

TABLE 2.—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION—Continued

EPA Company No.	Company Name and Address
050534 ..	GB Biosciences Corp., c/o Zeneca Ag Products, 1800 Concord Pike, Box 15458, Wilmington, DE 19850.
058185 ..	Scotts-Sierra Crop Protection Co, Attn: Vincent Snyder, Jr, 14111 Scottslawn Rd, Marysville, OH 43041.
058266 ..	Shadow Mountain Products Corp., Box 1327, Hollister, CA 95024.
062719 ..	Dow Agrosciences LLC, 9330 Zionsville Rd 308/3E, Indianapolis, IN 46268.
066222 ..	Makhteshim-Agan of North America Inc., 551 Fifth Ave.- Ste 1100, New York, NY 10176.
069575 ..	Dekalb Genetics Corp., Biotechnology Regulatory Affairs, 3100 Sycamore Rd, Dekalb, IL 60115.

**III. What is the Agency's Authority for Taking this Action?**

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of

receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

**IV. Loss of Active Ingredient**

Unless the request for cancellation is withdrawn, one pesticide active ingredient will no longer appear in any

registered products. Those who are concerned about the potential loss of this active ingredient for pesticidal use are encouraged to work directly with the registrant to explore the possibility of withdrawing their request for cancellation. The active ingredient is listed in the following Table 3, with the EPA company and CAS number.

TABLE 3.—DISAPPEARING ACTIVE INGREDIENT

CAS No.	Chemical Name	EPA Company No.
Unknown .....	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> CryIA	069575

**V. Procedures for Withdrawal of Request**

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before December 11, 2000. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

**List of Subjects**

Environmental protection, Pesticides and pests, Product registrations.

Dated: May 31, 2000.

**Richard D. Schmitt,**

*Associate Director, Information Resources Services Division, Office of Pesticide Programs.*

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**ENVIRONMENTAL PROTECTION AGENCY**

[OPP-34221; FRL-6556-5]

**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 1999. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to publish this information annually. The 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 the next two fiscal years.

**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

**VI. Provisions for Disposition of Existing Stocks**

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received by the Agency. This policy is in accordance with the Agency's statement of policy as prescribed in **Federal Register** (56 FR 29362) June 26, 1991; (FRL 3846-4). Exception to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-

number [OPP-34221], should be received on or before August 14, 2000.

**ADDRESSES:** Comments may be submitted by regular 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, U.S. Environmental Protection Agency (7508C), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, telephone: (703) 308-8007, e-mail: stangel.carol@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Important Information**

*A. Does this apply to me?*

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

*B. How can I get additional information or copies of support documents?*

1. *Electronically.* You may obtain electronic copies of this document and various support documents from the EPA Internet Home page at [www.epa.gov](http://www.epa.gov). On the Home Page, select "Laws and Regulations," and then look up the entry for this document under "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at [www.epa.gov/fedrgstr](http://www.epa.gov/fedrgstr).

To access information about pesticide reregistration, go directly to the Home Page for the Office of Pesticide Programs at [www.epa.gov/pesticides](http://www.epa.gov/pesticides) and select "Pesticide Reregistration" under "Select Topic From List," the pull-down menu at the top of the screen.

2. *In person.* The official record for this notice, as well as the public version, has been established under docket control number [OPP-34221] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of any electronic comments, which does not include any information claimed as Confidential Business Information (CBI), is available for inspection in Rm. 119, Crystal Mall #2 (CM #2), 1921 Jefferson Davis Highway, Arlington, VA, from

8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Public Information and Records Integrity Branch telephone number is (703) 305-5805.

*C. How and to whom do I submit comments to?*

You may submit comments through the mail, in person, or electronically:

1. *By mail.* Submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

2. *In person.* Deliver written comments to Public Information and Records Integrity Branch, in Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

3. *Electronically.* Submit your comments and/or data electronically to [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please note that you should not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 6.1/8.0 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP-34221]. Electronic comments on this notice may also be filed online at many Federal Depository Libraries.

*D. How should I handle information that I believe is confidential?*

You may claim information that you submit in response to this document as confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed, except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice.

**II. Background**

EPA must establish and publish annually in the **Federal Register** its 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:

a. The status of reregistration;

b. The number of products reregistered, canceled, or amended;

c. The number and type of data requests or Data Call-In notices (DCIs) under section 3(c)(2)(B) issued to support product reregistration by active ingredient;

d. Progress in reducing the number of unreviewed, required reregistration studies;

e. The aggregate status of tolerances reassessed;

f. The number of applications for registration submitted under subsection (k)(3), expedited processing and review of similar applications, that were approved or disapproved;

g. The future schedule for reregistrations in the current and succeeding fiscal year; and

h. 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 prior to November 1, 1984. Those pesticides meeting today's scientific and regulatory standards may be declared "eligible" for reregistration. In order to be so designated, an older pesticide must have a substantially complete data base, and must be found not to cause unreasonable risks to human health or the environment when used in accordance with Agency approved label directions and precautions.

In addition, all pesticides with food uses must meet the safety standard of the Food Quality Protection Act (FQPA) of 1996. Under FQPA, 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.

FQPA 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<sup>1</sup> existing tolerances and exemptions within three years (by August 3, 1999), 66% within 6 years (by August 3, 2002), and 100% in 10 years (by August 3, 2006).

EPA is meeting FQPA's tolerance reassessment requirements through reregistration and several other key program activities. Schedules have been coordinated and integrated so that, in the course of making reregistration eligibility decisions, the Agency also is completing much of tolerance reassessment within the time frames mandated by the new law. Last summer, EPA met the FQPA goal of reassessing the first 33% of all food tolerances by August 3, 1999. Over 66% of these first completed tolerance reassessments are for pesticides identified as posing the greatest potential risks—i.e., pesticides in priority Group 1. EPA is focusing attention particularly on priority Group 1 pesticides; over half of the universe of tolerances to be reassessed are included in this category, including tolerances for the organophosphate pesticides (the Agency's highest priority for review), as well as the carbamates, organochlorines, and B<sub>2</sub> (probable human) carcinogens. EPA's approach to tolerance reassessment under FQPA, including the three priority Groups, is described fully in the Agency's document entitled, "Raw and Processed Food Schedule for Pesticide Tolerance Reassessment" (62 FR 42020, August 4, 1997) (FRL 5734 6).

### III. FQPA and Program Accountability

One of the hallmarks of FQPA is enhanced accountability. EPA has incurred several additional obligations under this law, including the requirement to publish annually a summary of the program's performance measures and goals for reregistration, tolerance reassessment, and expedited registration. The following sections describe EPA's progress in the areas specifically identified by FIFRA section 4(l).

#### A. Status of Reregistration

Through the reregistration program, EPA is reviewing current scientific data for older pesticides and requiring changes to improve their safety. Pesticides that have sufficient supporting human health and environmental effects data and do not

pose unreasonable risks may be declared "eligible" for reregistration. EPA presents these findings in Reregistration Eligibility Decision (RED) documents. At the end of fiscal year 1999 (FY '99) (that is, as of September 30, 1999), the Agency had completed 198 REDs out of a universe of 612 cases, or groups of related pesticide active ingredients subject to reregistration. Fifteen of the 198 decisions were voluntary cancellations that were counted as REDs because significant progress had been made in developing RED documents for these pesticides by the time the requests for their cancellation were received. An additional 231 reregistration cases were voluntarily canceled before EPA invested significant resources in developing their REDs. A total of 429 reregistration cases (70%), therefore, had completed the reregistration eligibility decision-making process by the end of the fiscal year, leaving 183 cases (30%) awaiting such decisions.

The 198 REDs completed by the end of FY '99 include 296 active ingredients and encompass over 7,000 pesticide products. Ninety-three (93) of these REDs have food uses. Between August 3, 1996, the date when FQPA was enacted, and September 30, 1999, EPA completed 57 REDs, 40 with food uses. According to EPA's Tolerance Reassessment Tracking System (TORTS), which was completed and began operating during FY '99, the Agency has reassessed 999 tolerances for these post-FQPA REDs.

[Note: Tolerances associated with the 53 food use REDs that were completed before FQPA was enacted will be revisited 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.]

The 14 REDs completed during FY '99 include seven decisions in which some or all uses of the pesticides were found to be eligible for reregistration, and seven voluntary cancellations. The first organophosphate (OP) pesticide RED, for Sulfotepp, is among these 14 decisions. The FY '99 REDs with their reregistration case numbers are listed below.

#### List—Reregistration Eligibility Decisions (REDs) Completed in FY '99

1. Bendiocarb (case 0409)—Voluntary Cancellation
2. Captan (case 0120)
3. S-Ethyl dipropylthiocarbamate (EPTC) (case 0064)
4. Folpet (case 0630)
5. Fonofos (case 0105) Voluntary Cancellation (OP)
6. Isufenphos (case 2345)—Voluntary Cancellation (OP)

7. Niclosamide (case 2455)
8. Oxythioquinox (case 2495)—Voluntary Cancellation
9. Pebulate (case 2500)
10. Ryanodine (case 2595)—Voluntary Cancellation
11. Sulfotepp (case 0338)—Voluntary Cancellation (OP) with phase-out
12. 3-trifluoromethyl-4-nitrophenol (TFM or Lamprecide) (case 3082)
13. Triphenyltin Hydroxide (TPTH) (case 0099)
14. Vernolate (case 2735)—Voluntary Cancellation

While not completed REDs, highlights of the reregistration program during FY '99 included EPA's actions in early August to increase protection for children and families by mitigating the risks posed by two OP pesticides, methyl parathion and azinphos-methyl. Agreements with the registrants resulted in voluntary cancellation of many of the most significant food crop uses of methyl parathion, one of the most toxic and widely used OPs. Removing all fruit and many vegetable crop uses considerably reduced risks to children from residues in food, as well as risks to workers and the environment. The Agency also accepted voluntary measures to reduce both food and worker risks of azinphos-methyl, an OP used on a wide variety of fruits and vegetables. Both methyl parathion and azinphos-methyl currently are part of the Agency's ongoing review of all OP pesticides.

EPA also intends to issue "interim REDs" for most OPs which will include risk management decisions to address occupational and ecological risks, as well as food/water/residential risks on an individual chemical basis. The first two of these, for profenofos and bensulide, will be issued shortly. Final regulatory decisions or final REDs cannot be made until a cumulative risk assessment is conducted for all OPs, which are being analyzed on the basis of a common mechanism of toxicity.

At the end of FY '99, the Agency also had recently reached an agreement with the registrant to reduce dietary, worker, and ecological risks of the carbamate pesticide, formetanate hydrochloride.

Reducing pesticide risks is an important aspect of the reregistration program. In developing REDs, EPA works with stakeholders including pesticide registrants, growers, USDA, and others to develop voluntary measures or regulatory controls needed to effectively reduce risks of concern. Every RED includes some measures or modifications to reduce risks. The options for such risk reduction are extensive and include voluntary

<sup>1</sup> Although the total number of tolerances existing on August 3, 1996, and subject to FQPA reassessment was initially reported as 9,728, the correct number based on the Agency's more recently completed Tolerance Reassessment Tracking System is 9,721.

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.

EPA's current goal in conducting the reregistration program is to complete 20 REDs in FY 2000 and 30 in FY 2001. EPA intends to reassess tolerances within time frames set forth in FQPA, building on the reassessment of 33% of the existing tolerances by August 3, 1999, giving priority to those food use pesticides that appear to pose the greatest risk. As noted above, the integration of these two programs has added complexity to the reregistration process for food use pesticides.

*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 calls in any product-specific data and revised labeling needed to make final reregistration decisions for each of the individual pesticide products covered by the RED. Based on the results of EPA's review of this data and labeling, products that are found to meet FIFRA and FQPA 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 Data Call-In (DCI) 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 '99.* EPA counts each of the 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, through this process, 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 '99, EPA completed 748 product reregistration actions, as detailed in the following Table 1. The program nearly met its goal, to complete 750 product reregistration actions during the fiscal year.

TABLE 1.—PRODUCT REREGISTRATION ACTIONS COMPLETED DURING FY 1999

Product Reregistration Actions	167
Product Amendment Actions ....	70
Product Cancellation Actions ...	511
<b>TOTAL Actions in FY '99 .....</b>	<b>748</b>

2. *Status of the product reregistration universe.* At present, a universe of over 7,000 pesticide products is subject to product reregistration based on REDs completed as of September 30, 1999. The current status of these products is shown in Table 2 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 2 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 2.—STATUS OF THE UNIVERSE OF PRODUCTS SUBJECT TO PRODUCT REREGISTRATION, AS OF SEPTEMBER 30, 1999.

Products Reregistered .....	1,281
Products Amended .....	185
Products Canceled .....	2,671
Products Sent for Suspension ..	144
TOTAL Products with Actions Completed .....	4,281
Products with Actions Pending	2,764
<b>TOTAL Products in Product Reregistration Universe .....</b>	<b>7,045</b>

The universe of 7,045 products in product reregistration at the end of FY '99 represents an increase of 249 products from the FY '98 universe of 6,796 products. The increase consists of 237 products associated with FY '99 REDs, plus 12 products that were added as a result of data call-in activities and processing for several previously issued REDs.

At the end of FY '99, 2,764 products had product reregistration decisions pending. Some of these products are awaiting science reviews, label reviews, or reregistration decisions by EPA. Other products 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 750 product reregistration actions during fiscal year 2000.

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

The number and type of data requests or Data Call-In notices (DCIs) issued by EPA under FIFRA section 3(c)(2)(B) to support product reregistration for pesticide active ingredients included in FY 1999 REDs are shown in Table 3. The FY '99 REDs that consisted of voluntary cancellations are not included in this table because products containing these pesticides will not be reregistered and therefore do not require DCIs.

TABLE 3.—DATA CALL-INS ISSUED TO SUPPORT PRODUCT REREGISTRATION FOR FY 1999 REDS

Case No.	Case Name	Number of Products Covered by the RED <sup>1</sup>	Number of Product Chemistry Studies Required <sup>2</sup>	Number of Acute Toxicology Studies Required <sup>3</sup>	Number of Efficacy Studies Required
0120 .....	Captan	159	21	384 (17 batches/47 not batched)	0
0064 .....	EPTC	31	21	30 (2 batches/3 not batched)	0
0630 .....	Folpet	16	17	66 (2 batches/ 9 not batched)	0
2455 .....	Nicosamide	7	21	18 (3 batches)	0
2500 .....	Pebulate	2	21	12 (2 not batched)	0
3082 .....	TFM	2	21	12 (2 batches)	0
0099 .....	TPTH	20	21	30 (3 batches/ 2 not batched)	0

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

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

<sup>3</sup> 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, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). 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.

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

EPA is making good progress in reviewing scientific studies submitted by registrants in support of pesticides undergoing reregistration. As of October 1999, 27,926 studies have been received by the Agency through the reregistration program. Over 75% (21,001) of these studies either have been reviewed (19,732 or 70.7%), or have been found to be extraneous (1,269 or 4.5%). (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.) Less than 25% (6,925) of all studies received are "awaiting review" for future REDs, to complete the reregistration program. A more detailed account of the number and percent of studies received, reviewed, and awaiting review by reregistration list appears in Table 4 below.

The overall universe of studies to be reviewed has increased during the past two years, while the proportion of

studies reviewed by EPA has also increased somewhat. A number of studies have been submitted voluntarily by pesticide registrants, to address new FQPA provisions during reregistration and tolerance reassessment. At the end of 1999, over 75% of all studies received by the Agency in support of reregistration had been reviewed, compared to less than 75% at the end of 1997. Thus, the reregistration study review "backlog" decreased slightly during 1999 but remained fairly constant.

TABLE 4.—REVIEW STATUS OF STUDIES SUBMITTED FOR PESTICIDE REREGISTRATION

List	Studies Reviewed + Extraneous	Studies Awaiting Review	Total Studies Received
List A .....	10,490 + 292 = 10,782 (80.2%)	2,656 (19.8%)	13,438
List B .....	5,795 + 655 = 6,450 (68.8%)	2,924 (31.2%)	9,374
List C .....	2,140 + 228 = 2,368 (70%)	1,012 (30%)	3,380
List D .....	1,307 + 94 = 1,401 (80.8%)	333 (19.2%)	1,734
<b>TOTAL Lists A-D .....</b>	<b>21,001 (75.2%)</b>	<b>6,925 (24.8%)</b>	<b>27,926</b>

*E. Aggregate Status of Tolerances Reassessed*

Last summer, EPA met and surpassed the FQPA goal of reassessing 33% of all food tolerances by August 3, 1999, including many tolerances for pesticides identified as posing the greatest potential risks. At the end of FY '99, EPA had completed 3,430 tolerance reassessment decisions, covering over 35% of the 9,721 tolerances that require reassessment. The Agency is well on its way to meeting the next FQPA goal to complete 66% of all tolerance

reassessment decisions by August 3, 2002.

As required by FQPA, 2 years ago, the Agency announced its general schedule for tolerance reassessment in the **Federal Register** on August 4, 1997. This document identified three groups of pesticides to be reviewed; the grouping reflects EPA's overall scheduling priorities for tolerance reassessment. The Agency has given priority to pesticides in Group 1, particularly to the organophosphate pesticides (OPs).

1. *Tolerance reassessment and the organophosphates.* Because of the intense public interest in tolerance reassessment for the OPs, EPA and USDA created the Tolerance Reassessment Advisory Committee (TRAC) in 1998, to advise us on the best way to enhance public participation in the tolerance reassessment process, beginning with this class of pesticides (see List 1). With guidance from TRAC, EPA piloted an approach to tolerance reassessment that allows for much greater transparency and public

involvement in developing both our risk assessments and risk management decisions. Scientific analyses, risk assessments and related information for the OPs have been made far more accessible to the public through a systematic notice and comment process, complemented by an Agency website ([www.epa.gov/pesticides/op/](http://www.epa.gov/pesticides/op/)) and supplemented by public meetings and technical briefings.

**List 1. The Organophosphate Pesticides**

- Acephate
- Azinphos-methyl
- Bensulide
- \*+Cadusafos
- ++Chlorethoxyfos
- \*\*Chlorfenvinphos
- Chlorpyrifos
- ++Chlorpyrifos-methyl
- \*\*Chlorthiophos
- +Coumaphos
- \*\*Dialifor
- Diazinon
- Dichlorvos (DDVP)
- Dicrotophos
- Dimethoate
- \*\*Dioxathion
- Disulfoton
- Ethion
- Ethoprop
- Ethyl parathion
- Fenamiphos
- +Fenitrothion
- Fenthion
- \*\*+Fonofos
- \*\*++Isazophos
- \*\*+Isofenphos
- Malathion
- Methamidophos
- Methidathion
- Methyl parathion
- \*\*+Mevinphos
- \*\*Monocrotophos
- Naled
- Oxydemeton-methyl
- Phorate
- \*\*Phosalone
- Phosmet
- \*\*+Phosphamidon
- ++Phostebupirim
- Pirimiphos-methyl
- Profenofos
- Propetamphos
- \*\*+Sulfotepp
- \*\*+Sulprofos
- Temephos
- Terbufos
- +Tetrachlorvinphos
- Tribufos (DEF)
- +Trichlorfon
- \* Import tolerances only; no U.S. registrations.
- \*\* Canceled or proposed for cancellation; will be included in the organophosphate risk assessment if import tolerances remain after other tolerances are revoked.
- + Reregistration Eligibility Decision has been completed.
- ++ Registered post-'84 (not subject to reregistration).

During FY '99, through the ongoing public participation process for the OPs,

EPA obtained additional health and environmental effects data, use data, and other information that has been valuable in revising and completing many of our risk assessments. EPA initiated action in early August 1999 to reduce the risks associated with two OPs, methyl parathion and azinphos methyl, based partly on information developed through this process. Near the end of the fiscal year, EPA began examining the results of the pilot process, and considering ways to amend the process so that it will be most effective in the future. During FY 2000, the Agency proposed for comment (65 FR 14199, March 15, 2000) and plans to establish a final public participation process for pesticides in tolerance reassessment and reregistration, encompassing both the OPs and other types of chemicals. Our goal is to develop a process that fully involves stakeholders, starting early and continuing throughout the development of risk assessments and risk mitigation options, for all pesticides still awaiting reregistration and tolerance reassessment decisions.

EPA expects to present its risk management conclusions for the first several OP pesticides early in 2000, elucidating both risk mitigation measures and possible transition strategies to alternative pest control approaches. The Agency also is developing an approach for assessing cumulative risk for the OPs as a group as required by FQPA, and expects to issue draft guidance in 2000 for review and comment. EPA presented a comprehensive guidance document on cumulative risk assessment to the Scientific Advisory Panel in December 1999, and will revise its guidance as necessary based on the panel's recommendations.

Although all individual OP tolerances were not reassessed in the first one-third, EPA is making significant progress with this group of chemicals. We expect to complete the risk assessments for each of the individual OP pesticides during calendar year 2000. The Agency will develop a cumulative assessment for all the OPs once the individual assessments are complete and a cumulative assessment methodology is available.

**2. Fiscal Year 1999 accomplishments.** During FY '99, EPA reassessed 1,445 tolerances through the reregistration and registration programs and in conducting follow-up activities to revoke tolerances for pesticides that had been canceled previously, many as a result of reregistration. EPA also completed the Tolerance Reassessment Tracking System (TORTS), which is making it

possible for the Agency to compile and report, accurately and consistently, numbers of tolerance reassessment accomplishments. We have a high degree of confidence in TORTS, which was designed, created, and quality controlled internally and is being operated in-house. Based on records for all 9,721 permanent tolerances subject to reassessment under FQPA, TORTS is providing timely, detailed, accurate reports highlighting many important aspects of completed tolerance reassessments.

Of EPA's 1,445 tolerance reassessment actions during FY '99, 513 were tolerance revocation decisions, implemented through rule-making. The Agency made decisions to revoke these tolerances, signed final rule-making to effect these decisions, and published the relevant rules in the **Federal Register** during the fiscal year. Other FY '99 reassessments occurred through reregistration/REDs (359), through registration (340), and through other actions not directly related to either registration or reregistration (233). During FY '99, over 61% of the tolerance reassessment decisions completed were for pesticides in priority Group 1 (883); others were for pesticides in Group 2 (216) and Group 3 (346). EPA reassessed 180 OP tolerances, 77 carbamate tolerances, 50 organochlorine tolerances, and 266 carcinogen tolerances during FY '99. The Agency completed 243 tolerance reassessments for children's foods (i.e., foods among the top 20 raw agricultural commodities eaten by children age one to six years old, and among the top 20 commodities consumed by infants, according to a 1989-1991 survey). Of the tolerances reassessed, 837 were for pesticide minor uses. Please see the following Table 5 for a summary of these FY '99 accomplishments.

<b>Sources of FY '99 Tolerance Reassessments.</b>	
Reregistration/ REDs ..	359
Registration Actions ....	340
Tolerance Revocations .....	513
Other .....	233
<b>TOTAL .....</b>	<b>1,445</b>
<b>Numbers of Reassessments by Priority Group.</b>	
Group 1 .....	883 (61%)
Group 2 .....	216 (15%)
Group 3 .....	346 (24%)
<b>TOTAL .....</b>	<b>1,445 (100%)</b>

		3. <i>Cumulative accomplishments.</i> EPA is conducting a variety of tolerance reassessment activities throughout the pesticide program that are enabling the Agency to meet its FQPA goals. As of September 30, 1999, of the 9,721 tolerances subject to reassessment, EPA had reassessed a net total of 3,430, over 35% of all tolerances requiring reassessment. The Agency 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); and through other decisions not directly related to registration or reregistration (described further below). (Please see Table 6.)
Tolerances Reassessed for Certain Types of Pesticides and Groups.			
Organophosphates .....	180		
Carbamates .....	77		
Organochlorines .....	50		
Carcinogens .....	266		
Kids Foods .....	243		
Minor Uses .....	837		

TABLE 6.—TOLERANCE REASSESSMENTS COMPLETED POST-FQPA BY FISCAL YEAR, AS OF SEPTEMBER 30, 1999

Tolerances Reassessed Through	During Late FY '96	During FY '97	During FY '98	During FY '99	Total, End of FY '99
Reregistration/REDS .....	25	337	278	359	999
Registration .....	0	221	311	340	872
Tolerance Revocations .....	3	0	809	513	1,325
Other Decisions .....	0	1	0	233	234
<b>TOTAL Tolerances Reassessed .....</b>	<b>28</b>	<b>559</b>	<b>1,398</b>	<b>1,445</b>	<b>3,430</b>

i. *Reregistration/REDS.* EPA is using the reregistration program to accomplish much of tolerance reassessment. As of September 30, 1999, a total of 999 tolerance reassessment decisions had been completed through reregistration. EPA has reviewed each of these existing tolerances and made the finding that there is a reasonable certainty of no harm, as required by FQPA. Many of the tolerances reassessed through reregistration will remain the same while others are subject to modification, i.e., they may be raised, lowered, or revoked.

ii. *Registration.* Like older pesticides, all new pesticide registrations must meet the safety standard of FQPA. Many of the registration applications EPA receives are for new uses of pesticides already registered for other uses. To reach a decision on a proposed new food use of an already registered pesticide, EPA must reassess the existing tolerances, as well as the proposed new tolerances, to make sure there is reasonable certainty that no harm will result to the public from aggregate exposure from all uses. As of September 30, 1999, a total of 872 tolerances were reassessed as a result of the registration process. The Agency has specifically discouraged submission of applications and petitions for any new uses of the organophosphate pesticides, given the associated risk concerns.

iii. *Tolerance Revocations.* EPA also has formally revoked, through rule-making, a total of 1,325 tolerances. These 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. In this situation, tolerances were revoked because there is no longer a need for them. No registered uses of the pesticides remain in the U.S., and tolerances are not required to cover residues in or on either domestic or imported food commodities. Tolerance revocations are important; although many of the pesticides are no longer used in the United States, commodities treated with them could still have been imported before the revocations became effective.

iv. *Other Reassessment Decisions.* In addition to those described above, a total of 234 additional tolerance reassessment decisions have been made, not directly related to registration or reregistration. These include 65 tolerances reassessed through the Plant Growth Regulator Rule which were scientifically reviewed and the exemption was retained (64 FR 31501; June 11, 1999) (FRL-6076-5); 80 organophosphate meat, milk, poultry, and egg tolerances that were determined to have no reasonable expectation of finite residue on July 7, 1999; 73 Inert Polymer Tolerances that were determined on July 20, 1999, to meet the terms and criteria of the Toxic Substances Control Act Polymer Exemption Rule (and so they also meet the FQPA safety standard); 13 tolerance exemptions for *Trichoderma harzianum* KRL-AG2 (64 FR 16856; April 7, 1999) (FRL-6070-3); one tolerance exemption for *Bacillus thuringiensis* subspecies *Kurstake CryIA(c)* (62 FR 17722; April 11, 1997) (FRL-5596-7); one tolerance exemption for Red Pepper (63 FR 66999; December 4, 1998) (FRL-6039-5); and one tolerance exemption for

Cinnamaldehyde (64 FR 7801; February 17, 1999) (FRL-6049-9).

#### 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 '99, EPA considered and approved the following numbers of applications for registration requiring expedited processing (also known as "fast track" applications):

- Me-too product registrations/fast track: 513
- Amendments/fast track: 3,141
- Total applications processed by expedited means: 3,654

Regarding numbers of applications disapproved, 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 '99.

On a financial accounting basis, EPA devoted approximately 33.3 full-time equivalents (FTEs) to reviewing and processing applications for me-too product registrations and fast-track label amendments. The Agency spent \$2.8 million in direct costs (not including administrative expenses, computer systems, management overhead, and

other indirect costs) during FY '99 on expedited processing and reviews.

#### G. Future Schedule for Reregistrations

EPA is now conducting reregistration in conjunction with tolerance reassessment under FQPA. That law requires the Agency to reassess all existing tolerances over a 10 year period to ensure consistency with the new safety standard, and to consider pesticides that appear to pose the greatest risk first. In prioritizing pesticides for reregistration eligibility review and tolerance reassessment, EPA is continuing to consider their potential risks, as reflected in the Agency's tolerance reassessment schedule published in the **Federal Register** on August 4, 1997. EPA is giving highest priority to pesticides in Group 1, particularly the organophosphates (OPs).

1. *OP REDs*. The organophosphate pesticides are the focal point of EPA's reregistration and tolerance reassessment programs at present. EPA currently is reviewing the OP pesticides individually, and expects to complete individual risk assessments and risk management decisions for each of these pesticides during calendar year 2000 (see List 2). Although the Agency is not making final reregistration decisions for most of the OP pesticides now, the results of the individual OP assessments will include risk mitigation measures, and any resulting tolerance revocations will be counted as completed tolerance reassessments. EPA will conduct a cumulative assessment for the OP pesticides when the individual assessments and necessary methodology are complete, and will encourage the public to participate in this assessment. The Agency's final decisions for the OP pesticides will be made at the conclusion of the cumulative assessment process.

EPA generally will not count individual OP decisions as completed REDs or tolerance reassessments until the Agency completes the cumulative risk assessment and risk management decision for all the OP pesticides. Decisions for individual OP pesticides with no FQPA-related uses (i.e., no uses resulting in food, drinking water, residential, or bystander exposure) may be counted as REDs prior to the cumulative decision. In addition, when the Agency accept requests for voluntary cancellation of individual OP pesticides, EPA will count these actions as REDs, and will count the associated tolerances as reassessed when they are revoked.

#### List 2. OP RED Candidate Pesticides

1. Acephate
2. Azinphos-methyl
3. Bensulide
4. Chlorpyrifos
5. Diazinon
6. Dichlorvos (DDVP)
7. Dicrotophos
8. Dimethoate
9. Disulfoton
10. Ethion
11. Ethoprop
12. Ethyl Parathion
13. Fenamiphos
14. Fenthion
15. Malathion
16. Methamidophos
17. Methidathion
18. Methyl Parathion
19. Naled
20. Oxydemeton-methyl
21. Phorate
22. Phosmet
23. Pirimiphos-methyl
24. Profenofos
25. Propetamphos
26. Temephos
27. Terbufos
28. Tribufos (DEF)

2. *Non-OP RED candidates for FY 2000*. REDs for pesticides other than the OPs also are in preparation. EPA expects to complete REDs for most or all of the non-OP RED candidate pesticides in List 3 below, and perhaps some other pesticides, during FY 2000. The Agency will be increasing opportunities for public involvement in the development of non-OP REDs during FY 2000 and beyond.

#### List 3. Non-OP RED Candidate Pesticides for Fiscal Year 2000

1. Aldicarb
2. Atrazine
3. Benomyl
4. Bis (bromoacetoxy)-2-butene
5. Carbofuran
6. Diclofop methyl
7. Endosulfan
8. Etridiazole (Terrazole)
9. Imazalil
10. Molinate
11. Omadine Salts
12. Oxamyl
13. Propargite
14. Propylene oxide
15. Sodium acifluorfen
16. Thiabendazole
17. Thiophanate methyl
18. Thiram
19. Triallate
20. Vinclozolin

3. *Non-OP RED candidate pesticides for FY 2001*. EPA's goal is to complete 30 REDs during FY 2001. Although it is based on many variables and can be expected to change, our tentative list of RED candidate pesticides for FY 2001 appears in List 4 below.

#### List 4. RED Candidate Pesticides for Fiscal Year 2001

1. Amical 48
2. 4-t Amylphenol

3. Benfluralin
4. Benzisothiazolin-3-one
5. Cacodylic acid
6. Carbaryl
7. Chlorine dioxide
8. Chloropicrin
9. Chromated Arsenicals
10. Coal Tar/Creosote
11. Cycloate
12. Cypermethrin
13. Dazomet
14. Dimethipin
15. Dimethyldithiocarbamate salts including Ferbam, Ziram, and Sodium dimethyldithiocarbamate
16. Dinocap
17. Dipropyl isocinchomeronate or MGK 326
18. Ethylene oxide
19. Formetanate hydrochloride
20. Irgasan DP-300
21. Lindane
22. Mancozeb
23. Maneb
24. Methanearsonic acid, salts including CAMA, DSMA, MSMA
25. Methyl bromide
26. Methyl isothiocyanate
27. Methylthiocarbamate salts including metam-sodium
28. Metiram
29. MGK-264
30. Naphthaleneacetic acid
31. Oxadiazon
32. Oxyfluorfen
33. Pentachloronitrobenzene or PCNB
34. Pentachlorophenol
35. Permethrin
36. Phenol and salts
37. Phenylphenol
38. Piperonyl butoxide
39. Propiconazole
40. Pyrethrin
41. Simazine
42. TCMTB or 2-(Thiocyanomethylthio) benzothiazole
43. Triadimefon

4. *Voluntary cancellations as REDs*. When for business or other reasons a pesticide registrant requests that the Agency cancel all remaining registered products containing a pesticide in reregistration, EPA stops work on the development of a reregistration eligibility decision document for the pesticide and counts the RED as completed. Voluntary cancellations are counted as REDs on the date when an Agency official signs and dates a decision memorandum documenting the Agency's intent to accept the registrant's request for cancellation. EPA then publishes in the **Federal Register** for public comment a FIFRA section 6(f) notice of receipt of the request for voluntary cancellation. The cancellations requested do not become effective until a designated time after the public comment period closes.

5. *Tolerance reassessment decision documents*. When EPA reassesses the tolerances for a pesticide that is not in the queue for reregistration (that is, a pesticide for which a RED was

completed prior to FQPA, or a pesticide initially registered after 1984 and not subject to reregistration), the Agency will produce a document explaining the basis for these decisions. During FY 2000 and FY 2001, the Agency expects to complete tolerance reassessment decision documents for the pesticides in Lists 5 and 6 below.

#### List 5. Tolerance Reassessment Decisions for Fiscal Year 2000

1. Butylate
2. Lactofen
3. Several OPs going through the pilot process, including Cadusafos and Chloethoxyfos

#### List 6. Tolerance Reassessment Decisions for Fiscal Year 2001

1. Acetochlor
2. Amitraz
3. Asulam
4. Bromine
5. Chlorpropham
6. Cyhexatin
7. Desmedipham
8. Diphenamid
9. Inorganic Bromide
10. Linuron
11. Norflurazon
12. Oxadixyl
13. Procymidone
14. Propamide
15. Triadimenol
16. Tribenuron methyl
17. Tridiphane

#### H. Projected Year of Completion of Reregistrations

EPA is now conducting reregistration in conjunction with tolerance reassessment, which FQPA mandates be completed by 2006. EPA plans to complete reregistration of pesticide active ingredients and products prior to the statutory deadline for completing tolerance reassessment.

#### List of Subjects

Environmental protection.

Dated: May 31, 2000.

**Susan H. Wayland,**

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

[FR Doc. 00-15034 Filed 6-13-00; 8:45 am]

**BILLING CODE 6560-50-F**

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-00654; FRL-6553-4]

### Pesticides; Guidance for Pesticide Registrants on Disposal Instructions on Residential/Household Use Pesticide Product Labels

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability.

**SUMMARY:** The Agency seeks public comment on a draft Pesticide Registration (PR) Notice entitled "Disposal Instructions on Residential/Household Use Product Labels." This draft notice would provide guidance to registrants concerning disposal instructions for residential/household products and how to determine what is a residential/household product. The Agency has discovered that the existing instructions may conflict with the laws, regulations, or practices of some states and localities which tell consumers to direct these materials away from their landfills and instead to their local household hazardous waste (HHW) management facilities or programs. Through the revised instructions in the PR Notice, EPA addresses this issue.

**DATES:** Comments, identified by docket control number OPP-00654, must be received on or before August 14, 2000.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00654 in the subject line on the first page of your response.

#### FOR FURTHER INFORMATION CONTACT:

Amy Breedlove (7506C), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9069; fax number: (703) 305-5884; e-mail address: breedlove.amy@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 those persons who are required to register, regulate, or label pesticides, or who manage or regulate household hazardous waste facilities or collection events, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under "FOR FURTHER INFORMATION CONTACT."

##### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document and the PR Notice from the Office of

Pesticide Programs' Home Page at <http://www.epa.gov/pesticides>. You can also go directly to the listings from the EPA Internet Home Page at <http://www.epa.gov>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgrstr>.

2. *Fax-on-demand.* You may request a faxed copy of the draft PR Notice entitled "Disposal Instructions on Residential/Household Use Pesticide Product Labels," by using a faxphone to call (202) 401-0527 and selecting item 6127. You may also follow the automated menu.

3. *In person.* The Agency has established an official record for this action under docket control number OPP-00654. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

##### C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00654 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.