



## NATIONAL PESTICIDE PROGRAM

# FY 2006

## ANNUAL REPORT

### CAPPING A SUCCESSFUL DECADE

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OUTREACH AND EDUCATION  
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**Jim Jones, Director**

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 CONTAINMENT

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 EMERGENCY USES OF PESTICIDES  
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December 2006

This has been a successful year, capping a successful decade. With the last FQPA deadline approaching, the priority for 2006 was meeting the deadline and maintaining the quality – the reassessment of more than 9,700 tolerances and the reregistration of all food-use pesticides. We met our deadline through collaboration and partnership with stakeholders and use of cutting-edge science, while maintaining transparency and openness. At the same time, we continued to expand our efforts in international cooperation, we made significant strides in implementing a new regulatory basis for our program that will carry us into the future, and we met our goals for registering new pesticides to meet the pest-management needs of the U.S. public. The program has also increased its focus on performance accountability, including moving from counting outputs to understanding outcomes; enhancing the linkages among the strategic plan, the budget, and our annual commitments; and improving our public communication, performance tracking, and accountability.

The brief reports on the following pages represent the range of accomplishments of the National Pesticide Program in 2006. See our Web site at [epa.gov/pesticides](http://epa.gov/pesticides) for more information about these and other activities of this dynamic program.

**SPECIAL ACCOMPLISHMENTS**

**FQPA Deadline—2006 Culminated 10 Years of Effort**

In 1996, the two houses of Congress unanimously enacted the [Food Quality Protection Act \(FQPA\)](#). Through this historic action, Congress presented EPA with the immense challenge of implementing the most comprehensive overhaul of the Nation’s pesticide and food safety laws in decades. The centerpiece of Congress’s challenge was the requirement to review and reassess—within a decade—the tolerances (maximum permitted residues) for all food-use pesticides to ensure they met a new, strict safety standard.

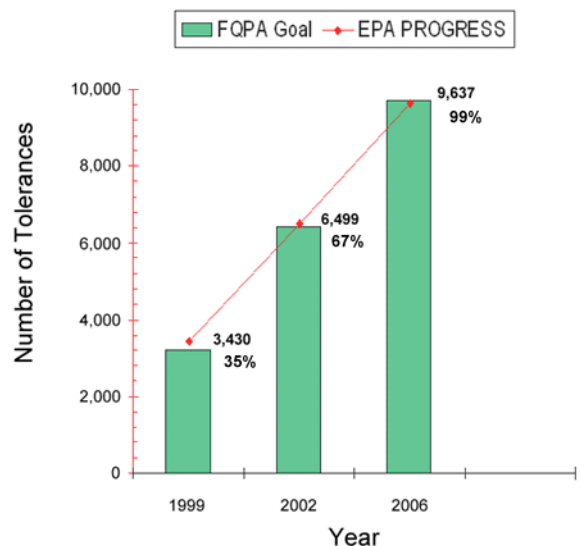
By the end of fiscal year 2006, the Pesticide Program had reassessed more than 99 percent of the 9,721 subject tolerances, an effort that necessitated the detailed review of tens of thousands of toxicology, chemistry, and environmental studies and the application of new risk assessment methods and policies. This 10-year effort, based on sound science and broad public participation, has resulted in the strictest protective standards for pesticide regulation for all Americans, especially infants and children.

Simultaneously with tolerance reassessment, the Pesticide Program determined reregistration eligibility of existing pesticides. This resulted in cancellation of more than 4,300 individual pesticide end-use product registrations in the 10-year span, while still ensuring that pesticides are available to protect Americans, their homes, and their food supply.

Through FQPA, Congress required EPA to reassess 9,721 maximum allowable pesticide residue limits, called tolerances, by August 2006. This graph indicates progress toward that goal. As of FY 2006, 9,637 of a total 9,721 tolerances have been reassessed.

New active ingredients meeting FQPA standard FY1997-2006 – 254

Inert ingredients reassessed – 870  
 tolerance exemptions for food use inert ingredients reassessed, including 135 revocations



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Over the past 10 years, EPA registered many new active ingredients and new uses of pesticides. These decisions met the strict safety standards of FQPA and provided critical alternatives to uses that were restricted or eliminated. With these lower-risk alternatives, America's shift to safer pesticides ensures that effective pest management tools are available to support production of an abundant, affordable, healthy food supply.

#### Cumulative Risk Assessment Decisions: Triazines, Organophosphates, Chloroacetanilides

FQPA directs EPA to consider available information on the cumulative effects on human health resulting from exposure to multiple pesticide chemicals that have a common mechanism of toxicity to ensure that there is a reasonable certainty of no harm for cumulative exposure to such pesticides.

**Triazines.** The Agency concluded that, with mitigation measures for atrazine and simazine, the cumulative exposure associated with the triazines meets the FQPA safety standard. The chlorinated triazines include atrazine, simazine, propazine, and their three chlorinated degradates. Atrazine and simazine are used on a variety of food and feed crops including grains, fruits, and nuts, as well as on turf grasses grown in the Southeastern United States. Propazine is registered for indoor greenhouse use only and has existing tolerances established for residues on sorghum. EPA looked at food, drinking water, and home lawn and golf course exposure where triazine residues are likely to co-occur (the Midwest, California, and Florida). No dietary, drinking water, or residential human exposure to propazine is anticipated from any of the currently registered uses.

**Organophosphates.** The Agency concluded that with mitigation measures put into place for more than 40 individual OP pesticides from risk management decisions completed during the past several years, the cumulative risks associated with the OPs are below FQPA regulatory levels of concern. EPA canceled several OP uses that contributed most significantly to dietary and residential risk, including the cancellation or phaseout of more than 50 uses on foods that make up a large part of children's diet. The OP class of pesticides now comprises 32 chemicals used primarily as insecticides on a wide variety of food and feed crops and for non-agricultural, residential, and other uses.

#### New Regulation Sets Rigorous Ethical and Scientific Standards for Human Studies with Pesticides

In January 2006, EPA issued a final rule, "Protections for Subjects in Human Research." This rule prohibits intentional dosing studies of pesticides on *all* children and *all* pregnant women. These prohibitions apply regardless of whether the studies are conducted by EPA, supported by EPA, or intended to be submitted by third parties to EPA under the pesticide laws. In addition, the final rule prohibits EPA in its actions under the pesticide laws from relying on any research—regardless of who conducted it, or where or why it was conducted—involving intentional exposure of pregnant women or children, except in a very narrowly defined circumstance when more stringent regulatory action would result.

Also, non-pregnant adult volunteers who choose to participate in human studies research will be protected by the highest level of ethical safeguards available. In June 2006, EPA issued a direct final rule that banned nursing women from participating in intentional dosing studies, thereby protecting infants who may be indirectly exposed to the pesticides being tested. In the January rule, EPA also extended the ethical protections in the Federal Policy for the Protection of Human Subjects of Research (the "Common Rule") to human research involving intentional exposure of non-pregnant adults to pesticides intended for submission to EPA under the pesticide laws. Human research studies must comply with these rules, and protocols and related information must be submitted to EPA before actual testing in order to ensure that safety standards are met.

An independent Human Studies Review Board (HSRB) has been established to provide independent advice and recommendations to EPA regarding both proposals for new research and completed third-party research—again regardless of who conducted it or where or why it was conducted—involving human subjects. Only after HSRB's rigorous reviews, will EPA decide whether or not to rely on a human study.

By establishing the new regulations, EPA can help prevent the conduct of human research that does not meet rigorous ethical and scientific standards and make clear that certain kinds of human research can never be ethically acceptable. <http://www.epa.gov/oppfead1/guidance/human-test.htm>

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**Chloroacetanilides.** The Agency concluded that the cumulative risk associated with the chloroacetanilides, acetochlor and alachlor, is below the Agency's level of concern. The chloroacetanilides can cause nasal tumors by the same sequence of major biochemical events. EPA also has evaluated the dietary (food and drinking water) human health risks associated with all currently registered uses of the herbicide acetochlor. The Agency has determined that there is a reasonable certainty that no harm will result from exposures to the pesticide from food and non-occupational sources, including drinking water, residential uses, and other non-occupational sources of pesticide exposure for which there is reliable information.

#### CORE PROGRAM SUCCESSES

The strength and consistency of our core program has made possible the sustained productivity and the achievement of risk reduction that has taken place over the past 10 years.

#### Rule Processing

In 2006, EPA proposed or completed several important regulations that form the basis for the Pesticide Program's work. These efforts in some cases are the culmination of many years of effort with stakeholders to ensure that up-to-date processes and protective procedures are in place.

**Standards for Pesticide Containers and Containment.** EPA published a final rule establishing standards for refillable and nonrefillable containers, including design specifications for rinsing, durability, and standardized closures. It requires pesticide labels to provide instructions on how to properly clean containers before disposal or recycling. The rule also establishes standards for secondary containment structures at certain agricultural storage sites and for containment pads at certain agricultural pesticide dispensing operations. EPA believes that as the industry follows these standards pesticide containers will be safely and effectively rinsed before recycling or disposal and large quantities of agricultural pesticides will be stored and transferred under conditions that prevent spills and releases of pesticides into the environment. Additional information about the rule and who is affected by the rule is available at <http://www.epa.gov/pesticides/regulating/containers.htm>.

**Registration Review.** EPA completed developing and began implementing a new rule that establishes a program to ensure that all pesticide registrations are systematically reviewed every 15 years. This program, called registration review, will ensure the protection of public health and the environment. The registration review program challenges EPA to continuously improve its processes, science, and information management while maintaining a collaborative and open process for decision-making. The program enables the Agency to systematically consider our knowledge about the uses and potential risks of each pesticide in light of advances in science and risk assessment methods and, if necessary, modify the pesticide's uses to ensure acceptable risks. EPA began its reviews of the first group of pesticides under this program in early 2007. Further information is available at [http://www.epa.gov/opsrrd1/registration\\_review/](http://www.epa.gov/opsrrd1/registration_review/).

#### International Accomplishments

The Pesticide Program's international program goals and activities directly support our mission through projects that lead to strengthening and accelerating public health and environmental protection, minimizing barriers, capturing efficiencies, and saving resources. For example, in 2006 the **North American Free Trade Agreement (NAFTA) project** completed 76 registrations under the Joint Review program (including 30 conventional, 29 reduced-risk, 4 minor-use, 10 microbial, and 2 pheromone pesticides). In addition, one import food use pesticide Maximum Residue Limit (MRL) was established, resulting in resource savings and efficiencies in program implementation. A NAFTA Label Task Force was created to promote consistency in labeling requirements for importing and exporting pesticides, which reduces barriers to trade.

**Codex Alimentarius.** If appropriate pesticide residue standards are not in place in export markets, the United States will not realize the full benefits of registration of new pesticides, since growers may hesitate to use them. MRLs for pesticides set by the Codex Alimentarius Commission are recognized as international food safety standards under trade agreements and used by many U. S. trading partners as food safety standards. Our agricultural producers who wish to export to countries that rely on Codex MRLs have been concerned about the length of time (up to eight years) it has taken in the past to establish MRLs for newer, often safer, pesticides.

EPA has been working to expedite this process for several years. In 2006, it was decided to make routine use of an already existing accelerated approval process for new MRLs. Criteria as to when the accelerated MRL approval process could be used were agreed to including no dietary risk concerns associated with an individual MRL and the availability of an assessment done from the Joint Meeting on Pesticide Residues. Using this approach, 207 MRLs for 13 pesticides were established in only 9 months. Codex also approved new criteria for determining the scheduling of pesticides to be reviewed and a new process for dealing with objections/concerns to advancing a Codex MRL through the stepwise approval process.















