

DEPARTMENT OF AGRICULTURE**Agricultural Research Service;
Cooperative State Research,
Education and Extension Service****Biotechnology Risk Assessment
Research Grants Program; Fiscal Year
1996; Solicitation of Applications****Purpose**

Applications are invited for competitive grant awards under the Biotechnology Risk Assessment Research Grants Program (the "Program") for fiscal year 1996. The authority for the Program is contained in section 1668 of Pub. L. No. 101-624 (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.

The purpose of the Program is to assist Federal regulatory agencies in making science-based decisions about the safety of introducing genetically modified plants, animals, and microorganisms into the environment. The Program accomplishes this purpose by providing scientific information derived from the risk assessment research conducted under it. Research proposals submitted to the Program must be applicable to the purpose of the Program to be considered. Awards will not be made for clinical trials, commercial product development, product marketing strategies, or other research not appropriate to risk assessment.

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 fiscal year 1996 is \$1.7 million.

It is expected that Congress, in the final version of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1996 (H.R. 1976), will prohibit CSREES from using the funds available for fiscal year 1996 to pay indirect costs exceeding 14 percent of the total Federal funds provided under each award on competitively-awarded research grants.

In addition, it is expected that, pursuant to the final version of the Agriculture, Rural Development, Food

and Drug Administration, and Related Agencies Appropriations Act, 1996 (H.R. 1976), in the case of any equipment or product that may be authorized to be purchased with the funds provided under this Program, entities will be encouraged to use such funds to purchase only American-made equipment or products.

Program Description

Under the Program, USDA 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 to help regulators develop policies concerning such introduction. Proposals are invited in the area of biotechnology risk assessment research as appropriate to agricultural plants, animals and microbes. Proposals based upon field research and whole organism-population level studies are strongly encouraged. Although emphasis will be given to risk assessment research involving genetically modified organisms, model systems using nongenetically modified organisms also will be considered if they can provide information that could lead to improved assessment of potential risks associated with the introduction of genetically modified organisms into the environment. Proposals should be applicable to current regulatory issues surrounding the ecological impacts of genetically modified organisms.

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 for current regulatory issues.

**Areas of Research to be Supported in
Fiscal Year 1996**

Proposals addressing the following research topics are requested:

1. Development of new risk assessment methods (e.g., monitoring organism escape, measuring biological impacts), and risk assessment procedures (e.g. comparative analysis of ecosystems, models to predict risks) that could be used in risk assessment of genetically modified fungi, bacteria, viruses (including animal vaccines), plants, arthropods, fish, birds, and mammals. Applicants should address the need for, and development of, new risk assessment methods in the course of addressing a specific and defined risk assessment issue, especially as pertains to genetically modified organisms. The

development of better risk assessment methods for field testing genetically modified organisms also will be considered.

2. Creation of information systems and computer models to support regulatory agency decision-making in regards to potential impacts to the environment over time (e.g., computer models to describe the interaction of environmental and organismal factors especially for establishment and dispersal of the organism).

3. Risk assessment of the environmental fate (e.g. survival, reproductive fitness, genetic stability, horizontal gene transfer) as correlated with effects (e.g., loss of genetic diversity, enhanced competition) of genetically modified fungi, bacteria, viruses, plants, arthropods, fish, birds, and mammals introduced into the environment (i.e., not in a contained laboratory, greenhouse or building); and studies or identification of traits which may influence fate and effects.

In response to requests to Program Directors and Federal regulatory agencies, as stipulated in the authorizing legislation for the Program, section 1668 of Public Law 101-624, the following specific areas of risk assessment research have been identified as eligible for competition as research topics for this year:

4. The bidirectional rates, effects of selection pressures, mechanisms and impact of gene transfer between currently genetically transformable crop species and existing North American weedy, free living relatives of those crops including studies of methods of mitigation of potential gene exchange. Research could rely on reanalysis of published information and/or laboratory/field studies.

5. The potential for recombination between plant viruses and plant-encoded noncapsid viral genes (e.g. replicase), especially for those viruses in supergroup B (carmovirus, tombusvirus, luteovirus, sobemovirus). Such studies should identify recombination potentials and, if demonstrated, define frequencies and effect on symptom expression. Comparisons with recombination frequencies between naturally occurring viral sequences are encouraged.

6. Changes in viral host ranges or the types of viral vectors as a result of the use of transgenic plants expressing viral genes.

7. The potential for nontarget effects of introduced plant-defense compounds expressed in genetically modified plant-associated microorganisms (e.g., compounds in 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.

8. Identification of genes which can confer additional pathogenicity to animal pathogens.

9. Environmental risk analysis of large scale deployment of genetically engineered organisms; especially commercial uses of such organisms, with special reference to consideration that may not be revealed through small scale evaluations and tests.

All research proposals submitted should include a statement describing the relevance of the proposed project to one or more of the research topics requested. When appropriate, detailed descriptions of statistical analyses to be done should be included in the proposal. The inclusion of statisticians as co-principal investigators or contractors is encouraged.

Note: Individual investigators whose research projects are funded under the Program will be required to attend, present data and provide a manuscript on the results of their research at an Annual Conference. Attendance costs at such a conference do not need to be included in the budgets of proposed research projects; such costs will be paid from funds provided under a cooperative agreement between CSREES and the University of Maryland for an annual risk assessment symposium. Additionally, a final project report on research results will be required in a fixed protocol, electronic format, suitable for distribution by USDA.

Applicable Regulations

This Program is subject to the administrative provisions found in 7 CFR part 3415 (58 FR 65646, December 15, 1993), 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 1.1—USDA implementation of the Freedom of Information Act;

7 CFR Part 1c—USDA implementation of the Federal Policy for the Protection of Human Subjects;

7 CFR Part 3—USDA implementation of OMB Circular A-129 regarding debt collection;

7 CFR Part 15, Subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964;

7 CFR Part 520—ARS implementation of the National Environmental Policy Act;

7 CFR Part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (*i.e.*, Circular Nos. A-110, A-21, and A-122) and incorporating provisions of 31 U.S.C. 6301-6308 (formerly, the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95-224), as well as general policy requirements applicable to recipients of Departmental financial assistance;

7 CFR Part 3016—USDA Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments;

7 CFR Part 3017, as amended—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants);

7 CFR Part 3018—USDA implementation of New Restrictions on Lobbying. Imposes new prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans;

7 CFR Part 3051—Audits of Institutions of Higher Education and Other Nonprofit Institutions;

7 CFR Part 3407—CSREES implementation of the National Environmental Policy Act; 29 U.S.C. 794, section 504—Rehabilitation Act of 1973, and 7 CFR Part 15B (USDA implementation of the statute), prohibiting discrimination based upon physical or mental handicap in federally assisted programs;

35 U.S.C. 200 *et seq.*—Bayh-Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR part 401).

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, Ag Box 2241, Washington, DC 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.

How to Obtain Application Materials

Copies of this solicitation, the administrative provisions for the

Program (7 CFR Part 3415), and the Application Kit contains required forms, certifications, and instructions for preparing and submitting grant applications. The administrative provisions include guidelines for proposal format.

Copies of this solicitation, the administrative provisions, and the Application Kit may be obtained by contacting:

Proposal Services Branch, Awards Management Division, Cooperative State Research, Education and Extension Service, U.S. Department of Agriculture, Ag Box 2245, Washington, DC 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 psb@reeusda.gov which states that you wish to receive a copy of the application materials for the Fiscal Year 1996 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 fiscal year 1996. (Note that the Department elects not to solicit preproposals nor conference grant proposals in fiscal year 1996.)

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. 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

What to Submit

An original and 14 copies of a proposal must be submitted. 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 received by 4:30 p.m. eastern standard time on December 11, 1995. Proposals sent by First Class mail must be sent to the following address:

Proposal Services Branch, Awards Management Division, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Ag Box 2245, Washington, DC 20250-2245, Telephone: (202) 401-5048

Proposals that are delivered by Express mail, a courier service, or by hand must be submitted to the following address (note that the zip code differs from that shown above): Proposal Services Branch, Awards Management Division, Cooperative State Research, Education and Extension Service, U.S. Department of Agriculture, Room 303, Aerospace Center, 901 D Street, SW., Washington, DC 20024, Telephone: (202) 401-5048

Supplementary 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 1980 (44 U.S.C. 3504(h)), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524-0022.

Done at Washington, DC, on this 1st day of September, 1995.

William D. Carlson,

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

Robert J. Reginato,

Acting Administrator, Agricultural Research Service.

[FR Doc. 95-22464 Filed 9-8-95; 8:45 am]

BILLING CODE 3410-22-M