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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 by a peer review group and/or *ad hoc* reviewers in accordance with the provisions of this part and said reviewers have made recommendations concerning the merit 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 official.

§ 3411.15 Evaluation factors.

Subject to the varying conditions and needs of States, Federally funded agricultural research supported under this program shall be designed to, among other things, accomplish one or more of the following purposes: Continue to satisfy human food and fiber needs; enhance the long-term viability and competitiveness of the food production and agricultural system of the United States within the global economy; expand economic opportunities in rural America and enhance the quality of life for farmers, rural citizens, and society as a whole; improve the productivity of the American Agricultural system and develop new agricultural crops and new uses for agricultural commodities; develop information and systems to enhance the environment and the natural resource base upon which a sustainable agricultural economy depends; or enhance human health. Therefore, in carrying out its review under § 3411.14, the peer review group shall take into account the following factors unless, pursuant to § 3411.5(a), different evaluation criteria are specified in the 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; and

(6) Novelty, uniqueness and originality.

(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 long-range improvements in and sustainability of United States agriculture or to one or more of the research purposes outlined in the first paragraph of this section.

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

(2) Relevance of the research to agricultural, environmental, or social needs.

[56 FR 57952, Nov. 14, 1991. Redesignated at 60 FR 63368, Dec. 8, 1995, as amended at 61 FR 45319, Aug. 29, 1996]

PART 3415—BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS PROGRAM

Subpart A—General

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AUTHORITY: 5 U.S.C. 301 and 7 U.S.C. 5921.

SOURCE: 58 FR 65647, Dec. 15, 1993, unless otherwise noted.

Subpart A—General

§ 3415.1 Applicability of regulations.

(a) The regulations of this part apply to research grants awarded under the authority of section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990, (7 U.S.C. 5921). Grants awarded under this section will support biotechnology risk assessment research to help address concerns about the effects of introducing certain biotechnology products into the environment and to help regulators develop policies concerning the introduction of such products. Taking into consideration any determinations made through consultations with such entities as the Animal and Plant Health Inspection Service, the Forest Service, the Environmental Protection Agency, the Office of Agricultural Biotechnology, and the Agricultural Biotechnology Research Advisory Committee, the Administrators of CSREES and ARS shall determine and announce, through publication of a Notice in such publications as the FEDERAL REGISTER, professional trade journals, agency or program handbooks, the Catalog of Federal Domestic Assistance, or any other appropriate means, specific areas of research for which preproposals or proposals will be solicited and the extent that funds are available therefor.

(b) The regulations of this part do not apply to grants awarded by the Department of Agriculture under any other authority.

§ 3415.2 Definitions.

As used in this part:

(a) *Ad hoc reviewers* means experts or consultants qualified by training and experience in particular scientific or technical fields to render special expert advice, through written evaluations of grant applications, in accordance with the provisions of this part, on the scientific or technical merit of grant applications in those fields.

(b) *Administrator* means the Administrator of the Cooperative State Research, Education, and Extension Service (CSREES) and/or the Administrator of the Agricultural Research Service (ARS) and any other officer or employee of the Department of Agriculture to whom the authority involved may be delegated.

(c) *Awarding official* means the Administrator and any other officer or employee of the Department to whom the authority to issue or modify grant instruments has been delegated.

(d) *Biotechnology* means any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific use. The development of materials that mimic molecular structures or functions of living systems is included.

(e) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(f) *Department* means the Department of Agriculture.

(g) *Grant* means the award by the Administrator of funds to a grantee to assist in meeting the costs of conducting, for the benefit of the public, an identified project which is intended and designed to establish, discover, elucidate, or confirm information or the underlying mechanisms relating to a research program area identified in program solicitation.

(h) *Grantee* means the entity designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part.

(i) *Peer review group* means an assembled group of experts or consultants qualified by training and experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this part, on the scientific and technical merit of grant applications in those fields.

(j) *Principal investigator* means a single individual who is responsible for the scientific and technical direction of the project, as designated by the grantee in the grant application and approved by the Administrator.

(k) *Project* means the particular activity within the scope of one or more

of the research program areas identified in the annual program solicitation that is supported by a grant under this part.

(l) *Project period* means the total time approved by the Administrator for conducting the proposed project as outlined in an approved grant application.

(m) *Research* means any systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(n) *Methodology* means the project approach to be followed to carry out the project.

§ 3415.3 Eligibility requirements.

(a) Except where otherwise prohibited by law, any public or private research or educational institution or organization shall be eligible to apply for and to receive a grant award under this part, provided that the applicant qualifies as a responsible grantee under the criteria set forth in paragraph (b) of this section.

(b) To qualify as responsible, an applicant must meet the following standards as they relate to a particular project:

(1) Adequate financial resources for performance, the necessary experience, organizational and technical qualifications, and facilities, or a firm commitment, arrangement, or ability to obtain same (including by proposed subagreements);

(2) Ability to comply with the proposed or required completion schedule for the project;

(3) Satisfactory record of integrity, judgment, and performance, including, in particular, any prior performance under grants or contracts from the Federal government;

(4) Adequate financial management system and audit procedures that provide efficient and effective accountability and control of all funds, property, and other assets; and

(5) Otherwise be qualified and eligible to receive a grant under the applicable laws and regulations.

(c) Any applicant who is determined to be not responsible will be notified in writing of such finding and the basis therefor.

§ 3415.4 How to apply for a grant.

(a) A program solicitation will be prepared and announced through publications such as the FEDERAL REGISTER, professional trade journals, agency or program handbooks, the Catalog of Federal Domestic Assistance, or any other appropriate means, as early as practicable each fiscal year.

The Department may elect to solicit preproposals each fiscal year in order to eliminate from consideration proposed research that does not address narrowly focused program objectives. A preproposal will be limited in length (in comparison to a full proposal) to alleviate waste of time and effort by applicants in the preparation of proposals and USDA staff in the review of proposals. If the Department solicits preproposals through publication of the annual program solicitation, the Department does not anticipate publishing a subsequent solicitation for full proposals. Applicants submitting preproposals deemed appropriate to the objectives of this program as set out in the annual solicitation will be requested to submit full proposals; the full proposals will then be evaluated in accordance with § 3415.5 through § 3415.15 of this part.

The annual program solicitation will contain information sufficient to enable applicants to prepare preproposals or full proposals under this program and will be as complete as possible with respect to:

(1) Descriptions of the specific research areas that the Department proposes to support during the fiscal year involved, including anticipated funds to be awarded;

(2) Eligibility requirements;

(3) Obtaining application kits;

(4) Deadline dates for submission of preproposal or proposal packages;

(5) Name and mailing address to send preproposals or proposals;

(6) Number of copies to submit; and

(7) Special requirements.

(b) *Application Kit.* An Application Kit will be made available to any potential grant applicant who requests a copy. This kit contains required forms, certifications, and instructions applicable to the submission of grant preproposals or proposals.

(c) *Format for preproposals.* As stated above, the Department may elect to solicit preproposals under this program. Unless otherwise indicated by the Department in the annual program solicitation, the following general format applies for the preparation of preproposals:

(1) *''Application for Funding (Form CSREES–661)''.* All preproposals submitted by eligible applicants should contain an ''Application for Funding'', Form CSREES–661, which must be signed by the proposing principal investigator(s) and endorsed by the cognizant authorized organizational representative who possesses the necessary authority to commit the applicant's time and other relevant resources. The title of the proposal must be brief (80-character maximum), yet represent the major thrust of the project. Because this title will be used to provide information to those who may not be familiar with the proposed project, highly technical words or phraseology should be avoided where possible. In addition, phrases such as ''investigation of'' and ''research on'' should not be used.

(2) *Project summary.* Each preproposal must contain a project summary, the text of which may not exceed three (3) single- or double-spaced pages. The Department reserves the option of not forwarding for further consideration a preproposal in which the project summary page limit is exceeded. The project summary is not intended for the general reader; consequently, it may contain technical language comprehensible primarily by persons in disciplines relating to the food and agricultural sciences. The project summary should be a self-contained specific description of the activity to be undertaken and should focus on:

(i) Overall project goal(s) and supporting objectives;

(ii) Plans to accomplish project goal(s); and

(iii) Relevance or significance of the project to United States agriculture.

(3) *Budget.* A budget detailing requested support for the proposed project period must be included in each preproposal. A copy of the form which must be used for this purpose, along with instructions for completion, is included in the Application Kit identified under § 3415.4(b) of this part and may be reproduced as needed by applicants. Funds may be requested under any of the categories listed on the budget form, provided that the item or service for which support is requested may be identified as necessary for successful conduct of the proposed project, is allowable under applicable Federal cost principles, and is not prohibited under any applicable Federal statute.

(4) *Special requirements.* (i) The annual program solicitation will describe any special preproposal submission requirements, such as paper size or type pitch to be used in the preparation of preproposals. The solicitation will also describe special program requirements, such as conference attendance or electronic project reporting, for which applicants may allocate funds when preparing proposed budgets.

(ii) By signing the ''Application for Funding'' identified under § 3415.4(c)(1) in its submission of a preproposal, the applicant is certifying compliance with the restrictions on the use of appropriated funds for lobbying set out in 7 CFR part 3018.

(5) *Evaluation of preproposals.* Preproposals shall be evaluated to determine whether the substance of the proposed project is appropriate to the objectives of this program as set out in the annual program solicitation. Subsequently, the Administrator shall request full proposals from those applicants proposing projects deemed appropriate to the objectives of this program as set out in the annual program solicitation. Such proposals shall conform to the format for full proposals set out below and shall be evaluated in accordance with § 3415.5 through § 3415.15 of this part.

(d) *Format for full proposals.* Unless otherwise indicated by the Department in the annual program solicitation, the following general format applies for the preparation of full proposals under this program:

(1) *''Application for Funding'' (Form CSREES–661).* All full proposals submitted by eligible applicants should contain an Application for Funding'', Form CSREES–661, which must be

signed by the proposed principal investigator(s) and endorsed by the cognizant authorized organizational representative who possesses the necessary authority to commit the applicant's time and other relevant resources. Investigators who do not sign the full proposal cover sheet will not be listed on the grant document in the event an award is made. The title of the proposal must be brief (80-character maximum), yet represent The major emphasis of the project. Because this title will be used to provide information to those who may not be familiar with the proposed project, highly technical words or phraseology should be avoided where possible. In addition, phrases such as ''investigation of'' or ''research on'' should not be used.

(2) *Project summary*. Each full proposal must contain a project summary, the length of which may not exceed three (3) single- or double-spaced pages. This summary is not intended for the general reader; consequently, it may contain technical language comprehensible primarily by persons in disciplines relating to the food and agricultural sciences. The project summary should be a self-contained, specific description of the activity to be undertaken and should focus on:

(i) Overall project goal(s) and supporting objectives;

(ii) Plans to accomplish project goal(s); and

(iii) Relevance or significance of the project to United States agriculture.

(3) *Project description*. The specific aims of the project must be included in all proposals. The text of the project description may not exceed 15 single- or double-spaced pages. The Department reserves the option of not forwarding for further consideration proposals in which the project description exceeds this page limit. The project description must contain the following components:

(i) *Introduction*. A clear statement of the long-term goal(s) and supporting objectives of the proposed project should preface the project description. The most significant published work in the field under consideration, including the work of key project personnel on the current application, should be reviewed. The current status of research in the particular scientific field also should be described. All work cited, including that of key personnel, should be referenced.

(ii) *Progress report*. If the proposal is a renewal of an existing project supported under this program, include a clearly marked performance report describing results to date from the previous award. This section should contain the following information:

(A) A comparison of actual accomplishments with the goals established for the previous award;

(B) The reasons established goals were not met, if applicable; and

(C) A listing of any publications resulting from the award. Copies of reprints or preprints may be appended to the proposal if desired.

(4) *Rationale and significance*. Present concisely the rationale behind the proposed project. The objectives' specific relationship and relevance to the area in which an application is submitted and the objectives' specific relationship and relevance to potential regulatory issues of United States biotechnology research should be shown clearly. Any novel ideas or contributions that the proposed project offers also should be discussed in this section.

(5) *Experimental plan*. The hypotheses or questions being asked and the methodology to be applied to the proposed project should be stated explicitly. Specifically, this section must include:

(i) A description of the investigations and/or experiments proposed and the sequence in which the investigations or experiments are to be performed;

(ii) Techniques to be used in carrying out the proposed project, including the feasibility of the techniques;

(iii) Results expected;

(iv) Means by which experimental data will be analyzed or interpreted;

(v) Pitfalls that may be encountered;

(vi) Limitations to proposed procedures; and

(vii) Tentative schedule for conducting major steps involved in these investigations and/or experiments.

In describing the experimental plan, the applicant must explain fully any materials, procedures, situations, or activities that may be hazardous to personnel (whether or not they are directly related to a particular phase of

the proposed project), along with an outline of precautions to be exercised to avoid or mitigate the effects of such hazards.

(6) *Facilities and equipment.* All facilities and major items of equipment that are available for use or assignment to the proposed research project during the requested period of support should be described. In addition, items of nonexpendable equipment necessary to conduct and successfully conclude the proposed project should be listed.

(7) *Collaborative arrangements.* If the nature of the proposed project requires collaboration or subcontractual arrangements with other research scientists, corporations, organizations, agencies, or entities, the applicant must identify the collaborator(s) and provide a full explanation of the nature of the collaboration. Evidence (i.e., letters of intent) should be provided to assure peer reviewers that the collaborators involved have agreed to render this service. In addition, the proposal must indicate whether or not such a collaborative arrangement(s) has the potential for conflict(s) of interest.

(8) *Personnel support.* To assist peer reviewers in assessing the competence and experience of the proposed project staff, key personnel who will be involved in the proposed project must be identified clearly. For each principal investigator involved, and for all senior associates and other professional personnel who expect to work on the project, whether or not funds are sought for their support, the following should be included:

(i) An estimate of the time commitments necessary;

(ii) Curriculum vitae. The curriculum vitae should be limited to a presentation of academic and research credentials, e.g., educational, employment and professional history, and honors and awards. Unless pertinent to the project, to personal status, or to the status of the organization, meetings attended, seminars given, or personal data such as birth date, marital status, or community activities should not be included. The vitae shall be no more than two pages each in length, excluding the publication lists. The Department reserves the option of not forwarding for further consideration a proposal in which each vitae exceeds the two-page limit; and

(iii) Publication List(s). A chronological list of all publications in referred journals during the past five years, including those in press, must be provided for each professional project member for whom a curriculum vitae is provided. Authors should be listed in the same order as they appear on each paper cited, along with the title and complete reference as these items usually appear in journals.

(9) *Budget.* A detailed budget is required for each year of requested support. In addition, a summary budget is required detailing requested support for the overall project period. A copy of the form which must be used for this purpose, Form CSREES–55, along with instructions for completion, is included in the Application Kit identified under § 3415.4(b) of this part and may be reproduced as needed by applicants. Funds may be requested under any of the categories listed, provided that the item or service for which support is requested may be identified as necessary for successful conduct of the proposed project, is allowable under applicable Federal cost principles, and is not prohibited under any applicable Federal statute.

(10) *Research involving special considerations.* A number of situations encountered in the conduct of research require special information and supporting documentation before funding can be approved for the project. If any such situation is anticipated, the proposal must so indicate. It is expected that a significant number of proposals will involve the following:

(i) *Recombinant DNA and RNA molecules.* All key personnel identified in a proposal and all endorsing officials of a proposed performing entity are required to comply with the guidelines established by the National Institutes of Health entitled, ''Guidelines for Research Involving Recombinant DNA Molecules,'' as revised. The Application Kit, identified above in § 3415.4(b), contains a form which is suitable for such certification of compliance (Form CSREES–662).

(ii) *Human subjects at risk.* Responsibility for safeguarding the rights and welfare of human subjects used in any

proposed project supported with grant funds provided by the Department rests with the performing entity. Regulations have been issued by the Department under 7 CFR Part 1c, Protection of Human Subjects. In the event that a project involving human subjects at risk is recommended for award, the applicant will be required to submit a statement certifying that the project plan has been reviewed and approved by the Institutional Review Board at the proposing organization or institution. The Application Kit, identified above in § 3415.4(b), contains a form which is suitable for such certification (Form CSREES–662).

(iii) *Experimental vertebrate animal care.* The responsibility for the humane care and treatment of any experimental vertebrate animal, which has the same meaning as ''animal'' in section 2(g) of the Animal Welfare Act of 1966, as amended (7 U.S.C. 2132(g)), used in any project supported with grant funds rests with the performing organization. In this regard, all key personnel associated with any supported project and all endorsing officials of the proposed performing entity are required to comply with the applicable provisions of the Animal Welfare Act of 1966, as amended (7 U.S.C. 2131 *et seq.*) and the regulations promulgated thereunder by the Secretary of Agriculture in 9 CFR parts 1, 2, 3, and 4. The applicant must submit a statement certifying that the proposed project is in compliance with the aforementioned regulations, and that the proposed project is either under review by or has been reviewed and approved by an Institutional Animal Care and Use Committee. The Application Kit, identified above in § 3415.4(b), contains a form which is suitable for such certification (Form CSREES–662).

(11) *Current and pending support.* All proposals must list any other current public or private research support (including in-house support) to which key personnel identified in the proposal have committed portions of their time, whether or not salary support for the person(s) involved is included in the budget. Analogous information must be provided for any pending proposals that are being considered by, or that will be submitted in the near future to, other possible sponsors, including other USDA programs or agencies. Concurrent submission of identical or similar proposals to other possible sponsors will not prejudice proposal review or evaluation by the Administrator or experts or consultants engaged by the Administrator for this purpose. However, a proposal that duplicates or overlaps substantially with a proposal already reviewed and funded (or that will be funded) by another organization or agency will not be funded under this program. The Application Kit, identified above in § 3415.4(b), contains a form which is suitable for listing current and pending support (Form CSREES–663).

(12) *Additions to project description.* Each project description is expected by the Administrator, the members of peer review groups, and the relevant program staff to be complete while meeting the page limit established in § 3415.4(d)(3). However, if the inclusion of additional information is necessary to ensure the equitable evaluation of the proposal (e.g., photographs that do not reproduce well, reprints, and other pertinent materials that are deemed to be unsuitable for inclusion in the text of the proposal), the number of copies submitted should match the number of copies of the application requested in the program solicitation. Each set of such materials must be identified with the name of the submitting organization, and the name(s) of the principal investigator(s). Information may not be appended to a proposal to circumvent page limitations prescribed for the project description. Extraneous materials will not be used during the peer review process.

(13) *Organizational management information.* Specific management information relating to an applicant shall be submitted on a one-time basis prior to the award of a grant identified under this Part if such information has not been provided previously under this or another program for which the sponsoring agency is responsible. The Department will contact an applicant to request organizational management information once a proposal has been recommended for funding.

§ 3415.5 Evaluation and disposition of applications.

(a) *Evaluation.* All proposals received from eligible applicants and submitted in accordance with deadlines established in the annual program solicitation shall be evaluated by the Administrator through such officers, employees, and others as the Administrator determines are uniquely qualified in the areas of research represented by particular projects. To assist in equitably and objectively evaluating proposals and to obtain the best possible balance of viewpoints, the Administrator shall solicit the advice of peer scientists, *ad hoc* reviewers, or others who are recognized specialists in the areas covered by the applications received and whose general roles are defined in § 3415.2. Specific evaluations will be based upon the criteria established in subpart B, § 3415.15, unless CSREES and/or ARS determine that different criteria are necessary for the proper evaluation of proposals in one or more specific program areas, or for specific types of projects to be supported, and announces such criteria and their relative importance in the annual program solicitation. The overriding purpose of these evaluations is to provide information upon which the Administrator may make an informed judgment in selecting proposals for support. Incomplete, unclear, or poorly organized applications will work to the detriment of applicants during the peer evaluation process. To ensure a comprehensive evaluation, all applications should be written with the care and thoroughness accorded papers for publication.

(b) *Disposition.* On the basis of the Administrator's evaluation of an application in accordance with paragraph (a) of this section, the Administrator will (1) approve support using currently available funds, (2) defer support due to lack of funds or a need for further evaluation, or (3) disapprove support for the proposed project in whole or in part. With respect to approved projects, the Administrator will determine the project period (subject to extension as provided in § 3415.7(c)) during which the project may be supported. Any deferral or disapproval of an application will not preclude its reconsideration or a reapplication during subsequent fiscal years.

§ 3415.6 Grant awards.

(a) *General.* Within the limit of funds available for such purpose, the awarding official of CSREES or ARS shall make grants to those responsible, eligible applicants whose proposals are judged most meritorious in the announced program areas under the evaluation criteria and procedures set forth in this part. The date specified by the Administrator as the effective date of the grant shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. It should be noted that the project need not be initiated on the grant effective date, but as soon thereafter as practicable so that project goals may be attained within the funded project period. All funds granted by CSREES or ARS under this Part shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, the applicable Federal cost principles, and the Department's assistance regulations (part 3015 and part 3016 of this title).

(b) *Grant award document and notice of grant award*—(1) *Grant award document.* The grant award document shall include at a minimum the following:

(i) Legal name and address of performing organization or institution to whom the Administrator has awarded a grant under the terms of this Part;

(ii) Title of project;

(iii) Name(s) and address(es) of principal investigator(s) chosen to direct and control approved activities;

(iv) Identifying grant number assigned by the Department;

(v) Project period, specifying the amount of time the Department intends to support the project without requiring recompetition for funds;

(vi) Total amount of Departmental financial assistance approved by the Administrator during the project period;

(vii) Legal authority(ies) under which the grant is awarded;

(viii) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the grant award; and

(ix) Other information or provisions deemed necessary by CSREES or ARS to carry out their respective granting activities or to accomplish the purpose of a particular grant.

(2) *Notice of grant award.* The notice of grant award, in the form of a letter, will be prepared and will provide pertinent instructions or information to the grantee that is not included in the grant award document.

(c) *Types of grant instruments.* The major types of grant instruments shall be as follows:

(1) *New grant.* This is a grant instrument by which CSREES or ARS agrees to support a specified level of effort for a project that generally has not been supported previously under this program. This type of grant is approved on the basis of peer review recommendation.

(2) *Renewal grant.* This is a grant instrument by which CSREES or ARS agrees to provide additional funding for a project period beyond that approved in an original or amended award. When a renewal application is submitted, it should include a summary of progress to date from the previous granting period. A renewal grant shall be based upon new application, *de novo* peer review and staff evaluation, new recommendation and approval, and a new award action reflecting that the grant has been renewed.

(3) *Supplemental grant.* This is an instrument by which CSREES or ARS agrees to provide small amounts of additional funding under a new or renewal grant as specified in paragraphs (c)(1) and (c)(2) of this section and may involve a short-term (usually six months or less) extension of the project period beyond that approved in an original or amended award. A supplement is awarded only if required to assure adequate completion of the original scope of work and if there is sufficient justification to warrant such action. A request of this nature normally will not require additional peer review.

(d) *Funding mechanisms.* The two mechanisms by which CSREES or ARS may elect to award new, renewal, and supplemental grants are as follows:

(1) *Standard grant.* This is a funding mechanism whereby CSREES or ARS agrees to support a specified level of effort for a predetermined time period without the announced intention of providing additional support at a future date.

(2) *Continuation grant.* This is a funding mechanism whereby CSREES or ARS agrees to support a specified level of effort for a predetermined period of time with a statement of intention to provide additional support at a future date, provided that performance has been satisfactory, appropriations are available for this purpose, and continued support would be in the best interests of the Federal government and the public. This kind of mechanism normally will be awarded for an initial one-year period, and any subsequent continuation project grants also will be awarded in one-year increments. The award of a continuation project grant to fund an initial or succeeding budget period does not constitute an obligation to fund any subsequent budget period. Unless prescribed otherwise by CSREES or ARS, a grantee must subject a separate application for continued support for each subsequent fiscal year. Requests for such continued support must be submitted in duplicate at least three months prior to the expiration date of the budget period currently being funded. Decisions regarding continued support and the actual funding levels of such support in future years usually will be made administratively after consideration of such factors as the grantee's progress and management practices and the availability of funds. Since initial peer reviews are based upon the full term and scope of the original grant application, additional evaluations of this type generally are not required prior to successive years' support. However, in unusual cases (e.g., when the nature of the project or key personnel change or when the amount of future support requested substantially exceeds the grant application originally reviewed and approved), additional reviews may be required prior to approving continued funding.

(e) *Obligation of the Federal Government.* Neither the approval of any application nor the award of any project grant commits or obligates the United States in any way to make any renewal, supplemental, continuation, or other award with respect to any approved application or portion thereof.

§ 3415.7 Use of funds; changes.

(a) *Delegation of fiscal responsibility.* The grantee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of grant funds.

(b) *Change in project plans.* (1) The permissible changes by the grantee, principal investigator(s), or other key project personnel in the approved grant shall be limited to changes in methodology, techniques, or other aspects of the project to expedite achievement of the project's approved goals. If the grantee or the principal investigator(s) is uncertain whether a particular change complies with this provision, the question must be referred to the awarding official of CSREES or ARS, as appropriate, for a final determination.

(2) Changes in approved goals, or objectives, shall be requested by the grantee and approved in writing by the awarding official of CSREES or ARS, as appropriate, prior to effecting such changes. Normally, no requests for such changes that are outside the scope of the original approved project will be approved.

(3) Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the grantee and approved in writing by the awarding official of CSREES or ARS, as appropriate, prior to effecting such changes.

(4) Transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not Federal funds are involved, shall be requested by the grantee and approved in writing by the awarding official of CSREES or ARS, as appropriate, prior to effecting such changes, unless prescribed otherwise in the terms and conditions of a grant.

(c) *Changes in project period.* The project period determined pursuant to § 3415.5(b) may be extended by the awarding official of CSREES or ARS, as appropriate, without additional financial support, for such additional period(s) as the appropriate awarding official determines may be necessary to complete, or fulfill the purposes of, an approved project. Any extension of time shall be conditioned upon prior request by the grantee and approval in writing by the appropriate awarding official, unless prescribed otherwise in the terms and conditions of a grant.

(d) *Changes in approved budget.* The terms and conditions of a grant will prescribe the circumstances under which written approval must be requested and obtained from the awarding official of CSREES or ARS, as appropriate, prior to instituting changes in an approved budget.

§ 3415.8 Other Federal statutes and regulations that apply.

Several other Federal statutes and regulations apply to grant preproposals or proposals considered for review or to grants awarded under this part. These include but are not limited to:

7 CFR 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. 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).

§ 3415.9 Other conditions.

The Administrator may elect to use a portion of available funding each fiscal year to support an Annual Conference, the purpose of which will be to bring together scientists and regulatory officials relevant to this program. At the Annual Conference, the participants may offer individual opinions regarding research needs, update information 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 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.

(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

Sec.

3418.1 Definitions.
3418.2 Scope and purpose.
3418.3 Applicability.
3418.4 Reporting requirement.
3418.5 Failure to comply and report.
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 the Equity in Educational Land-Grant Status Act of 1994 (7 U.S.C. 301 note); research funds provided to forestry schools under the McIntire-Stennis Act of 1962 (16 U.S.C. 582a, et seq.); and animal health and disease research funds provided to veterinary schools and agricultural experiment stations under section 1433 of NARETPA (7 U.S.C. 3195).

Recipient institution means any 1862 institution, 1890 institution, 1994 institution, or any other institution that receives formula funds from the Department of Agriculture.

Seek stakeholder input means an open, fair, and accessible process by which individuals, groups, and organizations may have a voice, and one that treats all with dignity and respect.

Stakeholder means any person who has the opportunity to use or conduct agricultural research, extension, or education activities of recipient institutions.

§ 3418.2 Scope and Purpose.

Section 102(c) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7612(c)) requires land-grant institutions, as a condition of receipt of formula funds, to solicit and consider input and recommendations from stakeholders concerning the use of formula funds. This regulation implements this requirement consistently for all recipient institutions that receive formula funds.

§ 3418.3 Applicability.

To obtain formula funds after September 30, 1999, each recipient institution shall establish and implement a process for obtaining stakeholder input on the uses of formula funds in accordance with this part.

§ 3418.4 Reporting requirement.

Each recipient institution shall report to the Department of Agriculture by October 1 of each fiscal year, the following information related to stakeholder input and recommendations:

(a) Actions taken to seek stakeholder input that encourages their participation;

(b) A brief statement of the process used by the recipient institution to identify individuals and groups who are stakeholders and to collect input from them; and

(c) A statement of how collected input was considered.

§ 3418.5 Failure to comply and report.

Formula funds may be withheld and redistributed if a recipient institution fails to either comply with § 3418.3 or report under § 3418.4.

§ 3418.6 Prohibition.

A recipient institution shall not require input from stakeholders as a condition of receiving the benefits of, or participating in, the agricultural research, education, or extension programs of the recipient institution.