Pesticide Registration Manual:

Chapter 12 - Applying for an Experimental Use Permit

Introduction to Experimental Use Permits

This chapter describes the requirements for Experimental Use Permits (EUPs) and includes how to apply for an EUP, labeling requirements, application format, and data reporting requirements.

EPA requires that a pesticide product undergo extensive chemical, toxicological, and field-testing before being registered as a pesticide. Some testing is done under field conditions using commercial application equipment to fully understand the pesticide's chemical properties, safety, and efficacy.

Because testing undertaken as part of the registration process necessarily involves an unregistered product or is for a use not previously approved in the registration of the pesticide, EPA sometimes must first authorize the distribution and sale for testing purposes by means of an experimental use permit (EUP) under FIFRA section 5.

The EUP establishes limited conditions for the transportation, application, and disposal of the pesticide material used in the tests. Pesticides registered under an EUP may not be sold or distributed other than through approved participants in the test program, and use is limited to the conditions specified in the EUP. Please refer to 40 CFR Part 172 for detailed information on EUPs.

Requirements for an Experimental Use Permit

A first step for the applicant is to determine whether an EUP is required for the particular testing being considered. If the product is not intended to be used as a pesticide, an EUP would not be needed to test the product. Additionally, certain pesticide testing operations may not require an EUP if the criteria of 40 CFR 172.3 are met, as discussed below.

In general, EUPs are issued for:

- pesticides containing any chemical or combination of chemicals that have not been included in any previously registered pesticide; and
- registered pesticides for which a use, e.g., application to a particular crop, is not registered with the Agency.

However, there are certain tests and circumstances that are exempt from the requirements of an EUP because they are presumed not to involve unreasonable adverse effects. These exemptions are summarized below and described in detail in 40 CFR 172.3(b) and (c).

Exemptions from EUP Requirements

EPA generally will not require an EUP for a substance or mixture of substances if the EUP is limited to:

- **Laboratory or Greenhouse Tests**
- **Limited Replicated Field Trials** involving fewer than 10 acres per pest for terrestrial tests or less than one acre per pest for aquatic tests, in which the sole purpose is to determine pesticidal value, toxicity, or other properties under the following small-scale field testing scenarios:
    - **Land** - Pesticide testing on plots of land 10 acres or less in size. Specifically, test plots may be as large as 10 acres per pest if the effect of each pesticide on several pests is being investigated at a different time for each pest. However, if pesticide effects on more than one pest are being investigated all at the same time, the test plot may not exceed 10 acres in size. Furthermore, any food or feed crops involved in or affected by the tests must be destroyed or consumed only by experimental animals unless a tolerance or exemption from a tolerance has been established. Please refer to 40 CFR 172.3(c)(1).
    - **Aquatic Uses** - Pesticide testing on water bodies one surface acre or less in size. Specifically, water bodies may be as large as one acre per pest if the effect of each pesticide on several pests is being investigated at a different time for each pest. However, if pesticide effects on more than one pest are being investigated all at the same time, the water body may not exceed one acre in size.
        - Bodies of water involved in or affected by the tests may not be used for irrigation, drinking water supplies, or body contact through recreational activities. In addition, pesticides may not be tested in waters that contain or that affect any fish, shellfish, or other plants or animals that may be taken for food or feed unless a tolerance or exemption from tolerance exists for the test product. Please refer to 40 CFR 172.3(c)(2).
- **Animal Treatment Uses** - Tests may be conducted only in cases where experimental animals will not be used for food or feed unless a tolerance or exemption from tolerance exists for the test product. Please refer to 40 CFR 172.3(c)(3).
- **Other Uses** - For testing operations for which acreage limits do not accurately reflect whether the testing is to be considered small- or large-scale, the Agency will determine on a case-by-case basis whether an exemption from the requirement of an

EUP is appropriate. Applicants should consult with the appropriate regulatory division in OPP before initiating such testing.

The exemptions described above are not definitive. 40 CFR 172.3 gives EPA discretionary authority to exempt particular testing operations from the EUP requirements under other conditions, as well as allowing EPA discretionary authority to require EUPs for testing operations even when the exemption conditions of 40 CFR 172.3(b) and (c) are met.

Important Note: EUPs are required for testing of pesticides indoors, as well as in outdoor agricultural settings. This includes testing pesticides to control roaches in domestic dwellings and institutions, and for field-testing of swimming pool sanitizers and disinfectants under actual use conditions.

EUPs for Nonagricultural and Certain Antimicrobial Uses

EUPs are generally required for testing of pesticides indoors, some non-agricultural uses as well as in outdoor agricultural settings. This includes testing pesticides to control roaches and other insects in domestic dwellings and institutions, control termites in and around structures and buildings, control invasive species, and control birds and animals. EPA will determine on a case-by-case basis when an EUP will be required in these situations in accordance with 40 CFR 172.3(e). Applicants should contact the appropriate registration ombudsman who will consult with appropriate staff to determine whether an EUP will be required.

EUPS are required for field-testing of swimming pool sanitizers and disinfectants under actual use conditions. 40 CFR 172.3(c)(2) states that an EUP is not required for a small scale test conducted on a cumulative total of no more than one surface acre of water per pest with several exceptions including that the treated body of water cannot be used for irrigation, drinking water supplies, or body contact through recreational activities. However, a swimming pool disinfection/sanitization use requires an EUP because the efficacy testing required to support the use involves in-use field testing in at least two swimming pools.

There are numerous factors that influence the concentrations necessary for disinfection of swimming pool water in practical applications such as the numbers of swimmers in the pool, frequency of use, frequency with which water is changed, general weather conditions, types and degree of organic contamination of the water by the swimmers themselves (e.g., suntan lotions and oils) and other types of debris. These factors need to be considered when evaluating the effectiveness of a swimming pool sanitizer or disinfectant.

Thus, the efficacy data required to support a swimming pool disinfection/sanitization use consists of a two-phased study (laboratory testing and field testing). The EUP application should include an efficacy protocol that describes in detail all tests and step-by-step procedures that are proposed for the in-use swimming pool field tests. Guidance for field testing water that the public may come into contact with through recreational activities such as swimming in pools and spas, is located in the Pesticide Assessment Guidelines Subdivision G, Section 91-8(c) .

EUPs for Small-Scale Field Testing of Microbial Pesticides

Because of concern about the potential for microorganisms to reproduce and multiply in the environment and the potential for these microbials to cause unforeseen adverse impacts, the Agency may require an EUP for small-scale field-testing of certain microbial pesticides (i.e., genetically altered and nonindigenous microbial pest control agents).

Before the initiation of certain small scale testing involving genetically altered or nonindigenous microbial pest control agents, the research organization, company, or individual must submit a notification to EPA so a determination can be made as to whether an EUP is required. 40 CFR 172.43-59 presents the requirements for an EUP for field-testing of microbial pesticides. Note that these differ significantly from the EUP requirements for testing other pesticides.

Applicants should also refer to Chapter 3 of this document for a more detailed discussion of the Agency's policy and requirements for small-scale field-testing for microbial pesticides.

Applying for an EUP

An application for an EUP may be submitted by any company or person wishing to generate information necessary to register a product under FIFRA as per 40 CFR 172.2(a). The applicant may be a potential registrant, an independent researcher or testing laboratory, or any similar agent or consultant of a manufacturer. Applications must be submitted to the appropriate address given in Chapter 21.

EPA Form 8570-17, Application for Experimental Use Permit, must be submitted to EPA with each EUP application. The type of information to be submitted with the application

depends on whether the product is already registered and whether a tolerance is required for the testing covered under the EUP. 40 CFR 172.4 lists the information required in each case.

Information Required in All EUP Applications

Each EUP application must contain the following information together with a completed copy of EPA Form 8570-17, *Application for Experimental Use Permit*, and five copies of the proposed labeling (refer to the Labeling Requirements section of this chapter):

- applicant's name and address;
- the registration number of the product, if it has been registered (Information requirements for unregistered products are listed below in a separate section);
- purpose or objectives of the proposed testing;
- detailed description of the proposed testing program including the following test parameters:
    - pest organism(s) involved;
    - amount of pesticide proposed to be used;
    - crops, fauna, and flora involved;
    - sites and modes of pesticide applications;
    - pesticide dosage rates;
    - location of test site, including states;
    - number of acres in test site;
    - number of structural sites or number of animals by state to be included in the testing;
    - proposed dates of the testing;
    - how the testing will be supervised;
    - name, street address, telephone number and qualifications of program participants, including those not employed by the applicant;
    - names and street addresses of cooperators (persons owning or controlling application sites and granting permission to permittees to use these sites), if available at the time of the application or as soon thereafter as available;
    - results of prior testing of product by applicant to determine:
    - toxicity and effects in or on target organisms;
    - toxicity and effects in or on nontarget plants, animals and insects at or near the application site;
    - harm to the environment from application of this product; and
    - how the applicant intends to store and dispose of unused pesticide and containers from the proposed experimental use.

Information Required When the Product to be Tested is Not Already Registered

In addition to the information listed immediately above, when the product to be tested has not been registered, the applicant must provide the following information:

- a complete confidential statement of formula of the product to be tested that provides a tabulation of the names and percentage by weight of each ingredient, both active and inert (EPA Form 8570-4), Confidential Statement of Formula)
- chemical and physical properties of each active ingredient of the formulation being tested, including the analytical methods to be used to determine these (40 CFR 158.210, 158.220, 40 CFR 158.310, 40 CFR 158.2081, 40 CFR 158.2171 and 40 CFR 161.150-161.190);
- available data on the rate of decline of residues on the treated crop or site together with other information relevant to determining when workers can safely re-enter treated areas (40 CFR 158.250, 40 CFR 158.270, 40 CFR 2082, 40 CFR 158.2172, 40 CFR 161.240 and 40 CFR 161.390);
- available toxicity and exposure data, including human epidemiological data, relevant to assessing the potential of the product to cause injury to users and other people who may be exposed (40 CFR 158.230, 40 CFR 158.240, 40 CFR 158.243, 40 158.260, 40 CFR 158.2083, 40 CFR 158.2084, 40 CFR 158.2173, 40 CFR 158.2174 and 40 CFR 161.340).
- submitted data (three copies) should be bound and formatted in accordance with the requirements of PR Notice 86-5.

When Testing May Result in Pesticide Residues on Food

When the product to be tested is to be used in such a manner as to leave residue on food or feed, the applicant has three options regarding tolerances:

- The applicant may submit evidence that a tolerance or a tolerance requirement exemption has been established under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA).
- The applicant may submit a petition for a new tolerance or for an exemption from the requirement for a tolerance established under section 408 of FFDCA. Chapter 11 of this document, Tolerance Petitions, describes this process in detail. Or
- The applicant may certify that the food or feed derived from the experimental program will be destroyed or will be fed only to experimental animals, which will be destroyed. Alternatively, the applicant may certify that the food or feed derived from the experimental program will be disposed of in another manner that does not endanger man or the environment. The permit application shall specify the means of such disposal.

Important Note: The Agency review process is greatly facilitated if applicants include a table indicating the states to which the product is to be shipped, the pounds of product to be shipped to each state for each pest or pest complex, and the total pounds of product to be shipped to each state. Also note that if the participants change, the permit needs to be modified (40 CFR 172.4(iv)).

Labeling Requirements

40 CFR 172.6 requires that all pesticides shipped or used under an experimental use permit must be labeled with directions and conditions for use, including the following:

- the prominent statement "For Experimental Use Only";
- the Experimental Use Permit Number;
- the statement "Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program";
- the name, brand, or trademark;
- the name and address of the permittee, producer, or registrant;
- the net contents;
- an ingredient statement;
- warning or caution statements;
- any limitations on entry of persons into treated areas;
- the establishment registration number, except in those cases where application of the pesticide is made solely by the producer; and
- the directions for trial use.

In the case of a registered pesticide, EPA may permit a pesticide to be used under an experimental use permit with approved supplemental labeling.

Note: Please refer to Chapter 2 for more information on label and labeling formats.

Fee Requirements

Refer to Chapter 5 for detailed information on fees.

Based on legislative requirements, fees are assessed for specific EPA review actions for conventional chemical pesticides, antimicrobial products, and biological products. In return, EPA is obligated to perform certain review functions and make regulatory determinations within a specific timeframe.

Suggested Format for an Experimental Use Permit Application

The following format is an example of an acceptable EUP application. Please note that all of the items are not necessary in every case. Depending on whether the product being tested is already registered with EPA, and whether a tolerance is necessary because treated crops will be used as food or feed, several of these entries may not be necessary. See the section earlier in this chapter entitled "Applying for an EUP" for an explanation of what information is required in each of these situations.

Section A

This section should include a data sheet detailing the chemical and physical properties of the test chemical along with a complete statement of the names and percentages by weight of each active and inert ingredient in the formulation to be shipped. The Confidential Statement of Formula, EPA Form 8570-4 can be used for some of this information.

Section B

This section should include a copy of the proposed experimental label. The minimum labeling requirements are set forth in 40 CFR 172.6.

Section C

This section should include toxicity data, including oral and dermal LD50 values, inhalation LC50 values, and eye and skin irritation data for the formulated product, as well as subchronic toxicity, developmental toxicity (one species), mutagenicity, and potentially, chronic toxicity and reproduction data on the active ingredient. Data on the product's toxicity to fish and wildlife may also be included in Section C, as appropriate (40 CFR Part 158) and for antimicrobial pesticides, 40 CFR Part 161).

Section D

This section should include residue data, including, when appropriate, data on: (1) food or feed commodities; (2) nonfood crops such as tobacco; or (3) foliage or other sites where the product may be used and on which remaining residues of the product may pose a risk to humans or the environment. Section D also includes a description of the analytical methods used, a summary of the residue data acquired, and when appropriate, environmental fate data.

Section E

This section should include product performance information demonstrating that the product is useful for the purposes proposed. Because EPA has waived the requirement for submitting efficacy data for all products except those with public health uses, Section E need not contain actual efficacy data, but should include a summary of the results of all efficacy testing performed on the product.

Section F

This section should include a statement explaining whether a tolerance exists or is being requested, especially if the product is to be tested in a manner that may result in residues in food or feed. If a tolerance is being requested, the temporary tolerance petition must be provided with the EUP application. Whenever all food or feed derived from the experimental program is to be destroyed or fed to experimental animals, a statement must be included explaining this.

Section G

The section should include details concerning the proposed experimental program, including:

- qualifications, names, addresses, and telephone numbers of all EUP participants, including cooperators, i.e., persons who grant permission for an experimental use pesticide to be used on application sites they own or control;
- names of states in which the product will be used, along with the amount of active ingredient and acreage (or other appropriate measures) to be used in each state, and the names of states in which the pesticide may be shipped for further distribution;
    - details of the proposed EUP program:
    - types of pests or organisms targeted;
    - the crops, animals, surface, or sites to be treated;
    - the geographical areas where the material is to be used;
    - the use patterns, intended plot sizes, number of plots, number of replicates, and other test parameters to be used;
- information on prior testing:
    - 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 any target organisms at the site of application,
    - phytotoxicity and other forms of toxicity or effects on nontarget plants, animals, and insects, at or near the site of application, or
    - adverse effects on the environment;
- objectives of the EUP program, including a statement specifying the type of data to be collected and the intended gain from conducting the program;

- justification for the quantity (volume) of active ingredient proposed to be used under the EUP, including a statement specifying the various parameters used to determine the quantity of active ingredient;
- a statement proposing a suitable duration for the EUP commensurate with the program objectives; and
- details concerning the method of disposing of unused materials at the conclusion of the testing program.

Extensions or Renewal of Experimental Use Permits

EUPs and associated temporary tolerances are usually issued for a period of one or two years. The permit and any associated temporary tolerances may be extended, renewed, or amended upon written request to the Agency, if circumstances warrant. The written request should include an explanation/justification for requesting the extension/renewal/amendment. Please note that the Agency processing time may, in certain circumstances, be similar to new EUPs. The applicant must request an amendment to an EUP if one or more of the following changes are requested:

- if the EUP was established as a crop destruct, but the applicant seeks to change it to a noncrop destruct;
- if the applicant seeks to reallocate acreage across states or add new states; and
- if the applicant intends to make EUP labeling change

Program Surveillance and Data Reporting Requirements for an Experimental Use Permit

Once the permit is issued and the pesticide testing is under way, the applicant is required to track the results at each test site and submit to EPA within 180 days after the expiration of the permit a final report that shall include (40 CFR 172.8):

- All data gathered during the testing program. Although field notes need not be included in this report, they must be kept available for EPA review upon request.
- A report of how pesticide containers and unused pesticides were disposed of, including the quantity disposed of, disposal sites, and disposal methods.
- The method of disposition of affected food and/or feed.
- In the case where meat-producing animals or birds are treated by or exposed to an experimental use pesticide, the applicant must report the name and location where the animals will be processed to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, DC 20250.

EPA, as well as the state, may require advance notice from the applicant of the intended test dates, sites, and times. The applicant must also allow EPA and state access to the testing site to determine whether the testing complies with the terms and conditions of the permit.

References Cited in Chapter 12

Refer to Chapter 19 for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide registration and classification procedures
- Part 158 - Data requirements for registration
- Part 161 – Data requirements for antimicrobial pesticides
- Part 172 - Experimental use permits
- Part 180 - Tolerances and exemptions from tolerances for pesticide chemicals in food

Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality Protection Act of August 3, 1996

- Section 3 - Registration of pesticides
- Section 5 - Experimental use permits
- Section 33 - Pesticide registration service fees

Federal Food, Drug and Cosmetic Act

- Section 408 - Tolerances and exemptions for pesticide chemical residues

PR Notice 2011-3 - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).