

**NATIONAL INSTITUTE OF FOOD AND AGRICULTURE; U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS
PROGRAM**

INITIAL ANNOUNCEMENT

IMPORTANT INFORMATION: Changes in the FY 2012 RFA

In FY 2012, a submission of a full proposal application with a corresponding LOI is strongly encouraged (with exception to conference grant applications), but not required. The time and date of receipt of a LOI is 5:00 p.m. EDT, Thursday, December 1, 2011. For instructions on how to prepare a LOI, please see Part IV, A. The deadline for submission of a full proposal application is 5:00 p.m. EDT, Wednesday, February 1, 2012. Beginning in FY 2013, submission of a full proposal without a corresponding LOI will not be considered for review.

The purpose of the BRAG program is to support the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the effects of introducing into the environment genetically engineered organisms (GE), 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 BRAG program accomplishes its purpose by providing Federal regulatory agencies with scientific information relevant to regulatory issues.

The BRAG program supports applied and/or fundamental risk assessment research, 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 environmental risk assessment, including biological risk, and the federal regulatory process. When evaluating GE organisms, Federal 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; identifying likely exposure scenarios);
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 unmodified organism or an organism that has similar traits, but was developed using other technologies?

The BRAG program will also 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.

Although project directors (PDs) are not required to perform actual risk assessments as part of 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 engineered (GE) organisms. Accordingly, applicants are encouraged to address the following questions in their applications:

- What is the relevance of this research to the evaluation of GE organisms?
- What information will be provided by this research to help regulators adequately assess GE organisms?;
- How does this research provide information or methods or model exposures useful in identifying and/or characterizing hazards associated with introducing GE organisms into the environment?

Applications to the BRAG program must address one of the following program areas or seek partial funding for a conference that addresses science-based risk assessment or risk management of GE organisms released into the environment:

1. Research designed to identify and develop appropriate management practices to minimize physical and biological risks to the environment associated with GE animals, plants, and microorganisms;
2. Research designed to develop methods to monitor the dispersal of GE animals, plants, and microorganisms;
3. Research designed to further existing knowledge with respect to the characteristics, rates, and methods of gene transfer that may occur between GE animals, plants, and microorganisms, and related wild and agricultural organisms;
4. Environmental assessment research designed to provide analysis which compares the relative impacts of animals, plants, and microorganisms modified through genetic engineering to other types of production systems; or
5. Other areas of research designed to further the purposes of the BRAG program.

Awards will not be made for food safety risk assessment or risk management, health risk assessment or risk management of humans or domestic food animals exposed to GE organisms, social or economic research, methods for seed storage, clinical trials, commercial product development, product marketing strategies, product stewardship, or other research deemed inappropriate to risk assessment or risk management relative to the environment.

For full RFA, see: http://www.nifa.usda.gov/funding/rfas/pdfs/12_brag.pdf