

# ARS □ CSREES □ ERS □ NASS

## *Policies and Procedures*

**Title:** Cooperative Research to Evaluate Chemicals Potentially Beneficial to Agriculture

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This Directive states policy for initial selection of and conditions governing the conduct of cooperative research with agricultural chemicals.

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## 1. Summary

This DIRECTIVE:

- States policy for the initial selection of and conditions governing the conduct of cooperative research with agricultural chemicals produced by individuals or company suppliers outside the U.S. Department of Agriculture (USDA).
- States procedures to be followed by ARS scientists in accepting chemicals for cooperative research.
- Reflects changes in ARS-409 and ARS-410.
- Designates the ARS authorized representative(s) who will be responsible for approving research conducted under this DIRECTIVE by signing ARS-409 and ARS-410.

## 2. Forms

- ARS-409, Cooperative Research Evaluation of Chemicals
- ARS-410, Cooperative Research Evaluation of Chemicals Request for Extension of Period of Confidence

These forms are available from the Pesticide Assessment Laboratory, Building 1070, BARC - East, Beltsville, Maryland 20705.

## 3. Background

- In its research and action programs, ARS is interested in research to facilitate development of useful chemicals for agricultural production and for the protection of crops, livestock, and agricultural products. ARS is 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, defoliant, 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. In particular, ARS scientists are interested in researching compounds with novel properties related to mode of action in animals and plants.
- Most of the chemicals useful for these purposes have been synthesized and developed by industry, sometimes with the aid of the USDA's Research Agencies or with other public

research agencies. In some instances, the chemicals have been discovered by personnel in ARS or other public research agencies with subsequent commercial development by industry. Generally, USDA'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 USDA is engaged.

- It is strongly in the public interest that ARS scientists conduct cooperative evaluation research which contributes to new approaches to pest control technology. Cooperative evaluation research is a term often used in a generic manner to describe a broad spectrum of basic and applied research on candidate chemical and biological materials. Obviously, through such research, assessments are made of the properties of candidate materials that are of immediate practical economic benefit not only in Federal action programs, but also in all aspects of agriculture, public health, and commerce.

Cooperative evaluation research also provides valuable information often on a nationwide basis of properties of candidate materials that relate to risks to the environment and to human health and safety. Thus, evaluation research provides data on absorption, translocation, degrees of selective action on various species, metabolic fate in plants and animals, movement and fate in air, soil and water, persistence, movement in food chains and other data that are accumulated under a wide variety of ecological and environmental conditions.

Equally important, biologically active materials serve as probes in basic research to determine how living systems grow, develop, and function. For example, much of what is known about photosynthesis has been gleaned from studies with herbicides, and much of what is known about neurotransmission has been learned from studies involving insecticides and their analogs.

#### **4. USDA Policy on Cooperative Research With Chemicals**

ARS will seek to assist in cooperative research to evaluate and characterize the biological properties of candidate chemicals under the terms set forth in this DIRECTIVE.

To achieve the objectives of its research and action programs USDA 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/or 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, USDA cannot assume the role of a public testing service for the purpose of establishing commercial utility of proprietary materials. This

DIRECTIVE sets forth the conditions under which USDA will select chemicals for research evaluation.

## **5. ARS Policy on Cooperative Research With Chemicals**

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.

## **6. Patent Provision For Cooperative Research With Chemicals**

The supplier shall be required to state in writing on ARS-409 at the time of acceptance of the chemical by USDA, 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 USDA by supplier, and which is first reduced to practice under this cooperative evaluation research. Provided the invention meets U.S. 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 licensee 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 U.S. Government for Governmental purposes.

## **7. Appointment of ARS Authorized Representative(s)**

Authority to select and evaluate chemicals for their potential benefits to agriculture is delegated, subject to approval by the ARS's Authorized Representative(s), to all individual Scientists who have responsibilities for such research. Authority is delegated to ARS's Authorized Representative(s) for approving the acceptance of chemicals by ARS as required by this DIRECTIVE, and they will be responsible for signing appropriate items on ARS-409 and ARS-410.

A National Program Staff official will serve as ARS's Authorized Representative(s) and will be responsible for signing forms ARS-409 and ARS-410 for the following classes of agricultural chemicals:

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

- Insecticides, other agents for insect control, and animal growth modifiers and protectants; c Fungicides, nematicides, antivirals, and bacteriacides.

## 8. Election of Chemicals

ARS will conduct research on agricultural chemicals when (a) they fit into an ARS program need; (b) adequate personnel and facilities are available; and (c) ARS believes that the research will serve the best interests of the public.

ARS may conduct research on chemicals, experimental formulations, proprietary compounds, or commercial formulations (hereafter referred to as "chemicals") provided the supplier agrees to complete ARS-409 and to the following conditions:

- The supplier shall provide data to show that evaluation is warranted.
- A statement giving the name of the chemical and its structural formula, if known, and all information requested on ARS-409 shall be furnished to the maximum extent that it is known. If the exact formula is not known, sufficient information regarding the chemical nature of the material shall be furnished to enable ARS to ascertain whether it has been previously evaluated.
- If the supplier requests, all ARS 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 DIRECTIVE and in ARS-409 are made known to the scientist and the Authorized Representatives of ARS. 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 or 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-409 and ARS-410 and signed by the Authorized Representative(s) of the supplier and ARS. It is USDA policy to publish results of scientific research as soon as the research data justify publication. Therefore, an agreement of confidence will be entered into only when it is determined to be in the best interest of the public.
- The supplier will furnish ARS available data on the toxicity of the chemical, and 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 ARS. In such cases, the provisions of this section pertaining to toxicity shall not apply. The supplier also agrees to

arrange for the return of any unused portion of any chemical supplied by them which was not utilized by ARS during its evaluation.

- Radiolabeled agricultural chemical use must be approved by USDA's Radiological Safety Committee and must comply with the USDA and U.S. Nuclear Regulatory Commission's rules and regulations as specified in the USDA's Radiological Safety Handbook.

## **9. Research Evaluation of Chemicals**

If a chemical is accepted for research under the conditions stated in this DIRECTIVE, 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 ARS without the written prior concurrence of the supplier and the Authorized Representative(s) of ARS. 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 ARS determines that such evaluations are justified. In such instances, appropriate quantities of chemicals formulated as specified by ARS may be accepted from the supplier as part of the cooperative research.

## **10. Commercial Formulations or Proprietary Materials**

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

- The commercial name or designation of the product.
- A common name of the active ingredient(s), if there is such.
- The chemical name of the active ingredient(s).
- The structural formula(e) of the active ingredient(s).
- The chemical composition of impurities present, so far as they are known.
- Percent active ingredient(s) of formulations. -
- Solubility in water and common organic solvents.
- Adequate toxicological information to permit the investigator's taking reasonable precautions to safeguard health and other components of the environment.

- Information on inert ingredients of formulations that is essential to the safe and effective evaluation of the formulation.

## **11. ARS Procedures For Research Evaluation of Chemicals**

- 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 some 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, the scientist conducting the research, the Authorized Representative(s) of the National Program Staff, and an official of the Pesticide Assessment Laboratory, will know the identity of the compounds accepted for evaluation in confidence. The confidential information will be handled in accordance with procedures established in accordance with form ARS-409 and this DIRECTIVE.

When other U.S. Government officials need to have information on chemicals accepted in confidence, it can be made available to them on a need-to-know basis.

- ARS scientists are not authorized to accept chemicals for evaluation unless they know their identity and have the information required by ARS-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 an ARS scientist, the ARS scientist will sign an ARS-409 and send it to the supplier. If an ARS scientist has previously evaluated a chemical, ARS-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-410. Instructions for completion and distribution are printed on the forms.
- Scientists need to be aware that such studies require special attention to record keeping since the data could be used for compound registration by a regulatory agency and therefore be subject to a data audit. This should include development of a written study protocol, recording of standardized procedures and provisions to retain the raw data and any other written materials developed in the course of the work.



## **12. Forms to be Used by USDA**

When there is an agreement to conduct cooperative research with a chemical, the USDA scientist will send a signed ARS-409 to the supplier for each chemical. 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-410. This form will be signed by the supplier's authorized representative and submitted in an original and two copies to the appropriate ARS Authorized Representative(s) at least 60 calendar days prior to termination of the initial period of confidence. The Authorized Representative(s) will complete appropriate items on the form and return a copy to the supplier and to the cooperating USDA scientist as a record of the new period of confidence.

## **13. Reports**

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 ARS findings to the supplier for his/her 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 USDA and shall not be used in any advertisement to imply endorsement by the USDA. ARS will publish promptly or make available to the public all information resulting from its cooperative research, subject to any agreement as to confidence.

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Administrator