DEPARTMENT OF AGRICULTURE

Agricultural Research Service
Cooperative State Research, Education, and Extension Service

Biotechnology Risk Assessment Research Grants Program for Fiscal Year 2000; Request for Proposals and Request for Input

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

ACTION: Notice of request for proposals and request for input.

SUMMARY: The Agricultural Research Service (ARS) and the Cooperative State Research, Education, and Extension Service (CSREES) are announcing the Biotechnology Risk Assessment Research Grants Program (the ''Program'') for fiscal year (FY) 2000. Proposals are hereby requested from eligible institutions as identified herein for competitive consideration of Biotechnology Risk Assessment Grant awards. 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 CSREES and ARS of the U.S. Department of Agriculture.

CSREES also is soliciting comments regarding this request for proposals from any interested party. These comments will be considered in the development of the next request for proposals for this program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA).

DATES: All proposals must be received at USDA on or before April 10, 2000. Proposals not received on or before this date will not be considered for funding.

User comments are requested within six months from the issuance of the request for proposals. Comments received after that date will be considered to the extent practicable (see Part VII.C.).

ADDRESSES: Proposals must be submitted to the following mailing address: Biotechnology Risk Assessment Research Grants; Proposal Services Unit, Office of Extramural Programs, c/o Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, STOP 2245, 1400 Independence Ave., SW, Washington, DC 20250–2245.

The address for hand-delivered proposals or proposals submitted using an express mail or overnight courier service is: Biotechnology Risk Assessment Research Grants, 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, SW, Washington, DC 20024, telephone: (202) 401–5048.

Written user comments should be submitted by mail to: Policy and Program Liaison Staff, Office of Extramural Programs, USDA–CSREES, STOP 2299, 1400 Independence Avenue, SW, Washington, DC 20250–2299; or via e-mail to: RFP–OEP@reeusda.gov. (This e-mail address is intended only for receiving stakeholder input comments regarding this RFP, and not for requesting information or forms.)

FOR FURTHER INFORMATION CONTACT:

Dr. Deborah Sheely, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Stop 2241, 1400 Independence Avenue, SW, Washington, DC 20250–2241; telephone: (202) 401–1924, e-mail: dsheely@reeusda.gov; 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, e-mail: rmf@ars.usda.gov.

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Part I. General Information

A. Legislative Authority

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 administrative regulations for this program are found at 7 CFR part 3415.

B. Applicant Eligibility

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

Part II. Program Description

CSREES and ARS will competitively award research grants to support science-based biotechnology regulation, thereby helping to address concerns about the effects of introducing genetically modified organisms into the environment and helping regulators to develop 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. Research funded through this program will be relevant to risk assessment and the regulatory process. When evaluating transgenic organisms, regulators must answer the following four general questions: (1) Is there a hazard (potential hazard identification)? (2) How likely is the hazard to occur (quantifying the probability of occurrence)? (3) What is the severity and extent of the hazard if it occurs (quantifying the effects)? and (4) Is there an effect above and beyond what might occur with an organism, with similar traits, developed using other technologies?

Although investigators are not required to perform actual risk assessments in the research they propose, they should design studies that will provide information useful to regulators for making science-based decisions in their assessments of genetically-modified organisms. Accordingly, program applicants are encouraged to address the following questions in their proposals: (1) What is the relevance of this research to the evaluation of transgenic organisms? (2) What information will be provided by this research to help regulators adequately assess transgenic organisms? and (3) How does this research model appropriate studies necessary to identify and/or characterize hazards associated with introducing genetically-modified organisms into the environment?

The Program does not support risk management research, which is defined to include either: (1) Research aimed primarily at reducing effects of specific biotechnology-derived agents; or (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.

In addition to addressing the questions posed above, proposals must include a statement describing the relevance of the proposed project to one or more of the research topics requested in this request for proposals. 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.

A. Purpose of the Program

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 (including fungi, bacteria, and 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.

B. Available Funding

Subject to the availability of funds, the anticipated amount available for support of the Program in FY 2000 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; Pub. L. No. 106–78, sec. 711).

C. Areas of Research To Be Supported

Proposals addressing the following topics are requested:

1. Research relevant to assessing the effects of the introduction into the environment of genetically engineered organisms. Potential subject areas include but are not limited to:

(a) Research on the potential for recombination between plant viruses and plant-encoded viral transgenes;

(b) Research on the potential for non-target effects of introduced foreign gene products 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, including their impact on beneficial or soil organisms;

(c) Changes in ecosystem or agro-ecosystem function and composition;

(d) Research on gene flow from transgenic crops to related plants and exploration of factors influencing gene transfer rates. Gene flow experiments on crops with a high potential for gene introgression into wild or weedy relatives (*e.g.,* those with high rates of outcrossing and with overlapping habitats are of particular interest);

(e) Research on the role that insects and/or pathogens play in limiting populations of crops and weeds as this relates to acquisition of transgenic pest protection by crops and/or weeds; and

(f) Research on how transgenic plants, especially grasses, that are resistant or tolerant to environmental stresses (such as drought or salt) affect land use practices (new habitats or tillage), water use (irrigation) patterns, and species displacement.

The data collected may include: survival; reproductive fitness; genetic stability (*e.g.,* transgene retained during backcrossing); genetic recombination; horizontal gene transfer; loss of genetic diversity; or enhanced competitiveness. As long as the data gathered are relevant to the assessment of the effects of genetically modified organisms, the experiments need not utilize transgenic organisms. When feasible, measures 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 and may address cumulative effect concerns. Studies should attempt to project impacts over as large a spatial and temporal scale as feasible. Potential focus areas include but are not limited to:

(a) Studies of insects and viruses that have developed resistance to plants possessing transgenic protection from them. This may be done by monitoring locations where such plants are grown on a commercial scale or in large scale production. The analysis of resistant viral strains should include analyzing whether the strain arose via recombination between viral transgenes and the viral genome and an analysis of how the resistance was effected (*e.g.,* changed coat protein with increased seed or insect vector transmissibility). The potential for transcapsidation in transgenic plants to alter seed transmission can be evaluated by comparing the levels of infected seed from transgenic plants inoculated with a virus, that could be transcapsidated, with seed from nontransgenic plants inoculated in a similar manner. Analysis should include the presence of satellite RNA (satRNA) which may replicate with the help of a suitable helper virus. Such projects should survey the production sites for two to three years.

(b) Studies to assess the impact of transgenic plants, especially insect resistant or herbicide tolerant plants, on biodiversity of agro-ecosystems. This could include changes in population dynamics and species diversity of nontarget arthropods (particularly beneficial predators, parasites, and pollinators), plants, mammals, avian or microbial species (including both pathogenic or beneficial fungi or bacteria associated with the crop plant). These studies should be conducted in such a way as to compare the impacts of transgenic plants to nontransgenic cultivars with otherwise similar phenotypes using the commonly recommended or adopted practices for tillage, irrigation, and control of pests or weeds. Also, effects of these plants on soil erosion or water quality could be included. Extensive documentation of agricultural practices will be a necessary component.

(c) Monitoring for the occurrence of individual or stacked resistance traits in wild/weedy relatives of commercialized transgenic crops, and subsequently, any effects of such genes on fitness, competitiveness, and weediness.

3. Research to assess the effects of transgenes in wild relatives of crop species. This research could evaluate the potential for unexpected fitness effects by comparing fitness characteristics in hybrids or introgressants between a transgenic line and the wild relative to hybrids or introgressants between the nontransgenic line and the wild relatives, or could evaluate fitness effects of the introduced trait by evaluating survival or reproductive success under natural conditions, or through planned competition experiments. Crop species could include those with compatible wild relatives in the U.S. which have been deregulated (*e.g.,* rice, rapeseed, melon, and squash) or are being developed (*e.g.,* sunflower, turfgrasses, strawberry). Introduced traits could include those

that have potential effects on fitness (*e.g.,* pest or disease resistance), or that have potential physiological or metabolic effects.

4. Research to assess the effects of genetically engineered plants with ''stacked'' resistance genes or genes that confer broad resistance to insects or diseases. These genes may give recipient plants a greater selective advantage and lead to less predictable ecological consequences. Possible areas of research include, but are not limited to: (a) The impact of gene stacking on non-target species; (b) the effects of stacked genes on pest populations; (c) transmission and establishment of multiple resistance genes into weedy relatives; (d) influence of genetic factors such as linkage on the transmission and establishment of multiple genes; and (e) ecological importance in weedy hosts of pest complexes sufficiently variable as to require broad resistance or stacked genes for their control.

5. Research to develop statistical methodology and quantitative measures of risks associated with field testing of genetically modified organisms.

6. The Program will, subject to resource availability, provide partial funding to organize a conference that brings together scientists, regulators, and others to review the science-based data relevant to risk assessment of genetically modified organisms released into the environment. The steering committee for the conference should include representatives from a variety of relevant scientific disciplines, such as ecology, population biology, pathology, production and resource management science, as well as educators, extension specialists and others, as appropriate. The goals of such a conference may include sharing of scientific information and identification of gaps in knowledge, and/or public education and outreach, among others. Publication of the proceedings will be required. The Program will fund a maximum of two conference proposals.

Part III. Content of a Proposal

The format guidelines for full research proposals, found in the administrative provisions for the Program at 7 CFR 3415.4(d), should be followed for the preparation of proposals under the Program in FY 2000. In addition, please note the following items: (1) The Department elects not to solicit preproposals in FY 2000; (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 vita (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 (as described in the proposal project 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 four years, including current and planned collaborations;

(B) All co-authors on publications within the past four 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 four years; and

(D) All thesis or postdoctoral advisees/advisors within the past four 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 (NEPA), as amended (42 U.S.C. 4321 *et seq.*)), environmental data or documentation for the proposed project is to be provided to CSREES and ARS in order to assist CSREES and ARS in carrying out their responsibilities under NEPA. These responsibilities include determining whether the project requires an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) or whether it can be excluded from this requirement on the basis of the categorical exclusions listed in 7 CFR 3407.6. To assist CSREES and ARS in this determination, the applicant should review the categories defined for exclusion to ascertain whether the proposed project may fall within one of the exclusions.

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 information submitted in association with NEPA compliance should be identified in the Table of Contents as ''NEPA Considerations'' and Form CSREES–1234 and supporting documentation should be placed after the Form CSREES–661, Application for Funding, in the proposal.

Even though the applicant considers that a proposed project may fall within a categorical exclusion, CSREES and ARS may determine that an EA or an EIS is necessary for an activity if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present that may cause such activity to have a significant environmental effect.

Part IV. How To Obtain Application Materials

Copies of this request for proposals, 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, SW, Washington, DC 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 2000 Biotechnology Risk Assessment Research Grants Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

This request for proposals and other application information and materials also are available at the Program's website (http://www.reeusda.gov/crgam/biotechrisk/biotech.htm).

Part V. Submission of a Proposal

A. What to Submit

An original and 14 copies of a proposal must be submitted. Proposals should be typed on 8½″ x 11″ white paper, single- or double-spaced, and one side of the page only. The text of the proposal should be prepared using no type smaller than 12 point font size and one-inch margins. 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.

B. Where and When To Submit

Hand-delivered proposals (brought in person by the applicant or through a courier service) must be received on or before April 10, 2000, at 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, Room 303, Aerospace Center; 901 D Street, SW; Washington, DC 20024. The telephone number is (202) 401–5048. Proposals transmitted via a facsimile (fax) machine will not be accepted.

Proposals submitted through the U.S. mail must be received on or before April 10, 2000. Proposals submitted through the U.S. mail should be sent to the following address: Biotechnology Risk Assessment Research Grants Program; Proposal Services Unit; Office of Extramural Programs, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW; Washington, DC 20250–2245.

C. Acknowledgment of Proposals

The receipt of all proposals will be acknowledged in writing or via the Internet (e-mail). Therefore, it is important to include your e-mail address on Form CSREES–661 when applicable. This acknowledgment will contain a proposal identification number. Once your proposal has been assigned a proposal number, please cite that number in future correspondence.

Part VI. 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 and/or public understanding; 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.

Part VII. Supplementary Information

A. 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 Other Agreements with Institutions of Higher Education, Hospitals and Other Nonprofit Organizations.

B. Programmatic Contact

For additional information on the Program, please contact:

Dr. Deborah Sheely, Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Stop 2241; 1400 Independence Avenue, SW; Washington, DC 20250–2241; Telephone: (202) 401–1924; e-mail: dsheely@reeusda.gov; 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, e-mail: rmf@ars.usda.gov.

C. Stakeholder Input

CSREES is soliciting comments regarding this solicitation of applications from any interested party. In your comments, please include the name of the program and the fiscal year of the request for proposals to which you are responding. These comments will be considered in the development of the next request for proposals for the program. Such comments will be used 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)). Comments should be submitted as provided for in the **ADDRESSES** and **DATES** portions of this notice.

D. 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, as amended (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, DC, on this 28th day of February, 2000.

Charles W. Laughlin,

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

Edward B. Knipling,

Acting Administrator, Agricultural Research Service.

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