Armed Forces Pest Management Board
Technical Guide No. 22

Guidelines for Testing Experimental Pesticides on DoD Property

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Acknowledgements

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Foreword

This Technical Guide (TG) was developed as guidance to be used when designing and conducting research with experimental pesticides on Department of Defense property. The Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC 20460 has reviewed the information in this TG.

DoD Components are encouraged to adopt the information contained herein as guidance when use of experimental pesticides on DoD property is contemplated.

1. Introduction

The purpose of these guidelines is to highlight actions that should, or must, be taken when designing and conducting research with experimental pesticides on Department of Defense (DoD) property. This guidance is to ensure that researchers and project managers involved in pesticide investigations are familiar with the applicable legal requirements not only of DoD, but also of other federal and state agencies.

2. Applicable Laws and Regulations

Researchers and project managers must become familiar with all applicable laws and regulations during the design and evaluation phases of a project. Some of the most important regulations are listed in Appendix l of these guidelines. Components will comply with all applicable documents.

3. Discussion

An experimental use permit (EUP) is generally required for testing of any unregistered pesticide or any registered pesticide being tested for an unregistered use. EUPs will frequently be required in order to test experimental pesticides on DoD property. In some situations, however, the test site conditions are sufficiently small to allow the researchers to be exempt from filing an EUP. Applicators or cooperators should be reminded that no treated food or feed crops may be consumed in the absence of a tolerance or exemption, regardless of program size. Each of the following subsections cover the probable situations for testing experimental pesticides on DoD property.

3-1. Exemptions

3.1.1. Experimental use permits are <u>not</u> required in the following situations (40 CFR, Part 172.3):

3.1.1.1. Substance or mixture of substances tested in the laboratory, greenhouse or limited replicated field trials in which the purpose is to determine the pesticide potential efficacy, toxicity or other properties, and from which the producer, applicator or any other person conducting the test does not expect to receive any benefit in pest control from its use. This purpose will be presumed for the following types of tests:

- Tests conducted on a cumulative total of 10 acres or less for the evaluation of a particular substance or mixture of substances against a particular pest, **except that**:

- - 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.

- - Any food or feed crops involved in or affected by such test shall be destroyed or consumed only by experimental animals unless appropriate tolerance or exemption from a tolerance has been established under the Federal Food and Drug Control Act for residues of the pesticide.

- Tests conducted on water of a surface acre or less involving use of a particular substance or mixture of substances against a particular pest, **except that**:

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

- - Waters that are involved or affected by such tests will not be used for irrigation purposes, drinking water supplies, or body contact recreational activities.

- - Tests may not be conducted in waters that contain, or that affect any fish, shellfish, or other plants or animals taken for recreation or commercial purposes and used for food or feed, unless a tolerance or exemption from tolerance has been established.

- Tests on experimental animals. These animals may not be tested if they are used in food or feed, unless a tolerance has been established and is adhered to.

- Substances or mixtures of substances being put through tests for the sole purpose of gathering data required for approval of such substances or mixture under the Federal Food, Drug and Cosmetic Act (21 USC 301 et seq.) as:

- - "New Drug"

- - "New Animal Drug"

- - "Animal Feed"

[This paragraph shall not apply when a purpose of such test is to accumulate information necessary to register the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3.]

3.1.2. Review/Approval Process: Cognizant pest management consultants should review and approve any use of experimental pesticides not requiring EUPs.

3.2. Evaluation of an Experimental Pesticide on DoD Property for Which an EPA Experimental Use Permit Has Been Obtained by the Manufacturer.[1]

3.2.1. Members of the pesticide industry will occasionally approach DoD elements to utilize DoD property or personnel in order to evaluate a pesticide for which the manufacturer is planning to obtain an EUP from EPA for testing nationwide.

[1] Manufacturer is construed to mean a basic producer of a pesticide or a producer's agent.

3.2.2. Review/Approval Process:

3.2.2.1 The manufacturer should send the cognizant pest management consultant background information on the pesticide's toxicity (particularly for mammalian and nontarget aquatic/marine species).

3.2.2.2. Cognizant pest management consultants should coordinate with installation environmental/natural resources personnel to avoid application in areas where endangered or threatened species are known to exist. (Note: Preparation of an environmental assessment should be strongly considered when an experimental pesticide is applied in environmentally sensitive areas, even when endangered or threatened species are not present.)

3.2.2.3. The pest management consultant should coordinate the EUP with appropriate legal offices which may frequently require pesticide manufacturers to enter into hold harmless agreements with the government before an experimental pesticide is tested on DoD property. A sample hold harmless agreement is provided as Appendix 2.

3.2.2.4. Personnel conducting the test must strictly follow the specific EUP protocol approved by EPA for the particular pesticide being tested in order to avoid violating 40 CFR, Part 172, and FIFRA, Section 5.

3.2.2.5. Personnel conducting the test must provide a report of findings to the cognizant pest management consultant, the Armed Forces Pest Management Board, and the manufacturer. A copy of the EUP shall become an appendix to the installation pest management plan.

3.3. Evaluation of an Experimental Pesticide on DoD Property for Which a State Experimental Use Permit Has Been Obtained by the Manufacturer.

3.3.1. DoD elements will also occasionally be approached by the pesticide industry to evaluate a pesticide for which the manufacturer has already obtained an EUP from a state for testing in that particular state.

3.3.2. Review/Approval Process: The same review/approval process will be used in this situation as for EUPs obtained from EPA (Paragraph 3.2., above.)

3.4. Evaluation of Experimental Pesticides for Which DoD/Component Is Obtaining the Experimental Use Permit.

3.4.1. DoD has not yet applied for an EUP at the national or state level. However, there are conceivable situations where this might occur.

3.4.2. It is presumed that pest management consultants and/or the AFPMB Research Liaison Officer will assist in coordination of EUPs initiated by DoD or its components.

3.4.3. Review/Approval Process:

3.4.3.1. Determine test sites, duration, target pests, and participants in evaluations.

3.4.3.2. Submit EUP application in triplicate to: Office of Pesticide Programs, EPA, Washington, DC 20460 as far in advance of test as possible (40 CFR, Part 172.5). Application must contain:

- General requirements. This constitutes the most tedious part of the EUP, involving submission of registration number for compound (if available), address/phone numbers of participants, target pest, target site, dosage rates, mode of action, method of application, disposal procedures, and toxicity to nontarget organisms. EUP applications must list the total size of the programs (acreage to be treated and amount of chemical to be applied). Three copies of the draft labels should also be included.

- Tolerance/exemption data if pesticide is to be used on food or feed, or certification that the food will be destroyed in a manner that will not endanger humans or the environment.

- Confidential data on formulation and physical/chemical properties of the pesticide if it has not yet been registered.

3.4.3.3. Components are encouraged to send EUPs to the AFPMB (Pesticides Committee) for review prior to submittal to EPA. However, an information copy of the EUP submitted to EPA shall be sent to the AFPMB.

3.4.3.4. EPA will normally issue an EUP for a one-year period (40 CFR, Part 172.5). If more time is needed, DoD must request a longer test period, or be prepared to submit a renewal application (40 CFR, Part 172.9). Requirements for renewal are the same as for a new EUP (40 CFR Part 172.4).

3.4.3.5. Submit a final report no later than 6 months after expiration of the EUP.

3.5. Experimental Pesticides Evaluated on Humans or Animals on DoD Property.

3.5.1. DoD periodically tests experimental pesticides on humans and other animals. Applicable DoD and Component regulations must be adhered to, as well as the guidance set forth in FIFRA, Section12(a)(2)(P) and the Federal Policy for the Protection of Human Subjects, dated November 10, 1988, 56 FR 28002-280032 and October 2, 1996, 61 FR 51491-51531.

3.5.2. Review/Approval Process: Every time DoD evaluates an experimental pesticide, the potential exists that the project will be unique, precluding formulation of any guidelines to address the situation. However, previous work done for DoD in this research area suggests that the following review process may be applicable in many instances:

3.5.2.1. Policies concerning the coordination of biological and toxicological testing of pesticides involving human volunteers are outlined in a Memorandum of Understanding between the USACHPPM, USAMEDCOM, DAOTSG, AFPMB and the USDA (see Appendix 1 for full title).

3.5.2.2. Submit application (including the testing protocol and available toxicological screening data from USACHPPM or analogous facility) to the appropriate Office of the Surgeon General, or Office of Naval Research, which reviews use of investigational drugs in humans or animals (AFIJ 40-401, AFIJ 40-402, AFIJ 40-403, AR 40-7, and SECNAVINST 3900.39B).

3.5.2.3. After approval of the application to test the experimental pesticides on humans and/or test animals, obtain written consent statements when using volunteers, as specified in AFIJ 40-401, AFIJ 40-402, AFIJ 40-403, AR 70-25, and SECNAVINST 3900.39B.

Appendix 1

Regulations Affecting the Testing of Experimental Pesticides on DoD Property

1. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as Amended by the Food Quality Protection Act (FQPA), August 3, 1996, 7 U.S.C. §§ 136 et seq.

2. 40 CFR - Protection of Environment; Part 172, Experimental Use Permit.

3. AR 200-2, Environmental Effects of Army Actions, 23 Dec 88.
   AR 200-5, Pest Management, 29 Oct 99.
   AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, 4 Jan 91.
   AR 70-25, Use of Volunteers as Subjects of Research, 25 Jan 90.

4. AFI 32-7061, Environmental Impact Analysis Process (EIAP), 10 Aug 82.
   AFIJ 40-401, The Use Of Animals In DoD Programs, 1 Jun 84.
   AFIJ 40-402, Using Human Subjects in Research, Development, Test, and Evaluation, 19 Jul 94.
   AFIJ 40-403, Clinical Investigations In Medical Research Guidance And Procedures, 19 May 94.

5. SECNAVINST 3900.39B, Protection of Human Subjects, 27 Feb 84.

6. Memorandum of Understanding among the United States Army Medical Command, and the Department of the Army, Office of the Surgeon General, and the Department of the Navy, Office of the Surgeon General, and the Armed Forces Pest Management Board, and the United States Department of Agriculture, Agricultural Research Service. SUBJECT: Biological and Toxicological Testing of Pesticides. Effective 29 April 1996.

Appendix 2

Hold Harmless Agreement [Sample]

1. Pesticide evaluations are conducted for the sole purpose of evaluating the capability of particular item(s) and not for fulfilling mission requirements in an interim time frame. The examination and evaluation of item(s) will in no way, expressed or implied, obligate the government to purchase, rent, or otherwise procure the item(s) evaluated. Manufacturers[1] shall have sole responsibility for furnishing all equipment, supplies, and other aids necessary to accomplish the evaluation. Manufacture, transportation, maintenance, and evaluation of items are accomplished without cost to the government. An authorized representative of the manufacturer furnishing the item(s) for evaluation conducts the evaluations. Personnel will not endorse the manufacturer's product. The government will exercise due care in handling item(s) being evaluated. The government assumes no cost or obligation, expressed or implied, for damage to, destruction of, or loss of such equipment, or for damages or injuries resulting from the submission to the government of defective item(s) for examination.

2. It is understood that acceptance for test evaluation for potential usefulness to the government does not imply a promise to pay, a recognition of novelty, originality, uniqueness, or a contractual relationship such as would render the government liable to pay for any use of information to which it would otherwise be entitled. The government has no intention of using any article or disclosure in which the submitter has established property rights, without proper compensation, and no use during test or evaluation shall establish any basis for such compensation. The manufacturer will not file any claim against the government or otherwise seek compensation for any information or services provided.

3. The manufacturer agrees to indemnify and hold harmless the government, its agents, and employees from any and all claims or causes of action of whatsoever kind as may be incident to or arise from the government's acceptance of and its participation in the test and evaluation of any article covered by this policy agreement.

4. The manufacturer of any article or articles for evaluation will furnish instructions to the government for disposal of such articles prior to completion of the test or evaluation. Any disposal in accordance with such instructions shall be at the expense of the manufacturer. Disposal will comply with applicable federal and state environmental laws.

5. In the event that the government decides to procure the item(s) tested and/or evaluated, the manufacturer will provide new articles unless the government specifically elects otherwise.

[1] Manufacturer is construed to mean a basic producer of a pesticide or a producer's agent.

6. The articles submitted will be handled in accordance with established government procedures for safeguarding such articles against unauthorized disclosure. The manufacturer agrees that any liability by reason of unauthorized disclosure by the government will not extend beyond the actual damage to the manufacturer caused by acts of the government.

7. Reports covering the results of evaluations or tests will be furnished to the manufacturer upon request. Such reports shall not be construed as an endorsement of articles by the government, nor shall they be used in whole or in part for advertising purposes or sales promotion.

8. The acceptance of articles for evaluation or testing is not to be construed in any way as an acceptance or offer to accept such articles for government use, nor is it to be construed as any promise implied or otherwise that any contract or purchase is to follow from the evaluation, test, or demonstration as the case may be.

9. The terms of the agreement shall apply to the articles listed below, and shall also apply to all articles submitted hereafter until this agreement is terminated in writing by either party or by date of expiration.

Period of this agreement: _____

Description of services to be provided: _____

_____

10. Any data provided as a result of this evaluation or submittal for testing shall be available at no cost to the government for use as necessary, and the manufacturer shall acquire no proprietary interest in such data.

I_____, certify that I have read the agreement set forth above and understand and agree to the terms and conditions thereof. I further certify that I am ( ) sole owner of all articles and disclosure submitted for evaluation or testing; ( ) a member of the partnership or association known as and have full authority to bind said corporation.

_____
(Signature of Manufacturer/Agent)

_____
(Signature of Chief/Deputy Chief, Contracting Division)

_____
(Typed Name)

_____
(Address)

_____
(City, State, and Zip Code)

_____
(Date)