

Nomination Received by Council on Environmental Quality, Executive Office of the President
For the CEQ NEPA Pilot Project Program
<http://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/nepa-pilot-project-nominations>

PART I. NOMINATOR

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|-----------------------|------------------|
| First Name: | David |
| Last Name: | Reinhold |
| Organization: | USDA, APHIS, BRS |
| Project Title: | [None Submitted] |
| Submitted by: | Federal Agency |
| Date Received: | 06/07/2011 |

PART II. SHORT ANSWERS

I. What Federal agency or agencies will be involved in this pilot project?

United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services (USDA APHIS/BRS)

II. What is the Federal action to which this NEPA pilot project applies?

The USDA regulates certain genetically engineered (GE) organisms that may be plant pests. As part of this regulatory system, developers of regulated GE organisms can petition the agency to seek a determination that an article should not be regulated under 7 CFR part 340. These determinations for nonregulated status are made based on the procedures in 7 CFR 340.6. APHIS conducts NEPA analyses to inform the decisionmaker and the public of the potential environmental consequences associated with the action requested in the petition, as well as other reasonable alternatives, if any, for accomplishing the requested action.

III. How will this pilot project reduce the costs and time needed to complete the NEPA process?

APHIS is implementing a NEPA Pilot Project that will involve working with petitioners and outside experts for their assistance in developing high quality NEPA analyses for determinations of nonregulated status. The project will test new approaches to developing and obtaining environmental analyses and documents required under NEPA to determine the extent to which these approaches can improve overall timeliness and costs to the agency while maintaining the high quality standard that is required. This pilot project is part of a larger effort to improve the petition for nonregulated status evaluation process and is one of the strategies identified in USDAs High Priority Performance Goal for biotechnology regulation in the Presidents Performance Agenda. The pilot project will explore two voluntary mechanisms: (1) a petitioner-submitted environmental report (ER) which APHIS will use to develop an environmental assessment (EA) or an environmental impact statement (EIS); and (2) an EA or EIS prepared by an APHIS-selected contractor, funded by a cooperative services agreement (CSA) between the petitioner and APHIS. The pilot project will compare the quality of, and time and cost to complete NEPA analyses using these mechanisms against those prepared by the current mechanisms.

IV. How will this pilot project ensure rigorous environmental protection?

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This pilot project is designed to objectively measure the quality, time, and cost of NEPA analyses prepared utilizing petitioner-prepared ERs or CSA-funded NEPA analyses. APHIS will ensure rigorous environmental evaluation and oversight through thorough scientific, policy, and legal reviews of all analyses prepared under this pilot project. APHIS will continue to independently evaluate and critique all data provided by the petitioners, consult with technical experts, and use peer-reviewed scientific literature to prepare NEPA analyses. APHIS will continue to be fully responsible for the content of the analyses and the conclusions drawn from the analyses, regardless of whether they are based on an ER, or on a document prepared by a qualified contractor funded by a CSA. Consistent with current practice, petitions, ERs, and draft EAs will be made available to the public for comment prior to any decision on the petition. EISs will follow the CEQ regulations for scoping, public comment, and review.

V. How will this pilot project improve the quality and transparency of agency decisionmaking?

All ERs submitted to the agency by petitioners will be made available to the public on the agency website along with the petitions for nonregulated status. The agency will independently evaluate the information provided by petitioners and use this information along with the agency-prepared plant pest risk assessment, literature searches, and consultations with subject-matter experts to prepare in-house, or via contract, an environmental analysis of the agency-determined alternatives. The agency currently obtains much of the information, which is specific to the subject of the petition, from the petitioner when conducting NEPA analyses. The pilot project will provide the petitioners with guidance on the types of information used by the agency for NEPA analyses through a more formal mechanism than the current case-by-case inquiry. Throughout the pilot program, the guidance will be revised and updated based on feedback from the pilot participants and issues identified by APHIS. All developed guidance will be made publically available. By providing publically available guidance, petitioners can identify data needs early in their product development. This will allow petitioners to more efficiently collect and provide information. It will also allow interested members of the public to review the guidance and better understand the decisions made under the agency's regulations. APHIS will provide a transparent web-based mechanism for the public and interested parties to easily access information regarding the NEPA Pilot, including relevant environmental documents and guidance for NEPA Pilot processes and procedures. APHIS will also provide the public with quarterly updates on the number of pilot project petitions and a catalog of the stages of these petitions.

VI. Will this pilot project develop best practices that can be replicated by other agencies or applied to other Federal actions or programs? Please describe?

The goal of this pilot project is to evaluate methods for increasing the quality and efficiency (less time, lower costs) of NEPA analyses for decisions related to petitions for nonregulated status under 7 CFR part 340. While the evaluations in this pilot will be specific to these activities, the general approach to process improvement could be applied to other actions within this agency or to other Federal programs or actions. A successful pilot project will identify a suite of tools to be used by the agency and petitioners that balance agency and

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petitioner resources, lower costs and decrease times for decisions, increase the predictability of the process duration, and inform decisionmakers, as well as the public, of the potential environmental consequences associated with a proposed action.

PART III. PROJECT DESCRIPTION

(See attachment on following page.)

The USDA, Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services (BRS) announced a NEPA pilot program on April 7, 2011. This 2-year, voluntary pilot project will evaluate the quality, time, and cost of NEPA analyses developed using two different tools. The two tools are petitioner-submitted environmental reports (ERs), and cooperative service agreements (CSAs) between APHIS and the petitioner to fund APHIS-selected contractors to prepare environmental assessments (EAs) or environmental impact statements (EISs).

ERs are petitioner-prepared technical documents that aid the agency in preparing NEPA analyses. ERs provide information about a specific genetically engineered (GE) organism and can accompany a petition for nonregulated status (submitted under the regulations at 7 CFR 340.6), but are not a required component of the submission. An ER presents data beyond that required for a plant pest risk determination. It provides the background information necessary to analyze impacts on different resource areas from the action proposed in the petition. ERs are not NEPA documents. The agency will use the information in the ER to prepare a NEPA analysis in-house or by a qualified contractor. As required by the CEQ regulations, the agency is responsible for ensuring that the analyses in the NEPA documents (EAs and EISs) are balanced, address relevant issues, and take a hard look at the potential environmental impacts. As is the agency's current practice, all draft EAs will be available for public comment before the document is finalized and a decision document is prepared. EISs will follow the CEQ-defined public involvement requirements.

Petitioner-funded NEPA documents will be prepared through a CSA between the petitioner and APHIS. The CSA will outline the timeline for completion of the project, set a schedule for milestone reports, and stipulate how cost accounts will be reported to the petitioner. In accordance with the CSA, APHIS will use the money provided by the petitioner to pay for services to prepare an EA or EIS. APHIS will select and enter directly into a contract with the qualified environmental service provider. The petitioner will not be a party to this contract. All services will be reviewed and approved by APHIS only.

APHIS has begun to receive unsolicited ERs prepared by petitioners. The agency has found some of the information in these reports to be useful in preparing NEPA analyses. As part of this pilot project, APHIS will provide guidance to petitioners who wish to prepare ERs and use feedback from participants and observed issues to refine that guidance throughout the pilot program. APHIS will independently evaluate each ER and document the ways in which the report contributed to the final NEPA analysis. The agency will also track the time required to review and evaluate a report.

In the past, APHIS has prepared the majority of its environmental analyses in-house. However, more recently, APHIS has contracted for the preparation of some EAs and EISs. Most of these contracts have been funded directly by the agency, although a few have been funded through CSAs with the petitioner. This pilot program seeks to gather data to assess the impact of these practices on the overall quality, and the time for NEPA analyses to be conducted prior to making decisions on petitions for nonregulated status, as well as the cost to the agency. The pilot project will document agency resources needed to manage and review contractor-prepared analyses. The agency will compare resources used for contracted analyses to those prepared in-house. As part of the pilot project, APHIS will provide

participants with information on contract mechanisms for funding the preparation of a NEPA documents by contractors through use of CSAs.

In addition to providing general guidance to participants, APHIS will meet with participants to discuss their specific petition for nonregulated status and provide guidance on the specific types of data or analyses needed for that product.

Deliverables:

- Provide a transparent web-based mechanism for the public and interested parties to easily access information regarding the NEPA Pilot, including relevant environment documents and guidance for NEPA Pilot processes and procedures.
- Provide the public with quarterly updates on the number of pilot project petitions and a catalog of the stages of these petitions.
- Workshop on ERs and CSAs.
- Provide guidance to participants on ERs and CSAs.
- Updated guidance based on feedback from participants and identified issues.
- Final report evaluating the effectiveness of the tools used in this pilot to reduce cost and time of preparation of NEPA analyses related to petitions for nonregulated status and the impacts of these tools on the quality of the analyses.