slides for distribution to the participants and public at the meeting. *Written Comments:* Although written comments are accepted until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the DFO at the address/contact information noted above in the following formats: One hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 35 copies of their comments for public distribution.

Meeting Accommodations: Individuals requiring special accommodation to access these meetings, should contact Dr. Nugent at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: July 22, 2003.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 03–19277 Filed 7–29–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0327; FRL–7284–6]

Pesticide Reregistration Performance Measures and Goals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's progress in meeting its performance measures and goals for pesticide reregistration during fiscal year 2002. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to publish information about EPA's annual achievements in this area. This notice discusses the integration of tolerance reassessment with the reregistration process, and describes the status of various regulatory activities associated with reregistration and tolerance reassessment. The notice gives total numbers of chemicals and products reregistered, tolerances reassessed, Data Call-Ins issued, and products registered under the ''fast-track'' provisions of FIFRA. Finally, this notice contains the schedule for completion of activities for specific chemicals during fiscal years 2003 and 2004.

DATES: This notice is not subject to a formal comment period. Nevertheless, EPA welcomes input from stakeholders and the general public. Written comments, identified by the docket ID number [OPP–2002–0327], should be received on or before September 29, 2003.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Carol P. Stangel, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, telephone: (703) 308–8007, e-mail: stangel.carol@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Important Information

A. Does this Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who are interested in the progress and status of EPA's pesticide reregistration and tolerance reassessment programs, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information or Copies of Support Documents?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2002–0327. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. To access information about pesticide reregistration, go to the home page for the Office of Pesticide Programs at www.epa.gov/pesticides and select ''Reregistration'' under ''Regulating Pesticides,'' or go directly to www.epa.gov/pesticides/reregistration/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or

other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment, and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

2. *EPA Dockets—i*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2002–0327. The system is an, ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2002–0327. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP– 2002–0327.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2002–0327. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

EPA must establish and publish in the **Federal Register** its annual performance measures and goals for pesticide reregistration, tolerance reassessment, and expedited registration, under section 4(l) of FIFRA, as amended by the Food Quality Protection Act of 1996 (FQPA). Specifically, such measures and goals are to include:

- The status of reregistration.
- The number of products reregistered, canceled, or amended.
- The number and type of data requests or Data Call-In (DCI) notices under section 3(c)(2)(B) issued to support product reregistration by active ingredient.
- Progress in reducing the number of unreviewed, required reregistration studies.
- The aggregate status of tolerances reassessed.
- The number of applications for registration submitted under subsection (k)(3), expedited processing and review of similar applications, that were approved or disapproved.
- The future schedule for reregistrations in the current and succeeding fiscal year.
- The projected year of completion of the reregistrations under section 4.

FIFRA, as amended in 1988, authorizes EPA to conduct a comprehensive pesticide reregistration program--a complete review of the human health and environmental effects of older pesticides originally registered before November 1, 1984. Pesticides meeting today's scientific and regulatory

standards may be declared ''eligible'' for reregistration. To be eligible, an older pesticide must have a substantially complete data base, and must not cause unreasonable adverse effects to human health or the environment when used according to Agency approved label directions and precautions.

In addition, all pesticides with food uses must meet the safety standard of section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) of 1996. Under FFDCA, EPA must make a determination that pesticide residues remaining in or on food are ''safe''; that is, ''that there is reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue'' from dietary and other sources. In determining allowable levels of pesticide residues in food, EPA must perform a more comprehensive assessment of each pesticide's risks, considering:

- Aggregate exposure (from food, drinking water, and residential uses).
- Cumulative effects from all pesticides sharing a common mechanism of toxicity.
- Possible increased susceptibility of infants and children; and
- Possible endocrine or estrogenic effects.

As amended by FQPA, FFDCA requires the reassessment of all existing tolerances (pesticide residue limits in food) and tolerance exemptions within 10 years, to ensure that they meet the safety standard of the law. EPA was directed to give priority to the review of those pesticides that appear to pose the greatest risk to public health, and to reassess 33% of the 9,721 existing tolerances and exemptions within 3 years (by August 3, 1999), 66% within 6 years (by August 3, 2002), and 100% in 10 years (by August 3, 2006). (Note: Although the total number of tolerances existing on August 3, 1996, and subject to FQPA reassessment was initially reported as 9,728, that number has been corrected to 9,721, based on the Agency's Tolerance Reassessment Tracking System.)

EPA is meeting the FFDCA's tolerance reassessment requirements through reregistration and several other program activities. In making reregistration eligibility decisions, the Agency also is completing much of tolerance reassessment, which is helping us meet the time frames mandated by the new law. EPA reassessed the first 33% of all food tolerances by August 3, 1999, and the second 33% of all food tolerances by August 3, 2002. EPA is focusing particularly on priority Group 1 pesticides, those identified as posing the greatest potential risks. Over half of the universe of tolerances to be reassessed are included in this category, including tolerances for the organophosphate (OP) pesticides, the Agency's highest priority for review. Carbamate, organochlorine, and B2 (probable human) carcinogen pesticides also are included in priority Group 1. Although EPA is directing most of its resources toward this group, a number of Group 1 pesticides will nevertheless be reassessed in the third 33% owing to the challenging issues they present. EPA's approach to tolerance reassessment under FFDCA, including the three priority Groups, is described fully in the Agency's document, ''Raw and Processed Food Schedule for Pesticide Tolerance Reassessment'' (62 FR 42020, August 4, 1997) (FRL–5734–6). In conducting the pesticide reregistration and tolerance reassessment programs at present, EPA is developing measures that show results in terms of outcomes, as well as traditional outputs, as directed by OMB.

III. FQPA and Program Accountability

One of the hallmarks of the FQPA amendments to the FFDCA is enhanced accountability. Through this summary of performance measures and goals for pesticide reregistration, tolerance reassessment, and expedited registration, EPA describes progress made during the past year in each of the program areas included in FIFRA section 4(l).

A. Status of Reregistration

During fiscal year (FY) 2002 (from October 1, 2001, through September 30, 2002), EPA made significant progress in completing risk assessments and risk management decisions for the OP pesticides, the Agency's highest priority chemicals for reregistration and tolerance reassessment, and for other pesticides. See Table 1.

TABLE 1.—REREGISTRATION/RISK MANAGEMENT DECISIONS COMPLETED: FY 2002 AND TOTAL

FY 2002: 36 Decisions	Total, End of FY 2002
7 REDs 1,4-Bis(bromoacetoxy)-2-butene Endosulfan[1] Fenamiphos (Voluntary Cancellation)[2] (HOCH2-)methyldithiocarbamate (Voluntary Cancellation) Lindane[1] Oxyfluorfen Thiabendazole	214 REDs
8 IREDs Azinphos-methyl[1,2] Diazinon[1,2] Dicrotophos[2] Disulfoton[2] Methamidophos[2] Naled[2] Oxydemeton-methyl[2] Phosmet[1,2]	21 IREDs

TABLE 1.—REREGISTRATION/RISK MANAGEMENT DECISIONS COMPLETED: FY 2002 AND TOTAL—Continued

FY 2002: 36 Decisions	Total, End of FY 2002
21 TREDs Asulam Calcium hypochlorite Chlorine gas Chlorpropham Difenzoquat Diquat dibromide Diuron (RED to be completed in FY 2003) Fenarimol Fenbutatin-oxide Hexazinone Imazalil (RED to be completed in FY 2003) Linuron Metolachlor Norflurazon Primisulfuron-methyl Pronamide Propanil (RED to be completed in FY 2003) Sodium hypochlorite Tebuthiuron Tetrachlorvinphos[2] Urea	32 TREDs

[1]Subject to NRDC consent decree
[2]Organophosphate (OP) pesticide

The Agency's decisions are embodied in Reregistration Eligibility Decision (RED) documents, Interim Reregistration Eligibility Decisions (IREDs), or Reports on FQPA Tolerance Reassessment Progress and Interim Risk Management Decisions (TREDs).

1. *REDs.* Through the reregistration program, EPA is reviewing current scientific data for older pesticides (those initially registered before November 1984), reassessing their effects on human health and the environment, and requiring risk mitigation measures as necessary. Pesticides that have sufficient supporting data and whose risks can be successfully mitigated may be declared ''eligible'' for reregistration. EPA presents these pesticide findings in a RED document.

i. *Overall RED progress.* EPA's overall progress at the end of FY 2002 in completing Reregistration Eligibility Decisions (REDs) is summarized in Table 2.

TABLE 2.—OVERALL RED PROGRESS, END OF FY 2002

REDs completed	214 (35%)
Cases canceled	231 (38%)
REDs to be completed	167 (27%)
Total reregistration cases	612 (100%)

ii. *Profile of completed REDs.* A profile of the 214 REDs completed by the end of FY 2002 is presented in Table 3.

TABLE 3.—PROFILE OF 214 REDS COMPLETED, END OF FY 2002

Pesticide active ingredients	313
Pesticide products	8,600+
REDs with food uses	107
Post-FQPA REDs	73
Post-FQPA REDs with food uses	54
Tolerance reassessments completed for post-FQPA REDs*	1,322

*EPA is revisiting tolerances associated with the 53 food use REDs that were completed before FQPA was enacted to ensure that they meet the safety standard of the new law, as set forth in the Agency's August 4, 1997, Schedule for Pesticide Tolerance Reassessment.

iii. *Risk reduction in REDs.* Reducing pesticide risks is an important aspect of the reregistration program. In developing REDs, EPA works with stakeholders including pesticide registrants, growers and other pesticide users, and environmental and public health interests, as well as the States, USDA, and other Federal agencies and others to develop voluntary measures or regulatory controls needed to effectively reduce risks of concern. Almost every RED includes some measures or modifications to reduce risks. The options for such risk reduction are extensive and include voluntary cancellation of pesticide products or deletion of uses; declaring certain uses ineligible or not yet eligible (and then proceeding with follow-up action to cancel the uses or require additional supporting data); restricting use of products to certified applicators; limiting the amount or frequency of use; improving use directions and precautions; adding more protective clothing and equipment requirements; requiring special packaging or engineering controls; requiring no-treatment buffer zones; employing ground water, surface water, or other environmental and ecological safeguards; and other measures.

2. *Interim REDs or IREDs.* EPA issues IREDs for pesticides that are undergoing reregistration, require a reregistration eligibility decision, and also must be included in a cumulative assessment under FQPA because they are part of a group of pesticides that share a common mechanism of toxicity. An IRED is issued for each individual pesticide in the cumulative group when EPA completes the pesticide's risk assessment and interim risk management decision. An IRED may include measures to reduce food, drinking water, residential, occupational, and/or ecological risks, to gain the benefit of these changes before the final RED can be issued following the Agency's consideration of cumulative risks. For example, EPA generally does not consider individual

OP or N-methyl carbamate pesticide decisions to be completed REDs or tolerance reassessments. Instead, the Agency is issuing IREDs for these chemicals at this time. EPA will make final decisions and may issue REDs for these pesticides when the cumulative risks of the OPs or carbamates have been considered. Once the Agency completes a cumulative evaluation of the OPs, final decisions will be made and REDs may be issued for the 24 OP pesticides that initially had IREDs.

3. *Tolerance reassessment ''TREDs.''* EPA issues Reports on FFDCA Tolerance Reassessment Progress and Interim Risk Management Decisions, known as TREDs, for pesticides that require tolerance reassessment decisions under FFDCA, but do not require a reregistration eligibility decision at present because:

- The pesticide was first registered after November 1984 and is considered a ''new'' active ingredient, not subject to reregistration (e.g., fenarimol and primisulfuron-methyl in FY 2002);
- EPA completed a RED for the pesticide before FQPA was enacted (most FY 2002 TREDs are in this post-RED category); or
- The pesticide is not registered for use in the U.S. but tolerances are established that allow crops treated with the pesticide to be imported from other countries (e.g., mevinphos).

During FY 2002, EPA also completed TREDs for three pesticides (diuron, imazalil, and propanil) whose REDs are under development. The Agency expects to complete REDs for these pesticides in FY 2003.

As with IREDs, EPA will not take final action on pesticides subject to TREDs that are part of a cumulative group until cumulative risks have been considered for the group.

4. *Goals for FY 2003 and future years.* EPA's major pesticide reregistration and tolerance reassessment goals for FY 2003 and future years are as follows. In addition to achieving these traditional output-oriented goals, EPA also is working to develop measures that show results in terms of outcomes, as directed by OMB.

i. *Complete individual pesticide risk management decisions.* EPA's goal in conducting the reregistration and tolerance reassessment program is to complete 20–35 Reregistration Eligibility Decisions (REDs) and Interim REDs each year during fiscal years 2003 through 2006, giving priority to pesticides with associated tolerances. Candidate pesticides for these decisions are listed near the end of this document.

ii. *Evaluate OP and other cumulative risks.* EPA began developing methods for cumulative risk assessment and the components of a cumulative risk assessment for the OP pesticides soon after FQPA was enacted in August 1996, although the Agency had begun considering this approach earlier, when it was recommended by NAS in their 1993 report, ''Pesticides in the Diets of Infants and Children.'' These efforts came to fruition in FY 2002. In addition to completing most of the remaining risk assessments and risk management decisions for individual OP pesticides, EPA issued the preliminary OP cumulative risk assessment in December 2001. After considering public comment, stakeholder input, and the results of additional scientific review, EPA issued a revised OP cumulative risk assessment in June 2002 and has begun risk management actions based on this revised assessment. The Agency plans to review public and SAP comments on the revised cumulative risk assessment as well as examine newly submitted data in further evaluating OP cumulative risks during 2003. The Agency then may issue final reregistration eligibility and tolerance reassessment decisions for individual OP pesticides with IREDs and TREDs. Consideration of the cumulative risks of N-methylcarbamates, chloroacetanilides, and perhaps other common mechanism groups of pesticides will follow. For further information, see EPA's cumulative risk website, http://www.epa.gov/pesticides/cumulative/.

iii. *Complete 100% of tolerance reassessment decisions.* EPA is continuing to reassess tolerances within time frames set forth in FFDCA as amended by FQPA, giving priority to those food use pesticides that appear to pose the greatest risk. Integration of the reregistration and tolerance reassessment programs has added complexity to the reregistration process for food use pesticides. The Agency successfully reached its first two tolerance reassessment milestones by completing over 33% of all tolerance reassessment decisions by August 3, 1999, and over 66% by August 3, 2002. EPA is working toward meeting the final FQPA tolerance reassessment goal: To complete 100% of all required tolerance reassessment decisions by August 3, 2006.

B. Product Reregistration; Numbers of Products Reregistered, Canceled, and Amended

At the end of the reregistration process, after EPA has issued a RED and declared a pesticide reregistration case eligible for reregistration, individual end-use products that contain pesticide active ingredients included in the case still must be reregistered. This concluding part of the reregistration process is called ''product reregistration.''

In issuing a completed RED document, EPA sends registrants a Data Call-In (DCI) notice requesting any product-specific data and specific revised labeling needed to make final reregistration decisions for each of the individual pesticide products covered by the RED. Based on the results of EPA's review of these data and labeling, products found to meet FIFRA and FFDCA standards may be reregistered.

A variety of outcomes are possible for pesticide products completing this final phase of the reregistration process. Ideally, in response to the DCI notice accompanying the RED document, the pesticide producer, or registrant, will submit the required product-specific data and revised labeling, which EPA will review and find acceptable. At that point, the Agency may reregister the pesticide product. If, however, the product contains multiple active ingredients, the Agency instead issues an amendment to the product's registration, incorporating the labeling changes specified in the RED; a product with multiple active ingredients may not be fully reregistered until the last active ingredient in its formulation is eligible for reregistration. In other situations, the Agency may temporarily suspend a product's registration if the registrant has not submitted required product-specific studies within the time frame specified. The Agency may cancel a product's registration because the registrant did not pay the required registration maintenance fee. Alternatively, the registrant may request a voluntary cancellation of their end-use product registration.

1. *Product reregistration actions in FY 2002.* EPA counts each of the post-RED product outcomes described above as a product reregistration action. A single pesticide product may be the subject of several product reregistration actions within the same year. For example, a product's registration initially may be amended, then the product may be reregistered, and later the product may be voluntarily canceled, all within the same year. During FY 2002, EPA completed the product reregistration actions detailed in Table 4. The program's goal is to complete 400–450 product reregistration actions in FY 2003.

TABLE 4.—PRODUCT REREGISTRATION ACTIONS COMPLETED DURING FY 2002

Product reregistration actions	77
Product amendment actions	51
Product cancellation actions	186
Total actions	314

2. *Status of the product reregistration universe.* The status of the universe of pesticide products subject to reregistration at the end of FY 2002 is shown in Table 5 below. This overall status information is not ''cumulative''--it is not derived from summing up a series of annual actions. Adding annual actions would result in a larger overall number since each individual product is subject to multiple actions--it can be amended, reregistered, and/or canceled, over time. Instead, the ''big picture'' status information in Table 5 should be considered a snapshot in time. As registrants and EPA make marketing and regulatory decisions in the future, the status of individual products may change, and numbers in this table are expected to fluctuate.

TABLE 5.—STATUS OF THE UNIVERSE OF PRODUCTS SUBJECT TO PRODUCT REREGISTRATION, FOR FY 2002 (AS OF SEPTEMBER 30, 2002)

Products reregistered	1,637
Products amended	345
Products canceled	3,806
Products sent for suspension	12
Total products with actions completed	5,800
Products with actions pending	2,817
Total products in product reregistration universe	8,617

The universe of 8,617 products in product reregistration at the end of FY 2002 represented an increase of 745 products from the FY 2001 universe of 7,872 products. The increase consists of 324 products associated with FY 2002 REDs, and 412 products associated with IREDs, plus 9 products that were added as a result of DCI activities and processing for several previously issued REDs and IREDs.

At the end of FY 2002, 2,817 products had product reregistration decisions pending. Some pending products await science reviews, label reviews, or reregistration decisions by EPA. Others are not yet ready for product reregistration actions; they are associated with more recently completed REDs, and their product-specific data are not yet due to be submitted to or reviewed by the Agency. EPA's goal is to complete 400–450 product reregistration actions during fiscal year 2003.

C. Number and Type of DCIs to Support Product Reregistration by Active Ingredient

1. *DCIs for REDs.* The number and type of data call-in requests or DCIs that EPA is preparing to issue under FIFRA section 3(c)(2)(B) to support product reregistration for pesticide active ingredients included in FY 2002 REDs are shown in Table 6. Starting in FY 2001, for the first time, OMB clearance has been required to issue REDs and IREDs. Since the Fenamiphos and (HOCH2-)methyldithiocarbamate REDs consisted of voluntary cancellations, products containing these pesticides will not be reregistered and therefore do not require DCIs.

TABLE 6.—DCIS PREPARED TO SUPPORT PRODUCT REREGISTRATION FOR FY 2002 REDS

Case Number	Case Name	Number of Products Covered by the RED[1]	Number of Product Chemistry Studies Required[2]	Number of Acute Toxicology Studies Required[3]	Number of Efficacy Studies Required
3030	1,4-Bis(bromoacetoxy)-2-butene	2	22	12 (6 studies x 2 products)	--
0014	Endosulfan	98 (includes 4 SLN products)	22	102 (7 batches/10 not batched)	0
0333	Fenamiphos (Voluntary Cancellation)	15	N/A	N/A	N/A
3076	(HOCH2-) methyldithiocarbamate (Voluntary Cancellation)	0	N/A	N/A	N/A
0315	Lindane	29	22	126 (5 batches/16 not batched)	0
2490	Oxyfluorfen	117 (includes 8 SLN products)	22	60 (4 batches/6 not batched)	0
2670	Thiabendazole	63	22	144 (4 batches/20 not batched)	0

[1]The number of registered products containing a pesticide active ingredient can change over time. The number of products that appears in the RED document (counted when the RED is signed) may be different than the number of products that EPA is tracking for product reregistration (counted later, when the RED is issued). This table reflects the final number of products associated with each RED, as they are being tracked for product reregistration.

[2]This column shows the number of product chemistry studies that are required for each product covered by the RED.

[3]In an effort to reduce the time, resources, and number of animals needed to fulfill acute toxicity data requirements, EPA ''batches'' products that can be considered similar from an acute toxicity standpoint. For example, one batch could contain five products. In this instance, if six acute toxicology studies usually were required per product, only six studies (rather than 30 studies) would be required for the entire batch. Factors considered in the sorting process include each product's active and inert ingredients (e.g., identity, percent composition, and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular), and labeling (e.g., signal word, use classification, precautionary labeling). The Agency does not describe batched products as ''substantially similar,'' because all products within a batch may not be considered chemically similar or have identical use patterns.

2. *DCIs for IREDs*. The number and type of data requests or DCIs that EPA is preparing to issue to support product reregistration for pesticide active ingredients included in FY 2002 Interim REDs (IREDs) are shown in Table 7.

TABLE 7.—DCIS PREPARED TO SUPPORT PRODUCT REREGISTRATION FOR FY 2002 IREDS

Case Number	Case Name	Number of Products Covered by the IRED	Number of Product Chemistry Studies Required	Number of Acute Toxicology Studies Required	Number of Efficacy Studies Required
0235	Azinphos-methyl	24	22	54 (4 batches/5 not batched)	0
0238	Diazinon	182	22	186 (15 batches/16 not batched)	0
0145	Dicrotophos	3	22	6 (1 batch)	--
0102	Disulfoton	62	22	114 (4 batches/15 not batched)	0
0043	Methamidophos	47	22	24 (1 batch/3 not batched)	0
0092	Naled	35	22	78 (2 batches/11 not batched)	2
0258	Oxydemeton-methyl	19 (includes 2 SLN products)	22	12 (2 batches)	0
0242	Phosmet	40	22	42 (6 batches/1 not batched)	2

Note: FIFRA section 24(c) or Special Local Need (SLN) registrations are not included in acute toxicity batchings because they are supported by a valid parent product (section 3) registration.

3. *DCIs not needed for TREDs*. The Agency does not issue product-specific data requests or DCIs for pesticides included in tolerance reassessment decisions or TREDs because, at present, these pesticides do not require product reregistration decisions; they are subject to tolerance reassessment only.

D. Progress in Reducing the Number of Unreviewed, Required Reregistration Studies

EPA is making progress in reviewing scientific studies submitted by pesticide registrants in support of pesticides undergoing reregistration. See Table 8.

TABLE 8.—REVIEW STATUS OF STUDIES SUBMITTED FOR PESTICIDE REREGISTRATION, END OF FY 2002

Pesticide Reregistration Group or List, per FIFRA Section 4(c)(2)	Studies Reviewed + Extraneous[1]	Studies Awaiting Review	Total Studies Received
List A	11,237 + 470 = 11,707 (84%)	2,201 (16%)	13,908
List B	6,453 + 746 = 7,199 (75%)	2,408 (25%)	9,607
List C	2,271 + 239 = 2,510 (73%)	938 (27%)	3,448
List D	1,342 + 94 = 1,436 (82%)	308 (18%)	1,744
Total Lists A - D	21,303 + 1,549 = 22,852 (80%)	5,855 (20%)	28,707

[1]Extraneous studies is a term used to classify those studies that are not needed because the guideline or data requirement has been satisfied by other studies or has changed.

Studies reviewed by EPA increased (or the study review ''backlog'' decreased) during FY 2002. At the end of the fiscal year, over 80% of all studies received by the Agency in support of reregistration had been reviewed, compared to 79% at the end of FY 2001. During FY 2002, the Agency continued an effort to clean up the data base used to track the review status of studies submitted for reregistration. The percent of studies reviewed should continue to increase in future years.

E. Aggregate Status of Tolerances Reassessed

During FY 2002, EPA completed 2,649 tolerance reassessments and ended the fiscal year with a total of 6,499 tolerance reassessment decisions to date, addressing almost 67% of the 9,721 tolerances that require reassessment (See Table 9). Over 60% of the tolerance reassessment decisions completed were for pesticides in priority Group 1.

Just as EPA reassessed over 33% of all food tolerances by August 3, 1999, including many tolerances for pesticides identified as posing the greatest potential risks, the Agency also met the next FQPA goal during FY 2002 and completed over 66% of all required tolerance reassessment decisions by August 3, 2002. EPA's general schedule for tolerance reassessment (**Federal Register**, August 4, 1997) identified three groups of pesticides to be reviewed; this grouping continues to reflect the Agency's overall scheduling priorities. In completing tolerance reassessment, EPA continues to give priority to pesticides in Group 1.

1. *Aggregate accomplishments through reregistration and other programs.* EPA is accomplishing tolerance reassessment through the registration and reregistration programs; by revoking tolerances for pesticides that have been canceled (many as a result of reregistration); by reevaluating pesticides with pre-FQPA REDs, and through other decisions not directly related to registration or reregistration, described further below. EPA is using the Tolerance Reassessment Tracking System (TORTS) to compile this updated information and report on the status of tolerance reassessment (See Table 9).

TABLE 9.—TOLERANCE REASSESSMENTS COMPLETED POST-FQPA BY FISCAL YEAR, THROUGH FY 2002

Tolerances Reassessed Through...	During Late FY 96	During FY 1997	During FY 1998	During FY 1999	During FY 2000	During FY 2001	During FY 2002	Total, End of FY 2002
Reregistration/REDs	25	339	278	359	44	46	231	1,322
Tolerance Reassessments/TREDs	--	--	--	--	--	--	776	776
Registration	0	221	308	341	55	215	200	1,340
Tolerance revocations	3	0	812	513	22	35	545	1,930
Other decisions	0	1	0	233	0	0	897	1,131
Total tolerances reassessed	28	561	1,398	1,446	121	296	2,649	6,499

i. *Reregistration/REDs.* EPA is using the reregistration program to accomplish much of tolerance reassessment. For each of the tolerance reassessment decisions made through REDs since FQPA, the Agency has made the finding as to whether there is a reasonable certainty of no harm, as required by FFDCA. Many tolerances reassessed through reregistration remain the same while others may be raised, lowered, or revoked.

ii. *Tolerance reassessments/TREDs.* Tolerances initially evaluated through REDs that were completed before FQPA was enacted in August 1996 now are being reassessed to ensure that they meet the new FFDCA safety standard. EPA issues these post-RED tolerance reassessment decisions as TREDs. The Agency also issues TREDs summarizing tolerance reassessment decisions for some developing REDs, for new pesticide active ingredients not subject to reregistration, and for pesticides with import tolerances only. Tolerance reassessments in TREDs for pesticides that are not part of a cumulative group (i.e., pesticides that are not OPs or carbamates) may be counted at present and are included in the FY 2002 accomplishments. In completing OP IREDs and TREDs during FY 2002, the Agency also completed tolerance reassessment decisions for these pesticides. Many of these tolerance reassessments will not become final, however, until EPA completes a cumulative evaluation of the OPs.

iii. *Registration.* Like older pesticides, all new pesticide registrations must meet the safety standard of FFDCA. Many of the registration applications EPA receives are for new uses of pesticides already registered for other uses. To reach a decision on a proposed new food use of an already registered pesticide, EPA must reassess the existing tolerances, as well as the proposed new tolerances, to make sure there is reasonable certainty that no harm will result to the public from aggregate exposure from all uses. During FY 2002, the Agency has continued to discourage submission of applications and petitions for any new uses of the OP pesticides, given the need to consider cumulative risks from OP's as a group before any new uses can be fully evaluated.

iv. *Tolerance revocations.* Revoked tolerances represent uses of many different pesticide active ingredients that have been canceled in the past. Some pesticides were canceled due to the Agency's risk concerns. Others were canceled voluntarily by their manufacturers, based on lack of support for reregistration. Tolerance revocations are important even if there are no domestic uses of a pesticide because residues in or on imported commodities treated with the chemical could still present dietary risks that may exceed the FFDCA ''reasonable certainty of no harm'' standard, either individually or cumulatively with other substances that share a common mechanism of toxicity.

v. *Other reassessment decisions.* In addition to the types of reassessment actions described above, a total of 1,131 additional tolerance reassessment decisions have been made, not directly related to registration or reregistration. A list of these other tolerance reassessment decisions with their **Federal Register** citations is available in the docket for this **Federal Register** notice.

2. *Accomplishments for priority pesticides.* During FY 2002, EPA completed tolerance reassessment decisions for many high priority pesticides in review, including OPs, carbamates, organochlorines, and carcinogens. (See Table 10.)

TABLE 10.—TOLERANCE REASSESSMENTS COMPLETED FOR PRIORITY PESTICIDES

Pesticide Class	Tolerances to be Reassessed	Reassessed by End of FY 2002
Organophosphates	1,691	1,127 (66.65%)
Carbamates	545	303 (55.6%)
Organochlorines	253	253 (100%)
Carcinogens	2,008	1,278 (63.65%)
High hazard inerts	5	3 (60%)
Other	5,219	--
Total	9,721	6,499 (66.86%)

3. *Tolerance reassessment and the organophosphates*. EPA has developed an approach for assessing cumulative risk for the OPs as a group, as required by FFDCA, and applied this methodology in conducting the OP cumulative risk assessment during FY 2002. The Agency presented a comprehensive guidance document on cumulative risk assessment to the Scientific Advisory Panel in December 1999, issued draft guidance in 2000 for review and comment, and presented a case study on cumulative risk assessment to the SAP in December 2000. In 2001, EPA refined the methodology and began developing components of the OP cumulative preliminary risk assessment. With input from the Committee to Advise on Reassessment and Transition (CARAT) workgroup, the Agency developed a process to inform stakeholders and encourage their participation during the assessment of OP cumulative risks. At CARAT's recommendation, EPA held a series of technical briefings to explain and answer questions about the Agency's methods for assessing OP cumulative hazard, as well as exposure through drinking water, food, and in residential settings. An EPA website was established to share updated information on pesticide cumulative risk assessment with the public (http://www.epa.gov/pesticides/cumulative). In FY 2002, the Agency issued a preliminary OP cumulative risk assessment on December 3, 2001, and issued a revised OP cumulative risk assessment on June 10, 2002, both for public comment.

Through this assessment of the OP pesticides, EPA has evaluated 1,127 OP tolerances and found that most require no modification to meet the new FFDCA safety standard. The Agency's regulatory actions on individual OP pesticides during the past few years have substantially reduced the risks of these pesticides. The OP cumulative assessment strongly supports the Agency's confidence that the U.S. has one of the safest food supplies in the world.

Most of the reregistration and tolerance reassessment decisions that EPA is making for the OP pesticides at present will not be considered final until after the Agency completes its cumulative evaluation of the OPs. The results of individual OP assessments (IRED and TRED documents) include significant risk mitigation measures, however, and any resulting tolerance revocations are counted as completed tolerance reassessments. In addition, some OP tolerances make at most a minimal or negligible contribution to the cumulative risk from OP pesticides; these tolerances also were counted as reassessed during FY 2002. Once EPA completes a cumulative evaluation of the OPs, the Agency will reconsider individual OP IREDs and TREDs, and may issue final REDs and tolerance reassessments for these pesticides.

4. *Status of individual OP decisions*. The status of each of the 49 known OP pesticides at the end of FY 2002 is reflected in this discussion.

i. *OP decisions completed*. During FY 2002, through the public participation process, EPA completed risk assessments and made individual risk management decisions for 10 OP pesticides, bringing the number of OPs with individual decisions completed to 35 (See List 1).

List 1.—OP Pesticides with Individual Decisions Completed (35), End of FY 2002

20 IREDs
- Acephate
- Azinphos-methyl
- Bensulide
- Chlorpyrifos
- Diazinon
- Dicrotophos
- Disulfoton
- Ethoprop
- Fenthion
- Methamidophos
- Methidathion
- Naled
- Oxydemeton-methyl
- Phorate
- Phosmet
- Pirimiphos methyl
- Profenofos
- Propetamphos
- Terbufos
- Tribufos (DEF)

10 TREDs
- Cadusafos
- Chlorethoxyfos
- Chlorpyrifos methyl
- Coumaphos
- Fenitrothion
- Mevinphos
- Phosalone
- Phostebupirim
- Tetrachlorvinphos
- Trichlorfon

5 REDs
- Ethion
- Ethyl parathion
- Fenamiphos
- Sulfotepp
- Temephos

ii. *OP decisions pending*. Four other OP pesticides had completed most or all earlier phases of the public participation process and were awaiting individual decisions at the end of FY 2002. EPA plans to complete individual risk management decisions for these 4 pesticides during FY 2003 (See List 2).

List 2.—OP Pesticides with Individual Decisions Pending (4), End of FY 2002
- Dichlorvos (DDVP)
- Dimethoate
- Malathion
- Methyl parathion

iii. *Early OP cancellations*. Ten OP pesticides were canceled prior to or early in the pilot public participation process (See List 3).

List 3.—OPs Canceled Prior to/Early in the Pilot Public Participation Process (10)
- Chlorfenvinphos
- Chlorthiophos

Dialifor
Dioxathion
Fonofos
Isazophos
Isofenphos
Monocrotophos
Phosphamidon
Sulprofos

F. Applications for Registration Requiring Expedited Processing; Numbers Approved and Disapproved

By law, EPA must expedite its processing of certain types of applications for pesticide product registration, i.e., applications for end use products that would be identical or substantially similar to a currently registered product; amendments to current product registrations that do not require review of scientific data; and products for public health pesticide uses. During FY 2002, EPA considered and approved the numbers of applications for registration requiring expedited processing (also known as ''fast track'' applications) shown in Table 11.

TABLE 11.—FAST TRACK APPLICATIONS APPROVED IN FY 2002

Me-too product registrations/Fast track	368
Amendments/Fast track	3,466
Total applications processed by expedited means	3,834

Regarding numbers of applications disapproved, instead the Agency generally notifies the registrant of any deficiencies in the application that need to be corrected or addressed before the application can be approved. Applications may have been withdrawn after discussions with the Agency, but none were formally ''disapproved'' during FY 2002.

On a financial accounting basis, EPA devoted approximately 28.7 full-time equivalents (FTEs) in FY 2002 to reviewing and processing applications for fast track me-too product registrations and label amendments. The Agency spent approximately $2.87 million in FY 2002 in direct costs (i.e., time on task, not including administrative expenses, computer systems, management overhead, and other indirect costs) on expedited processing and reviews.

G. Future Schedule for Reregistrations

During the past several years, EPA has been conducting reregistration in conjunction with tolerance reassessment under FFDCA. That law requires the Agency to reassess all existing tolerances over a 10–year period to ensure consistency with the new safety standard, and to consider pesticides that appear to pose the greatest risk first. In prioritizing pesticides for reregistration eligibility review and tolerance reassessment, EPA is continuing to consider their potential risks, as reflected in the Agency's tolerance reassessment schedule published in the **Federal Register** on August 4, 1997. EPA is giving highest priority to pesticides in Group 1, including the OP pesticides, and the carbamates, organochlorines, and B2 (probable human) carcinogens.

1. *RED, IRED, and TRED Candidate Pesticides for FY 2003*. List 4 contains candidate pesticides for Reregistration Eligibility Decisions (REDs), Interim REDs (IREDs), and Reports on FQPA Tolerance Reassessment Progress and Interim Risk Management Decisions (TREDs) in FY 2003. As in previous years, any pesticides for which decisions are not completed during FY 2003 will automatically become candidates for decisions in FY 2004.

List 4.—FY 2003 RED, IRED, and TRED Candidate Pesticides

REDs
Chlorsulfuron
Chromated copper arsenate (CCA)
Coal tar/Creosote
Dihalodialkylhydantoins
Dinocap
Diuron
Ethoxyquin
Imazalil
MGK-326
Molinate
Oxadiazon
Pentachlorophenol
Poly(hexamethylenebiguanide) (PHMB)
Propanil
Thiophanate-methyl (completed 3–28–03)
Zinc omadine
Ziram

IREDs
Atrazine (completed 1–31–03)
Carbaryl (due 6–30–03)
Dichlorvos (DDVP)
Dimethoate
Malathion
Methyl parathion

TREDs
4-CPA (completed 4–3–03)
Dacthal (DCPA)
Ethephon
Fenridazon potassium
Potassium bromide

2. *RED, IRED, and TRED Candidate Pesticides for FY 2004*. The pesticides that are in the pipeline for RED, IRED, and TRED decisions in FY 2004 are included in List 5.

List 5.—FY 2004 RED, IRED, and TRED Candidate Pesticides

REDs
2,4-D
2,4-DB
Azadioxabicyclo-octane
Benfluralin
Benzisothiazolin-3-one (BIT)
Bioban P-1487
Busan 77
Cacodylic acid/DSMA/MSMA
Carboxin
Cycloate
Cypermethrin
Fenvalerate
Formaldehyde
Mancozeb
Maneb
MCPA
Metiram
PCNB
Sodium acifluorfen
Sodium fluoride
Thiram
Trichloromelamine
Triethylene glycol

IREDs
Aldicarb
Atrazine revised IRED (due 10–31–03)
Carbofuran
Formetanate HCl

TREDs
Amitraz
Ethylene glycol monobutyl ether
Fluazifop butyl
Lactofen
Oryzalin
Sodium xylenesulfonate
Sulfonated oleic acid, sodium salt
Trifluralin

H. Projected Year of Completion of Reregistrations

EPA is now conducting reregistration in conjunction with tolerance reassessment, which FFDCA mandates be completed by August 2006. EPA plans to complete reregistration of pesticide active ingredients with tolerances and as many others as possible in meeting the statutory deadline for completing tolerance reassessment.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 11, 2003.

Stephen L. Johnson,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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