



DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000



REPLY TO
ATTENTION OF

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
AGRICULTURE RESEARCH SERVICE

SUBJECT: Biological and Toxicological Testing of Pesticides

1. Purpose. The purpose of this Memorandum of Understanding (MOU) is to outline responsibilities, provisions, and coordination involving evaluation of candidate repellents and other pesticides which are of mutual interest to the agencies listed herein.
2. References.
 - a. Title 31, United States Code (USC), Section 1535, Agency Agreements.
 - b. Title 31, USC, Section 6305, Using Cooperative Agreements.
 - c. Title 21, Code of Federal Regulations (CFR), Part 58, Good Laboratory Practice for Non-clinical Laboratory Studies.
 - d. Title 32, CFR Part 219, Protection of Human Subjects
 - e. Title 40, CFR, Part 160, Good Laboratory Practice Standards.
 - f. Title 45, CFR, Part 46, Promotion of Human Subjects
 - g. Title 7, USC, Section 136 et. seq. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
 - h. Department of Defense (DOD) Directive 3216.1, 17 April 1995, Use of Laboratory Animals in DOD Programs.
 - i. DOD Directive 3216.2, 7 January 1983, Protection of Human Subjects in DOD Supported Research, with change 1, 31 January 1983 and change 2, 20 July 1983.

SUBJECT: Biological and Toxicological Testing of Pesticides

j. DOD Directive 4000.19, 9 August 1995, Interservice and Intragovernmental Support.

k. Memorandum, Office of the Secretary of Defense, June 1993, subject: DOD Guidance for Assurance of Compliance with the Federal Policy for the Protection of Human Subjects.

l. AR 5-16, 21 August 1985, Army Supplement to Defense Regional Interservice Support Regulation (DOD 4000.19R).

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

n. AR 70-18, 1 June 1994, The Use of Animals in DOD Programs, with Change 1, 1 August 1984.

o. Master MOU, 3 July 1992, between DOD and the U.S. Department of Agriculture (USDA), subject: Cooperation with Respect to Food, Agriculture, Pest Management, Nutrition and Other Research of Mutual Interest.

p. OTSG Reg 15-2, 11 March 1986, Human Subjects Research Review Board (HSRRB).

q. Department of Health and Human Services, U.S. Public Health Service, National Institutes of Health Publication No. 86-23, 1986, Guide for the Care and Use of Laboratory Animals.

r. USDA/Agriculture Research Service Directive 605.1 19 September 1986, Protection of Human Subjects.

s. Toxicity of Candidate Arthropod Repellents. Appraisal of the Armed Forces Topical Hazard Evaluation Program. Committee on Toxicology, National Research Council. National Academy Press, Washington D.C. 1987.

t. Policy and Procedures for Evaluating Candidate Repellents. Armed Forces Pest Management Board, February 1992.

3. Problem. The military services require safe, effective methods to protect forces from vector-borne disease during field operations. Chemoprophylaxis and vaccines are not available for many vector-borne diseases. Thus, field forces must rely on repellents and other vector control strategies for protection. However, standard repellents and toxicants do not provide optimum protection against all disease vectors and have other documented deficiencies that limit their effectiveness.

SUBJECT: Biological and Toxicological Testing of Pesticides

4. Scope. This MOU includes provisions of human subjects, funding, publication of results, and coordination among the cooperating parties. Specific procedures to be followed and conditions of testing will be outlined in procedural guides and protocols prepared by each operating agency and regularly updated to maintain compliance with federal regulations and implementing agency directives. Copies of applicable procedural guides and protocols will be provided to the Executive Director, Armed Forces Pest Management Board (AFPMB) within 60 days of official agency approval for review and distribution.

5. Agreements

a. General.

(1) Projects of immediate concern to each operating agency will, when necessary, take priority over testing described in this MOU.

(2) All testing involving human subjects or laboratory animals will be conducted in accordance with the applicable regulations, directives and guidelines governing such testing.

b. Responsibilities

(1) The USDA Insect Chemical Ecology Laboratory will synthesize candidate repellents or other pesticides for biological and toxicological testing.

(2) The USDA Medical and Veterinary Entomology Research Laboratory (MAVERL) will evaluate candidate compounds for biological efficacy. Tests with volunteers will comply with the provisions for human subjects as stated in 5c, below, of this MOU. Tests will not involve direct human contact with the compound until toxicological clearance of the specific compound for skin testing and approval by the AFPMB.

(3) The U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM) will evaluate candidate compounds using standard toxicological procedures (reference 2c, above) to determine each compound's suitability for further testing and to provide data on potential hazards that might be expected from proposed uses. For each compound, the CHPPM will recommend toxicologic clearance or nonclearance for human testing to the AFPMB and testing agencies.

SUBJECT: Biological and Toxicological Testing of Pesticides

(4) The U.S. Army Medical Research and Materiel Command will conduct basic research on mechanisms of repellency of insect/arthropod repellents as well as in vitro and in vivo efficacy testing in the laboratory and field against vectors and pests of military medical importance. Candidate compounds tested will have successfully cleared advanced toxicological evaluation and efficacy testing by the CHPPM and MAVERL. Tests involving human subjects will comply with the human subjects provisions as stated in 5c, below, of this MOU.

(5) The U.S. Navy will conduct efficacy testing against vector and pest species of military medical importance, with emphasis on species not endemic to the United States. Candidate compounds tested will have successfully cleared advanced toxicological evaluation and efficacy testing by the CHPPM and MAVERL. Tests involving human subjects will comply with the human subjects provisions as stated in 5c, below, of the MOU.

(6) For unsolicited materials, the submitter must comply with reference 2t, above, and provide at no cost to the U.S. Government, sufficient test material(s) to conduct additional field or laboratory testing as may be deemed necessary by the agency involved.

(7) The AFPMB will coordinate all aspects of this MOU among the participating agencies and will evaluate unsolicited requests for product testing from individuals or commercial organizations. The AFPMB will assist with interservice coordination on testing of candidate repellents and toxicants as needed and maintain records on the status of the compounds.

c. Human Subjects

(1) Safeguarding the rights and welfare of human subjects participating in tests conducted by the USDA and/or Department of the Army or Department of the Navy or supported by one of these departments is the responsibility of the department conducting the tests and any party responsible for projects sponsored by that department. All such studies must protect the rights and welfare of volunteers; assure that risks to the subjects do not outweigh potential benefits or the expected value of the knowledge sought; and, assure that each person receives in writing information of the testing that is adequate and appropriate for the individual, and by means of which he/she may

SUBJECT: Biological and Toxicological Testing of Pesticides

give a free and knowing informed consent. In conducting such tests with humans, the appropriate standards as set forth in federal regulations and agency directives concerning the use of human subjects in research will be followed, with strict adherence to the intent, policy, and formalized procedures described therein.

(a) Prior to initiation of testing by the USDA involving the use of human subjects, written protocols of studies to be conducted must be reviewed and approved by a properly constituted Institutional Review Board (IRB), as described in paragraph 2f, above, and the USDA Agricultural Research Service (ARS) Human Studies Review Committee as described in the paragraph 2r, above. The IRB shall include in its written review a statement of the level of risk to human subjects and adequacy of consent standards and shall provide recommendations, as appropriate, to the Administrator, ARS, USDA or his officially designated representative. The Administrator, or his representative, shall verify in writing the decisions reached by the IRB. Extramural studies funded by the USDA in support of this MOU but not involving USDA facilities or personnel shall not start until the USDA has received written assurance from the extramural organization conducting the study that an IRB has reviewed and approved the protocol.

(b) As stated in reference 2m, above, The Surgeon General, U.S. Army, has responsibility for protection of the rights and welfare of human subjects used in tests conducted by the Army Medical Department. The Surgeon General's Human Subjects Research Review Board (HSRRB) will review written protocols of study and consent standards involving proposed use of volunteers. The Surgeon General or his officially designated representative shall verify in writing the decision reached by the HSRRB as required by reference 2p, above.

(2) In all projects covered by this MOU, selection of persons or groups for study shall be made without regard to sex, race, color, religion, or national origin unless these characteristics are factors to be evaluated in the testing. Any investigator planning a project that involves evaluation of these characteristics as factors must provide specific justification and clearly state the objective of the study in his/her project statement. The responsible agency must approve of such plans in writing before testing is initiated. Appropriate documentation shall be kept when a test includes members of minority groups selected for the study because of their minority status.

SUBJECT: Biological and Toxicological Testing of Pesticides

(3) Studies conducted under this MOU will not use pregnant or lactating women, individuals who are allergic to insects or chemicals, minors, prisoners (to include prisoners of war and detainees), or individuals who are impaired to the extent that they are unable to provide informed consent.

d. Funding.

(1) This MOU does not constitute a financial obligation to serve as a basis for expenditures. Each party shall budget, manage, and expend its own funds in support of this MOU. All expenditures from federal funds by the USDA in conformity with this MOU must be in accordance with USDA rules and regulations and in each instance based upon appropriate financial management. Expenditures made by Department of Defense or Department of the Army or Department of the Navy organizations will be in accordance with applicable rules, regulations, and policies, and in each instance based upon appropriate financial management.

(2) Testing in support of a military service-unique requirement or to meet nonrecurring special needs may be undertaken on a reimbursable basis when specifically authorized by the appropriate DOD, DA, or DN fund obligating authorities. In such cases, the USDA will submit a voucher to the authorized agent of the cooperating party for reimbursement of expenditures specific to the agreed upon project.

(3) The responsibilities assumed by the cooperating parties for projects covered by this MOU are limited to the available funding from which expenditures legally may be made

e. Publication.

(1) Any party to this agreement shall be free to use in official correspondence any of the results obtained in studies conducted under this MOU, provided that due credit is given to the other participating parties. No party will publish in open literature, or present at a scientific meeting, results from a cooperative study without first consulting the participating organizations. Joint publication is encouraged, but any party may publish data collected under this MOU after due notice and submission of the proposed manuscripts to the others. In such instances, the party publishing the data will assume full responsibility for the data and interpretations of results in the publication. Results on testing of proprietary materials will be reported only as prescribed in applicable procedural guides and protocols.

SUBJECT: Biological and Toxicological Testing of Pesticides

(2) It is the responsibility of each co-authoring party to obtain clearance or approval to publish a manuscript in accordance with the current regulations and policies of its organization.

f. Coordination. Liaison meetings among all participating organizations shall be scheduled as required, but not less than once annually. These meetings may be in conjunction with scheduled AFPMB meetings or reviews as funding permits. Liaison meetings will provide an opportunity to review the status of requests for specific research and make recommendations. With the concurrence of the AFPMB council, requests and recommendations will be forwarded to the participating agencies through their appropriate channels.

6. Effective date.

a. This MOU shall be in effect upon the date of final signature of the approving authority for each party and shall remain in effect until superseded or terminated by any of the concerned parties by written request with 120 calendar days' notice.

b. This agreement may be amended by mutual agreement among the parties. Amendments to add or update references or make other minor modifications, deletions, additions shall be made by correspondence among all concerned parties and shall not require a new agreement unless specifically requested by one of the participating parties. Proposals to amend the MOU shall give at least 60 calendar days' notice for review by all parties.


SUBJECT: Biological and Toxicological Testing of Pesticides



ALCIDE M. LANOUE
Lieutenant General
The Surgeon General, U.S. Army/
Commander, U.S. Army Medical Command

25 OCT 1995

Date



F. G. SANFORD
Rear Admiral, MC
Assistant Chief, Operational
Medicine and Fleet Support, U.S. Navy

21-2-195



for FLOYD P. HORN
Administrator
Agricultural Research Service
U.S. Department of Agriculture

29 Apr 96

Date



SHERRI W. GOODMAN
Deputy Under Secretary of Defense
(Environmental Security)

1/17/96