

(5) or (6) will be published in the FEDERAL REGISTER.

(d) *Termination of suspension.* Suspension of a State's authority will be effective for the period specified in the notice of suspension, or if no period was specified, until such time as the Administrator is satisfied that the State can and will exercise adequate control over its program. In the latter case, the Administrator will notify the State that the suspension is terminated, or that it will be terminated on a specific date. In either case, the Administrator will publish a notice of the termination of suspension in the FEDERAL REGISTER.

(e) *Judicial review.* Any State whose authority to register pesticides has been finally suspended by the Administrator may seek judicial review of the Administrator's decision under sec. 16 of FIFRA, at any time prior to termination of the suspension. Such suspension shall remain in effect during the period of judicial review unless otherwise ordered by the Administrator.

§ 162.156 General requirements.

(a) *Requirements for distribution and use.* (1) Any product whose State registration has been issued in accordance with §§ 162.152 and 162.153 may be distributed and used in that State, subject to the following provisions of the Act and the regulations promulgated thereunder:

(i) Sec. 12(a)(1) (A) through (E), in accordance with:

(A) Sec. 2(q)(1) (A) through (G).

(B) Sec. 2(q)(2) (A) through (D).

(ii) Sec. 12(a)(2) (A) through (G) and (I) through (P).

(2) A product or use classified by a State for restricted use under § 162.153(g) may be used only by, or under the direct supervision of, an applicator certified under a plan approved by EPA in accordance with sec. 4 of FIFRA.

(3) State registrations which are not issued in accordance with § 162.152 (a) and (b)(2) (i), (ii) and (iii) are not authorized by section 24(c) and are not considered valid for any purposes under FIFRA. When the Administrator determines that a registration is invalid, the Administrator shall notify the registering State that the registration is

invalid, and may specify the reason for the invalidity.

(b) *Establishment registration requirements.* No person may produce any pesticide, including any pesticide registered by a State under section 24(c), unless the establishment in which it is produced is registered by the Administrator in accordance with sec. 7 of FIFRA and 40 CFR part 167.

(c) *Books and records requirements.* All producers of pesticides, including those producers of pesticides registered by States under sec. 24(c), must maintain records in accordance with the requirements imposed under sec. 8 of FIFRA and 40 CFR part 169.

Subpart E [Reserved]

PART 163—CERTIFICATION OF USEFULNESS OF PESTICIDE CHEMICALS

Sec.

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163.12 Opinion as to residue.

AUTHORITY: 21 U.S.C. 346a.

SOURCE: 36 FR 22533, Nov. 25, 1971, unless otherwise noted.

§ 163.1 Words in the singular form.

Words in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§ 163.2 Definitions.

Unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301

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et seq.), as amended by Pub. L. 518, 83d Congress, 2d Session, "An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to residues of pesticide chemicals in or on raw agricultural commodities" (68 Stat. 511).

(b) *Director* means the Director of the Pesticides Regulation Division, Environmental Protection Agency, Washington, D.C.

(c) *Agency* means the Environmental Protection Agency.

(d) *Pesticide chemical* and *raw agricultural commodity* shall have the same meanings as they have in paragraphs (q) and (r), respectively, of section 201 of the Act.

(e) *Economic poison* shall have the same meaning as it has under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135-135k) and the regulations issued thereunder.

(f) *Person* means individuals, partnerships, corporations, and associations.

(g) *Certification* means a certification by the Director that a pesticide chemical is useful for the purpose for which a tolerance or exemption is sought under the act.

(h) *Petition* means a petition filed with the Administrator, Environmental Protection Agency pursuant to section 408(d)(1) of the Act.

[36 FR 22533, Nov. 25, 1971, as amended at 53 FR 15999, May 4, 1988]

§ 163.3 Administration.

The Director is authorized to take such action as, in his discretion, may be necessary to carry out the provisions of sections 408(i) and 408(l) of the Act and the regulations in this part.

§ 163.4 Filing of requests for certification.

All requests for a certification shall be made in writing to the Director. Action upon such a request will not be undertaken unless (a) the person making the request has, pursuant to the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, registered or submitted an application for the registration of an economic poison consisting of or containing the pesticide chemical for which the certification is sought and (b) the request is accompanied by a copy of the petition. The person requesting certification

may at any time withdraw such request for certification.

§ 163.5 Material in support of the request for certification.

In addition to the data required by section 408(d)(1) of the Act to be included in the petition, the request for certification should be supported by the following material, to the extent it is relied upon by the petitioner:

(a) A complete report of the results of any experimental work by the petitioner on the effectiveness of the pesticide chemical for the purposes intended;

(b) Data relating to the usefulness of the pesticide chemical obtained by other qualified investigators;

(c) Any other material which the petitioner believes will justify a finding of usefulness.

If such material is fully shown in the petition, it need not be set forth separately in the request for certification.

§ 163.6 Certification limited to economic poison uses.

If the product for which a certification is sought is intended for both economic poison and noneconomic poison uses, any certification relative to the usefulness of such product will refer only to economic poison uses. No action will be taken with respect to the noneconomic poison uses of such product.

§ 163.7 Factors considered in determining usefulness.

In determining whether a pesticide chemical is useful for the purposes for which a tolerance or exemption is sought, consideration will be given, among other things, to:

(a) The results of any experimental work by the petitioner on the effectiveness of the pesticide chemical for the purposes intended.

(b) Data relating to the usefulness of the pesticide chemical obtained by other qualified investigators.

(c) Reports of other experimental work before the Director in publications, the official files of the Agency, or otherwise.

(d) Opinions of experts qualified in the fields involved.

§ 163.8 Basis for determination of usefulness.

Usefulness of a pesticide chemical for the purposes intended will be determined upon the basis of its practical pesticidal, or biological, effectiveness. Pesticidal effectiveness may be established in terms of percentage reduction or control of pests or, when appropriate, increase in yield or quality of crop following application of the specified pesticide under the conditions prescribed, compared with the results from adequate controls. Consideration may also be given to other economic gain or practical benefit, including: Economy or ease of production, harvest, or storage of crop; flexibility as regards the time of planting or harvest, even at the possible sacrifice of yield; and general benefit to livestock, plants, or human welfare.

§ 163.9 Proposed certification; notice; request for hearing.

(a) If, upon the basis of the data before him, it appears to the Director that the pesticide chemical is not useful for the purpose or purposes for which a tolerance or exemption is sought, or is useful for only some of the purposes for which a tolerance or exemption is sought, the Director shall notify the person requesting the certification of his proposal to so certify. Notice of such proposed certification will be given by registered mail.

(b) Within one week after receipt of such notice of proposed certification the person requesting the certification may, by filing a request with the Director, (1) request that the certification be made on the basis of the proposed certification; (2) request a hearing on the proposed certification or the parts objected to; (3) request both such certification and such hearing; or (4) withdraw the request for certification as provided for in § 163.10.

If no such request or withdrawal is filed with the Director within such time, the certification will be made as proposed.

§ 163.10 Withdrawal of request for certification pending clarification or completion.

In some cases it may be necessary for the Director to notify the petitioner of

his proposal to certify that the pesticide chemical does not appear to be useful for some or all of the purposes for which a tolerance or exemption is sought only because the data submitted by the petitioner are not sufficiently clear or complete to justify a finding of usefulness. In such cases the petitioner may withdraw his request for certification pending its clarification or the obtaining of additional data, and no further action will be taken with respect to the making of the certification until the request for certification is resubmitted. Upon the resubmission of the request for certification, the time limitation within which final certification is required to be made will begin to run anew from the date of the resubmission.

§ 163.11 Registration under the Federal Insecticide, Fungicide, and Rodenticide Act.

(a) Since in most cases where a pesticide chemical may leave a residue in or on a raw agricultural commodity there can be no determination of the adequacy of the directions for use or the warning or caution statements appearing on the labeling of an economic poison until a tolerance or exemption has been established for the pesticide chemical which is, or is a part of, such economic poison, it will not ordinarily be possible to register the economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act until such tolerance or exemption has been established.

(b) Factors other than pesticidal, or biological, effectiveness are considered in the granting of registration under the Federal Insecticide, Fungicide, and Rodenticide Act. Therefore, the criteria for registration are not all applied in considering the certification of usefulness, and the fact that such a certification has been made does not mean that the economic poison can be registered for the uses concerned.

§ 163.12 Opinion as to residue.

(a) In forming an opinion whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the

manner proposed, consideration will be given, among other things, to:

(1) Data furnished by the petitioner showing (i) the results of tests to ascertain the amount of residue remaining, including a description of the analytical methods used, and (ii) practicable methods for removing residue which exceeds any proposed tolerance;

(2) Reports of other experimental work before the Director in publications, the official files of the Agency, or otherwise;

(3) Opinions of experts qualified in the fields involved.

(b) If a tolerance proposed by the petitioner is reasonably to reflect the amount of residue likely to result when a pesticide chemical is used, it must be large enough to include all residue which is likely to result when the pesticide chemical is used in the manner proposed by the petitioner, but not larger than needed for this purpose. The tolerance proposed by the petitioner may take into account reduction of residue by washing, brushing, or other applicable method.

(c) If there is insufficient information before the Director to support an opinion as to whether the tolerance proposed by the petitioner reasonably reflects the amount of residue likely to result, the opinion will so state.

PART 164—RULES OF PRACTICE GOVERNING HEARINGS, UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, ARISING FROM REFUSALS TO REGISTER, CANCELLATIONS OF REGISTRATIONS, CHANGES OF CLASSIFICATIONS, SUSPENSIONS OF REGISTRATIONS AND OTHER HEARINGS CALLED PURSUANT TO SECTION 6 OF THE ACT

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