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

the use of the experimental program as labeling provided that such program is to be distributed with the product.

(b) *Supplemental labeling.* In the case of a registered pesticide, the Administrator may, at his discretion, permit a pesticide to be used under an experimental use permit with supplemental labeling as approved by him.

§ 172.7 Importation of technical material.

Technical materials may be imported without registration in sufficient quantities to formulate a pesticide for which an Experimental Use Permit has been requested if the application for such permit states that such importation will occur.

§ 172.8 Program surveillance and reporting of data.

(a) The permittee shall supervise the test program and evaluate the results of testing at each site of application. It will further be the responsibility of the permittee to report immediately to the Administrator, or to any person designated by him, any adverse effects from use of, or exposure to, the pesticide.

(b) The permittee shall submit the following reports to the Registration Division during the experimental program.

(1) [Reserved]

(2) A final report shall be submitted within 180 days after the expiration of the permit, unless a request for extension of time is approved, and shall include:

(i) All data gathered during the testing program; field notes need not be submitted but must be maintained and submitted upon request;

(ii) A description of the disposition of any pesticide containers and any unused pesticides including amounts disposed of and the method and site of disposition; and

(iii) The method of disposition of affected food and/or feed.

The data under paragraph (b)(2)(i) of this section above may be submitted as part of an application for registration submitted within 180 days after the expiration of the permit, provided that the final report shall include a statement that such application has been made, and the date of such application.

(c) In addition to the reporting requirements provided for elsewhere in this part, in the case of any meat-producing animals or birds that receive a direct treatment or application of any experimental use pesticide, the name and location of the packing plant where the animals will be processed shall be sent to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, DC 20250, at least 10 days before the animals are to be shipped for slaughter. This requirement may be waived, on request, by the USDA. These provisions do not exempt treated food-producing animals and their products from compliance with other applicable inspection requirements.

(d) Failure to submit required reports may constitute grounds for revocation of the permit.

(e) For the purpose of supervising the use of experimental use pesticides, the Agency may require the permittee or any participant to give reasonable advance notification of the intended dates, times, and sites on which such experimental use pesticide will be applied.

(f) The permittee or participants in the experimental use program will permit any authorized representative of the Agency, upon presentation of official identification, entry, at any reasonable time, to any premises involved in the testing program to inspect and to determine whether there has been compliance with the terms and conditions of the permit.

[40 FR 18782, Apr. 30, 1975, as amended at 60 FR 32097, June 19, 1995]

§ 172.9 Renewals.

Applications for renewal of experimental use permits and temporary tolerances, to provide for additional testing, shall be submitted prior to expiration of the permit. Requirements for renewals are the same as for applications under § 172.4, except that information previously submitted may be incorporated by reference.