EPA-735-R-05-001

PRIA
Pesticide Registration Improvement Act

Taking Care of Business: Protecting Public Health and the Environment

EPA's Pesticide Program
FY 2004 Annual Report

FIFRA
Federal Insecticide, Fungicide, and Rodenticide Act

GPRA
Government Performance and Results Act

ESA
Endangered Species Act

DQA
Data Quality Act

FOIA
Freedom of Information Act

FQPA
Food Quality Protection Act

FFDCA
Federal Food, Drug, and Cosmetic Act

Message from the Director

Looking back over 2004, I can see the important strides OPP made in meeting its goals to protect public health and the environment from pesticide risks and to ensure that growers and other pesticide users have access to appropriate tools. Clearly, our successes came about because of the joint efforts of many talented and hard working employees within OPP as well as our partners in the EPA regional offices and state and tribal pesticide regulatory agencies.

Standing at the gateway to a multi-billion dollar pesticide market, OPP faces an enormous challenge each year to deliver to the public it serves. Our annual track record of successfully making literally thousands of decisions continued throughout 2004. Through these actions, we protect public health and the environment; e.g., by registering safer alternatives; reregistering older chemicals, which brings about meaningful risk mitigation; training applicators; and communicating with the public. While achieving high numbers of outputs is important, outputs alone do not tell the whole story. Over the past year, OPP has made performance accountability a high priority, and we are making good progress with measuring the outcomes of our work. For example, recent data are demonstrating that some of our regulatory actions have reduced numbers of pesticide poisonings and that the residue levels of pesticides in food are lower. These results are encouraging, and I look forward to more progress in this arena for 2005.

The passage of the Pesticide Registration Improvement Act (PRIA) in March of 2004 represented a major paradigm shift to the program's process for bringing new pesticides to market. In anticipation of this important legislation, we were prepared to develop and implement the necessary process changes and hire an impressive cadre of new employees so that we could "hit the ground running" and produce some outstanding results for the first year of PRIA. In fact, all PRIA deadlines were met, with decisions rendered on more than 1,000 applications and registration actions.

In the new chemicals program, we kept the momentum going with the registration of 26 new active ingredients, of which 14 are biological, 2 are antimicrobial, 5 are reduced-risk conventional, and 5 are conventional pesticides. Among these are alternatives for an organophosphate and for methyl bromide. The program also registered 231 new food uses for previously registered active ingredients, of which 40 are reduced risk, 20 are organophosphate alternatives, and 10 are methyl bromide alternatives. The improvements and innovation evident in the risk profiles of the new chemicals across all three registering divisions demonstrate how registration has become one of our most important tools for protecting public health and the environment.

In the old chemicals program, OPP is well on its way to meeting the Food Quality Protection Act deadline to reassess all 9,721 tolerances by August 2006, with more than 7,000 completed at the end of fiscal year 2004. These reassessments must meet the new safety standard of "a reasonable certainty of no harm." I am very confident that we will succeed in meeting the deadline. We also completed 17 Reregistration Eligibility Decisions or REDs (10 conventional and 7 antimicrobial) as well as 18 Tolerance Reassessment Eligibility Decisions or TREDs. We accomplished some very meaningful risk mitigation; e.g., our work on thiram will offer better protection of children by eliminating almost all residential uses, in addition to the voluntary cancellation of its use on apples. Endangered species from Washington State to Texas will also benefit through thiram use

cancellations, reduced rates of application, and buffer zones around endangered species' habitats. Also worth noting is the good work that has been under way to create a Registration Review program as called for by FQPA. A cross-divisional team has worked closely with our external stakeholders to design and test in a relatively short timeframe a new approach so that we will have a smooth transition from reregistration to registration review. We are now well positioned to put a rule into place and begin serious planning around this new program.

Another continuing high priority focus in FY 2004 was endangered species. In many ways, FY 2004 was a milestone year for our endangered species program, e.g., the Counterpart Regulations were promulgated in record time, we worked with our federal partners to upgrade our risk assessment methodology for endangered species assessments, we continued to meet the court-supervised schedule in the Washington Toxics Coalition case, and we began the process of integrating endangered species risk assessments into our registration and reregistration programs. These solid achievements will serve us well in our future efforts to address endangered species issues.

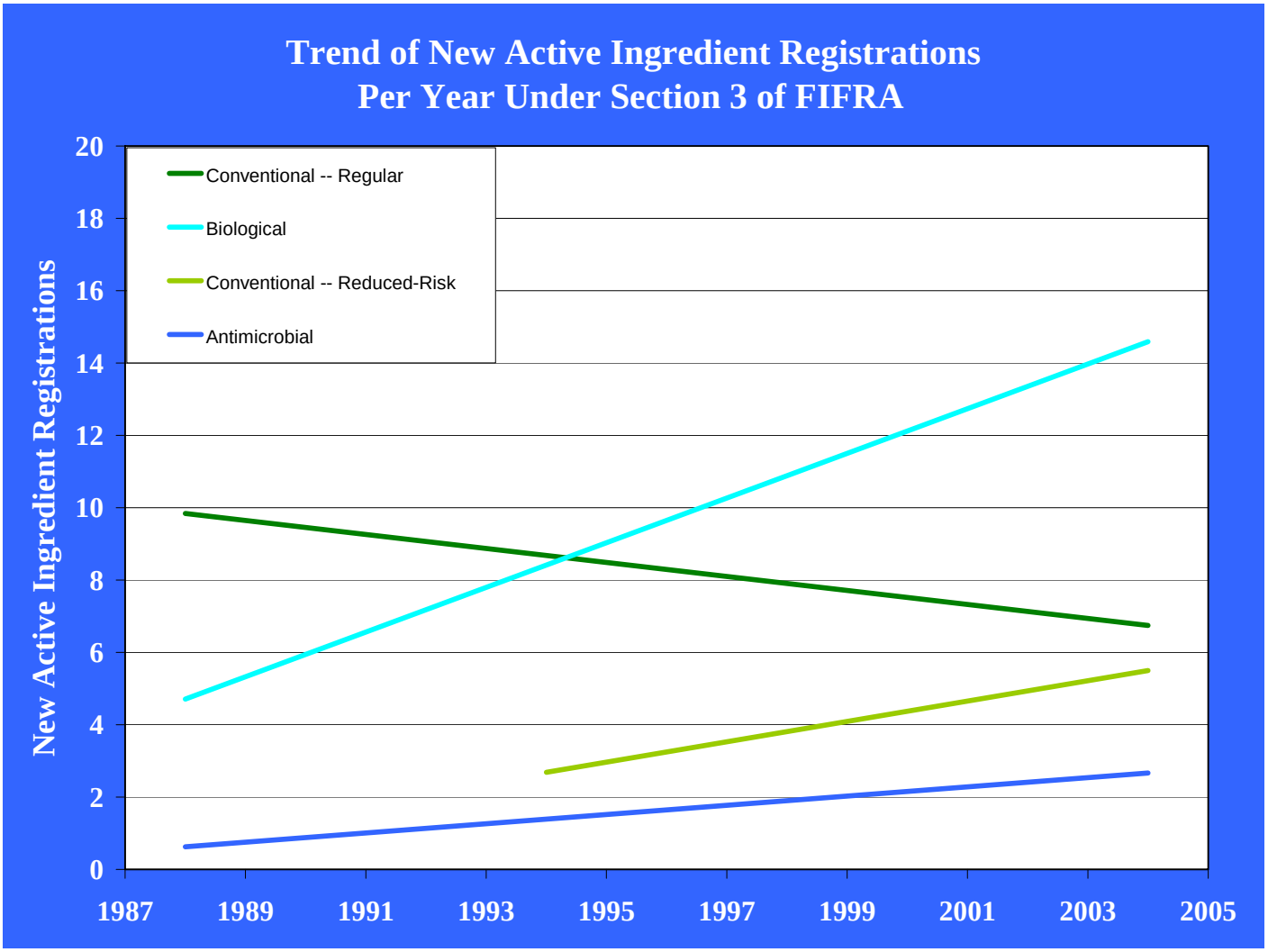
Good progress was also made during FY 2004 in furthering our policy development and rulemaking for some very key issues, e.g., Section 18 rule, Part 158 data requirements, Registration Review, and use of Human Studies issues. As a result, the stage is set for a very productive FY 2005. In the area of information management, many system enhancements were accomplished, including PRIA process improvements. The high number of controlled letters and Freedom of Information Act (FOIA) and docket requests were also managed very effectively. While it is impossible to list every accomplishment, I hope you will join me in reviewing our newly formatted Annual Report for 2004 and that you will gain a greater understanding of the depth and breadth of work accomplished throughout the pesticide program during the past year.

James J. Jones, Director
Office of Pesticide Programs

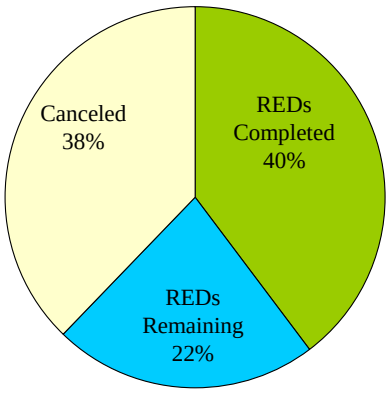
EPA's Pesticide Program in Action

Just the Facts

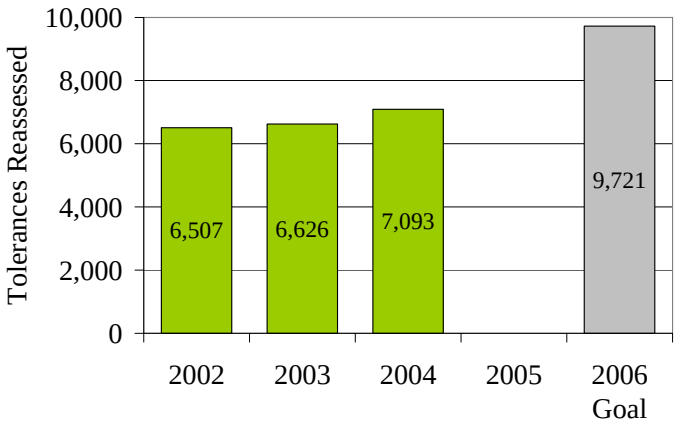
FY 2004 Pesticide Program Budget	$137.7 million	
Program Administration and Implementation (Payroll and administrative expenses for HQ and Regions)	$77.2 million	56.1%
Grants and Contracts (For regional and state programs)	$48.2 million	35.0%
Other (Lab expenses and support activities for HQ and Regions)	$12.3 million	8.9%
Reregistration Eligibility Decisions	17	
Tolerance Reassessment Eligibility Decisions	18	
Tolerance Reassessments Completed in 2004	467	
Tolerances Reassessed Through 2004	7,093 (2,628 left to reassess)	
New Active Ingredient Registrations	26	
Biological	14	54%
Conventional - Reduced Risk	5	19%
Conventional	5	19%
Antimicrobial	2	8%



Overall Status of REDs



Status of Tolerance Reassessments



Taking Care of Business:
Protecting Public Health and the Environment Through

Results

E-Government

Harmonization

The principal business of EPA's Pesticide Program is protecting human health and the environment, but the Agency also must help ensure that society has access to pesticides and the benefits they can provide. The Government Performance and Results Act of 1993 (GPRA) charged EPA, and other federal agencies, to create strategic plans and program performance measures to increase effectiveness in reaching our public health and environmental goals. These tools are designed to help agencies focus on real-world results. Measuring public health and environmental program performance is especially challenging because the environment is an extremely complex system. There are confounding variables and interactions that make identifying, collecting, and analyzing credible performance data difficult and expensive. In the face of these challenges, EPA is creating and implementing strategic plans with short-, medium-, and long-term goals that make explicit the importance of aligning priority actions with strategic goals and incorporating results testing into our day-to-day business.

With strategic planning and a lot of creativity, EPA's Pesticide Program is making measuring performance outcomes part of our daily routine. The Program has launched a multifaceted initiative to improve our performance accountability system. The goals of this effort are to strengthen our program management through improved priority-setting and decisions, accurately track program progress, and promote clear and meaningful communication. In pursuing this initiative, we are balancing, among other things, the competing forces of statutory directives, demands of sound science, available resources, information system and data quality requirements, stakeholder concerns and partner interests, and time pressures.

This approach is exemplified by the development of an innovative watershed monitoring and mitigation method for regulating atrazine in 40 vulnerable watershed sites in 10 Midwestern states. These 40 watersheds are representative of the 1,172 watersheds defined as most vulnerable to atrazine surface water contamination from use of atrazine on corn and sorghum. If any of these watersheds show levels of atrazine above the level of concern, the registrants will initiate watershed-management activities in concert with existing state or local watershed teams, protecting water from excessive contamination. This innovative approach not only measures the real-world results of the Pesticide Program's reregistration decision for atrazine; it also provides a response mechanism if the results indicate that further action is necessary.

Though not every registration and reregistration decision that the Pesticide Program makes lends itself to the approach used for atrazine, the fact is that each and every one is based on scientific risk assessments that are designed to be protective of human health and the environment. For example, the thiram reregistration decision not only reduces dietary risk to humans, but also addresses environmental risks through voluntary cancellation of certain uses

and large reductions in quantity and frequency of application for other uses. The thiram reregistration decision will also improve protection for endangered species by prohibiting the use of thiram-treated seeds within one mile of Attwater's prairie chicken habitat and providing outreach to growers who use thiram. In another reregistration decision, manufacturers of phenol agreed to cancel its use in paint due to well-documented risks to painters. The voluntary phaseout of chromated copper arsenate (CCA), a preservative used to treat wood, for uses around the home and in children's play areas became effective on December 31, 2003. This action removed an estimated 60 million pounds of CCA from the market in 2004 and will continue to do so in each year thereafter, reducing children's exposure to arsenic, a known human carcinogen. EPA pesticide reregistration decisions in response to the Food Quality Protection Act of 1996 (FQPA) have also resulted in removal of 15 million to 20 million pounds of organophosphates (a class of older, riskier pesticides that are acutely toxic) from use in and around homes annually. At the same time, we have worked to ensure that growers and citizens have the products they need to control pests.

Measurable indicators of human health and environmental improvements resulting from Pesticide Program activities tell only part of the story of program performance. Objective evidence that EPA is complying with the law is another measure of our progress. With only 60 days between the passage of the Pesticide Registration Improvement Act (PRIA) and its effective date, EPA's Pesticide Program successfully developed and implemented processes for billing and collecting fees, assessing incoming pesticide registration applications, and generating invoices to applicants for actions subject to PRIA fees. In exchange for these fees, EPA guarantees applicants timely registration decisions. The Pesticide Program met all PRIA deadlines by rendering decisions on more than 1,000 PRIA applications and registration actions between March 23 and September 30, 2004. We also demonstrated outstanding human capital leadership in a major hiring campaign in which 85 highly qualified new employees were efficiently and rapidly brought on board to handle the demands placed on the registration process by PRIA. In addition, EPA developed a screening procedure for pesticide applications to identify data gaps early in the review process for new biopesticides, saving resources for both the program and the applicants.

The Pesticide Program has more work to do in improving performance accountability measurement for better risk assessment, risk management, and risk communication. However, we are off to a good start and have a solid foundation for our next steps. EPA is committed to constant improvement in this area, and measuring performance outcomes will continue to be a priority in FY 2005.

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Information technology (IT) is an increasingly important, capacity-enhancing tool, allowing the Pesticide Program to take care of its business of protecting human health and the environment. The Pesticide Program is using E-Government to fulfill its mission in new and exciting ways that were impractical if not impossible before the digital age.

In 2004, the Pesticide Program began a concentrated effort to make its Web site, http://www.epa.gov/pesticides/, *the* source for accurate, easy-to-find pesticide facts and information. We are increasing our efforts to test our computer applications and Web pages before posting them online to ensure that information is easy to find. For every decision or announcement, we carefully consider what information should be posted on our Web site and ensure that it is available when the announcement is made. As www.epa.gov/pesticides/ continues to grow, we will continue to evaluate and restructure the site to ensure the accessibility of our information. We welcome user input to help us in that endeavor.

EPA actively provides information about pesticide-related hot topics and Agency actions through its EPA Pesticide Program Updates newsletter, formerly the OPP Update, which we send out electronically several times a week. If you have not already signed up for EPA Pesticide Program Updates, you can do so at http://www.epa.gov/oppfead1/cb/csb_page/form/form.html.

Improvements to the Pesticide Program's Web site help EPA protect human health and the environment by encouraging public participation in the registration process. Citizen and stakeholder input in the Pesticide Program's registration and reregistration decisions increases the range of perspectives and information available to EPA and makes our regulatory processes easier to engage in and understand. Now anyone who has access to a computer can go to www.epa.gov/pesticides/ and easily find a schedule of open and upcoming comment periods for pesticides in review for reregistration and tolerance reassessment, in addition to the complete schedule of reregistrations and tolerance reassessment decisions through 2008. For those interested in going to the source for pesticide reregistration information, risk assessment documents, Reregistration Eligibility Decision (RED) documents, and summary fact sheets are also available online. Interested parties can also submit comments on specific pesticide registration issues electronically via the e-docket system during open comment periods. Accessing this information empowers citizens and gives all stakeholders equal advance notice of opportunities to voice concerns and present evidence that can help guide EPA's pesticide regulatory programs and decisions in ways that reduce risk to human health and the environment.

Advances in IT have allowed us to augment our E-Government initiatives, moving the Agency away from traditional paper-and-ink reports and registration decision announcements toward electronic ones, and stakeholders are already realizing the benefits. E-Government innovations are speeding the registration process for reduced-risk pesticides and others, helping us accomplish our core mission more efficiently. Now registrants can use eSign, an electronic version of the traditional signature and notary public stamp on paper, for faster processing of Confidential Business Information (CBI) authorizations. EPA has also made available online the templates that we use for documenting our scientific evaluations. Registrants are also encouraged to use the template format to report their studies, thereby reducing the possibility of data omissions and providing information in a standard format compatible with that of the Agency. Templates save time and resources and improve the quality and consistency of scientific work for both EPA and registrants.

EPA redesigned its Endangered Species County Bulletins to make them easier to read and more useful as a tool to protect endangered species. Though their use has historically been voluntary, County Bulletins are an online resource that pesticide users will be required to use when directed by product labels to do so. Through collaboration with the U.S. Geological Survey, the Pesticide Program made extensive use of Geographic Information Systems (GIS) data, an increasingly popular technology that drastically improves the accuracy of mapping applications like the one used for the bulletins, to create a bulletin system that is easily updated and very precise. When so directed by pesticide labels, users will be able to use the bulletins to look up pesticides that are restricted in areas where there may be an impact on endangered species. Ease of updating and the pinpoint accuracy of GIS will help to ensure maximum protection of endangered species' habitats without being overly burdensome to nearby growers and other pesticide users.

Harmonization

Many health and safety issues can be best addressed by working collaboratively with other countries and international organizations, federal and state agencies, and tribes. Every year new pesticides enter the marketplace, and old pesticides must be reassessed to meet modern standards. Governments rigorously assess each one to ensure that they meet current health and safety standards.

EPA's Pesticide Program has worked with other countries and international organizations since 1992 to streamline pesticide review. Working together ensures sound, sustainable management of new and older pesticides; helps governments and their stakeholders move to safer pesticides and pest control measures more efficiently; and facilitates trade in pesticide products and food products, with the assurance that they meet safety standards. Working with other countries to review pesticides is part of the Program's day-to-day business.

The United States, Canada, and Mexico are working to make the North American region a world model for common approaches to pesticide regulation and free trade in pesticides and food. Achieving this level of performance, while protecting human and environmental health, will set a global standard and enhance world trade in North American products. This vision is outlined by the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides (TWG) in its 5-year strategy. To prevent the creation of trade problems, the NAFTA TWG has established a Joint Review program for new pesticides and new uses of pesticides. As of November 1, 2004, the United States and Canada have issued 53 registrations under this precedent-setting program, including 24 registrations for reduced-risk pesticides. Currently, there are 16 submissions in the Joint Review program, including a trilateral review between Canada, Mexico, and the United States. Most recently, the United States and Canada have announced a new minor use partnership between the two countries. Under this arrangement, the two governments are coordinating their respective minor use data-gathering and registration processes to provide growers in both countries simultaneous access to newer pesticides in both countries, meeting growers' needs for safer products.

To streamline the process of working together, broaden the opportunities for working together, and ensure consistently high quality, scientifically sound evaluations, the NAFTA TWG has developed data evaluation templates that, when fully implemented, will save resources and ensure more scientifically sound registration decisions by pesticide registration agencies. Pesticide manufacturers who take advantage of those templates are able to minimize delays caused by the use of nonstandard data submissions and bring their products to markets across the continent sooner. Pesticide users will have quicker access to these newer pesticides, including reduced-risk pesticides that replace older, riskier, conventional ones.

The United States and Canada are also working together within the Organisation for Economic Co-operation and Development (OECD), to achieve broader use of these data evaluation templates by all OECD member countries. Adoption of these templates within OECD countries will facilitate work-sharing between all OECD countries and with international organizations. The vision of the OECD working group on pesticides, which has been published in both full text and brochure versions, is that over the next 10 years work-sharing arrangements will be routine and evaluations of pesticides done by one country can routinely be used in other countries and by international organizations. Work-sharing allows governments to find ways of reducing regulatory burdens, while maintaining effective public oversight. The benefits of work-sharing are worth pursuing; according to a report by the OECD, sharing the burden of testing new pesticides saved EPA and other pesticide regulatory bodies an estimated $21 million in 1998.

The Pesticide Program is also building other international relationships. Building on the experience of the North American Regional Action Plan (NARAP) development process for lindane, EPA has formalized an agreement with China to explore areas of mutual benefit through regulatory cooperation. We have nearly completed work on harmonizing pesticide worker training after collaborating closely with EPA's counterpart agency in Mexico and soliciting input from industry. The Pesticide Program also worked with the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) pilot on trifloxystrobin, a first effort to work-share globally to streamline international pesticide regulatory standards. The pilot demonstrated a need for globally harmonized templates, and EPA was a key player in the effort.

The Agency is also a leader in implementing the new Globally Harmonized System of Classification and Labeling of Chemicals, or GHS, which will improve protection and facilitate trade. In 2004 EPA prepared and made available for public comment its White Paper on GHS implementation for pesticides in the United States. The GHS is a standardized, consistent approach to classifying labeling and chemicals based on agreed-upon hazard criteria that are used throughout the world.

Other harmonization efforts involved following up on the Agency's Train-the-Trainer pilot programs from FY 2003, which successfully demonstrated the benefits of training workers who handle pesticides to communicate pesticide safety to co-workers. Recognizing that the U.S. labor pool extends out to neighboring countries, EPA in FY 2004 continued to coordinate pesticide-use training with its counterparts in Mexico and Honduras. These training programs will increase the overall effectiveness and efficiency of educational programs targeting pesticide handlers and applicators, as well as farm owners, operators, workers, and their families. Such programs should also contribute to increasing awareness of pesticide risks and decreasing incidence of pesticide poisonings. EPA anticipates continuing this relationship and potentially expanding the program to other Central American countries, depending on levels of funding.

As EPA continues its efforts in international harmonization, we expect to increasingly see positive results indicating that this approach is helping the Pesticide Program take care of its business of protecting human health and the environment.

Registration of New Active Ingredients and New Uses

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA's Pesticide Program is entrusted with the responsibility of evaluating and registering pesticides so that effective means for pest control are available. The Pesticide Program must also ensure that these pesticides meet stringent federal standards designed to protect public health and the environment.

The Pesticide Program works to coordinate its registration activities with EPA's pesticide reregistration and tolerance reassessment program, as well as with other voluntary pesticide stewardship and risk-reduction programs, to make new pesticides and alternatives available as older pesticides are phased out. Through its expedited registration process for reduced-risk chemicals, the registration program is promoting the availability and use of safer pest control products. The registration program also places priority on registering pesticides that may be used as alternatives to organophosphate and methyl bromide products.

In March 2004, the Pesticide Registration Improvement Act (PRIA) was passed. The legislation extends the collection of maintenance fees for an additional five years, creates an enhanced registration service fee program for registration-related actions, and provides a more predictable evaluation process for affected pesticide decisions, coupling the collection of individual fees with specific decision review periods. The fees paid by the pesticide industry have supported various pesticide regulatory programs and decisions at EPA for many years, and with implementation of PRIA, EPA will have the authority to collect additional fees that will help to ensure that there is a more predictable evaluation process for affected pesticide decisions.

Registration Highlights

In FY 2004, EPA registered 26 new active ingredients, of which 14 are biopesticides, 2 are antimicrobials, 5 are reduced-risk conventional pesticides, and 5 are conventional pesticides. Among these new registrations are one organophosphate alternative and one methyl bromide alternative. EPA also registered 223 new food uses for previously registered active ingredients, of which 40 are reduced risk, 20 are organophosphate alternatives, and 10 are methyl bromide alternatives.

Biopesticides

Aspergillus flavus NRRL 21882 - a microbial pesticide to reduce aflatoxin contamination in peanuts. This strain of *A. flavus* does not produce the toxin and is applied to the soil at the pre-pegging stage of peanut plant growth to out-compete the toxin-producing strain, thus reducing the potential for aflatoxin in foods.

Chondrostereum purpureum strain PFC 2139 - a microbial herbicide for inhibiting sprouting and regrowth in cut stumps of certain deciduous tree species in rights-of-way and forests. It is a nonchemical, biological control alternative to glyphosate, triclopyr, picloram + 2,4-D, and hexazinone.

Trypsin Modulating Oostatic Factor (TMOF) - a protein produced by yeast cells (*Pichia pastoris*) to control mosquito larvae on aquatic sites. This pesticide is presently registered only for manufacturing use and is not yet registered for general use, but as products become available they may serve as low-risk alternatives to existing mosquito control pesticides.

Rhamnolipid biosurfactant - a biofungicide intended to prevent and control plant disease in agricultural, turf, and horticultural settings. It represents a less-toxic alternative to conventional fungicides, and its development earned the Jeneil Biosurfactant Company the Presidential Green Chemistry Challenge Award in the small business category for incorporating the principles of 'green chemistry' into chemical design, manufacture, and use, and for contributing to pollution reduction and prevention.

Ammonium bicarbonate: Olive Fly Attract and Kill Device - a product for use on olive trees containing three active ingredients: ammonium bicarbonate (feeding attractant), Spiroketal (pheromone), and lambda cyhalothrin (insecticide). The olive fly is attracted to the device by both the pheromone and the feeding attractant and is killed when exposed to the insecticide.

Antimicrobials

Calcium carbonate - a naturally occurring compound used as an active ingredient in anti-foulant paints for application on boat bottoms to control algae, barnacles, marine-fouling organisms, and zebra mussels. It is a potential low-risk alternative to tributyltin, an older compound that poses severe potential risks to aquatic organisms.

Reduced-Risk Conventionals

Penoxsulam - a reduced-risk conventional herbicide for controlling grass and sedge weeds in rice. Penoxsulam is an alternative to molinate, an older rice herbicide that is in the process of being phased out. Putting new alternatives on the market as old chemicals are phased out illustrates the kind of risk reduction EPA's Pesticide Program seeks to achieve by coordinating the activities of its registration and reregistration programs.

Dinotefuran - a reduced-risk conventional insecticide and organophosphate alternative for use on leafy vegetables, turfgrass, and ornamentals to control a variety of sucking and chewing insects such as aphids, whiteflies, leafhoppers, and leaf miners.

Cyazofamid - a reduced-risk conventional fungicide for control of early and late blight on tomatoes and potatoes and downy mildew on cucurbit vegetables. Tolerances were established for residues on tomatoes, potatoes, and cucurbit vegetables, and an import tolerance was established for imported grape wine. EPA conducted the evaluation for cyazofamid in cooperation with Canada's Pest Management Regulatory Agency.

New Food Uses

Acequinocyl - a reduced-risk miticide for use on pome fruits, citrus, almond, pistachios, and strawberries, first registered in 2003 for commercial greenhouses and shade house ornamentals. It is used for the control of the two-spotted spider mite, citrus and European red mites, Texas citrus mite, strawberry spotted mite, and spruce spider mite.

Fluroxypyr - a reduced-risk herbicide and organophosphate alternative for corn (field and sweet). It is also registered for sorghum and range and pastureland.

Deltamethrin - an insecticide and organophosphate alternative for onion, corn (field), cucurbit vegetables, fruiting vegetables, pome fruits, root and tuber vegetables, and tree nuts.

Sulfuryl fluoride - an insecticide and methyl bromide alternative for use on processed foods, dried fruits, pistachios, stored grains, and tree nuts.

Process Improvements

Other Pesticide Ingredient (Inert) Assessments - In FY 2004, the Pesticide Program utilized new, streamlined processes to evaluate the hazard and risk of "other" pesticide ingredients (inerts). While these "other" ingredients, such as solvents or carriers, in a pesticide formulation are not intended to affect the target pest, they may be the "active" ingredients in other pesticide formulations. Thus, EPA is continuing to assess these ingredients to ensure that their use will not pose unreasonable risks to human health or the environment. The new processes allowed EPA to publish final rules in FY 2004 establishing or amending tolerance exemptions for 15 inert ingredients that may be used in products with food uses, as well as to approve an inert ingredient for use in an insect repellent with dermal application for humans.

Section 18 Pilot - The Pesticide Program continued its pilot program for testing revisions to the emergency exemption (Section 18) process. In April 2004, EPA took first steps toward revising regulations governing the program to incorporate results of the pilot, with a formal proposal issued for comment in September 2004. The pilot involves two revisions to the Section 18 process: (1) an allowance for states to "re-certify" an emergency condition that continues to exist in the second and third years of use for certain eligible uses and (2) a revised, loss-based economic analysis for determining significant economic losses. It is expected that these changes will reduce the paperwork burden for both applicants and the Agency, allowing for quicker decisions and shortened turnaround times.

For more information about EPA pesticide registration program activities, please visit EPA's Registration Web site at: http://www.epa.gov/pesticides/regulating/registering/index.htm.

Partnerships, Outreach, and Education

An important element of the Pesticide Program's process for carrying out its regulatory and program implementation activities is communication with the public. Through partnerships, outreach, and education, the Pesticide Program is working in a vast number of arenas to help encourage responsible pesticide management practices. Among the activities being carried out in both agricultural and urban settings are efforts to reduce pesticide risks and exposure in vulnerable communities and to conduct training programs to educate workers and applicators about safe pesticide use.

Partnering for Responsible Pest Management and Pesticide Use in Agriculture

Pesticide Environmental Stewardship Program (PESP) - PESP is a voluntary program of over 135 partnerships with pesticide users to reduce the potential risks associated with pesticide use and to implement pollution-prevention strategies. In FY 2004, close to 80 PESP Partners, including users of antimicrobial pesticides, submitted comprehensive pesticide risk-reduction strategies for hundreds of activities, including technical assistance, training, outreach, research, efficacy demonstrations, and benefit evaluations.

Strategic Agricultural Initiative (SAI) - SAI staff in EPA's regional offices work closely with the Pesticide Program to facilitate the transition away from high-risk pesticides. In FY 2004, EPA provided $1.8 million in grants to help growers achieve this transition. SAI staff, in conjunction with American Farmland Trust, also developed a reference toolbox that will help grantees choose successful projects, set appropriate performance measures, and produce outcomes that contribute to EPA's Strategic Plan. EPA and U.S. Department of Agriculture (USDA) staff also worked together in FY 2004 to discuss how to measure the impacts of implementing integrated pest management (IPM) nationwide. The group explored mutual goals in measuring success and began to create a long-term strategy for cooperation in establishing performance measures and reporting outcomes for IPM adoption.

Biopesticide Demonstration Grants - USDA's IR-4 Program works with growers, scientists, and commodity organizations to identify minor crop pest-control needs. In FY 2004, EPA collaborated with IR-4 to fund nine grants designed to demonstrate and promote the effective use of biopesticides in agriculture. Projects included: biopesticide-based approaches to managing codling moth in apples, use of Mycotrol (Beauveria bassiana) enhanced with canola oil to prevent grasshopper infestation in pastures, incorporation of nuclear polyhedrosis virus into an IPM program for corn earworm, and control of dollar spot in turfgrass.

Reaching Out to Communities

Spanish-Language Outreach - EPA, in partnership with the Hispanic Radio Network, ran public service announcements about pesticide safety on 194 radio stations throughout the United States and Puerto Rico in June and July 2004. The most popular of the announcements had an IPM focus, discussing the connection between cockroaches and asthma, and provided tips for preventing roach infestations in the home. Other announcements provided information about protecting children from exposure to pesticides and responsible use, storage, and disposal of pesticides. Additional outreach efforts to Spanish-speaking communities included interviews on Spanish radio shows, Spanish newspaper articles, and television spots targeting both urban and rural audiences.

Lawns and the Environment - EPA's Pesticide Program is actively involved in the Lawns and the Environment Initiative, a voluntary effort aimed at encouraging environmentally responsible lawn and landscaping practices on 30 million acres of turf in the United States. In FY 2004, a national conference held in San Antonio, TX, with experts from all over the country, focused on developing and ratifying a set of guidelines for sustainable landscaping practices. Pilot projects were also identified for implementation in 2005.

IPM for Apartments - EPA coordinated with the National Apartment Association (NAA) to publish an article, "Scram: Keeping Apartment Homes Pest-Free, Without Toxic Pesticides." Focusing on low-risk IPM strategies, the article was featured in the June 2004 edition of NAA's magazine "Units," which is distributed to approximately 45,000 apartment managers and residents, nationwide.

Reaching Out to Tribal Partners

Continued Support for the Tribal Pesticide Program - In October 2004, EPA awarded a cooperative agreement to Native Ecology Initiative (NEI) to support a five-year continuation of the Tribal Pesticide Program Council (TPPC), a tribal development group focused on pesticide issues. The TPPC serves to effectively convey tribal concerns related to pesticides to EPA's Pesticide Program. EPA's regional offices also received $445,000 to fund 10 grants to tribal groups for projects that assess or reduce potential risks posed by pesticide exposure in tribal communities. Descriptions of awarded grants are available on the Tribal Pesticide Program Web page.

The Penobscot Nation Environmental Justice Project - Since the 1990s, EPA's Region I, the State of Maine, and several federal and state agencies have assisted New England tribes in assessing environmental risks. In FY 2004, to address concerns over the potential accumulation of contaminants in wildlife and wildlife consumers, Region I assisted the Penobscot Nation in developing a program to analyze sediment and biological material from the Penobscot River for human health and ecological risk assessments. The risk assessments will focus on the analysis of tissues from fish, turtles, ducks, and other species consumed by tribal members for dioxins, furans, and coplanar polychlorinated biphenyls. Region I is seeking funding through the Regional Applied Research Effort (RARE) so that the Pesticide Program's Environmental Chemistry Lab (ECL) can conduct these analyses. ECL is world renowned for its dioxin expertise.

Reducing Children's Pesticide Exposure

IPM and Schools Initiative - Through the IPM in Schools Initiative, EPA encourages schools to adopt IPM practices to reduce children's exposure to pesticides. In FY 2004, IPM programs were initiated in District of Columbia and Florida schools. National IPM experts also joined efforts to build a Schools IPM Toolbox for 2005, which will provide schools with guidance on how to initiate, sustain, and measure their school IPM programs.

Protecting Children from Pesticides - During National Poison Prevention Week in March, EPA continued its efforts to protect children from pesticide poisonings and exposure through the Lock It Up! Campaign, which focuses on raising public awareness about proper household chemical storage and poison prevention.

Join Our Pest Patrol - In FY 2004, EPA distributed over 60,000 copies of Join Our Pest Patrol, a children's activity book about integrated pest management (IPM). Teaching IPM provides children with important information about pests and the effects that various pest control methods can have on the environment.

Promoting Pesticide Safety Education

Protection of Agricultural Workers - EPA, in partnership with farmworker service organizations, brings safety education to farmworkers in farms, community centers, and clinics. Farmworkers are taught how to protect themselves and their families. In FY 2004, working with trainers and service providers, EPA developed a pesticide safety train-the-trainer program that will help create a national network of qualified pesticide safety trainers.

Pesticide Applicator Competency - EPA, in partnership with state pesticide regulatory agencies and state training services, establishes standards for programs that certify individuals as competent to apply pesticides safely and properly. Through EPA support of state-run pesticide applicator certification and training programs, applicators receive pesticide safety training and are tested to determine their competency to be safe applicators of pesticides. Currently, there are 1,065,553 certified applicators in the United States.

Pesticides and National Strategies for Health Care Providers Initiative - EPA, in partnership with health care professionals, implemented recommendations from "Pesticides and National Strategies for Health Care Providers" in FY 2004 by issuing "National Pesticide Competency Guidelines for Medical and Nursing Education" and "National Pesticides Practice Skills Guidelines for Medical and Nursing Practice." These guidelines are part of EPA's Pesticides and National Strategies for Health Care Providers Initiative and will improve the ability of health care providers to recognize, diagnose, manage, and prevent adverse health effects due to pesticide exposure.

For more information about EPA outreach, education, and partnerships, please visit EPA's Pesticide Grants and Partnerships Web page at: http://www.epa.gov/pesticides/grants/.

Reregistration and Tolerance Reassessment

As part of its ongoing effort to ensure that all pesticides meet current public health and environmental standards and product labeling requirements, EPA's Pesticide Program is reevaluating older pesticides and determining whether or not they are eligible for reregistration. EPA is also reassessing tolerances (limits on pesticide residues in food) to ensure that they meet the safety standards established by the Food Quality Protection Act (FQPA) of 1996. In conducting these assessments, EPA relies on the best available scientific data, as well as extensive input from the public and other stakeholders.

In FY 2004, EPA completed 17 Reregistration Eligibility Decisions (REDs) for a total of 244 completed and 231 canceled cases. EPA also completed 18 Tolerance Reassessment Eligibility Decisions (TREDs) and reassessed 467 tolerances. More than 7,000 tolerance reassessments have been completed to date, and EPA expects that all 9,721 tolerances will be reassessed by the August 2006 FQPA deadline. Of the 2,628 tolerances remaining, 548 have been individually assessed through Interim Reregistration Eligibility Decisions (IREDs) but will also be considered in a cumulative assessment before the reassessment is considered complete.

The Pesticide Program is committed to completing REDs for all food-use pesticides and all TREDs by August 3, 2006, and completing REDs for the remaining reregistration pesticides by October 3, 2008. EPA has placed considerable emphasis on ensuring that the resources are in place and schedules are clearly articulated and tracked toward meeting these goals. Also, in anticipation of completing the reregistration program, EPA is taking steps to develop the Registration Review program, under which all pesticides will be reviewed every 15 years to ensure that they meet current health and safety standards.

Reregistration and Tolerance Reassessment Highlights

Increasing Public Participation in the Reregistration Process - In FY 2004, EPA issued its public participation process and posted a public comment schedule on the EPA Pesticide Web page. Because all pesticide reassessments do not present the same degree of risk or complexity, the public participation process provides options for conducting a full six-phase process, modified four-phase process, or streamlined process for low-risk pesticides, as appropriate. This approach promotes robust public and stakeholder involvement while enabling EPA to make timely pesticide regulatory decisions to meet statutory deadlines and program goals. EPA also posted a chemical decision schedule showing when REDs for the remaining pesticides in the reregistration process will be completed.

Soil Fumigants Assessment Under Way - EPA is conducting human health risk assessments for soil fumigant pesticides that are used in similar ways and that may result in similar human exposures: methyl bromide, metam sodium, chloropicrin, and dazomet, all of which are undergoing evaluation for reregistration eligibility; telone, which was deemed eligible for reregistration in 1998; and iodomethane, a pending new active ingredient. By evaluating these pesticides as a group, EPA is ensuring that its risk assessment approaches are consistent, that its risk management decisions fully consider the risks and benefits of each pesticide, and that its recommended label revisions are applied as appropriate across the group of fumigants. As part of this effort, the Pesticide Program is also collaborating with EPA's Office of Air and Radiation to ensure that there is harmonization between pesticide registration decisions, particularly regarding methyl bromide, and regulatory provisions of the Clean Air Act and the Montreal Protocol.

Methyl Bromide Critical Use Exemption (CUE) Program - Methyl bromide is scheduled to be phased out globally in 2005 because of its contributions to destruction of the ozone layer. The Methyl Bromide CUE Program provides a means for growers to legally use methyl bromide after the phaseout, provided that they demonstrate that there are no technically and economically feasible alternatives available, that the use and emissions are minimized, and that there have been and will be efforts to find alternatives. In FY 2004, EPA received and reviewed requests totaling 60-65 percent of the 1991 baseline from approximately 70 applicants. These were reduced to 37 percent of the baseline after analysis by EPA and USDA. EPA delivered the U.S. nomination to the United Nations in February 2004, and later responded to several rounds of followup questions. The United States has been complimented by the international body on the quality of its work.

Antimicrobial Reassessments - In accordance with new statutory requirements, antimicrobial formulations for sanitizing or disinfecting food-contact surfaces other than food packaging, previously regulated by the Food and Drug Administration, are to be regulated by EPA. In accordance with these new requirements, EPA is responsible for reassessing tolerances for over 100 pesticides by FY 2006, 14 of which were completed in FY 2004. To accomplish this goal, EPA has categorized and grouped the pesticides according to chemical characteristics and developed a schedule for completing the reassessments on time.

Eliminating Risks of Arsenic Used in Wood Preservative - The cancellation of residential uses of chromated copper arsenate (CCA) became effective December 31, 2003. By working with manufacturers to voluntarily phase out its use as a wood preservative for products around the home and in children's play areas, EPA has taken steps to reduce the exposure of children to arsenic, a known carcinogen, and to make safer substitutes available in the marketplace. EPA, in partnership with industry, states, consumers, EPA regions, and public interest groups, also provided guidance on the Internet as to which uses of CCA are still permitted and which are disallowed. Additionally, a compliance strategy was developed to ensure that wood treaters were adhering to current CCA labels. The Pesticide Program has also coordinated with EPA's Office of Solid Waste to ensure that CCA-treated wood is properly disposed of.

Pine Oil RED - Pine oil is registered for use as a disinfectant, sanitizer, microbiocide, and virucide. Potential dietary exposure, including that of infants and children, from food coming in contact with surfaces where pine oil is used, was considered and showed potential risks of concern. As a risk mitigation measure, limitations were placed on the amount of pine oil used in pesticide formulations as well as on where the products can be used.

Last Diazinon Residential-Use Products Canceled - To better protect children, all residential uses of the organophosphate diazinon are being phased out as part of a December 2000 agreement between EPA and diazinon's registrants. Diazinon products formulated for indoor uses have been canceled since December 31, 2002. In August 2004, EPA announced the cancellation of all remaining outdoor, non-agricultural diazinon products, which may no longer be sold after December 31, 2004. EPA also issued a notice to retailers in September 2004, reminding them of the upcoming stop-sale date. The notice was also intended to prevent improper disposal of unsold products and to reduce the enforcement burden on states.

Dacthal Tolerance Reassessment - EPA completed a tolerance reassessment for tolerances associated with approved uses of dacthal (DCPA) on ginseng and a set of minor crops for which residues may be found from use on nearby soils or past use. It was determined that a metabolite of dacthal, TPA, is widely found as a groundwater contaminant at substantial levels. While TPA is not likely to be carcinogenic, its presence posed concerns from a resource conservation standpoint. Based on the presence of TPA in groundwater, all of dacthal's residential uses and its use on cotton, potatoes, chestnuts, walnuts, and crabapples have been dropped.

Thiram RED - Thiram is a fungicide used for foliar treatment of apples, peaches, and strawberries, and for seed treatment of numerous vegetable and field crops. It is also used on nonresidential turf. The Thiram RED includes risk mitigation measures, including dropped uses and rate changes, for achieving reductions in dietary, residential, occupational, and environmental exposure. The RED also addresses risks to endangered species, prohibiting the use of thiram-treated seeds within one mile of protected Attwater's prairie chicken habitat. By identifying the critical habitat and establishing a buffer zone for this endangered species, EPA is able to mitigate risks to the Attwater's prairie chicken while also continuing to meet the needs of agricultural stakeholders.

Carboxin RED - Carboxin is a fungicide used for seed treatment to control various diseases on barley, oats, rice, cotton, vegetables, corn, and wheat. To address potential risks of carboxin to the endangered Attwater's prairie chicken, the Carboxin RED establishes a buffer zone requiring minimum planting depths and subsequent discing for carboxin-treated seeds planted within one mile of protected Attwater's prairie chicken habitat. As with thiram (above), this approach allows EPA to mitigate risks to the Attwater's prairie chicken, while also meeting the needs of agricultural stakeholders.

For more information about EPA's reregistration and tolerance reassessment activities, please visit the Reregistration Web page at: http://www.epa.gov/pesticides/reregistration/.

Advancements in Science and Technology

In FY 2004, EPA's Pesticide Program continued to make advancements in science and technology that improve the ability to understand, assess, and ultimately mitigate the potential risks of pesticides to the public and the environment. EPA relies on the best available science and technology to carry out its mission of protecting public health and the environment and constantly works to develop and employ new and improved techniques for conducting human health and ecological risk assessments and refining risk assessment processes. EPA also maintains a high level of commitment to collaborating with experts in the field and will continue to receive and seek input from the Scientific Advisory Panel (SAP) and stakeholders to identify and address areas where methods and procedures could be improved.

Improving Ecological Risk Assessment

Refining Terrestrial and Aquatic Risk Assessment Models - In FY 2004, the Pesticide Program presented its revised Level II Terrestrial and Aquatic Models (Version 2.0) for conducting probabilistic or refined ecological risk assessments for pesticides to the SAP. These models are a key component of EPA's Initiative to Revise the Ecological Risk Assessment Process and move beyond current deterministic or single-point screening assessments. The refined models incorporate probabilistic tools and methods that provide information on the probability or likelihood of ecological impact and on the magnitude or severity of the effects resulting from pesticide use.

Harmonizing Ecological Risk Assessments - The Pesticide Program worked with EPA's Office of Water, EPA's Office of Research and Development, and the principal registrant to develop a harmonized approach to atrazine risk assessment and risk mitigation. As a result, the regulatory decision made by the Pesticide Program on atrazine is consistent with the Clean Water Act (CWA) Total Maximum Daily Load Program. The draft aquatic life criterion issued by the Office of Water was derived in a manner identical to the level of concern used by the Pesticide Program. These actions ensure that the most vulnerable watersheds are protected and benefits to users are preserved.

Improving Dietary and Drinking Water Risk Assessments

Degradation of Pesticides in Chlorinated Drinking Water Studies - As part of the effort to ensure the quality of the public drinking water supply, EPA laboratories in FY 2004 continued to study the conversion of various organophosphate insecticides (such as diazinon and malathion) to more toxic breakdown products (diazoxon and maloxon) in chlorinated drinking water through a multi-phase project. The research requires developing analytical methodology that permits direct analysis of water samples with Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) technology without any preparation, extraction, or cleanup. With the LC/MS/MS analysis of water samples, it is possible to analyze a small sample of water directly, and the direct analysis saves time and permits low parts-per-billion sensitivity.

Triazole Multi-residue Method Development - In FY 2004, EPA developed a multi-residue method for the triazole class of fungicides (12 pesticides). The analytical method included degradates of concern, which can potentially be found in water. The U.S. Department of Agriculture (USDA) Pesticide Data Program (PDP) and the Triazole Task Force used this method to generate residue data for fruit, vegetables, and water samples. The residue data were then used to refine the dietary risk assessment, resulting in more refined dietary risk estimates. These more accurate risk estimates result in a risk assessment that is protective of human health while supporting the benefits of pesticide uses.

Developing Exposure and Risk Assessment Tools

Swimmer Exposure Assessment Model (SWIMODEL) - In FY 2004, EPA developed the SWIMODEL as a screening tool to conduct exposure assessments of pesticides found in indoor swimming pools and spas. These include the more than 200 pesticides registered for swimming pool uses, as well as those that may be in the source water for the pool or spa.

New Models for Exposure and Risk Assessment of Antimicrobial Pesticides - Antimicrobials have different use and exposure scenarios that standard models do not address well. In FY 2004, EPA developed several new models for assessing exposure and risk for antimicrobial pesticides that will improve risk assessment capabilities and result in better protection where necessary:

1. The Antimicrobial Heating Ventilation and Air Conditioning (HVAC) Model - measures the post-application concentration of antimicrobials in residential and commercial HVAC systems to estimate exposure to building occupants,
2. Utility Pole Model - estimates the leaching of pentachlorophenol from utility poles, and
3. Antimicrobial Exposure Model - estimates dermal and inhalation exposure to antimicrobial chemicals of workers who handle the chemicals.

Advances in Pesticide Exposure Assessment - EPA continues to make advances in pesticide exposure assessment, including: (1) utilizing full temporal distributions of drinking water exposure in probabilistic dietary assessments (in reregistration eligibility decisions and the organophosphate cumulative assessment); (2) developing regional percent-cropped area factors; (3) working with the U.S. Geological Survey to develop a regression model (WARP) that can be used to provide estimates of surface water vulnerability; (4) developing modeling templates (PE4 and EXPRESS) to run multiple scenarios more efficiently; and (5) working with EPA's Office of Research and Development to develop a protocol to evaluate the effects of drinking water treatment on pesticides.

Assessing Exposure to Dermal Sensitizers - In FY 2004, EPA sought advice from the SAP on developing methods to protect the public from exposure to pesticides that are dermal sensitizers. This issue is of particular concern in cases where fabric or wood is treated with pesticides. Currently, EPA requires label warnings about potential sensitization and also requires use of protective equipment in situations of occupational exposure. Because labeling is not feasible for situations of general public exposure (for example, exposure to a treated-wood deck), EPA is working to develop quantitative methods to assess the potential for dermal sensitization from exposure to pesticides. Hexavalent chromium, for which there is a pending registration as a wood preservative, was used as a test case.

Methods and Research Development

Analytical Methods Development - To address the serious human health and environmental effects posed by dioxin exposure and persistence, EPA's Environmental Chemistry Lab (ECL) has been providing analytical support to the Agency's Dioxin Reassessment and the Dioxin Exposure Initiative since the mid-1990s. Samples were analyzed for 17 toxic, dioxin-like substances and certain PCBs with dioxin-like activity. During this time, the World Health Organization identified additional polychlorinated biphenyls (PCBs) with dioxin-like activity. In FY 2004, the ECL added these specific substances to its list of analytes routinely analyzed for and has successfully participated in two international intercalibration studies that validated the methodology. The ECL continues to focus on method development in this area and plans to add a method for "Total PCBs." Improvements in analytical methods support efforts to identify and clean up contamination, and improve protection of public health.

Quantitative Carrier Testing of Antimicrobials - EPA's use of qualitative methods to evaluate the effectiveness of various public health antimicrobial products has led to questions concerning the reproducibility of some test results. In FY 2004, EPA implemented a plan to replace qualitative methods (present or absence of growth) presently employed in efficacy testing of antimicrobial products with a quantitative (log reduction) testing method. Under this plan, a new quantitative method under development through an EPA grant to the University of Ottawa will be presented to the SAP, industry, and other stakeholders for validation. Once implemented, the new method may provide improved information on product effectiveness and will also enable harmonization with other countries where quantitative methods are being explored.

For more information about EPA advancements in science and technology, please visit EPA's Science and Policy Web page at: http://www.epa.gov/pesticides/science/

Endangered Species Protection

In accordance with the Endangered Species Act, EPA's Pesticide Program has included endangered species considerations in its pesticide risk assessments for many years, working to ensure that its actions will not jeopardize the continued existence of endangered and threatened species or their designated critical habitat. The Program also seeks to minimize the impact to pesticide users.

In recent years, the Pesticide Program has undertaken major efforts to improve its Endangered Species Protection Program in three significant ways: (1) cooperating with the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS), jointly referred to as the Services, and the U.S. Department of Agriculture (USDA) to retool the process for consultation between EPA and the Services; (2) developing an approach to public participation in endangered species risk mitigation decisions and implementing them in the field; and (3) upgrading the scientific basis for endangered species risk assessments and routinely incorporating these assessments into registration, reregistration, and for the future, into registration review decisions. In FY 2004, the Pesticide Program made major advancements in these areas.

Improving the Endangered Species Consultation Process

Joint Regulations for Improving the Endangered Species Consultation Process - On July 27, 2004, the Services signed final Counterpart Regulations that create new processes for consultation regarding the effects of pesticides on listed species. These new regulations allow EPA to make determinations that a pesticide is "not likely to adversely affect" a listed species without having first to engage in a consultation process with the Services. By making the process more efficient and effective, the new regulations will allow EPA and the Services to jointly focus the bulk of their resources on determining how best to manage the use of more-risky pesticides that may pose the greatest threat to listed species. This will improve protection for endangered and threatened species.

Interagency Agreement for Implementing the New Consultation Process - On August 26, 2004, EPA and the Services signed an Alternative Consultation Agreement (ACA) outlining procedures for implementing efficient consultation practices set out in the Services' Counterpart Regulations. Since August, EPA has worked with the Services to make the relationships described in the ACA operational. For example, EPA and the Services are working collaboratively on the pesticides metolachlor and methomyl to ensure that EPA's risk assessments address the issues most relevant to listed species. A jointly developed training program for EPA risk assessors will also improve the ability to make sound determinations regarding risk to listed species and their critical habitats.

Involving the Public and Communicating Decisions

Endangered Species Bulletins - In FY 2004, EPA improved the Endangered Species Bulletins to make them more readable, user friendly, and visually appealing, and upgraded the bulletin design and mapping process from using outdated computer-assisted design methods to incorporating Geographic Information Systems. EPA also worked extensively with the U.S. Geological Survey to develop an interactive mapping site to address pesticide use related to 26 listed Pacific salmon and steelhead, with an eye toward creating this type of information for any situation in which geographically specific pesticide use modifications are necessary to protect a listed species.

Public Outreach and Public Input - To ensure public awareness and involvement in its efforts to protect listed species, in FY 2004, EPA hosted two public workshops focusing on its listed species risk assessment process. These included an overview of the enhanced assessment process endorsed by the Services, as well as a public workshop using a pesticide recently assessed in accordance with the new assessment process to demonstrate in real terms the enhancements being made. EPA also presented information about its Endangered Species Protection Program to the Pesticide Program Dialogue Committee (PPDC) and asked for input on program development and implementation. The input and advice provided by the PPDC is viewed as critical by EPA to ensure the success of this enhanced program to protect listed species from the potential effects of pesticides.

Assessing and Mitigating Risks

Protecting the Attwater's Prairie Chicken - EPA evaluated the potential risks of thiram and carboxin to the Attwater's prairie chicken and in FY 2004 proposed measures to mitigate these risks. The Thiram Reregistration Eligibility Decision (RED) establishes a buffer zone, prohibiting the use of thiram-treated seeds within one mile of protected Attwater's prairie chicken habitat. The Carboxin RED also establishes a buffer zone, requiring minimum planting depths and subsequent disking for carboxin-treated seed planted within one mile of protected Attwater's prairie chicken habitat. Both REDs require label additions and amendments, including requirements to follow the revised instructions in EPA's Endangered Species Bulletins, modifications to minimum planting depths, and modifications to allowed use sites and use rates. These decisions relied on close coordination with local experts to determine what measures would protect the chickens while still allowing farmers needed seed treatments.

Completing Endangered Pacific Salmonid Assessments for 48 Pesticide Active Ingredients - Under a court-ordered schedule stemming from *Washington Toxics Coalition v. EPA*, which focused on the potential effects of 55 pesticides on endangered or threatened Pacific salmonids, EPA met deadlines in December 2003, April 2004, and August 2004 for assessing 21 of the 55 pesticides. This brings the total number of completed assessments to 48. Where EPA determined that a pesticide's use may have an effect on any of the 26 subspecies of listed salmon and steelhead, EPA transmitted requests for consultation to NMFS. EPA completed the final seven assessments by the December 2004 deadline.

For more information about how EPA is protecting endangered species, please visit EPA's Endangered Species Protection Program Web site at: http://www.epa.gov/espp.

Homeland Security

EPA's Pesticide Program has been working with EPA's Office of Homeland Security, regional offices, other federal agencies, states, and the pesticide industry to meet its obligations to help protect the nation's public health, food supplies, and agriculture from potential threats of terrorism.

In FY 2004, EPA continued to pursue initiatives that strengthen the capacity to prevent, prepare for, and if necessary respond to the potential threat of chemical and biological agents that might be intentionally used against the United States. The Pesticide Program has focused its homeland security resources on coordinating response capabilities with other agencies, identifying suitable pesticides for exotic crop and livestock diseases, and improving laboratory research capabilities and methods development.

Homeland Security Highlights

Protecting Food and Agriculture - EPA, under Homeland Security Presidential Directive 9 (HSPD 9), leads an effort to develop a comprehensive plan that will delineate responsibilities of government agencies and industry for responding to the introduction of plant and livestock diseases and other pests of high consequence to the nation's agriculture and the food supply. This effort involves collaboration with other key agencies including the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Department of Defense, and the Department of Homeland Security, as well as EPA's Office of Homeland Security and Office of Solid Waste and Emergency Response.

Participating in the Food Emergency Response Network - The Pesticide Program represents EPA on the Food Emergency Response Network (FERN) Steering Committee, which is administered by USDA and FDA and consists of 88 federal labs, state agriculture labs, and veterinary labs that do food analyses. FERN 's mission is to analyze food samples in the event of a biological, chemical, or radiological attack on the food supply of the United States. In FY 2004, FERN continued to develop short- and long-term training to federal and state analysts on select agent methods. FERN is also instituting a proficiency-testing program for all areas (biological, chemical, and radiological), and it has established a secure electronic communications network (eLexnet).

Controlling Soybean Rust and Other Crop and Livestock Diseases - As part of its homeland security effort, EPA has been working with USDA, states, and the pesticide industry to identify pesticides that EPA could approve to control pathogens of concern that might be naturally or intentionally introduced into the United States. In FY 2004, for example, EPA approved emergency (Section 18) exemptions for potential use of myclobutanil, propiconazole, and tebuconazole to control soybean rust, which is considered a select agent under the Agricultural Bioterrorism Protection Act. EPA also registered chlorothalonil and azoxystrobin for control of soybean rust and established tolerances (allowable residues on food) for boscalid and pyraclostrobin, making them eligible for registration. When soybean rust was found in the United States later in the year, all these tools were in place for rapid use. EPA is continuing this effort for other crop and livestock diseases.

Cleaning Up the Last Anthrax-Contaminated Site - In July 2004, EPA's Pesticide Program worked with EPA's Office of Solid Waste and Emergency Response to issue the final crisis (Section 18) exemption for using chlorine dioxide gas to decontaminate a building in Boca Raton, FL, the last site to be contaminated as a result of the October 2001 "anthrax attacks." Since 2001, EPA has approved 28 and rejected 35 crisis exemption requests from a total of 63 received.

Developing Efficacy Test Methods for Products to Inactivate *Bacillus anthracis* - Because anthrax spores are difficult to destroy, EPA established the "Interagency Expert Panel on Efficacy Test Methods and Surrogates for Anthrax Spores" to evaluate and improve test methods for the effectiveness of antimicrobial products against anthrax spores. Through this group, EPA led extensive intra- and interagency coordination on testing that measures the effectiveness of various liquid, gaseous, and vaporized chemical sporicides for inactivating *Bacillus anthracis* spores. (More details are available on the CD.)

Developing Technology for Homeland Security Preparedness - The Pesticide Program's Analytical Chemistry Lab is investigating the use of technology that will enable labs to quickly respond to a homeland security incident where little may be known about the agents in question and where quick analytical response, including the capability of using a single analysis for multiple analyses, is required. Some of the instruments being investigated include Purge and Trap Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS).

Building Laboratory Preparedness for Biological Incidents - The Pesticide Program's Microbiology Laboratory is registered under the Center for Disease Control and Prevention (CDC) Select Agent Program to possess, use, or transfer *Bacillus anthracis*. The laboratory includes two Biosafety Level 3 laboratories that are appropriately configured to work with *Bacillus anthracis* and other infectious pathogens. Construction was completed in June 2004 on a triage area for processing samples that may contain biological and chemical agents, allowing scientists to conduct analyses covered by the CDC Select Agent Program.

For more information about how EPA is contributing to homeland security, please visit EPA's Homeland Security Measures for Agriculture Web site at: http://www.epa.gov/agriculture/thom.html *and EPA's Anthrax Web page at:* http://www.epa.gov/epahome/hi-anthrax.htm.

Biotechnology

Products of biotechnology are playing a key role in reducing the use of pesticides and exposure to pesticide residues. In FY 2004, EPA's Pesticide Program continued to register products of biotechnology, such as Plant-Incorporated Protectants (PIPs), while at the same time taking action to ensure their safety. Products of biotechnology undergo vigorous scientific review and public comment, and major products receive independent peer reviews held at public meetings. EPA also coordinates its biotechnology regulatory activities with other government offices and stakeholders.

Biotechnology Highlights

Registration of Bt Cotton Products - WideStrike cotton incorporates the *Bacillus thuringiensis* Cry1Ac and Cry1F proteins to control a variety of pests in the lepidopteran family. This product has the potential to reduce the use of insecticides currently registered for cotton, including organophosphates, pyrethroids, and carbamates, which can be applied several times per season and may pose risks to workers and the environment. Conditional registrations for Bollgard and Bollgard II Cotton were also renewed in September 2004.

Registration of Bt Corn Product - Early in FY 2004, EPA registered YieldGard Plus corn, a stacked PIP product. This stacked PIP contains separate PIP active ingredients that target different kinds of pests. YieldGard Plus corn produces both the Cry1Ab and Cry3Bb1 proteins to control leaf, stalk, and root damage from various pests, including European corn borer (a moth) and corn rootworm (a beetle), that can cause serious economic losses to corn farmers. This product also has the potential to reduce the use of older insecticides currently registered for corn.

Insect Resistance Management - To address concerns over the potential for insect resistance, EPA consulted the Scientific Advisory Panel (SAP) on Insect Resistance Management (IRM) plans for Widestrike Cotton, Bollgard Cotton, and Bollgard II Cotton. The SAP evaluated the IRM program for Bollgard and Bollgard II cotton to grow 95 percent Bt cotton and a 5 percent unsprayed refuge, and agreed with EPA that studies support continued use of the 95/5 refuge approach.

Experimental Use Permits for PIPs - Six PIP Experimental Use Permits (EUPs), either extensions or amendments to active ingredients already under field trial or new active ingredients, were issued in 2004. These experimental Bt PIP products for corn and cotton indicate a potential for reducing the use of conventional chemical pesticides currently used for these crops. EPA held a multi-stakeholder meeting in February aimed at gathering information to improve the consistency, adequacy, and efficacy of its regulatory program for PIP EUPs.

Continued Testing for StarLink Corn - The food industry, specifically corn millers and elevator operations, continues to test for StarLink corn in the corn for dry milling and export. The StarLink corn, which contains the insecticidal protein Cry9C for control of European and Southwestern corn borer, is not allowed in human food, nor is it allowed in corn being shipped overseas. The levels remain low, but StarLink protein is still detected. When found to be positive for StarLink, the corn is diverted to animal feed or other allowed uses.

PIP Analytical Method Validation Program - To ensure the safety of the U.S. food supply, scientifically validated analytical methods are necessary to detect PIP residues, just as with chemical residues. The emerging field of biotechnology therefore requires new testing methods. In FY 2004, EPA's Microbiology Laboratory conducted the first PIP analytical method validation. The lab evaluated the ability of a lateral-flow test strip system to detect the presence of Cry1Ab (an insecticidal protein) in corn seed. A second validation of an Enzyme Linked Immunsorbent Assay (ELISA) for the detection of Cry1F protein in cottonseed is currently under way. This program will allow PIPs to be detected in food and will allow EPA to comply with Food and Drug Administration (FDA) testing requirements for registered PIPs in food commodities.

U.S. Regulatory Agencies Unified Biotechnology Web Site - In FY 2004, EPA played a key role in working with other federal agencies to provide the public with an Internet database on agricultural biotechnology products in the United States. The searchable database, which covers all genetically engineered crop plants intended for food or feed that have completed the recommended or required reviews for food, feed, or planting use in the United States, is part of the federal government's effort to support an international clearinghouse of information on agricultural biotechnology, further the understanding of the United States' oversight system for products of biotechnology, and ensure that new biotechnology products are safe for public health and the environment. Web users around the world now have access to one-stop information on these products and their regulatory status. The Web site is available at: http://usbiotechreg.nbii.gov/.

North American Biotechnology Initiative - In FY 2004, EPA continued to improve communication and regulatory coordination among biotechnology officials in Canada, Mexico, and the United States. Through the initiative, EPA also developed programs of technical assistance for Mexico and Central and South American countries.

For more information about EPA activities related to biotechnology, please visit EPA's Biotechnology Web page at: http://www.epa.gov/pesticides/biopesticides

Looking Toward the Future

EPA's Pesticide Program met its commitments to the public in 2004; the Program is also ready for the challenges of the future in 2005 and beyond.

Reducing Risks and Meeting Needs

The fundamental challenges for pesticide regulation are to reduce risks from pesticide exposure and to meet pest control needs in a timely way. Since enactment of the Food Quality Protection Act (FQPA), the Pesticide Program has worked to coordinate the operation of the registration and reregistration programs to make new, safer and effective pesticides available as older, riskier pesticides are phased out. Working with registrants, IR-4, users, and others, the Program has approved many new, safer uses, particularly for minor crops. New resources authorized by the Pesticide Registration Improvement Act (PRIA) will advance this effort by shortening decision review times for reduced-risk pesticides.

The Strategic Agricultural Initiative (SAI), designed in 1998 to help agricultural producers achieve a reasonable transition away from the highest-risk pesticides, aims to support and promote across the United States environmentally sound agricultural and pest management practices that are economically viable and socially responsible. The SAI has already helped to meet critical needs of underserved growers. For the future, the work of the SAI will be closely integrated with recommendations from the Committee to Advise on Reassessment and Transition to prioritize pest management needs, accommodate traditional and emerging technology transfer, assess progress in environmental stewardship, and find ways to connect pest management needs to other programs managed by the U.S. Department of Agriculture (USDA) and EPA.

To ensure completion of Reregistration Eligibility Decisions (REDs) for pesticides with food uses and tolerance reassessments by August 3, 2006, and completion of REDs for the remaining reregistration pesticides by October 3, 2008, PRIA has authorized collection of an additional $116 million over five years, with an immediate influx of resources in the first three years. The Program is also making a number of improvements to its tolerance reassessment and reregistration program to ensure success. These include developing risk assessment methodologies tailored to lower-risk pesticides and inert ingredients and streamlining the use of scientific resources in a variety of ways. In addition, the Program has also issued its public participation policy to provide for stakeholder involvement tailored to the complexity of the specific pesticide at hand. To help stakeholders better plan and effectively participate in the completion of tolerance reassessment and reregistration, the Program has established a pesticide decision schedule, available on the Pesticide Program Web site.

Beyond completion of tolerance reassessment and reregistration, FQPA has also mandated a new program: registration review. This new program will make sure that, as the ability to assess risk evolves and as policies and practices change, pesticides in the marketplace will still meet the statutory standard of no unreasonable adverse effects. In 2004, the Program, together with its stakeholders, designed and tested the feasibility of an approach to registration review that matches the evaluation of a pesticide to the scope of changes that have taken place over a 15-year period. The framework for this new program will be proposed in 2005, to be in place so that the registration review program can start in 2006 as the reregistration program enters its concluding phase.

Protecting Endangered Species

The Pesticide Program has included endangered species considerations in its risk assessments for many years. In the last several years, the Program has undertaken a major effort to improve its Endangered Species Protection Program in three principal aspects: (1) upgrading the scientific basis for endangered species risk assessments and routinely incorporating these assessments into registration, reregistration, and for the future, into registration review decisions; (2) cooperating with the Fish and Wildlife Service, National Marine Fisheries Service, and USDA to retool the process for consultation between EPA and the Services; and (3) developing an approach to public participation in endangered species risk mitigation decisions and implementing them in the field.

In 2005 and beyond, the Pesticide Program expects to continue the deployment of this Endangered Species Protection Program, ensuring better protection for endangered species through refined risk mitigation measures where necessary, through FIFRA-enforceable labeling, and by assisting users in complying with these measures.

Improving Policy, Science, and Information Technology

The Pesticide Program will continue to update and improve its policy, scientific, and information management bases to achieve better protection of public health and the environment through efficient and effective use of resources. Starting in 2005, the Program expects to propose revisions to its Part 158 rules on data requirements for conventional chemicals, antimicrobials, and biopesticides. In early 2006, the Program also expects to issue final streamlining revisions to emergency exemption procedures, as well as to the procedures governing disposal of pesticide containers and containment facilities.

The Pesticide Program will continue working with other governments, academia, industry, and public interest groups to improve and update toxicity testing to maximize the useful information collected, better explain why a pesticide is toxic on a molecular level, and reduce the number of animals needed for testing. We are also investigating a number of new technologies that would allow risk assessors to use available data and computer modeling rather than live animals to simulate certain health effect tests. We are developing new methods for forecasting how much of a crop is treated with pesticides, which will allow for improved human health and environmental risk assessments. In the area of homeland security, we are developing standardized methods for testing the efficacy of products against anthrax.

We have adopted a corporate approach to information management and are making significant investments in improving our information technology infrastructure. Good management of the Pesticide Program's information bases enhances our workload capacity, leading to increased productivity; it enhances our scientific capabilities, improving the quality of our risk assessments; and it enhances stakeholder abilities to participate in our work, enhancing the quality of our decisions.

Agency Contact Information:

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone: (703) 305-5017
Web page: www.epa.gov/pesticides

Pesticide Registration Contact Information:

Antimicrobials: (703) 308-6432
Biopesticides: (703) 305-7973
Conventionals: (703) 308-8893

Pesticide Information Resources:

EPA Pesticide Program Updates
Join the e-mail Listserv at:
www.epa.gov/oppfead1/cb/csb_page/form/form.html

National Pesticide Information Center (NPIC)
Phone: (800) 858-7378
E-mail: npic@ace.orst.edu
Web site: npic.orst.edu

Local Poison Control Center
Phone: (800) 222-1222

FY 2004 New Active Ingredient Registrations	
Total New Active Ingredients Registered * Total new uses = 198	26
Conventional Chemicals (includes 1 methyl bromide alternative) New uses = 6	5
Conventional Reduced-Risk Chemicals (includes 1 organophosphate alternative) New reduced-risk uses = 7 Other uses = 9	5
Biopesticides New uses = 179	14
Antimicrobials New uses = 1	2

* In FY 2004, new import tolerances were also established for residues of an active ingredient that is not registered in the United States but found on imported food products.

FY 2004 New Uses for Previously Registered Active Ingredients	
Total New Uses (food and nonfood)	244
Total New Food Uses	223
Total New Nonfood Uses	21
New Biopesticide Nonfood Uses	1
New Biopesticide Food Uses	2
New Antimicrobial Nonfood Uses	10
New Antimicrobial Food Uses	0
New Conventional Nonfood Uses	7
New Conventional Food Uses	184
New Conventional Reduced-Risk Nonfood Uses	3
New Conventional Reduced-Risk Food Uses	37
New Methyl Bromide Alternative Uses	10
New OP Alternative Uses	20
Total Tolerances Established for New Uses (for new & existing active ingredients)	606
Total Major Crops Associated with New Uses (for new & existing active ingredients)	120
Total Minor Crops Associated with New Uses (for new & existing active ingredients)	1,300

FY 2004 Section 18 Emergency Exemptions	
Exemption Requests Received	536
Exemptions Granted	352
Exemptions Withdrawn	41
Exemptions Denied	4
Crises Declared	58
Tolerances Established for Section 18s	6

FY 2004 Reregistration Risk Management Decisions Completed	
REDs	17
Interim REDs	0
Tolerance Reassessment Decisions	18
Total REDs Completed Through FY 2004	244

FY 2004 Product Reregistration Actions Completed	
Product Reregistration Actions	78
Product Amendment Actions	35
Product Cancellation Actions	14
Product Suspension Actions	0
Total Product Reregistration Actions for FY 2004	127

FY 2004 FQPA Tolerance Reassessment Summary			
Class	**Total # of Tolerances to be Reassessed**	**Total Reassessed Since August 3, 1996**	**Percent Reassessed**
Organophosphates	1,691	1,131	66.88
Carbamates	545	309	56.70
Organochlorines	253	253	100.00
Carcinogens	2,008	1,425	70.97
High Hazard Inerts	5	5	100.00
Other	5,219	3,970	76.07
Total	9,721	7,093	72.97

FY 2004 Fast-Track and Nonfast-Track Decisions		
	Fast-Track	**Nonfast-Track**
Me-Too Product Registrations	328	509
Amendments	4,379	484
Total	4,707	993

Special Local Needs Accepted (Section 24(c))

Total for FY 2004 = 477

Experimental Use Permits (EUPs)

Total for FY 2004 = 13

Temporary Tolerances Established for EUPs

Total for FY 2004 = 8