Environmental Protection Agency

FY 2002 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 1999 Enacted	FY 2000 Actual	FY 2001 Enacted	FY 2002 Request
Goal 03	**Safe Food**	**$77,562.8**	**$83,259.7**	**$109,303.9**	**$108,245.0**
Obj. 01	Reduce Risks from Pesticide Residues in Food	$34,389.8	$38,373.3	$44,577.4	$45,199.4
Obj. 02	Eliminate Use on Food of Pesticides Not Meeting Standards	$43,173.0	$44,886.4	$64,726.5	$63,045.6
	Total Workyears	711.3	778.7	796.9	770.9

*For proper comparison with the FY 2002 request, the historic data has been converted to be consistent with the new 2000 Strategic Plan structure. Goal and Objective resources for FY 1999, FY 2000, and FY 2001 may therefore differ from the resources reported in the FY 2001 Annual Plan and Budget and the FY 2000 Annual Report.

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 with the goal of protecting 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).

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, liver, or 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
- One million farms
- Several million industry and government users
- About 100 million households

Pesticides subject to EPA regulation include 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. Total U.S. pesticide usage in 1997 was 4.6 billion pounds. Biopesticides and reduced risk pesticides make up about 20 percent of the total. Agriculture accounts for about 80 percent of all applications. There are about 1.3 million certified pesticide applicators in the U.S. Herbicides are the most widely used pesticides and account for the greatest expenditure and volume.

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 agencywide FY 2002 request supporting FQPA includes $148.8 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; and

- Expediting the approval of reduced risk pesticides.

Means and Strategy

The Agency uses a two-fold strategy for accomplishing the objectives of the Safe Food goal:

- Encouraging the introduction of new, reduced risk pesticides (including new plant incorporated protectants) within the context of new pest-management practices; and

- Reducing the use of currently registered pesticides with the highest potential to cause adverse health effects

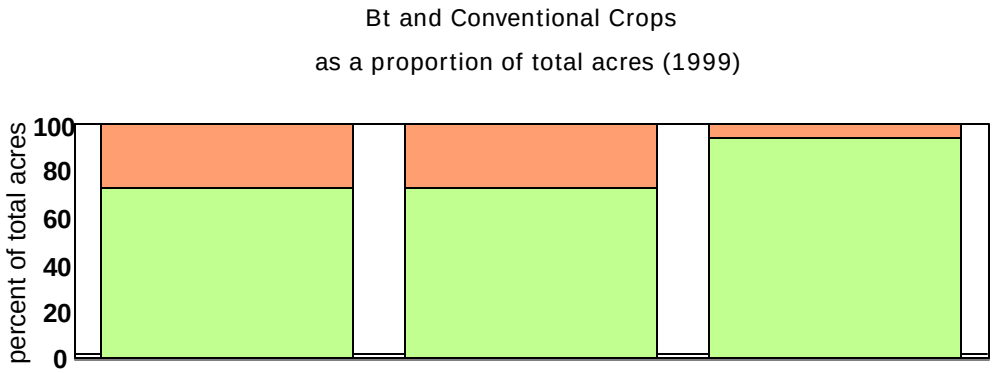
In 2002, the Agency will continue to promote accelerated registrations for pesticides that provide improved risk reduction or risk prevention compared to those currently on the market. Progressively replacing older, higher-risk pesticides is one of the most effective methods for curtailing adverse impact on health and the ecosystem while preserving food production rates.

EPA uses its authorities to systematically manage the risks of pesticide exposures by establishing legally permissible food-borne pesticide residue levels, or tolerances. EPA manages 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 2002 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 test 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.

New registration actions result in more pesticides on the market that meet FQPA 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



	Field C	Cott	Pota
Acres of Conventior	57.6	10.7	1.3
Acres of Bt	19.7	3.8	0.0
Total Acres (in m	77.3	14.5	1.3

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.

Biotechnology is likely to be the focus of continued public scrutiny in fiscal year 2002 as it accounts for a large share of acres planted. For example, Bt corn and cotton made up about 25 percent of all field corn and cotton acres in 1999 (see box). Biotechnology has great potential to reduce our reliance on some older, more risky chemical pesticides, and to lower worker risks. Given the public interest in foods derived from biotechnology, EPA has increased the number of public meetings and scientific peer reviews of our policies and assessments.

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 FY 2002 will include: advancing scientific knowledge of allergenicity; finalizing decisions on exemptions to 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, which is working on international standards governing foods derived from biotechnology. In addition, EPA plans to register three new plant incorporated protectants, provided they are found not have adverse effects on human health or the environment.

Finally, in addition to setting the requirements of 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.

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 subpopulations and considering effects from cumulative exposures.

EPA must develop tools adequate to address the needs imposed by FQPA. In FY 2002, EPA's research program will continue to focus on developing and validating methods to identify and characterize, and models to predict, the potential increased susceptibility to human health effects experienced by infants and children; identifying and understanding major exposure routes, and pathways and processes, and developing theoretical and experimentally based multipathway exposure models for pesticides and other toxic substances; and addressing the adequacy of current risk assessment methods and providing the necessary risk assessment guidance. More specifically, health effects research will continue to focus on developing new and improved test methods to evaluate the effects of environmental exposure to pesticides and other chemicals in sensitive subpopulations.

Strategic Objectives and FY2002 Annual Performance Goals

Objective 01: 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.

- 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.

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

Objective 02: Eliminate Use on Food of Pesticides Not Meeting Standards

- 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 70% of the 893 tolerances having the greatest potential impact on dietary risks to children.

- 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.

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, new uses, and handling experimental use permits and emergency exemptions.

In 2002, 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 pose lower potential dietary risks to consumers, lower risks to agricultural workers, and reduce potential 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

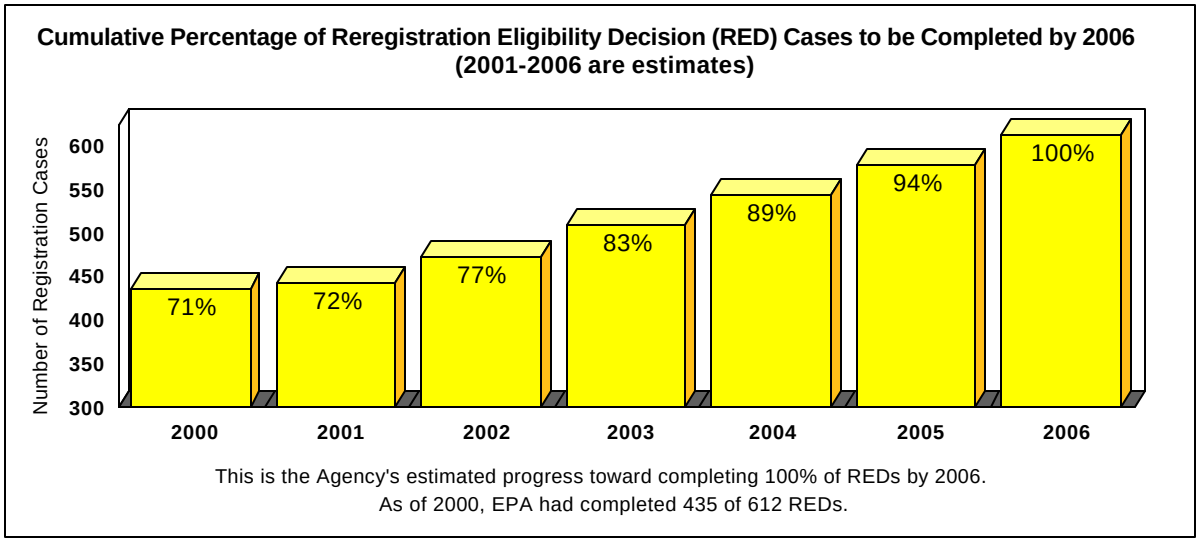
In FY 2002, the Agency will continue toward its ten year statutory deadline of reassessing all 9,721 tolerances by meeting its second statutory deadline of reassessing a cumulative 66 percent of these tolerances by August 2002. The Agency will also continue to develop tools to screen pesticides for their potential to disrupt the endocrine system. In 2002, EPA will work toward completing 30 Reregistration Eligibility Decisions (REDs) and 750 product reregistrations.

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 2002, EPA will continue its effort to reduce dietary risks to children, by completing a cumulative 70 percent of these tolerances of special concern.

Organophosphates and carbamates are believed to pose higher risks than other groups of pesticides. These pesticides are widely used and curtailing or restricting the use of these chemicals will mean changes in current farming practices. The need for broad input and participation lead to a special stakeholder process to address data, analysis and regulatory requirements, protocol, and scientific and public review as the Agency moves to reduce the risks posed by some of these pesticides. The Agency will continue this important dialogue with stakeholders as we work together to protect human health and the environment.

The reregistration maintenance fee, which funds the salaries of the 200 FTE that are involved in reregistering older pesticides to ensure they meet current health and safety standards, expires at the end of FY 2001. The FY 2002 President's Budget reflects the expiration of the authority to collect reregistration maintenance fees. Despite the expiration of the fee, the reregistration program will be fully funded in 2002. The 2002 budget request fills the resource gap with funds previously appropriated for the tolerance reassessment program.

The Reregistration program was accelerated by the 1988 amendments to FIFRA and enhanced by FQPA, which included adding 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. The findings determine whether the products registered under this chemical are eligible for reregistration.



FQPA added considerably more complexity into the process of reregistering pesticides. New statutory requirements have made risk assessment more complex and lengthened the "front end" of reregistration. These requirements include considering aggregate exposure and cumulative risk, 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 pest control tools and practices. Over the longer run, these changes will enhance protection of human health and the environment.

Also, by the end of FY 2002, EPA expects to have incorporated public comments into all science policy papers, finalizing most of them, and will begin implementing these policies in our risk assessments. Developing and implementing these science policies - particularly the policy for cumulative risk assessment for pesticides with common methods of toxicity - will cause a sharp increase in the number of tolerances reassessed in 2002.

In FY 2000, the Agency targeted the organophosphate pesticides (OPs) for tolerance reassessment. Because the OPs share a common mechanism of toxicity, a cumulative risk assessment across all of the OPs is required before the reassessment of their tolerances is completed. This extra stage of cumulative assessment was not needed for the tolerances reassessed in FY 1999 since pesticides reviewed at that time either were canceled voluntarily or had no common mechanism of toxicity. The cumulative assessment requires that EPA establish a cumulative risk policy, which has taken the Agency longer than first anticipated. EPA expects to issue that policy by the end of FY 2001. Following that, the Agency will be able to complete the reassessment of all of the OP tolerances, producing a surge of reassessments completed in FY 2002. We are on schedule to meet our statutory deadline of 66% of all tolerances reassessed by August 3, 2002.

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. The tolerance program will be fully funded through a combination of appropriated funds and fees that begin in FY 2002. In future years, the program will be entirely funded through the new tolerance fee.

FQPA also requires that EPA establish a process for periodic review of pesticide registrations. This requires the updating of all pesticide registrations using current health standards, scientific data, risk assessment methodology, program policies and effective risk reduction measures. In 2002, the Agency will continue developing the framework for the registration review program.

Research

In FY 2002, 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, health effects research will continue to focus on developing new and improved test methods to evaluate the effects of environmental exposure to pesticides and other chemicals in sensitive subpopulations. The exposure research program will continue to devote attention to identifying those pesticides, media, pathways, and activities that represent the highest potential exposures to children and other susceptible and/or sensitive subpopulations and determine the factors that influence these exposures. Risk assessment research will develop methods for combining exposures and assessing exposure-dose-response relationships for pesticides and other compounds with common modes of action and different exposure patterns.

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 2002 Annual Performance Plan and Congressional Justification

Safe Food

Objective #1: 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 1999 Enacted	FY 2000 Actual	FY 2001 Enacted	FY 2002 Request
Reduce Risks from Pesticide Residues in Food	**$34,389.8**	**$38,373.3**	**$44,577.4**	**$45,199.4**
Environmental Program & Management	$31,494.6	$36,181.9	$42,312.6	$42,926.7
Science & Technology	$2,895.2	$2,191.4	$2,264.8	$2,272.7
Total Workyears	296.0	322.5	330.0	335.0

Key Programs
(Dollars in thousands)

	FY 1999 Enacted	FY 2000 Enacted	FY 2001 Enacted	FY 2002 Request
Pesticide Registration	$25,031.5	$24,964.3	$29,229.2	$29,669.3
Pesticide Reregistration	$4,724.0	$4,730.3	$5,381.1	$6,632.6
Endocrine Disruptor Screening Program	$1,237.3	$1,695.5	$2,264.0	$1,975.4
Pesticide Residue Tolerance Reassessments	$1,040.8	$1,262.3	$1,234.5	$649.9
Rent, Utilities and Security	$0.0	$3,660.3	$4,250.0	$4,923.8

	FY 1999 Enacted	FY 2000 Enacted	FY 2001 Enacted	FY 2002 Request
Administrative Services	$0.0	$424.7	$669.9	$456.3

FY 2002 Request

This request is targeted toward improving the safety of the food produced and consumed by the American public, and continuing the commitment to implement the high standards of 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), Organization for Economic and Cooperation Development (OECD) and various others to engage and share information with stakeholders, to develop strategies for a smooth transition to FQPA standards, for the public, industry and agriculture. EPA will continue to ensure that the best available science is incorporated into the implementation of the statute.

Many pesticides currently on the market with approved food uses are suspected to be potential human carcinogens, neurotoxins or endocrine disruptors. They may also pose other significant health concerns, especially to children. The Food Quality Protection Act (FQPA) provides unprecedented opportunities to protect the health of the U.S. public, and to positively impact agricultural production techniques, lessening the overall risk of pesticide use. Further, it mandates that the Agency continue to review pesticides on a periodic basis to ensure that those registered for use meet the most current health standards, thus ensuring that when properly used, we maintain a reasonable certainty of no harm to human health or the environment. To address these concerns, EPA will continue the Registration and Reregistration/Special Review regulatory programs. Combined with the review of existing pesticides through reregistration and tolerance reassessment, the availability of safer pesticides has improved 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 (use) the registrant requests for the specific pesticide. The Registration program gives priority to accelerated processing of reduced risk substitutes 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 actions in response to industry's need. Registration's include 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 has added requirements for reviewing the ingredients added to pesticide products called inert ingredients. Though called "inert" because they have no pesticidal properties, those agents are often chemically active and must be reviewed for unintended effects on humans and the environment. In addition, increased public education and full ingredient disclosure (including inerts) on pesticide product labels must be balanced against industry interests in protecting confidential business information (CBI).

In March 2000, the Agency established a diverse workgroup with members from public health, environmental, industry, academic, and state government organizations. EPA's charge to the workgroup is to consider potential measures to increase the availability of information about inerts to the public. EPA will continue to work on this issue in FY 2002.

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. In 2002, the Agency will have finished its policy for assessing cumulative risk for these groups of chemicals and begin to apply it to pesticide registration and reregistration decisions. Aggregate exposure brings issues of residential exposures and drinking water residues into the equation. The extra ten-fold safety factor for children's health has an impact on data collection. A lower factor can be used, FQPA states, "...only if, on the basis of reliable data, such margin will be safe for infants and children." These new science policies will likely result in a safer food supply for the American public.

FQPA Science Policies

EPA worked with the Tolerance Reassessment Advisory Committee (TRAC) to identify nine science policy issues that are key to the implementation of the Food Quality Protection Act (FQPA) and tolerance reassessment. Papers on all of these polices have been made publicly available for comment. By the end of FY 2002, EPA will have revised all papers. Several of these papers to be revised in FY2002 involve particularly complex policy issues, including under what circumstances to apply the 10-fold safety factor for vulnerable populations in registration decisions; how to properly account for cumulative risk in the risk assessment process, and how to characterize residential exposure.

The following are all nine science policies:

1. Applying the FQPA 10-fold safety factor
2. Dietary exposure assessment methods
3. Exposure assessment
4. Dietary exposure estimates
5. Drinking water exposures
6. Assessing residential exposure
7. Aggregating exposures from non-occupational sources
8. Cumulative risk assessment for pesticides with common methods of toxicity

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 FY2002, EPA will continue to work with the pesticide industry and farmers to explore new pest management approaches and to provide reasonable phase out periods 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.

The Agency allows for the unpredictability of agricultural conditions and pest outbreaks and takes action to meet emerging needs. States and industry submit registration actions to meet rapidly changing needs, including petitions for temporary uses of pesticides to meet emergency conditions, and for research purposes. 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) allowing 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. Minor use pesticides are those that produce relatively little revenue for their manufacturers, considering the cost of maintaining these registrations. EPA policy has defined minor uses as being used on crops grown on less than 300,000 acres. Minor use pesticides are of major significance in agricultural production and in public health protection, to growers and consumers. 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 2002, 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.

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.

Reduced Risk Chemicals and Biopesticides

In FY 2002, 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 2002, expects to register 15 new reduced risk pesticides.

Reduce Agricultural Use of Potential Carcinogenic or Neurotoxic Pesticides

EPA is moving deliberately to minimize exposure from pesticides, currently on the market, with the highest potential to cause cancer or neurotoxic effects. In 2002, EPA must address these chemicals and make decisions on how to minimize potential risk resulting from their use. In order to accomplish this, the Agency must complete its cumulative risk policy and expand or refine its usage data. The development and registration of appropriate alternatives to these risky chemicals is also a priority. 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.

Foods that Children Eat

The following 19 foods that children commonly eat were surveyed for organophosphorus 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 2002, regulatory actions by EPA should result in a 15% reduction of detection of residues from carcinogenic and neurotoxic pesticides on these foods. from 1994-

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).

FY 2002 Change from FY 2001 Enacted

EPM

- (-$291,600) Base endocrine disruptor activities were reduced to help meet increased workforce costs. Alternative contract structure will allow the program to conduct priority research with no significant delays due to this change.

- (-$507,600) Tolerance reassessment and tolerance petition programs will be partially funded through the new tolerance fee. Resources were shifted to fund the reregistration program. There will be no impact to the program from changing the source of funds.

- (+$1,385,460) This increase reflects an increase in workforce costs.

- (+$584,230, 6.2 FTE) Staff previously funded under the expired maintenance fee will be funded from the appropriated budget in EPM. There will be no impact to the program from changing the source of funds.

- (-$858,300) This reduction in contract dollars for tolerance petitions and antimicrobial registration actions will provide funds for the salary for the reregistration FTE formerly funded through the maintenance fee which expires in 2001. The new tolerance fee will fund one half of tolerance reassessment and tolerance petition programs in 2002. Registration actions for antimicrobials will be slowed or handled directly by staff.

- (-$240,000) This is a reduction in working capital fund and other base programs to fund payroll and continuing emphasis on scientific peer review. Cost streamlining is expected to reduce impact to decreased areas.

Annual Performance Goals and Performance Measures

Decrease Risk from Agricultural Pesticides

In 2002	Provide timely decisions to the pesticide industry on the registration of active ingredients for conventional pesticides.
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 2001	Provide timely decisions to the pesticide industry on the registration of active ingredients for conventional pesticides including tolerance setting, product registrations and inert ingredients.
In 2001	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.
In 2000	The Registration Program completed registrations for 9 new chemicals, 3069 amendments, 1106 me-toos, 427 new uses, 95 inerts, 458 special registrations, 452 tolerances, and 13 reduced risk chemicals/biopesticides.

In 1999 In FY 1999, EPA registered 19 additional reduced risk pesticides, including 13 biopesticides. EPA established 351 new pesticide food tolerances and acted on 681 proposed new pesticide uses, ensuring that all meet the new health safety standard of "reasonable certainty of no harm."

Performance Measures:	FY 1999 Actuals	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Request	
Register safer chemicals and biopesticides	19	13	96	109	Regist. (Cum)
New Chemicals	7	9	51	58	Regist. (Cum)
New Uses	681	427	1979	2329	Actions (Cum)

Baseline: The baseline year is 1996, the year FQPA was enacted. Cumulative totals for safer chemicals, biopesticides, new chemicals, and new uses are displayed because this more clearly shows progress made in implementing FQPA since 1996 than would a display of single-year results shown in earlier years.

Reduced Risk Pesticides

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

Performance Measures:	FY 1999 Actuals	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Request	
Percentage of acre treatments with reduced risk pesticides				1%	acre treatments

Baseline: Each year's total acre-treatments with pesticides, as reported by USDA's National Agricultural Statistical Survey serve as the baseline for computing the percentage using reduced risk pesticides.

Reduce use of highly toxic pesticides

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 Use of pesticides classified as having the highest potential to cause cancer or neurotoxic effects will be reduced.

In 2000 Due to regulatory actions and trends in usage, we are seeing a larger decrease (15%) in the use of carcinogenic or neurotoxic pesticides than expected. We anticipate that this trend will continue.

Performance Measures:	FY 1999 Actuals	FY 2000 Actuals	FY 2001 Estimate	FY 2002 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%	15%	Reduced Detect.

Baseline: Average detection frequencies for these foods in the 1994-1996 PDP data are 25% for carcinogenic pesticides and 33.5% for cholinesterase-inhibiting neurotoxic pesticides.

Verification and Validation of Performance Measures

Performance Measure: Number of registrations of reduced risk pesticides.
Number of registration actions for new chemicals.

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.

Data Source: OPP Staff (reviewers)

QA/QC Procedures: Program output. 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 nontarget 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 output counts.

Data Limitations: None

New / Improved Data or Systems: Database (Office of Pesticide Programs Information Network) consolidates various OPP program databases.

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 and 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

Safe Food

Objective #2: 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 1999 Enacted	FY 2000 Actual	FY 2001 Enacted	FY 2002 Request
Eliminate Use on Food of Pesticides Not Meeting Standards	**$43,173.0**	**$44,886.4**	**$64,726.5**	**$63,045.6**
Environmental Program & Management	$35,396.3	$35,179.6	$52,680.6	$50,796.7
Science & Technology	$7,776.7	$9,706.8	$12,045.9	$12,248.9
Total Workyears	415.3	456.2	466.9	435.9

Key Programs
(Dollars in thousands)

	FY 1999 Enacted	FY 2000 Enacted	FY 2001 Enacted	FY 2002 Request
Pesticide Reregistration	$27,851.0	$24,424.2	$28,088.1	$36,699.3
Endocrine Disruptor Screening Program	$1,435.5	$4,869.8	$3,457.0	$3,314.8
Pesticide Residue Tolerance Reassessments	$9,057.3	$10,335.5	$13,567.1	$5,196.1
Rent, Utilities and Security	$0.0	$458.0	$6,354.9	$5,514.0
Administrative Services	$0.0	$552.4	$1,139.5	$861.2

FY 2002 Request

EPA is reviewing risk assessments for data and studies - pesticides that are used on foods to ensure that pesticides residues (tolerances) meet stricter FQPA safety standards. Risk assessments are the basis for the Agency's decisions on tolerance setting. They involve a series of sophisticated analyses of the potential health and environmental effects resulting from exposure to a chemical through various means. 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. 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). In reassessing tolerances, EPA reviews data currently available and may request additional data if requirements (data call-in) have changed or there appear to be data gaps or risk questions that are not answered adequately.

FQPA sets in place a new program, called Registration Review, which will periodically update the pesticide registrations, including tolerances every 15 years, avoiding the need for "catch-up" programs in the future.

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. Those 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. This finding determines whether the products registered under this chemical are eligible for reregistration. In 2002, the Agency will complete 30 REDs. EPA plans to complete reregistration for active ingredients by 2006 and inert ingredients by 2008.

As pesticides go through reregistration, they may meet certain criteria that will trigger a process called a special review. These criteria include findings of (a) acute toxicity to humans or domestic animals, (b) potentially chronic or delayed toxic effects in humans or hazards to non-target organisms, (c) risk to threatened or endangered species, (d) risk to critical habitats of threatened or endangered species, and (e) any other unreasonable adverse effects to humans or the environment. The special review subjects the pesticide to a more in-depth analysis to determine with reasonable certainty that no harm will occur when used.

EPA's authority to collect Reregistration Maintenance Fees expires in September 2001. The President's budget 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 fully funded by fee revenue beginning March 2002.

Registration Review

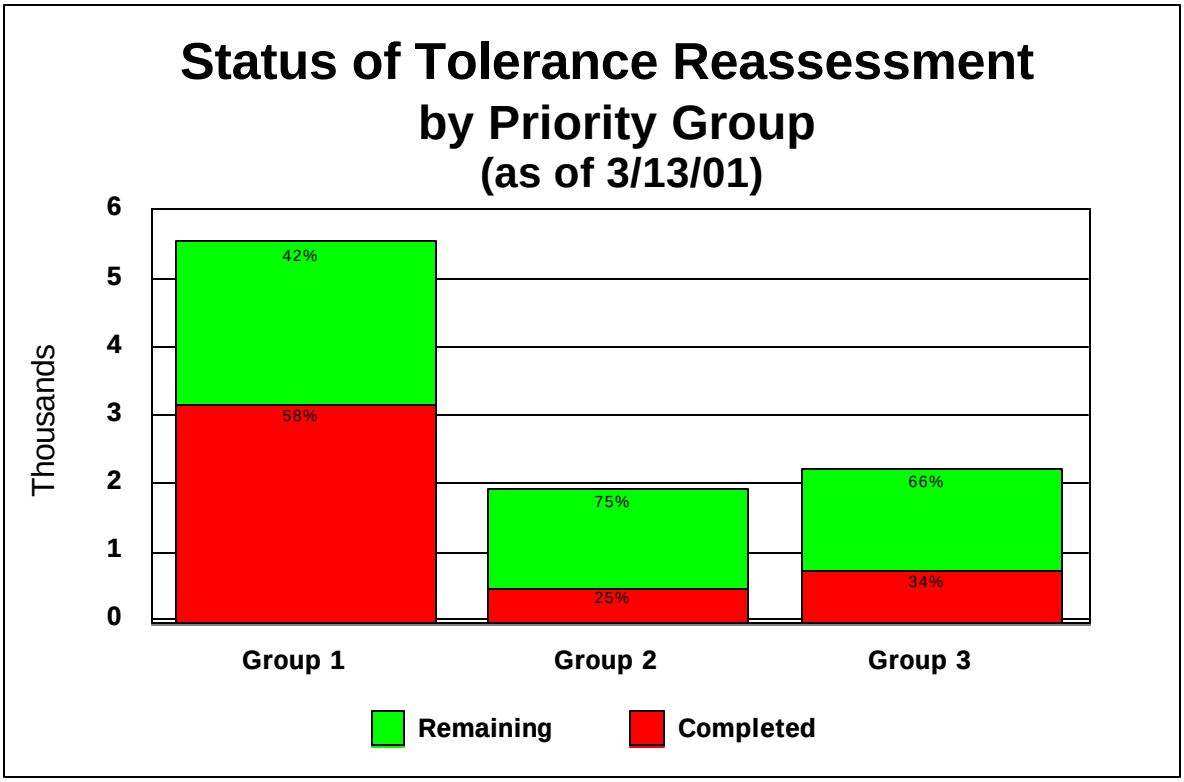
FQPA requires that EPA establish a process for periodic review of pesticide registrations with a goal of completing this process every 15 years. The registrations of all pesticides will be continuously updated with respect to current scientific data, risk assessment methodologies, program policies, and effective risk reduction measures, ensuring that they meet the most current health standards. In 2002, EPA will finish the regulation, 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 Agency will continue its reassessment of these tolerances and expects to meet its next statutory deadline of reassessing a cumulative 66 per cent of the tolerances requiring reassessment by August 2002.

FQPA standards are having a great impact on the way pesticides are reviewed and the Agency continues to ensure the most recent, sound science is applied consistently as part of a broad process including all stakeholders as well as the scientific community. The Agency has worked extensively with stakeholders through the Pesticide Program Dialogue Committee and the Tolerance Reassessment Advisory Committee to ensure transparency in decision making and a fuller understanding of the implications for growers, producers and the public. EPA will continue to emphasize a smooth transition to safer pesticides, and the Agency continues to coordinate closely with USDA as well as industry and commodity groups in finding alternatives and sharing information. Organophosphates, a higher risk set of pesticides, are also widely used and changes in availability will impact farmers. To address the issues around OP replacement, the Agency and USDA have developed a pilot review process that expands public participation.

The risk assessment 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.



Options for risk reduction range from revocation of the tolerance to modifications in use and label changes to reflect changes in 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.

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 as well as pesticides in the reregistration process that have not had a decision, for a total of 1,928 tolerances and Group 3 includes the remaining pre-FQPA and post-1984 pesticides. EPA expects to complete almost all Group 1 tolerance reassessments by the end of 2002. Some tolerances in all groups have been reassessed as part of the work already underway in the reregistration program.

EPA has developed a statutorily required tolerance fee rule that lays out and justifies a fee schedule for industry. This budget assumes that there will be no impediment to implementing the rule effective March 2002. The tolerance program is funded by appropriated dollars for part of the year.

Endocrine Disruptors

FQPA and the Safe Drinking Water Act Amendments of 1996 require the Agency to screen new chemicals and test those currently in use for their potential to disrupt the endocrine systems of humans and wildlife. The human endocrine system helps guide development, growth, reproduction and behavior. This is a critical issue, especially for children, since exposure to endocrine disruptors during the gestation period or infancy can pose serious and permanent developmental problems.

EPA is currently focusing on two activities: 1) development of a priority setting system to choose the first chemicals for screening, and 2) the development and validation of the screens to be used in the screening program. The program will first validate relatively simple, less expensive screens (Tier 1) to look for evidence of the potential to interact with the endocrine system. Two out of eight Tier 1 screens will be validated by the end of 2001. EPA is projecting that all Tier 1 screens will be validated by the end of 2003. Testing of chemicals that are found to have the potential to interact with the endocrine system through Tier 1 screens will begin at that time. Pesticide registrants and manufacturers of commercial chemicals will be required to test the chemicals EPA designates. More complex, expensive and accurate Tier 2 screens will be validated and implemented by the end of 2005.

Work on pesticide and chemical endocrine disruptors crosses two EPA goals, relating to both pesticides and all other toxic chemicals (Goals 3 & 4). However, the measures for both chemicals and pesticides endocrine disruptor work are displayed under Objective 4.3.

Research

The Food Quality Protection Act (FQPA) of 1996 identifies clear science needs consistent with the evaluation of the effects from all potential routes and pathways of exposures to pesticides, particularly for children and other susceptible and/or sensitive subpopulations as well as consideration of effects from cumulative exposures. This research program is designed to provide to the Agency information on human health effects of aggregate exposure, information on cumulative risk, and the information needed to assess the risks to children and other susceptible and/or sensitive subpopulations exposed to pesticides.

Major uncertainties in the area of sensitive subpopulations relate to the degree to which current risk assessment practices provide adequate protection. These uncertainties elicit questions about the health endpoints of greatest concern in children and whether current risk assessments adequately protect children and other sensitive subpopulations from unreasonable risk. Similarly, questions about exposures experienced by children and other susceptible and/or sensitive subpopulations and whether they produce qualitatively different effects from those experienced by adults are raised.

Uncertainties associated with cumulative risk relate to our ability to assess risk from aggregate or cumulative exposure to single chemicals or to mixtures of chemicals. These uncertainties are explored through addressing questions about the level of cumulative exposures and effects resulting from multiple, short-term

exposures from various sources and the characteristics of toxic chemical mixtures in the environment that are important for assessing risks to humans .

To address these uncertainties and other issues related to implementing FQPA, research in FY 2002 will continue to: 1) develop new/revised human health effects test methods to improve EPA's understanding of the key factors influencing exposures and the resulting health effects of pesticides on infants and children and high-exposure groups; and 2) develop new methods, measures, and models, to characterize real world exposures to pesticides in order to evaluate the health effects of cumulative exposures, including multiple acute exposures, and mixtures of chemicals with similar modes of action from the same source, mixtures of chemicals with similar modes of action from different sources, and to pesticides and other toxic substances.

More specifically, health effects research will continue to focus on developing new and improved test methods to evaluate the effects of environmental exposure to pesticides and other chemicals in sensitive subpopulations. A specific element of this work will be directed at the continued development of methods to evaluate the effects to developing organisms as a result of pre- and perinatal exposures. These include in utero (i.e., transplacental) and lactational exposure studies.

Health effects research will also continue to focus on: 1) developing methods to evaluate the effects of cumulative exposures to pesticides and toxic chemicals, including both long-term exposures and multiple acute exposures; and 2) developing or improving models to extrapolate findings and predict health effects, including physiologically-based pharmacokinetic (PBPK) models to improve dose estimation across exposure scenarios, biologically-based dose-response (BBDR) models to reduce uncertainty in extrapolations (e.g., from high doses in animals to environmental exposures in humans), and structure-activity relationship (SAR) models to improve hazard characterization.

In FY 2002, the exposure research program will continue to devote attention to identifying those pesticides, media, pathways, and activities that represent the highest potential exposures to children and other susceptible and/or sensitive subpopulations and determine the factors that influence these exposures. The research will be used to develop methods, data, and models for evaluating aggregate and cumulative exposures to pesticides and toxic chemicals. This research will target high level, short-term exposure resulting from recent pesticide applications.

Exposure studies will be supported in five areas: microenvironments/macroactivity patterns for children; pesticide use patterns; distribution of pesticide residues in nonoccupational microenvironments; exposure assessments using the microactivity approach; and exposure assessments using the macroactivity approach. The outputs from these studies will provide critical data needed to improve the approach for exposure assessments, and inputs for models of children's exposure.

Risk assessment research will develop methods for combining exposures and assessing exposure-dose-response relationships for pesticides and other compounds with common modes of action and different

exposure patterns. Case studies using data from all available sources will be developed focusing on aggregating exposure and risk to multiple chemicals from multiple pathways.

Additionally, in FY 2002, the Agency will continue its efforts to address uncertainties in the areas of cumulative risk and intermittent exposure. The Agency will address uncertainties related to intermittent exposure by developing 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), with an emphasis on developing a foundation for a cumulative risk assessment methodology.

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 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 source(s)-pathway(s)-exposure-dose-cumulative risk.

Understanding these relationships would 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.

The FQPA research program provides direct support to EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) through the development of specific test methods that will be used to develop new or revised test guidelines under the Toxics Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended by the FQPA of 1996. 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 2002 Change from FY 2001 Enacted

EPM

- (+$6,355,430, +76.3 FTE) Reregistration staff previously funded under the expired maintenance fee will be funded under the appropriated budget. There will be no program impact from changing the source of funds.

- (-$7,656,438) Tolerance reassessment and tolerance petition programs will be partially funded through fees. Resources are shifted to fund the reregistration program staff which will now be funded under the appropriated budget.

- (-$298,462,-3.0 FTE) Tolerance reassessment and tolerance petition programs reduced by three FTE to meet new Agency workforce levels. Start-up of review of certain second- tier tolerances will be delayed and certain outreach activities will be reduced in scope.

- (+$981,900) This increase reflects an increase in workforce costs.

- (-$143,600) The base endocrine disruptor program was reduced to meet increased workforce costs. Alternative contract structure will allow the program to conduct priority research with no significant delays due to this change.

Research

S&T

- There is no significant change.

Performance Goals and Performance Measures

Reassess Pesticide Tolerances

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 70% of the 893 tolerances having the greatest potential impact on dietary risks to 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 2001 By the end of 2001 EPA will reassess a cumulative 40% of the 9721 tolerances required to be reassessed over ten-years and complete reassessment of a cumulative 46% (or 411) of the 893 tolerances of special concern in protecting the health of children.

In 2001 Assure that older pesticides active ingredients and the products that contain them are regularly 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 our regulatory decisions.

In 2000 We did not achieve our FY2000 target for tolerance reassessments due to the ongoing work to establish a science policy on cumulative risk. Although we missed our annual target, we are still on track to meet our statutory deadlines to reassess all tolerances.

In 1999 Tolerances reassessed by EPA through Sept. 30, 1999 totaled 35%, exceeding both our cumulative target and the statutory deadline of reassessing 33% of the existing tolerances by August 1999.

Performance Measures:	FY 1999 Actuals	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Request	
Tolerance Reassessment	1445	121	40%	66%	tolerances(Cum)
REDs	14	6	72.4%	77.3%	decisions(Cum)
Product Reregistration	746	552	750	750	actions
Tolerance reassessments for top 20 foods eaten by children			46%	70%	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.

Registration Review

In 2002 Issuance of final rule for registration review

In 2001 Issuance of proposed rule for registration review

In 2000 The Advance Notice of Public Rulemaking (ANPR) for the new Pesticides Registration Review Program was issued on schedule.

Performance Measures:	FY 1999 Actuals	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Request	
Issue Registration Review rule		1 ANPR	1 Proposed	1 Final	rule

Baseline: FQPA requires that EPA establish a registration review program to review active ingredients every 15 years.

Research

Research to Support FQPA

In 2002 For food-use products, develop innovative methods, measurements, and models for measuring and predicting pesticide exposures and effects, conduct assessments of pesticide risk to children's health, and improve characterization of differential risks to infants and children.

In 2001 Develop pesticides exposure and effects data, risk assessment methods and models for children, and control technologies needed to comply with the requirements of FQPA.

In 2000 EPA provided improved methodologies to evaluate the risk to human health posed by food-use products by completing the products listed below and other research activities.

Performance Measures:	FY 1999 Actuals	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Request	
First generation multimedia, multipathway exposure model for infants and young children and the identification of critical exposure pathways and factors.		30-Sep-2000		model	
Develop and validate a new and improve an existing method to evaluate the effects of pre- and perinatal exposure to pesticides and other toxic substances.		30-Sep-2000		method	
Develop a method to evaluate the human health effects of cumulative exposure to pesticides and other toxic substances.		0			method
Develop dose-response relationships to evaluate risks to human health from exposures to mixtures of pesticides and other toxic chemicals with the presumed same mode of action.		30-Sep-2000			
Describe age-dependent differences in responses to one or more pesticides			1		evaluation
Develop a protocol for conducting an exposure analysis for children that includes all relevant pathways.			1		protocol
Summary and comparison of multiple toxicities following developmental exposure to pesticides: Neurotoxicity, immunotoxicity, and reproductive toxicity.				1	analysis
Develop a prototype source-to-exposure-to-dose modeling framework that enables the complex computation for human exposure modeling.				1	model assessment
Analysis and report on factors for children's exposure to pesticides that may lead to high-level, short-term exposure to pesticides.				1	report
Advance the human exposure and dose model by improving the modules for dermal and dietary exposure.				2	modules
Report - Database of Body Burden Measurements of Pesticides and Toxic					

Chemicals to support future analysis of aggregate exposure and risk.	1	report
NHEXAS: Evaluate available measurement data on aggregate human pesticide exposures in the NHEXAS probability sample of people in 3 areas of the U.S.	1	evaluations

Baseline: Currently, there is limited understanding of when and why infants' and children's exposures and effects are different from those of adults. In addition, while health effects information exists for individual pesticides, few data are available on the potential combined health effects resulting fromexposure to mixtures of pesticides and toxic chemicals. Improved risk assessment methods will be developed to better predict age-related susceptibilities and actual human exposures and differences in exposures in causing variation in adverse health effects within the general population and vulnerable subgroups including infants and children.

Verification and Validation of Performance Measures

Performance Measure: **Number of Products Reregistered**
Number of Reregistration Eligibility Decisions

Performance Database: Pesticide Regulatory Action Tracking System (see description under Goal 3, Objective 1).

Performance Measure: **Number of tolerance reassessments**

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 count 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: Program output

Data Quality Review: Management reviews the program output counts. Tolerance counting rules reviewed for consistency across programs.

Data Limitations: None

New / Improved Data or Systems: Database (Office of Pesticide Programs Information Network) consolidates various OPP program databases.

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 Food Safety Advisory Committee (FSAC)--created to specifically provide advice from grower groups, industry, public health organizations, Congress and academia. FSAC held its final meeting in December 1996.

- 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--includes representatives of industry, state and federal government, public health, environmental, labor organizations, small businesses and academia.

- 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 and the National Toxicology Program (NTP) develop new technologies for high throughput toxicity testing, and these agencies are responsible for one-third of all toxicity testing performed world-wide.

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 toxicants, as well as to hazards resulting from technologic or natural disasters. These are mainly surveillance and epidemiology studies. NCEH is particularly interested in studies that benefit children, the elderly, and persons with disabilities. The NCEH laboratory supports many of EPA studies and will be the laboratory for samples collected in the EPA-sponsored pesticide study in National Health and Nutrition Examination Survey - NHANES-4. The National Center for Health Statistics (NCHS) of CDC is conducting the (NHANES)-4. NHANES-4 is a population based 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

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

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