Chapter Five
EXPERIMENTAL-USE PERMIT INSPECTIONS

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AUTHORITY

Section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and 40 CFR 172 of the Regulations (Experimental Use Permits) authorizes experimental-use permit inspections.

The Administrator is authorized to issue an experimental use permit (EUP) after determining that the applicant needs such a permit in order to accumulate information necessary to register a pesticide under section 3.

Section 5(c) states that use of a pesticide under an experimental-use permit shall be under the supervision of the Administrator and subject to the terms, conditions, and periods of time prescribed in the permit.

Section 5 (e) authorizes the Administrator to revoke any EUP, at any time, if he/she finds that the terms or conditions of the permit are being violated or that the terms or conditions are inadequate to avoid unreasonable adverse effects on the environment. (Note: Section 1(j) of FIFRA defines "environment" to include "plant and man and other animals.")

After publication of regulations under section 5(f) and upon approval of the State plan by the Administrator or his/her designee, a State agency designated by the State may issue EUPs.

Unlawful Acts

Under section 12(a)(2)(H), it is unlawful for any person to use any pesticide that is under an EUP contrary to the provisions of such permit.

OBJECTIVES

The objectives of FIFRA section 5 investigations are to (1) determine whether the terms and conditions of the permit are

adequate to avoid unreasonable adverse effects on the environment; and (2) determine whether the terms and conditions of the permit are being met.

RESPONSIBILITY

The Office of Pesticide Programs (OPP), EPA

The Registration Divisions (Antimicrobial Division, Biopesticides and Pollution Prevention Division, and the Registration Division) review and evaluate applications for experimental use permits and approve, issue, or disapprove such permits. The OPP also has the responsibility and final authority to take such action as necessary to modify or revoke a permit, if warranted.

OPP will furnish a copy of each EUP, the accepted label, names of the participants, and terms of the program to the region where the pesticide testing will occur.

States may conduct EUP Inspections under cooperative enforcement agreements.

EPA Regional Offices

The regional office is responsible for supervision, on a selected basis, of the experimental uses conducted in its region. State agencies participating in cooperative enforcement agreements may conduct EUP inspections. Procedures will be the same as for EPA unless modified by grant agreements or regional policy. Before undertaking an experimental use surveillance program, the region should contact the region where the home office of the permittee is located to determine whether the permit has been previously monitored. This does not preclude any region from surveying experimental use within that region but rather seeks to avoid over surveillance of widely distributed experimental chemicals.

Each regional office will establish its own supervision schedule based on the following list of priorities:

< Permits for pesticides that are completely new classes of compounds (e.g., juvenile hormones).

< Permits for chemicals with special potential hazards to humans or the environment, such as:

- Highly toxic products
- Products with propensity to drift
- Products with high terrestrial or aquatic mobility
- Products of a particularly persistent nature

< Permits for chemicals with previously registered uses that were subject to adverse action by EPA.

< Permits for chemicals manufactured by companies that have a history of noncompliance, inadequate supervision, or other indications of problems.

- Permits for those chemicals that may potentially have a widespread major use (e.g., chemicals that will replace a major pesticide which has been canceled by the Agency).
- Any other permits for which the Office of Pesticide Programs (OPP) or the Office of Enforcement and Compliance Assurance (OECA) has requested special information or monitoring.

Review and become familiar with the requirements of the EUP.

Upon learning of the names of the participants in the experimental program, the regional office or State may contact those persons responsible for the test program to obtain further details of the program (i.e., dates, times, sites, etc). Such persons would include sales representatives and field representatives. In addition, the regional office or State may contact the permittee for additional details regarding the program, if necessary, to expedite the monitoring of the permit.

CONDUCTING THE EUP INSPECTION

The inspector must obtain and review a copy of the specific EUP and its accepted label. EUPs may allow a product registered under section 3 to be used for experimental use. The inspector should be aware that the EUP label can permit application rates or frequencies of use that exceeds the rate or frequency on the section 3 accepted product label. Take a copy of the EUP and label on the inspection for reference. The following items must be checked for compliance with the provisions of the permit in addition to any specific instructions issued by the Regional office:

- The labels on the containers and accompanying literature must be the same as the accepted label and labeling.
- The products must be applied in accordance with the label directions, precautions, and terms of the permit.
- If testing activities are taking place, such activities must be supervised by a representative of the permittee.
- The inspector should check for evidence of adverse effects (e.g. worker complaints, signs of plant/crop damage from the application of non-herbicides, etc.).
- If evidence of adverse effects are observed, the inspector should ask for documentation to prove that EPA Headquarters has been notified of this adverse effect.
- The amount of pesticide sold or provided.
- The quantities of product shipped and/or received.
- The shipments have been made to designated participants only.
- The disposition of food or feed that is not covered by a tolerance.

- The disposition of the unused pesticide in accordance with permit instructions.

In certain instances, follow-up may be required to verify crop rotation, crop destruction, grazing restrictions, etc.

Adverse Effects

The following adverse effects must be documented and reported to EPA:

- Accidents observed or claimed.
- Non-target animal or bee kills (domestic or wild).
- Phytotoxicity to non-target plants (in or out of the target site).
- Unique problems with handling, preparing, mixing, or applying the pesticide.
- Other complaints.

REPORTING

The inspector must submit a written report to the Regional office (or State office, if appropriate) on all permits monitored. The report must cover all items previously mentioned, in addition to any inspection requested by headquarters or the Regional office. If follow-up inspections are conducted to verify (1) crop rotation, (2) crop destruction, and (3) grazing restrictions, etc., submit a report covering all items previously mentioned in addition to any points requested by the Regional office.

If it appears that the terms of the permit have been violated, the inspector must document evidence to prove the violation. Photographs, affidavits or statements, and samples showing the manner in which the terms of the permit are being violated must be obtained. Physical samples should be collected in consultation with the Regional office. The inspector must immediately report any suspected violation to the Regional or State office to determine what follow-up action may be required.