

DEPARTMENT OF AGRICULTURE**Agricultural Research Service****Cooperative State Research,
Education, and Extension Service****Biotechnology Risk Assessment
Research Grants Program for Fiscal
Year 1999; Solicitation of Applications**

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

ACTION: Notice of Biotechnology Risk Assessment Research Grants Program; Fiscal Year 1999 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) 1999. 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, 1999.

FOR FURTHER INFORMATION CONTACT: Dr. Edward K. Kaleikau, USDA/CSREES, (202) 401-1901, Dr. Robert M. Faust, USDA/ARS, (301) 504-6918, or Dr. Deborah Sheely, USDA/CSREES, (202) 401-1924.

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Stakeholder Input

CSREES is soliciting comments regarding this solicitation of applications from any interested party. These comments will be considered in the development of the next request for proposals for the Program. Such comments will be forwarded to the Secretary or his designee for use in meeting the requirements of section

103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998, 7 U.S.C. 7613(c)(2). Written comments should be submitted by first-class mail to: Office of Extramural Programs; Competitive Research Grants and Awards Management; USDA-CSREES; STOP 2299; 1400 Independence Avenue, S.W., Washington, D.C. 20250-2299, or via e-mail to: RFP-OEP@reusda.gov.

In your comments, please include the name of the program and the fiscal year solicitation of applications to which you are responding. Comments are requested within six months from the issuance of the solicitation of applications. Comments received after that date will be considered to the extent practicable.

Purpose

The purpose of the Program is to assist Federal regulatory agencies in making science-based decisions about the effects of introducing into the environment genetically modified organisms, including plants, microorganisms, fungi, bacteria, viruses, arthropods, fish, birds, mammals and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. 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 1999 is \$1.5 million. The agency intends to award these funds for project proposals in the targeted areas with no more than two awards for conference proposals.

CSREES is prohibited from paying indirect costs exceeding 19 percent of the total Federal funds provided under each award on competitively awarded research grants (7 U.S.C. 3310). However, Section 711 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1999, Sec. 107(a), Pub. L. No. 105-277 prohibits CSREES from using the funds available for the Program for FY 1999 to pay indirect costs exceeding 14 percent of the total Federal funds provided under

each award on competitively awarded research grants.

Program Description

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 emphasis is on risk assessment, which is defined 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. Investigators are encouraged to design studies in which answers to three general questions are sought: 1) what is the risk (potential risk identification)?; 2) how likely is the risk to occur (quantifying the probability of occurrence)?; and 3) what is the severity and extent of the effect if it occurs (quantifying the effects)? Proposals that address all three questions are preferred. However, studies of a single question will also be considered if developed within the broader context of risk assessment. The Program does not support risk management research, which is defined as (1) research aimed primarily at reducing risks of specific 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 research topics requested in this solicitation. In addition, proposals should include detailed descriptions of the experimental design and appropriate statistical analyses to be done.

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 Administrators of ARS and CSREES 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. Proposals for funding a scientific research conference grant will

be evaluated on the following criteria: 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. All proposals are considered together in making award decisions. However, no more than two conference grants will be awarded.

Areas of Research To Be Supported in Fiscal Year 1999

Proposals addressing the following topics are requested:

1. Research relevant to assessing the risk of the introduction into the environment of genetically engineered organisms. Potential subject areas include but are not limited to: research on the potential for recombination between plant viruses and plant-encoded viral transgenes; research on the potential for nontarget effects of introduced plant-defense compounds expressed in genetically modified plant-associated microorganisms (e.g., compounds in the phyllosphere or rhizosphere-inhabiting bacteria) or in plants (e.g., *Bacillus thuringiensis* delta-endotoxin), especially in regard to persistence of the organisms and material in the environment; changes in ecosystem or agro-ecosystem function and composition; or research on gene flow from transgenic crops to related plants. 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 excluding humans. As long as the data gathered are relevant to the assessment of the risk of genetically modified organisms, the experiments need not utilize genetically engineered organisms. When feasible, measure of risk should include estimates of expected frequency and impact, and address the availability of effective mitigation measures to reduce or avoid impacts.

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. Studies should attempt to project impacts over as large a spatial and temporal scale as feasible. Of particular interest are studies that survey transgenic insect and virus resistant plants for insects and viral strains that have overcome the resistance phenotype. This may be done by monitoring locations where such plants are grown on a commercial scale or in large scale production. The analysis of resistance-breaking viral 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 data relevant to risk assessment of genetically modified organisms released into the environment. The scientific steering committee for the conference should include representatives from a variety of relevant disciplines, such as ecology, population biology, pathology, production and resource management science, and others, as appropriate. The Program will fund a maximum of two conference proposals.

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—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. Robert M. Faust, Agricultural Research Service, U.S. Department of Agriculture, Room 338, Building 005, BARC-West, Beltsville, MD 20705,
Telephone: (301) 504-6918,
or
Dr. Deborah Sheely, 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) 401-1924

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, 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 also may 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 1999 Biotechnology Risk Assessment Research Grants Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

This Solicitation and other application information and materials also are available at the Program's website (<http://www.reeusda.gov/crgm/biotechrisk/biotech.htm>).

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 1999. In addition, please note the following items: (1) The Department elects not to solicit preproposals in FY 1999; (2) a proposal's project summary may not exceed one single- or double-spaced page. Include on this page the proposal title, as well as names and institutions of each investigator; and (3) a separate conflict of interest list must be submitted with the proposal for each investigator for whom a curriculum vitae (C.V.) is required. This list is

necessary to assist program staff in excluding from proposal review those individuals who have conflicts of interest with the project personnel in the grant proposal.

For each investigator (and other personnel as described in the program description), list alphabetically the full names of only the individuals in the following categories. It is not necessary to list individuals in each category separately; rather, a single alphabetized list for each investigator is preferred. Additional pages may be used as necessary. A conflict of interest list must be submitted before a proposal is considered complete. Inclusion of a C.V. or publication list in lieu of a conflict of interest list is not sufficient. Other investigators working in the applicant's specific research area are not in conflict of interest with the applicant unless those investigators fall within one of the categories listed below:

(A) All collaborators on research projects within the past five years, including current and planned collaborations;

(B) All co-authors on publications within the past five years, including pending publications and submissions;

(C) All persons in your field with whom you have had a consulting or financial arrangement within the past five years; and

(D) All thesis or postdoctoral advisees/advisors within the past five years.

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 therefore. 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 sent by First Class, an express mail service, or courier service must be postmarked on or by March 24, 1999, to be eligible for the program. Proposals hand-delivered must be received on or by March 24, 1999. Proposals received after the deadline date of March 24, 1999, 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 sent via First Class must be sent to the following address: Biotechnology Risk Assessment Research Grants Program, c/o Proposal Services Unit, 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, express mail, or overnight courier must be sent to the following address (note that the zip code differs from that shown above): Biotechnology Risk Assessment Research Grants Program, c/o Proposal Services Unit, 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 third day of December, 1998.

Colien Hefferan,

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

Floyd Horn,

Administrator, Agricultural Research Service.

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