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§ 172.3 Scope of requirement.

(a) An experimental use permit (EUP) is generally required for testing of any unregistered pesticide or any registered pesticide being tested for an unregistered use. However, as described in paragraph (b) of this section, certain of such tests are presumed not to involve unreasonable adverse effects and, therefore, do not require an EUP.

(b) Except as provided in subpart C of this part or as specifically determined by the Environmental Protection Agency (EPA), it may be presumed that EUPs are not required when:

(1) The experimental use of the pesticide is limited to:

(i) Laboratory or greenhouse tests,

(ii) Limited replicated field trials as described in paragraph (c) of this section to confirm such tests, or

(iii) Other tests as described in paragraph (c) of this section whose purpose is only to assess the pesticide's potential efficacy, toxicity, or other properties.

(2) The producer, applicator, or any other person conducting the test does not expect to receive any benefit in pest control from the pesticide's use.

(c) For purposes of paragraphs (b)(1)(ii) and (b)(1)(iii) of this section, the following types of experimental tests are presumed not to need an EUP:

(1) A small-scale test involving use of a particular pesticide that is conducted on a cumulative total of no more than 10 acres of land per pest, except that:

(i) When testing for more than one target pest occurs at the same time and in the same locality, the 10 acre limitation shall encompass all of the target pests.

(ii) Any food or feed crops involved in, or affected by, such tests (including, but not limited to, crops subsequently grown on such land which may reasonably be expected to contain residues of the tested pesticides) shall be destroyed or consumed only by experimental animals unless an appropriate tolerance or exemption from a tolerance has been established under the Federal Food, Drug, and Cosmetic Act (FFDCA) for residues of the pesticide.

(2) A small-scale test involving the use of a particular pesticide that is conducted on a cumulative total of no more than 1 surface acre of water per pest, except that:

(i) When the testing for more than one target pest occurs at the same time and in the same locality, the 1 acre limitation shall encompass all of the target pests.

(ii) Waters which are involved in or affected by such tests are not used for irrigation purposes, drinking water supplies, or body contact recreational activities.

(iii) Testing shall not be conducted in any waters which contain or affect fish, shellfish, plants, or animals taken for recreational or commercial purposes and used for food or feed, unless an appropriate tolerance or exemption from a tolerance has been established under the FFDCA for residues of the pesticide.

(3) Animal treatment tests involving the use of a particular pesticide that are conducted only on experimental animals which will not be used for food or feed, unless an appropriate tolerance or an exemption from a tolerance has been established for animal products and byproducts under the FFDCA for residues of the pesticide.

(d) The examples in paragraphs (c)(1), (c)(2), and (c)(3) of this section are not all-inclusive and do not preclude testing in larger areas or larger numbers of units if the intended use meets the criteria of paragraph (a) of this section. However, tests which do not come within the examples in paragraphs (c)(1), (c)(2), and (c)(3) of this section, absent a specific determination by EPA to the contrary, require an EUP. Subdivision I of the Pesticide Assessment Guidelines provides guidance on the procedures, data requirements, and general aspects pertaining to the issuance and use of EUPs. Persons intending to conduct tests who are uncertain whether the testing may be conducted without a permit may submit a request for determination to the Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Telephone: (703–305–5447). Such a request shall include the information listed in § 172.4(b)(1)(ii) and (b)(1)(iii) and in the case of an unregistered product, the information in § 172.4(b)(3)(i).

(e) Notwithstanding paragraphs (b) through (d) of this section, EPA may, on a case-by-case basis, require that certain testing of a particular pesticide or class of pesticides be carried out under an EUP, if it is determined that such EPA oversight is warranted. If EPA determines that an EUP is required, it will notify the developer of the pesticide of the need for an EUP and provide opportunity for comment or objections before imposing the requirement.

(f) No EUP is required for a substance or mixture of substances being put through tests for the sole purpose of gathering data required for approval of such substance or mixture under the FFDCA (21 U.S.C. 301 *et seq.*) as:

(1) A "new drug" (21 U.S.C. sec. 321(p) and sec. 355).

(2) A "new animal drug" (21 U.S.C. sec. 321(w) and sec. 360(b)), or

(3) An "animal feed" (21 U.S.C. sec. 321 (x)) containing a "new animal drug" (21 U.S.C. sec. 360(b)).

(g) Paragraph (f) of this section shall not apply when a purpose of such test is to accumulate information necessary to register a pesticide under section 3 of the Act.

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§ 172.4 Applications.

(a) *Time for submission.* An application or request for amendment to an existing permit shall be submitted in triplicate to the Registration Division, Office of Pesticide Programs, Environmental Protection Agency, Washington, DC 20460, as far as possible in advance of the intended date of shipment or use. Applications will be processed as expeditiously as possible.

(b) *Contents of applications*—(1) *General requirements.* (i) The name and address of the applicant;

(ii) The registration number of the product, if registered;

(iii) The purpose or objectives of the proposed testing; a description in detail of the proposed testing program including test parameters; a designation of the pest organism(s) involved; the amount of pesticide product proposed for use; the crops, fauna, flora, sites, modes, dosage rates, and situation of application on or in which the pesticide is to be used; the States in which the proposed program will be conducted; the number of acres, number of structural sites, or number of animals by State to be treated or included in the area of experimental use; the proposed dates or period(s) during which the testing program is to be conducted; and the manner in which supervision of the program will be accomplished;

(iv) The name, street address, telephone number, and qualifications of all participants in the program (whether or not in the employ of the applicant). A permit must be amended to add or change participants;

(v) The name and street address of all cooperators, if available at the time an application is submitted or as soon thereafter as available;

(vi) A description and the specific results of any appropriate prior testing of the product conducted by the applicant to determine toxicity and effects in or on target organisms at the site of application; and to determine phytotoxicity and other forms of toxicity or effects on nontarget plants, animals, and insects at or near the site of application; and to determine adverse effects on the environment;

(vii) The proposed method of storage and disposition of any unused experimental use pesticide and its containers; and

(viii) Such other additional pertinent information as the Administrator may require.

(2) *Requirement for tolerance.* If the experimental use pesticide is to be used in such a manner that any residue can reasonably be expected to result in or on food or feed, the applicant must:

(i) Submit evidence that a tolerance or exemption from the requirement of a tolerance has been established for residues of the pesticide in or on such food or feed under section 408 of the Federal Food, Drug, and Cosmetic Act, or a regulation promulgated under section 409 of that Act; or

(ii) Submit a petition proposing establishment of a tolerance or an exemption from the requirement of a tolerance under section 408, or a regulation under section 409, of the Federal Food, Drug, and Cosmetic Act; or

(iii) Certify that the food or feed derived from the experimental program