

active ingredients used in producing a pesticide.

(a) *Recordkeeping and inspection.* Exporters of pesticides, devices and active ingredients must keep records and permit inspections of those records in accordance with part 169 of this chapter. Exporters must keep records of the product labeling used, including the EPA registered labeling, any foreign labeling on or attached to the product when shipped, and, as applicable, any supplemental labeling used. Producers of pesticides for export shall maintain these records in a manner that shows exactly which labels and labeling accompanied each shipment of a pesticide product to a foreign country. As stated at §168.75(c), when research product identity information appears on the labeling in an encoded manner, information translating the code shall be maintained in records. These records shall be maintained for the time period required by §169.2(h) of this chapter following the last export of such pesticides. All records required by part 169 of this chapter shall be made available for inspection and copying by EPA or its duly authorized representatives.

(b) *Pesticide production establishment requirements.* Exporters of pesticides, devices, and active ingredients must submit annual reports to EPA in accordance with part 167 of this chapter, concerning those products that are exported. All products required to be labeled "Not Registered for Use in the United States of America" must be reported as unregistered production regardless of whether a purchaser acknowledgement statement is required.

## PART 169—BOOKS AND RECORDS OF PESTICIDE PRODUCTION AND DISTRIBUTION

Sec.

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AUTHORITY: 7 U.S.C. 136f and 136w.

SOURCE: 45 FR 54338, Aug. 15, 1980, unless otherwise noted.

### § 169.1 Definitions.

Terms used in this part shall have the meanings set forth for such terms

in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. In addition, as used in this part, the following terms shall have the meanings set forth below:

(a) *Amount of pesticide or active ingredient.* The term "amount of pesticide or active ingredient" means the weight or volume of the pesticide or active ingredient used in producing a pesticide expressed as weight for solid or semi-solid products and as weight or volume of liquid products.

(b) *Batch.* The term "batch" means a quantity of a pesticide product or active ingredient used in producing a pesticide made in one operation or lot or if made in a continuous or semi-continuous process or cycle, the quantity produced during an interval of time to be specified by the producer.

(c) *Device.* The term "device" means any device or class of device as defined by the Act and determined by the Administrator to be subject to the provisions of the Act.

(d) *Inability.* The term "inability" means the incapacity of any person to maintain, furnish or permit access to any records under this Act and regulations, where such incapacity arises out of causes beyond the control and without the fault or negligence of such person. Such causes may include, but are not restricted to acts of God or of the public enemy, fires, floods, epidemics, quarantine restrictions, strikes, and unusually severe weather, but in every case, the failure must be beyond the control and without the fault or negligence of said person.

(e) *Producer.* The term "producer" means the person, as defined by the Act, who produces or imports any pesticide or device or active ingredient used in producing a pesticide.

### § 169.2 Maintenance of records.

All producers of pesticides, devices, or active ingredients used in producing pesticides subject to this Act, including pesticides produced pursuant to an experimental use permit and pesticides, devices, and pesticide active ingredients produced for export, shall maintain the following records:

(a) Records showing the product name, EPA Registration Number, Experimental Permit Number if the pesticide is produced under an Experimental Use Permit, amounts per batch and batch identification (numbers, letters, etc.) of all pesticides produced. In cases where the product is an active ingredient used in producing a pesticide or where the product is a pesticide which is not registered, is not the subject of an application for registration, or is not produced under an Experimental Use Permit, the records shall also show the complete formula. The batch identification shall appear on all production control records. These records shall be retained for a period of two (2) years.

(b) Records showing the brand names and quantities of devices produced. These records shall be retained for a period of two (2) years.

(c) Records showing the following information regarding the receipt, by the producer, of all pesticides, devices, and active ingredients used in producing pesticides:

- (1) Brand name of the pesticide or device, or common or chemical name of the pesticide active ingredient;
- (2) Name and address of shipper;
- (3) Name of delivering carrier;
- (4) Date received; and
- (5) Quantities received.

These records are not intended to cover receipt of pesticides used for in-plant maintenance, extermination, or sanitation programs, etc. Shipping and receiving documents such as invoices, freight bills, receiving tickets, etc., which provide the required information will be considered satisfactory for the purposes of this section. These records shall be retained for a period of two (2) years.

(d) Records showing the following information regarding the shipment of all pesticides, devices, and active ingredients used in producing pesticides:

- (1) Brand name of pesticide or device, or the common or chemical name of the pesticide active ingredient;
- (2) Name and address of consignee;
- (3) Where the pesticide is produced pursuant to an experimental use permit (FIFRA section 5), a special exemption (section 18), or a special local need (section 24), the information re-

quired under these sections and any regulations promulgated thereto regarding the distribution of such pesticides;

- (4) Name of originating carrier;
- (5) Date shipped or delivered for shipment; and
- (6) Quantities shipped or delivered for shipment.

Such records are required regardless of whether any shipment or receipt of shipment is between plants owned or otherwise controlled by the same person. Shipping and receiving documents such as invoices, freight bills, receiving tickets, etc., which provide the required information will be considered satisfactory for purposes of this section. These records shall be retained for a period of two (2) years.

(e) Inventory records with respect to the types and amounts of pesticides or pesticide active ingredients, or quantities of devices in stock which he has produced. These records may be disposed of when a more current inventory record is prepared.

(f) Copies of all domestic advertising of the restricted uses of any pesticide registered for restricted use which the producer caused to have prepared, including any radio or television scripts for all such pesticides. These records shall be retained for a period of two (2) years.

(g) Copies of all guarantees given pursuant to section 12(a)(2)(C) of the Act. These records shall be retained for a period of one (1) year after expiration of the guarantee.

(h) In the case of all pesticides, devices, and active ingredients used in producing pesticides intended solely for export to any foreign country:

- (1) Copies of the specification or directions of the foreign purchaser for the production of such pesticides, devices, or pesticide active ingredients;
- (2) Copies of labels or labeling required to comply with section 17(a)(1) of the Act; and
- (3) For any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of the Act, copies of a statement signed by the foreign purchaser of the pesticide acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and

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cannot be sold in the United States under this Act.

These records shall be retained for a period of 2 years after expiration of the contract.

(i) Records on the method of disposal (burial, incineration, etc.) date or dates of disposal, location of the disposal sites, and the types and amounts of pesticides or pesticide active ingredients disposed of by the producer or his contractor. With regard to the disposal of containers accumulated during production, the Agency will consider satisfactory a statement, attested to by a responsible firm official, describing in general terms the method and location of disposal, e.g., all containers are taken periodically to a certain site. Records of deviations from normal practice must be maintained. In addition, any records on the disposal of pesticides or pesticide active ingredients and/or containers specified pursuant to section 19 of the Act and any regulations promulgated thereto shall also be maintained. The above requirements apply to those products bearing label instructions for disposal and to any other products specified under any regulations promulgated pursuant to section 19. These records shall be retained for twenty (20) years or may be forwarded after three (3) years to the Environmental Protection Agency Regional Administrator for maintenance. Notwithstanding these record keeping requirements, whenever any producer of pesticides or pesticide active ingredients is complying with a rule promulgated under the authority of the Resource Conservation and Recovery Act of 1976 (RCRA) (Pub. L. 94-580, 90 Stat. 2795, October 21, 1976), for the handling or disposal of hazardous wastes, as defined by RCRA or any regulations promulgated thereunder, such producer will no longer be required to maintain records in accordance with this subsection.

(j) Records of any tests conducted on human beings whether performed by the producer himself or authorized and/or paid for by the producer. Such records shall include: The names and addresses of subjects tested, dates of tests, types of tests, written consent of subjects to test, and all information and instructions given to the subjects

regarding the nature and purpose of the tests and of any physical and mental health consequences which were reasonably foreseen therefrom, and any adverse effects of the test on the subjects, including any such effects coming to the attention of the producer after completion of the tests. These records shall be retained for twenty (20) years or may be forwarded after three (3) years to the Environmental Protection Agency Regional Administrator for maintenance.

(k) Records containing research data relating to registered pesticides including all test reports submitted to the Agency in support of registration or in support of a tolerance petition, *all* underlying raw data, and interpretations and evaluations thereof, whether in the possession of the producer or in the possession of the independent testing facility or laboratory (if any) which performed such tests on behalf of the producer. These records shall be retained as long as the registration is valid and the producer is in business.

[45 FR 54338, Aug. 15, 1980, as amended at 58 FR 9090, Feb. 18, 1993]

### § 169.3 Inspection.

(a) *Producers.* Any producer of any pesticide, device, or active ingredient used in producing a pesticide which is subject to this Act shall, upon request of any officer or employee of the Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and to copy all records required to be maintained by this part, including records in the possession of an independent testing facility or laboratory which performed tests on behalf of the producer. Such inspection will be conducted in accordance with procedures detailed in section 8(b) of the Act.

(b) *Distributors, carriers, dealers, etc.* Any distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide, device, or active ingredient used in producing a pesticide which is subject to this Act, shall, upon request of any officer or employee of the Agency or of any State or political subdivision, duly designated by the Administrator, furnish or permit such person