BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

October 15, 2008

Public Comment Processing
Attention: 1018-AT50
Division of Policy and Directives Management
U.S. Fish and Wildlife Service
4401 North Fairfax Drive
Suite 222
Arlington, VA 22203

Transmitted via Federal eRulemaking Portal at www.regulations.gov

Re: Interagency Cooperation Under the Endangered Species Act; Proposed Rule;
Docket No: FWS-R9-ES-2008-0093

To whom it may concern:

This letter is submitted by the Biotechnology Industry Organization (BIO) in response to the request for comments published by the Departments of Interior and Commerce in the Federal Register on August 15, 2008. 73 Fed. Reg. 47,868. BIO appreciates this opportunity to provide comment on behalf of its members.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

A number of BIO members work to develop food, feed, fuel and fiber crops through the techniques of modern biotechnology. The strong, multi-faceted federal regulation of biotechnology-derived crops includes review of potential impacts to threatened and endangered species and other "non-target" organisms by the relevant action agencies. The agencies conduct these reviews as part of their oversight responsibilities under the statutes that govern their

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regulation of biotechnology-derived products, independent of the requirements of the Endangered Species Act (ESA). BIO applauds regulatory efforts to improve the workability of the ESA section 7 consultation process, to recognize the expertise that exists within the action agencies, and to make the best possible use of scarce governmental resources.

Studies have repeatedly shown that biotechnology-derived crops have provided significant environmental benefits since their introduction. Pest-resistant and herbicide-resistant varieties of crops developed through biotechnology reduce the need for conventional pesticides and enable farmers to use low toxicity herbicides. A report by the National Center for Food and Agricultural Policy (NCFAP) found that in 2005, the eight biotechnology-derived crop varieties grown that year in the United States reduced pesticide applications by 69.7 million pounds.[1] Crops improved through biotechnology can actually help the environment by improving habitats for birds and other wildlife, and by enabling farmers to reduce the consumption of fuel and greenhouse gas emissions. Farmers have found that the use of biotechnology-derived crops can reduce the need for plowing to control weeds, which leads to better conservation of soil and water and a decrease in soil erosion and compaction.

Biotechnology-derived crops are among the most thoroughly tested plants in history, and are closely overseen by federal agencies to ensure that they do not cause harm to consumers, to agriculture or to the environment. The United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulates these plants as they are being field tested, prior to commercial sale, to ensure, among other things, that they will not pose a danger to beneficial organisms, such as honeybees, or to threatened or endangered species.

APHIS is not always the only federal agency that reviews these crops. Some of the crops being developed produce their own insecticides, lessening the need for conventional insecticide sprays. The United States Environmental Protection Agency (EPA) regulates the insecticide within these plants, referred to as a plant-incorporated protectant (PIP). This ensures, among other things,

[1] Quantification of the Impacts on US Agriculture of Biotechnology-derived Crops Planted in 2005: Executive Summary, National Center for Food and Agricultural Policy (Nov. 2006), available at http://www.ncfap.org/documents/2005biotechExecSummary.pdf. The full report is available at http://www.ncfap.org/documents/2005biotechimpacts-finalversion.pdf.

that the PIP does not cause undue harm to non-target organisms, including threatened or endangered species. Finally, for crops intended for food or animal feed, the United States Food and Drug Administration (FDA) reviews the safety of the whole food for human and animal consumption.

The regulatory decisions made by APHIS and EPA specifically address the impacts of biotechnology-derived crops on non-target species and the environment. These agencies have developed significant expertise both in the molecular biology of these crops, as well as the agricultural practices associated with their use. Each agency's decision making is grounded in sound science and a thorough analysis of the potential impacts these crops may have on the environment, including on threatened and endangered species. The final regulatory decision clearing these crops for commercialization is subject to public notice and comment.

Currently, an ESA section 7 review is also required for much of USDA's decision making regarding these crops, and for EPA's regulatory actions regarding PIPs, as well. Both USDA and EPA work with the Services[2] to ensure a thorough, science-based review. However, this review involves educating Services personnel on issues outside their normal areas of expertise and spending time and resources of both the action agencies and the Services in a process that is, in many ways, duplicative of the action agency's underlying regulatory action. In some cases, this duplication can delay the introduction of products that have significant environmental benefits.

To allow for the most effective use of limited resources, both within the Services and the action agencies, BIO supports the finalization of regulations that will recognize the expertise within action agencies such as APHIS and EPA, and that will provide clarity and certainty to the ESA section 7 review process. Under the proposed regulations, APHIS and EPA would retain the ability to consult informally with the Services under any circumstances, and be required to consult when an agency decision is likely to adversely affect listed species or critical habitat.

[2] Collectively, the National Marine Fisheries Service and the Fish and Wildlife Service.

It is worth noting, however, that no biotechnology-derived crop has ever been found likely to harm or adversely affect threatened or endangered species. Of course, individual determinations are made on a case-by-case basis after review of the available data. Any "not likely to adversely affect" determination would be based on a specific plant's traits, not on the fact that it is the product of biotechnology. However, because the impacts of these plants on agriculture and the environment are so carefully studied by the action agencies that regulate them, BIO supports regulations that would recognize the careful work and unique expertise of the action agencies, minimize duplicative regulation and better focus limited agency and Services resources.

This type of coordination with the action agencies may not be appropriate for all actions under the Services' review. However, when actions are supported by the scientific and programmatic depth of APHIS and EPA review of biotechnology-derived crops, closer cooperation, including the potential for counterpart regulations, is appropriate, and should be encouraged.

As discussed above, biotechnology-derived plant products on the market today have proven environmental benefits. BIO appreciates this opportunity to provide this discreet example of how improving the workability of the ESA review process can result in environmentally beneficial products reaching the market sooner.

Respectfully submitted,

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Food and Agriculture