

EIS No. 20060218, Draft EIS, FHW, NY, Williamsville Toll Barrier

Improvement Project, Improvements from New York Thruway, Interstate 90 between Interchange 48A and 50, Funding, Erie and Genesee Counties, NY, Comment Period Ends: 7/24/2006, Contact: Amy Jackson-Grove 518-431-4125. Revision to FR Notice Published 6/2/2006: Correction to Comment Period from 7/17/2006 to 7/24/2006.

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Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2005-0484; FRL-8068-1]

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 2005. 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 2006 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 [EPA-HQ-OPP-2005-0484], should be received on or before August 22, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2005-0484, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov/>. Follow the on-

line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2005-0484. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at <http://www.regulations.gov/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be captured automatically and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/docket.htm/>.

Docket: All documents in the docket are listed in the index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other

material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Carol P. Stangel, Special Review and Reregistration Division (7508P), 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. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, [regulations.gov](http://www.regulations.gov), or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying

information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity, obscene language, or personal threats.

viii. Make sure to submit your comments by the comment period deadline.

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 is available on the Agency's website at www.epa.gov/pesticides/reregistration/decision_schedule.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) 2005 (from October 1, 2004, through September 30, 2005), 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 2005 AND FY 1991 THROUGH FY 2005

FY 2005 Decisions	Total, FY 1991 through FY 2005
28 REDs (27 countable) 2,4-D 2,4-DB Ametryn 4-Amylphenol Aquashade Azadioxabicyclooctane Benzisothiazolin-3-one Chloroneb Chlorsulfuron Dimethipin Dodine Endothall Ethofumesate Ferbam (case 2180 already counted with Ziram) Fluometuron Inorganic polysulfides Maneb Mancozeb Metiram Napropamide Nitrapyrin Phenmedipham Pyrazon Sethoxydim Tau-fluvalinate Thidiazuron Trichloromelamine Xylene (Aromatic solvents)	271 REDs
0 IREDs	23 IREDs
13 TREDs Ammonia Bromine Cyhexatin Fluazifop-p-butyl Flumiclorac-pentyl Imazamethabenz-methyl Maleic hydrazide Methyl eugenol Nicosulfuron Procymidone Putrescent whole egg solids Sulfuric acid monourea Tanol derivatives	83 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 2005 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 2005

REDs completed	271 (44%)
Cases canceled	231 (38%)
REDs to be completed	110 (18%)
Total reregistration cases	612 (100%)

ii. *Profile of completed REDs.* A profile of the 271 REDs completed by

the end of FY 2005 is presented in Table 3.

TABLE 3.—PROFILE OF 271 REDS COMPLETED, FY 1991 THROUGH FY 2005

Pesticide active ingredients	45
Pesticide products	about 11,600
REDs with food uses	155
Post-FQPA REDs	130

TABLE 3.—PROFILE OF 271 REDS COMPLETED, FY 1991 THROUGH FY 2005—Continued

Post-FQPA REDs with food uses*	102
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*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 has issued IREDs for these chemicals. 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 2005, in addition to completing 13 TREDs, EPA also completed 168 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 573 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 2005, AD completed 35 tolerance exemption reassessments decisions for 22 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 2006 and future years.* EPA's major pesticide reregistration and tolerance reassessment goals for FY 2006 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 about 45 Reregistration Eligibility Decisions (REDs) and Interim REDs (IREDs) during FY 2006, for pesticides with associated tolerances, and to complete a total of about 45 REDs in FY 2007 and 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 Web site at http://www.epa.gov/pesticides/reregistration/decision_schedule.htm.

ii. *Complete 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.

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 FFDCFA 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 2005.* 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 2005, EPA completed the product reregistration actions detailed in Table 4.

TABLE 4.—PRODUCT REREGISTRATION ACTIONS COMPLETED DURING FY 2005

Product reregistration actions	99
Product amendment actions	63
Product cancellation actions	342
Product suspension actions	0
Total actions	504

2. *Status of the product reregistration universe.* The status of the universe of pesticide products subject to reregistration at the end of FY 2005 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 2005 (AS OF SEPTEMBER 30, 2005)

Products reregistered	1,875
Products amended	505
Products canceled	4,375

TABLE 5.—STATUS OF THE UNIVERSE OF PRODUCTS SUBJECT TO PRODUCT REREGISTRATION, FOR FY 2005 (AS OF SEPTEMBER 30, 2005)—Continued

Products sent for suspension	30
Total products with actions completed	6,785
Products with actions pending	4,828
Total products in product reregistration universe	11,613

The universe of 11,613 products in product reregistration at the end of FY 2005 represented an increase of 1,210 products from the FY 2004 universe of 10,403 products. The increase consists of 1,150 products associated with FY 2005 REDs, 35 products associated with TREDs, and 25 products that were added as a result of DCI activities and processing for several previously issued REDs and IREDs.

At the end of FY 2005, 4,828 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 2006.

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 2005 REDs are shown in Table 6.

TABLE 6.—DCIs ISSUED TO SUPPORT PRODUCT REREGISTRATION FOR FY 2005 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
2,4-D	0073	696	31	Not Completed Yet	0
2,4-DB	0196	22	31	48 (6 batches/2 products not batched)	0

TABLE 6.—DCIS ISSUED TO SUPPORT PRODUCT REREGISTRATION FOR FY 2005 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
4-t Amylphenol and Salts	3016	37	PDCI has not been completed yet	Antimicrobial RED—Acute toxicity batching not completed yet	PDCI has not been completed yet
Ametryn	2010	4	31	24 (4 products not batched)	0
Aquashade	4010	4	31	24 (4 products not batched)	0
Azadioxabicyclooctane	3023	2	PDCI has not been completed yet	Antimicrobial RED—Acute toxicity batching not completed yet	PDCI has not been completed yet
Benzisothiazolin-3-one	3026	47	PDCI has not been completed yet	108 (5 batches/13 not batched)	PDCI has not been completed yet
Chloroneb	0007	12	31	60 (2 batches/8 not batched)	0
Chlorsulfuron	0631	16	31	72 (2 batches/10 products not batched)	0
Dimethipin	3063	5	31	24 (4 products not batched)	0
Dodine	0161	5	31	24 (4 products not batched)	0
Endothall	2245	30	31	36 (2 batches/4 products not batched)	0
Ethofumesate	2265	18	31	66 (3 batches/8 products not batched)	0
Ferbam	2180	7	31	24 (4 products not batched)	0
Fluometuron	0049	19	31	36 (5 batches/1 product not batched)	0
Inorganic Polysulfides	4054	17	31	96 (16 products not batched)	0
Mancozeb	0643	100	31	144 (5 batches/19 products not batched)	0
Maneb	0642	21	31	60 (3 batches/7 products not batched)	0
Metiram	0644	4	31	18 (3 products not batched)	0
Napropamide	2450	15	31	48 (5 batches/3 not batched)	0
Nitrapyrin	0213	4	31	12 (1 batch/1 product not batched)	0

TABLE 6.—DCIs ISSUED TO SUPPORT PRODUCT REREGISTRATION FOR FY 2005 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
Phenmedipham	0277	16	31	96 (16 products not batched)	0
Pyrazon	2570	3	31	18 (3 products not batched)	0
Sethoxydim	2600	10	31	48 (1 batch/7 not batched)	0
Tau-Fluvalinate	2295	5	31	18 (3 products not batched)	5
Thidiazuron	4092	18	31	42 (4 batches/3 products not batched)	0
Trichloromelamine	3144	8	PDCI has not been completed yet	36 (1 batch/5 not batched)	PDCI has not been completed yet
Xylene	3020	5	31	18 (3 products not batched)	0
Total No. of Products		1,150			

¹The 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.

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

³In 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 for TREDs. There are special cases where product-specific DCIs may

be required for TREDs, particularly if the Agency believes that adequate product chemistry or acute toxicity data are not currently on file to support the

reregistration of the products associated with the TREDs. The Agency is requiring a product-specific DCI for the following TRED:

TABLE 7.—DCIs ISSUED TO SUPPORT PRODUCT REREGISTRATION FOR FY 2005 TRED

Case Name	Case Number	Number of Products Covered by the TRED ¹	Number of Product Chemistry Studies Required ²	Number of Acute Toxicology Studies Required ³	Number of Efficacy Studies Required
Fluazifop-p-butyl	2285	35	31	84 (4 batches/10 not batched)	0
Total No. of Products		35			

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

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

³In 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.)

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

EPA has made progress in reviewing scientific studies submitted by pesticide

registrants in support of pesticides undergoing reregistration (See Table 8). The percent of studies reviewed by EPA remained constant in FY 2005.

TABLE 8.—REVIEW STATUS OF STUDIES SUBMITTED FOR PESTICIDE REREGISTRATION, END OF FY 2005

Pesticide Reregistration List, per FIFRA Section 4(c)(2)	Studies Reviewed + Extraneous ¹	Studies Awaiting Review	Total Studies Received
List A	11,238 + 589 = 11,827 (87%)	1,788 (13%)	13,615
List B	6,542 + 1,033 = 7,575 (81%)	1,748 (19%)	9,323
List C	2,096 + 334 = 2,430 (84%)	464 (16%)	2,894
List D	1,248 + 133 = 1,381 (86%)	229 (14%)	1,610
Total Lists A–D	21,124 + 2,089 = 23,213 (84.6%)	4,229 (15.4%)	27,442 (100%)

¹Extraneous 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 2005, EPA completed 772 tolerance reassessments and ended the fiscal year with a total of 7,817 tolerance reassessment decisions to date, addressing over 80% of the 9,721 tolerances that require reassessment (See Table 9).

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 9).

TABLE 9.—TOLERANCE REASSESSMENTS COMPLETED POST-FQPA BY FISCAL YEAR, THROUGH FY 2005*

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	During FY 2005	Total, End of FY 2005
Reregistration/REDs	25	339	277	359	44	46	231	79	87	413	1,897
Tolerance Reassessments/TREDs	0	0	0	0	0	0	776	14	119	69	970
Registration	0	224	308	340	55	216	200	0	71	--	1,412
Tolerance revocations	3	0	812	513	22	35	545	0	172	75	2,239
Other decisions	0	1	0	233	0	0	905	26	18	165	1,299
Total tolerances reassessed	28	564	1,397	1,445	121	297	2,657	119	467	722	7,817

*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 2005

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 1,299 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 EPA-HQ-OPP-2002-0162.

2. *Accomplishments for priority pesticides.* During FY 2005, 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 2005
Carbamates	545	317 (58.17%)
Carcinogens	2,008	1,530 (76.20%)
High hazard inerts	5	5 (100%)
Organochlorines	253	253 (100%)
Organophosphates (OPs)	1,691	1,147 (67.83%)
Other	5,219	4,565 (87.47%)
Total	9,721	7,817 (80.41%)

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 Web site 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 and REDs 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 2005, 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 2005

Me-too product registrations/Fast track	340
Amendments/Fast track	2,639
Total applications processed by fast track means	2,979

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 2005.

On a financial accounting basis, EPA devoted 31.7 full-time equivalents (FTEs) in FY 2005 to reviewing and processing applications for fast track me-too product registrations and label amendments. The Agency spent approximately \$3.56 million in FY 2005 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/decision_schedule.htm.

1. *RED, IRED, and TRED Schedules for FY 2006.* List 1 contains pesticides scheduled for Reregistration Eligibility Decisions (REDs), Interim REDs (IREDs), and Reports on FQPA Tolerance Reassessment Progress and Risk Management Decisions (TREDs) in FY 2006. Although this list 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 2006 RED, IRED, and TRED Schedule REDs

ADBAC
Aliphatic alkyl quarternaries
Aliphatic solvents
Alkylbenzene sulfonates
Cacodylic acid

Chlorine dioxide
Copper compounds II
Copper salts
Copper sulfate
Cypermethrin
Dicamba
Dichloran (DCNA)
Ethylene oxide
Glutaraldehyde
Imazapyr
Inorganic chlorates
Inorganic sulfites
Iodine
MCPB
Metaldehyde
Methanearsonic acid, salts (DSMA, MSMA, CAMA)
MGK-264
Mineral acids, weak (sodium carbonate)
PCNB
Permethrin
2-Phenylphenol and salts
Phytophthora palmivora
Piperonyl butoxide
Propiconazole
Propylene oxide
Pyrethrins
Resmethrin
Rotenone
Salicylic acid
TCMB
Triadimefon

IREDs

Aldicarb
Carbofuran
Dichlorvos (DDVP)
Dimethoate
Formetanate HCl
Malathion
Simazine

TREDs

Acetochlor
Amitraz
Azadirachtin
Benzaldehyde
Bitertanol
Boric acid group
CP enolpyruvylshikimate-3-phosphate
Ethephon
Fomesafen
Imazaquin
Methyl bromide
Neomycinphosphotransferase II
Oxytetracycline
Propazine
Sodium cyanide
Streptomycin
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 2 and 3 contain pesticides scheduled for REDs in FY 2007 and FY 2008.

List 2.—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
Chloropicrin
Chromated arsenicals (CCA)
Coal tar/creosote
Copper and oxides
Dazomet
Dikegulac sodium
Formaldehyde
Grotan
Irgasan
MCPB
Methyl bromide
Methyldithiocarbamate salts (metam sodium/metam potassium)
MITC
Ochthilnone
Pentachlorophenol

List 3.—FY 2008 RED Schedule

4-Aminopyradine
Busan 77
Flumetralin
Mefluidide
Naphthalene
Naphthalene salts
Nicotine
Organic esters of phosphoric acid (new case)
p-Dichlorobenzene
Polypropylene glycol
Prometon
Siduron
Sodium fluoride
Sodium/potassium dimethyldithiocarbamate salts (case 2180 already counted with ziram)
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). Product reregistration, which takes place only after the reregistration eligibility decisions have been completed for the active ingredients, will not likely be completed before 2012.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 16, 2006.

Susan B. Hazen,

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

[FR Doc. E6-9956 Filed 6-22-06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2006-0516; FRL-8073-8]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from May 22, 2006 to June 2, 2006, consists of the PMNs pending or expired, and the notices of

commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

DATES: Comments identified by the specific PMN number or TME number, must be received on or before July 24, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) no. EPA-HQ-OPPT-2006-0516, by one of the following methods.

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO, EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number EPA-HQ-OPPT-2006-0516. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

- *Instructions:* Direct your comments to docket ID number EPA-HQ-OPPT-2006-0516. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *regulations.gov* or e-mail. The *regulations.gov* website is an "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *regulations.gov* or in hard copy at the OPPT Docket, EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280.

FOR FURTHER INFORMATION CONTACT: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7408M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, 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