

Strategic Goal: Safe Food

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

BACKGROUND AND CONTEXT

The U.S. Environmental Protection Agency (EPA) plays a major role in the lives of all Americans by ensuring the safety of the food supply. EPA accomplishes this by working to protect human health and the environment from risks associated with agricultural pesticide use, while ensuring that exposure from any individual agricultural pesticide use will not, with reasonable certainty, cause harm.

EPA regulates pesticides under two main statutes: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and 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 on 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 food. Tolerance requirements apply equally to domestically-produced and imported food. Any food with residues not covered by a tolerance, or in amounts that exceed an established tolerance, may not be legally marketed in the United States.

Both FIFRA and FFDCA have been amended by the Food Quality Protection Act (FQPA) of

1996, which enhances protection of children and other sensitive sub-populations. Because of EPA's work under these laws, Americans enjoy one of the safest, most abundant, and most affordable food supplies in the world.

Pesticides subject to EPA regulation include insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators and other substances intended to control pests. The regulations directly affect pesticide producers, formulators, distributors, retailers, commercial pest control firms, farms, farm workers, industrial and governmental users, and all households.

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, and 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. Biopesticides and other non-conventional, or safer, pesticides make up about 20 percent of the total. Agriculture accounts for over 70 percent of all applications.

Through its food safety programs, EPA enhances health and environmental protection in a number of ways, including the following:

- Establishing a single, health-based standard for all pesticide residues in food, eliminating past inconsistencies in the law which treated residues in some processed foods differently from residues in raw and other processed foods.
- 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.
- Expediting the approval of safer, reduced risk pesticides.

Consumers are at risk for potential adverse effects from pesticide residues ingested either directly or through processed foods. Pesticides also "bioaccumulate" throughout the food chain. 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, or short term effects such as headaches or disorientation. Ensuring that any residues on food are at safe levels is the essence of the Safe Food goal.

MEANS AND STRATEGY

The Agency has a dual strategy to: 1) encourage the introduction of new, safer pesticide ingredients (including new biological agents) within the context of new pest-management practices; while 2) systematically reducing the use of the currently registered pesticides with the highest potential to cause adverse health effects. FIFRA mandates Special Review, re-registration reviews and other risk-management measures available in the registration authority. FQPA mandates additional screening for aggregate exposure, common mechanisms of toxicity and an additional ten-fold safety factor to ensure protection of children and infants.

In 1999, the Agency will continue to register new pesticides that prevent or reduce risk compared to those currently on the market. Progressively replacing older, higher-risk pesticides is one of the most effective methods for curtailing unwanted health and ecosystem impacts while preserving food production rates.

Another priority in 1999 will be testing and screening of existing pesticides to establish new tolerance levels, where appropriate, and to evaluate their potential for disrupting endocrine systems in animals or in humans. The emphasis will be on balancing the need for pesticides, allowing for smooth transitions to alternatives, with the risks of use and exposure.

EPA uses its FIFRA registration authorities and the FFDCA mechanism (to establish legally permissible food-borne exposure levels, or tolerances), in tandem to systematically manage the risks posed by such exposures. Using the comprehensive review of existing pesticide use (according to the benchmark of contemporary risk-assessment practices) entailed in re-registration, together with the FQPA requirement to comprehensively reassess and update existing tolerances on a six-year schedule, 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.

An additional dimension is the pursuit and incorporation of the latest scientific advances in health-risk assessment practices, 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.

Finally, in addition to setting the requirements of continued legal use of agricultural pesticides is the broader effort of preventing the misuse of agricultural pesticides, which EPA shares in partnership with USDA, FDA and the states.

More information about EPA’s food safety efforts is available on the Office of Pesticides Program’s website at <http://www.epa.gov/pesticides>.

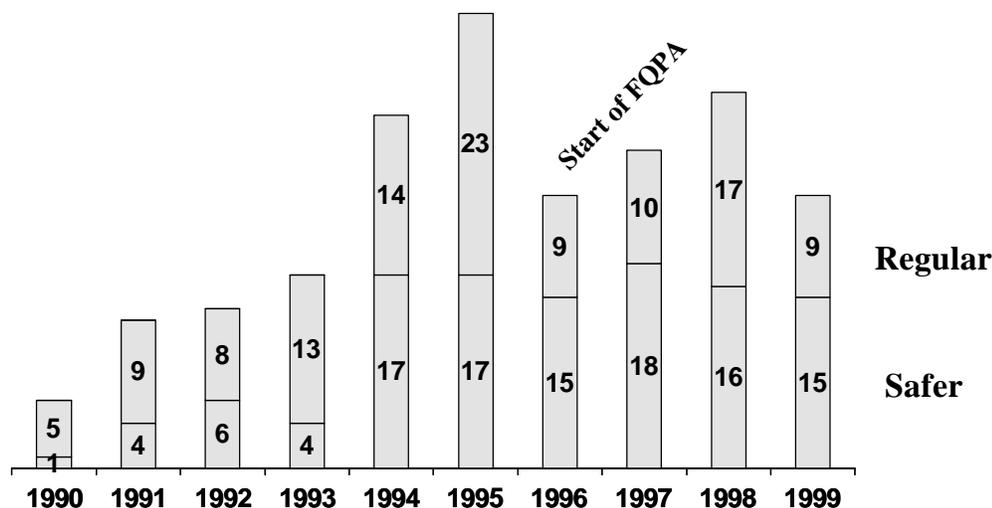
Research

FQPA identifies the need for science to evaluate all potential routes and pathways of exposures to pesticides and their effects on human health. Research will center on such initiatives as assessing the risk of exposures of varying frequency and duration. Research will also compare the effects of exposure to a mixture of pesticides and other toxic chemicals with exposure to the individual chemicals.

STATUTORY AUTHORITY

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

New Pesticide Registrations



Regular: Conventional Chemicals and Antimicrobials
Safer: Biopesticides and Reduced Risk Chemicals

Resource Summary

(Dollars in thousands)

	FY 1999 Pres. Budget	FY 1999 Enacted
Safe Food	\$65,205.9	\$67,546.4
Reduce Agricultural Pesticides Risk	\$26,477.5	\$29,139.0
EPM	\$23,479.3	\$26,243.8
S&T	\$2,998.2	\$2,895.2
Reduce Use on Food of Pesticides Not Meeting Standards	\$38,728.4	\$38,407.4
EPM	\$37,276.6	\$30,587.9
S&T	\$1,451.8	\$7,819.5
Total Workyears:	692.0	702.4

Strategic Objective: Reduce Agricultural Pesticides Risk

Key Programs

(Dollars in thousands)

	1999 Pres Bud	1999 Enacted
Pesticide Registration	\$16,166	\$17,492
Pesticide Re-registration	\$4,170	\$4,253
Endocrine Disruptor Screening Program	\$1,164	\$1,164
Pesticide Residue Tolerance Reassessments	\$977	\$976

Annual Performance Goals and Measures

PESTICIDE RISK

By 1999: Decrease adverse risk from agricultural pesticides from 1995 levels and assure new pesticides that enter the market are safe for humans and the environment.

Performance Measures:	Target:
Register safer chemicals and biopesticides	15 Registrations
New Chemicals	9 Registrations
Amendments	2000 Actions
Me-toos	600 Actions
New Uses	90 Actions
Inerts	45 Actions
Special Registrations	370 Actions
Tolerance Petitions	95 Actions

Baseline: Risk levels for pesticides registered 1995 or before; targets are annual and as such, have no baseline.

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

Key Programs (Dollars in thousands)

	1999 Pres Bud	1999 Enacted
Pesticide Re-registration	\$25,274	\$20,718
Endocrine Disruptor Screening Program	\$1,418	\$1,418
Pesticide Residue Tolerance Reassessments	\$8,561	\$8,564

Annual Performance Goals and Measures

PESTICIDE TOLERANCES

By 1999: Under pesticide re-registration, EPA will reassess 19% of the existing 9,700 tolerances (cumulative 33%) for pesticide food uses to meet the new statutory standard of "reasonable certainty of no harm."

Performance Measures:	Target:
Tolerance Reassessment	1850 Actions
REDs	34 Decisions
Product Re-registration	750 Actions

Baseline: 9,700 tolerances developed prior to 1996

EXTERNAL FACTORS

The ability of the Agency to achieve its strategic goals and 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 environment and human health.

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 environmental goals.

Much of the success of EPA programs also depends on the voluntary cooperation of the private sector and the public.

EPA's ability to achieve the goals and objectives is also predicated on an adequate level of resources for direct program implementation by EPA as well as for delegated programs. Other factors that could delay or prevent the Agency's

achievement of some objectives include: lawsuits that delay or stop EPA's and/or State partners' planned activities; new or amended legislation; and new commitments within the Administration. Economic growth and changes in producer and consumer behavior, such as shifts in energy prices or automobile use, could have an influence on the Agency's ability to achieve several of the objectives within the time frame specified.

New environmental technology, unanticipated complexity or magnitude of environmental problems, or newly identified environmental problems and priorities could affect the time frame for achieving many of the goals and objectives. In particular, pesticide use is affected by unanticipated outbreaks of pest infestations and/or disease factors, which requires EPA to review emergency uses to ensure no unreasonable risks to the environment will result. EPA has no control over requests for various registration actions (new products, amendments, uses, etc.), so its projection of regulatory workload is subject to change.

VERIFICATION AND VALIDATION OF PERFORMANCE MEASURES

The performance measures for this goal include program outputs for the Registration program and are used as an indirect measure of reducing risk.

New pesticides and tolerance settings undergoing registration under the FQPA standard are deemed to be less risky than those which were registered before FQPA, because the new registrations have to meet a more stringent health standard. Additionally, the registration of reduced risk pesticides could potentially reduce the use of the higher risk pesticides, and in doing so, reduce risk. Specific outputs include the numbers of new registered pesticides, new uses of existing pesticides, inert ingredients, “me-toos” or pesticides produced by more than one manufacturer, special registrations and newly registered safer chemicals and biopesticides.

The performance measures are tracked internally by the Office of Pesticides (OPP) and the information is readily available to the public. The database used to track Registration outputs is the Pesticides Regulatory Action Tracking System (PRATS), which we update as an action is completed. The Chemical Review Management System (CRMS) tracks study requirements for company submission information. PRATS and CRMS thus provide internal means for ensuring that goals are being met. Additional information on pesticide usage is available from the National Pesticide Residue Database (NPRD).

Other performance measures for this goal include outputs for the Re-registration program and are direct measures of reducing the use of pesticides which do not meet the FQPA standard. The performance measures are tracked internally by the Office of Pesticides (OPP). The Pesticide

Regulatory Action Tracking System (PRATS) which tracks registration actions, also tracks product re-registration actions. Outputs include the number of tolerance reassessments, re-registration eligibility decisions (REDS) which are a portion of the re-registration process, and the final product re-registrations completed in a given year.

Research

EPA has several strategies to validate and verify performance measures in the area of environmental science and technology research. Most performance measures are verifiable through quantitative means. For those measures that are output-oriented, actual outputs or products can be objectively verified. Because the major output of research is technical information, primarily in the form of reports, software, protocols, etc., key to the validation and verification strategies is the performance of both peer and quality assurance reviews.

Peer reviews provide assurance during the pre-planning, planning, and reporting of environmental science and research activities that the work meets peer expectations. Only those science activities and resulting information products that pass Agency peer review are addressed and published. This applies to program-level, project-level, and research outputs. The quality of the peer review activity is monitored by EPA to ensure that peer reviews are performed consistently, according to Agency policy, and that any identified areas of concern are resolved through discussion or the implementation of corrective action.

A quality assurance system is implemented at all levels in the EPA research organization. The Agency-wide quality assurance system is a management system that provides the necessary elements to plan, implement, document, and assess the effectiveness of quality assurance and quality control activities applied to environmental programs conducted by or for EPA. This quality management

system provides for identification of environmental programs for which Quality Assurance/Quality Control (QA/QC) is needed, specification of the quality of the data required from environmental programs, and provision of sufficient resources to assure that an adequate level of QA/QC is performed.