

and discuss progress, or may offer individual opinions on areas of risk assessment research appropriate to agricultural biotechnology. The annual program solicitation will indicate whether funds are available to support an Annual Conference and, if so, will include instructions on the preparation and submission of proposals requesting funds from the Department for support of an Annual Conference. The Department may also elect to require principal investigators whose research is funded under this program to attend an Annual Conference and to present data on the results of their research efforts. Should attendance at an Annual Conference be required, the annual program solicitation will so indicate, and principal investigators may include attendance costs in their proposed budgets.

The Administrator may, with respect to any grant or to any class of awards, impose additional conditions prior to or at the time of any award when, in the Administrator's judgment, such conditions are necessary to ensure or protect advancement of the approved project, the interests of the public, or the conservation of grant funds.

### Subpart B—Scientific Peer Review of Research Grant Applications

#### § 3415.10 Establishment and operation of peer review groups.

Subject to § 3415.5, the Administrator shall adopt procedures for the conduct of peer reviews and the formulation of recommendations under § 3415.14.

#### § 3415.11 Composition of peer review groups.

(a) Peer review group members and *ad hoc* reviewers will be selected based upon their training and experience in relevant scientific or technical fields, taking into account the following factors:

(1) The level of formal scientific or technical education by the individual and the extent to which an individual is engaged in relevant research activities;

(2) The need to include as peer reviewers experts from various areas of specialization within relevant scientific or technical fields;

(3) The need to include as peer reviewers experts from a variety of organizational types (e.g., universities, Federal laboratories, industry, private consultant(s), Federal and State regulatory agencies, environmental organizations) and geographic locations; and

(4) The need to maintain a balanced composition of peer review groups related to minority and female representation and an equitable age distribution.

(b) [Reserved]

#### § 3415.12 Conflicts of interest.

Members of peer review groups covered by this part are subject to relevant provisions contained in title 18 of the United States Code relating to criminal activity, Departmental regulations governing employee responsibilities and conduct (part O of this title), and Executive Order No. 11222, as amended.

#### § 3415.13 Availability of information.

Information regarding the peer review process will be made available to the extent permitted under the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a.), and implementing Departmental regulations (part 1 of this title).

#### § 3415.14 Proposal review.

(a) All grant applications will be acknowledged. Prior to technical examination, a preliminary review will be made for responsiveness to the program solicitation (e.g., relationship of application to announced program area). Proposals that do not fall within the guidelines as stated in the program solicitation will be eliminated from competition and will be returned to the applicant.

(b) All applications will be carefully reviewed by the Administrator, qualified officers or employees of the Department, the respective peer review group, and *ad hoc* reviewers, as required. Written comments will be solicited from *ad hoc* reviewers when required, and individual written comments and in-depth discussions will be provided by peer review group members prior to recommending applications for funding. Applications will be ranked and support levels recommended within

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the limitation of total available funding for each research program area as announced in the program solicitation.

(c) No awarding official will make a grant based upon an application covered by this part unless the application has been reviewed in accordance with the provisions of this part and unless said reviewers have made recommendations concerning the scientific merit and relevance to the program of such application.

(d) Except to the extent otherwise provided by law, such recommendations are advisory only and are not binding on program officers or on the awarding officials of CSREES and ARS.

### § 3415.15 Evaluation factors.

In carrying out its review under § 3415.14, the peer review group will take into account the following factors unless, pursuant to § 3415.5(a), different evaluation criteria are specified in the annual program solicitation:

- (a) Scientific merit of the proposal.
- (1) Conceptual adequacy of hypothesis;
- (2) Clarity and delineation of objectives;
- (3) Adequacy of the description of the undertaking and suitability and feasibility of methodology;
- (4) Demonstration of feasibility through preliminary data;
- (5) Probability of success of project;
- (6) Novelty, uniqueness and originality; and
- (7) Appropriateness to regulation of biotechnology and risk assessment.
- (b) Qualifications of proposed project personnel and adequacy of facilities.
- (1) Training and demonstrated awareness of previous and alternative approaches to the problem identified in the proposal, and performance record and/or potential for future accomplishments;
- (2) Time allocated for systematic attainment of objectives;
- (3) Institutional experience and competence in subject area; and
- (4) Adequacy of available or obtainable support personnel, facilities, and instrumentation.
- (c) Relevance of project to solving biotechnology regulatory uncertainty for United States agriculture.

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(1) Scientific contribution of research in leading to important discoveries or significant breakthroughs in announced program areas; and

(2) Relevance of the risk assessment research to agriculture and environmental regulations.

## PART 3418—STAKEHOLDER INPUT REQUIREMENTS FOR RECIPIENTS OF AGRICULTURAL RESEARCH, EDUCATION, AND EXTENSION FORMULA FUNDS

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- 3418.1 Definitions.
- 3418.2 Scope and purpose.
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- 3418.6 Prohibition.

AUTHORITY: 5 U.S.C. 301; 7 U.S.C. 7612(c)(2).

SOURCE: 65 FR 5998, Feb. 8, 2000, unless otherwise noted.

### § 3418.1 Definitions.

As used in this part:

*1862 institution* means a college or university eligible to receive funds under the Act of July 2, 1862 (7 U.S.C. 301, *et seq.*).

*1890 institution* means a college or university eligible to receive funds under the Act of August 30, 1890 (7 U.S.C. 321, *et seq.*), including Tuskegee University.

*1994 institution* means an institution as defined in section 532 of the Equity in Educational Land-Grant Status Act of 1994 (7 U.S.C. 301 note).

*Formula funds* means agricultural research funds provided to 1862 institutions and agricultural experiment stations under the Hatch Act of 1887 (7 U.S.C. 361a, *et seq.*); extension funds provided to 1862 institutions under sections 3(b) and 3(c) of the Smith-Lever Act (7 U.S.C. 343(b) and (c)) and section 208(c) of the District of Columbia Public Postsecondary Education Reorganization Act, Pub. L. 93-471; agricultural extension and research funds provided to 1890 institutions under sections 1444 and 1445 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (NARETPA)(7 U.S.C. 3221 and 3222); education formula funds provided to 1994 institutions under section 534(a) of