

DEPARTMENT OF AGRICULTURE**Agricultural Research Service****Cooperative State Research,
Education, and Extension Service****Biotechnology Risk Assessment
Research Grants Program for Fiscal
Year 1998; Solicitation of Applications**

AGENCY: Agricultural Research Service; Cooperative State Research, Education, and Extension Service, USDA.

ACTION: Notice of Biotechnology Risk Assessment Research Grants Program; Fiscal Year 1998 solicitation of applications.

SUMMARY: Applications are invited for competitive grant awards under the Biotechnology Risk Assessment Research Grants Program (the "Program") for fiscal year (FY) 1998. The authority for the Program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921). The Program is administered by the Cooperative State Research, Education, and Extension Service (CSREES) and the Agricultural Research Service (ARS) of the U.S. Department of Agriculture.

DATES: Proposals are due March 24, 1998.

FOR FURTHER INFORMATION CONTACT: Dr. Edward K. Kaleikau, USDA/CSREES, (202) 401-1901, Dr. Daniel D. Jones, USDA/CSREES, (202) 401-6854, or Dr. Robert M. Faust, USDA/ARS, (301) 504-6918.

SUPPLEMENTARY INFORMATION:**Table of Contents**

Purpose
Applicant Eligibility
Available Funding
Program Description
Proposal Evaluation
Areas of Research to be Supported in Fiscal Year 1998
Applicable Regulations
Programmatic Contact
How to Obtain Application Materials
Proposal Format
Compliance with the National Environmental Policy Act (NEPA)
Proposal Submission and Due Date
Additional Information

Purpose

The purpose of the Program is to assist Federal regulatory agencies in making science-based decisions about the safety of introducing into the environment genetically modified organisms, including plants, microorganisms, fungi, bacteria, viruses, arthropods, fish, birds, mammals and other animals. The Program accomplishes this purpose by providing

scientific information derived from the risk assessment research that it funds. Research proposals submitted to the Program must be applicable to the purpose of the Program to be considered.

Applicant Eligibility

Proposals may be submitted by any United States public or private research or educational institution or organization.

Available Funding

Subject to the availability of funds, the anticipated amount available for support of the Program in FY 1998 is \$1.5 million.

Section 712 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1998 (Pub. L. 105-86), prohibits CSREES from using the funds available for the Program for FY 1998 to pay indirect costs exceeding 14 per centum of the total Federal funds provided under each award on competitively awarded research grants.

Section 716 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1998, encourages entities to use grant funds to purchase only American-made equipment or products in the case of any equipment or product that may be authorized to be purchased with the funds provided under this program.

CSREES and ARS will competitively award research grants to support science-based biotechnology regulation and thus help address concerns about the effects of introducing genetically modified organisms into the environment and help regulators in developing policies regarding such introduction.

The Program's research emphasis is on risk assessment and not risk management. The Program defines risk assessment research as the science-based evaluation and interpretation of factual information in which a given hazard, if any, is identified, and the consequences associated with the hazard are explored. The Program defines risk management as (1) research aimed primarily at reducing risks of biotechnology-derived agents and (2) a policy and decision-making process that uses risk assessment data in deciding how to avoid or mitigate the consequences identified in a risk assessment. Proposals must be relevant to risk assessment to be eligible for this Program.

Proposals must include a statement describing the relevance of the proposed project to one or more of the topics

requested in this solicitation. In addition, proposals must include detailed descriptions of the experimental design and appropriate statistical analyses to be done. The Program strongly encourages the inclusion of statisticians and risk analysis researchers as co-principal investigators or contractors.

Awards will not be made for clinical trials, commercial product development, product marketing strategies, or other research deemed not appropriate to risk assessment.

Proposal Evaluation

Proposals will be evaluated by the Administrator assisted by a peer panel of scientists for scientific merit, qualifications of project personnel, adequacy of facilities, and relevance to both risk assessment research and regulation of agricultural biotechnology.

Areas of Research To Be Supported in Fiscal Year 1998

Proposals addressing the following topics are requested:

1. Research on the introduction into the environment (not in a contained facility) of genetically engineered organisms. The data collected may include: survival; reproductive fitness; genetic stability; genetic recombination; horizontal gene transfer; loss of genetic diversity; or enhanced competitiveness. The organisms may include: fungi; bacteria; viruses; microorganisms; plants; arthropods; fish; birds; mammals; and other animals.
2. Research on large-scale deployment of genetically engineered organisms; especially commercial uses of such organisms, with special reference to considerations that may not be revealed through small-scale evaluations and tests. This may include monitoring locations where transgenic virus resistant plants (expressing viral transgenes) are grown on a commercial scale or in large-scale production for viral strains which overcome the resistance phenotype. The analysis of resistance-breaking strains should include analyzing whether the strain arose via recombination between viral transgenes and the viral genome. Such projects should survey the production sites for two to three years.
3. Research to develop statistical methodology and quantitative measures of risks associated with field testing of genetically modified organisms.
4. The Program will, subject to resource availability, provide partial funding to organize a scientific research conference that brings together scientists and regulators to review the science-based evidence, if any, that the

introduction of a pest resistance gene into a crop plant poses the risk of increasing the fitness of weedy, sexually compatible relatives of the crop plant. Data considered should include the introduction of pest resistance genes by conventional breeding or by a process involving recombinant DNA. The conference should provide an opportunity to address how experiments could be designed to test whether a pest resistance gene increases the fitness of weeds in the field. The scientific steering committee for the conference should include a broad representation of disciplines, including ecology, population biology, plant pathology, entomology, plant breeding, and others as appropriate. Evaluation criteria of submitted proposals will include: choice of topics and selection of speakers; general format of the conference, especially with regard to its appropriateness for fostering scientific exchange; provisions for wide participation from the scientific and regulatory community and others as appropriate; qualifications of the organizing committee and appropriateness of invited speakers to the topic areas being covered; and appropriateness of the budget requested and qualifications of the project personnel.

Applicable Regulations

This Program is subject to the administrative provisions found in 7 CFR part 3415, which set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals, the awarding of grants, and post-award administration of such grants. Several other Federal statutes and regulations apply to grant proposals considered for review or to grants awarded under this Program. These include but are not limited to:

7 CFR Part 3019, as amended by 62 FR 45934—USDA implementation of OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Nonprofit Organizations.

Programmatic Contact

For additional information on the Program, please contact:

Dr. Edward K. Kaleikau, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, STOP 2241, 1400 Independence Avenue, S.W., Washington, D.C. 20250-2241, Telephone: (202) 401-1901
or

Dr. Daniel D. Jones, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, STOP 2220, 1400 Independence Avenue, S.W., Washington, D.C. 20250-2220, Telephone: (202) 401-6854
or

Dr. Robert M. Faust, Agricultural Research Service, U.S. Department of Agriculture, Room 338, Building 005, BARC-West, Beltsville, MD 20705, Telephone: (301) 504-6918

How To Obtain Application Materials

Copies of this solicitation, the administrative provisions for the Program (7 CFR Part 3415), and the Application Kit, which contains required forms, certifications, and instructions for preparing and submitting applications for funding, may be obtained by contacting: Proposal Services Unit, Grants Management Branch, Office of Extramural Programs, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, STOP 2245, 1400 Independence Avenue, S.W., Washington, D.C. 20250-2245, Telephone Number: (202) 401-5048.

Application materials may also be requested via Internet by sending a message with your name, mailing address (not e-mail) and telephone number to psb@reeusda.gov which states that you wish to receive a copy of the application materials for the FY 1998 Biotechnology Risk Assessment Research Grants Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

Proposal Format

The format guidelines for full research proposals, found in the administrative provisions for the Program at § 3415.4(d), should be followed for the preparation of proposals under the Program in FY 1998. (Note that the Department elects not to solicit preproposals in FY 1998.)

Compliance With the National Environmental Policy Act (NEPA)

As outlined in 7 CFR Part 3407 and 7 CFR Part 520 (the CSREES and ARS regulations implementing the National Environmental Policy Act of 1969), environmental data for any proposed project is to be provided to CSREES and ARS so that CSREES and ARS may determine whether any further action is needed. Form CSREES-1234, "NEPA Exclusions Form" (copy in Application Kit), indicating the applicant's opinion of whether or not the project falls within one or more categorical exclusions, along with supporting documentation,

must be included in the proposal. The applicant shall review the following categorical exclusions and determine if the proposed project may fall within one of the categories:

(1) Department of Agriculture Categorical Exclusions (7 CFR 1b.3)

(i) Policy development, planning and implementation which are related to routine activities such as personnel, organizational changes, or similar administrative functions;

(ii) Activities which deal solely with the funding of programs, such as program budget proposals, disbursements, and transfer or reprogramming of funds;

(iii) Inventories, research activities, and studies, such as resource inventories and routine data collection when such actions are clearly limited in context and intensity;

(iv) Educational and informational programs and activities;

(v) Civil and criminal law enforcement and investigative activities;

(vi) Activities which are advisory and consultative to other agencies and public and private entities; and

(vii) Activities related to trade representation and market development activities abroad.

(2) CSREES and ARS Categorical Exclusions (7 CFR 3407.6 and 7 CFR 520.5)

Based on previous experience, the following categories of CSREES and ARS actions are excluded because they have been found to have limited scope and intensity and to have no significant individual or cumulative impacts on the quality of the human environment:

(i) The following categories of research programs or projects of limited size and magnitude or with only short-term effects on the environment:

(A) Research conducted within any laboratory, greenhouse, or other contained facility where research practices and safeguards prevent environmental impacts;

(B) Surveys, inventories, and similar studies that have limited context and minimal intensity in terms of changes in the environment; and

(C) Testing outside of the laboratory, such as in small, isolated field plots, which involves the routine use of familiar chemicals or biological materials.

(ii) Routine renovation, rehabilitation, or revitalization of physical facilities, including the acquisition and installation of equipment, where such activity is limited in scope and intensity.

In order for CSREES and ARS to determine whether any further action is

needed with respect to NEPA, pertinent information regarding the possible environmental impacts of a particular project is necessary; therefore, a separate statement must be included in the proposal indicating whether the applicant is of the opinion that the project falls within a categorical exclusion and the reasons therefor. If it is the applicant's opinion that the project proposed falls within the categorical exclusions, the specific exclusions must be identified. The information submitted shall be identified as "NEPA Considerations" and the narrative statement shall be placed after the coversheet of the proposal.

Even though a project may fall within the categorical exclusions, CSREES and ARS may determine that an Environmental Assessment or an Environmental Impact Statement is necessary for an activity, if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present which may cause such activity to have a significant environmental effect.

Proposal Submission and Due Date

What To Submit

An original and 14 copies of a proposal must be submitted. Proposals

should be typed on one side of the page only. Each copy of each proposal must be stapled securely in the upper lefthand corner (DO NOT BIND). All copies of the proposal must be submitted in one package.

Where and When To Submit

Proposals must be postmarked by March 24, 1998 to be eligible for the program. Proposals received after the deadline date of March 24, 1998, as indicated either by the postmark date on First Class or express mail, or by the date on a courier bill of lading, will be returned without review. Proposals must be sent to the following address: Biotechnology Risk Assessment Research Grants Program, c/o Proposal Services Unit, Grants Management Branch, Office of Extramural Programs, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, STOP 2245, 1400 Independence Avenue, S.W., Washington, D.C. 20250-2245, Telephone: (202) 401-5048.

Proposals delivered by hand must be received at the following address by March 24, 1998 (note that the zip code differs from that shown above): Biotechnology Risk Assessment Research Grants Program, c/o Proposal Services Unit, Grants Management Branch, Office of Extramural Programs,

Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Room 303, Aerospace Center, 901 D Street, S.W., Washington, D.C. 20024, Telephone: (202) 401-5048.

Additional Information

The Biotechnology Risk Assessment Research Grants Program is listed in the Catalog of Federal Domestic Assistance under No. 10.219. For reasons set forth in the final rule-related Notice to 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), this Program is excluded from the scope of Executive Order No. 12372 which requires intergovernmental consultation with State and local officials.

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524-0022.

Done at Washington, D.C., on this 15 day of December, 1997.

Colien Hefferan,

Associate Administrator, Cooperative State Research, Education, and Extension Service.

Edward B. Knipling,

Associate Administrator, Agricultural Research Service.

[FR Doc. 97-33500 Filed 12-23-97; 8:45 am]

BILLING CODE 3410-22-P