

Common Questions and Answers
Reporting Requirements for
Pesticide, Active Ingredient, and Device Producers
(EPA Form 3540-16)
December 2003

1. What must I report?

Each producer operating an establishment must submit the following information for each **pesticide, active ingredient, or pesticide device** [including, but not limited to, unregistered pesticides, Experimental Use Permits, Special Local Need products under § 24(c) of FIFRA, or pesticides produced for export only]:

/ types and amounts *produced* in 2003;

/ types and amounts *sold/distributed* in 2003, regardless when the product was produced; and

/ an *estimate* of the amount expected to be produced in 2004.

For each of the above amounts, **round all numbers to the nearest whole number.**

2. What does the term "produce" include?

"Produce" means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. (FIFRA)

"Produce" means also to "manufacture, prepare, propagate, compound or process any pesticide, including any pesticide product pursuant to Section 5 of the Act, any active ingredient or device, or to package, repack, label, relabel, or otherwise change the container of any pesticide or device." (40 CFR 167.3)

(NOTE: This includes repackaging of pesticides in bulk containers.)

3. How is the information I provide used by the EPA?

The information is used by EPA's Office of Enforcement and Compliance Assurance and the Office of Prevention, Pesticides, and Toxic Substances to support risk-benefit analysis, inspection, compliance, and enforcement activities.

4. How do I make corrections to the name(s) or addresses shown?

All companies or producers must provide name and address changes to the EPA within 30 days after such change occurs.

Domestic (United States) companies or producers should send such information to the EPA regional office where the company headquarters is located.

Foreign companies or producers should send such information to the EPA Washington, D.C. office. *See page 4 of Instructions for Completing EPA Form 3540-16 (hereinafter "Instructions") for all EPA mail and telephone contacts.*

5. Where can I get assistance in completing this report?

Domestic producers should contact the EPA regional office which services their company headquarters.

Foreign producers should contact EPA's Washington, D.C. office. (See Instructions - Page 4)

6. What constitutes "bulk repackaging" of pesticides?

"Bulk repackaging" means the repackaging of pesticides into refillable containers which are designed and constructed to accommodate the return and refill of greater than 55 gallons or 100 pounds of product, in accordance with EPA's July 11, 1977, Bulk Enforcement Policy, and the Amendment dated March 4, 1991.

7. What constitutes "custom blends" of pesticides? What is a "custom blender?"

A custom blender is any establishment which provides the service of mixing registered pesticides to a customer's specifications, specifically, a pesticide-pesticide, pesticide-fertilizer, or pesticide-animal feed mixture. The blend must not be held in inventory, the pesticides used in the blend must bear end-use labeling which does not prohibit the use of the pesticide in the blend, and the blend is delivered to the end-user with the labeling of the pesticide(s) used in the blend and a statement specifying the composition of the mixture. A facility where **only** custom blending activities take place is not considered a pesticide-producing establishment and therefore does not need to be registered. An establishment that custom blends in addition to pesticide production activities, must report only the pesticide production activities, not the custom blending activities.

8. What if I fail to file this production report?

Failure to file an initial and annual production report is a violation of FIFRA, and may result in termination of the establishment's registration, civil penalties up to \$5,500 per violation, and/or criminal penalties. In addition, it is unlawful to knowingly falsify all or part of any pesticide production information reported on EPA Form 3540-16. (Section 12(a)(2)(M) of FIFRA).

United States Environmental Protection Agency
Instructions for Completing EPA Form 3540-16
Pesticide Report for Pesticide-Producing and
Device-Producing Establishments - Reporting Year 2003

Electronic copies of these instructions and EPA Form 3540-16 can be downloaded from
http://www.epa.gov/pesticides/regulating/establishments/est_forms.htm

It is unlawful to knowingly falsify all or part of any pesticide production information
reported on EPA Form 3540-16. (Section 12(a)(2)(M) of FIFRA).

GENERAL INSTRUCTIONS

1. Each page of EPA Form 3540-16 has space to enter production for only three products. If you produce more than three products **make photocopies of the form as necessary**.
2. Complete report by printing in ink or typing.
3. **"Produce"** means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. (Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)).
"Produce" also means to "manufacture, prepare, propagate, compound or process any pesticide, including any pesticide product pursuant to Section 5 of the Act, any active ingredient or device, or to package, repack, label, relabel, or otherwise change the container of any pesticide or device." (EPA regulations at 40 CFR § 167.3)
4. **Establishments with Zero Production in 2003.**
If your establishment did not produce or distribute products subject to this report in 2003 complete Blocks 1-15, and write "NO PRODUCTION" in Block 16. **The report is complete. Submit the report as directed on Page 4.**
5. **Closed Establishments (Out of business/ceased production)**
 - / Enter all production and distribution information for 2003. If there was none, write "NO PRODUCTION" in Block 16.
 - / State on the report that the company/establishment is no longer in business.
 - / If you wish to inactivate your establishment registration number, please attach your request on company letterhead.
6. A company **official must sign** the report in Block 15.
7. For all pages, **complete, at the bottom: "This is Page ____ of ____."**
8. **DO NOT REPORT:**
 - / Production or distribution or sale of products NOT produced by your establishment, e.g., no changes are made to the product formulation, container, or label;
 - / Products shipped from your supplier directly to your customer;
 - / Any products for which lines 25-27 are zero.
 - / Custom-blended products (See Common Questions and Answers - Question 7)
 - / Pesticides that are **applied by your establishment**.
9. **Submit completed reports** as directed on Page 4.
10. **Initial Reports:** Section 7 of FIFRA requires all registered establishments to submit a report to the US EPA **30 days** after receipt of notification of establishment registration. Failure to file the Initial report is an unlawful act and may result in termination of the establishment's registration.

***REPORT DUE DATE: On or before March 1, 2004, even if there has been no production.
Incomplete reports may be returned to the establishment for correction or completion.***

INSTRUCTIONS - COMPLETING THE REPORT

Blocks 1-16. Name and Location of Company Headquarters and Producing Establishment

- Blocks 1-4. Enter the Company Headquarters *mailing* address of the producing establishment, unless it is a foreign establishment. Foreign establishments should enter the US mailing address of the company headquarters or US agent.
- Block 5. Enter name of establishment official signing report (should match Block 15)
- Block 6. Enter title of establishment official signing report (should be the title of person signing Block 15)
- Block 7. Date report is signed
- Blocks 8-13. A label showing the establishment SITE address should appear in Blocks 8-13.
- Block 14. Telephone number of establishment official responsible for the report.
- Block 15. Signature of establishment official signing report.
- Block 16. Use this block to report NO PRODUCTION, if this is the case, for 2003. **If there was No Production, the report is complete.** Do not list products which you did not produce.

Block 17 - Product Code

- Enter "1" - product is registered with EPA
- Enter "2" - product registration is pending
- Enter "3" - product is an Experimental Use Permit
- Enter "4" - product is a pesticide device, an unregistered pesticide, or a Special Local Need (SLN) registration

Block 18 - EPA Product Registration No.

- Product Code 1 - Enter EPA Registration No. (as it appears on product label) (See NOTE below on reporting production of distributor registrations.)
- Product Code 2 - Enter EPA File Symbol assigned
- Product Code 3 - Enter the Experimental Use Permit number
- Product Code 4 - For **DEVICES**, leave Block 18 blank
- For **UNREGISTERED PESTICIDES**, leave Block 18 blank, and attach the chemical formulation of the product, showing the product's active and inert ingredients, their common names, their CAS Registry numbers (if available), and the percentage, by weight of each ingredient (must total 100%). Multiple formulations may appear on the same page; clearly identify each by product name.
- For stand-alone **SLN REGISTRATIONS**, enter the SLN registration number in Block 18, e.g. SLN-CA-890022. A "stand-alone" SLN is one for which there are no uses other than the 24(c) uses.

NOTE: Reporting Distributor Registrations. If you produce multiple pesticide products under the same basic EPA registration number (such as distributor products):

- / Report the total quantities for all **distributor products** under the basic EPA registration number, and add "and supplementals" following the product name. On a separate paper, list the basic registration number with each distributor company number and brand name, and attach it to the report.

Block 19 - Product Name. List the most common brand name. If marketed under alternate brand names, add the wording "and alternate brand names" and report total production under all names for the formulation.

Block 20 - Product Classification

Classifications for Devices

- 14 Water Purifier - Point of Use 15 Water Purifier - Small System 13 Device

Classifications for Pesticides

- 01 Insecticide 02 Fungicide 03 Rodenticide
- 04 Herbicide 05 Algaecide 06 Nematocide
- 07 Plant Regulator 08 Defoliant, Desiccant 09 Disinfectant, Germicide, Sanitizer
- 10 Antifouling Paint 11 Animal Repellent 12 Other Pesticides (includes Insect
Repellants & Slug Baits)
- 21 Insecticide-Fungicide 44 Herbicide-Fungicide

16 Multi-Use Active Ingredient (Chemicals that have both pesticidal and non-pesticidal uses.) Producers are required to register both the product and their establishment(s) and report production on an annual basis under Section 7 of FIFRA, if a producer has actual or constructive knowledge that a chemical or substance they produce is used or intended for use as an active ingredient in the manufacture of a pesticide. These producers are required to report only the amount of the chemical or substance manufactured and distributed/sold for pesticidal purposes. These chemicals do not have an EPA Reg. No. (This Classification is rarely appropriate.)

Block 21 - Product Type. Describe the type of product:

Enter 1 - Technical material or active ingredient for Manufacturing Use Only

Enter 2 - End-use product; this includes products where the formulation has been blended, diluted, or changed;

Enter 3 - Repackaged or relabeled (does not include any blending, dilution or change in the formulation)

Enter 4 - Device

Block 22 - Market Sold/Distributed To

Domestic Establishments

Enter 1 - All product was marketed in the United States

Enter 2 - Product was marketed both *in* the United States and *exported*

Enter 3 - All product was exported

Foreign Establishments

Enter 1 - Product was marketed in/exported to the United States. *DO NOT REPORT products that were sold to countries other than the United States.*

Block 23 - Use Classification

Enter 1 - Product label states RESTRICTED USE PESTICIDE

Enter 2 - All other pesticides and devices

Block 24 - Unit of Measure

G = Gallons (liquid chemical product)

P = Pounds (dry or solid chemical product)

L = Liters (liquid chemical product)

K = Kilograms (dry or solid chemical product)

T = Tons (short ton = 2,000 lbs. or 907.2 kilograms) (dry or solid chemical product)

U = Units (devices and pesticides that the label does not declare as gallons, pounds, liters, kilograms, or tons)

Block 25 - Amount Produced Last Year (2003)

/ Round all quantities to the nearest whole number

/ **Do not include amounts which are custom blended or custom applied by you**

Block 26 - Amount Distributed/Sold Last Year (2003) - United States

/ Enter only those products distributed/sold *which were produced by your establishment, regardless when the product was produced*;

/ **Do not include amounts which are custom blended or custom applied by you;**

/ Foreign producers should enter only the amount of product or number of devices exported to the United States.

/ Round all quantities to the nearest whole number.

Block 27 - Amount Distributed/Sold Last Year (2003) to Foreign Markets (Exported)

/ Enter the quantity exported from the United States in 2003, regardless when the product was produced;

/ **Foreign establishments should leave Block 27 blank;**

/ Round all quantities to the nearest whole number.

Block 28 - Amount (Estimated) to be Produced in 2004

/ Enter an estimate of the quantity to be produced in 2004.

/ Round all quantities to the nearest whole number.

Confidentiality. Under FIFRA Section 7(d) [7 U.S.C. § 136e], information reported in Items 25, 26, 27, and 28 of EPA Form 3540-16 will be treated as business confidential, subject to the provisions of FIFRA Section 10 [7 U.S.C. § 136h]. You are not required to assert a claim of confidentiality on this information.

If you wish to assert a claim of confidentiality for other information you have provided on this form, you must identify by the box number(s) information for which you are asserting a claim of confidentiality. Information so designated will be disclosed by the EPA only to the extent allowed by, and by means of, the procedures set forth in 40 CFR Part 2. If you do not claim the information as confidential upon submission of the report, it may be made available to the public without further notice to you.

Public Reporting Burden. The time required to complete this report is estimated to average one hour and 26 minutes, per response, including reviewing instructions, searching data sources, gathering and maintaining data needed, and completing review and collection of information. Send comments regarding this burden estimate or other aspects related to this information collection, including suggestions for reducing this burden, to: Director, OP/ORMI Regulatory Information Division (2137), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460, Attention: Desk Officer for EPA, and to the Paperwork Reduction Project, Office of Information and Regulatory Management Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503.

WHERE TO SUBMIT REPORTS

DOMESTIC PRODUCERS: Submit reports to the following EPA Regional Office *in which your company headquarters is located*

EPA Regional Offices	States/Terr. Covered	EPA Regional Offices	States/Terr. Covered
U.S. EPA Region 1 Lee Weller PO Box 8636 Boston, MA 02114 Telephone 617-918-1849	CT, MA ME, NH RI, VT	U.S. EPA Region 6 Marie Conroy Pesticides Section (6PD-P) 1445 Ross Avenue Dallas, TX 75202-2733 Telephone 214-665-7560	AR, LA NM, OK TX
U.S. EPA Region 2 Deborah Rosenthal Pesticides Team (MS-500), Building 5 2890 Woodbridge Avenue Edison, NJ 08837-3679 Telephone 732-321-4391	NJ, NY PR, VI	U.S. EPA Region 7 Lou Banks Pesticides Branch (WWPD/PEST) 901 N. 5 th Street Kansas City, KS 66101-2798 Telephone 913-551-7125	IA, KS MO, NB
U.S. EPA Region 3 Kyla Townsend-McIntyre Pesticides Programs (3WC32) 1650 Arch Street Philadelphia, PA 19103-2029 Telephone 215-814-2045	DE, DC MD, PA VA, WV	U.S. EPA Region 8 Cornelia Maes Enforcement Division (ENF-PT) 999 18th Street, Suite 300 Denver, CO 80202-2466 Telephone 303-312-6049	CO, MT ND, SD UT, WY
U.S. EPA Region 4 Jacquelyn Wilkerson AFC Pesticides Section (APTMD) 61 Forsyth Street, SW Atlanta, GA 30303-8960 Telephone 404-562-9011	AL, FL GA, KY MS, NC SC, TN	U.S. EPA Region 9 Glenda Dugan Pesticides Office (CMD-5) 75 Hawthorne Street San Francisco, CA 94105-3901 Telephone 415-947-4204	AZ, CA, HI, NV
U.S. EPA Region 5 Gail Muffitt PTES (DT-8J) 77 W. Jackson Blvd. Chicago, IL 60604-3507 Telephone 312-886-6008	IL, IN MI, MN OH, WI	U.S. EPA Region 10 Theresa Pimentel Pesticides Unit (ECO-084) 1200 Sixth Avenue Seattle, WA 98101-1128 Telephone 206-553-0257	AK, ID OR, WA

FOREIGN PRODUCERS: Submit report to the following EPA Washington, DC address:

<p><u>U.S. Postal Service Mail Address</u> Carol L. Buckingham/Michelle Stevenson US Environmental Protection Agency Agriculture Division (2225A) 1200 Pennsylvania Ave., NW Washington, DC 20460-0001 USA Telephone: 202-564-5008/202-564-2320</p>	<p><u>Courier Delivery Address</u> Carol L. Buckingham (Room 6102) Michelle Stevenson (Room 5104) US Environmental Protection Agency Agriculture Division 1200 Pennsylvania Ave., NW Washington, DC 20004 USA E-mail: buckingham.carol@epa.gov E-mail: stevenson.michelle@epa.gov</p>
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NOTE: The Agency does not notify you when your Report is received. To ensure the Agency receives the report, you may wish to send it by certified or registered mail, return receipt requested.