

concerning a pesticide active ingredient, "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration," before calling in product-specific data on individual end-use products and either reregistering products or taking other "appropriate regulatory action."

Section 408(q) of the FFDCA, 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 14, 2005.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2005-0013; FRL-7696-1]

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 2004. 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 2005 through 2008.

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-2005-0013], should be received on or before November 22, 2005.

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. General Information

A. Does this Action 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2005-0013. 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, CrystalMall #2, 1801 S. Bell St., 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/>.

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. 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. 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.

i. *EPA Dockets.* 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-2005-0013. 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-2005-0013. 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) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2005-0013.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP-2005-0013. 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.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

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). The Agency met the first two statutory deadlines and is on schedule to meet the third. EPA's approach to tolerance reassessment under FFDCA 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).

The Pesticide Registration Improvement Act (PRIA) of 2003

became effective on March 23, 2004. Among other things, PRIA directs EPA to complete Reregistration Eligibility Decisions (REDs) for pesticides with food uses/tolerances by August 3, 2006, and to complete all non-food use pesticide REDs by October 3, 2008. EPA's schedule for meeting these deadlines are available on the Agency's website at www.epa.gov/pesticides/reregistration/candidates.htm.

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) 2004 (from October 1, 2003, through September 30, 2004), EPA made significant progress in completing risk assessments and risk management decisions for pesticide reregistration (See Table 1).

TABLE 1.—REREGISTRATION/RISK MANAGEMENT DECISIONS COMPLETED: IN FY 2004 AND FY 1991 THROUGH FY 2004

| FY 2004 Decisions | Total, FY 1991 through FY 2004 |
|--|--------------------------------|
| <p>17 REDs Benfluralin Carboxin Cycloate Dihalodialkylhydantoins Ethoxyquin MCPA Methoxychlor (Voluntary Cancellation) Naphthalene Acetic Acid Naptalam Oleic Acid Sulfonates Phenol and Salts PHMB or Poly(hexamethylenebiguanide) Pine Oil Propylene Glycol and Dipropylene Glycol Sbadilla Alkaloids Thiram Zinc Pyrethione (Omadine Salts)</p> | <p>244 REDs</p> |
| <p>0 IREDs</p> | <p>23 IREDs</p> |

TABLE 1.—REREGISTRATION/RISK MANAGEMENT DECISIONS COMPLETED: IN FY 2004 AND FY 1991 THROUGH FY 2004—Continued

| FY 2004 Decisions | Total, FY 1991 through FY 2004 |
|--|--------------------------------|
| 18 TREDs Bacillus thuringiensis var. Kurstaki (delta endotoxin) Bacillus thuringiensis var. San Diego Carbon dioxide Chlorimuron ethyl DCPA (Dacthal) Desmedipham Dimethenamid Flumetsulam Fluridone Limonene Nitrogen Oil of Lemon Oil of Menthol Oil of Orange Oryzalin Thifensulfuron-methyl Tribenuron methyl Trifluralin | 63 TREDs |

The Agency's decisions are embodied in Reregistration Eligibility Decision (RED) documents, Interim Reregistration Eligibility Decisions (IREDs), and 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 2004 in completing Reregistration Eligibility Decisions (REDs) for groups of related pesticide active ingredients or cases is summarized in Table 2.

TABLE 2.—OVERALL RED PROGRESS, FY 1991 THROUGH FY 2004

| | |
|----------------------------|------------|
| REDs completed | 244 (40%) |
| Cases canceled | 231 (38%) |
| REDs to be completed | 137 (22%) |
| Total reregistration cases | 612 (100%) |

ii. *Profile of completed REDs.* A profile of the 244 REDs completed by the end of FY 2004 is presented in Table 3.

TABLE 3.—PROFILE OF 244 REDS COMPLETED, FY 1991 THROUGH FY 2004

| | |
|--------------------------------|--------------|
| Pesticide active ingredients | 357 |
| Pesticide products | about 10,400 |
| REDs with food uses | 128 |
| Post-FQPA REDs | 103 |
| Post-FQPA REDs with food uses* | 75 |

*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.* Through the reregistration program, EPA seeks to reduce risks associated with the use of older pesticides. 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 measures 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 has not considered individual organophosphate (OP) pesticide decisions to be completed REDs or tolerance reassessments. Instead, the Agency is issuing IREDs for these chemicals at this time. EPA will complete the risk assessments and reregistration eligibility decisions for OP pesticides with IREDs, once the Agency completes a cumulative assessment of the OPs.

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 1, 1984, and is considered a “new” active ingredient, not subject to reregistration;
- EPA completed a RED for the pesticide before FQPA was enacted; 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.

As with IREDs, EPA will not complete risk assessment and risk management for pesticides subject to TREDs that are part of a cumulative group until cumulative risks have been considered for the group.

During FY 2004, in addition to completing 18 TREDs, EPA also completed 27 tolerance assessment decisions for pesticide inert ingredients that are exempted from the tolerance requirement. Almost 900 of the 9,721 tolerance reassessment decisions required by the amended FFDCA are for such inert ingredient tolerance exemptions. EPA has reassessed 404 of these inert ingredient tolerance exemptions to date, and plans to complete the reassessment of all the inert ingredient tolerance exemptions by August 2006.

As a result of the Food Quality Protection Act of 1996, food-contact surface sanitizers previously regulated by both EPA and the Food and Drug Administration were transferred to EPA's sole jurisdiction. Consequently, the approximately 107 ingredients that made up these sanitizer solutions in 21 CFR 178.1010 were transferred to 40 CFR part 180, subpart D. In addition to reassessing the 9,721 tolerances and exemptions for food and feed commodities, EPA also must reassess these sanitizer tolerance exemptions by August 3, 2006. The Antimicrobials Division (AD) in EPA's Office of Pesticide Programs is responsible for reassessing exemptions from the requirement of a tolerance for the food-contact surface sanitizing solutions requiring reassessment. AD is reassessing 60 of the 107 exemptions, either as free-standing decisions or through REDs. During FY 2004, AD completed tolerance exemption reassessments for 14 of these 60 food-contact surface sanitizing solution ingredients. EPA is reassessing tolerance exemptions for the other food-contact surface sanitizing solutions through other REDs and inert exemption decisions.

4. *Goals for FY 2005 and future years.* EPA's major pesticide reregistration and tolerance reassessment goals for FY 2005 and future years are as follows.

i. *Complete individual pesticide risk management decisions.* EPA's goal in conducting the reregistration and tolerance reassessment program is to complete 30–40 Reregistration Eligibility Decisions (REDs) and Interim REDs each year during fiscal years 2005 and 2006, for pesticides with associated tolerances, and to complete a total of 40 REDs in FY 2007 and in FY 2008 for pesticides with no food uses or tolerances. This will satisfy PRIA requirements and support the Agency's tolerance reassessment goal. EPA's schedule for completing these decisions appears near the end of this document, and also is available on the Agency's website at <http://www.epa.gov/pesticides/reregistration/candidates.htm>.

ii. *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 plans to meet the final FQPA tolerance reassessment goal: To complete 100% of all required tolerance reassessment decisions by August 3, 2006.

iii. *Evaluate cumulative risks.* Once EPA completes individual risk assessments for the OPs, carbamates and others, the Agency will make cumulative risk findings for each of these common mechanism groups of pesticides. For further information, see EPA's cumulative risk website, <http://www.epa.gov/pesticides/cumulative/>.

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 complete reregistration 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 2004.* 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 2004, EPA completed the product reregistration actions detailed in Table 4.

TABLE 4.—PRODUCT REREGISTRATION ACTIONS COMPLETED DURING FY 2004

| | |
|--------------------------------|-----|
| Product reregistration actions | 78 |
| Product amendment actions | 35 |
| Product cancellation actions | 14 |
| Product suspension actions | 0 |
| Total actions | 127 |

2. *Status of the product reregistration universe.* The status of the universe of pesticide products subject to reregistration at the end of FY 2004 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 2004 (AS OF SEPTEMBER 30, 2004)

| | |
|---|--------|
| Products reregistered | 1,770 |
| Products amended | 427 |
| Products canceled | 4,033 |
| Products sent for suspension | 30 |
| Total products with actions completed | 6,260 |
| Products with actions pending | 4,143 |
| Total products in product reregistration universe | 10,403 |

The universe of 10,403 products in product reregistration at the end of FY 2004 represented an increase of 747 products from the FY 2003 universe of 9,656 products. The increase consists of 713 products associated with FY 2004 REDs, and 34 products that were added as a result of DCI activities and

processing for several previously issued REDs and IREDs.

At the end of FY 2004, 4,143 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 450 product reregistration actions during fiscal year 2005.

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 2004 REDs are shown in Table 6.

TABLE 6.—DCIS PREPARED TO SUPPORT PRODUCT REREGISTRATION FOR FY 2004 REDS

| Case Name | Case Number | 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 |
|---------------------------------------|-------------|--|---|--|-------------------------------------|
| Benfluralin | 2030 | 119 | 31 | 138 (15 batches/ 8 products not batched) | 0 |
| Carboxin | 0012 | 44 | 31 | 186 (2 batches/ 29 products not batched) | 0 |
| Cycloate | 2125 | 9 | 31 | 6 (1 Batch) | 0 |
| Dihalodialkyldantoinis | 3955 | 106 | 34 | Antimicrobial RED - Acute toxicity batching not completed yet. | 2 |
| Ethoxyquin | 0003 | 4 | 31 | 18 (No batch) | 0 |
| MCPA | 0017 | 170 | 31 | Acute toxicity batching not completed yet | 0 |
| Methoxychlor (Voluntary Cancellation) | 0249 | 2 | NA | NA | NA |
| Napthalene acetic acid (NAA) | 0379 | 46 | 31 | Acute toxicity batching not completed yet. | 0 |
| Naptalam | 0183 | 1 | 31 | 6 (No Batch) | 0 |
| Oleic acid sulfonates | 4069 | 1 | 34 | 6 (No Batch) | 1 |
| Phenol and salts | 4074 | 6 | 34 | Antimicrobial RED - Acute toxicity batching not completed yet. | 5 |

TABLE 6.—DCIs PREPARED TO SUPPORT PRODUCT REREGISTRATION FOR FY 2004 REDS—Continued

| Case Name | Case Number | 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 |
|------------------------------|-------------|--|---|--|-------------------------------------|
| PHMB | 3122 | 17 | 34 | 42 (3 batches/4 products not batched) | 4 |
| Pine oils | 3113 | 89 | 34 | Antimicrobial RED - Acute toxicity batching not completed yet. | 4 |
| Propylene/Dipropylene glycol | 3126 | 14 | 34 | Antimicrobial RED - Acute toxicity batching not completed yet. | 5 |
| Sabadilla alkaloids | 3128 | 1 | 31 | 6 (No Batch) | 0 |
| Thiram | 0122 | 66 | 31 | Acute toxicity batching not completed yet. | 0 |
| Zinc pyrithione | 2480 | 18 | 34 | 84 (3 batches/11 products not batched) | 0 |
| Total No. of Products | | 713 | | | |

¹ The number of registered products containing a pesticide active ingredient can change over time. The product total 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. (Note: FIFRA section 24(c) or Special Local Need (SLN) registrations are not included in the acute toxicity batchings because they are supported by a valid parent product (section 3) registration.)

2. *DCIs for IREDS.* EPA completed no IREDS during FY 2004.

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 has made making progress in reviewing scientific studies submitted

by pesticide registrants in support of pesticides undergoing reregistration (See Table 7). The percent of studies reviewed by EPA remained constant in FY 2004.

TABLE 7.—REVIEW STATUS OF STUDIES SUBMITTED FOR PESTICIDE REREGISTRATION, END OF FY 2004

| Pesticide Reregistration List, per FIFRA Section 4(c)(2) | Studies Reviewed + Extraneous ¹ | Studies Awaiting Review | Total Studies Received |
|--|--|-------------------------|------------------------|
| List A | 11,220 + 583 = 11,803 (87%) | 1,786 (13%) | 13,589 |
| List B | 6,520 + 1,032 = 7,552 (81%) | 1,748 (19%) | 9,300 |
| List C | 2,087 + 334 = 2,421 (84%) | 464 (16%) | 2,885 |
| List D | 1,233 + 133 = 1,366 (86%) | 229 (14%) | 1,595 |
| Total Lists A - D | 21,060 + 2,082 = 23,142 (84.6%) | 4,227 (15.4%) | 27,369 (100%) |

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.

E. Aggregate Status of Tolerances Reassessed

During FY 2004, EPA completed 467 tolerance reassessments and ended the fiscal year with a total of 7,093 tolerance reassessment decisions to date, addressing 73% of the 9,721 tolerances that require reassessment (See Table 8).

EPA reassessed over 33% of all food tolerances by August 3, 1999, and completed over 66% of all required tolerance reassessment decisions by August 3, 2002, meeting two important

statutory deadlines established by the FQPA. EPA's general schedule for tolerance reassessment (62 FR 42020, 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, the Agency's highest priority group for reassessment.

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 8).

TABLE 8.—TOLERANCE REASSESSMENTS COMPLETED POST-FQPA BY FISCAL YEAR, THROUGH FY 2004*

| 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 | During FY 2003 | During FY 2004 | Total, End of FY 2004 |
|----------------------------------|-------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-----------------------|
| Reregistration/ REDs | 25 | 339 | 277 | 359 | 44 | 46 | 231 | 79 | 87 | 1,487 |
| Tolerance Reassessments/ TREDs | 0 | 0 | 0 | 0 | 0 | 0 | 776 | 14 | 119 | 909 |
| Registration | 0 | 224 | 308 | 340 | 55 | 216 | 200 | 0 | 71 | 1,414 |
| Tolerance revocations | 3 | 0 | 810 | 513 | 22 | 35 | 545 | 0 | 172 | 2,100 |
| Other decisions | 0 | 1 | 0 | 233 | 0 | 0 | 905 | 26 | 18 | 1,183 |
| Total tolerances reassessed | 28 | 564 | 1,395 | 1,445 | 121 | 297 | 2,657 | 119 | 467 | 7,093 |

* Includes corrected counts for some previous years.

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 enactment of the 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 for pesticides that are not part of a cumulative group may be counted at present and are included in the FY 2004 accomplishments. Tolerance reassessments for pesticides

that are part of a cumulative group are not included in the Agency's lists of accomplishments. These tolerances will be considered again and their reassessment will be completed after EPA completes a cumulative risk evaluation for the group.

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 aggregate risk of the 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.

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 1,182 additional tolerance reassessment decisions have been made, some for inert ingredient tolerance exemptions, through actions 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. Other support documents are available in docket ID number OPP-2002-0162.

2. *Accomplishments for priority pesticides.* During FY 2004, EPA completed tolerance reassessment decisions for many high priority pesticides in review, including OPs, carbamates, organochlorines, and carcinogens (See Table 9).

TABLE 9.—TOLERANCE REASSESSMENTS COMPLETED FOR PRIORITY PESTICIDES

| Pesticide Class | Tolerances to be Reassessed | Reassessed by End of FY 2004 |
|------------------------|-----------------------------|------------------------------|
| Carbamates | 545 | 309 (56.7%) |
| Carcinogens | 2,008 | 1,425 (70.97%) |
| High hazard inerts | 5 | 5 (100%) |
| Organochlorines | 253 | 253 (100%) |
| Organophosphates (OPs) | 1,691 | 1,131 (66.88%) |
| Other | 5,219 | 3,970 (76.07%) |
| Total | 9,721 | 7,093 (72.97%) |

3. *Tolerance reassessment and the organophosphates.* EPA developed an approach for assessing cumulative risk for the OP pesticides as a group, as required by FFDCA, and applied this methodology in conducting an OP cumulative risk assessment. The Agency issued preliminary and revised OP cumulative risk assessment documents in December 2001 and June 2002, available on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

Through this assessment of the OP pesticides, EPA has evaluated several hundred 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. EPA plans to complete IREDs for the three remaining

individual OP pesticides (DDVP, dimethoate, and malathion) in FY 2006.

Most of the reregistration and tolerance reassessment decisions that EPA has made for the OP pesticides will not be considered complete until after the Agency concludes 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 that make at most a minimal or negligible contribution to the cumulative risk from OP pesticides 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 complete reregistration

eligibility and tolerance reassessment decisions for these pesticides.

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 2004, EPA considered and approved the numbers of applications for registration requiring expedited processing (also known as "fast track" applications) shown in Table 10.

TABLE 10.—FAST TRACK APPLICATIONS APPROVED IN FY 2004

| | |
|--|-------|
| Me-too product registrations/Fast track | 328 |
| Amendments/Fast track | 4,379 |
| Total applications processed by fast track means | 4,707 |

For those applications not approved, 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 2004.

On a financial accounting basis, EPA devoted over 32.7 full-time equivalents (FTEs) in FY 2004 to reviewing and processing applications for fast track me-too product registrations and label amendments. The Agency spent approximately \$3.6 million in FY 2004 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

EPA plans to complete tolerance reassessment by August 3, 2006, as required by FFDCA, and also to complete reregistration eligibility decisions for pesticides with food uses by that date. REDs for pesticides that have no food uses or tolerances will be completed by October 3, 2008. The Agency's schedule for completing these decisions is as follows. This schedule also is available on EPA's website at <http://www.epa.gov/pesticides/reregistration/candidates.htm>.

1. *RED, IRED, and TRED Schedules for FY 2005 and FY 2006.* Lists 1 and

2 contain pesticides scheduled for Reregistration Eligibility Decisions (REDs), Interim REDs (IREDs), and Reports on FQPA Tolerance Reassessment Progress and Risk Management Decisions (TREDs) in FY 2005 and FY 2006. Although these lists may change due to the dynamic nature of the review process, EPA is committed to meeting the reregistration and tolerance reassessment deadlines. Any pesticides for which decisions are not completed during the current fiscal year will be rescheduled for decisions the following year.

List 1.—FY 2005 RED, IRED, and TRED Schedule

REDs

2,4-D

2,4-DB
 Ametryn
 4-t-Amylphenol
 Aquashade
 Aromatic solvents
 Azadioxabicyclo-octane
 Benzisothiazoline-3-one
 Chloroneb
 Chlorsulfuron
 Dimethipin
 Endothall
 Ethofumesate
 Ferbam (Dimethyldithiocarbamate salts; case has completed RED)
 Fluometuron
 Inorganic polysulfides
 Inorganic sulfites
 Iodine
 Mancozeb
 Maneb
 Metiram
 Napropamide
 Nitrapyrin
 PCNB
 Phenmedipham
 Phytophthora palmivora
 Pyrazon
 Trichloromelamine
IREDs
 None
TREDS
 Bromine
 Cyhexatin
 Fluazifop-p-butyl
 Flumiclorac-pentyl
 Imazamethabenz methyl
 Imazaquin
 Maleic hydrazide
 Methyl eugenol
 Nicosulfuron
 Procymidone
 Putrescent whole egg solids
 Sulfuric acid monourea
List 2.—FY 2006 RED, IRED, and TRED Schedule
REDS
 ADBAC
 Aliphatic alkyl quaternaries
 Aliphatic solvents
 Alkylbenzene sulfonates
 Aromatic solvents
 Cacodylic acid
 Chlorine dioxide
 Chloropicrin
 Chromated arsenicals (CCA)
 Coal tar/creosote
 Copper and oxides
 Copper compounds
 Copper sulfate
 Cypermethrin
 Dicamba
 Dichloran (DCNA)
 Dodine
 Ethylene oxide
 Fluvalinate
 Formaldehyde
 Glutaraldehyde
 Imazapyr
 Inorganic chlorates

MCPB
 Metaldehyde
 Methanearsonic acid, salts (DSMA, MSMA, CAMA)
 Methyl bromide
 Methylthiocarbamate salts (Metam sodium/metam potassium)
 MGK-264
 MITC
 Pentachlorophenol
 Permethrin
 2-Phenylphenol and salts
 Piperonyl butoxide
 Propiconazole
 Propylene oxide
 Pyrethrins
 Resmethrin
 Rotenone
 Salicylic acid
 Sethoxydim
 TCMB
 Thiadiazuron
 Triadimefon
IREDs
 Aldicarb
 Carbofuran
 Dichlorvos (DDVP)
 Dimethoate
 Formetanate
 Malathion
 Simazine
TREDS
 Acetochlor
 Amitraz
 Ammonia
 Azadirachtin
 Benzaldehyde
 Bitertanol
 Boric acid group
 Ethephon
 Fomesafen
 Oxytetracycline
 Propazine (Interim TRED for triazine pesticide)
 Sodium cyanide
 Streptomycin
 Tetradifon
 Triadimenol
 Tridemorph
2. Post-2006 REDs. REDs for pesticides with no associated tolerances will be completed in FY 2007 and FY 2008, unless decisions for these pesticides can be completed sooner. Lists 3 and 4 contain pesticides scheduled for REDs in FY 2007 and FY 2008.
List 3.—FY 2007 RED Schedule
 2,4-DP
 Acrolein
 Aliphatic alcohols
 Aliphatic esters
 Alkyl trimethylenediamine
 Allethrin stereoisomers
 Amical 48
 Antimycin A
 Benzoic acid
 Bioban-p-1487
 Bromonitrostyrene

Chlorflurenol
 Copper salts
 Dazomet
 Dikegulac sodium
 Grotan
 Irgasan
 MCPP
 Othilinone
List 4.—FY 2008 RED Schedule
 4-Aminopyradine
 Busan 77
 Flumetralin
 Mefluidide
 Naphthalene
 Naphthalene salts
 Nicotine
 p-Dichlorobenzene
 Polypropylene glycol
 Prometon
 Siduron
 Sodium fluoride
 Sodium/potassium dimethyldithiocarbamate salts (case has completed RED)
 Sulfometuron methyl
 Sumithrin
 TBT-containing compounds
 Tetramethrin
 Triforine
 Trimethoxysilyl quats

H. Projected Year of Completion of Reregistrations

EPA generally is conducting reregistration in conjunction with tolerance reassessment, which FFDCAs mandates be completed by August 2006. EPA plans to meet the statutory deadline for completing tolerance reassessment, and in so doing, to complete reregistration eligibility decisions for pesticides with tolerances, as required by PRIA. The Agency expects to complete remaining reregistration eligibility decisions for pesticides with no food uses or tolerances during FY 2007 and FY 2008 (by October 3, 2008).

List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 15, 2005.

Susan B. Hazen,

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

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ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2005-0048; FRL-7739-1]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).