Environmental Protection Agency

FY 2004 Annual Performance Plan and Congressional Justification

Safe Food

Strategic Goal: The foods Americans eat will be free from unsafe pesticide residues. Particular attention will be given to protecting subpopulations that may be more susceptible to adverse effects of pesticides or have higher dietary exposures to pesticide residues. These include children and people whose diets include large amounts of noncommercial foods.

Resource Summary
(Dollars in thousands)

	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Safe Food	**$113,098.3**	**$109,814.6**	**$119,011.5**	**$9,196.9**
Reduce Risks from Pesticide Residues in Food	$47,447.6	$45,290.4	$43,427.9	($1,862.5)
Eliminate Use on Food of Pesticides Not Meeting Standards	$65,650.7	$64,524.2	$75,583.6	$11,059.4
Total Workyears	781.3	770.1	785.0	14.9

Background and Context

The United States Environmental Protection Agency (EPA) plays a major role in the lives of the American public by ensuring that agricultural use of pesticides will not result in unsafe food. EPA accomplishes this by registering new pesticide products and reviewing older pesticide products by strict standards that protect human health and the environment from risks associated with pesticide use.

EPA uses the latest scientific information to ensure that there is "a reasonable certainty" that no harm will result to human health from all combined sources of exposure to pesticides (aggregate exposures). Moreover, it submits for review its critical risk assessment science issues, its methodologies for toxicity testing and related science issues, to the Science Advisory Panel (SAP), an independent, expert advisory committee. The SAP plays a critical role in EPA's decision-making process, assuring that decisions impacting health and the environment rely on sound science.

The potential risk of adverse effects to consumers from pesticide residues in foods is a primary concern for the Agency, as is the potential bioconcentration of certain pesticides in plant and animal tissues that may result in even higher levels of exposure. Critical to protecting human health is the review of food use pesticides for potential toxic effects such as birth defects, cancer, disruption of the endocrine system, changes in fertility, harmful effects to the kidneys

and liver, and nervous system bioaccumulation. Under Goal 3, the Safe Food goal, EPA ensures that any residues on food do not exceed established limits.

All pesticides are subject to EPA regulation including insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators, plant incorporated protectants and other substances intended to control pests. Pesticides are used in agriculture, greenhouses, on lawns, in swimming pools, industrial buildings, households, and in hospitals and food service establishments. The total United States pesticide usage in 1999 was 5 billion pounds.[1] Agriculture accounts for about 80 percent of all pesticide applications. Herbicides are the most widely used pesticides and account for the greatest expenditure and volume, approximately $6.4 billion and 534 million pounds in 1999. Biopesticides and reduced risk pesticides are assuming an increasingly important role. For example, safer pesticides, which include biopesticides and reduced risk pesticides, increased in use from 3.6% in 1998 to 7.5% of total pounds reported for 2002.[2]

EPA's Pesticide Regulations Affect a Cross Section of the US Population

- 18 major pesticide producers and another 100 smaller producers
- 2,200 formulators
- 33,100 commercial pest control firms
- 1.9 million farms
- Several million industry and government users
- About 77 million households

Source: EPA's 1998/1999 Pesticides Sales and Usage Report[1]

EPA regulates pesticides under two main statutes: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food and Drug Cosmetic Act (FFDCA). FIFRA requires pesticides to be registered (licensed) by EPA before they may be sold or distributed in the United States, and that they perform their intended functions without causing unreasonable adverse effects to people or the environment when used according to EPA-approved label directions. At the same time, recognizing the role of pesticides in ensuring a diverse, abundant and affordable food supply, EPA works to streamline its licensing procedures and increase transparency in the review process.

FFDCA authorizes EPA to set tolerances, or maximum legal limits, for pesticide residues in or on food. Tolerance requirements apply equally to domestically produced and imported food. Any food with residues not covered by a tolerance, or in amounts that exceed an established tolerance, may not be legally marketed in the United States.

Amendments to both FIFRA and FFDCA by the Food Quality Protection Act (FQPA) of 1996 enhance protection of children and other sensitive sub-populations. FQPA establishes a single, health-based safety standard for all pesticide residues. The agency-wide FY 2004 request supporting FQPA includes $150 million for EPA's work under these laws, enabling the public to enjoy one of the safest, most abundant, and most affordable food supplies in the world. FQPA also enhanced EPA's ability to protect human health and the environment in several other ways, including:

[1] Ibid.
[2] Doane Marketing Research, Inc.: http://www.doanemr.com

- **$** Providing for a more complete assessment of potential risks, with special protections for sensitive groups, such as infants and children;

- **$** Improvement of antimicrobial registration process and establishment of tolerances for food use inert ingredients;

- **$** Expediting the approval of reduced risk pesticides;

- **$** Encouraging farmers' adoption of safer pest management practices;

- **$** Ensuring that pesticides are periodically reassessed for consistency with current safety standards and the latest scientific and technological knowledge; and

- **$** Educating consumers about pesticide risks and benefits.

Means and Strategy

The Agency's strategy for accomplishing the objectives of Safe Food is based on five pillars, four of which are in Goal 3 and one is in Goal 4. Under Goal 3, the EPA is:

- Assuring that new chemicals and new uses are registered in accordance with the FQPA's strict standard, a "reasonable certainty of no harm," so that no harm will result to human health from exposure to pesticides;

- Assuring that pesticide maximum legally allowable tolerances for foods eaten by children are in conformance with FQPA requirements that protect children;

- Re-evaluating older, potentially higher-risk pesticides using the best current scientific data and methods to determine whether additional limits on a pesticides use are needed to provide reasonable certainty of no harm, especially for children and other sensitive populations; and

- Expediting review and registration of alternative pesticides that are less risky than pesticides currently in use and that may be substituted effectively for higher risk pesticides.

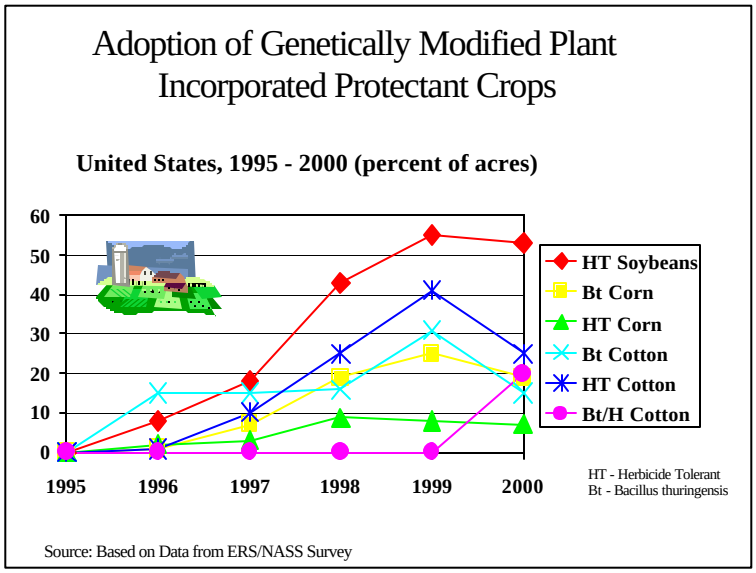
New registration actions result in more pesticides on the market that meet the strict FQPA pesticide risk-based standards, which brings the Agency closer to the objective of reducing adverse risks from pesticide use. In 2004, the Agency will continue to promote accelerated registrations for pesticides that provide improved risk reduction or risk prevention compared to those currently on the market. Progressively replacing older, higher-risk pesticides is one of the most effective methods for curtailing adverse impact on health and the ecosystem while preserving food production rates.

EPA uses its authorities to manage systematically the risks of pesticide exposures by establishing legally permissible food-borne pesticide residue levels, or tolerances. EPA defines

the legal use of pesticides, up to and including the elimination of pesticides that present a danger to human health and the environment. This task involves a comprehensive review of new and existing pesticides as stipulated by the FIFRA mandated registration and reregistration programs, as well as a comprehensive reassessment and update of existing tolerances within ten years, as required by FQPA. Requested resources include enhancing the efforts to review antimicrobials as well as inert ingredients, in order to meet the FQPA deadlines. In FY 2004, EPA will also increase support for the homeland security activities related to identifying antimicrobials that are effective against potential bio-agents that could be used against the United States

Tolerance reassessments may mean mandatory use changes because a revision in the allowable residue levels can involve changes in pesticide application patterns, changes in the foods the pesticides may be applied to, and other risk management methods. As measured by the number of tolerances that have been reassessed, the Agency's progress in the tolerance reassessment program directly serves the objective of reducing the use on food of pesticides that do not meet the new standards. EPA uses the latest scientific advances in health-risk assessment practices in its reviews. This includes the incorporation of new scientific data relating to the effects of endocrine disruption and the special needs of susceptible populations such as children and Native Americans.

Biotechnology has presented the Agency with a range of new issues and scientific challenges as well. Outreach activities on the subject of biotechnology such as public meetings and scientific peer reviews of our policies and assessments are likely to be expanded to keep pace with changing science and the public's demand for information in this area. EPA is working closely with other Federal agencies involved in biotechnology and is also actively involved in developing international standards for the regulation of biotechnology products.



Biotechnology is becoming increasingly more important in our economy with bio-engineered plants accounting for a larger share of acres planted than ever before in the United States. For example, in 1996, Herbicide Resistant (HT) Soybeans accounted for only eight percent of the total United States acres planted in soybeans. In 2000, HT Soybeans accounted for 53 percent of the acres planted for other crops. Trends also indicate increases, though not as dramatically as for soy. (See chart.)[3]

Adoption of biotechnology has great potential to reduce reliance on some older, more risky chemical pesticides, and to lower worker risks. For example, the use of Bt cotton has

[3] ERS/NASS Survey: http://www.usda.gov/nass

affected the use of other insecticides that present higher risk to wildlife. According to the reported number of insecticide treatments per planted acre of cotton, use of insecticides labeled either toxic or extremely toxic to wildlife has undergone significant reduction since 1995, with the extremely toxic pesticides decreasing from 1.6 to 0.5 acre treatments, a 68% reduction.

In addition to setting the requirements for continued legal use of agricultural pesticides, EPA works in partnership with USDA, FDA and the states toward the broader effort to prevent the misuse of pesticides. In the ever-changing environment of pesticide use, accessibility to information is a primary component of an effective strategy to inform the public on the appropriate, safe use of pesticides to minimize risk. More information about EPA's food safety efforts is available on the Agency's website at http://www.epa.gov/pesticides.

Research

Current approaches to human health risk assessment focus on single pesticides and do not adequately account for cumulative risks arising from complex exposure patterns and human variability due to age, gender, pre-existing disease, health and nutritional status, and genetic predisposition. The Food Quality Protection Act (FQPA) identifies clear science needs, including the evaluation of all potential routes and pathways of exposures to pesticides, and resulting health effects, particularly for sensitive sub-populations and considering effects from cumulative exposures.

To support the FQPA, tools are needed for assessing aggregate and cumulative risks across the exposure-to-dose-to-effects continuum that result from multimedia, multipathway exposures to pesticides with like mechanisms of action. Research is also needed to further understand the magnitude and extent of aggregate and cumulative exposures of pesticides used on food, in drinking water, and through non-occupational exposures in and around residential environments and other indoor/outdoor environments. Special emphasis will be placed on characterizing exposures and the corresponding critical factors influencing these exposures in those environments where young children spend the majority of their time.

Several mechanisms are in place to ensure a high-quality research program at EPA. The Research Strategies Advisory Committee (RSAC) of EPA's Science Advisory Board (SAB), an independent chartered Federal Advisory Committee Act (FACA) committee, meets annually to conduct an in-depth review and analysis of EPA's Science and Technology account. The RSAC provides its findings to the House Science Committee and sends a written report on the finding to EPA's Administrator after every annual review. Also, under the Science to Achieve Results (STAR) program all research projects are selected for funding through a rigorous competitive external peer review process designed to ensure that only the highest quality efforts receive funding support. In addition, EPA's scientific and technical work products must undergo either internal or external peer review, with major or significant products requiring external peer review. The Agency's Peer Review Handbook (2nd Edition) codifies procedures and guidance for conducting peer review.

Strategic Objectives and FY 2004 Annual Performance Goals

Highlights

Reduce Public Health Risk from Pesticide Residues

FFDCA and FIFRA authorize EPA to set terms and conditions of pesticide registration, marketing and use. EPA will use these authorities to reduce residues of pesticides with the highest potential to cause cancer or neurotoxic effects, including those which pose particular risks to children and other susceptible populations. All new pesticides, including food/feed-use pesticides are registered after an extensive review and evaluation of human health and ecosystem studies and data, applying the most recent scientific advances in risk assessment. The Registration program includes registration activities, such as setting tolerances, registering new active ingredients and new uses, and handling experimental use permits and emergency exemptions.

In 2004, the Agency will continue its efforts to decrease the risk the public faces from agricultural pesticides through the regulatory review of new pesticides, including reduced risk pesticides and biopesticides. EPA expedites the registration of reduced risk pesticides, which are generally presumed to pose lower risks to consumers, lower risks to agricultural workers, and lower risk to the earth's ozone layer, groundwater, aquatic organisms or wildlife. These accelerated pesticide reviews provide an incentive for industry to develop, register, and use lower risk pesticides. Additionally, the availability of these reduced risk pesticides provides alternatives to older, potentially more harmful products currently on the market.

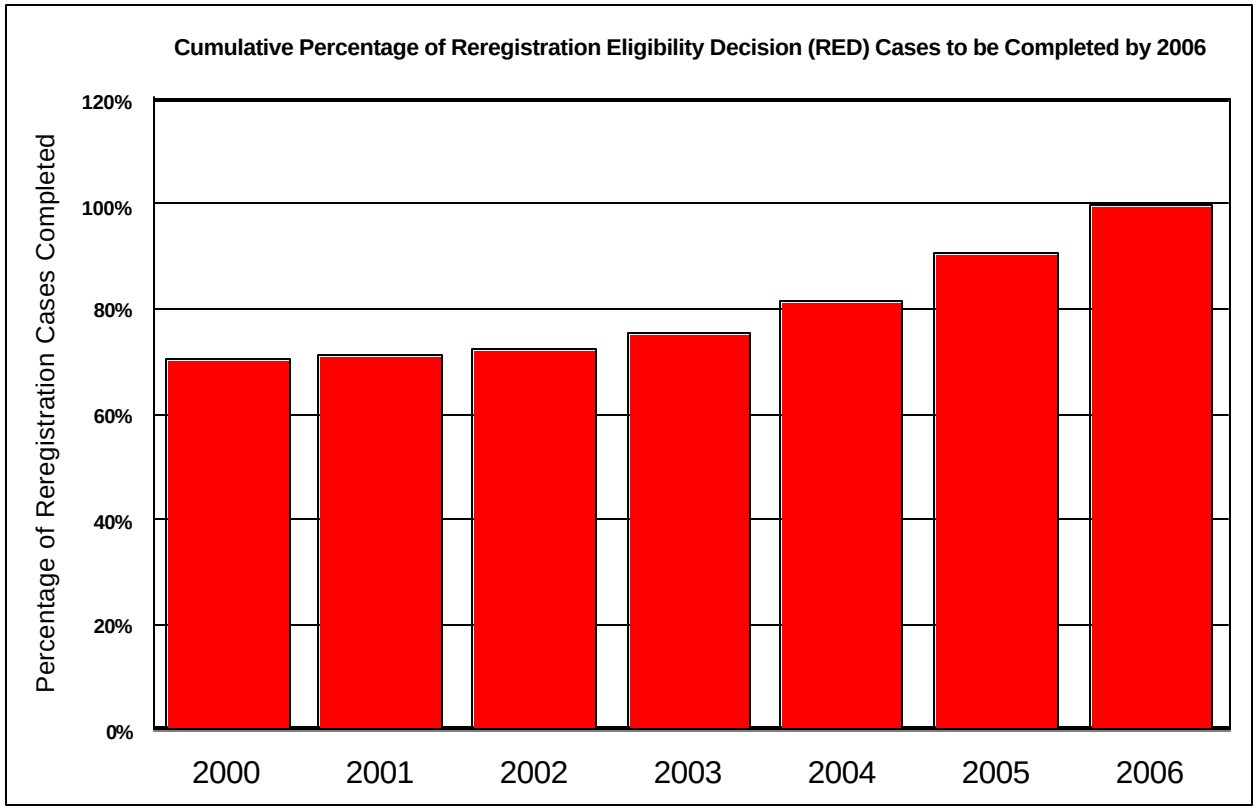
Reduce Use on Food of Pesticides Not Meeting Current Standards

Pesticide reregistration is a statutory requirement under the 1988 amendments to FIFRA. Under the law, all pesticides registered prior to November 1984 must be reviewed to ensure that they meet current health and safety standards. The 1996 Food Quality Protection Act requires the reassessment of pesticide tolerances by 2006. Many pesticides must be reviewed under both statutes. New program requirements and priorities include:

- review of inert ingredients;
- reform of the antimicrobial review process;
- transparency of our regulatory decisions;
- incorporation of aggregate and cumulative risk into our reviews;
- special protection for infants and children; and
- endocrine screening of pesticides, minor use enhancements and reduced risk registration emphasis.

In FY 2004, the Agency will continue its review of older pesticides and move forward toward its ten-year statutory deadline of reassessing all 9,721 tolerances, after having met the statutory deadline of reassessing a cumulative 66 percent of those tolerances by August 2002. The Agency will also continue to develop tools to screen pesticides for their potential to disrupt the endocrine system. In 2004, EPA will work toward completing 35 Reregistration Eligibility Decisions (REDs), 400 product reregistrations and 1050 tolerance reassessments.

The tolerance reassessment process addresses the highest-risk pesticides first. Using data surveys conducted by the USDA, the FDA and other sources, EPA has identified a group of "top 20" foods consumed by children and matched those with the tolerance reassessments required for pesticides used on those foods.[4] The Agency has begun to track its progress in determining appropriate tolerances for these pesticides under the new FQPA standards. In 2004, EPA will continue its effort to reduce dietary risks to children, by completing approximately a cumulative 83 percent of these tolerances of special concern.



Two widely used groups of pesticides, organophosphates and carbamates, are believed to pose higher risks, particularly to children. Curtailing or restricting the use of these pesticides will significantly change current farming practices that have relied upon them. These changes will likely mean adopting integrated pest management strategies that draw on cultural and biological, as well as mechanical and chemical techniques. With new strategies comes a steep learning curve on how to use them effectively. This transition requires broad input and participation by

[4] USDA Food Consumption Survey, 1989-1991; http://www.ers.usda.gov/epubs/pdp/sb965

stakeholders to minimize adverse, unintended consequences on agriculture, as well as pilot projects to field-test and demonstrate the new methods.

Through the Reregistration program, EPA reviews pesticides currently on the market to ensure they meet the latest health standards. Pesticides not in compliance with the new standards will be eliminated or restricted in order to minimize potentially harmful exposure. FQPA added considerably more complexity to the pesticide reregistration process, lengthening the "front end" of reregistration. These requirements include considering aggregate exposure and cumulative risk in our risk assessments, implementing new processes to increase involvement of pesticide users and other stakeholders, and ensuring a reasonable opportunity for agriculture to make the transition to new, safer pest control tools and practices. Over the longer run, these changes will enhance protection of human health and the environment. The Agency's progress in achieving goals for production of REDs and its tolerance reassessment component are summarized in the chart.

The FY 2004 President's Budget assumes the tolerance assessment and reassessment programs will be partially funded by fees to be collected under a revised Tolerance Fee rule. The FY 2004 request also includes a proposal to extend the Maintenance Fee through 2006, to provide stable funding for reregistration and expedited processing activities.

The Administration evaluated the Pesticide Registration and Reregistration Programs this past year using the Performance Assessment Rating Tool (PART). The evaluation found that both programs address important nationwide programs and have clear missions, however further work is needed in the area of performance measurement.

Research

In FY 2004, EPA's research program will continue to develop pesticides exposure and effects data, risk assessment methods and models for children, and control technologies needed to comply with the requirements of Food Quality Protection Act (FQPA).

Specifically, exposure research will develop new and enhance existing tools to estimate aggregate and cumulative exposures of young children to pesticides and other toxic chemicals. Research will address major data gaps and uncertainties associated with the exposure assessment requirements for the FQPA. Health effects research will focus on understanding dose-response relationships and using this understanding to develop new and enhance existing methods to evaluate the effects of cumulative exposures to pesticides and toxic chemicals, including both long-term exposures and multiple acute exposures.

Risk assessment research will complete a framework for use of toxicokinetic data and models in risk assessment as a foundation for comprehensive risk assessment guidance. The guidance will provide analysis and recommendations for: 1) use of physiologically-based pharmacokinetic (PBPK) models and data in risk assessment; 2) analysis of relevant issues such as age-related dosimetry and extrapolation between species and age groups; 3) databases relevant to toxicokinetic approaches; and 4) risk assessment methods that reduce the use of default assumptions. Risk management research will begin developing standard protocols for assessing treatment effects on pesticide residues in drinking water, and testing the efficiency of drinking

water treatment and the formation of degradation bi-products for pesticide classes of high priority that are not on the Candidate Contaminant List (CCL). Information collected from these protocols will be used in aggregate and cumulative exposure assessments.

External Factors

The ability of the Agency to achieve its strategic objectives depends on several factors over which the Agency has only partial control or little influence. EPA relies heavily on partnerships with states, tribes, local governments and regulated parties to protect the nation's food supply, the environment, and human health, from pesticides.

EPA assures the safe use of pesticides in coordination with the USDA and FDA, who have responsibility to monitor and control residues on food and other environmental exposures. EPA also works with these agencies to coordinate with other countries and international organizations with which the United States shares pesticide-related environmental goals. The Agency employs a number of mechanisms and programs to assure that our partners will have the capacity to conduct the activities needed to achieve the objectives. Much of the success of EPA's pesticide programs also depends on the voluntary cooperation of the private sector and the public.

Other factors that may delay or prevent the Agency's achievement of the objectives include lawsuits that delay or stop the planned activities of EPA and/or state partners, new or amended legislation and new commitments within the Administration. Economic growth and changes in producer and consumer behavior could also have an influence on the Agency's ability to achieve the objectives within the time frame specified.

Large-scale accidental releases, such as pesticide spills, or rare catastrophic natural events (such as hurricanes or large-scale flooding) could impact EPA's ability to achieve objectives in the short term. In the longer term, the time frame for achieving many of the objectives could be affected by new technology or unanticipated complexity or magnitude of pesticide-related problems.

Newly identified environmental problems and priorities could have a similar effect on long-term goals. For example, pesticide use is affected by unanticipated outbreaks of pest infestations and/or disease factors, which require EPA to review emergency uses in order to preclude unreasonable risks to the environment. While the Agency can provide incentives for the submission of registration actions such as reduced risk and minor uses, EPA does not control incoming requests for registration actions. As a result, the Agency's projection of regulatory workload is subject to change.

Environmental Protection Agency

FY 2004 Annual Performance Plan and Congressional Justification

Safe Food

Objective: Reduce Risks from Pesticide Residues in Food

By 2006, reduce public health risk from pesticide residues in food from pre-Food Quality Protection Act (FQPA) levels (pre-1996).

Resource Summary
(Dollars in Thousands)

	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Reduce Risks from Pesticide Residues in Food	**$47,447.6**	**$45,290.4**	**$43,427.9**	**($1,862.5)**
Environmental Program & Management	$45,091.3	$42,964.7	$40,504.6	($2,460.1)
Science & Technology	$2,356.3	$2,325.7	$2,923.3	$597.6
Total Workyears	332.6	331.1	339.5	8.4

Key Program
(Dollars in Thousands)

	FY 2002 Enacted	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Endocrine Disruptor Screening Program	$1,860.4	$2,096.3	$2,052.3	($44.0)
Facilities Infrastructure and Operations	$4,725.2	$4,462.6	$4,526.5	$63.9
Homeland Security-Critical Infrastructure Protection	$500.0	$0.0	$0.0	$0.0
Homeland Security-Preparedness, Response and Recovery	$0.0	$0.0	$1,218.3	$1,218.3
Legal Services	$1,019.7	$1,095.3	$1,143.6	$48.3
Management Services and Stewardship	$504.0	$420.6	$450.3	$29.7

	FY 2002 Enacted	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Pesticide Registration	$31,832.4	$30,882.2	$25,042.4	($5,839.8)
Pesticide Reregistration	$6,227.0	$5,673.4	$6,143.8	$470.4
Pesticide Residue Tolerance Reassessments	$813.3	$660.0	$2,806.2	$2,146.2
Planning and Resource Management	$0.0	$0.0	$44.5	$44.5
Safe Pesticide Applications	$25.0	$0.0	$0.0	$0.0

FY 2004 Request

This request highlights EPA's efforts to improve the safety of our food supply and continues emphasis on implementing FQPA, especially in the protection of infants and children. The Agency will expand partnerships with the United States Department of Agriculture (USDA), Food and Drug Administration (FDA) and other components of the Department of Health and Human Services (HHS), and with the international Organization for Economic and Cooperation Development (OECD) and others to engage and share information with stakeholders and to develop and facilitate the implementation of strategies for the public, industry and agriculture to conduct a smooth transition to safer pest management for food crops. EPA will continue to ensure that the best available science is incorporated into the implementation of the statute.

Pesticides currently on the market with approved food uses include some which are suspected human carcinogens, neurotoxins or endocrine disruptors and thus may pose significant health concerns, especially to children. FQPA provides unprecedented opportunities to protect human health and to positively impact agricultural production techniques, lessening the overall risk of pesticide use. FQPA further requires that the Agency review pesticides on a periodic basis to ensure that those registered for use meet the most current health standards. Through this registration review, FQPA ensures that when properly used, there is "a reasonable certainty of no harm" to human health or the environment. The review of existing pesticides through reregistration and tolerance reassessment combined with the availability of safer pesticides through registration continues to improve the risk picture for agriculture.

Registration Activities

Under the Registration program, EPA registers new pesticides after extensive review and evaluation of studies and data on human health and ecological effects. As part of the process, the Agency analyzes data and sets a tolerance level for each crop or crop grouping (use) the registrant requests for the specific pesticide. The tolerance level is the legal limit for how much pesticide may remain on a food. The Registration program gives priority to accelerated processing of reduced risk pesticides which may substitute for products already on the market, thus giving farmers and other users' new tools that are better for health and the environment.

There are many types of registration requests submitted by industry for EPA approval. These include requests for registration of new active ingredients, new pesticides that may simply be new formulations of ingredients already registered (me-toos), new uses that add a crop type to the approved uses of the registered pesticide and minor uses for low volume crops.[5]

The FY 2004 Agency request includes additional resources for the review of inert ingredients. FQPA also requires that EPA review inert ingredients added to pesticide products. These "inert" ingredients have no pesticidal properties; however, these agents are often chemically active and must be reviewed for unintended effects on humans and the environment. Increased public education and full ingredient disclosure (including inerts) on pesticide product labels must be balanced to protect confidential business information (CBI) from being disclosed. Under FQPA, the "reasonable certainty of no harm" safety standard applies to inert ingredients for establishing a tolerance or tolerance exemption.

Until recently, the Agency did not have an established methodology for the review of inerts. In March 2000, the Agency established a diverse workgroup with members from public health, environmental, industry, academic, and state government organizations to address measures to increase the availability of information about inerts to the public. The workgroup presented their proposed risk assessment methodology for inerts to the Pesticide Program Dialogue Committee (PPDC) in December 2001 which was published late in FY 2002. The methodology incorporates a sorting system that will greatly streamline the process which will help the Agency address the existing backlog.

Active and Inert Ingredients[6]

Pesticide products contain both "active" and "inert" ingredients. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has defined the terms "active ingredient" and "inert ingredient," since 1947. An active ingredient is one that prevents, destroys, repels or mitigates a pest, or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. By law, the active ingredient must be identified by name on the label together with its percentage by weight.

An inert ingredient is simply any ingredient in the product that is not intended to affect a target pest. For example, isopropyl alcohol may be an active ingredient and antimicrobial pesticide in some products; however, in other products, it is used as a solvent and may be considered an inert ingredient. The law does not require inert ingredients to be identified by name and percentage on the label, but the total percentage of such ingredients must be declared.

During the last several years, the Agency has engaged the public and the scientific community in developing and reviewing nine science policies that shape EPA's approach to screening pesticides. While all of the policies are significant, the requirements to consider cumulative and aggregate risk and the ten-fold safety factor for children's health have important ramifications for risk assessments of many chemicals.

Cumulative risk requires that EPA consider the combined effects of exposures to multiple chemicals sharing a common mechanism of toxicity. Aggregate exposure brings issues of residential exposures and drinking water residues into the equation. The extra ten-fold safety factor impacts risk assessments affecting children's health. A lower factor can be used, ". . . only if, on the basis of reliable data, such margin will be safe for infants and children."[7] In FY 2004, the Agency will continue applying its cumulative risk policy to pesticide registration and

[5] FIFRA Sec 3
[6] FIFRA Sec 2(a); FIFRA Sec 2(m)
[7] FFDCA Sec 408(b)(2)(C)

reregistration decisions. Research planned for FY 2004 will provide additional information on assessing and managing cumulative risks where appropriate, and the information will be used to enhance EPA's existing risk assessment policies.

EPA will continue to actively encourage and engage the pesticide industry, farmers and the public to participate in the implementation of FQPA. EPA uses common-sense strategies for reducing risk to acceptable levels while retaining pesticides of the greatest public value, including those employed in minor uses and integrated pest management needs. In FY 2004, EPA will continue to work with the pesticide industry and farmers to explore new pest management approaches and to provide a reasonable phase-out period for canceled pesticides. EPA will also continue its stakeholder consultation process through regular meetings with the Committee to Advise on Reassessment and Transition (CARAT), an advisory body composed of environmental/public interest groups; pesticide industry and trade associations; pesticide user, grower, processor and commodity organizations; public health organizations, including children's health representatives; Federal agencies; State, local and tribal governments; academia; consumers and the public.

States and industry submit requests for registration actions to meet rapidly changing or emerging needs, including petitions for temporary uses of pesticides to meet emergency conditions, and for research purposes. The Agency allows for the unpredictability of agricultural conditions and pest outbreaks and takes action to meet emerging needs. These actions include issuance of emergency exemptions under FIFRA sec. 18, which allows the use, for a limited time, of a pesticide not registered for that specific purpose. Emergency conditions could include controlling a new pest or the spread of a pest to new areas, or controlling an outbreak of a pest that poses a public health risk, such as the West Nile virus spread by migration. FIFRA addresses other special needs, including provisions to register products by states for specific local uses not Federally registered and provisions for experimental use permits (under FIFRA sec.5), which allow pesticide producers to test new pesticide uses outside the laboratory to generate information to apply for amendments to previously approved pesticides (e.g., to reflect label revisions or changed formulations for products already registered).

The Agency and USDA work collaboratively to ensure that minor use registrations receive appropriate support. EPA policy has defined minor uses as pesticide usage on crops grown on less than 300,000 acres. Minor crops account for about 40 percent of the total agricultural sales for the United States. Although minor use pesticides are of major significance in agricultural production and to growers and consumers, they produce relatively little revenue for their manufacturers, considering the cost of maintaining these registrations. Without these small-scale but vital pesticide uses, many of the fruits, vegetables, and ornamentals grown in the United States, worth billions of dollars, could not be produced successfully. In FY 2004, EPA and USDA will continue to work closely to meet the need for newer, reduced risk pesticides registered for minor uses. As needed, the Agency uses the data collected under USDA's Interregional Research Project No. 4 (IR-4) program to establish tolerances for minor uses and provides priority status for registrations for vulnerable crops and minor agricultural uses. IR-4 helps minor crop producers obtain tolerances and registrations for pest control products.

Bioengineered crops are playing an ever-increasing role in the agricultural marketplace. Each bioengineered product must be reviewed to ensure adequate safety to the public and

environment alike. As with any new technology, there is lively public and scientific debate of the best ways to incorporate the products into the market and the possible long-term implications for agriculture. EPA must keep abreast of new science and perform its traditional role of evaluating the types of organisms being used for the genetic modification, the stability of the genetic insert in the environment, and the potential exposures of workers and consumers to the biotechnology product. Other areas of concern include potential impacts on non-target organisms and the potential for pests to become resistant to the bioengineered product. The Agency will continue to work with industry and USDA on issues that arise from this major change in the agricultural industry.

The Plant Incorporated Protectant (PIP) Rule clarifies which genetically modified products are subject to review under FIFRA and FFDCA and which ones are exempt. The rule also reaffirmed that the plant itself is still subject to USDA authorities, while PIPs are subject to EPA authorities. The rule ensures that genetically engineered PIPs meet Federal safety standards that EPA evaluates PIPs as rigorously as traditional pesticide registrations. In addition to the rule, EPA participates in the White House Agricultural Biotechnology Workgroup and works closely with FDA and with USDA's Animal Plant Health Inspection Service (APHIS), which also regulates biotechnology products. The three agencies (EPA, USDA, and FDA) discuss all major actions on PIP's. There are several new products coming into the EPA for review that are likely to be decisions made in FY 2004.

The Agency plays a key role in international biotechnology programs concerned with food safety sponsored by the Organization for Economic Cooperation and Development (OECD), the United Nations (UN), and the European Union (EU). Biotechnology products include new chemicals and chemical preparations, which may be used in food and feed, as well as genetically modified foods. The Agency is working with OECD and other stakeholders to improve dissemination of information on biotechnology products, regulations, guidelines, and safety issues. The use of biotechnology to modify plants so that they resist harmful insects or the effects of herbicides is likely to attract continued public scrutiny, particularly on issues such as allergenicity and gene transfer.

Homeland Security

Biological agents are potential weapons that could be exploited by terrorists against the United States. EPA's pesticides antimicrobial program has been very responsive to the anthrax crisis, meeting rapid timeframes while maintaining the pace of longer-term reviews. However, the complexities associated with the assessment and remediation work on anthrax, when dispersed as a weapon of terror, dramatically highlight the need for the Agency to improve its ability in detection and decontamination of biological agents. EPA proposes to conduct comprehensive scientific assessments of potential biological agents, develop test protocols to determine the safety and efficacy of antimicrobial products used against biological agents, and register new products or new uses of existing products as necessary. EPA will develop a timeline for prioritizing and implementing tests on technologies and products.

Using the Center for Disease Control's (CDC) category list of possible bio-agents as a starting point, the Agency proposes reviewing antimicrobials that may be effective against bio-agents in addition to anthrax. Based on experience with anthrax, reviews for other bio-agents

would require development of new models and protocols for defining a reasonable standard of efficacy, including determination if substantially different pathways and media for potential contamination should be addressed. The number of products whose efficacy is verified with new models and protocols, both new active ingredients and new uses, will vary depending on the organism in question but is likely to be fewer per bio-agent than for anthrax, which involved 37 products.

Reduced Risk Chemicals and Biopesticides

In FY 2004, EPA will continue to provide incentives to the pesticide industry to decrease risk levels from agricultural pesticides through the expedited regulatory review of reduced risk pesticides, including biopesticides. Reduced risk criteria include pesticides with reduced toxicity, potential to displace other chemicals posing potential human health concerns, reduced exposure to workers, low toxicity to non-target organisms, low potential for groundwater contamination, lower use rates than alternatives, low pest resistance potential, or high compatibility with integrated pest management and efficacy. The Agency is committed to expediting the registration of additional alternative products and in FY 2004, expects to register 13 new reduced risk pesticides.[8]

Reducing Risky Pesticides on Children's Foods

The following 19 foods that children commonly eat were surveyed for organophosphate and carbamate pesticides during 1994 through 1996: apples, apple juice, bananas, broccoli, carrots, celery, grapes, green beans (fresh, canned and frozen), lettuce, milk, oranges, peaches, potatoes, spinach, sweet corn (canned and frozen), sweet peas (canned and frozen), sweet potatoes, tomatoes, and wheat. By the end of 2004, regulatory actions by EPA, including expedited registration of safer pesticides, should result in a 25 percent reduction of occurrence of residues from carcinogenic and neurotoxic pesticides on these foods from 1994-1996 levels.

Reduce Agricultural Use of Potential Carcinogenic or Neurotoxic Pesticides

EPA is moving deliberately to minimize exposure from currently marketed pesticides with the highest potential to cause cancer or neurotoxic effects. In FY 2004, using the best available science and incorporating stakeholder concerns, EPA will continue to reduce risk from these pesticides through implementation of our decisions in the field, encouraging development of alternatives, and the expedited registration of alternatives. The Agency is especially conscious of the potential impacts on minor crop growers and integrated pest management programs and will continue to work with growers and registrants to focus attention on those situations where limited crop protection alternatives exist. FQPA emphasizes the need to protect children from adverse effects of pesticide exposure. EPA is targeting pesticides used on the foods children commonly eat. Through its regulatory efforts, EPA will contribute to reducing detections from pre-FQPA levels (see box). Also, as part of EPA's ongoing efforts to collect and analyze data to support improved performance measures, the Office of Pesticide Programs has begun examining and tracking pesticide sales and usage data in more detail.

[8] USDA PDP, http://www.ams.usda.gov/science/pdp/download.htm

Overall pesticide use appears to be declining as well, based on estimates derived from sales figures, which show about a 15 percent decline between 1985 and 1999. Insecticides as a class tend to be acutely toxic pesticides, and their use is also declining. Acre-treatments using pesticides labeled 'danger for humans' has gone down by 43 percent between 1997 and 2001. [9]

FY 2004 Change from FY 2003 Request

EPM

- (+$718,300, +2.0 FTE) This increase supports the registration of bio-agents and other products used against weapons of mass destruction. Resources will also be used to identify technologies and products to be tested for safety and efficacy.

- (+$2,146,200) This increase reflects additional support for the Tolerance Reassessment Program.

- (-$5,975,600, -66.5 FTE) Revenues from Pesticide Tolerance Fees will be substituted for appropriated funds in the Registration program. In addition, there are some funding realignments across objectives to more accurately portray our costs for the reregistration program.

S&T

- (+$500,000) This increase will support laboratory improvements and development of test protocols to determine the safety and efficacy of products used against chemical and biological weapons.

- There are additional increases for payroll, cost of living, and enrichment for new and existing FTE.

GOAL: SAFE FOOD

OBJECTIVE: REDUCE RISKS FROM PESTICIDE RESIDUES IN FOOD

Annual Performance Goals and Measures

Decrease Risk from Agricultural Pesticides

In 2004	Decrease adverse risk from agricultural uses from 1995 levels.
In 2003	Decrease adverse risk from agricultural uses from 1995 levels and assure that new pesticides that enter the market are safe for humans and the environment, through ensuring that all registration action are timely and comply with standards mandated by law.
In 2002	In FY 2002, EPA continued to register pest control products, including "safer" pesticides, thus ensuring that growers have an adequate number of pest control options available to them.

[9] EPA Pesticides Industry Sales and Usage 1998 and 1999 Market Estimates, August 2002, http://www.epa.gov/oppbead1/pestsales

Performance Measures:	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	
Register safer chemicals and biopesticides	107	118	131	Regist. (Cum)
New Chemicals	60	67	74	Regist. (Cum)
New Uses	2329	2679	3,079	Actions (Cum)
Reduction of detections on a core set of 19 foods eaten by children relative to detection levels for those foods reported in 1994-1996.	Data Not Avail			Reduced Detect.
Percentage of acre-treatments with reduced risk pesticides	7.5%	8.1%	8.5%	Acre-Treatments
Occurrences of residues on a core set of 19 foods eaten by children relative to occurrence levels for those foods reported in 1994-1996.		20	25%	reduc. of occur
Number of new uses for previously registered antimicrobial products			8	new uses

Baseline: The baseline for registration of reduced risk pesticides, new chemicals, and new uses, the baseline is zero in the year 1996 (the year FQPA was enacted). Progress is measured cumulatively since 1996. The baseline for acres-treated is 3.6% of total acreage in 1998, when the reduced-risk pesticide acres-treatments was 30,332,499 and total (all pesticides) was 843,063,644 acre-treatments. Each year's total acre-treatments, reported by USDA's National Agricultural Statistical Survey serve as the basis for computing the percentage of acre-treatments using reduced risk pesticides. Acre-treatments count the total number of pesticide treatments each acre receives each year. The baseline for residues on children's foods is occurrence on 33.5% of composite sample of children's foods in the baseline years 1994-1996. There are currently no products registered for use against other potential bio-agents (non-anthrax).

Baseline: There are currently no products registered for use against other potential bio-agents (non-anthrax).

Program Assessment Rating Tool

Pesticide Registration

As part of the Administration's overall evaluation of effectiveness of Government programs, the Pesticide Registration program was evaluated with the following specific findings:

1. The program has a clear mission and statutory authority, and it provides for the safe use of pesticides on a nationwide basis.

2. The program has established long-term goals but they are not adequate because the goals lack quantified baselines and/or performance targets and they need to be more outcome-focused.

3. The program regularly reviews overall progress toward annual goals and does make management decisions to address issues that impede progress.

4. The program does not use efficiency or cost effectiveness metrics to monitor program management or performance.

5. Generally the program has met its annual goals but it is unclear how achieving these annual targets leads to quantifiable progress toward the program's long-term goals. One new long-term efficiency goal that targets reductions in decision-making time has been proposed for this program by EPA, but further work is needed to finalize the goal and to develop appropriate annual targets to support it.

In response to these findings the Administration will:

1. Implement appropriate long-term measures.

2. Develop adequate efficiency and cost effectiveness measures to improve program performance and goal-setting.

Verification and Validation of Performance Measures

FY 2004 Performance Measure: Reduction in occurrences of carcinogenic and cholinesterase-inhibiting neurotoxic pesticide residues on a core set of 19 children's foods reported in 1994-1996

Performance Database: United States Department of Agriculture (USDA) Pesticide Data Program (PDP)

Data Source: Data collection is conducted by the states.

Methods, Assumptions and Suitability: The information is collected by the states and includes statistical information on pesticide use, food consumption, and residue detections, which provide the basis for realistic dietary risk assessments and evaluation of pesticide tolerance. Information is coordinated by USDA agencies and cooperating state agencies. Pesticide residue sampling and testing procedures are managed by USDA's Agricultural Marketing Service (AMS). AMS also maintains an automated information system for pesticide residue data and publishes annual summaries of residue detections.

QA/QC Procedures: The core of USDA's PDP's QA/QC program is Standard Operating Procedures (SOPs) based on EPA's Good Laboratory Practices. At each participating laboratory, PDP relies on a quality assurance (QA) unit which operates independently from the rest of the laboratory staff. Final QA procedures are provided by PDP staff responsible for collating and reviewing data for conformance with SOPs. PDP staff also monitors the performance of participating laboratories through proficiency evaluation samples, quality assurance internal reviews, and on site visits.

Data Quality Review: None

Data Limitations: Participation in PDP sites is voluntary. Sampling is limited to 10 states but designed in a manner to represent the food supply nationwide. The number of sampling sites and volume vary by state. Sampling procedures are described at the website, see reference below.

Error Estimate: Uncertainties and other sources of error are minor and not expected to have any significant effect on performance assessment. More information is available on the website.

New/Improved Data or Systems: These are not EPA data; thus improvements are not known in any detail at this time.

References: PDP Annual Reports, http://www.ams.usda.gov/science/pdp/download.htm; http://www.ams.usda.gov/process/; CFR 40 Part 160; http://www.epahome/Standards.html

FY 2004 Performance Measures: Number of registrations of reduced risk pesticides registered (Register safer chemicals and biopesticides).

- **Number of new conventional pesticides registered (New Chemicals).**

- **Number of conventional new uses registered (New Uses).**

Performance Database: Pesticide Regulatory Action Tracking System (PRATS). PRATS is maintained by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) and is designed to track regulatory data submissions and studies, organized by scientific discipline, which are submitted by the registrant in support of a pesticide's registration. Additionally, the program divisions maintain manual counts of the registrations of reduced risk pesticides. The information is provided to the Office Director's immediate office for consolidation and record keeping.

Data Source: The Office of Pesticide Programs (OPP) Staff (reviewers) update the status of the submissions and studies as they are received and as work is completed by the reviewers. The status indicates whether the application is ready for review, the application is in the process of review, or the review has been completed.

Methods, Assumptions and Suitability:
The measures are program outputs. When finalized they represent the program's statutory requirements to ensure: 1) that pesticides entering the marketplace are safe for human health and the environment and 2) when used in accordance with the packaging label present a reasonable certainty of no harm. While program outputs are not the best measures of risk reduction, they do provide a means for reducing risk in that the program's safety review prevents dangerous pesticides from entering the marketplace.

QA/QC Procedures: A reduced risk pesticide must meet the criteria set forth in Pesticide Registration Notice 97-3, September 4, 1997. Reduced risk pesticides include those which reduce the risks to human health; reduce the risks to non-target organisms; reduce the potential for contamination of groundwater, surface water or other valued environmental resources; and/or broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective. In addition, biopesticides are generally considered safer (and thus reduced risk). All registration actions must employ sound science and meet the Food Quality Protection Act (FQPA) new safety standard. All risk assessments are subject to public and scientific peer review.

Data Quality Review: These are program outputs. EPA staff and management review the program outputs in accordance with established policy for the registration of reduced-risk pesticides as set forth in Pesticide Regulation Notice 97-3, September 4, 1997.

Data Limitations: None. All required data must be submitted for the risk assessments before the pesticide, including a reduced risk pesticide, is registered. If data are not submitted, the

pesticide is not registered. As stated above, a reduced risk pesticide must meet the criteria set forth in PRN 97-3 and all registrations must meet FQPA safety requirements. If a pesticide does not meet these criteria, it is not registered. If an application for a reduced risk pesticide does not meet the reduced risk criteria, it is reviewed as a conventional active ingredient.

Error Estimate: N/A

New/Improved Data or Systems: The OPPIN (Office of Pesticide Programs Information Network) consolidates various OPP program databases. Phased implementation of the OPPIN began in FY 2001 and will continue through FY 2003, after which the system will be reevaluated to ensure that it is meeting program needs.

References: FIFRA Sec 3(c)(5); FFDCA Sec 408(a)(2); EPA Pesticide Registration Notice 97-3, September 4, 1997

FY 2004 Performance Measure: Percentage of acre treatments with reduced risk pesticides.

Performance Database: Two non-EPA databases are used for this measure. One is the Doane Marketing Research data, the other is the United States Department of Agriculture's (USDA) National Agricultural Statistical Survey (NASS) database.

Data Source: Doane Marketing Research (a private sector research database) and USDA surveys (e.g., NASS data).

Methods, Assumptions and Suitability: A reduced-risk pesticide must meet the criteria set forth in Pesticide Registration Notice 97-3, September 4, 1997. Reduced-risk pesticides include those which reduce the risks to human health; reduce the risks to non-target organisms; reduce the potential for contamination of groundwater, surface water, or other valued environmental resources; and/or broaden the adoption of integrated pest management strategies or make such strategies more available or more effective. In addition, biopesticides are generally considered safer (and thus reduced-risk).

EPA's statistical and economics staff review data from Doane and NASS. Information is also compared to prior years for variations and trends as well as to determine the reasons for the variability.

QA/QC Procedures: All registration actions must employ sound science and meet the Food Quality Protection Act (FQPA) new safety standard. All risk assessments are subject to public and scientific peer review. Doane data and USDA's NASS data are subject to extensive QA/QC procedures, documented at their websites. Additionally, Doane and NASS information are compared as a cross-reference.

Data Quality Review: Doane data and USDA's NASS data are subject to extensive internal quality review, documented at their websites. EPA's statistical and economics staff review data from Doane and NASS. Information is also compared to prior years for variations and trends as well as to determine the reasons for the variability.

Data Limitations: Doane data are proprietary; thus in order to release any detailed information, the Agency must obtain approval. The NASS data include only major crops for annual surveys. Other crops are surveyed biennially. Additionally, all states are not included, although those that are a representative sample of the nation.

New/Improved Data or Systems: These are not EPA databases; thus improvements are not known in any detail at this time.

Error Estimate: Error estimates differ according to the data/database and year of sampling. Doane sampling plans and QA/QC procedures are available to the public at their website. More specific information about the data is proprietary and a subscription fee is required. Data are weighted and multiple regression procedure is used to adjust for known disproportionalities and ensure consistency with USDA and state acreage estimates. NASS data reliability and sampling/estimating techniques also are discussed at their website.

References: OPP Website; OPP Annual Report; Annual Performance Plan and Annual Performance Report, http://www.ams.usda.gov/science/pdp/download.htm; Doane Marketing Research, Inc.: http://www.doanemr.com; http://www.usda.gov/nass/pubs and http://www.usda.nass/nass/nassinfo; FFDCA Sec 408(a)(2); EPA Pesticide Registration Notice 97-3, September 4, 1997.

Coordination with Other Agencies

EPA coordinates with and uses information from a variety of Federal, state and international organizations and agencies in our efforts to protect the safety of America's food supply from hazardous or higher risk pesticides.

In May 1991, the United States Department of Agriculture (USDA) implemented the Pesticide Data Program (PDP) to collect objective and statistically reliable data on pesticide residues on food commodities. This action was in response to public concern about the effects of pesticides on human health and environmental quality. EPA uses PDP data to improve dietary risk assessment to support the registration of pesticides for minor crop uses.

PDP is critical to implementing the Food Quality Protection Act. The system provides improved data collection of pesticide residues, standardized analytical and reporting methods, and increased sampling of foods most likely consumed by infants and children. PDP sampling, residue, testing and data reporting are coordinated by the Agricultural Marketing Service using cooperative agreements with ten participating states representing all regions of the country. PDP serves as a showcase for Federal-State cooperation on pesticide and food safety issues.

FQPA requires EPA to consult with other government agencies on major decisions. Further, EPA, USDA and FDA work closely together using both a memorandum of understanding and working committees to deal with a variety of issues that affect the involved agencies' missions. For example, these agencies work together on residue testing programs and on enforcement actions that involve pesticide residues on food, and we coordinate our review of antimicrobial pesticides.

While EPA is responsible for making registration and tolerance decisions, the Agency relies on others to carry out some of the enforcement activities. Registration-related requirements under FIFRA are enforced by the states. The Department of Health and Human Services/Food and Drug Administration enforce tolerances for most foods and by the United States Department of Agriculture/Food Safety and Inspection Service for meat, poultry and some egg products.

Internationally, the Agency collaborates with the Intergovernmental Forum on Chemical Safety (IFCS), the CODEX Alimentarius Commission, the North American Commission on Environmental Cooperation (NACEC), the Organization for Economic Cooperation and Development (OECD) and the North American Free Trade Agreement (NAFTA) commission to coordinate policies, harmonize guidelines, share information, correct deficiencies, build other nations' capacity to reduce risk, develop strategies to deal with potentially harmful pesticides and develop greater confidence in the safety of the food supply.

One of the Agency's most valuable partners on pesticide issues is the Pesticide Program Dialogue Committee (PPDC), which brings together a broad cross-section of knowledgeable individuals from organizations representing divergent views to discuss pesticide regulatory, policy and implementation issues. The PPDC consists of members from industry/trade associations, pesticide user and commodity groups, consumer and environmental/public interest groups and others.

The PPDC provides a structured environment for meaningful information exchanges and consensus building discussions, keeping the public involved in decisions that affect them. Dialogue with outside groups is essential if the Agency is to remain responsive to the needs of the affected public, growers and industry organizations.

EPA relies on data from HHS to help assess the risk of pesticides to children. Other collaborative efforts that go beyond our reliance on the data they collect include developing and validating methods to analyze domestic and imported food samples for organophosphates, carcinogens, neurotoxins and other chemicals of concern. These joint efforts protect Americans from unhealthful pesticide residue levels.

The Agency will work with the full range of stakeholders: USDA, CDC, other Federal agencies, industry and the scientific community. Review of the agents that may be effective against anthrax has involved GSA, State Department, USAMRIID, FDA, CDC, EOSA, USPS, and others, and this effort will build on this network.

Statutory Authorities

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Federal Food, Drug and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) of 1996

Environmental Protection Agency

FY 2004 Annual Performance Plan and Congressional Justification

Safe Food

Objective: Eliminate Use on Food of Pesticides Not Meeting Standards

By 2008, use on food of current pesticides that do not meet the new statutory standard of "reasonable certainty of no harm" will be eliminated.

Resource Summary
(Dollars in Thousands)

	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Eliminate Use on Food of Pesticides Not Meeting Standards	**$65,650.7**	**$64,524.2**	**$75,583.6**	**$11,059.4**
Environmental Program & Management	$53,660.0	$52,478.3	$62,288.6	$9,810.3
Science & Technology	$11,990.7	$12,045.9	$13,295.0	$1,249.1
Total Workyears	448.7	439.0	445.5	6.5

Key Program
(Dollars in Thousands)

	FY 2002 Enacted	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Endocrine Disruptor Screening Program	$3,388.7	$3,264.1	$3,275.1	$11.0
Facilities Infrastructure and Operations	$4,575.2	$5,154.0	$6,311.8	$1,157.8
Homeland Security-Critical Infrastructure Protection	$500.0	$0.0	$0.0	$0.0
Homeland Security-Preparedness, Response and Recovery	$14.0	$0.0	$0.0	$0.0
Legal Services	$433.5	$465.5	$486.0	$20.5
Management Services and	$931.5	$854.6	$904.6	$50.0

	FY 2002 Enacted	FY 2003 Pres. Bud.	FY 2004 Request	FY 2004 Req. v. FY 2003 Pres Bud
Stewardship				
Pesticide Reregistration	$27,170.8	$38,592.4	$41,207.7	$2,615.3
Pesticide Residue Tolerance Reassessments	$13,858.5	$4,607.9	$10,004.3	$5,396.4
Planning and Resource Management	$0.0	$0.0	$46.0	$46.0
Research to Support FQPA	$11,377.4	$10,821.3	$12,041.9	$1,220.6
Science Coordination and Policy	$315.1	$764.4	$1,306.2	$541.8

FY 2004 Request

Pesticides licensing involves both registration of new chemicals and the review of older chemicals.[10] This objective focuses on the review of older pesticides as well as some of the scientific effort involved in identifying potential endocrine disrupting chemicals. The reregistration and the tolerance reassessment programs look at older pesticides and review their safety in light of the latest science and the new safety standards mandated by FQPA.

During the Reregistration and the Tolerance Reassessment processes, EPA reviews data and studies submitted by registrants supporting the reregistration or the approved use on food of a pesticide in order to ensure that pesticides meet FQPA's stricter standards. During this review, the Agency conducts a risk assessment that forms the basis for the Agency's decisions and determines the safe residue that may remain on the food product (a tolerance) for a food use pesticide. Risk assessments involve a series of sophisticated analyses of the potential health and environmental effects resulting from exposure to a chemical through various means. FQPA brought a number of new analyses into these risk assessments.

Complete Active Ingredient and Product Reregistration

Through the Reregistration program, EPA will continue to review pesticides currently on the market to ensure that these also meet the FQPA health standard. Pesticides found not in compliance will be eliminated or otherwise restricted to minimize harmful exposure. The issuance of a Reregistration Eligibility Decision (RED) summarizes the health and environmental effects findings during the reregistration review of the chemical. These findings determine whether the products registered under this chemical are eligible for reregistration. In 2004, the Agency will complete 35 REDs. EPA plans to complete issuing REDs for active ingredients by FY 2006 and for inert ingredients by FY 2008.

Once the reregistration or tolerance reassessment analysis is performed, findings may call for modifications in ways the pesticides are used, in order to reduce risks. Options for risk

[10] FIFRA Sec 3; FIFRA Sec 4 (i) (5)

reduction range from revocation of the tolerance to modifications in use such as re-entry intervals or application rates. For example, the pesticide could be applied in lower quantities, or less frequently, or at a greater distance from water bodies.

The FY 2004 request includes additional resources for reregistration of antimicrobials. EPA has made great strides in addressing FQPA requirements and incorporating them into its core programs. The Agency has met much shorter review periods for antimicrobials and virtually eliminated the backlog in this area, however, success in these and other areas has meant some trade-offs were necessary. Further, antimicrobials are different from other pesticides in that science issues, uses, constituencies and stakeholders differ from agricultural pesticides. Use patterns such as wood preservatives and antifouling paints have raised public health and environmental concerns. Also, for many antimicrobial products, (e.g., hospital disinfectants, swimming pool disinfectants, medical waste treatment products), product performance, i.e., efficacy, is an area where the Agency plays a major regulatory role. These differences mean it is difficult to leverage work on other pesticides to help make progress with antimicrobials. These new resources will support the antimicrobial tolerance reassessments required to meet the FQPA deadline for completing tolerance reassessments by August 2006 and for maintaining the established goal for reregistration.[11]

Additional resources are also required for inert ingredients. There are 870 tolerance exemptions for pesticide inerts that must be reassessed as part of meeting the FQPA statutory deadline for completing tolerance reassessment by August 2006. There is no defined database for inert ingredients and new methods for evaluating inerts have had to be developed. EPA has developed an initial methodology for sorting the inerts to be reviewed and identified those for which no data exists. EPA is largely unable to process tolerances or tolerance exemptions for those inert ingredients unless there is a data base substantially similar to that of an active ingredient, but is examining other analytic methods. The proposed resources also will allow the application in FY 2004 of streamlined methods that were recently proposed for assessing the lower toxicity pesticide chemicals. In FY 2004, EPA will evaluate 100 of the existing 870 tolerance exemptions. Review of inert ingredients is crucial because these ingredients are sometimes more toxic than the active ingredients.

The FY 2004 President's Budget assumes the tolerance assessment and reassessment programs will be partially funded by fees to be collected under a revised Tolerance Fee rule. The FY 2004 request also includes a proposal to extend the Maintenance Fee through 2006, to provide stable funding for reregistration and expedited processing activities.

Registration Review

FQPA requires that EPA establish a process for periodic review of pesticide registrations with a goal of completing this process every 15 years. The registrations of all pesticides will be continuously updated with respect to current scientific data, risk assessment methodologies, program policies, and effective risk reduction measures, ensuring that they meet the most current health standards. In 2004, EPA will address comments on the proposed rule, develop final procedural regulations, and continue preparations to implement the new program.

[11] FIFRA Sec 4 (i) (5)

Implementation tasks include establishing and prioritizing registration review cases, developing internal procedures for conducting the program, developing information management procedures, and training staff on the objectives and procedures. As the reregistration program draws to a close, the new registration review program will continue to protect human health and the environment using the most current scientific standards. There are also provisions in FQPA that mandate ongoing review of certain tolerances, on a five year cycle, following the full reassessment process.

Reassessment of Existing Pesticide Residue Tolerances on Food

A tolerance is the maximum legal amount of a pesticide residue permissible on food. FQPA requires that EPA reassess within ten years the more than 9,721 pesticide tolerances existing in 1996. EPA met its second statutory deadline to complete reassessment of 66 percent of the existing tolerances by August 2002. The final tolerance reassessment deadline requires reassessment of 100 percent of these tolerances by August 2006. In FY 2004, the Agency will continue its reassessment of these tolerances completing approximately a cumulative 78 percent.

The risk assessment is the basis for decision-making on reregistration and tolerance reassessment and includes consideration of the amounts and types of food people eat and how widely the pesticide is used (that is, how much of the crop is actually treated with the pesticide). The risk assessment also includes chemistry, toxicity and exposure information. EPA obtains data from a wide variety of sources including USDA surveys on types and quantities of foods people eat, FDA residue monitoring, and United States Geological Survey information on pesticide levels in ground, surface and drinking water. The risk assessment and adjunct analyses determine the outcomes for the tolerances on food. FQPA requires new assessment analyses, looking at both aggregate risk and cumulative exposures to pesticides with a common mechanism of toxicity. Draft risk assessments go through both scientific peer review and a public review process. The science and policies behind these assessments is complex and the standards developed will impact many pesticides on the market. In particular, the cumulative risk policy, which will impact chemical groups of pesticides such as organophosphates and carbamates, was completed late in 2002, and full implementation will occur in FY 2003 and FY 2004. As new research results are obtained, EPA will update and enhance the existing cumulative risk policy as appropriate to make sure risk assessments maintain pace with advancing science.

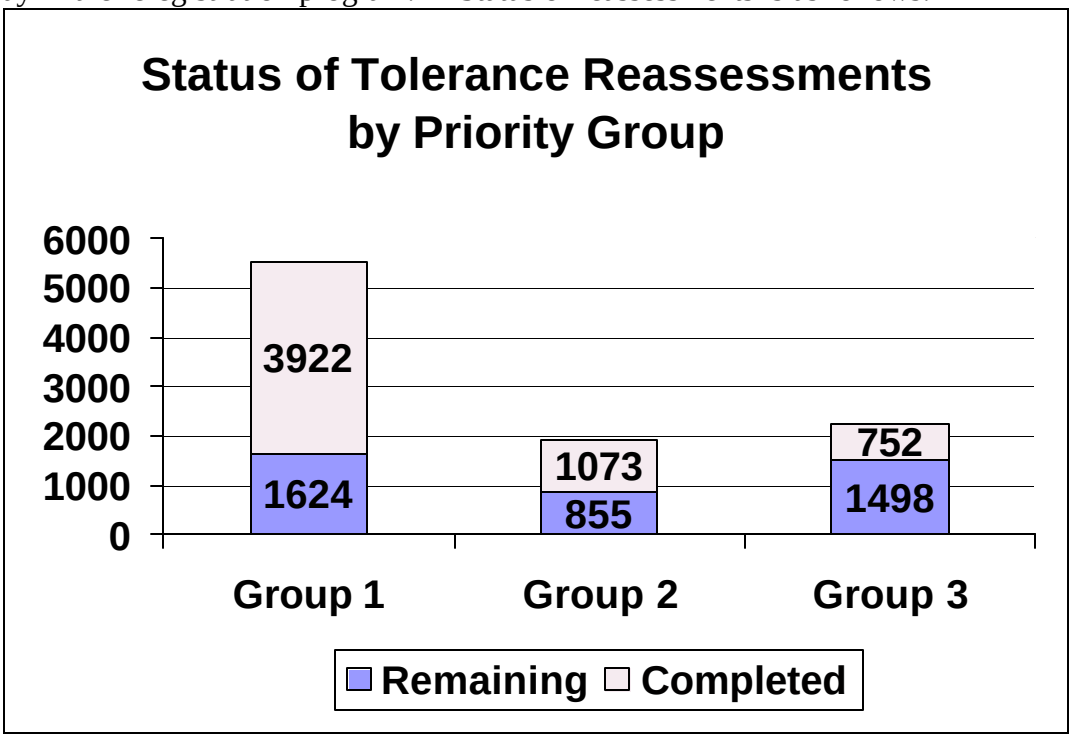
As mandated by FQPA, the Agency continues to ensure that sound science is applied consistently in our pesticide reviews and also that this process includes stakeholder and scientific community input to discuss the policies and their impacts. The Agency has worked extensively with stakeholders through the Pesticide Program Dialogue Committee (PPDC) and the Committee to Advise on Reassessment and Transition (CARAT) to ensure transparency in decision-making and a fuller understanding of the implications for growers, producers and the public. EPA will continue to encourage transition to safer pesticides, and to coordinate closely with USDA, industry and commodity groups in finding alternatives and sharing information.

The cumulative risk policy is expected to impact the decisions on many older, less expensive pesticides, affecting farmers' available choices. As an example, the Agency is completing review of a group of higher risk pesticides, the organophosphates, which, because of

their wide use, heavily affect the farming community. In FY 2004, the Agency expects to review the carbamates, among other chemicals. Carbamates are a broad-spectrum, older (less expensive) class of pesticides, including many insecticides that are also often used for mosquito control. To address the issues around replacement and review of these widely used pesticides, the Agency and USDA collaborated in development and implementation of a review process, which greatly expanded public participation. In 2004, this process will continue to be reviewed, improved and expanded as necessary as we continue our review of other groups of high risk, older pesticides.

Protecting children's health is of central concern under FQPA, which provides for an additional safety factor to be applied to certain pesticides to adjust for children's higher sensitivity to chemical exposure. EPA understands the importance of protecting children's health and as such has identified and given priority to the tolerance reassessments that affect the top 20 foods eaten by children. The Agency projects completion of 83 percent of this set of tolerance reassessments in FY 2004. Another, more general FQPA approach to reducing risks more quickly is to give priority to the review tolerances or exemptions that appear to pose the greatest risk to public health. As a result, EPA divided all pesticide chemicals into three priority groups, published in the Federal Register in the first year of the FQPA provisions.

There are 9,721 tolerances that must be reassessed. Tolerances for the highest risk pesticides are in Priority Group 1, which includes organophosphates, carbamates, and probable carcinogens, among other high-risk chemicals, and totals 5,546 tolerances. Group 2 includes some carcinogens and other tolerances, and Group 3 includes the remaining pre-FQPA and post-1984 pesticides. Some tolerances in all groups have been reassessed as part of the work already underway in the reregistration program.[12] Status of reassessments is as follows:



[12] EPA FRN "Raw and Processed Food Schedule for Pesticide Tolerance Reassessment; Notices" Aug 4, 1997

Status of Tolerance Reassessment by Priority Group (as of 8/5/02)

- Group 1: 3,922 reassessments out of 5,546 (29 percent remaining and 71 percent reassessed)
- Group 2: 1,073 reassessments out of 1,928 (44 percent remaining and 56 percent reassessed)
- Group 3: 1,498 reassessments out of 2,250 (33 percent remaining and 67 percent reassessed)

Endocrine Disruptors

Fish and wildlife in some areas of the world have been affected by chemicals that interfere with the endocrine system resulting in abnormal development, low fertility and greater susceptibility to disease. The link to human disease is less clear, particularly at low ambient environmental levels. Effects have been seen after high exposures. Since the human endocrine system helps guide development, growth, reproduction and behavior, possible endocrine disruption is an important issue, especially for children. The concern that chemicals may affect the endocrine system of humans led to the inclusion of a provision in the Food Quality Protection Act (FQPA) mandating that EPA test pesticides for endocrine disrupting effects on human health. Endocrine Disrupting Chemicals are also addressed in the Safe Drinking Water Act Amendments of 1996.

Work on pesticide and chemical endocrine disruptors crosses two EPA goals, relating to both pesticides and all other toxic chemicals (Goals 3 and 4). For details concerning the Endocrine Disruptor Program and its screening activities, consult Goal 4, Objective 3. For Goal 3, in 2004, the Agency will continue its efforts to develop alternative, non-animal methods that can be validated and incorporated into its program.

Research

The Food Quality Protection Act of 1996 (FQPA) requires EPA, in its assessment of pesticide safety, to consider aggregate exposure from dietary and all other non-occupational sources and the cumulative effects of pesticides that have a common mechanism of toxicity. Implementation of the directive required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk and resulted in the identification of a number of areas with significant research needs.

Tools such as methods, data, models, risk assessment guidance, and toxicity testing methods and protocols are needed for assessing aggregate and cumulative risks across the exposure-to-dose-to-effects continuum that result from multimedia, multipathway exposures to pesticides with like mechanisms of action. Research is also needed to understand the magnitude and extent of aggregate and cumulative exposures of pesticides used on food, in drinking water, and through non-occupational exposures in and around residential environments and other

indoor/outdoor environments. Special emphasis will be placed on characterizing exposures and the corresponding critical factors influencing these exposures in those environments where young children spend the majority of their time. EPA has research in all of these areas and is expected to continue this research into the future to support pesticide registration and reregistration activities and to provide data for risk assessments.

In order to address the risks surrounding pesticides, health effects research is needed to understand dose-response relationships and use this understanding to develop new and improve existing methods to evaluate the effects of cumulative exposures to pesticides and toxic chemicals, including both long-term exposures and multiple acute exposures. Specific objectives of this work will be to further study whether exposure to multiple pesticides with a similar mode of action produces additive and/or non-additive interactions and if effects vary between adult and juvenile animals, which will then be extrapolated to humans.

Exposure research will develop new and enhance existing tools to estimate aggregate and cumulative exposures of young children to pesticides and other toxic chemicals. Research will address major data gaps and uncertainties associated with exposure assessment requirements for the FQPA. Currently, research is aimed at developing data and models for aggregate assessments to pesticides. In FY 2004, work will extend these concepts to cumulative assessments of pesticides and toxics. Research results will be used by the Agency to better characterize, assess, and manage aggregate and cumulative exposures to pesticides and toxics. EPA will also use these results to better understand and develop programs to reduce children's exposures to pesticides and other environmental pollutants.

In addition, exposure modeling research will focus on improving and integrating EPA's exposure to dose models, analyzing current aggregate exposure data from EPA-sponsored aggregate exposure studies to identify remaining exposure data gaps, and developing a research plan for addressing high priority cumulative pesticide exposure issues.[13] The current models will be upgraded to include new modules for gastrointestinal and dermal exposure to reflect the latest scientific data. Also, the results of EPA's aggregate exposure studies will be statistically analyzed to improve our understanding of the key factors influencing aggregate exposures.

The Agency will continue its efforts to address uncertainties in the areas of intermittent exposure and cumulative risk to pesticides. Additionally, EPA will continue to develop tools for characterizing and combining exposures and assessing exposure-dose-response relationships for pesticides with different exposure patterns with an emphasis on enhancing the foundation for cumulative risk assessment methodology. The Agency will also develop improved risk management strategies and tools for reducing potential health risks to children and other highly exposed populations.

In FY 2004, a major population-based field study that focuses on young children's (ages 0-3 years old) aggregate exposure to pesticides in homes, day care centers and schools will continue. This study will be completed in FY 2005 with delivery of major products (e.g., validated protocols, statistical analyses) starting in FY 2005 and continuing through FY 2007.

[13] Exposure-to-dose models include Stochastic Human Exposure Dose Simulation Modeling and Exposure Related Dose Estimating Model. Aggregate exposure models include Children's Total Exposure to Pesticides and Other Persistent Pollutants (CTEPP) and National Human Exposure Assessment Survey (NHEXAS).

Study results will be used to: 1) evaluate and refine a protocol for measuring aggregate exposure for children of different age groups; 2) verify those pathways and activities that represent the highest exposures to children; 3) generate high quality distributional data on exposure concentrations, estimated exposures, and exposure factors; 4) evaluate age and developmental differences to exposures; 5) develop a measurement database for model evaluations and risk assessments; and 6) provide input into the design and implementation of the National Children's Study.

EPA will complete an approach for using pharmacokinetic data and models in risk assessment as a foundation for comprehensive guidance for conducting risk assessments under FQPA. The approach and guidance will provide analysis and recommendations for use of physiologically-based pharmacokinetic models and data in risk assessment, addressing relevant issues such as age-related dosimetry and extrapolation between species and age groups, dose assessment for aggregate and cumulative risk assessment, databases relevant to toxicokinetic approaches, and risk assessment methods that reduce the use of default assumptions.

In FY 2004, new risk management research will begin developing standard protocols for assessing treatment effects on pesticide residues in drinking water, and testing the efficiency of drinking water treatment and the formation of degradation bi-products for pesticide classes of high priority that are not on the Candidate Contaminant List (CCL). Information collected from these protocols will be used in aggregate and cumulative exposure assessments.

Additionally, the Agency will collect longitudinal activity and dietary consumption data on sub-populations (e.g., children, elderly) for modeling daily/seasonal variability inherent in human activities and dietary consumption patterns. This research will produce data that are not captured in previous and planned dietary or population surveys. Data collected will be used to support EPA's risk assessments.

Recognizing the complexity associated with determining the cumulative risk for a given set of exposure conditions, research will use a systematic approach that starts with less complex paradigms, such as risk from aggregate exposure to a single chemical or class of chemicals with a common mode of action which is present in multiple pathway, and build towards the more complex, including consideration of different temporal dimensions of exposure. A better understanding of these relationships will also focus and guide risk management decisions and will allow for more accurate predictions if determinants change.

FY 2004 Change from FY 2003 Request

<u>EPM</u>

- (+$1,000,000) This increase will be directed to increased reregistration of antimicrobial pesticides and associated tolerance reassessments. Reregistration of antimicrobials is critical to meeting our final statutory deadlines for tolerance reassessment.

- (+$400,000) This increase will fund expanded effort to review inert ingredients needed to meet the FQPA tolerance reassessment deadlines.

- (+$1,376,600, +1.8 FTE) Resources, dollars and FTE, associated with rent are allocated in proportion to Agency-wide FTE located in each goal, objective. Resources, dollars and FTE, associated with utilities, security and human resource operations are allocated in proportion to Headquarters FTE located in each goal, objective. Changes reflect shifts in FTE between goals and objectives. Resources, dollars and FTE, associated with contracts and grants are allocated in proportion to Headquarters' contracts and grants resources located in each goal, objective. Changes in these activities reflect shifts in resources between goals and objectives. *(Total changes -> rent: +$1,417,000, utilities: +$2,374,800, Security: +$3,425,000 and 75 FTE, Human Resources: +$870,400 and +5.4 FTE, Contracts: +$642,400 and -18.5 FTE, Grants: +$3,015,500 and +19.7 FTE)*

Research

S&T

- (+$415,400) This increase reflects a redirection from Drinking Water research (Goal 2) to a research effort that will collect longitudinal activity and dietary consumption data on sub-populations (e.g., children, elderly) for modeling daily and seasonal variability inherent in human activities. This research will produce data that are not captured in current dietary or population surveys (e.g., NHANES) and will improve our ability to meet performance commitments in support of FQPA.

- (+$130,000) This increase reflects a redirection from socioeconomics research to new risk management research that will begin developing standard protocols for testing the efficiency of drinking water treatment and assessing treatment effects on pesticide residues in drinking water. This research will focus on pesticide classes of high priority that are not on the CCL.

- (-$87,570, -0.9 FTE) These workyears are being redirected to support the Agency's Homeland Security Strategic Plan in the area rapid risk assessment research (Goal 8)

- There are additional increases for payroll, cost of living, and enrichment for new and existing FTE.

GOAL: SAFE FOOD

OBJECTIVE: ELIMINATE USE ON FOOD OF PESTICIDES NOT MEETING STANDARDS

Annual Performance Goals and Measures

GOAL: SAFE FOOD

OBJECTIVE: ELIMINATE USE ON FOOD OF PESTICIDES NOT MEETING STANDARDS

Annual Performance Goals and Measures

Reassess Pesticide Tolerances

In 2004 Ensure that through on-going data reviews, pesticide active ingredients and the products that contain them are reviewed to assure adequate protection for human health and the environment, taking into consideration exposure scenarios such as subsistence lifestyles of Native Americans.

In 2003 Assure that pesticides active ingredients registered prior to 1984 and the products that contain them are reviewed to assure adequate protection for human health & the environment. Also consider the unique exposure scenarios such as subsistence lifestyles of Native Americans in regulatory decisions.

In 2002 Reregistration efforts delayed to focus on reviewing and testing pesticides against anthrax.

Performance Measures:	FY 2002 Actuals	FY 2003 Pres. Bud.	FY 2004 Request	
Tolerance Reassessment	66.9	68%	78%	Tolerances(Cum)
Reregistration Eligibility Decisions (REDs)	72.7%	76%	81.7%	Decisions (Cum)
Product Reregistration	307	400	750	Actions
Tolerance reassessments for top 20 foods eaten by children	65.6	75%	83%	Tolerances(Cum)
Number of inert ingredients tolerances reassessed			100	tolerances

Baseline: The baseline value for tolerance reassessments is the 9,721 tolerances that must be reassessed using FQPA health and safety standards. In FY2004, EPA plans to reassess 1,050 additional tolerances. The baseline for REDS is the 612 REDs that must be completed. In FY2004, EPA plans to complete 35 REDs. The baseline for product reregistration is under development. The baseline for inert tolerances is 870 that must be reassessed. The baseline for the top 20 foods eaten by children is 893 tolerances that must be reassessed.

Program Assessment Rating Tool

Pesticides Reregistration

As part of the Administration's overall evaluation of effectiveness of Government programs, the Pesticides Reregistration program was evaluated with the following specific findings:

- The program is the only entity that reviews existing pesticides to ensure they keep pace with advancing safety standards. The program has a clear mission and statutory authority.

- The program has established long-term goals but they are not adequate because the goals lack quantified baselines and/or targets and because they need to be more outcome-focused.

- The program regularly reviews progress toward annual goals and does make management decisions to address issues that impede progress but the program does not use efficiency or cost effectiveness measures to monitor program management and performance.

- EPA has proposed a long-term efficiency goal for this program that targets reductions in decision-making time but further work is needed to finalize the goal and to develop appropriate annual targets to support it.

- The program has met statutory deadlines but does not always meet annual goals and it is unclear how achieving annual targets leads to quantifiable progress toward the program's long-term goals. Progress toward future deadlines will require additional work on antimicrobial pesticides.

As a result of this review, the Administration:

- Recommends providing an additional $1.0 million for antimicrobial pesticides and $0.5 million for inerts reregistration activities.

- Will implement appropriate long-term performance measures, improved annual targets, and adequate long and short term efficiency measures.

Verification and Validation of Performance Measures

FY 2004 Performance Measures:

- **Number of Tolerance Reassessments issued.**

- **Number of Reregistration Eligibility Decisions (REDs) issued.**

- **Number of Product Reregistration decisions issued.**

- **Tolerance Reassessments for top 20 foods eaten by children**

- **Number of inert ingredients tolerances reassessed.**

Performance Database: Pesticide Regulatory Action Tracking System (PRATS). PRATS is maintained by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) and is designed to track regulatory data submissions and studies, organized by scientific discipline, which are submitted by the registrant in support of a pesticide's registration. Additionally, the program divisions maintain manual counts of the registrations of reduced risk pesticides. The information is provided to the Office Director's immediate office for consolidation and record keeping.

Data Source: Office of Pesticide Programs' reviewers. Methods, Assumptions and Suitability: The measures are program outputs which represent the program's statutory requirements to ensure that pesticides entering the marketplace are safe for human health and the environment and when used in accordance with the packaging label present a reasonable certainty of no harm. While program outputs are not the best measures of risk reduction, they do provide a means for reducing risk in that the program's safety review prevents dangerous pesticides from entering the marketplace.

QA/QC Procedures: All registration actions must employ sound science and meet the Food Quality Protection Act (FQPA) new safety standard. All risk assessments are subject to public and scientific peer review.

Data Quality Review: Management reviews the program counts and signs off on the decision document, which is then forwarded to the Office Director.

Data Limitations: None known.

Error Estimate: N/A. There are no errors associated with count data.

New/Improved Data or Systems: The OPPIN (Office of Pesticide Programs Information Network) consolidates various Pesticides program databases. Phased implementation of the OPPIN began in FY 2001 and will continue through FY 2003, after which the system will be reevaluated to ensure that it is meeting program needs.

References: Office of Pesticide Programs (OPP) Website; OPP Annual Report; Annual Performance Plan and Annual Performance Report

Coordination with Other Agencies

USDA supplies EPA with important data on food consumption, pesticide use and pesticide residues on foods. The data are used in making reregistration and tolerance setting decisions. USDA's Pesticide Data Program (PDP) collects pesticide residue data through the cooperation of 10 participating states. FDA monitors food imports and also conducts the Total Diet Study, monitoring pesticide residues present in prepared food. The states provide support services in collection and testing of commodities for pesticides using uniform national standard operating procedures.

EPA also actively solicits advice and comments on the implementation of pesticide programs from key stakeholders and the public. EPA works with other government officials, regulated industry, agricultural and other user groups, food processors, academia, environmental and public interest groups, the international community and the media to reach all interested parties.

In implementing FQPA, EPA has consulted with key constituencies on a wide range of critical issues. Standing committees that are providing, or have provided advice to EPA include:

- The Endocrine Disruptors Screening and Testing Advisory Committee (EDSTAC)—This committee was established to give advice and counsel on developing strategy to screen and test endocrine disrupting chemicals and pesticides. The committee included representatives of industry, state and Federal government, public health, environmental, labor organizations, small businesses and academia. In 2001, a new Endocrine Disruptor Methods Validation Subcommittee was established under the National Advisory Committee for Environmental Policy and Technology (NACEPT) to provide guidance regarding the design, conduct and interpretation of studies to validate the endocrine disruptor screening and testing program. The Subcommittee members represent a wide range of stakeholders drawn from the scientific community as well as Federal and non-profit organizations.

- The Pesticide Program Dialogue Committee (PPDC), a previously chartered group designed to assist EPA in making decisions related to pesticide regulation, consists of a diverse group of representatives with a broad range of interests. The PPDC will provide EPA with continuing advice on implementation of FQPA.

- EPA's FIFRA Science Advisory Panel (SAP) and Science Advisory Board (SAB) provide independent scientific peer review.

- The State FIFRA Issues Research and Evaluation Group (SFIREG) allows state input and comments from the public.

- The Consumer Labeling Initiative (CLI) was established to learn how to make important health, safe use and environmental information on household product labels easier to find, read, understand and use–includes members from EPA, industry, other Federal and state agencies, and private groups.

- Committee to Advise on Reassessment and Transition (CARAT). The purpose of CARAT is to provide advice and counsel to the Administrator of EPA and the Secretary of Agriculture regarding strategic approaches for pest management planning and tolerance reassessment for pesticides as required by the Food Quality Protection Act of 1996. CARAT is preceded by the Tolerance Reassessment Advisory Committee.

Research

The research program of the National Institute of Environmental Health and Safety (NIEHS) is closely allied with that of EPA's in studying the impact of environmental contaminants on public health. Under their extramural programs, EPA and NIEHS jointly sponsor Centers for Children's Environmental Health and Disease Prevention Research. The centers conduct research to improve detection, treatment, and prevention of environmentally related diseases in children.

The National Institute for Child Health and Human Development (NICHD) supports research on the reproductive, neurobiological, developmental, and behavioral processes that determine and maintain the health of children and adults. The NICHD program includes research on the effects of exposure to environmental agents on human development. NICHD, EPA, CDC, and other Federal agencies are designing the National Children's Study, a large longitudinal epidemiology study of children's exposure to environmental agents. EPA and NICHD jointly sponsor research on genetic susceptibility and variability of human malformations. EPA's efforts in this area focus on identifying environmental agents that cause birth defects and other developmental disorders, the molecular mechanisms of birth defects, and how to use mechanistic and other data in the risk assessment process.

The National Cancer Institute's (NCI) Agricultural Health Study (AHS) is a large epidemiology study of cancer in farm workers and their families. EPA is participating in the AHS through an exposure study of a subgroup of participants. CDC's National Center for Health Statistics (NCHS) is conducting the fourth National Health and Nutrition Examination Survey (NHANES IV), a national survey of health and nutrition. The NHANES surveys have about 30,000 respondents and include sufficient numbers of children in selected age ranges and other potentially sensitive subgroups to allow statistical inferences about their health, nutrition, and food intake, and the concentrations of some environmental contaminants in their blood and urine. EPA is collaborating with NCHS to collect information on children's exposure to pesticides and other environmental contaminants. NHANES has been conducted since 1971.

Statutory Authorities:

Federal Fungicide, Insecticide and Rodenticide Act (FIFRA)

Federal Food, Drug and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) of 1996

Toxic Substances Control Act (TSCA)