Armed Forces Pest Management Board
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Guidelines for Testing Experimental Pesticides on DoD Property

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ARMED FORCES PEST MANAGEMENT BOARD
TECHNICAL GUIDE NO. 22, Guidelines for Testing Experimental Pesticides on DoD Property

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ACKNOWLEDGEMENTS

This Technical Guide (TG) was initially prepared by the Armed Forces Pest Management Board (AFPMB) Ad Hoc Committee on Experimental Use Permits. Participating Pesticide Committee Members included: Maj George K. Pratt, USAF; LTC Marvin A. Lawson, USA; and CDR Frederick J. Santana, USN. It was originally published in November 1983. It was last updated in September 2000 by Mr. Ken Olds, and reviewed by the Pesticides Committee membership, to include the AFPMB-EPA Liaison, Ms. Linda Arrington. Final technical review, editing and reformatting was performed by DPMIAC staff: CDR George W. Schultz, USN; LTC Richard N. Johnson, USA; Capt Daniel J. Mauer, USAF; 1st Lt Jessica Finkelstein, and Dr. Richard G. Robbins. The current updated document was revised and edited from November 2022 through January 2023 by LT Adam Salyer, USN and MAJ Donald A. Beasley, USA. The final edited document was then reviewed and approved by the AFPMB Research, Development, Testing and Evaluation Committee membership in February 2023.

FOREWORD

This 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 (EPA), 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 1 of this TG. Components will comply with all applicable documents.

3. DISCUSSION

Per 40 CFR, Part 172.3, an Experimental Use Permit (EUP) is generally required for testing of any unregistered pesticide, or any registered pesticide being tested for an unregistered use. The following subsections cover exemptions and probable situations for testing experimental pesticides on DoD property.

3.1. Exemptions. EUPs are not required in the following situations:

3.1.1. The experimental use of the pesticide is limited to laboratory, greenhouse, or limited replicated field trials in which the purpose is to determine the potential efficacy, toxicity, or other properties, and from which the producer, applicator, or any other person conducting the evaluation does not expect to receive any benefit in pest control from its use.

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

3.1.2.1. 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 the target pests.

3.1.2.2. Any food or feed crops involved in, or affected by, such tests (including, but not limited to, crops subsequently grown on such land which may reasonably be expected to contain residues of the tested pesticides) shall be destroyed or consumed only by experimental animals unless an appropriate tolerance or exemption from a tolerance has been established under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 USC 301 et seq.) for residues of the pesticide.

3.1.3. Tests conducted on water of 1 surface acre or less for the evaluation of a substance or mixture of substances against a particular pest, except that:

3.1.3.1. When testing for more than one target pest occurs at the same time and in the locality, the 1-surface acre limitation shall encompass all target pests.

3.1.3.2. Waters which are involved in or affected by such tests are not used for irrigation purposes, drinking water supplies, or body contact recreational activities.

3.1.3.3. Testing shall not be conducted in any waters which contain or affect fish, shellfish, plants, or animals taken for recreation or commercial purposes and used for food or feed, unless a tolerance or exemption from a tolerance has been established under the FFDCA (21 USC 301 et seq.) for residues of the pesticide.

3.1.4. Tests conducted only on experimental animals which will not be used for food or feed unless an appropriate tolerance or an exemption from a tolerance has been established for animal products and byproducts under the FFDCA (21 USC 301 et seq.) for residues of the pesticide.

3.1.5. 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 FFDCA (21 USC 301 et seq.) as a “new drug”, “new animal drug”, or “animal feed”.

3.1.6. 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 FFDCA (21 USC 301 et seq.) as a “new drug”, “new animal drug”, or “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 (7 USC 136 et seq.).]

3.1.7. Command pest management consultants should be given the opportunity to review all plans for experimental pesticides, including usages not requiring EUPs.

3.2. Evaluations Conducted Under an EPA EUP Obtained by the Manufacturer.

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

3.2.2. Review and Approval Process:

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

3.2.2.2. Command 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 a Hold Harmless Agreement (HHA) with the government before an experimental pesticide is tested on DoD property. A sample HHA is provided as Appendix 2.

3.2.2.4. Personnel conducting the test must strictly follow the specific EUP protocol approved by the EPA for the experimental pesticide being tested to avoid violating 40 CFR, Part 172, and FIFRA, Section 5 (7 USC 136 et seq.).

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's Integrated Pest Management Plan.

3.3. Evaluations Conducted Under a State EUP Obtained by the Manufacturer.

3.3.1. Members of the pesticide industry will occasionally approach DoD elements to utilize DoD property or personnel to evaluate an experimental pesticide for which the manufacturer is planning to obtain an EUP for testing in a particular state.

3.3.2. Review and Approval Process: The same review/approval process will be used in this situation as for EUPs obtained from the EPA (Paragraph 3.2.2. above).

3.4. Evaluations Conducted Under an EUP Obtained by the DoD or Component.

3.4.1. The DoD has not yet applied for an EUP at the federal 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 and Approval Process:

3.4.3.1. Determine participant(s), test site(s), target site parameters, test duration, target pest(s), toxicity to nontarget organisms, dosage rates, method(s) of application, experimental pesticide formulation, chemical and physical properties, tolerance data (if experimental pesticide is to be used on food or feed), and other information and documents you will need for the application.

3.4.3.2. Components are encouraged to send EUP applications to the AFPMB

(Research, Development, Testing and Evaluation Committee) for review prior to EPA, or State agency, submittal and maintain communication throughout the process.

3.4.3.3. Directions for the EPA EUP application process can be found here: https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit

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

3.4.3.5. The EPA will normally issue an EUP for a 1-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).

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

3.4.3.7. Check with the respective State agency for their application requirements.

3.5. Evaluations Conducted on Humans or Animals.

3.5.1. The DoD periodically evaluates experimental pesticides on humans and other animals. Applicable DoD and component regulations must be adhered to, as well as the law set forth in FIFRA, Section12(a)(2)(P) (7 USC 136 et seq.), and the Federal Policy for the Protection of Human Subjects (40 CFR, Part 26).

3.5.2. Review and 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 Army Public Health Center (APHC), United States Army Medical Command (USAMEDCOM), Department of the Army Office of the Surgeon General (DAOTSG), AFPMB, and the United States Department of Agriculture (USDA) (see Appendix 1 for full title).

3.5.2.2. Submit application (including the testing protocol and available toxicological screening data from APHC 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 (AFMAN 40-401, 59MDWI 40-402, AR 40-7, and SECNAVINST 3900.39E).

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 AFMAN 40-401, 59MDWI 40-402, AR 70-25, and SECNAVINST 3900.39E.

APPENDIX A. REGULATIONS

1. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as Amended Through Public Law 112–177, 7 U.S.C. §§ 136 et seq. (2017).

2. Federal Food, Drug, and Cosmetic Act, as Amended Through Public Law 115-52, 21 U.S.C. §§ 301 et seq. (2017).

3. Experimental Use Permits, as Amended at 73 FR 75599, 40 C.F.R. §§ 172 et seq. (2008).

4. Protection of Human Subjects, as Amended at 82 FR 7273 40 C.F.R. §§ 26 et seq. (2017).

5. AR 200-1, Environmental Protection and Enhancement, 13 December 2007.

6. AR 40-7, Use of U.S. Food and Drug Administration-Regulated Investigational Products in Humans Including Schedule I Controlled Substances, 19 October 2009.

7. AR 70-25, Use of Volunteers as Subjects of Research, 25 January 1990.

8. 45SWI 32-7002, Environmental Impact Analysis Process (EIAP), 28 March 2018.

9. AFMAN 40-401, The Care and Use of Laboratory Animals in DoD Programs, 20 October 2022.

10. 59MDWI 40-402, Animal Care and Use in Clinical Investigations, Training, Research and Development, 15 September 2022.

11. SECNAVINST 3900.39E, Human Research Protection Program, 29 May 2018.

12. 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.

[Policy Agreement Number]

APPENDIX B. 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. Manufacturers1 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.

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

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.

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)