

BRS STAKEHOLDER MEETING DISCUSSION QUESTIONS

To facilitate an interactive dialogue at the upcoming BRS Stakeholder Meeting, BRS is providing the questions below for stakeholder consideration. We hope these questions will assist your preparation for the meeting and stimulate feedback to improve BRS overall program design and delivery. These questions are intended to promote interactive plenary and small table group discussions.

PROGRAM DELIVERY INITIATIVES

- How can APHIS continue to improve on efficiencies and effectiveness in the regulatory process?

PETITION PROCESS IMPROVEMENTS

- What concerns do you have with the BRS petition process?
- What steps can be taken to improve the petition process so that both public and private sector researchers can more efficiently navigate the regulatory system?
- Given the increased complexity of petition submissions and the process for determining when the petition is complete, when should petitions be posted for public comment?

NEPA IMPLEMENTATION

The National Environmental Policy Act (NEPA) requires all Federal agencies to prepare certain environmental analyses which evaluate the potential impacts of agency actions on the quality of the human environment. Following APHIS NEPA implementing regulations, APHIS often prepares an EA or, in some instances, an EIS to inform decisions to issue a permit for environmental release of a GE organism into the environment or to grant nonregulated status to a GE organism. The Council on Environmental Quality (CEQ), the White House office which ensures that Federal agencies meet their NEPA obligations, allows Federal agencies to accept, for review, EAs and EISs prepared by applicants and third parties, respectively and many agencies have included this practice in their NEPA implementing procedures. Third-party contracting refers to the independent preparation of an environmental document such as an environmental impact statement (EIS) or environmental assessment (EA) by a contractor selected by the Federal Government and paid for by the applicant. To evaluate whether these options improve the quality and timeliness of our NEPA analyses and the efficiency with which they are produced, BRS is implementing a pilot that will allow applicants to submit environmental assessments and to consider third-party contracting as an additional option to preparing environmental documents related to regulatory determinations. BRS is seeking input from its stakeholders on how to best implement such a pilot.

- What advice do you have for USDA as we move forward with this pilot?
- How do you envision creating a system that works for a wide range of stakeholders?
- What criteria should we use to evaluate requests to participate in the pilot?

- What criteria should we use to evaluate the pilot?

BIOTECHNOLOGY QUALITY MANAGEMENT SYSTEM

- What could USDA/APHIS do to encourage participation in the BQMS audit program by industry and academia?
- How can USDA/APHIS facilitate participation in BQMS for those organizations that wish to enroll?
- What is the perception by the regulated community and others from the public of the BQMS audit program?