

APHIS DIRECTIVE 120.1
6/06/77

RESEARCH EVALUATION OF AGRICULTURAL CHEMICALS

I. PURPOSE

To state policy and procedures for obtaining research evaluation on chemicals produced by individual or company suppliers.

II. POLICY

APHIS will follow the procedures contained in ARS AM 120.4, when conducting research on agricultural chemicals.

III. AUTHORIZED REPRESENTATIVES

Officials designated to serve as ARS Authorized Representatives will also serve as APHIS Authorized Representatives. APHIS scientists should send ARS Forms 409, Cooperative Research Evaluation of Chemicals, and ARS Forms 410, Request for Extension of Period of Confidence, to the appropriate Representative through established Agency channels.

Signed by:

T. MULHERN

Attachment

(1) ARS AM 120.4, Cooperative Research Evaluation of Chemicals
Potentially Beneficial to Agriculture

ARS AM 120.4
ISSUE DATE 08/01/75

COOPERATIVE RESEARCH EVALUATION OF CHEMICALS POTENTIALLY BENEFICIAL TO
AGRICULTURE

I PURPOSE

This AM states policy for the initial selection of, and conditions governing, the conduct of research to evaluate potential agricultural chemicals produced by individual or company suppliers outside the Department. The Department will aggressively seek to assist in the evaluation of candidate chemicals under the terms set forth in this AM.

This revision reflects changes in ARS Form 409, Cooperative Research Evaluation of Chemicals, and ARS Form 410, Request for Extension of Period of Confidence, that were revised April 1975. Authorized Representatives, and procedures to be followed by ARS scientists in accepting chemicals for research evaluation, are covered in Attachment 3 to this AM.

AM 120.4 (12/7/72) and 120.18 (12/7/72) are canceled.

II BACKGROUND

In its research and action programs, the Department is interested in research to develop useful chemicals for agricultural; production and for the protection of crops, livestock, and agricultural products. Agencies are especially interested in chemicals that have a low order of toxicity to man, livestock, crop and forest plants, and that are compatible with a quality environment. Chemicals are needed for use as antibiotics, antiparasitic agents, antiseptics, attractants, biologics, chemotherapeutics, defoliants, desiccants, disinfectants, fumigants, fungicides, herbicides, insecticides,

nematicides, plant and animal growth regulators, plant and animal nutrients, repellents, seed protectants, soil conditioners, and for other agricultural uses.

Many of the chemicals useful for these purposes have been synthesized and developed by industry, sometimes with the aid of the Department's Research Agencies or with other public research agencies. In some instances, the chemicals have been discovered by the Department or by industry. Generally, the Department's programs of synthesis and analysis relate to long-term basic problems such as chemical investigations of naturally occurring products and certain classes of chemicals of importance to specific pest control programs in which the Department is engaged.

III POLICY

To achieve the objectives of its research and action programs, the Department will evaluate the effectiveness and environmental safety of biologically active and otherwise useful compounds. This will include formulations thereof that are proprietary or patented products, when such evaluation serves the best interest of the public, and when such compounds and formulations are useful in connection with an official program. The results of such research evaluations will be made known to the public. However, the Department cannot assume the role of a public testing service for the sole purpose of establishing commercial utility of proprietary materials. This AM sets forth the conditions under which the Department will select chemicals for research evaluation.

Implementation of the policy of this AM shall be consonant with Secretary's Memorandum to Heads of Department Agencies dated April 6, 1970, concerning adherence to P.L. 91-190, the National Environment Policy Act of 1969, and Executive Order No. 11514 on Protection and Enhancement of Environmental Quality, and with any other applicable directives, including 1 AR 708, "Acceptance of Contribution to Research."

IV SELECTION AN EVALUATION OF CHEMICALS

The Department's Research Agencies will conduct research on agricultural chemicals when (a) they fit into an Agency's program needs; (b) adequate Agency personnel and facilities are available; and (c) the Agency believes that the research will serve the best interests of the public.

Agencies may conduct research on chemicals, experimental formulations, proprietary compounds, or commercial formulations (hereafter referred to as "chemicals") provided the supplier agrees to complete ARS Form 409 and to certain conditions. These conditions are:

- A The supplier shall provide data to show that evaluation is warranted.
- B A statement giving the name of the chemical and its structural formula, if known, shall be furnished. If the exact formula is not known, sufficient information regarding the chemical nature of the material shall be furnished to enable the Agency concerned to ascertain whether it has been previously evaluated.
- C If the supplier requests, all Agency scientists are authorized to accept chemicals and to hold identities in confidence for a reasonable period of time provided the chemical identity and other information required in this AM and in ARS Form 409 are made known to the scientist and an Authorized Representative. The period of confidence must be determined at the time of acceptance, but should not exceed 1 year. If there is a need for an extension, the period of confidence will be extended for up to 1 additional year. Any such agreement as to confidence, and any extension

thereof, must be in writing on ARS Form 409 and 410 and signed by an authorized representative of the supplier and an Authorized Representative of the Agency. It is the policy of the Department to publish results of scientific research as soon as the research data justify publication. Therefore, an agreement of confidence should be entered into only when it is determined to be in the best interest of the public.

- D The supplier will furnish to the cooperating Agency available data on the toxicity of the chemical and its major impurities to man, animals, and plants; precautions necessary for safe evaluation and experimental use of the chemical; its solubility in available ordinary solvents; and other pertinent characteristics. Information on the toxicity of degradation, reaction, or metabolic products shall be fully disclosed. Compounds of unknown biological activity that are of special interest because of their chemical structure or other properties may be requested by the Research Agencies. In such cases, the provisions of this section pertaining to toxicity shall not apply.
- E The supplier shall be required to state in writing, at the time of acceptance of the chemical by the Department, whether steps for patent applications with respect to the chemical furnished have been taken or are contemplated. This information will be held in confidence. The supplier shall own any patentable invention first suggested to the Department by supplier, and which is first reduced to practice under this cooperative evaluation research. Provided the invention meets Government standards of safety and efficacy, the supplier shall take steps within a reasonable period of time to bring the benefits thereof to the public by working the patent: otherwise, the supplier shall grant patent licenses at reasonable terms to responsible applicants. Where the results of this cooperative evaluation research are submitted to the U.S. Patent Office for the purpose of obtaining allowance of a U.S. patent application, the resulting patent shall be made available royalty-free to the Government for Governmental purposes.
- F If a chemical is accepted for evaluation under the conditions stated in this AM, a scientist may conduct preliminary evaluation research under laboratory conditions or in small-plot field experiments. Samples provided by suppliers will be held in strict confidence and not subsampled to any other person or persons within or outside the Agency without the written prior concurrence of the supplier and an Authorized Representative of the Agency. The extent to which any advanced evaluations are made after the initial preliminary evaluations will be determined by the scientist. Arrangements for large-scale field evaluation research will be made with the supplier if the Agency determines that such evaluations are justified. In such instances, appropriate quantities of chemicals formulated as specified by the Agency may be accepted from the supplier as part of the cooperative research.
- G Progress reports will be made to the supplier by the cooperating USDA scientist prior to publication. If a period of confidence is established, reports will be sent to the supplier prior to termination of the initial period of confidence. Upon completion of the evaluation, the scientist will report USDA findings to the supplier for his information and comment. Information and results in progress reports or final reports shall not be published by the supplier in whole or in part without the consent of the Department and shall not be used in any advertisement to imply endorsement by the U.S. Department of Agriculture. The Department will publish promptly or make available to the public all information resulting from its cooperative research subject to any agreement as to

confidence.

H In addition to the provisions outlined above, the following information shall be obtained for the evaluation of proprietary materials or commercial formulations:

- 1 The commercial name or designation of the product.
- 2 A common name of the active ingredient(s), if there is such.
- 3 The chemical name of the active ingredient(s).
- 4 The structural formula(s) of the active ingredient(s).
- 5 The chemical composition of impurities present, so far as they are known.
- 6 Percent active ingredient(s) of formulations.
- 7 Solubility in water and common organic solvents.
- 8 Adequate toxicological information to permit the investigator's taking reasonable precautions to safeguard health and other components of the environment.
- 9 Information on inert ingredients of formulations that is essential to the safe and effective evaluation of the formulation.

V FORMS TO BE USED BY USDA

When there is an agreement to evaluate a chemical, the USDA scientist will send a signed ARS Form 409 (see Attachment 1) to the supplier for each chemical to be evaluated. Instructions for completion and distribution are printed on the reverse of the form.

If there is a need for an extension of the period of confidence, the supplier will complete ARS Form 410 (see Attachment 2). This form will be signed by the supplier's authorized representative and submitted in an original and two copies to the appropriate Agency Authorized Representative at least 60 days prior to termination of the initial period of confidence. The Authorized Representative will complete appropriate items on the form and return a copy to the supplier and to the cooperating USDA scientist(s) as a record of the new period of confidence.

ARS Form 409 and 410 are stocked in Central Supply Branch, Office of Operations.

Signed by:

T. W. Edminster

Attachments

- 1 ARS Form 409, Cooperative Research Evaluation of Chemicals
- 2 ARS Form 410, Request for Extension of Period of Confidence
- 3 Statement of Policy and Procedures Applicable to ARS

Concurred in:

T. Mulhern

John R. McGuire

PLEASE SEE HARD COPY OR CONTACT MSD, DOCUMENTS MANAGEMENT BRANCH, THROUGH
FTS2000 ON (301) 436-5524 FOR THE PAPER COPY OF THE FOLLOWING IMAGES:
COOPERATIVE RESEARCH EVALUATION OF CHEMICALS AND REQUEST FOR EXTENSION OF
PERIOD OF CONFIDENCE

Statement of Policy and Procedure Applicable to ARS

I POLICY

- A In order to achieve its mission, ARS will encourage scientists to evaluate the effectiveness and environmental safety of biologically active and otherwise useful chemicals and formulations that are potentially beneficial to agricultural production and for the protection of crops, livestock, and agricultural products.
- B Authority to select and evaluate chemicals for their potential benefits to agriculture is delegated, subject to approval by the Administrator's Authorized Representatives, to all individual scientists who have responsibilities for such research. Authority is delegated to the Administrator's Authorized Representatives for approving the acceptance of chemicals by ARS as required by AM 120.4, and they will be responsible for signing appropriate Items on ARS Forms 409 and 410.

II APPOINTMENT OF ARS AUTHORIZED REPRESENTATIVES

As required by AM 120.4, the following officials are designated as ARS Authorized Representatives and will be responsible for signing ARS Forms 409 and 410 for the following classes of agricultural chemicals.

- A Herbicides, fungicides, nematocides, plant growth modifiers (desiccants, defoliants, plant growth regulators, etc.); and soil conditioners:

Dr. Warren C. Shaw
National Program Staff, ARS-USDA
Beltsville, Maryland 20705
Telephone: Area Code 301 - 344-3301

- B Insecticides and other agents for insect control:

Dr. Waldemar Klassen
National Program Staff, ARS-USDA
Beltsville, Maryland 20705
Telephone: Area Code 301 - 344-3918

- C Animal growth modifiers and protectants:

Dr. Edwin R. Goode, Jr.
National Program Staff, ARS-USDA
Beltsville, Maryland 20705
Telephone: Area Code 301 - 344-2713

III PROCEDURES

New chemicals of interest and value to ARS research programs may be evaluated by ARS scientists in two ways: (a) without any requirements for confidentiality, and (b) in confidence. In most instances, cooperating suppliers of new candidate chemicals will provide these to ARS scientists for evaluation without requesting a period of confidence. In other instances, when patent rights are involved and other legal matters are pending, the supplier may request that the chemical be evaluated in confidence.

In ARS, only the scientist conducting the research and the Authorized Representative will know the identity of compounds accepted for evaluation in confidence. The confidential information will be handled in accordance with procedures established for information classified as "FOR OFFICIAL USE ONLY."

When other Government officials need to have information on chemicals accepted in confidence, it can be made available to them on a need-to-know basis after concurrence by the supplier.

ARS scientists are not authorized to accept chemicals for evaluation unless they know their identity and have the information required by ARS Form 409. However, in some ARS basic research programs, compounds of unknown biological activity and unknown toxicological properties are of special interest. In special cases where all of the chemical, physical, biological, and toxicological data are not available these data are not prerequisite to acceptance and evaluation of a chemical.

When an ARS scientist and a supplier agree to cooperative research to evaluate a chemical, not previously evaluated by the ARS scientist, the ARS scientist will sign an ARS Form 409 and send it to the supplier. If an ARS scientist has previously evaluated a chemical, ARS Form 409 is not required for subsequent samples required for advanced evaluation research. If an extension of the initial period of confidence is needed, the supplier should request a copy of ARS Form 410 from the ARS Authorized Representative. Instructions for completion and distribution are printed on the forms.

DISTRIBUTION: X90, P91, V91

OPR: OA