Charge to Peer Reviewers of Influential Scientific Information

Contained in the

APHIS BRS Draft Programmatic Environmental Impact Statement.

Background:

APHIS has over 18 years of experience regulating the safe introduction of genetically engineered (GE) organisms. To ensure the Agency continues to achieve its regulatory goals, APHIS has undertaken a revision of its CFR Part 340 regulations to address changes that have occurred in the field of agricultural biotechnology since the Coordinated Framework for Regulation of Biotechnology was published in 1986 and the Agency's regulations were finalized in 1987. On January 23, 2004, APHIS published in the Federal Register a Notice of Intent (NOI) to prepare a programmatic Environmental Impact Statement (EIS), in compliance with the National Environmental Policy Act (NEPA) and APHIS' own NEPA implementation rules, to better inform the rule revision process.

On December 16, 2004, the Office of Management and Budget (OMB) released the "Final Information Quality Bulletin for Peer Review" establishing minimum standards for the peer review of influential or highly influential scientific information disseminated by the government. The purpose of this OMB-mandated process is to realize the benefits of meaningful peer review for scientific information disseminated by the Federal Government. It is part of an ongoing effort to improve the quality, objectivity, utility, and integrity of the government's scientific information.

Portions of the unpublished draft programmatic EIS contain scientific information that meet criteria of "influential scientific information". Influential scientific information is defined as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." To ensure that influential scientific information meets the standards of quality required for scientific disseminations, APHIS is undertaking the review of the influential scientific information contained in the draft EIS.

Peer Review Process:

Expert peer reviewers have been selected by the contractor in consultation with APHIS based upon subject-matter expertise, freedom from conflict of interest, and independence from APHIS. After reviewing only the influential scientific information contained in the draft programmatic EIS within Chapter 4 on environmental consequences, each reviewer will submit a report to the contract agent.

Because transparency is an important component of regulatory decision-making, a list of peer reviewers' names and institutional affiliations will be publicly disclosed, as will all reports provided by reviewers. However, individual reviewer names will *not* be associated with individual reports or particular comments (i.e., there will not be attribution to particular comments).

Instructions to Reviewers

Purpose

The scientific information in Chapter 4 of the draft programmatic EIS on environmental consequences describes those aspects of the biological and physical environment that may be affected by the current or proposed regulations administered by APHIS Biotechnology Regulatory Services (BRS) as well as the method of assessing potential risks to human health and the environment, illustrated with some examples. Additional discussion and analysis of environmental issues identified by the Agency, the public, and stakeholders as likely to be affected by the alternatives discussed in the EIS is also included. The purpose of this scientific information is to identify and characterize the potential environmental factors that might be affected by changes in the Agency's regulations.

Nature of the Review

The presentation of the scientific information in the draft programmatic EIS is intended to provide non-expert readers with a sufficient context and background with which to understand the biological and environmental science used to by the APHIS to evaluate potential impacts on the human environment arising from possible changes to APHIS regulations for GE organisms. For this reason, the science included in the document is a summary of current knowledge. It is **not** intended to be an exhaustive exploration of all the presented scientific issues, but is instead intended to provide readers with a sufficient context with which to understand the potential kinds of impacts on the human environment affected by possible changes to APHIS regulations for GE organisms. With this in mind, reviewers are asked to comment on each of the following aspects of the scientific information presented in the section of the draft programmatic EIS that they are considering.

- **Completeness –** Are potential factors and relevant issues identified?
- **Currency** – Does the information reflect current scientific thinking on the subject? Are more recent references available confirming the text in the draft programmatic EIS or containing new information that substantively changes the body of knowledge?
- **Accuracy** – Is the information characterized in a scientifically accurate manner? Is any information presented that is factually incorrect? Does the information accurately characterize the content of references cited? Are conclusions and summary statements drawn scientifically justified?
- **Uncertainty** -- Does the presentation of information deal with scientific uncertainty on this subject in an appropriate manner? Has the likelihood of each of the potential impacts been appropriately characterized? Has the relative importance of each of the impacts been characterized appropriately?

- **Objectivity** –Is the presentation of the body of scientific knowledge balanced and objective? Are references selectively cited or discussed in such a way as to introduce bias into the document?
- **Clarity**– Is the information understandable for a non-expert audience with a modest understanding of biological and environmental sciences? Is any information presented in a vague or ambiguous manner?

Finally, after a careful review of the scientific document using the criteria above, please answer the following question:

Does this scientific information presented accurately and objectively provide non-expert readers with a broad base of knowledge to understand the aspect of the biological and physical environment that is likely to be affected by the regulations currently administered by APHIS BRS and by possible changes of those regulations?

Please select one of the following responses:

(1) Yes, subject to minor editorial changes (if any).

(2) Yes, but only after revisions have been made to address specific weaknesses.

(3) No, this scientific document has significant shortcomings in its treatment of the natural and physical environment affected by APHIS BRS regulations.

Please *do not* include comments addressing **Regulatory and policy implications** of the information contained in the document. Opportunity to provide comment on these subjects is provided at future points in the NEPA process.

Structure of the Reviewer Report

- Reviewers should summarize their conclusions in a report. The report should clearly state a selected response (1, 2 or 3) to the question above, and include enough supporting detail to justify the conclusions. **Please organize the report to include the aspects listed above (Completeness, Currency, Accuracy, Uncertainty, Objectivity, and Clarity).** Cite specific examples in the document text where possible. If option (2) or (3) is selected by a reviewer, enough detailed information should be included to allow the authors to make the requested changes to the draft programmatic EIS. We prefer that you not spend time and energy on m**inor editorial changes** to word choice, style, grammar, etc.

Additional References/Citations- Reviewers are encouraged to submit a "track changes" version of the reviewed chapter, when appropriate, as well as additional reference material or citations of scientific literature along with their report. When submitting references or citations please include a brief description of the information presented in the referenced literature.