Environmental Protection Agency

FY 2001 Annual Performance Plan and Congressional Justification

Safe Food

Strategic Goal: The foods Americans eat will be free from unsafe pesticide residues. Children especially will be protected from the health threats posed by pesticide residues, because they are among the most vulnerable groups in our society.

Resource Summary
(Dollars in thousands)

		FY 1999 Enacted	FY 2000 Enacted	FY 2001 Request	FY 2001 Req. v. FY 2000 Ena.
Goal 03	**Safe Food**	**$67,647.7**	**$82,285.1**	**$86,056.5**	**$3,771.4**
Obj. 01	Reduce Agricultural Pesticides Risk	$29,333.2	$35,826.6	$39,057.3	$3,230.7
Obj. 02	Reduce Use on Food of Pesticides Not Meeting Standards	$38,314.5	$46,459.2	$46,999.2	$540.0
	Total Workyears	702.4	701.0	711.8	$10.8

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 aim of protecting human health and the environment from risks associated with pesticide use. EPA uses the latest scientific information to ensure that the public's exposure to pesticides will not, with reasonable certainty, cause harm, either through residues of pesticides on the foods we eat, or through other exposures.

Consumers are at risk for potential adverse effects from pesticide residues ingested either directly or through processed foods. Some pesticides can also "bioaccumulate" in plant and animal tissue, resulting in higher levels of exposure than would occur through direct means. A critical step in protecting the public health is to evaluate food use pesticides for potential toxic effects such as birth defects, seizures, cancer, disruption of the endocrine system, changes in fertility, harmful effects to the kidneys or liver, bioaccumulation or short term effects such as headaches or disorientation. Ensuring that any residues on food are at acceptable levels is the essence of the Safe Food goal.

Pesticides subject to EPA regulation include insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators 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 1995 was about 4.5 billion pounds. Biopesticides and reduced risk pesticides make up about 20 percent of the total. Agriculture accounts for over 70 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 Control 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. Because of EPA's work under these laws, the public enjoys one of the safest, most abundant, and most affordable food supplies in the world.

Through its food safety programs, including encouraging and expediting the registration of reduced risk pesticides, EPA enhances health and environmental protection in a number of ways, including the following:

- Establishing a single, health-based standard for pesticide residues in food, and eliminating past inconsistencies in the law which treated residues in some processed foods differently from residues in raw and other processed foods;

EPA's Pesticide Regulations Affect a Cross-Section of the 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 90 million households

- Providing for a more complete assessment of potential risks, with special protections for potentially 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 advances;

- Expanding consumers' "right-to-know" about pesticide risks and benefits; and

- Expediting the approval of reduced risk pesticides.

Means and Strategy

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

- encouraging the introduction of new, reduced risk pesticide ingredients (including new biological agents) 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 2001, the Agency will accelerate the pace of new registrations for pesticides that offer improved prevention or risk reduction qualities 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.

The 2001 request also expands 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 also 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.

EPA uses its authority under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) to systematically manage the risks of such exposures by establishing legally permissible food-borne exposure 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.

Through developing and using the latest scientific advances in health-risk assessment practices, EPA is ensuring current uses 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.

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 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.

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.

More information about EPA's food safety efforts is available on the Office of Pesticides Program'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 consistent with 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.

These needs are overtaxing existing tools. To meet them, in FY 2001, research 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. Pesticide exposure and effects data, risk assessment methods and models for children, and control technologies developed by FY 2001 will help to improve the Agency's ability to fully comply with the requirements of FQPA, particularly requirements related to susceptible subpopulations and cumulative risk.

Strategic Objectives and FY 2001 Annual Performance Goals

Objective 01: Reduce Agricultural Pesticides Risk

- 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.

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

- EPA will reassess an additional 1,200 of the 9,721 existing pesticide tolerances to ensure that they meet the statutory standard of "reasonable certainty of no harm" (for a cumulative 60 percent).

- By the end of FY 2001, complete reassessment of a cumulative 66 percent (560) of the 848 tolerances of special concern in protecting the health of children.

Highlights

Reduce Agricultural Pesticides Risk

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

New 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 2001, the Agency will continue to decrease the risk the public faces from agricultural pesticides (from 1995 levels) 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 Food Use of Pesticides Not Meeting Current Standards

FQPA requires the Agency to revise its risk-assessment practices to incorporate additional safeguards to ensure the adequate protection of children's health and that of other vulnerable groups, such as tribes, and to reevaluate some 9,721 food residue tolerances approved before the passage of FQPA. The Agency has met its first statutory mandate, to reassess 33 percent of these tolerances by August 1999. In FY 2001, the Agency will continue toward its 10-year statutory deadline of reassessing all 9,721 tolerances by reassessing an additional 1,200 tolerances. The Agency will also continue screening and testing pesticides for their potential to disrupt the endocrine system.

The tolerance reassessment process strives to address 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. By 2001, EPA will reduce dietary risks to children by completing a cumulative 66 percent of these tolerances of special concern.

Organophosphates and carbamates have also been targeted as posing higher risks than many other pesticide types. These pesticides are widely used and limitations 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's Pesticide Reregistration program is now in its final phase. The Reregistration program was established in the 1988 amendments to FIFRA and has similar goals to the FQPA's tolerance reassessment program. Through the Reregistration program, EPA also reviews pesticides currently on the market to ensure they meet the latest health standards set by FQPA. Pesticides not in compliance with the new standard will be eliminated or restricted in order to minimize 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 has added considerably more complexity into the process of reregistering pesticides. New statutory requirements have made risk assessment more complex and lengthened the "front end" portion 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 and should speed risk reductions.

EPA is now conducting reregistration in conjunction with tolerance reassessment, which FQPA mandates be completed by 2006. Reregistration of pesticide active ingredients and products

will be completed prior to the statutory deadline for completing tolerance reassessment. However, there are increasing indications that all elements of reregistration, especially those elements also necessary to complete tolerance reassessment, will not be completed for all active ingredients by 2002.

In 2001, EPA will complete 30 REDs and approximately 750 product reregistrations. By 2006, all 9,721 of the tolerance reassessments mandated by FQPA will be completed. EPA has evaluated the two programs and consolidated analyses wherever possible while meeting the goals of both programs.

FQPA requires that EPA establish a process for periodic review of pesticide registrations. This requires the updating of all pesticide registrations using current scientific data, risk assessment methodology, program policies and effective risk reduction measures. In 2001, the Agency will continue developing the framework for the registration review program.

Research

In 2001, research 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 FQPA. One area of increased attention will be cumulative risk. Research will be enhanced to address some of the complex issues and uncertainties in this area. The Agency will begin to develop a systematic approach for determining cumulative risk for a given set of exposure conditions, beginning with less complex paradigms and building toward the more complex, including consideration of different temporal dimensions of exposure.

External Factors

The ability of the Agency to achieve its Goal 3 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.

In addition, EPA assures the safe use of pesticides in coordination with the USDA and FDA, who have responsibility to monitor and control residues 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 under Goal 3 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 Goal 3 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 2001 Annual Performance Plan and Congressional Justification

Safe Food

Objective # 1: Reduce Agricultural Pesticides Risk

By 2005, the public health risk from agricultural use of pesticides will be reduced by 50 percent from 1995 levels.

Resource Summary
(Dollars in thousands)

	FY 1999 Enacted	FY 2000 Enacted	FY 2001 Request	FY 2001 Req. v. FY 2000 Ena.
Reduce Agricultural Pesticides Risk	**$29,333.2**	**$35,826.0**	**$39,057.3**	**$3,231.3**
Environmental Program & Management	$26,438.0	$33,705.4	$36,784.8	$3,079.4
Science & Technology	$2,895.2	$2,120.6	$2,272.5	$151.9
Total Workyears	291.3	286.0	293.5	7.5

Key Programs
(Dollars in thousands)

	FY 1999 Enacted	FY 2000 Enacted	FY 2001 Request
Pesticide Registration	$19,661.7	$21,126.3	$25,014.4
Pesticide Reregistration	$4,724.0	$4,730.3	$5,087.2
Endocrine Disruptor Screening Program	$1,237.3	$1,695.5	$1,762.6
Pesticide Residue Tolerance Reassessments	$1,040.8	$1,262.3	$1,074.8
Rent, Utilities and Security	$0.0	$3,660.3	$7,724.0
Administrative Services	$0.0	$424.7	$443.1

FY 2001 Request

The FY 2001 Budget for this objective reflects a requested increase of $3,231,300 and 7.5 FTE over the 2000 Enacted Budget. This increase will be directed at accelerating the pace of new registrations of reduced risk pesticides, and at increasing the number of new tolerances established. It reflects the Administration's goals of improving the safety of the food produced and consumed by the American public, and of continuing the commitment to implement the higher statutory standard of FQPA, especially in the protection of infants and children. The proposed increases will build on our 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. Working with our partners, EPA will 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. EPA may require regulatory action where warranted to minimize exposure and thus reduce risk. To address these concerns, EPA will continue the Registration and Reregistration/Special Review regulatory programs, giving high priority to the FQPA mandates. Combined with the review of existing pesticides through reregistration and tolerance reassessment, the availability of safer pesticides has improved the risk picture for agriculture.

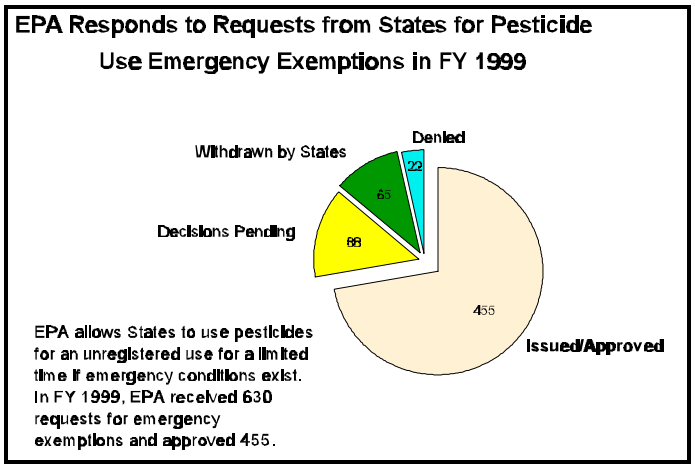
Registration Activities

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 impact data and sets a tolerance level for each crop (use) the registrant designates 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.

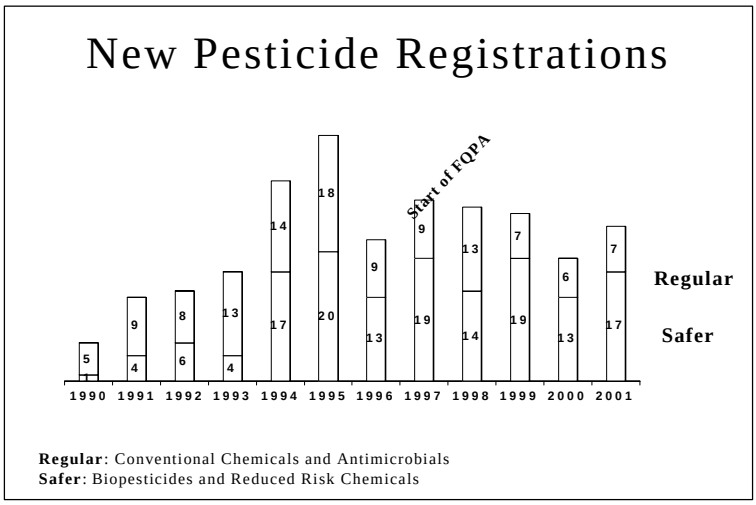
There is a variety of types of registration activities to meet the needs of the industry and to assist in internal planning. Registration activities include new active ingredients, new pesticides which may simply be new formulations of ingredients already registered, new uses which add a crop type to the approved uses of the registered pesticide, minor uses for low volume crops, and 'me-toos' for additional registrants for a pesticide.

In 2001, EPA will continue to implement new science standards required by FQPA and ensure that pesticides that do not meet current safety standards are removed from use. FQPA has also added requirements for reviewing the inactive ingredients added to pesticide products. The Agency will also continue to revisit and revise, as necessary, science policies and risk assessment tools, methods and models, to ensure sound science and adequate protection of human health.

EPA has actively encouraged and engaged the pesticide industry, farmers and the public to participate in the implementation of the new FQPA health-based standards for pesticides. EPA uses common-sense strategies for reducing risk to acceptable levels while retaining those pesticides of the greatest public value, including those utilized for minor uses and integrated pest management needs. EPA works with the pesticide industry and farmers to explore approaches in this transition period, such as granting priority status for registrations of lower risk substitutes for certain older pesticides and allowing for reasonable phase out periods for canceled pesticides.



Agricultural conditions and pest outbreaks are unpredictable and EPA has tools to meet new or emerging needs. EPA will take prompt action on all registration actions submitted, particularly 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. FIFRA address 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 worked to ensure minor use registrations receive appropriate support; in particular, working closely to meet the need for newer, reduced risk pesticides registered for minor uses. The law requires each crop to have its own tolerance for a specific pesticide but some crops are not produced in quantities to warrant additional investment in data collection by the registrant company. Still the crop may be of high economic significance to specific localities or groups of farmers. 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. Besides keeping abreast of new science, EPA must 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 chemical. In 2001, 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

Throughout 2001, EPA will continue 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. Between 1996 and 1999, EPA registered 51 pesticides that can serve as lower risk alternatives to more toxic pesticides. The Agency is committed to expediting the registration of additional alternative products and in 2001, the Agency will register 17 reduced risk pesticides.

Reduced risk pesticides are a key element of effective FQPA implementation. As the Agency re-evaluates older pesticides and consults with stakeholders on changes to use ("risk management"), suitable alternatives must be available for farmers to control pests. EPA biologists are also working with USDA to find alternatives to the products that pose a higher risk, through the Integrated Pest Management program and other strategies. Data generated through the USDA's Pesticide Data Program (PDP) is critical to dietary risk assessments as well as minor crop registration determinations.

FQPA provisions mandate a number of measures to increase the safety of the food supply, and many of the provisions have broad implications for how EPA conducts evaluations of pesticide uses. All tolerance decisions, either associated with tolerance reassessments or with new registrations, are subject to new science requirements. The Agency has engaged the public and the scientific community in developing and reviewing nine specific science policies for EPA's approach to screening pesticides.

While all of the policies are significant, the requirements to consider cumulative and aggregate impacts as well as the ten-fold safety factor for children's health have important ramifications for the 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 members of a widely used class of pesticides already in use that have a common mechanism of toxicity will show greater risk than if they were considered in isolation. In 2001, the Agency will expand research support for cumulative risk methodologies, as discussed under the research section. 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." Ultimately these new tools for screening pesticides will result in an even safer food supply for the American public. The broad impacts of the new requirements has lead EPA to engage all stakeholders as well as the scientific community in the development of the FQPA science policies.

Reduce Agricultural Use of Potential Carcinogenic or Neurotoxic Pesticides

A large number of current pesticides with approved food uses are classified as potential human carcinogens or neurotoxins. EPA is moving deliberately to minimize dietary exposure from pesticides with the highest potential to cause cancer or neurotoxic effects. Major tasks required over the next few years to address these groups of chemicals include the development and refinement of science policies, and the expansion and refinement of use information. Outreach and coordination are essential as well, through continued promotion and adoption of environmental stewardship and integrated pest management, acceleration of regulatory reviews and, where warranted, approvals of effective alternative tools for pest management.

FQPA 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
9. Selection of appropriate toxicity endpoints (critical effects)

Organophosphates, which are highly effective and in common use, are one class of pesticides of particular concern.

Organophosphates can inhibit normal functioning of the nervous system, causing nausea, dizziness, confusion, and at high exposures, respiratory paralysis and death. As a result, the registration of substitutes is a priority.

In addition to new products being introduced to the marketplace, EPA is focusing on reducing the risks of existing pesticides in a manner that is least disruptive to growers. The Agency has identified a spectrum of approaches for achieving risk management, to be applied depending on the level of unacceptable risk. The Agency is also 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. Working with USDA and HHS data, EPA has identified 20 foods most often consumed by children. Approximately 848 tolerances are currently in place for the use of various older pesticides on these foods. Reassessment of these tolerances is a priority, and in 2001 EPA expects to complete a cumulative 560 tolerances. In 2001, EPA will also work with HHS to enhance food consumption data, to provide additional information on what people eat with special interest in children's food consumption. Other joint projects focus on incorporating the latest science through developing and validating methods to analyze domestic and imported food samples for organophosphates, carcinogens, neurotoxins and other chemicals of concern. These efforts will help protect Americans' health by assisting in priority-setting as well as improving monitoring of imported foods for unhealthful pesticide residue levels.

FY 2001 Change from FY 2000 Enacted

<u>EPM</u>

- (+$1,000,000) New investment to increase and accelerate the registration of reduced risk pesticides, including biopesticides.
- (+$1,210,000) Increase in workforce cost of living.
- (+$600,000) New investment to increase the number of new tolerances set for reduced risk and conventional pesticides.
- (+$659,600) Realignment: 3.2.1 Reregistration to Antimicrobials (3.1.1) to more accurately display costs.

Annual Performance Goals and Performance Measures

Decrease Risk from Agricultural Pesticides

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 Decrease adverse risk from agricultural uses from 1995 levels and assure that new pesticides are safe by such actions as registering 6 new chemicals, 2,200 amendments, 600 me-toos, 200 new uses, 45 inerts, 375 special registrations, 105 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 Estimate	FY 2001 Request	
Register safer chemicals and biopesticides	19	13	17	Registrations
New Chemicals	7	6	7	Registrations
Amendments	3586	2200	2600	Actions
Me-toos	1022	600	800	Actions
New Uses	681	200	350	Actions
Inerts	109	45	45	Actions
Special Registrations	455	375	375	Actions
Tolerances	351	225	250	Actions

Baseline: The number of safer pesticides registered (51 as of 9/30/99) since the passage of the Food Quality Protection Act in 1996. Outputs compared with the previous year's performance.

Reduce use of highly toxic pesticides

In 2001 Use of pesticides classified as having the highest potential to cause cancer or neurotoxic effects that will be reduced by 10%.

In 2000 Use of pesticides classified as having the highest potential to cause cancer, or neurotoxic effects, will be reduced by 5%.

Performance Measures:	FY 1999 Actuals	FY 2000 Estimate	FY 2001 Request	
Reduction of pesticide use that has the highest potential to cause cancer or neurotoxic effects		5%	10%	Used

Baseline: Baseline (to be determined) is the use of carcinogenic or neurotoxic pesticides on food crops since the passage of the Food Quality Protection Act in 1996. (Percent achievement is cumulative).

Reduce Pesticides in Groundwater and Streams

In 2001 Certain pesticides are frequently detected in our nations streams and groundwater, and they are also among those with the highest current use. By reassessing the regulatory decisions made on these chemicals through reregistration, we will reduce by (to be determined) their presence in groundwater and streams.

Performance Measures:	FY 1999 Actuals	FY 2000 Estimate	FY 2001 Request	
Amount of atrazine and degradates in groundwater and streams			to be determined	ppm

Baseline: Source of data is the U.S. Geological Survey (USGS) National Water Quality Assessment Program (NAWQA) that monitors water quality in more than 50 river basins and aquifers in the US. Data from NAWQA will be used to develop a baseline for assessing the impact and effectiveness of our regulatory decisions on terrestrial and aquatic wildlife.

Verification and Validation of Performance Measures

Performance Measure: Number of registrations of reduced risk pesticides

Performance Database: Pesticide Regulatory Action Tracking System (PRATS). PRATS is the principle activity tracking system for OPPTS. It is designed to track regulatory submissions & collections of studies organized by scientific discipline (data packages) submitted by the registrant in support of a pesticide's registration. The Pesticide Registration Notice (PRN) 97-3 dated September 4, 1997 sets the criteria for a reduced risk pesticide.

Data Source: Office of Pesticide Programs staff (reviewers)

QA/QC Procedures: Program output

Data Quality Review: Management reviews the program output counts

Data Limitations: None for tracking because these are program outputs

New/Improved Data or Systems: Database (OPPIN) under development will consolidate various OPP databases - operational FY 2000. Consolidation will provide one system, merging all data versus separate systems now tracking different regulatory actions. This system will alleviate the need for duplicate entry into the separate systems.

Performance Measure: Number of registration actions for new chemicals, amendments, me-toos, new uses, inerts, special registrations, tolerances

Performance Database: PRATS (See above for description.); Tolerance Index System (TIS) is maintained within OPP and contains all the current tolerances, as well as crop residues by crop and crop grouping for food and feed use. As information is updated, Federal Register staff are notified of these changes and the registry is updated.

Data Source: OPP Staff

QA/QC Procedures: Program output

Data Quality Review: Management reviews the program output counts.

Data Limitations: None for tracking because these are program outputs.

New/Improved Data or Systems: Database (OPPIN) under development will consolidate various OPP databases - operational FY 2000. Consolidation will provide one system, merging all data versus separate systems now tracking different regulatory actions. This system will alleviate the need for duplicate entry into the separate systems.

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 now a critical component of implementing the Food Quality Protection Act by providing 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.

The Agency is also developing 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 validation of data submissions. 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 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.

Statutory Authorities

Federal Fungicide, Insecticide and Rodenticide Act (FIFRA)

Federal Food, Drug and Cosmetic Act (FFDCA)

Food Quality Protection Act (FQPA) of 1996

Objective # 2: Reduce Use on Food of Pesticides Not Meeting Standards

By 2005, use on food of current pesticides that do not meet the new statutory standard of "reasonable certainty of no harm" will be substantially eliminated.

Resource Summary
(Dollars in thousands)

	FY 1999 Enacted	FY 2000 Enacted	FY 2001 Request	FY 2001 Req. v. FY 2000 Ena.
Reduce Use on Food of Pesticides Not Meeting Standards	**$38,314.5**	**$46,459.2**	**$46,999.2**	**$540.0**
Environmental Program & Management	$30,537.8	$37,150.6	$35,380.9	($1,769.7)
Science & Technology	$7,776.7	$9,308.6	$11,618.3	$2,309.7
Total Workyears	411.1	415.0	418.3	3.3

Key Programs
(Dollars in thousands)

	FY 1999 Enacted	FY 2000 Enacted	FY 2001 Request
Pesticide Reregistration	$22,227.8	$20,586.3	$23,858.0
Endocrine Disruptor Screening Program	$1,436.5	$4,869.8	$3,978.8
Pesticide Residue Tolerance Reassessments	$9,057.2	$10,335.5	$6,647.9
Rent, Utilities and Security	$0.0	$458.0	$473.5
Administrative Services	$0.0	$552.4	$571.6

FY 2001 Request

The FY 2001 budget for this objective reflects a requested increase of $540,000 and 3.3 FTE from the FY 2000 Enacted Budget. This increase includes an offset to EPA's appropriated budget of $7,000,000 in anticipation of tolerance fee collections in FY 2001, an increase of $2,294,400 to start the Registration Review Program; and a $3,000,000 increase for tolerance reassessments. By reassessing tolerances, EPA is reviewing the risk assessment for each chemical with food uses to make sure that the tolerances meet the stricter FQPA safety standard. FQPA requires that EPA give priority to review of tolerances that appear to pose the highest risk to public health. FQPA also requires that EPA consider whether infants and children, or other sensitive subpopulations, are especially vulnerable to the effects of a pesticide.

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 have changed or there appear to be data gaps or risk questions that are not answered adequately.

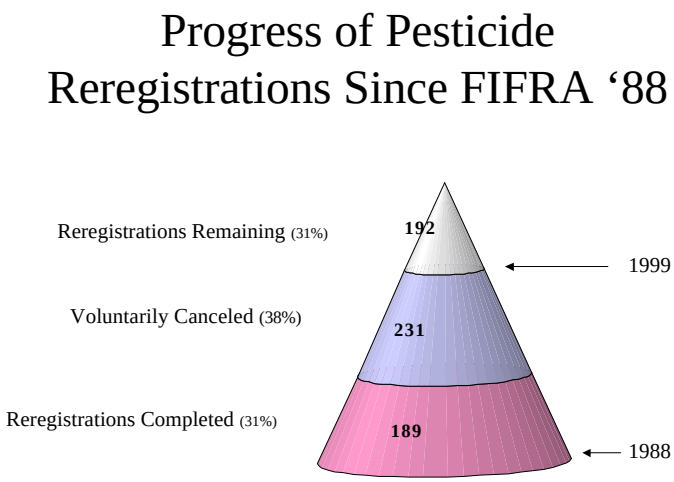
In 2001, EPA will begin receiving additional studies for about 140 pesticides of particular concern. In 1999, EPA issued a "data call-in" for specific studies on these pesticides. Many currently-registered pesticides are suspected of adversely affecting the nervous system. The data call-in identifies pesticides that are thought to have neurotoxic effects. At issue is the margin of safety that may be needed for tolerances on these pesticides, particularly where children are concerned. FQPA requires a ten-fold margin of safety for children unless data show it is not necessary.

1999 Data Call-in:
studies responding to the questions:

- ❑ Do these pesticides pose a greater risk to children?
- ❑ Do they harm the nervous system during critical stages of development, both before birth and after?
- ❑ Are the effects in the young different from those observed in an adult?

Keeping older tolerances levels updated using with the latest scientific information is an ongoing priority for the pesticides program. FIFRA '88 required a review of tolerances for all pesticides registered prior to 1984. FQPA sets in place a new program, called Registration Review, which will routinely and periodically update the tolerance levels for registered pesticides every 15 years, avoiding the need for "catch-up" programs in the future.

Complete Active Ingredient and Product Reregistration



Through the Reregistration program, now in its final phase, EPA will continue to review pesticides currently on the market to ensure that these too 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 2001, the Agency will complete 30 REDs.

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.

Many of the reviews that are required by the reregistration program overlap with tolerance reassessment efforts, although each program also has unique requirements. EPA has evaluated the separate and joint requirements and consolidated the work wherever possible. As a result, all tolerance work under the reregistration program meets the FQPA standards.

Reassessment of Existing Pesticide Residue Tolerances on Food

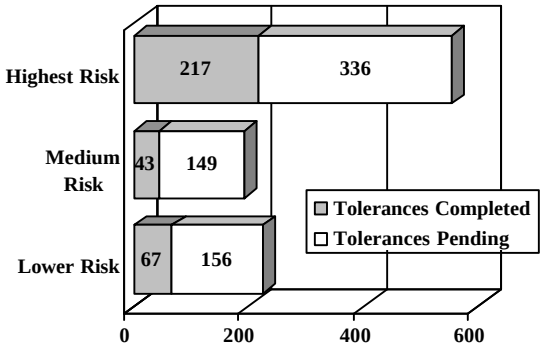
A tolerance is the maximum legal amount of a pesticide residue permissible on food. FQPA requires that EPA reassess within ten years the more than 9,721 pesticide tolerances existing in 1996. The first statutory deadline was to complete reassessment of 33 percent of the existing tolerances by August 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 reassess approximately 1,200 tolerances in 2001.

FQPA standards are having a great impact on the way pesticides are reviewed and the Agency requests increased resources of $3,000,000 to ensure the most recent, soundest 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. Particular emphasis remains with facilitating 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.

Current pesticides which do not meet the FQPA mandated standard of "reasonable certainty of no harm" will not receive approval for food use, or the approved use patterns may be changed. FQPA's more stringent standard for food reduces dietary exposure to potentially toxic pesticides. The Agency has revised its risk assessment practices to incorporate the new provisions and increase protection of the health of children and other vulnerable groups. While refining the nine key science policies addressed by FQPA through peer review and public comment, the Agency applies the policies as appropriate, where the weight of evidence supports the determination, after scientific peer review.

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.

Tolerance Reassessment Status



Options for risk reduction range from revocation of the tolerance to modifications in use, as reflected in label changes. Of the tolerances completed by July 1999, about 45 percent were revocations. Many of those resulted from canceled registrations or other actions other than full reassessments, while the remaining one-fourth or so were risk-based. Nonetheless all of the revocations reduced risk to some degree, since until the formal revocations were in place, it was legal

to import foods with residues from those pesticides. Risk can also be reduced through changes to the actual use of the pesticide. For example, the pesticide could be applied in lower quantities, or less frequently, or at a greater distance from water bodies. Other risk reduction possibilities are phase-outs and changes to the conditions of registration (e.g., production limitations).

One example of a regulatory risk reduction action was the one taken on two organophosphates in 1999. After months of reviewing studies, refining risk assessments, stakeholder discussions and negotiations with registrants, EPA moved to protect children's health by canceling the use of methyl parathion on all fruits and vegetables, and by modifying the current use practice for azinphos methyl on apples, pears and peaches. Risk assessment data indicated that methyl parathion is one of the most toxic organophosphate pesticides registered. The acute dietary risk to children was more than seven times the level of concern. For azinphos methyl, the aggregate risk from food and drinking water was above the level of concern for nursing infants and children up to age six.

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. 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 2001. Some Group 2 and lower priority Group 3 tolerances have been reassessed as part of the work already underway in the reregistration program.

FQPA stipulates that EPA's program to establish and reassess tolerances be self-supporting, and the tolerance fee rule was proposed in FY 99. During 2001, in anticipation of implementation of the Tolerance Fee Rule and collection of fees, resources for the tolerance program were offset by $7,000,000. This offset makes timely implementation of the rule essential for the continuity of program operations.

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. This program will be a major new undertaking for the Agency. 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. Ongoing efforts in 1999 and 2000 continue developing the infrastructure needed to establish the program, including the stakeholder involvement and issuance of a proposed rule.

In 2001, efforts will center on finalizing the regulation, taking into consideration stakeholder input. 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. The FIFRA fund that supports the reregistration process through the collection of maintenance fees will expire in 2001, so funding for the new registration review process will need to be planned.

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 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.

Adequate methods to determine endocrine disrupting potential are only now under development by the Agency, following an extensive and successful scientific advisory process. Additional resources are requested in FY 2001 to support the validation of the screening methods in this new area of science. During 1999, EPA began work on two major activities to implement the screening and testing program: the standardization and validation of mammalian screening assays and development of the priority-setting data base. Work will continue in both of these areas in FY 2000. EPA will complete work on the priority setting data base in FY 2000 and will complete validation of all the mammalian tier I screens in 2001. EPA will require screening of chemicals in commerce for endocrine disrupting potential in FY 2002. By 2005, the Agency expects to have screened all HPV chemicals for endocrine disrupting potential as part of the Administration's Right-to-Know Initiative. Testing will also have been initiated on some of the resulting priority chemicals using the methods validated by EPA.

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

Research

The Food Quality Protection Act (FQPA) of 1996 identifies clear science needs consistent with the evaluation of all potential routes and pathways of exposures and effects to pesticides, particularly for sensitive subpopulations and considering effects from cumulative exposures. Major uncertainties in the area of sensitive subpopulations relate to the degree to which current risk assessment practices provide adequate protection. These uncertainties can be expressed in questions such as the following:

- What are the health endpoints of greatest concern in children?

- What are the most vulnerable developmental/maturational periods?

- Do exposures experienced by children produce qualitatively different effects from those experienced by adults?

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 can be articulated through such scientific questions as:

- What are the human health effects associated with multiple, short-term exposures to pesticides and other toxic chemicals that differ from those resulting from chronic exposures?

- What are the human health effects associated with exposures to mixtures of pesticides and other toxic chemicals with similar modes of action that differ from those associated with the individual chemicals?

To address these and other issues related to implementing FQPA, research in FY 2001 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. A specific element of this work will be directed at the development of methods to evaluate the effects to the developing organism as a result of pre- and perinatal exposures. These include in utero (i.e., transplacental) and lactational exposure studies. Research will also 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.

Much of the exposure research will also focus on infants and children. One major goal is to identify those pesticides, pathways, and activities that represent the highest potential exposures to children and to determine the factors that influence these exposures. The research will be used to

develop methods, data, and models for evaluating aggregate exposure to pesticides and toxic chemicals. Efforts will focus on high level, short-term exposure resulting from recent pesticide applications. Studies 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) will be supported during FY 2001, providing critical data needed to develop the approach for exposure assessments, and inputs for models of children's exposure. The Agency will also support extramural grants to develop biological markers as new approaches for assessing aggregate exposures and effects in children.

Another important goal is to develop probabilistic models to estimate exposures and absorbed dose to environmental contaminants by children and adults. Initially this research places more emphasis on children's exposure to pesticides in residential settings, since young children are potentially at higher risk for greater exposures to pesticides. Exposures to other toxics in the environment will subsequently be investigated using a multimedia/multipathway modeling framework similar to that being developed for pesticide exposures.

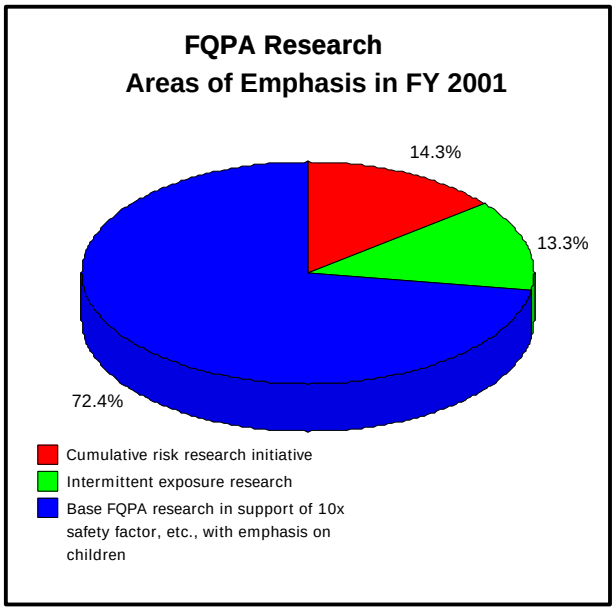
Risk assessment research will develop methods for combining exposures and assessing exposure-dose-response relationships for pesticides and other compounds with common modes of action and different exposure patterns. Case studies using data from all available sources will be developed focusing on aggregating exposure and risk to multiple chemicals from multiple pathways.

Additionally, in FY 2001, the Agency will initiate/enhance its efforts to address uncertainties in the areas of cumulative risk and intermittent exposure.

To address some of the complex uncertainties in the area of cumulative risk, the Agency will enhance efforts to develop a systematic approach for determining the cumulative risk for a given set of exposure conditions. This approach will start 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) and 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). Analyses will also be directed at defining the key drivers for each component of this pathway to facilitate extrapolation to similar exposure situations. This approach will also provide the opportunity to assess the validity of current risk assessment methods and models to account for multiple sources/exposures, stressors and toxicities.

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. Research will also be supported to improve risk management strategies and tools for reducing potential health risks to children and other highly exposed populations.

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) that will be necessary for the Agency to comply with the provisions of 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.



FQPA research is also supported through the Agency's Postdoctoral Initiative. The FY 2001 request continues the third year of the effort to enhance our intramural research program by supporting 1.4 additional postdoctoral positions under this objective. This enhancement continues to build upon the positive response by the academic community to EPA's announcement of 50 postdoctoral positions for FY1999.

Annual Performance Goals and Performance Measures

Reassess Pesticide Tolerances

In 2001	EPA will reassess an additional 1,200 of the 9,721 existing pesticide tolerances to ensure that they meet the statutory standard of "reasonable certainty of no harm" (for a cumulative 60 percent).
In 2001	By the end of FY 2001, complete reassessment of a cumulative 66% (560) of the 848 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	EPA will reassess 20% of the existing 9,721 tolerances to ensure that they meet the statutory standard of "reasonable certainty of no harm."

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 Aug. 1999.

Performance Measures:	FY 1999 Actuals	FY 2000 Estimate	FY 2001 Request	
Tolerance Reassessment	1445	1250	1200	Actions
REDs	14	20	30	Decisions
Product Reregistration	746	750	750	Actions
Tolerance reassessments for top 20 foods eaten by children			208	Tolerances

Baseline: Baseline is number of tolerances reassessed (from universe of 9,721) set in 2000 and number of REDs issued and pesticides reregistered in 2000. The Agency anticipates that the efforts currently being conducted on organophosphates in FY 2000 will result in tolerance completions in FY 2001. Of the total of 9,721 tolerances to be reassessed by EPA over ten years, 848 fall within the subset having the greastest potential impact on childrens' health. As of the end of FY 1999, a total of 352 of these tolerances have been reassessed.

Registration Review

In 2001 Issuance of proposed rule for Registration Review

In 2000 Issuance of the ANPR rule for Registration Review

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

Baseline: The rule will establish the framework for the registration review program required by FQPA.

Research

Research to Support FQPA

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 Provide methodologies to evaluate the risk to human health posed by food-use products.

Performance Measures:	FY 1999 Actuals	FY 2000 Estimate	FY 2001 Request	
First generation multimedia, multipathway exposure model for infants and young children and the identification of critical exposure pathways and factors.		09/30/2000		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.		09/30/2000	method
Develop a method to evaluate the human health effects of cumulative exposure to pesticides and other toxic substances.		1	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.	09/30/2000	"	
Describe age-dependent differences in responses to one or more pesticides		09/30/01	
Report on Factors for Children's Exposure to Pesticides.		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.			evaluation

Baseline: The Food Quality Protection Act (FQPA) of 1996 directs EPA in its assessments of pesticide safety to address the cumulative effects of pesticides that have a common mechanism of toxicity, considering aggregate dietary and non-occupational sources of exposure. Current approaches to human health risk assessment focus on single pesticides and do not adequately account for cumulative risks arising from complex exposure pattern and human variability due to age, gender, pre-existing disease, health and nutritional status, and genetic predisposition. Tools which are currently available to control and prevent exposure are limited to certain processes and materials. Research is needed to comply with the requirements of FQPA, with special attention to potential health risks to infants and children.

FY 2001 Change from FY 2000 Enacted

EPM

- (+1,700,000) This new investment will implement the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) and continue the screening and testing of pesticides, commercial chemicals and drinking water source contaminants for potential to disrupt the endocrine system and provide sound scientific methods information for protecting human health and wildlife.

- (-$2,500,000) Congressional add-on in FY 2000 enacted budget for endocrine disruptor program not carried forward into FY 2001.

- (+$3,000,000) Increased resources to support the Tolerance Reassessment program and to maintain pace with growing demands due to changes in risk assessments processes and stakeholder consultation.

- (-$7,000,000) Offset to appropriated dollars in anticipation of the promulgation and implementation of new tolerance fee rule to recover full cost of setting tolerances as required by FQPA. This offset makes timely implementation of the rule essential for the continuity of program operations.

- (+$2,294,400) Investment to establish the new Registration Review program that was required by FQPA and will review existing pesticide registrations every 15 years.

- (+$1,000,000) Increase in workforce cost of living.

- (-$216,200 and 2.3 FTE) represent share of additional FTE cuts as directed in the FY 2000 EPA enacted budget.

Research

S&T

- (+$1,458,300, +5.0 workyears) EPA will enhance research to address some of the complex uncertainties in the area of cumulative risk. The Agency will strengthen efforts to develop a systematic approach for determining the cumulative risk for a given set of exposure conditions. This approach will start with less complex paradigms and build towards the more complex, including consideration of different temporal dimensions of exposure. In each case, an integrated model will be used to estimate cumulative risk by identifying and defining the relationship between sources, pathways, exposure and dose. Understanding these relationships will improve the Agency's ability to meet its performance objectives in implementing the requirements of FQPA.

- (+$1,420,600, +3.0 workyears) Resources will be redirected to support research on intermittent exposure. Research will focus on developing data, methods, and models for characterizing and combining exposures and assessing exposure-dose-response relationships for pesticides with different exposure patterns. Improved risk management strategies and tools will also be developed for reducing potential health risks to children and other highly exposed populations. This research builds on the Agency's movement toward a capability to conduct health risk assessments based on conditions of real-life environmental exposure, and will improve the Agency's ability to fully implement the requirements of FQPA.

- (-$374,800, -1.3 workyears) The R&D program, including infrastructure support costs, is spread across eight of the ten goals in the Agency's GPRA/budget structure. Based on a review of actual infrastructure utilization under each goal (i.e., operating expenses and working capital fund), adjustments are being made across goals to more accurately reflect expectations for use in FY 2001.

Verification and Validation of Performance Measures

Performance Measure: Number of Reregistration Eligibility Decisions (REDs)

Performance Database: Pesticide Regulatory Action Tracking System (PRATS). PRATS is the principle activity tracking system for OPPTS. It is designed to track regulatory submissions & collections of studies organized by scientific discipline (data packages) submitted by the registrant in support of a pesticide's registration.

Data Source: OPP Staff

QA/QC Procedures: Program output

Data Quality Review: Management reviews the program output counts.

Data Limitations: None for tracking because these are program outputs.

New/Improved Data or Systems: Database (OPPIN) under development will consolidate various OPP databases - operational FY 2000. Consolidation will provide one system versus separate systems now tracking different regulatory actions.

Performance Measure: Number of tolerances reassessed

Performance Database: Tolerance Reassessment Tracking System (TORTS) is an in-house (OPP-wide) system containing records on all 9,721 tolerances subject to reassessment. Data was extracted from Tolerance Index System (TIS). It contains numbers of total tolerances reassessed; breakout by FY, 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, kids' foods, and minor uses.

Data Source: OPP staff

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 for tracking because these are program outputs.

New/Improved Data or Systems: New System. Established specifically for Food Quality Protection Act (FQPA) needs.

Performance Measure: Number of products reregistered

Performance Database: PRATS (See above for PRATS description.)

Data Source: OPP staff

QA/QC Procedures: Program output

Data Quality Review: Management reviews the program output counts.

Data Limitations: None for tracking because these are program outputs.

New/Improved Data or Systems: Database (OPPIN) under development will consolidate various OPP databases - operational FY 2000. Consolidation will provide one system versus separate systems now tracking different regulatory actions.

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.

- The Tolerance Reassessment Advisory Committee (TRAC) headed jointly by the EPA Deputy Administrator and the USDA Deputy Secretary received diverse stakeholder input on the tolerance reassessment of organophosphate pesticides and other implementation issues associated with carrying out FQPA.

Research

Two significant areas of interagency coordination with respect to implementation of the Food Quality Protection Act (FQPA) include: 1) submission of a cross-agency food safety budget for 2001; and 2) research under the National Health and Nutrition Examination Survey (NHANES).

In response to publicly identified needs to strengthen the coordination of food safety activities and responsibilities among federal agencies, the President issued Executive Order 13100 in August 1998 to establish the Council on Food Safety. The Council is co-chaired by the Secretary of the Department of Agriculture (USDA), the Secretary of the Department of Health and Human Services (DHHS), and the Director of the Office of Science and Technology Policy (OSTP). EPA is one of the primary federal agencies involved in food safety research. In 2001, EPA will be participating, together with these other agencies, in a cross-agency budget submission on food safety.

The National Center for Health Statistics (NCHS) of CDC is conducting the NHANES-4, which 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

Food Quality Protection Act (FQPA) of 1996

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

Toxic Substances Control Act (TSCA)

Federal Food, Drug, and Cosmetic Act (FFDCA)