

§ 163.8

§ 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

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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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