

pesticide registration federal register

Thursday
September 8, 1988

Part V

Environmental Protection Agency

40 CFR Part 167

Registration of Pesticide and Active
Ingredient-Producing Establishments,
Submission of Pesticide Reports; Final
Rule

**ENVIRONMENTAL PROTECTION
AGENCY**
40 CFR Part 167
[OPP-7000A; FRL-3363-9]
**Registration of Pesticide and Active
Ingredient-Producing Establishments,
Submission of Pesticide Reports**
AGENCY: Environmental Protection
Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule requires that producers of pesticide active ingredients register their establishments and submit reports to EPA. The Agency is taking this action in response to a Congressional amendment to section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which already imposes registration and reporting requirements upon producers of pesticide products. The Agency is providing a period of 6 months for compliance by producers of active ingredients after the effective date of this rule.

EFFECTIVE DATE: This rule will become effective upon publication in the Federal Register of a notice after 60 days of concurrent session of Congress.

FOR FURTHER INFORMATION CONTACT: Phyllis Flaherty, Office of Compliance Monitoring (EN-342), Environmental Protection Agency, Room E710, 401 M Street SW., Washington, DC 20460 (202-382-7825).

SUPPLEMENTARY INFORMATION: Public reporting burden for this collection of information is estimated to average 1.08 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

I. Background

FIFRA section 7 requires producers of pesticides and devices to register their producing establishments and file annual reports of pesticide production. In 1978, FIFRA section 7 was amended to add a requirement that producers of the active ingredients, incorporated into

pesticides, also register their establishments and file annual production reports. This final rule expands the establishment registration and reporting requirement found in the current regulation to include active ingredient producers. Requirements for establishment registration and production reports are codified in 40 CFR Part 167.

II. Proposed Regulation

EPA issued a proposed rule which was published in the Federal Register of March 25, 1987 (52 FR 9504), to implement the 1978 amendment to section 7 of FIFRA. The final rule responds to comments on that proposal.

The treatment of multiple-use active ingredient chemicals (i.e., chemicals which have both pesticidal and non-pesticidal uses) was the primary issue facing EPA in implementing the congressional change of requiring registration of establishments producing active ingredients.

In some instances, the primary uses of such multiple-use chemicals are non-pesticidal (such as with xylene, arsenic, and copper sulfate). This situation raises a number of problems in implementing the congressional change. First, a producer might not be aware that his multiple-use chemical is being used as a pesticide. If he does know, he may not know exactly what volume of his chemical production is used as a pesticide active ingredient, as opposed to a non-pesticidal use.

In 1980, the Agency intended to address these problems by proposing the following requirements:

1. Each active ingredient producer must register his establishment and report the entire production of any chemical which has pesticidal use.
 2. Each pesticide producer must notify the suppliers of any active ingredient used in his product if the ingredient is not already registered as a pesticide by the supplier.
 3. Both pesticide producers and active ingredient producers must keep records of the notices described in item 2 above.
- However, because of extensive comments from producers of large quantities of multiple-use chemicals, the Agency published a reproposal. This reproposal clarified the establishment registration requirement by requiring a producer to report only that production of an active ingredient for which the producer had actual or constructive knowledge that these active ingredients were used in the production of pesticide products. The reproposal also deleted the establishment registration requirement for custom blenders as well as several minor changes clarifying the

requirements for pesticide-producing establishments.

III. Discussion

In response to comments received during the comment period for EPA's proposal of March 25, 1987 (52 FR 9504), EPA is promulgating the rule with only minor modifications.

1. Minor Changes to the Rule

(a) The phrase "market produced for (domestic, foreign, etc.*)" had been inadvertently deleted from the definition of "type of pesticide" at § 167.3(j). This error was corrected.

(b) One comment suggested that companies which own establishments in EPA Regions that are different from the EPA Region containing the company headquarters only have the company headquarters submit establishment registration applications to its respective EPA Regional office. This comment was incorporated.

(c) Another comment requested that companies which change ownership or address be allowed to report such change on letterhead stationery as well as the form required by § 167.20(e). This comment was incorporated.

(d) A suggestion was made to include a statement clarifying the fact that while the Agency will have reporting forms available and the Agency does supply them to companies each year as a courtesy, the ultimate responsibility to obtain, complete, and submit the forms provided by the Agency is the company's. This comment was incorporated.

(e) Finally, it was suggested that the date of submission of the Annual Report required by § 167.85(c) be changed from February 28, as was suggested in comments responding to the first proposal, to March 1. The date was changed.

2. Who Must Register

Any producer who has actual or constructive knowledge that a substance he produces is used or intended for use as an active ingredient in the manufacture of a pesticide, will be required to register his establishment(s). Also, all establishments which produce any pesticide, device, or active ingredient subject to this provision must be registered. This includes biotechnology pesticide products.

3. What Quantities of Active Ingredient Must Be Reported

A producer is subject to FIFRA requirements if he intends that the substance produced be used as a pesticide or in the formulation of a

pesticide product. However, at the level of active ingredient production, a producer may not intend his substance to be used in a pesticide, but he may produce it with knowledge that it has pesticidal uses. The Agency, therefore, considers substances affected by this rule to be those produced, sold or distributed with the knowledge, actual or constructive, that they are used or intended for use as an active ingredient in the production of a pesticide.

The rule requires active ingredient producers to report only the amount of substance as to which the producer has actual or constructive knowledge of its use or intended use as an active ingredient in the manufacture of a pesticide.

The Agency will use an objective standard in determining whether a producer knows his substance is being used as an active ingredient for pesticides, and which amount of the substance is being used for those purposes. A producer will be considered to know that his substance is used for pesticidal purposes if a reasonable person in the position of an active ingredient producer would be considered to know of that use. Benchmarks of knowledge will include promotional claims and advertising, common knowledge of the general business of the formulator, and the length of the chain of production and distribution, that is, the commercial distance from the substance producer to the ultimate pesticide producer.

4. How to Report

The reports required by § 167.85(c) must be made by submitting to the Agency a form entitled "Pesticides Report," EPA Form 3540-16. The term "pesticide," as used in the form and in the instructions to the form, shall be read also to include pesticide products, devices, and active ingredients.

5. How to Register

Any person who wishes to register an establishment must complete and submit to the Agency a form entitled "Application for Registration of Pesticide-Producing Establishments," EPA Form 3540-8. Any establishment which has not previously been required to register and is not currently registered as a producing establishment must apply for establishment registration by submitting an application within 180 days after the effective date of this regulation.

6. Other Changes to the Rule

The language of Part 167 was rewritten in the proposed amendment to clarify the regulations. Proposed

changes in the language of the rule were made to reflect more accurately the existing practices of the Agency. However, except for those changes explained above which were made to include the active ingredient producers in the regulatory scheme, these changes do not reflect an substantive change in the requirements to register establishments and/or report production with the exception of deleting the registration and reporting requirement for custom blenders.

This rule no longer requires custom blenders to register their establishments and report production. Custom blenders provide the service of mixing pesticides to a customer's specifications. The custom blend can be a pesticide(s)/fertilizer(s) mixture, a mixture of end-use formulations derived from registered pesticides, or a mixture of animal feed and feed-through pesticide(s). Under the Agency's May 10, 1982 FIFRA Compliance Program Policy No. 3.4 entitled "Custom Blenders," the Agency determined that the registration of custom blend pesticides would not be necessary to fulfill the intent of FIFRA. Moreover, the May 10, 1982 FIFRA Compliance Policy No. 7.1, entitled "Custom Blenders," states that custom blenders are not required to report establishment production. Registration of custom blending establishments was required to allow the Agency to schedule inspections and trace pesticides which are contaminated or adulterated. The Agency no longer uses the registration of custom blending establishments as the targeting method for conducting inspections for contamination or adulteration of a pesticide. As a result of deleting the registration requirement for custom blenders the paperwork burden for such establishments will be reduced. Furthermore, since registrants keep or are required to keep records regarding sales, the Agency believes it can effectively locate such products without custom blending establishments being registered.

The Agency believes that the authority under section 8 of FIFRA will allow the Agency to detect and track the sale and distribution of products that are contaminated or adulterated. Custom blenders remains subject to the provisions of FIFRA section 8 as well as all the requirements relating to the proper use of pesticides including transport, storage and disposal. The Agency believes the public will be adequately protected without the registration and reporting requirements by custom blenders. Therefore, the Agency exempts producers of custom-blended pesticides from the requirement

of establishment registration and reporting of production under the authority of FIFRA section 25(b).

This exemption also applies to custom blenders of animal feed-through pesticides, especially those who blend feed-through larvicide products. Establishments which custom blend feed-through pesticides, and no other pesticides, are not currently registered as pesticide-producing establishments. This is due to an interim decision made by the Agency, that the final determination as to whether or not these establishments would be required to register would be made when the Agency issued amended section 7 regulations. The interim decision was based on the issue of dual jurisdiction between the Agency under FIFRA section 7 and the Food and Drug Administration under the Current Good Manufacturing Practice regulation (21 CFR Part 225).

Elimination of the establishment registration and reporting requirements for custom blenders of animal feed-through pesticides affects approximately 10,000 establishments, most of which are not currently registered with the Agency.

The change in date effecting the submittal of annual reports will provide adequate time for the forms to be sent to and received by the Agency. Section 167.85(d) reflects this revision.

This rule also permits producers to report changes in ownership or address of an establishment on the same form as the registration of establishments form (EPA Form 3540-8) or on company letterhead stationary. This is consistent with current Agency practice.

The elimination of establishment registrations for custom blenders caused some concern for States as expressed by some State Pesticide Lead Agency Officials and some Regions. The States expressed concern that the removal of this information from the data base supplied by the Regions could impair their inspection targeting. The Regions were concerned that some "custom blenders" are actually producing pesticides and as such should be reporting production under section 7. The Agency understands this concern and has agreed to:

(1) Maintain a listing of all the currently registered custom blending establishments as of the effective date of the regulations.

(2) Draft a letter to be included with the 1988 annual solicitation for pesticide production reports stating that custom blenders must evaluate their production status, and if they produce pesticides as outlined in section 2(w) of FIFRA, they

must notify the Regional Office. Otherwise they are removed from the Agency's producing establishment list. However, establishments producing registered pesticides and providing custom blending services are still required to maintain their establishment registration and report production of registered pesticide products.

The last change to Part 167 was to eliminate the labeling requirement at § 167.4 which discussed establishment number, placement and designation of the EPA establishment number. These labeling requirements are now found at § 162.10(f).

IV. Related Regulation

This rule should be read in conjunction with 40 CFR Part 169—Books and Records of Pesticide Production and Distribution, the latest amendment to which was published in the Federal Register of August 15, 1980 (45 FR 54338).

V. Conversion Table

For the convenience of the user, the following table shows the relationship between the old and new CFR section numbers.

Old Section	New Section
167.1.....	167.3
167.2.....	167.20
167.3.....	167.20
167.5.....	167.85
	167.90

Section 167.4 has been deleted since it is covered by § 162.10(f) of the *Labeling requirements*.

VI. Statutory Requirements

The Secretary of Agriculture has reviewed this rule as required by FIFRA section 25(a)(2)(A) and the Scientific Advisory Panel has waived review of this rule as required by FIFRA section 25(d).

VII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, the Agency must judge whether a rule is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. The Agency has determined that this rule is not major. Although it amends an existing rule by adding as well as deleting some respondents to registration and reporting requirements, it will not;

1. Have an annual effect on the economy of \$100 million or more.
2. Increase costs to consumers, industry, or Government.

3. Have a significant adverse effect on competition, employment, investment, productivity, or innovation.

This rule was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator may certify that a final rule will not, if promulgated, have a significant impact on a substantial number of small entities and, therefore, does not require a regulatory flexibility analysis.

This rule will require those establishments involved in producing multiple-use chemicals, where the manufacturers intend or have constructive knowledge that such chemicals are used as active ingredients in the production of pesticides, to register their establishments and report production on an annual basis under section 7 of FIFRA. The Agency believes that most establishments which produce multiple-use substances are larger businesses, which may already be registered. Additionally, it removes the requirement to register custom blender establishments.

Therefore, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and has assigned OMB control numbers 2070-0045 and 2070-0078.

Public reporting burden for this collection of information is estimated to average 1.08 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St. SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

List of Subjects in 40 CFR Part 167

Pesticides, Reporting and recordkeeping requirements, Establishment registration.

Dated: August 26, 1988.

John A. Moore,
Acting Administrator.

Therefore, 40 CFR Chapter I is amended by revising Part 167 to read as follows:

PART 167—REGISTRATION OF PESTICIDE AND ACTIVE INGREDIENT PRODUCING ESTABLISHMENTS, SUBMISSION OF PESTICIDE REPORTS

Subpart A—General Provisions

Sec.

167.3 Definitions.

Subpart B—Registration Requirements

167.20 Establishments requiring registration.

Subparts C and D—[Reserved]

Subpart E—Recordkeeping and Reporting Requirements

167.85 Reporting requirements.

167.90 Where to obtain and submit forms.

Authority: 7 U.S.C. 136 (e) and (w).

Subpart A—General Provisions

§ 167.3 Definitions.

Terms used in this part shall have the meanings set forth for such terms in the Federal Insecticide, Fungicide, and Rodenticide Act. In addition, when used in this part, the following terms shall have the meanings stated below:

"Act" means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*

"Amount of pesticidal product" means quantity, expressed in weight or volume of the product, and is to be reported in pounds for solid or semi-solid pesticides and active ingredients or gallons for liquid pesticides and active ingredients, or number of individual retail units for devices.

"Current production" [sales or distribution] means amount of planned production in the calendar year in which the pesticides report is submitted, including new pesticidal products not previously sold or distributed.

"Custom blender" means any establishment which provides the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when: (1) The blend is prepared to the order of the customer and is not held in inventory by the blender; (2) the blend is to be used on the customer's property (including leased or rented

property); (3) the pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend; (4) the blend is prepared from registered pesticides; (b) the blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of mixture; and (6) no other pesticide production activity is performed at the establishment.

"Device" means any device or class of devices as defined by the Act and determined by the Administrator pursuant to section 25(c) to be subject to the provisions of section 7 of the Act.

"Establishment" means any site where a pesticidal product, active ingredient, or device is produced, regardless of whether such site is independently owned or operated, and regardless of whether such site is domestic and producing a pesticidal product for export only, or whether the site is foreign and producing any pesticidal product for import into the United States.

"Past year" means the calendar year immediately prior to that in which the report is submitted.

"Pesticidal product" means a pesticide, active ingredient, or device.

"Pesticidal product report" means information showing the types and amounts of pesticidal products which were: (1) Produced in the past calendar year; (2) produced in the current calendar year; and, (3) sold or distributed in the past calendar year. For active ingredients, the pesticidal product report must include information on the types and amounts of an active ingredient for which there is actual or constructive knowledge of its use or intended use as a pesticide. This pesticidal product report also pertains to those products produced for export only which must also be reported. A positive or a negative annual report is required in order to maintain registration for the establishment.

"Produce" means to manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to section 5 of the Act, any active ingredient or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device.

"Producer" means any person, as defined by the Act, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling).

"Sold or distributed" means the aggregate amount of a pesticidal product released for shipment by the

establishment in which the pesticidal product was produced.

"Type of pesticidal product" refers to each individual product as identified by: the product name; EPA Registration Number (or EPA File Symbol, if any, for planned products, or Experimental Permit Number, if the pesticide is produced under an Experimental Use Permit); active ingredients; production type (technical, formulation, repackaging, etc.); and, market for which the product was produced (domestic, foreign, etc.). In cases where a pesticide is not registered, registration is not applied for, or the pesticide is not produced under an Experimental Use Permit, the term shall also include the chemical formulation.

Subpart B—Registration Requirements

§ 167.20 Establishments requiring registration.

(a) *Who must register.* (1) Any establishment where a pesticidal product is produced must be registered with the Agency. This requirement does not apply to custom blenders as defined in this part.

(2) Any establishment where a substance is produced must be registered with the Agency if the producer intends the substance to be used as an active ingredient of a pesticide, or has actual or constructive knowledge that the substance will be used by any person as an active ingredient of a pesticide.

(3) Any domestic establishment producing a pesticidal product for export, or any unregistered pesticide, or any foreign establishment producing a pesticidal product for import into the United States must be registered. Also, any establishment, either foreign or domestic, which produces a pesticidal product for use under an Experimental Use Permit, FIFRA section 18 Emergency Exemption or section 24(c) Special Local Needs registration, must be registered.

(b) *Information required.* An applicant for establishment registration must submit the following information:

(1) Name and address of the company.
(2) The type of ownership (individual, partnership, cooperative association, corporation, or any organized group of persons whether incorporated or not).

(3) The name and address of each producing establishment for which registration is sought.

(c) *When to apply.* An application for establishment registration must be submitted, and an establishment registration number must be assigned by the Agency, before any production may occur at an establishment. In the case of an establishment which has not

previously been required to be registered and is not currently registered, the producer must apply for establishment registration by submitting an application within 180 days after the effective date of this regulation.

(d) *Assignment of establishment registration number.* The Agency will return incomplete or inaccurately completed applications to the applicant. If the application is complete and accurate, the Agency will register the establishment and assign a registration number to the establishment. The establishment registration number will be entered on the application, and a copy of the application will be returned to the applicant.

(e) *Amendment.* If at any time after the first report there is a change in the information required to be submitted under paragraph (b) of this section, that new information must be reported to EPA, in writing on letterhead stationery or on forms supplied by the Agency, within 30 days after such change occurs.

(f) *Duration of registration.* Establishment registration will remain effective provided pesticide reports are submitted annually pursuant to the requirements of this part. Failure to submit a report may result in termination of establishment registration, civil and/or criminal penalty assessments.

(Approved by the Office of Management and Budget under control number 2070-0045)

Subparts C and D—[Reserved]

Subpart E—Recordkeeping and Reporting Requirements

§ 167.85 Reporting requirements.

(a) *Who must report.* Each producer operating an establishment must submit the reports required by this section concerning any pesticide, active ingredient, or device produced at each establishment. Custom blenders are not required to report production to the Agency.

(b) *Information required.* The pesticide report shall include the following: (1) Name and address of the establishment; (2) amount of each pesticidal product: (i) Produced during the past year; (ii) sold or distributed during the past year; (iii) estimated to be produced during the current year. The report shall only include those pesticidal products actually produced at the reporting establishment. Reports submitted by foreign-producing establishments shall cover only those pesticidal products exported to the United States.

(c) *How to report.* The reports required by this section must be made on forms supplied by the Agency. It is the ultimate responsibility of companies to obtain, complete, and submit the form each year.

(d) *When to report.* A producer operating an establishment must submit an initial report no later than 30 days after the first registration of each establishment the producer operates. Thereafter, the producer must submit an annual report on or before March 1 of each year, even if the producer has produced no pesticidal product for that reporting year.

{Approved by the Office of Management and Budget under control number 2070-0078}

§ 167.90 Where to obtain and submit forms.

(a) *Where to obtain forms.* Any person may obtain blank forms for the applications and reports required by this part from any EPA Regional Office, or from the address listed in paragraph (b) of this section.

(b) *Where to submit applications and reports.* Each producer operating an establishment, with the exception of those establishments not found at the same location as their company headquarters, must submit applications and reports required by this Part to the EPA Regional Office which serves the area where the establishment is located. The list of Regional Office addresses is

found in 40 CFR 1.7. Applications and reports for those establishments not found at the same location as their company headquarters to be submitted by the company headquarters to the Regional Office having jurisdiction over the State in which the company headquarters is located. A foreign producer who exports any pesticide product, device, or active ingredient to the United States must submit all applications and reports to:

U.S. Environmental Protection Agency, Office of Compliance Monitoring (EN-342), 401 M Street SW., Washington, DC 20460.

{FR Doc. 88-20320 Filed 9-7-88; 8:45 am}

BILLING CODE 6560-50-M

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