Environmental Protection Agency

FY 2003 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 2001 Actuals	FY 2002 Enacted	FY 2003 Request	FY 2003 Req. v. FY 2002 Ena.
Safe Food	**$124,949.3**	**$110,537.1**	**$109,814.6**	**($722.5)**
Reduce Risks from Pesticide Residues in Food	$44,288.8	$47,609.6	$45,290.4	($2,319.2)
Eliminate Use on Food of Pesticides Not Meeting Standards	$80,660.5	$62,927.5	$64,524.2	$1,596.7
Total Workyears	817.1	780.2	770.1	-10.1

Background and Context

The U.S. 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 pesticide regulations and related science issues to the Science Advisory Panel (SAP), an independent, expert advisory committee whose members are nominated by the National Institutes of Health and the National Academy of Sciences. The SAP plays a critical role in EPA's decision-making process, assuring decisions that impact on 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 which 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 the Safe Food goal, EPA ensures that any residues on food are below established limits.

EPA's Pesticide Regulations Affect a Cross Section of the U.S. Population

- 30 major pesticide producers and another 100 smaller producers
- 2500 formulators
- 29,000 distributors and other establishments
- 40,000 commercial pest control firms
- 1.2 million pesticide applicators
- One million farms
- Several million industry and government
- users
- About 100 million households

Source: OPP's Pesticides Industry Sales and Usage Report

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 U.S. pesticide usage in 1997 was 4.6 billion pounds, according to the report, "*Pesticide Industry Sales and Usage: 1996 and 1997*" (http://www.epa.gov/oppbead1/pestsales). 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 $6.6 billion and 568 million pounds in 1997. 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 7.1% of total pounds applied in 2000 (Doane Marketing Research, Inc.: http://www.doanemr.com).

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 that pesticides 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.

FFDCA authorizes EPA to set tolerances, or maximum legal limits, for pesticide residues in or on food. Tolerance requirements apply equally to domestically-produced as well as 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 enhances protection of children and other sensitive sub-populations. FQPA establishes a single, health-based safety standard for all pesticide residues. The agency-wide FY 2003 request supporting FQPA includes $142.3 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:

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

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

- Educating consumers about pesticide risks and benefits;

- Expediting the approval of reduced risk pesticides; and

- Encouraging farmers' adoption of safer pest management practices.

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 in Goal 4. Under Goal 3, the EPA is:

C Assuring that new chemicals and new uses are registered in accordance with the FQPA's strict standard, "reasonable certainty of no harm,"and that no harm will result to human health from all combined sources of exposure to pesticides (aggregate exposures);

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

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

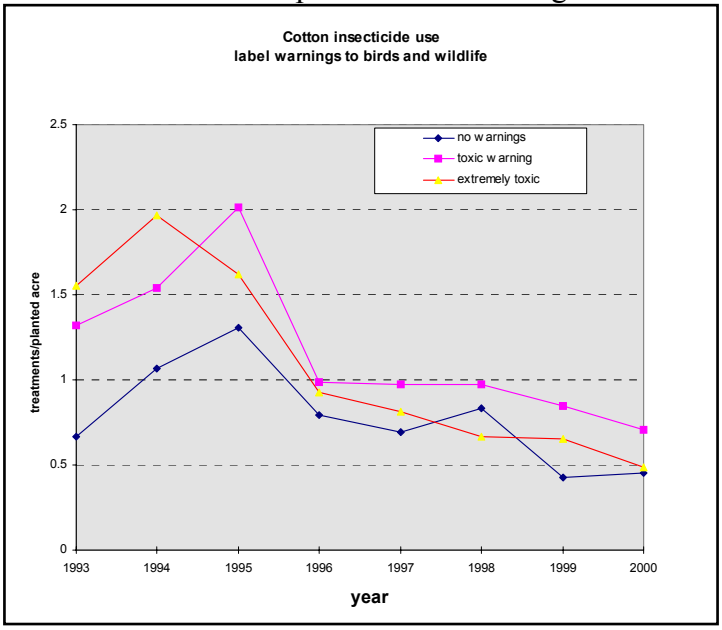
C Expediting review and registration of alternative pesticides that are less risky than pesticides currently in use and may be substituted effectively for higher risk pesticides.

In 2003, 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 existing pesticide use as stipulated by the reregistration provision, as well as a comprehensive reassessment and update of existing tolerances within ten years, as required by FQPA.

The 2003 request emphasizes efforts to evaluate existing tolerances for currently registered pesticides to ensure they meet the new Food Quality Protection Act (FQPA) health standards. This tolerance reassessment program screens and requires testing of certain pesticides and chemicals to evaluate their potential for disrupting endocrine systems in animals or in humans. The emphasis will be on balancing the need for pesticides with the risks of exposure and allowing for smooth transitions to safer pesticide alternatives, through an open and transparent process that seeks input from all stakeholders.

EPA uses the latest scientific advances in health-risk assessment practices, to ensure that current pesticides meet the standard of a reasonable certainty of no harm, as stipulated by FQPA. 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.



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 affected the use of other insecticides which 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, the extremely toxic pesticides decreasing from 1.6 to 0.5 acre treatments, a 68% reduction. (See chart.)

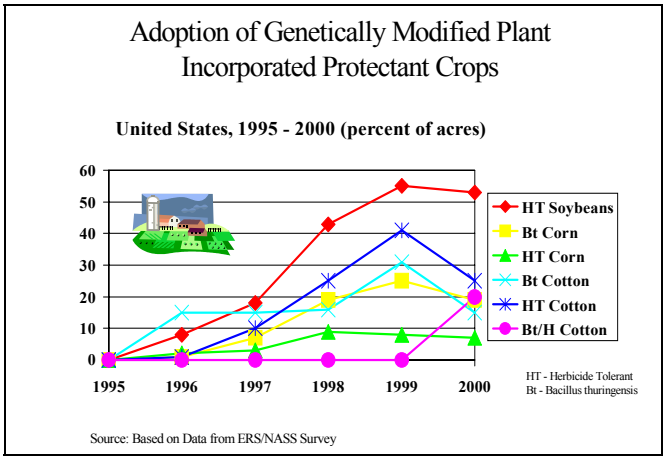
Outreach activities on the subject of biotechnology such as public meetings and scientific peer reviews of our policies and assessments are likely to be expanded to keep pace with changing science and the public's demand for information in this area. EPA is working closely with other federal agencies involved in biotechnology and is also actively involved in developing international standards for the regulation of biotechnology products. Specific activities in 2003 will include advancing scientific knowledge of allergenicity (i.e.human allergic reactions to pesticide residues); continued implementation of the Plant Incorporated Protectant rule, which defines the type of substances used in bioengineered plants that must undergo scientific evaluation by the Agency; and participating in the Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology. The Task force is involved in developing international standards governing foods derived from biotechnology.

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. Biotechnology is becoming increasingly more important in our economy with bioengineered 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 8% of the total

U.S. acres planted in soybeans. In 2000, HT Soybeans accounted for 53% of the acres planted for other crops, trends also indicate increases, though not as dramatically as for soy (see chart).

While certain issues remain to be addressed, among the potential benefits of biotechnology is a reduction of our reliance on some older, more risky chemical pesticides, thereby reducing worker exposure to these chemical pesticides. To ensure the safety of foods derived from biotechnology, EPA will continue to seek outside expert scientific advice through scientific peer reviews on our regulatory decisions, policies, methods and tools.

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. 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.



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. Existing tools for controlling and preventing exposure are limited to certain processes and materials.

To support the Food Quality Protection Act (FQPA), EPA must develop the tools (methods, models, approaches) and quality exposure data for characterizing aggregate risks from exposure to pesticides in order to reduce uncertainty in risk assessments. The 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 subpopulations and considering effects from cumulative exposures.

EPA's research program will continue to focus on: 1) developing and validating methods to identify and characterize, as well as models to predict, the potential increased susceptibility to human health effects experienced by infants and children; 2) identifying and understanding major exposure routes, pathways, and processes, and developing theoretical and experimentally based multipathway exposure models for pesticides and other toxic substances; and 3) addressing the adequacy of current risk assessment methods and providing the necessary risk assessment guidance.

Strategic Objectives and FY 2003 Annual Performance Goals

Reduce Risks from Pesticide Residues in Food

- 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.

- Occurrence of residues of carcinogenic and cholinesterase inhibiting neurotoxic pesticides on foods eaten by children will have decreased by 20 percent (cumulative) from their average 1994 to 1996 levels.

- At least six percent of acre-treatments will use applications of reduced risk pesticides.

Eliminate Use on Food of Pesticides Not Meeting Standards

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

- By the end of 2003 EPA will reassess a cumulative 68% of the 9,721 pesticide tolerances required to be reassessed over ten years and complete reassessment of a cumualtive 75% of tolerances of special concern in protecting the health of children.

Highlights

<u>Reduce Public Health Risk from Pesticide Residues</u>

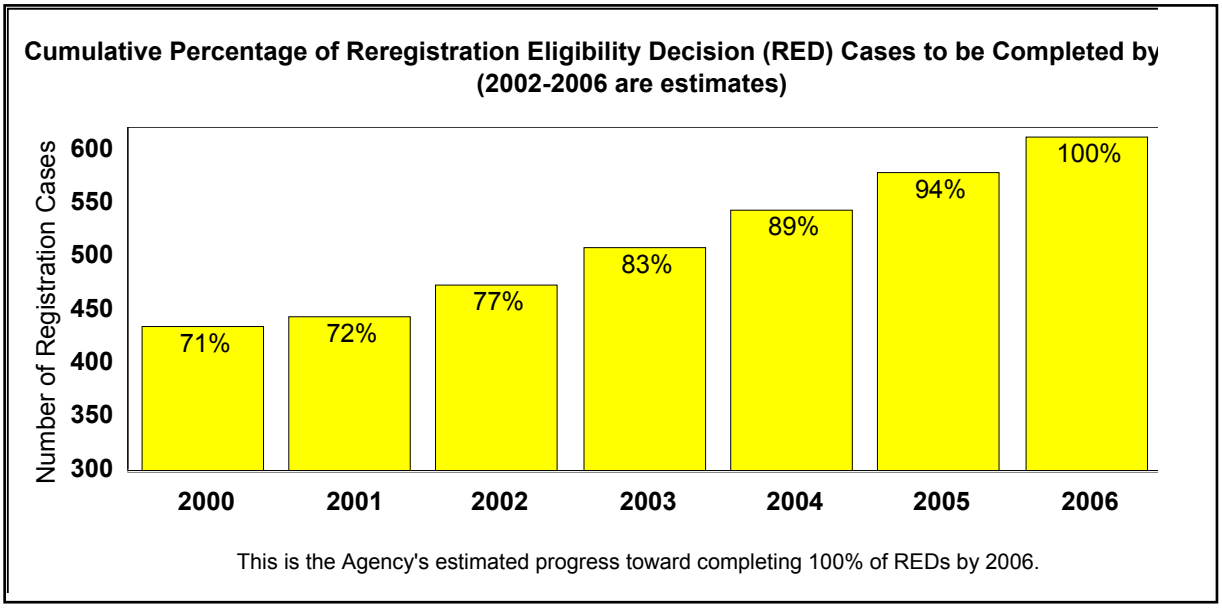
FFDCA and FIFRA authorize EPA to set terms and conditions of pesticide registration, marketing and use. EPA will use these authorities to reduce residues of pesticides with the highest potential to cause cancer or neurotoxic effects, including those which pose particular risks to children and other susceptible 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 2003, 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

In FY 2003, 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 meeting 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 2003, EPA will work toward completing 17 Reregistration Eligibility Decisions (REDs), 750 product reregistrations and 225 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. The Agency has begun to track its progress in determining appropriate tolerances for these pesticides under the new FQPA standards. In 2003, EPA will continue its effort to reduce dietary risks to children, by completing approximately a cumulative 75 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, by adopting integrated

pest management strategies that draw on cultural, biological, and mechanical techniques as well as chemical. With new strategies comes a steep learning curve on how to use them effectively. This transition requires broad input and participation by stakeholders to minimize adverse, unintended consequences on agriculture. To achieve input, EPA developed a special process for its stakeholder for addressing data analysis and regulatory requirements, protocols, and scientific and public review as the Agency continues to reduce risks posed by these pesticides through regulatory actions. The Agency will continue this important dialogue with stakeholders as we protect human health and the environment by assessing risks of other groups of pesticides.

EPA's authority to collect Reregistration Maintenance Fees expires at the end of FY 2002 under the 2002 appropriations bill for the Agency. The 2003 request substitutes appropriated funds for fees to fund the reregistration program. The appropriated dollars for this were reprogrammed from the tolerance assessment program which will be funded by fee revenue starting in March 2003.

The Reregistration program was accelerated by the 1988 amendments to FIFRA and enhanced by FQPA, which includes a tolerance reassessment requirement. 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. The issuance of a Reregistration Eligibility Decision (RED) for a pesticide under reregistration review summarizes the health and environmental effects findings of that pesticide and determines whether existing tolerances protect human health and the environment. The findings determine whether the products registered under this chemical are eligible for reregistration. The Agency's progress in achieving goals for production of REDs and its tolerance reassessment component are summarized in the chart.

FQPA added considerably more complexity into 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.

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.

The program has been working to integrate new FQPA requirements with the reregistration program to avoid duplication and increase efficiency. Implementing FQPA has also consumed time and effort as the technical challenge posed by reregistration of older pesticides has been increased by the health and safety enhancements of FQPA, including:

- 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.

These and other additional requirements required that the Agency revise, in some cases overhaul, its existing policies, procedures, process, and databases. The Agency also needed to consider a reasonable transition to FQPA for agriculture, and thus a substantive stakeholder participation process had to be developed for input from those affected. All these considerations resulted in the temporary slow-down of the program.

By the end of FY 2003, EPA expects to have implemented EPA's science policies, including the cumulative risk policy, to meet the ten-year tolerance reassessment deadline. As required by FQPA, EPA has developed a tolerance fee rule that recovers from pesticide manufacturers the full cost of setting and reevaluating pesticide tolerances on food.

Additionally, to meet another FQPA need, EPA is developing a process for periodic review of pesticide registrations. This new program will update all pesticide registrations using current health standards, scientific data, risk assessment methodologies, program policies and effective risk reduction measures. In 2003, the Agency will continue developing and refining the framework for the registration review program.

Research

In FY 2003, 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) - effectively engaging all components of the risk paradigm.

Specifically, exposure research will address major exposure data gaps, distributions of key exposure factors (especially across age groups for children and exposures for other susceptible subpopulations), and uncertainties associated with the exposure assessment requirements for FQPA. Health effects research will also develop 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 continue to compare pesticide exposures across age groups, identify factors leading to higher exposures, and analyze data to improve the evaluation of exposure factors for pesticide risk assessment. Results will support risk assessments under FQPA and the development of Agency guidelines for cumulative risk assessment through the EPA Risk Assessment Forum (ERAF). Risk management research will evaluate characteristics of commonly used pesticides or pesticides of particular concern to determine which chemicals should be targeted for development of risk management tools.

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. This plan discusses the mechanisms and programs the Agency employs 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 2003 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 2001 Actuals	FY 2002 Enacted	FY 2003 Request	FY 2003 Req. v. FY 2002 Ena.
Reduce Risks from Pesticide Residues in Food	**$44,288.8**	**$47,609.6**	**$45,290.4**	**($2,319.2)**
Environmental Program & Management	$37,994.5	$45,325.3	$42,964.7	($2,360.6)
Rereg. & Exped. Proc. Rev Fund	$3,790.4	$0.0	$0.0	$0.0
Science & Technology	$2,503.9	$2,284.3	$2,325.7	$41.4
Total Workyears	318.5	337.0	331.1	-5.9

Key Program
(Dollars in Thousands)

	FY 2001 Enacted	FY 2002 Enacted	FY 2003 Request	FY 2003 Req. v. FY 2002 Ena.
Administrative Services	$209.7	$0.0	$0.0	$0.0
Endocrine Disruptor Screening Program	$2,279.9	$1,860.4	$2,096.3	$235.9
Facilities Infrastructure and Operations	$4,250.0	$4,725.2	$4,462.6	($262.6)
Homeland Security	$0.0	$602.6	$0.0	($602.6)
Legal Services	$996.7	$1,019.7	$1,095.3	$75.6
Management Services and Stewardship	$460.2	$504.0	$420.6	($83.4)
Pesticide Registration	$29,613.9	$31,832.4	$30,882.2	($950.2)
Pesticide Reregistration	$5,371.5	$6,227.0	$5,673.4	($553.6)
Pesticide Residue Tolerance Reassessments	$1,177.4	$813.3	$660.0	($153.3)
Safe Pesticide Applications	$0.0	$25.0	$0.0	($25.0)

FY 2003 Request

This request highlights improving 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 impact positively 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 human health and ecological effects studies and data. 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 which 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 which may simply be new formulations of ingredients already registered (me-toos), new uses which add a crop type to the approved uses of the registered pesticide and minor uses for low volume crops.

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.

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 the risk assessment methodology for inerts to the Pesticide Program Dialogue Committee (PPDC) in December 2001. The Agency has made great strides in incorporating FQPA requirements into its registration program, but as resources become more scarce, continued effort in inerts review may be delayed due to more pressing priorities such as antimicrobial reregistration, tolerance reassessments and reduced risk registrations.

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 chemical 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. Pesticides that are widely used and have a common mechanism of toxicity are often riskier. 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." In 2003, the Agency will continue implementation of its policy for assessing cumulative risk for these groups of chemicals and continue applying this policy to pesticide registration and reregistration decisions, further ensuring the safety of our food supply.

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 those pesticides of the greatest public value, including those employed in minor uses and integrated pest management needs. In FY 2003, 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 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 minor use registrations receive appropriate support. EPA policy has defined minor uses as pesticide usage on crops grown on less than 300,000 acres. 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 U.S., worth billions of dollars, could not be produced successfully. In FY 2003, 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 IR-4 program to establish tolerances for minor uses and provides priority status for registrations for vulnerable crops and minor agricultural uses.

Interregional Research Project No. 4

The Interregional Research Project No. 4 (IR-4) helps minor crop producers obtain tolerances and registrations for pest control products. It supports development of test data in support of registrations and tolerances for these products and prepares specific instructions on the use of pesticides which appear on the label of the pesticide product. The IR-4 was organized in 1963 by the Directors of State Agricultural Experiment Stations. Minor crops account for about 40 percent of the total agricultural sales for the U.S.

Bioengineered crops are playing an ever increasing role in the agricultural marketplace and 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.

In 2001, EPA finished the Plant Incorporated Protectant (PIP) Rule which clarifies which plant-incorporated protectants are subject to review under FIFRA and FFDCA and clarifies which ones are exempt. This rule reaffirmed that the plant itself is still subject to USDA authorities, while the plant-incorporated protectants are subject to EPA authorities. The new rule ensures that genetically engineered plant-incorporated protectants meet federal safety standards through as rigorous an EPA evaluation as traditional pesticide registrations. In FY 2002 and 2003, additional work needs to be done on the regulatory framework to assure that bioengineered plants are protective of human health and the environment.

Reduced Risk Chemicals and Biopesticides

In FY 2003, 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 2003, expects to register 13 new reduced risk pesticides.

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 2003, EPA will continue to address these chemicals and make decisions on how to minimize potential risk resulting from their use. The Agency will continue implementing its cumulative risk policy, using the best available science and incorporating stakeholder concerns. The development and registration of appropriate alternatives to these risky chemicals will remain a priority for the program. 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, detections of residues will significantly decrease from pre-FQPA levels (see box.)

Foods that Children Eat

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 2003, regulatory actions by EPA, including expedited registration of safer pesticides, should result in a 20 percent reduction of occurrence of residues from carcinogenic and neurotoxic pesticides on these foods from 1994-1996 levels.

FY 2003 Change from the FY 2002 President's Budget

EPM

- (-$1,500,000) This decrease reflects non-continuation of one-year Congressional Directive for Safer Pesticide registration.

- (-$602,600, - 1.3 FTE) This decrease reflects return to base levels in registration completion of preliminary analyses of new antimicrobial registrations for products targeting potential bioterrorism threats, funded by the FY 2002 Emergency Supplemental.

- (-$1,195,000, -3.0 FTE) This decrease reflects shifts in FTE and administrative overhead to mirror fee structure changes as the Maintenance fee expires and the new Tolerance Fee is implemented.

Annual Performance Goals and Measures

Decrease Risk from Agricultural Pesticides

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 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 actionare timely and comply with standards mandated by law.

In 2002 Provide timely decisions to the pesticide industry on the registration of active ingredients for conventional pesticides.

In 2001 The Agency registered 9 new chemicals, exceeding its target by 2, and 267 new chemicals, underperforming its target by 83.

In 2001 The registration of new agricultural pesticides, and reregistration of older agricultural pesticides, were done under the strict health-based standard of FQPA: "reasonable certainty of no harm." "Safer" pesticides are those that meet a stricter set of criteria.

Performance Measures:	FY 2001 Actual	FY 2002 Enacted	FY 2003 Request	
Register safer chemicals and biopesticides	92	105	118	Regist. (Cum)
New Chemicals	53	60	67	Regist. (Cum)
New Uses	1896	2329	2679	Actions (Cum)

Baseline: The baseline year is 1996; baseline quantities are 0. 1996 is the year FQPA was enacted with its new risk reduction, safety standard "reasonable certainty of no harm" for pesticides used on foods. Cumulative totals measured from baseline for safer chemicals, biopesticides, new chemicals, and new uses are displayed because this more clearly shows progress implementing FQPA than would a display of single-year results.

Reduce use of highly toxic pesticides

In 2003 Occurence of residues of carcinogenic and cholinesterase inhibiting neurotoxic pesticides on foods eaten by children will have decreased by 20 percent (cumulative) from their average 1994 to 1996 levels.

In 2002 Detections of residues of carcinogenic and cholinesterase inhibiting neurotoxic pesticides on foods eaten by children will have decreased by 15 percent (cumulative) from their average 1994 to 1996 levels.

In 2001 Data will be available in March 2002.

Performance Measures:	FY 2001	FY 2002	FY 2003

	Actual	Enacted	Request	
Reduction of detections on a core set of 19 foods eaten by children relative to detection levels for those foods reported in 1994-1996.		15%	20%	Reduced Detect.

Baseline: Percent occurrence of residues of FQPA priority pesticides (organophosphates and carbamates) on samples of children's foods in baseline years 94-96. Baseline percent is 33.5% of composite sample of children's foods: apples, apple juice, bananas, broccoli, carrots, celery, grapes, green beans (fresh, canned, frozen), lettuce, milk, oranges, peaches, potatoes, spinach, sweet corn (canned and frozen), sweet peas (canned and frozen), sweet potatoes, tomatoes, and wheat.

Reduced Risk Pesticides

In 2003 At least six percent of acre-treatments will use applications of reduced risk pesticides.

In 2002 At least one percent of acre-treatments will use applications of reduced risk pesticides.

Performance Measures:	FY 2001 Actual	FY 2002 Enacted	FY 2003 Request	
Percentage of acre treatments with reduced risk pesticides		1%	6%	Acre Treatments

Baseline: Baseline is 1998 acre-treatments: 3.6% of total acreage. Each year's total acre-treatments (all pesticides and reduced risk pesticides), reported by USDA's National Agricultural Statistical Survey (NASS), 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.

Verification and Validation of Performance Measures

Performance Measures:

•Number of registrations of reduced risk pesticides.
•Percentage of acre treatments with reduced risk pesticides.
•Reduction of pesticide detection on foods eaten by children.

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 recordkeeping.

Data Source: The Office of Pesticide Programs (OPP) Staff (reviewers)

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).

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. 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. A reduced risk pesticide must meet the criteria set forth in PRN 97-3. If it does not meet the criteria, it is not reviewed as a reduced risk, but as a conventional active ingredient. All risk assessments are subject to public and scientific peer review.

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.

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 U.S. 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.

EPA is continuing the development of the National Pesticide Residue Database (NPRD), in coordination with chemists and information management specialists from FDA, USDA, California and Florida. This database will include automated data validation. The system will be integrated with the other EPA databases.

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. Tolerances are enforced by the Department of Health and Human Services/Food and Drug Administration for most foods, and by the U.S. 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 posed 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.

Statutory Authorities

Federal Fungicide, Insecticide and Rodenticide Act (FIFRA)

Federal Food, Drug and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) of 1996

Environmental Protection Agency

FY 2003 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 2001 Actuals	FY 2002 Enacted	FY 2003 Request	FY 2003 Req. v. FY 2002 Ena.
Eliminate Use on Food of Pesticides Not Meeting Standards	**$80,660.5**	**$62,927.5**	**$64,524.2**	**$1,596.7**
Environmental Program & Management	$58,202.0	$50,344.6	$52,478.3	$2,133.7
Rereg. & Exped. Proc. Rev Fund	$12,857.8	$0.0	$0.0	$0.0
Science & Technology	$9,601.6	$12,582.9	$12,045.9	($537.0)
Total Workyears	498.6	443.2	439.0	-4.2

Key Program
(Dollars in Thousands)

	FY 2001 Enacted	FY 2002 Enacted	FY 2003 Request	FY 2003 Req. v. FY 2002 Ena.
Administrative Services	$279.5	$0.0	$0.0	$0.0
Endocrine Disruptor Screening Program	$3,457.0	$3,388.7	$3,264.1	($124.6)
Facilities Infrastructure and Operations	$6,354.9	$4,575.2	$5,154.0	$578.8
Homeland Security	$0.0	$876.8	$0.0	($876.8)
Legal Services	$372.3	$433.5	$465.5	$32.0
Management Services and Stewardship	$860.0	$931.5	$854.6	($76.9)
Pesticide Reregistration	$27,621.2	$27,170.8	$38,592.4	$11,421.6
Pesticide Residue Tolerance Reassessments	$13,616.1	$13,858.5	$4,607.9	($9,250.6)
Research to Support FQPA	$10,905.5	$11,377.4	$10,821.3	($556.1)
Science Coordination and Policy	$275.8	$315.1	$764.4	$449.3

FY 2003 Request

Pesticides licensing work involves both registration of new chemicals and the review of older chemicals. 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 FQPA safety standards. 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 (a tolerance) of a pesticide in order to ensure that pesticides meet the stricter standard mandated by FQPA. During this review, the Agency conducts a risk assessment which forms the basis for the Agency's decisions.

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. Draft risk assessments go through both scientific peer review and a public review process. Pesticide companies must submit a wide variety of scientific studies for review before EPA will set a tolerance or reregister a pesticide. The data are designed to identify possible harmful effects the chemical could have on humans (its toxicity), the amount of the chemicals (or breakdown products) likely to remain on or in food, and other possible sources of exposure (e.g., through use in homes or other places).

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 2003, the Agency will complete 17 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 reduction range from revocation of the tolerance to modifications in use and 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 2003 request includes additional funds 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. 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.

EPA's authority to collect Reregistration Maintenance Fees expires at the end of FY 2002 under the 2002 appropriations bill for the Agency. The 2003 request substitutes appropriated funds for fees to fund the reregistration program. The appropriated dollars for this were reprogrammed from the tolerance assessment program which will be funded by fee revenue starting in March 2003.

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 2003, EPA will complete the final rule, setting up the new program. The regulation will define and outline the program. 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.

Reassessment of Existing Pesticide Residue Tolerances on Food

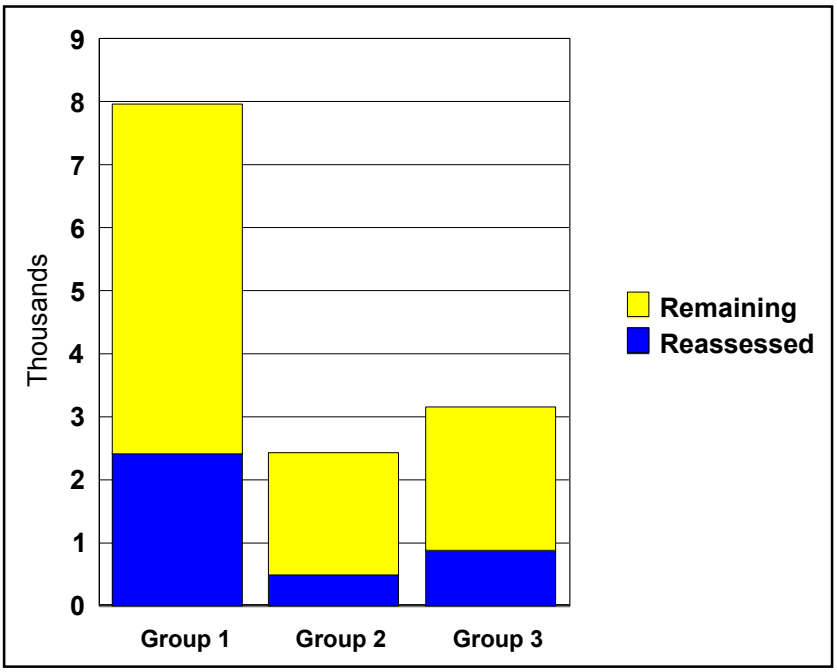
A tolerance is the maximum legal amount of a pesticide residue permissible on food. FQPA requires that EPA reassess within ten years the more than 9,721 pesticide tolerances existing in 1996. The first statutory deadline was to complete reassessment of 33 percent of the existing tolerances by August 1999. EPA surpassed this goal, reassessing approximately 39 percent of the tolerances, most of them among the highest priority group. The next deadline, which the Agency expect to meet, is to reassess 66 percent of these tolerances by August 2002. In FY 2003, the Agency will continue its reassessment of these tolerances completing approximately a cumulative 70 percent.

As mandated by FQPA, the Agency continues to ensure that sound science is applied consistently in our pesticide reviews and that this process includes stakeholder and scientific community input. 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. By FY 2003, the Agency will have completed review of a group of higher risk pesticides, the organophosphates, which, because of their wide use, heavily affect the farming community. To address the issues around organophosphate replacement, the Agency and USDA collaborated in development and implementation of a review process which greatly expanded public participation. This process will continue to be improved and expanded, as necessary as we continue our review of other groups of high risk, older pesticides.

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), as well as chemistry, toxicity and exposure information. EPA obtains data from a wide variety of sources including USDA surveys on what foods people eat and the quantity they eat, FDA residue monitoring, and U.S. 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. The science and policies behind these assessments is complex and the standards developed will impact many pesticides on the market. For this reason, EPA has sought the advice and peer review of the scientific community as well as stakeholders. This intensive effort lead to a lag in finalizing some tolerance reassessments in 2000 and 2001. With the final policies in place in 2002, the Agency will complete processing of the reassessments to meet its FQPA deadlines, and in 2003 will commence the last phase of the FQPA tolerance reassessments requirements.

Protecting children's health is of central concern under FQPA, which requires that EPA 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. Status of reassessments is as follows:



Status of Tolerance Reassessment by Priority Group (as of 12/31/01)

CGroup 1: 2,428 reassessments out of 5,546 (56 percent remaining and 44 percent reassessed)
CGroup 2: 506 reassessments out of 1,928 (74 percent remaining and 26 percent reassessed)
CGroup 3: 3,832 reassessments out of 2,247 (65 percent remaining and 35 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 2003, the Agency will continue its efforts to develop alternative, non-animal methods that can be validated and incorporated into its programs.

Research

The Food Quality Protection Act of 1996 (FQPA) identifies science needs consistent with characterizing and evaluating aggregate and cumulative exposures to pesticides and the effects associated with these relevant exposures. The FQPA also identifies the need to conduct research to ensure the safety of children. Aggregate exposure is defined as the exposure to a single pesticide through all routes and pathways, while cumulative exposure is defined as the exposure to multiple pesticides through all routes and pathways. Research in this objective focuses on the exposures and effects associated with children and other susceptible and/or sensitive subpopulations. The FQPA research program is designed to provide the scientific foundation for assessing aggregate and cumulative risk and susceptibilities of sensitive subpopulations (including children) from exposure to pesticides in order to reduce uncertainty in risk assessments conducted under FQPA.

Major uncertainties exist related to the degree to which current risk assessment practices provide adequate protection to those segments of the population (with a focus on protecting children) who are more sensitive than the average individual. These uncertainties elicit questions about the health endpoints of greatest concern in children, age-related differences in exposure, age-related physiological differences that might affect internal exposures and health outcomes, and whether current risk assessments adequately protect children and other sensitive subpopulations from unreasonable risk. Research will address questions about exposures experienced by children and other susceptible subpopulations and whether they produce quantitatively or qualitatively different effects than those experienced by adults.

Other uncertainties relate to our ability to assess risk from aggregate exposure to single chemicals and to cumulative exposures to multiple pesticides and other chemicals with like mechanisms of action. EPA research will address questions about the level of aggregate and cumulative exposures, the effects resulting from multiple, short-term exposures to various sources and the characteristics of toxic pesticide mixtures in the environment that are important for assessing risks to humans.

In FY 2003, health effects research will yield new and improved test methods to evaluate the effects of environmental exposure to pesticides and other chemicals in sensitive subpopulations. Research will also develop methods to evaluate the effects of cumulative exposures to pesticides and toxic chemicals, including both long-term exposures and multiple acute exposures. Specifically, this work will determine if exposure to multiple pesticides with a similar mode of action produce non-additive interactions, and if effects/interactions vary between adult and juvenile animals. The development of models (e.g, physiologically-based pharmacokinetic, biologically-based dose-response, and structure-activity relationship models) to extrapolate findings and predict effects is also included in this effort.

Exposure research will address major exposure data gaps, distributions of key exposure factors (especially across age groups for children and other susceptible subpopulations), and uncertainties associated with the exposure assessment requirements for FQPA. These efforts will produce: 1) tools and methods for conducting exposure research; 2) high quality exposure data that

identifies the key factors associated with aggregate and cumulative pesticide exposures and characterizes the distributions of pesticide exposures for children, other susceptibles, and the general population; and 3) a toolbox of source-to-dose probabilistic exposure models for extending the exposure research results, integrating exposure research with effects research, and identifying new science needs to support the FQPA mandates. The Agency will use these results to better characterize, assess, and manage aggregate and cumulative exposures to pesticides and toxics.

EPA will initiate a major population-based field study in FY 2003 that will focus on young children's aggregate exposure to pesticides in homes, day care centers, and schools (this research will be leveraged with corresponding research being planned and conducted within the core human health research program). This study will be completed in FY 2004 with delivery of major products in FY 2005. Study results will be used to: 1) evaluate and refine a protocol for measuring aggregate exposure for children of different age and developmental groups; 2) verify those pathways and activities that represent the highest exposures for children; 3) generate high quality distributional data on children's exposure concentrations, estimated exposures, and exposure factors; and 4) develop a measurement database for model evaluations, model improvement, hypothesis generation, and risk assessments.

Additionally, in FY 2003 the Agency will continue its efforts to address uncertainties in the areas of intermittent exposure and cumulative risk. EPA will develop data, methods, and models for characterizing and combining exposures and assessing exposure-dose-response relationships for pesticides with different exposure patterns (inclusive of temporal, spatial, and multipathway considerations). The emphasis of this research will be on developing a foundation for cumulative risk assessment methodology. EPA will also use the results from the exposure and effects research programs to develop improved risk management strategies and tools for reducing potential health risks to children and other highly exposed populations.

To address some of the complex uncertainties in the area of cumulative risk, the Agency will continue efforts to develop a systematic approach for determining the cumulative risk for a given set of exposure conditions. This approach, starting with less complex paradigms (e.g., risk from aggregate exposure to a single chemical, or a class with a postulated common mode of action, which is present in multiple pathways), will build towards the more complex, including consideration of different temporal dimensions of exposure. In each case, work will employ an integrated model for estimating cumulative risk by identifying and defining the relationship between the determinants of exposure, source(s), pathway(s), and exposure-to-dose.

Understanding these relationships will also better focus and guide risk management decisions and allow for more accurate prediction if determinants change (e.g., addition or reduction in a source in a given setting). This approach will provide the opportunity to assess the validity of current risk assessment methods and models to account for multiple sources/exposures, stressors, and toxicities.

Risk assessment research, another facet of the FQPA research program, will continue to focus on developing methods for combining exposures from different pathways, assessing exposure-dose-response relationships for pesticides and other compounds with common modes of action, and

reducing uncertainties in risk assessment for children. Analyses using data from available sources (e.g., the National Human Exposure Assessment Survey - NHEXAS and the National Health and Nutrition Examination Survey - NHANES) will be conducted focusing on aggregate exposure and risk to multiple chemicals from multiple pathways, particularly for children.

The Agency will continue to compare pesticide exposures across age groups, identify factors leading to higher exposures, and analyze data to improve the evaluation of exposure factors for pesticide risk assessment. Results will support risk assessments under FQPA and development of Agency guidelines for cumulative risk assessment through the EPA Risk Assessment Forum.

The risk management research program, the final component in the risk paradigm structure, will evaluate characteristics of commonly used pesticides or pesticides of particular concern to determine which chemicals should be targeted for development of risk management tools. Risk management tools will be identified that have the potential to reduce exposure from the identified chemicals and research projects specific to the chosen chemicals will begin.

In summary, the FQPA research program provides direct support to EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) through the development of specific methods, data, tools, and protocols that will be used to develop new or revised test guidelines under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended by FQPA. These test guidelines provide direction to the manufacturers of pesticides and industrial chemicals in collecting the data required for registering pesticides and gaining approval to manufacture chemicals.

FY 2003 Change from the FY 2002 President's Budget

EPM

- (+$2,000,000) 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.

- (+$9,000,000, 73.8 FTE) Appropriated funds are shifted from the tolerance program, to the reregistration program. The reregistration program will no longer be funded by the Maintenance fee, which expires at the end of FY 2002.

- (-$9,178,000 -73.8 FTE) Appropriated funds are being shifted from tolerance reassessment program and the reregistration program, as described above. The tolerance reassessment program will be funded through the new tolerance fee rule beginning in March 2003.

- (-$862,000, -1.3 FTE) This decrease reflects return to base levels in reregistration after completion of preliminary analysis for the reregistration of antimicrobials which may be effective against bioterrorism threats including anthrax. The effort was funded by the Emergency Supplemental.

C (+$760,700) 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: -$3,569,400, utilities: +$3,468,000, Security: -$9,103,900. Nominal increases/decreases occurred in human resource operations, grants and contracts related activities.)*

Research

S&T

C (-$765,000) This reduction eliminates funding for the Congressionally-directed research.

C (+$112,900, 1.0 FTE) This increase in resources will be used to coordinate EPA scientific participation in regulatory development with program office on major rules.

Annual Performance Goals and Measures

Reassess Pesticide Tolerances

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

In 2003 By the end of 2003 EPA will reassess a cumulative 68% of the 9,721 pesticide tolerances required to be reassessed over ten years and complete reassessment of a cumualtive 75% of tolerances of special concern in protecting the health of children.

In 2002 Assure that pesticides active ingredients registered prior to 1984 and the products that contain them are reviewed to assure adequate protection forhuman health and the environment.Also consider the unique exposure scenarios such as subsistence lifestyles of Native Americans in regulatory decisions.

In 2002 By the end of 2002 EPA will reassess a cumulative 66% of the 9,721 pesticide tolerances required to be reassessed over ten years. This includes 67% of the 893 tolerances having the greatest potential impact on dietary risks to children.

In 2001 EPA reassessed 40% of tolerances requiring reassessment under FQPA and issued a cumulative 72% of total REDs required, achieving both targets.

In 2001 EPA reregistered 856 products, exceeding its target by 14%.

Performance Measures:	FY 2001 Actual	FY 2002 Enacted	FY 2003 Request	
Tolerance Reassessment	40%	66%	68%	Tolerances(Cum)
REDs	71.6%	76.4%	83%	Decisions (Cum)
Product Reregistration	856	750	750	Actions
Tolerance reassessments for top 20 foods eaten by children	43.5%	67%	75%	Tolerances(Cum)

Baseline: The baseline value for tolerance reassessments is 9,721 tolerances that must be reassessed using FQPA health and safety standards; REDs is 612 REDs that must be completed; product reregistration is under development; and tolerances reassessed for the top 20 foods eaten by children is 893. Cumulative totals for tolerances reassessed and REDs are displayed because this more clearly shows progress in implementing FQPA than would a display of single-year results shown in earlier years.

Verification and Validation of Performance Measures

Performance Measures:

C**Number of tolerance reassessments**
C**Number of REDs**
C**Number of Product Reregistrations**

Performance Database: Tolerance Reassessment Tracking System (TORTS) is an in-house (Office of Pesticide Programs-wide) system containing records on all 9,721 tolerances subject to reassessment. It contains numbers of total tolerances reassessed; breakout by Fiscal Year, source, & priority group; outcomes of reassessments (number of tolerance levels raised, lowered, revoked, remaining same). It also provides counts of tolerances reassessed for organophosphates, carbamates, organochlorines, carcinogens and high hazard inerts, children's foods, and minor uses.

Data Source: Office of Pesticide Programs (OPP) Staff (reviewers)

QA/QC Procedures: OPP Management verifies/signs decision to count tolerance as reassessed or not, as a result of the Reregistration Eligibility Decision or decision to approve registration. Additionally, the Program Divisions maintain counts of the tolerances reassessed. The information is provided to the Office Director's immediate office for consolidation and record-keeping.

Data Quality Review: Management reviews the program output counts. Tolerance counting rules are reviewed for consistency across the programs. Decisions are made by management as to whether the tolerance requires cumulative risk assessment or individual risk assessment. This decision is made based on whether the tolerance belongs to a group of chemicals which have a common mode of toxicity.

Data Limitations: Because the measure is a numeric count, there are no data limitations. Data needed for registration or reregistration/tolerance reassessment are provided by the pesticide registrant. If the data required for the risk assessment is not provided with the original package, then the information is requested from the registrant. The pesticide is not registered or reregistered until the required data are submitted. Should the registrant choose not to support a reregistration and associated tolerance reassessments, the Agency may cancel the pesticide involved.

New / Improved Data or Systems: The OPPIN (Office of Pesticide Programs Information Network) database consolidates various OPP program databases. Phased implementation of the OPPIN began in FY 2001 and will continue through FY 2003. **Number of registrations of reduced risk pesticides.**

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 recordkeeping.

Data Source: The Office of Pesticide Programs (OPP) Staff (reviewers)

QA/QC Procedures: In order to meet the criteria of a reduced risk pesticide, the pesticide must meet the criteria set forth in PR Notice 97-3, September 4, 1997. 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).

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. All required data must be submitted for our risk assessments before the pesticide is registered. This applies to reduced risk candidates, as well. If data are not submitted, the pesticide is not registered. A reduced risk pesticide must meet the criteria set forth in PRN 97-3. If it does not meet the criteria, it is not reviewed as a reduced risk, but as a conventional active ingredient. All risk assessments are subject to public and scientific peer review.

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.

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)--established to give advice and counsel on developing a strategy to screen and test endocrine disrupting chemicals and pesticides--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)--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

EPA, in collaboration with the National Institute for Environmental Health Sciences (NIEHS), has established Centers for Children's Environmental Health and Disease Prevention to define the environmental influences on asthma and other respiratory diseases, childhood learning,

and growth development. NIEHS, through the National Toxicology Program (NTP), develops new technologies for high throughput toxicity testing, and is responsible for one-third of all toxicity testing performed worldwide.

The Centers for Disease Control and Prevention (CDC), through the National Center for Environmental Health (NCEH), studies health problems associated with human exposure to lead, radiation, air pollution, and other toxics, as well as to hazards resulting from technologic or natural disasters. These are mainly surveillance and epidemiology studies and NCEH is particularly interested in studies that benefit children, the elderly, and persons with disabilities. The NCEH laboratory supports many of EPA's studies and is the analytical laboratory for samples collected in the EPA-sponsored pesticide study in the National Health and Nutrition Examination Survey - NHANES-4, being conducted by the National Center for Health Statistics (NCHS) of CDC. NHANES-4 is a survey of the national population and includes data on potentially sensitive subpopulations such as children and the elderly. EPA is participating in this survey with NCHS to collect information on children's exposure to pesticides and other environmental contaminants. In FY 2003, EPA will collaborate with NCHS to produce an analysis of data collected on pesticides in NHANES-4.

The National Institute of Child Health and Human Development (NICHD) is the lead agency for conducting the National Children's Study (NCS) of environmental influences on children's health and development. EPA is part of a consortium of Federal agencies that are planning, developing and implementing the NCS.

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)

Research

Food Quality Protection Act of 1996 (FQPA)
Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
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Federal Food, Drug, and Cosmetic Act (FFDCA)