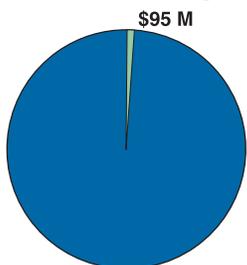


Goal 3 FY 2001 Obligations



Note: EPA FY 2001 Total Obligations were \$9,007 million

GOAL 3: SAFE FOOD

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.

PROGRESS TOWARD STRATEGIC GOAL AND OBJECTIVES

EPA is making steady progress toward ensuring that the foods people eat are safe. Working with state, local, tribal, and other partners, in FY 2001 EPA continued to carry out the Agency's three-part strategy for reducing risks from pesticide residues:

- Reevaluating older, potentially higher risk pesticides using the best current scientific data and methods to determine what additional limits on a pesticide's use are needed to provide reasonable certainty of no harm, especially to children and other sensitive groups of people.
- Accelerating EPA's review and registration of alternative pesticides that are less risky than those currently in use.
- Using partnerships and other means to promote the adoption and use of lower risk pest management methods.

A key element in meeting the Agency's safe food goal is ensuring the availability of reliable baseline data against which EPA can measure its progress. In FY 2001 EPA, Florida State University (FSU), and the National Pollution Prevention Roundtable began work to strengthen the data on which performance indicators and measures supporting EPA's safe food goal are based. This work builds on EPA's and FSU's efforts to inventory and describe environmental outcome indicators and measures, as part of the Chemical and Pesticides Results Measures (CAPRM) project (<http://www.pepps.fsu.edu/CAPRM>), nationwide for federal agencies, states, tribal entities, and local government entities.

CAPRM PROJECT: SAMPLE OF INDICATORS

- Percent of Foods with Detectable Pesticide Residues
- Percentage of Agricultural Acres Treated with Pesticides
- U.S. Volume of Pesticide Usage by Type of Active Ingredient
- Annual Pesticide Use of Select Field Crops by Pesticide Product Signal Word

FY 2001 PERFORMANCE

Reducing Agricultural Pesticide Risk

Older registered pesticides may cause health problems, such as birth defects, nerve damage, and cancer, after long-term exposures to residues in foods, drinking water, and residential uses. Moreover, test data from industry applicants indicate that some pesticides may adversely affect indigenous populations of birds, fish, mammals, beneficial insects, and other sensitive species that are not targets for pesticide applications. Consequently EPA seeks to eliminate or reduce human health and environmental risks by encouraging substitution of less risky pesticides for older chemicals that have potential for these adverse effects. Specifically during FY 2001 EPA took the following actions:

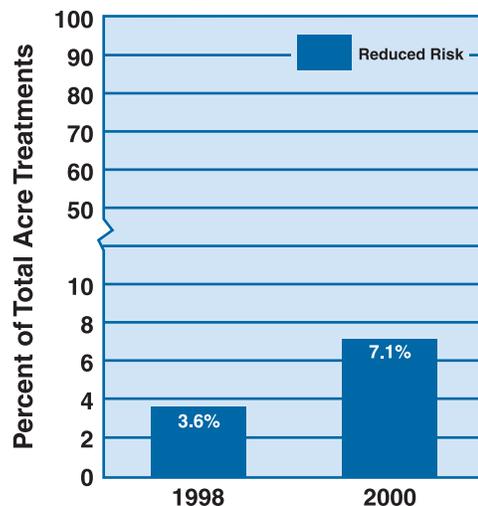
- The Agency registered 11 additional reduced-risk chemical pesticides and biopesticides, approved 103 additional uses of such lower risk pesticides, and approved 65 new uses as organophosphate alternatives. This increased availability of lower risk

pesticides, combined with public demand for safe food, encourages pesticide producers and users to shift to reduced-risk alternatives, thereby eliminating exposures to pesticides that have been associated with adverse neurological effects and cancer. As the use of reduced-risk alternatives increase, they also might become more cost-effective.

- Through the new Strategic Agricultural Initiative, EPA collaborated with state agriculture departments, universities, grower groups, and other partners and stakeholders on 10 to 15 local projects to assist growers in making the transition to reduced-risk pest management strategies. For example, in Michigan collection of commodity-specific data on pesticide use on local crops is helping growers make better informed decisions about pesticide choices. Partners in Oregon have been able to reduce synthetic pesticide use by 74 percent and organophosphate use by 66 percent. The Wisconsin Potato and Vegetable Growers Association, University of Wisconsin, and World Wildlife Fund are teaming with the American Farmland Trust and EPA to continue to demonstrate integrated pest management (IPM) on potatoes. The IPM techniques used achieved a 25 to 37 percent reduction in the toxic-load of pesticides used, as measured through a toxicity-scoring mechanism that reflects the decreased use of toxic pesticides.
- EPA registered three new pesticide alternatives to methyl bromide, a widely used fumigant, and the search for additional alternatives is ongoing. The United States accounts for 40 percent of methyl bromide use worldwide. Under the Clean Air Act, methyl bromide use is to be phased out by 2005 because of its contribution to depletion of stratospheric ozone.

Pesticides that EPA considers “safer” (those registered through the Reduced Risk Initiative and biopesticides) constituted an estimated 3.6 percent of all agricultural pesticide acre-treatments in 1998, increasing to 7.1 percent in 2000—significantly exceeding the Agency’s target of 1 percent. FY 2001 results are expected in the spring of 2002.

Percentage of Agriculture Acres Treated With Reduced-Risk Pesticides



Source: EPA, Office of Pesticides

Reducing Use on Food of Pesticides Not Meeting Health Standards

EPA continued its ongoing comprehensive reviews of pesticides initially registered before November 1, 1984, to ensure their continued safety. After a thorough review of the data, the Agency issues a Reregistration Eligibility Decision (RED). In cases where pesticides do not meet health and environmental requirements, EPA determines what changes are needed in allowable uses, including canceling use or limiting use to certified applicators. By the end of FY 2001 EPA had reviewed more than 71 percent of the 612 cases required to have a RED.

To further protect the food supply, the FQPA set stricter safety standards for pesticide residues in or on food and required EPA to reassess all existing tolerances by 2006 to ensure they meet the new safety standard of “reasonable certainty of no harm.” By the end of FY 2001 the Agency had completed reassessment of 40 percent of these tolerances, including approximately 34 percent of the organophosphates and carcinogens, which are among the pesticides considered of highest risk. Through these efforts, EPA expects to meet its objective to substantially eliminate pesticides that do not meet the FQPA standard.

FQPA'S ADDED PROTECTIONS

EPA builds in a **safety factor** when registering a pesticide for use on food and determining how much pesticide residue can remain on food with a reasonable certainty of no harm. This safety factor allows the Agency to be even more protective of human health than exposure studies suggest is necessary. However, EPA provides a higher safety factor in certain instances when assessing tolerance levels for foods routinely eaten by infants and children.

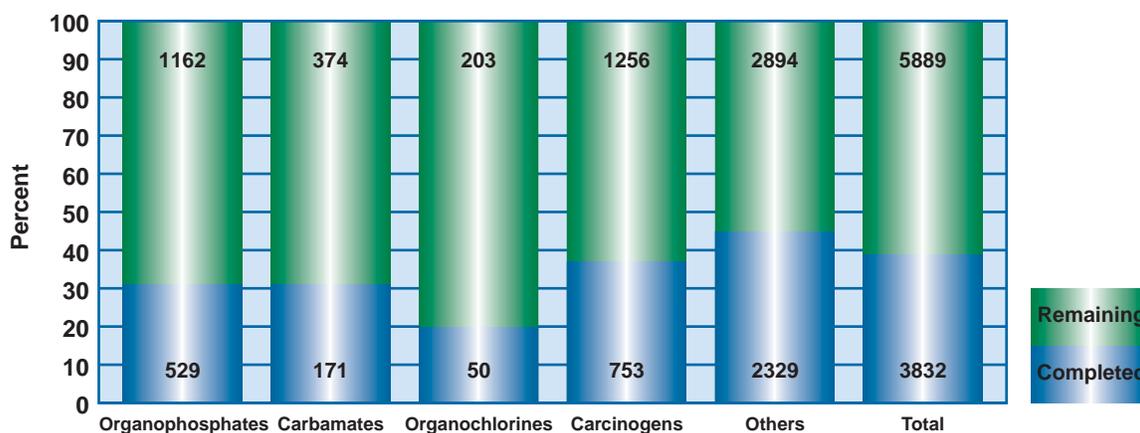
A **cumulative risk assessment**, which looks at more than one pesticide, is the process of combining exposure (the amount of a pesticide to which a person is exposed) and hazard (the health effects a pesticide could cause) from all substances that share a common mechanism of toxicity. Because people can be exposed to several pesticides that act the same way in the body at the same time through various foods, drinking water, and uses in and around the home, school, or recreational areas, assessing the effects of these cumulative exposures allows EPA to understand the risk of an individual pesticide.

An **aggregate risk assessment** looks at one specific pesticide. Such assessments include all potential, relevant routes of exposure—food, drinking water, and residential uses and by ingestion, dermal contact, and inhalation. Routes of exposure refer to how people potentially interact with pesticides in the environment.

EPA took action in FY 2001 to reduce the use of two organophosphate pesticides, diazinon and acephate. Organophosphate pesticides are widely used, older pesticides that are a priority for review because of their potential risks. Diazinon, for example, is both potentially neurotoxic to humans and highly toxic to birds, mammals, water invertebrates, honeybees, and other beneficial insects. When used in the home, it can pose a risk to children. EPA's action will end about 75 percent of the current use of diazinon and restrict remaining uses. Acephate, also a neurotoxicant in humans, has risks similar to that of diazinon for environmental effects. Additionally, EPA's efforts led to the voluntary cancellation of benomyl, a carcinogen used on several crops frequently consumed by children.

Pesticide tolerances are set with an ample margin of safety to avoid human health risks, including risks to vulnerable populations. The Food Quality Protection Act (FQPA) mandates extra protection for infants and children, and EPA uses an extra tenfold protection factor for infants and children in setting a pesticide tolerance (the legal maximum allowable pesticide residue on a food crop) unless scientific data indicate that a different factor is warranted. The special dietary patterns of other vulnerable groups, such as Native Americans, urban poor persons, and farm families, are also considered in the risk assessment and tolerance setting process. In FY 2001 the Agency continued to update and improve its pesticide toxicity testing guidelines and other assessment tools to ensure these populations are adequately protected.

Progress in Reassessing Pesticide Tolerances as of September 30, 2001



This graph shows the status of EPA's tolerance reassessment program by chemical class. In total, 3,832 tolerances (39.4 percent of 9,721) have been reassessed.

EPA made other important decisions to address the risks of pesticides in FY 2001. Because of high levels of worker and ecological risks, EPA, after conducting a special review and tolerance reassessment, entered into a memorandum and letters of agreement with manufacturers to cancel registration of ethyl parathion, which had been registered as a restricted-use pesticide. Ethyl parathion is among the most highly toxic registered pesticides; it is a particularly potent neurologic toxicant and possible carcinogen in humans.

The Agency also denied a request for a food tolerance for Starlink's unique protein in corn because of its potential to cause an allergic reaction and adopted a final rule strengthening federal oversight of plants that are genetically modified to produce pesticidal chemicals.

During FY 2001 EPA revised three science policy papers with broad scientific and stakeholder support detailing how EPA scientists will evaluate aggregate exposure and risk assessment, evaluate cumulative risk assessment, and apply the FQPA safety factor. Broadening stakeholder input led to increased cooperation from industry and growers in developing and implementing reduced-risk agricultural practices and brought wider understanding and acceptance of EPA's regulatory decisions.

The Agency also worked to improve its regulatory decisionmaking in FY 2001. EPA undertook extensive collaboration with scientists from other federal agencies, academia, and the private sector and held multiple meetings with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel, to address the challenges posed by the evolving field of biotechnology, as well as the need for new science policies for risk assessments.

The most recent data indicate that in the United States an annual average of 15,475 food-borne illness cases and 14 food-borne illness-related deaths are reported to the Centers for Disease Control (<http://web.health.gov/healthypeople/Document/HTML/Volume1/10Food.htm>). In FY 2001 EPA worked in partnership with the U.S. Department of Agriculture to expedite the review and conditional approval of a product to control the virus responsible for foot-and-mouth disease in livestock. EPA also worked with the Food and Drug Administration to register food contact preservatives and sanitizers,

providing new tools for controlling microorganisms in food production and handling. Additionally, the Agency encouraged greater public awareness about the precautions people should take in properly preparing and handling food.

Research Contributions

Research supporting Goal 3 is enabling EPA to better identify and characterize groups of people at highest risk, those which may require special regulatory consideration and protection. In FY 2001 the Agency developed tests for identifying pesticides that have increased toxicity for the young. These tests will help EPA determine how best to protect children from harmful pesticide exposure. The Agency also conducted studies to better understand age-dependent differences in response to various pesticides and the health effects associated with repeated pesticide exposure. Additionally, EPA produced an evaluative report on aggregate exposure to pesticides based on National Human Exposure Survey (NHEXAS) studies at three areas along the U.S.-Mexican border. By using various forms of data collection in the NHEXAS studies, EPA will learn how human exposure to pesticides varies according to location, as well as how to conduct effective future exposure assessments. Ultimately, the knowledge gained through these studies will help the Agency determine how best to keep the public protected from and informed of the risks associated with toxic pesticides.

STATE AND TRIBAL PARTNERSHIP CONTRIBUTIONS

State Contributions

Through grant agreements and with guidance provided by EPA, states enforce federal and state pesticide laws, maintain pesticide laboratory operations, train and certify commercial and private pesticide applicators, and develop groundwater pesticide management plans to protect groundwater from contamination. States play a pivotal role in ensuring that food-use and other pesticides are applied according to label instructions and that applicators of restricted-use pesticides are adequately trained. States also respond to emergency pest problems by submitting emergency exemption applications (more than 500 requests in FY 2001),

each of which the Agency reviews to ensure that it meets FQPA health-based standards.

In FY 2001 EPA and the states supported training on pesticide safety for farmworkers and farm families by partnering with the Association of Farmworker Opportunity Programs, AmeriCorps, and 37 community-based organizations in 22 states. EPA also consulted with the state Association of American Pesticide Control Officials and shared information with the State FIFRA Issues Research and Evaluation Group, a network of state officials interested in federal/state co-regulation of pesticides. One of EPA's successful partnerships with states has been the work-share program with California's Department of Pesticide Regulation, which conducts data review for Interregional Research Four (IR-4) petitions. The Directors of State Agricultural Experiment Stations organized IR-4 to expedite federal and state minor use registrations and establish tolerances for many crop uses. The program helps minor crop producers (whose crops account for approximately 40 percent of total agricultural sales for the United States) obtain tolerances and registrations for pest control products. The program supports development of test data for registrations and tolerances and prepares specific instructions for application to include on pesticide labels.

Tribal Contributions

EPA continues to incorporate the needs of Native Americans into its risk assessments. For example, in the reregistration process for lindane, EPA performed a dietary assessment of Alaskan indigenous populations, which rely heavily on subsistence foods that might contain lindane residues. A variety of organochlorine contaminants, including lindane, have been found in land, freshwater, and marine environments as a result of intercontinental transport in air and ocean currents. Fortunately the assessment found the levels of exposure to be well below a level of concern. EPA also collaborates with

the Tribal Pesticide Program Council and other tribal partners to develop a common approach to chemical exposures related to tribal subsistence lifestyles. For example, the Agency initiated discussions for a pilot in the northwest United States to collect food consumption and pesticide residue data for use in dietary risk assessments for groups of people that subsist on fishing, hunting and gathering. Results from this pilot are expected in late 2002.

ASSESSMENTS OF IMPACTS OF FY 2001 PERFORMANCE ON FY 2002 ANNUAL PERFORMANCE PLAN

Based on FY 2001 performance results, EPA modified its FY 2002 performance targets to reflect the impact of fewer reduced risk pesticide applications from industry, and the delay, resulting from the lack of the cumulative risk policy, in the development of tolerance reassessments of special concern to children. The Agency, with input from its partners and stakeholders, continues to invest in developing more outcome-oriented measures to support the achievement of its food safety goal.

PERFORMANCE DATA CHART

The following performance data chart includes performance results for the FY 2001 Annual Performance Goals (APGs) that support Goal 3. The performance chart reflects the Agency's 1997 Strategic Plan goals with which FY 2001 APGs are associated. Relevant FY 2000 and FY 1999 APGs are included for ease in comparing performance. Data quality information for Goal 3 can be found on pages B-13 to B-15 of Appendix B, "Data Quality." Additionally, the chart provides results for FY 2000 and FY 1999 APGs for which data were not available when the FY 2000 report was published as well as for FY 2000 APGs that are not associated with FY 2001 APGs.

Summary of FY 2001 Performance

1 Goal Met 2 Goal Not Met 0 Data Lag

Goal 3: Safe Food
Annual Performance Goals and Measures
FY 1999–FY 2001 Results

By 2005, the Risk From Agricultural Use of Pesticides Will Be Reduced by 50% From 1995 Levels.

Progress Toward Strategic Objective: Since 1996, the year the FQPA was enacted, EPA has made substantial progress toward reducing risk from pesticide residues in food. Nearly 100 safer pesticides—those which pose less risk to human health and the environment than conventional chemical pesticides—have been registered, substantially increasing the tools farmers have at their disposal to protect human health and the environment while ensuring productive agricultural yields. At the same time, use of pesticides that have the highest potential to cause cancer and neurotoxic effects has declined by more than 15% based on survey data. Increasing numbers of safer pesticides on the market and increasing numbers of acre-treatments using such pesticides are ensuring that EPA is on track to meet its revised objective to reduce public health risk from pesticides in food from pre-FQPA levels.

APG 16 **Planned** **Actual**

FY 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. Goal Not Met.**

Performance Measures

- Register safer chemicals and biopesticides. 96 92

FY 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, 225 tolerances and 13 reduced risk chemicals/biopesticides. Goal Met.* 6
3,069
1,106
427
95
458
452
16

FY 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. No Data.* --

FY 2001 Result: The registration of new agricultural pesticides and reregistration of older agricultural pesticides for use on food were done under the strict health-based standard of FQPA: “reasonable certainty of no harm.” “Safer” pesticides are those that meet an even stricter set of criteria. However, EPA did not meet the numerical registration goal for two reasons. First, EPA did not receive enough submissions from industry that met the criteria of “reduced risk.” In an effort to resolve this, the Agency held a workshop to provide registrants with information on what constitutes a reduced-risk pesticide and the data required to register one. Second, policy and scientific issues concerning biotechnology (such as concerns over resistance management and potential harm to non-target species) delayed the registration of some new biopesticides.

EPA is working internally with Florida State University and outside stakeholders, including industry and environmental organizations, to develop potential measures of risk. Although the Agency will continue to use the registration of safer chemicals as a performance measure under this goal, EPA also improved the measure of occurrence of residues to more accurately measure decreased risk for 2002 and beyond.

APG 17 **Planned** **Actual**

FY 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. Goal Met.**

Performance Measures

- New chemicals registered (cumulative) 51 53
 - New uses (cumulative) 1,979 1,896
actions **actions**

FY 2001 Result: The Agency registered nine new chemicals, exceeding its target by two. EPA also registered 267 new uses of chemicals, underperforming the target by 83. It has proven difficult to establish good targets for registration. It is difficult to predict within the Registration Program the number of requests that will come in from industry in any given time frame or the level of difficulty that the review

of these applications might entail. The targets represent EPA's best estimates. In FY 2001 the targets for new uses were adjusted upward for new uses by 150, based on prior-year experience, but the targets were overestimated when compared with actual completions.

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.

Progress Toward Strategic Objective: EPA is well on the way to meeting the revised objective to, by 2008, substantially eliminate the use on food of pesticides that do not meet the "reasonable certainty of no harm" standard of the FQPA. Since 1996, 40% of the 9,271 tolerances (legal pesticide residue levels on food) have been reassessed using the new standard. More than 70% of 612 reregistration eligibility decisions have been completed. In particular, the risk of pesticides used on foods frequently eaten by children is decreasing in part through work in EPA's tolerance reassessment program.

APG 18		Planned	Actual
FY 2001	By the end of 2001 EPA will reassess a cumulative 40% of the 9,721 tolerances required to be reassessed over ten-years and complete reassessment of a cumulative 46% (or 411) of the 893 tolerances of special concern in protecting the health of children. Goal Not Met.	40% 46%	40% 44%
<i>FY 2000</i>	<i>EPA will reassess 20% of the existing 9,721 tolerances to ensure that they meet the statutory standard of "reasonable certainty of no harm." Goal Not Met.</i>		<i>121</i>
<i>FY 1999</i>	<i>Under pesticide reregistration, EPA will reassess 19% (or 1,850) of the existing 9,700 tolerances (cumulative 33%) for pesticides food uses to meet the new statutory standards of "reasonable certainty of no harm." Goal Not Met.</i>		<i>1,445</i>

FY 2001 Result: The Agency reassessed 40% (3,664) of tolerances requiring reassessment under FQPA. By the end of 2001, EPA had reassessed 388 (44%) of the 893 tolerances of special concern to children (22 tolerances less than the target of 411). Because EPA continued to wrestle with the scientific and policy implications of the cumulative risk policy, the number of tolerances of special concern for children's health fell slightly short of the target. EPA's revised guidance for applying cumulative risk assessments was published on January 16, 2002. Therefore the pace of reassessments for tolerances of special concern for children's health should increase. EPA is still on track to meet the statutory deadline of 66% of tolerances reassessed by August 3, 2002, and 100% by August 2006.

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