(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.

[59 FR 45611, Sept. 1, 1994]

§ 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

will be destroyed or fed only to experimental animals for testing purposes, or otherwise disposed of in a manner which will not endanger man or the environment. The method of such destruction or disposition shall be provided in the application for the permit.

(3) *Additional requirements for unregistered pesticide products.* (i) A complete confidential statement of composition for the formulation to be tested giving the name and percentage by weight of each ingredient, active and inert;

(ii) Chemical and physical properties of each active ingredient of the formulation to be tested, including, but not limited to, the manufacturing or laboratory processes and analytical methods suitable for determining the active ingredients in the formulation;

(iii) Appropriate date, if available, on the rate of decline of residues on the treated crop or environmental site or other information for determination regarding entry of persons into treated areas; and

(iv) Results of toxicity tests and other data relevant to the product's potential for causing injury to the users or other persons who may be exposed, including any available epidemiological information as to man.

(c) *Fees.* The payment of fees for experimental use permits shall apply as specified in subpart U of part 152 of the chapter.

[40 FR 18782, Apr. 30, 1975, as amended at 53 FR 19115, May 26, 1988]

§ 172.5 The permit.

(a) *Issuance.* The Experimental Use Permit shall be issued when the Administrator determines that the conditions of section 5 of the Act, and the regulations thereunder, have been met subject to such terms and conditions as the Administrator determines are warranted.

(b) *Duration.* Permits will be effective for a specified period of time, normally one year, depending upon the crop or site to be tested and the requirements of the testing program submitted. The applicant should propose a suitable duration of the permit commensurate with the program submitted. Permits and associated temporary tolerances may be renewed, extended, or amended upon request if circumstances warrant.

(c) *Limitations.* The quantity of a pesticide allowed by a permit may be less than requested if it is determined that the available information on efficacy, toxicity or other hazards, the need for data, or the adequacy of program supervision does not justify the quantity of the pesticide requested. Other limitations may also be placed in the permit if necessary for the protection of the public health and the environment.

(d) *Additions.* With respect to an experimental use pesticide containing any chemical or combination of chemicals not included in any previously registered pesticides, the Administrator may require that additional studies be conducted during the permit period to gather data to support the establishment of tolerances and/or registration. To the extent practicable, the applicant will be notified of any such requirements before or at the time an experimental use permit is issued.

(e) *Maintenance of records.* All producers of pesticides produced pursuant to an experimental use permit shall maintain records in accordance with part 169.

§ 172.6 Labeling.

(a) *Contents.* Except as provided by paragraph (b) of this section, all pesticides shipped or used under an experimental use permit shall be labeled with directions and conditions for use which shall include the following:

(1) The prominent statement, "For Experimental Use Only";

(2) The Experimental Use Permit number;

(3) The statement, "Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program";

(4) The name, brand, or trademark;

(5) The name and address of the permittee, producer, or registrant;

(6) The net contents;

(7) An ingredient statement;

(8) Warning or caution statements;

(9) Any appropriate limitations on entry of persons into treated areas;

(10) The establishment registration number, except in those cases where application of the pesticide is made solely by the producer; and

(11) The directions for use, except that the Administrator may approve