits, stone fruits, peppers, tomatoes, roses	yes
Paccilomyces fumororoseus Apopka Strain 97	insecticide	microbial	greenhouses, interiorscapes	yes
Potassium hypochlorite	disinfectant	antimicrobial	indoor, non-food use	no
Propazine	herbicide	conventional	greenhouses	no
Pyrimethamil	fungicide	conventional	imported wine grapes	no

TABLE 3

Pesticide Active Ingredients Registered in FY 1999

Of the 26 new active ingredients registered, 19 are safer pesticides. For the purpose of this chart, safer pesticides are those that have at least one or more of the following characteristics: they have low risk to human health; low toxicity to non-target organisms (birds, fish and plants); low ground water contamination potential; low use rates; low pest resistance potential; are compatible with integrated pest management (IPM); or are biopesticides. Non-reduced-risk pesticides do not pose unreasonable adverse affects, but may have the potential to cause greater harm than reduced risk pesticides if not properly used.

PESTICIDE	TYPE	CLASS	USES	SAFER
Agrobacterium radiobacter (strain K 1026)	fungicide	biopesticide	crown gall	yes
Anthraquinone	repellent	biopesticide	geese	yes
Bifenazate	insecticide	conventional reduced risk	ornamentals	yes
Diflufenzopyr a-dod....	herbicide	conventional reduced risk	corn	yes
(E)-90dodecenyl acetate	insecticide/pheremone	biopesticide	shoot borers	yes
Emamectin Benzoate	insecticide	conventional	brassica, lettuce, celery	no
Fenhexamid	fungicide	conventional reduced-risk	grapes, strawberries	yes
Fluthiacct-metyl (Action)	herbicide	conventional	soybean seed	no
Formic Acid	insecticide	biopesticide	mites	yes
IR 3535	repellent	biopesticide	mosquitoes	yes
Lithium P. Sulfonate	insecticide	conventional	wasp bait station	no
Methylcyclopropene	plant growth regulator	biopesticide	cut flowers	yes
3-methyl-2-cyclohex-1-one	pheremone type	biopesticide	beetles (forestry)	yes
n-Methylneodecanamide	insecticide	conventional	indoor use	no
Nonanoyloxybenzene Sulfonate	antimicrobial	conventional	laundry sanitizer	no
Oxypurinol	insecticide	biopesticide	cockroach	yes
Potato Leafroll Virus Resistance Gene	fungicide	plant-pesticide	potatoes	yes
Pseudomonas aureofaciens strain TX-1	fungicide	biopesticide	turf	yes
Pymetrozine	insecticide	conventional reduced-risk	tuberous and corn vegetables, tobacco, ornamentals	yes
s-Dimethenamid	herbicide	conventional reduced-risk	dry beans, corn, popcorn, peanuts, soybean	yes
Sulfosulfuron	herbicide	conventional	wheat	no
Tralkoxydim	herbicide	conventional	wheat, barley	no
Trifloxystrobin	fungicide	conventional	pome fruits, grapes, cucurbits, peanuts, bananas, turf	yes
Xanthine	insecticide	biopesticide	cockroach	yes
Z,E-9, 12-Tetradecadien-1-yl acetate[4]	insecticide	biopesticide	beet army worm	yes
Z-9-Tetradecen-1-ol[4]	insecticide	biopesticide	beet army worm	yes

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TABLE 4

Registration Decisions Versus Targets in FY 1998

The following table summarizes, by action, the number of decisions that were made in the Office of Pesticide Programs versus the target, or goal, that the program anticipated could be made. The target numbers are determined by anticipating market influences and taking into account past trends.

REGISTRATION CATEGORY	TARGETS	DECISIONS
Old chemicals (fast track[1])	364	478
Old chemicals (non-fast track[2])	275	334
Amendments (fast track[1])	1810	2946
Amendments (non-fast track[2])	246	375
New uses	99	320
New active ingredients	29	27
Experimental use permits[3]	—	8
Tolerances	91	236
Temporary tolerances	—	18
Inerts (non-active ingredients)	41	110
Emergency exemption (Section 18) decisions	366	504
Emergency exemption (Section 18) tolerances	—	95
Special local needs[4]	—	349
Biotech notification[5]	—	3

[1]Fast Track An application for registration of a pesticide product that is substantially similar or identical in its uses and composition (both active and other ingredients) to a currently registered product. Typically, no significant data need to be reviewed before the Agency can issue a registration decision.

[2]Non-Fast Track An application for a registration of a pesticide product that is sufficiently different in composition and/or uses that additional product specific data must be reviewed prior to the issuance of a registration decision. Typically, these data include acute toxicology, product chemistry, and product-specific efficacy.

[3]Experimental Use Permits (EUP) EPA normally must first authorize field testing of unregistered pesticides through an experimental use permit (EUP). The EUP establishes limited conditions for the transportation, application and disposal of unregistered test products. The granting of an EUP limits the sale and distribution of the test product only between approved participants in the test program, and use of the test product only under conditions specified in the EUP. Registrants typically request EUPs to gather large-scale efficacy testing and/or crop-specific residue chemistry data.

[4]Special Local Needs Under Section 24(c) of FIFRA, states may register an additional use of a federally registered pesticide product, or a new end use product to meet special local needs. "Special local need" means an existing or imminent pest problem within a state for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available. EPA reviews these registrations, and may disapprove the state registration if, among other things, the use is not covered by necessary tolerances, or the use has been previously denied, disapproved, suspended or canceled, or voluntarily canceled subsequent to a notice concerning health or environmental concerns.

[5]Biotech Notification A Biotech Notification is a submission of information to OPP prior to any small-scale testing of certain genetically modified and nonindigenous microbial pesticides. OPP has 90 days to solicit public comment, review the submission, and decide, among other options, whether to allow the release or not, or to require an EUP.

TABLE 5

Registration Decisions Versus Targets in FY 1999

The following table summarizes, by action, the number of decisions that were made in the Office of Pesticide Programs versus the target, or goal, that the program anticipated could be made. The target numbers are determined by anticipating market influences and taking into account past trends.

REGISTRATION CATEGORY	TARGETS	DECISIONS
Old chemicals (fast track[1])	342	513
Old chemicals (non-fast track[2])	258	509
Amendments (fast track[1])	1760	3141
Amendments (non-fast track[2])	240	445
New uses	90	681
New active ingredients	24	26
Experimental use permits[3]	—	29
Tolerances	95	351
Temporary tolerances	—	6
Inerts (non-active ingredients)	45	109
Emergency exemption (Section 18) decisions	370	542
Emergency exemption (Section 18) tolerances	—	62
Special local needs[4]	—	596
Biotech notification[5]	—	1

[1]Fast Track An application for registration of a pesticide product that is substantially similar or identical in its uses and composition (both active and inert (other) ingredients) to a currently registered product. Typically, no significant data need to be reviewed before the Agency can issue a registration decision.

[2]Non-Fast Track An application for a registration of a pesticide product that is sufficiently different in composition and/or uses that additional product specific data must be reviewed prior to the issuance of a registration decision. Typically, these data include acute toxicology, product chemistry, and product-specific efficacy.

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[4]Special Local Needs Under Section 24(c) of FIFRA, states may register an additional use of a federally registered pesticide product, or a new end use product to meet special local needs. "Special local need" means an existing or imminent pest problem within a state for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available. EPA reviews these registrations, and may disapprove the state registration if, among other things, the use is not covered by necessary tolerances, or the use has been previously denied, disapproved, suspended or canceled, or voluntarily canceled subsequent to a notice concerning health or environmental concerns.

[5]Biotech Notification A Biotech Notification is a submission of information to OPP prior to any small-scale testing of certain genetically modified and nonindigenous microbial pesticides. OPP has 90 days to solicit public comment, review the submission, and decide, among other options, whether to allow the release or not, or to require an EUP.

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TABLE 6

Risk Reduction Measures Achieved through FY 1998 REDs

RED	Some uses canceled, deleted, not yet eligible	Limit amount, frequency, timing of use	Residential/kids' risks addressed	Application restrictions	Restricted use pesticide	PPE/REI	User safety requirements, recommendations	Engineering controls/special packaging	Ground or surface water safeguards	Spray drift labeling	Other environmental safeguards	Ecological safeguards	Improve labeling, use directions & precautions	Other measures	Tolerances reassessed
Alachlor		✔		✔	✔	✔	✔	✔	✔	✔	✔		✔		✔
Aluminum phosphide	✔[1]				✔								✔		✔
Magnesium phosphide	✔[1]				✔								✔		✔
Bromoxynil			✔	✔		✔	✔		✔	✔					✔
Chlorothalonil	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔			✔[2]	✔
DEET	✔[3]		✔	✔			✔						✔		
1,3-Dichloropropene		✔	✔	✔	✔	✔	✔	✔	✔		✔	✔		✔[4]	
Dicofol	✔[5]	✔	✔	✔		✔	✔	✔		✔	✔	✔			✔
Hydramethylnon			✔	✔		✔	✔			✔					✔
Iprodione	✔	✔	✔	✔		✔	✔	✔	✔	✔	✔	✔			✔
Methomyl		✔		✔	✔	✔	✔	✔	✔	✔	✔	✔		✔[6]	✔
Propachlor	✔			✔		✔	✔	✔	✔	✔	✔	✔	✔		✔
Thiodicarb		✔		✔	✔	✔	✔	✔	✔	✔	✔	✔		✔[6]	✔
Total	7	7	7	11	7	10	11	8	8	9	8	6	5	4	11

✔[1] STAKEHOLDER PROCESS UNDERWAY WILL HELP DETERMINE ELIGIBILITY AND FINAL RISK MITIGATION MEASURES FOR AL AND MG PHOSPHIDE.

✔[2] PRODUCTION CONTROLS–MUST REDUCE LEVEL OF HCB IMPURITY TO 40 PPM BY 1/1/03.

✔[3] STAKEHOLDER PROCESS UNDERWAY WILL HELP DETERMINE ELIGIBILITY OF DEET-PLUS-SUNSCREEN PRODUCTS

✔[4] TECHNOLOGICAL CONTROLS, IMPROVED PRODUCT STEWARDSHIP MATERIALS ARE REQUIRED FOR 1,3-D.

✔[5] RESIDENTIAL USES OF DICOFOL VOLUNTARILY CANCELED; NEW STUDIES TO DETERMINE ELIGIBILITY OF REMAINING USES; VOLUNTARY CANCELLATION IF RISKS DO NOT DECLINE.

✔[6] STATEMENT SUPPORTING USE OF AN IPM PLAN MUST BE ADDED TO METHOMYL AND THIODICARB LABELS.

TABLE 7

Risk Reduction Measures Achieved through FY 1999 REDs

RED	Voluntary cancellation	Some uses canceled, deleted, not yet eligible	Limit amount, frequency, timing of use	Residential/kids' risks addressed	Application restrictions	Restricted use pesticide	PPE/REI	User safety requirements, recommendations	Engineering controls/special packaging	Ground or surface water safeguards	Spray drift labeling/advisory	Environmental hazards statements	Improve labeling, use directions & precautions	Other measures	Tolerances reassessed *This includes the number and type of tolerance reassessment decisions made for each chemical listed.
Bendiocarb	✔[1]			✔										✔[1]	2 R[2]
Captan		✔[3]	✔	✔	✔		✔	✔	✔		✔	✔	✔		60 ✔
EPTC		✔[4]	✔	✔	✔		✔	✔	✔		✔	✔	✔		20 ✔
Folpet		✔[5]			✔		✔	✔	✔		✔	✔			10 ✔
Fonfos	✔														35 R
Isofenphos	✔													✔[6]	24 R
Niclosamide		✔[7]	✔		✔	✔	✔	✔				✔	✔		N/A[8]
Oxythioquinox	✔														22 R
Pebulate			✔		✔		✔	✔	✔		✔	✔	✔		3 ✔
Ryanodine	✔														1 R
Sulfotepp	✔			✔	✔	✔	✔	✔				✔	✔	✔[9]	N/A
TFM			✔		✔	✔	✔	✔				✔	✔		N/A
TPTH			✔		✔	✔	✔	✔	✔	✔	✔	✔	✔		13 ✔
Vernolate	✔														13 R
Total	7	4	6	4	8	4	8	8	5	1	5	8	7	3	106 ✔ +97 R =203 Total

✔[1] BENDIOCARB VOLUNTARY CANCELLATION INCLUDES PRODUCTION CAP AND PHASE OUT.

R[2] NUMBER OF TOLERANCE REVOCATIONS: AS A RESULT OF THE VOLUNTARY CANCELLATION, (2) TOLERANCES ARE BEING REVOKED.

✔[3] CAPTAN RED INCLUDES VOLUNTARY CANCELLATION OF RESIDENTIAL TURF USES TO MITIGATE RISKS TO CHILDREN.

✔[4] EPTC RED PROHIBITS RESIDENTIAL USE OF EMULSIFIABLE CONCENTRATE FORMULATIONS, AND PROHIBITS USE OF BELLY GRINDER FOR HOMEOWNER PRODUCTS.

✔[5] FOLPET RED INCLUDES VOLUNTARY CANCELLATION OF MOST AGRICULTURAL, ORNAMENTAL, AND GREENHOUSE USES (IMPORT TOLERANCES REMAIN)– THE ONLY REMAINING ELIGIBLE USES INCLUDE USE ON FLORIDA AVOCADOS AND IN PAINTS, COATINGS, AND SEALANTS.

✔[6] ISOFENPHOS VOLUNTARY CANCELLATION INCLUDES A SALES CAP FOR THE TECHNICAL PRODUCT.

✔[7] MOLLUSCICIDE USES OF NICLOSAMIDE ARE BEING VOLUNTARILY CANCELED OR DECLARED INELIGIBLE.

N/A[8] NOT APPLICABLE (I.E., THE PESTICIDE HAS NO FOOD USES).

✔[9] SULFOTEPP VOLUNTARY CANCELLATION INCLUDES A PRODUCTION CAP.

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FIGURE 1

Cumulative Status of Reregistration: Registration Eligibility Decisions (REDs) Completed

OPP presents the results of its reregistration reviews in Reregistration Eligibility Decision (RED) documents. In FY1998, OPP completed 13 REDs, and in FY 1999, OPP completed 14 REDs.

At present, the pesticide reregistration program has completed 70% of the number of reviews to be performed. OPP has issued 198 REDs, which represent 32% of the original 612 cases that were subject to reregistration when the program began in late 1988. (14 of the 198 are voluntary cancellations counted as REDs–OPP had made significant progress in developing RED documents for these pesticides when requests for their voluntary cancellation were received.) An additional 231 cases (38%) were voluntarily canceled earlier through the reregistration process. Therefore, 183 reregistration cases (30%) remain to be completed.

PROGRESS IN COMPLETING REDS

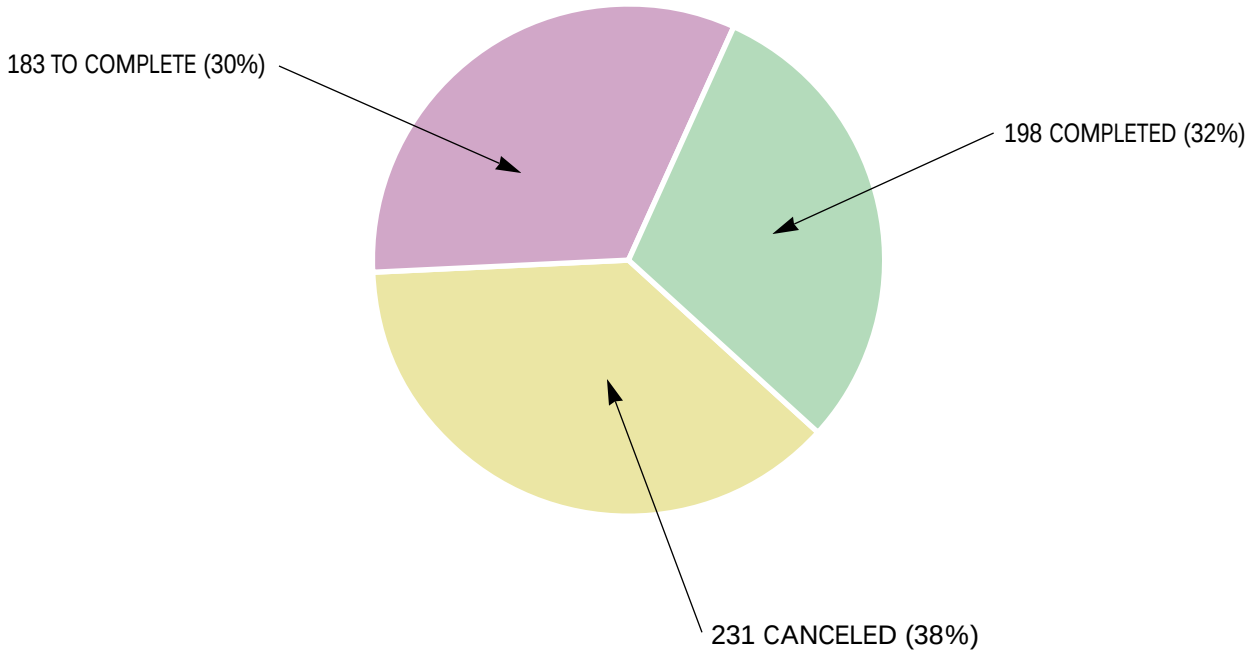
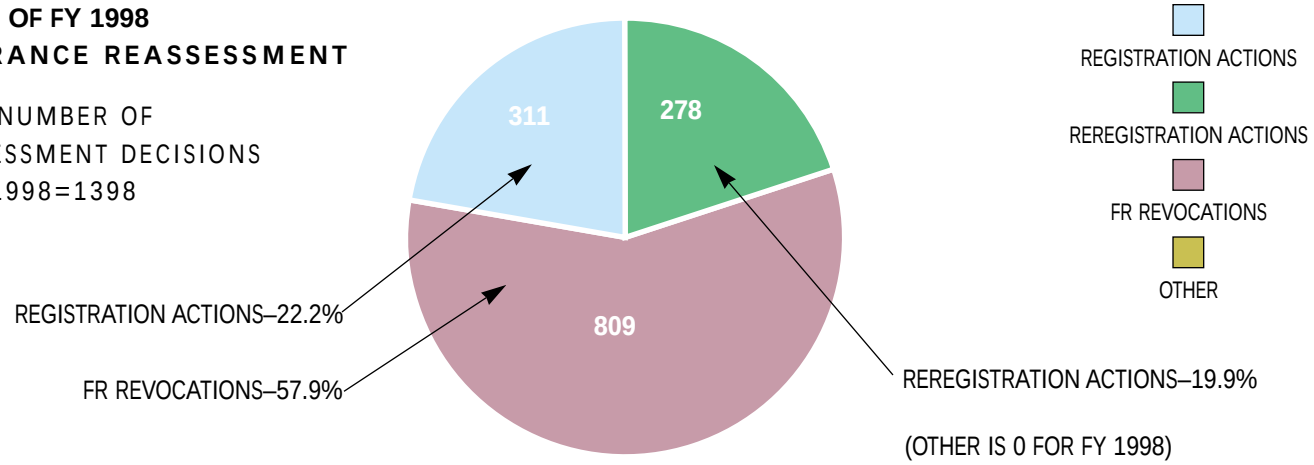


FIGURE 2

Tolerance Reassessment Accomplishments

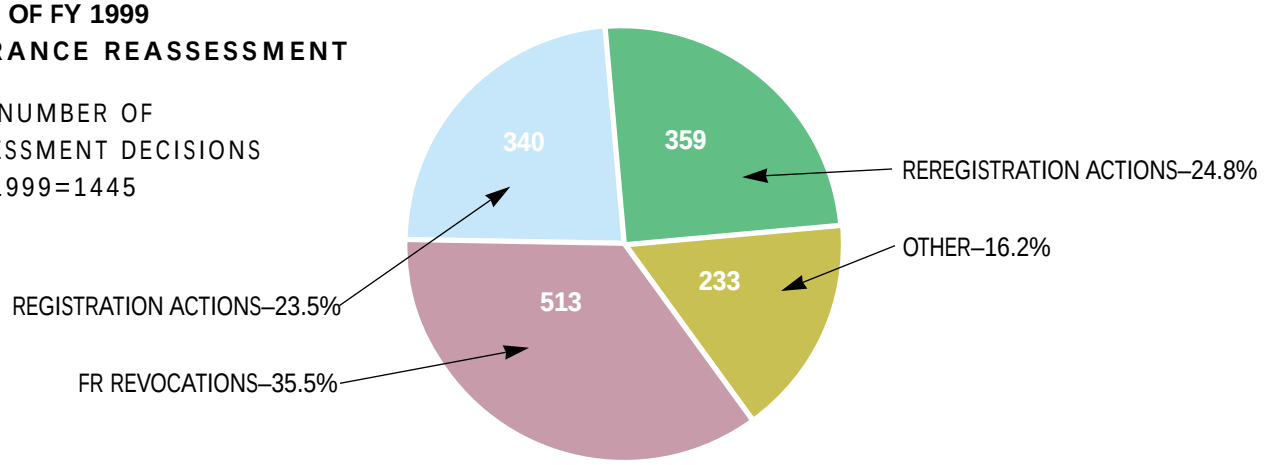
STATUS OF FY 1998 TOLERANCE REASSESSMENT

TOTAL NUMBER OF REASSESSMENT DECISIONS IN FY 1998=1398



STATUS OF FY 1999 TOLERANCE REASSESSMENT

TOTAL NUMBER OF REASSESSMENT DECISIONS IN FY 1999=1445



STATUS OF TOLERANCE REASSESSMENT

CUMULATIVE SINCE AUG. 3, 1996

TOTAL NUMBER OF REASSESSMENT DECISIONS AS OF OCTOBER 1, 1999=3430

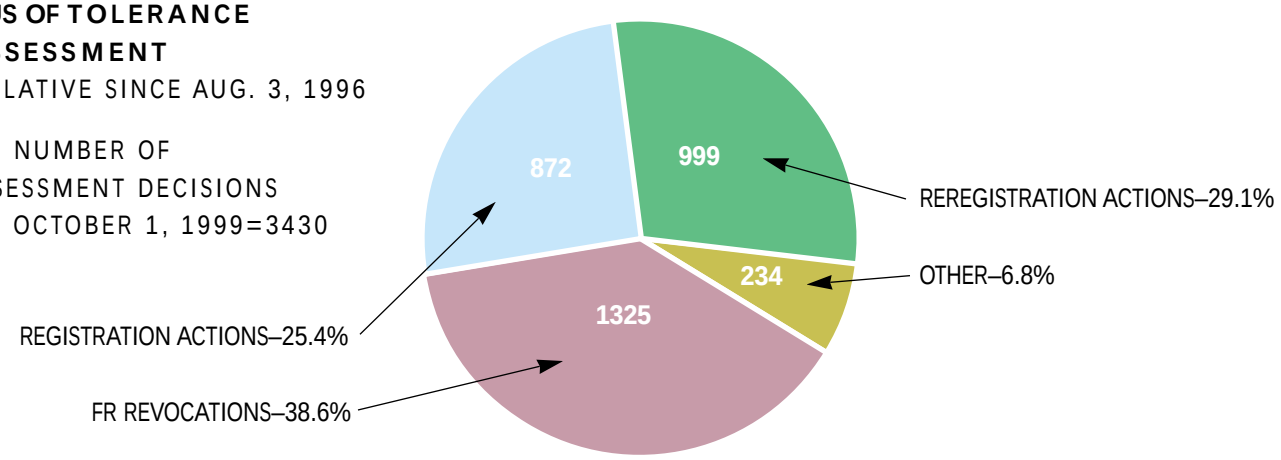


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FIGURE 3

Outcome of 6(a)(2) Submissions

Section 6(a)(2) of FIFRA requires pesticide product registrants to submit adverse effects information about their products to OPP. OPP reviews these submissions and studies to determine if there are risks associated with the product that were not anticipated at the time of registration. In late 1998, OPP's new adverse effects reporting requirements took effect. These regulations clarified and in many cases lowered the threshold for adverse incident reporting. As a result, 6(a)(2) submissions increased considerably during FY99.

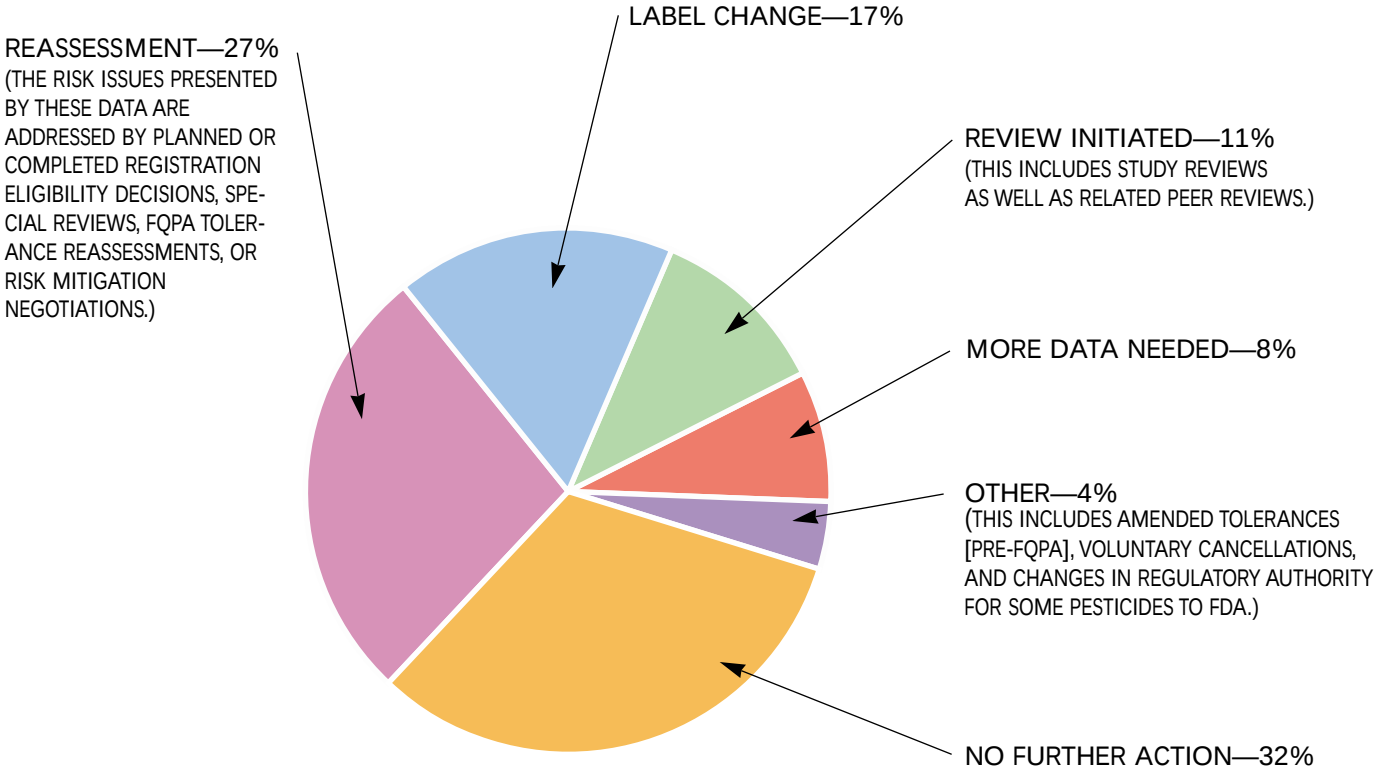
Incidents: In FY 1998, OPP received approximately 1,800 submissions, containing reports of more than 22,000 incidents.

Incidents: In FY 1999, OPP received nearly 1,500 submissions, containing reports of more than 46,000 incidents.

Studies: In FY 1998, OPP screened 411 adverse effects submissions consisting of studies and preliminary reports of possible adverse effects. About 15 percent of these submissions warranted expedited review and are being further tracked.

In FY 1999, OPP streamlined the 6(a)(2) study screening process by imaging key study information and routing it electronically to subject matter experts. This reduced the time necessary to complete the screening process. OPP screened 337 adverse effects submissions consisting of studies and preliminary reports of possible adverse effects. About 12 percent warranted expedited review and are being further tracked.

Outcome of submissions warranting expedited review: Since 1992, over 700 6(a)(2) submissions were judged to warrant expedited review. The outcomes for these submissions are presented in the chart that follows.



LIST 1

Pesticide Stewardship Program Partners and Supporters

New Partners during FY 1999

Kansas Grain Sorghum Producers Association
Kansas Corn Growers Association
Low Input Viticulture and Enology of Oregon
Central Virginia Electric Cooperative
Sarasota County Government Public Works
Massachusetts IPM Council
Ecolutions, Inc.

New Partners during FY 1998

All Service Pest Management, Inc.
American Peanut Council
Artichoke Research Association
California Floral Council
California Lettuce Research Board
California Cling Peach Growers Advisory Board
California Fresh Carrot Advisory Board
City/County of San Francisco, CA Dept. of Agriculture
Creative Technology, Inc.
Daystar Termite Control, Inc.
Enviroguard Pest Control
Florida Pest Control Association
Georgia Peach Council
Hawaii Banana Industry Association
Massey Services, Inc.
National Pest Control Association
Nature's Safeway Pest Control
New York City Board of Education
Northeast Utilities
Pest Birds, Inc.
Roses, Inc.
Sprague Pest Solutions
Steritech Group, Inc.
Texas Association of Nurserymen, Inc.
U.S. Hop Industry Plant Protection Committee
U.S. Canola Association
Walnut Marketing Board

New Supporters during FY 1999

National Council of Farmer Cooperatives
Miami Tribe of Oklahoma

New Supporters during FY 1998

Agricultural Conservation Innovation Center
Bio-Integral Resource Center
Claymont Center for Continuous Education
Northeast Research & Extension Committee–IPM

Existing Partners (prior to FY 1998)

Almond Board of California
American Pest Management, Inc.
American Mosquito Control Association
American Nursery and Landscape Association
American Electric Power Service Corporation
Arizona Public Service
California Tomato Commission
California Pear Growers
California Pear Advisory Board
California Citrus Research Board
California Pistachio Commission
California Prune Board
Carolina Power & Light
Central Maine Power Company
Chevy Chase Village, MD
City of Davis, CA
Connectiv
Cranberry Institute
Delta Pest Control
Duke Power Company
Eastern Utilities
Edison Electric Institute
Environ "Pest Elimination" Inc.
Fillmore Citrus Protective District
Florida Fruit & Vegetable Association
Global Integrated Pest Management
Golf Course Superintendents Association of America
Griggs County (ND) 319 Water Quality Project
Hawaii Agriculture Research Center
Hawaiian Electric Company
Hood River Grower-Shipper Association
Lodi-Woodbridge Wine Grape Commission
Michigan Cherry Committee

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(Continued)
Mint Industry Research Council
Monroe County School Corporation
National Potato Council
New Orleans Mosquito Control Board
New England Vegetable & Berry Growers Association
New York State Gas & Electric
New York Berry Growers Association
Northern Indiana Public Service Company
Northwest Alfalfa Seed Grower Association
Owen Specialty Services, Inc.
Pacific Coast Producers
Pear Pest Management Research Fund
Pebble Beach Company
Pennsylvania Power & Light
Pennsylvania Electric
Pennsylvania Rural Electric Association
Pest Police Pest Control
Pineapple Growers Association of Hawaii
Planet Pest Products Corporation
Processed Tomato Foundation
Professional Lawn Care Association of America
Redi National Pest Elimination
Reliable Pest Control
Sanitary Exterminating Company
South Dakota Cattlemen's Association
South Texas Cotton and Grain Association, Inc.
Sun-Maid Growers of California
Sunkist Growers
Tennessee Valley Authority
Texas Pest Management Association
U.S. Department of Defense
U.S. Apple Association
U.S. Public Health Service
University of Georgia
Utilicorp United
VA, MD, & DE Association of Electric Cooperatives
Vegetation Managers, Inc.
West Virginia Power
Winter Pear Control Committee
Wisconsin Public Service Corporation
Wisconsin Ginseng Growers Association

Existing Supporters (prior to FY 1998)

Aqumix, Inc.
Association of Applied Insect Ecologists
Audubon Cooperative Sanctuary System
Bay Area Stormwater Management Agencies Assoc.
Campbell Soup Company
Del Monte
Farm A Syst/Home A Syst National Office
Gempler's, Inc.
General Mills, Inc.
Gerber Products Company
Glades Crop Care, Inc.
Institute for Agriculture and Trade Policy
Rainforest Alliance–ECO o.k. Program
United States Golf Association

LIST 2

OPP Divisions

Office of the Director
703-305-7090
Responsible for overall management of the Office of Pesticide Programs.

Antimicrobials Division
703-308-6411
Responsible for all regulatory activities associated with antimicrobial pesticides, including product registrations, amendments, and reregistrations.

Biological and Economic Analysis Division
703-308-8200
Responsible for assessing pesticide use and benefits; and operating analytical chemistry and antimicrobial testing laboratories.

Biopesticides and Pollution Prevention Division
703-308-8712
Responsible for risk/benefit assessment and risk management functions for microbial pesticides; tolerance reassessment for biopesticides; biochemical pesticides; plant-pesticides and Pesticide Environmental Stewardship Program.

Environmental Fate and Effects Division
703-305-7695
Responsible for evaluating and validating environmental data submitted on pesticide properties and effects.

Field and External Affairs Division
703-305-7102
Responsible for program policies and regulations; legislation and Congressional interaction; regional, State, and tribal coordination and assistance; international and field programs; and communication and outreach activities.

Health Effects Division
703-305-7351
Responsible for reviewing and validating data on properties and effects of pesticides, as well as characterizing and assessing exposure and risks to humans and domestic animals.

Information Resources and Services Division
703-305-5440
Responsible for information support; Public Docket; records computer support; FIFRA section 6(a) (2) issues; pesticide incident monitoring; and National Pesticide Telecommunications Network.

Registration Division
703-305-5447
Responsible for product registrations, amendments, reregistrations, tolerances, experimental use permits, and emergency exemptions for all pesticides not assigned to BPPD or AD.

Special Review and Reregistration Division
703-308-8000
Responsible for Reregistration Eligibility Decisions (REDs), product reregistration, tolerance reassessment; and Special Reviews.

US EPA ARCHIVE DOCUMENT

LIST 3

Regional Pesticide Offices

Region 1
617-918-1501
John F. Kennedy Federal Building
One Congress Street
Boston, MA 02203-0001

Region 2
212-637-4000
290 Broadway
New York, NY 10007-1866

Region 3
215-814-3127
1650 Arch Street
Philadelphia, PA 19103

Region 4
404-562-9077
61 Forsyth Street
Atlanta, GA 30303

Region 5
312-886-7475
77 West Jackson Boulevard
Chicago, IL 60604-3507

Region 6
214-665-7200
Fountain Place, 12th Floor Suite 1200
1445 Ross Avenue
Dallas, TX 75202-2733

Region 7
913-551-7307
901 North 5th Street
Kansas City, KS 66101

Region 8
303-312-6390
999 18th Street, Suite 500
Denver, CO 80202-2466

Region 9
415-744-1585
75 Hawthorne Street
San Francisco, CA 94105

Region 10
206-553-4181
1200 Sixth Avenue
Seattle, WA 98101

LIST 4

List of Acronyms

AD	Antimicrobials Division
APIC	Association for Professionals in Infectious Control and Epidemiology
ARS	Agricultural Research Service
BBPD	Biopesticide and Pollution Prevention Division
CADDY	Computer Aided Dossier and Data Supply
CDPR	California Department of Pesticide Regulation
CLI	Consumer Labeling Initiative
DDT	Dichloro diphenyl trichloroethane (DDT)
EIIS	Ecological Incident Information System
FAO	Food and Agricultural Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FEAD	Field and External Affairs Division
FFDCA	Federal Food, Drug and Cosmetic Act
FQPA	Food Quality Protection Act
GLP	Good Laboratory Practices
HHS	Department of Health and Human Services
IFCS	Intergovernmental Forum on Chemical Safety
IPM	Integrated Pest Management
IR-4	Interregional Research Project No. 4
LAN	Local Area Network
MOU	Memorandum of Understanding
MRL	Maximum Residue Limits
NAFTA	North American Free Trade Agreement
NTIS	National Technical Information Service
OECD	Organization for Economic Cooperation and Development
OP	Organophosphates
OPP	Office of Pesticide Programs
PDSL	Pesticide Data Submitters List
PESP	Pesticide Environmental Stewardship Program
PIC	Prior Informed Consent
PMRA	Pesticide Management Regulatory Agency (Canada)
POPs	Persistent Organic Pollutants
PPDC	Pesticide Program Dialogue Committee
RED	Reregistration Eligibility Decision
TRAC	Tolerance Reassessment Advisory Committee
USDA	United States Department of Agriculture
WHO	World Health Organization
WPS	Worker Protection Standard

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NOTES