

MEMORANDUM OF UNDERSTANDING  
BETWEEN  
UNITED STATES DEPARTMENT OF INTERIOR  
UNITED STATES FISH AND WILDLIFE SERVICE  
AND THE  
UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
BIOTECHNOLOGY REGULATORY SERVICES

ARTICLE 1 - PURPOSE

The objective of this Memorandum of Understanding is to define and clarify policies and procedures for interaction between the United States Department of the Interior, Fish and Wildlife Service (FWS) and the United States Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services (BRS), in support of common objectives, interests, and statutory requirements of the Endangered Species Act. Further, it will identify when BRS actions and decisions taken during the process of regulating the release of genetically engineered (GE) plants require an effects analysis in accordance with the Act.

ARTICLE 2 - BACKGROUND

The Endangered Species Act was signed into law in 1973. Section 7 of the Act requires that Federal agencies, in consultation with the Fish and Wildlife Service, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. In fulfilling these requirements, agencies are to use the best available scientific and commercial data.

The Animal and Plant Health Inspection Service, through its BRS program, regulates the field release, movement, and importation of GE organisms that are known to be, or could be, plant pests. BRS issues various types of permits for each of these activities. In regulating biotechnology, BRS works in concert with the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA), which also play important roles in protecting agriculture, food safety, and the environment. An overview of the coordinated framework for regulation of genetically engineered organisms can be found on the United States Regulatory Agencies Unified Biotechnology Website at <http://usbiotechreg.nbio.gov/>. More detailed information explaining the regulatory and permitting systems that BRS uses can be found on the BRS website at [http://www.aphis.usda.gov/brs/regulatory\\_activities.html](http://www.aphis.usda.gov/brs/regulatory_activities.html).

Depending on the level of risk for a field release of a GE plant, BRS requires different levels of information, performance standards, and administrative controls. At a minimum, BRS requires all applicants to provide detailed information about the plant such as the source and identity of the genes introduced; the method of genetic engineering; and the size, duration and location of the field test. All field releases must not allow viable plant material to remain that is likely to germinate and create new plants (volunteers). The release sites must be monitored and any volunteers destroyed.

APHIS has determined that due to the nature of the regulated article, many of the releases would have no effect on federally listed threatened and endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation. If a regulated article meets the requirements below, the release would be considered to have a “no effect” determination, and would not require analysis under the Endangered Species Act.

- The GE plant is not listed as a Federal noxious weed and is not considered a weed in the area of introduction;
- The genetic material is stably integrated into the plant genome;
- The newly introduced gene’s function is known and will not result in plant disease;
- The genetic material does not cause production of a plant pest; cause the plant to produce substances that are toxic to nontarget organisms; or cause the plant to produce compounds intended for pharmaceutical or industrial use;
- The newly introduced gene does not cause the creation of a new plant virus;
- The plant is not engineered to contain the following genetic material: any nucleic acid sequence derived from an animal or human virus; or coding sequences whose products are known or likely causal agents of disease in animals or humans.
- The GE plant does not have sexually compatible relatives that are federally listed or proposed as threatened or endangered plant species.
- The proposed test site and all areas that could potentially be directly or indirectly affected by the GE plant are not in designated or proposed critical habitat for a federally listed threatened or endangered species.

For field releases of GE plants that do not meet the above requirements, the applicant must provide a detailed description of protocols for the field test, a detailed description of the molecular biology of the system, and a description of the anticipated or actual expression of the altered genetic material in the regulated article. During the field trial, the applicant must follow protocols that include precautions to be taken to prevent the escape of the regulated article from the field trial site, including destruction of remaining plant material and monitoring the site to ensure no volunteer plants survive. The field trials are subject to inspection and the frequency of inspection varies depending on the type of product being tested. Plants engineered for pharmaceutical, industrial, or phytoremediation purposes receive up to seven inspections, and have additional requirements compared to those GE crops being developed for use as food or feed.

### ARTICLE 3 – AUTHORITIES

Section 7 (a) (1) of the Endangered Species Act requires all Federal agencies, in consultation with and with the assistance of the Secretary (Interior or Commerce), to utilize their authorities in furtherance of the purposes of the Act by carrying out programs for the conservation of threatened and endangered species.

Section 7 (a) (2) of the Endangered Species Act requires that each Federal agency, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of a listed threatened or endangered species, or result in the destruction or adverse modification of designated critical habitat. Implementing regulations are found in 50 CFR Part 402, Interagency Cooperation Regulations.

APHIS is authorized by the Plant Protection Act, Sec. 431(a), Public Law 106-224, to cooperate with other Federal agencies, the governments of foreign countries, international organizations or associations, states and their political subdivisions, farmer's associations and similar organizations, and other persons to detect, eradicate, suppress, control, and prevent or retard the spread of plant pests and diseases.

### ARTICLE 4 – APHIS RESPONSIBILITIES

APHIS will evaluate all applications for releases that do not meet the exclusionary qualifications listed in Article 2 of this MOU for their potential effect on federally listed threatened and endangered species and species proposed for listing, and the effect on designated critical habitat and habitat proposed for designation, in accordance with requirements of the Endangered Species Act. The process will be as follows:

Step 1: Define the action area. The action area includes all areas that could be affected directly or indirectly by the release. The action area is dependent on factors such as the size of the field trial and the nature of the regulated article.

Step 2: Determine which federally listed threatened and endangered species, and species proposed for listing are in the action area. Resources available for this are:

[http://ecos.fws.gov/tess\\_public/StartTESS.do](http://ecos.fws.gov/tess_public/StartTESS.do) - to search by State and county

<http://www.fws.gov/Endangered/wildlife.html> - to find proposed species.

Additional data can be found at:

<http://www.natureserve.org/explorer/servlet/NatureServe?init=Species>

Step 3: Determine if designated critical habitat and proposed designated critical habitat is within the action area. The FWS website (<http://crithab.fws.gov>) can be used for this to obtain information at the county level.

Step 4: The following decision tree will then be used to determine if further analysis under the ESA is required, and also the parameters of the analysis.

1. Are federally listed threatened or endangered species or species proposed for listing found in the action area? Is there designated critical habitat or habitat proposed for designation in the action area? If both answers are no - if there are no federally listed threatened or endangered species or species proposed for listing, and no designated critical habitat or habitat proposed for designation in the action area, no further analysis is required. Document the permit file. If either of the answers is yes, proceed to step 1a.
  - a. If there is designated critical habitat or habitat proposed for designation within the action area, perform an effects analysis of the action on the critical habitat. If it is determined that the action “may affect, not likely to adversely affect” designated critical habitat, it will be necessary to consult with FWS before proceeding with the proposed action. If it is determined that the action “may affect, likely to adversely affect” designated critical habitat, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If it is determined that the action is likely to adversely modify proposed critical habitat, it will be necessary to confer with FWS before proceeding with the proposed action. If the evaluation determines there is “no effect,” document the file. Then proceed to 1.b.
  - b. If there are federally listed threatened or endangered species or species proposed for listing found in the action area, go to 2.
2. Will disturbance of the field site for the release (e.g. plowing, removing vegetation, burning etc.) directly or indirectly affect a federally listed threatened or endangered species or species proposed for listing?
  - If no, go to 3.
  - If yes, analyze the effect on the species (unless the site would be disturbed even if the action were not to occur, resulting in no change to the baseline). If it is determined that the action “may affect, not likely to adversely affect” listed threatened or endangered species, it will be necessary to informally consult with FWS before proceeding with the proposed action. If it is determined that the action “may affect, likely to adversely affect” listed threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If it is determined that the action is likely to jeopardize the continued existence of a proposed species, it will be necessary to confer with FWS before proceeding with the proposed action. If the evaluation determines there is “no effect”, document the file. Then proceed to 3.
3. Is the engineered plant sexually compatible with a federally listed threatened or endangered plant species or plant species proposed for listing that could be found in the area?
  - If no, go to 5.
  - If yes, go to 4.

4. Are there measures that can be taken to prevent escape of the genetic material to sexually compatible federally listed or proposed listed threatened or endangered species?
  - If no, analyze the effect to those species that are sexually compatible. If it is determined that the action “may affect, not likely to adversely affect” listed federally listed threatened or endangered species, it will be necessary to consult with FWS before proceeding with the proposed action.. If it is determined that the action “may affect, likely to adversely affect” listed threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If it is determined that the action is likely to jeopardize the continued existence of a proposed species, it will be necessary to confer with FWS before proceeding with the proposed action. If the evaluation determines there is “no effect”, document the file. Go to 5.
  - If yes, include the measures in the supplemental permit conditions and that the field site is inspected to ensure compliance. Go to 5.
  
5. Is the transgenic modification intended to result in the production, or increase the production, of a toxin, natural toxicant, allelochemical, pheromone, hormone, etc. that could directly or indirectly result in killing or interfering with the normal growth, development, or behavior of a federally listed threatened or endangered species or species proposed for listing?
  - If no, no further analysis is required. Document the permit file.
  - If yes, analyze the effect on those species that are likely to be susceptible to the mode of action with consideration of the route of exposure. If it is determined that the action “may affect, not likely to adversely affect” listed threatened or endangered species, it will be necessary to consult with FWS before proceeding with the proposed action. If it is determined that the action “may affect, likely to adversely affect” listed threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If it is determined that the action is likely to jeopardize the continued existence of a proposed species, it will be necessary to confer with FWS before proceeding with the proposed action. If the evaluation determines there is “no effect”, document the file.

#### End of Decision Tree

If for any reason, APHIS believes there could possibly be an effect on federally listed threatened or endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation, by a release of a regulated article that meets the exclusionary criteria listed in Article 2 of this MOU, APHIS will complete an effects analysis as described in the decision tree. Similarly, if it comes to APHIS’ attention that the action may have an effect that was not determined by the decision tree, APHIS will also perform the necessary effects analysis.

If the APHIS determination is “no effect”, consultation will not be required. BRS will file the analysis and decision in the permit file.

If APHIS determines that the action “may affect, but is not likely to adversely affect” federally listed threatened or endangered species, or designated critical habitat, APHIS will initiate consultation before proceeding with the proposed action. The effects analysis along with a copy of the applicant’s permit application from which confidential business information has been deleted will be submitted to FWS for review, comment, and concurrence. In addition, if an Environmental Assessment is being prepared as a requirement of the National Environmental Policy Act, a copy will be provided to FWS reviewers.

If APHIS determines that the action “is likely to adversely affect” federally listed threatened or endangered species, or designated critical habitat, APHIS will initiate a formal consultation. BRS will develop a Biological Evaluation (BE) that will be sent for review to the FWS Field Supervisor of Ecological Services and/or others within FWS as requested.

If it is determined that the action is likely to jeopardize the continued existence of a species proposed for listing, or adversely modify proposed designated habitat, BRS will confer with the FWS before proceeding with the proposed action.

If FWS timely requests more information from BRS, BRS will provide all information requested to the best of its ability. If FWS recommends modification to the proposed action, BRS will effectuate those FWS requested modifications to the extent appropriate and permitted pursuant to BRS’ statutory authorities.

BRS agrees not to make any binding or irreversible decisions regarding a particular proposed action that requires an ESA determination until FWS has completed its review and has concurred with the BRS analysis or has provided the Biological Opinion, as applicable. BRS will have the option of appropriately elevating its concerns through accepted agency procedures regarding any undue delays in receiving FWS’ review and/or Biological Opinion.

## ARTICLE 5 – USFWS RESPONSIBILITIES

If APHIS has determined that a release “may affect”, but is “not likely to adversely affect” listed species or designated critical habitat, BRS will enter into consultation with FWS. FWS will receive the effects analysis along with a confidential business information deleted copy of the applicant’s permit application, and a copy of the Environmental Assessment, if one has been prepared or completed as a requirement of the National Environmental Policy Act. Upon receipt of the effects analysis and any other supporting documents, FWS will reply by letter to the BRS Document Control Officer and/or other BRS regulatory official within 30 days and either:

1. Request additional information,

2. Offer concurrence on the “may affect, not likely to adversely affect” determination,
3. Recommend modification to the proposed action, or
4. Recommend that BRS initiate a formal consultation if there is a “may affect, likely to adversely affect” determination by FWS. In its recommendation, FWS will explain why the effects are not insignificant, discountable, or beneficial.

If a formal consultation is recommended, FWS will work with BRS to identify options to avoid adverse effects to listed species and/or critical habitat. If no solutions are available, BRS will initiate a formal consultation and submit a Biological Evaluation (BE). Within 30 working days of receipt of the BE, FWS will provide written acknowledgement of the consultation request, and request any information it needs that has not been submitted. BRS will modify the BE and provide all information requested by FWS. Within 90 days of receipt of the completed initiation package (the agreed upon BE), FWS will complete its evaluation. Within 45 days of completing their evaluation (not more than 135 days after receipt of the agreed upon BE), FWS will provide a written biological opinion. Both the 90 day review time and the 45 day period to develop the written biological opinion may be extended if both parties agree.

If it is determined that the action is likely to jeopardize the continued existence of a proposed species, or adversely modify proposed designated critical habitat, BRS will confer with FWS. FWS will provide recommendations to avoid or minimize the adverse effects of the action in a conference report or conference opinion. If the action also results in a formal consultation with FWS, the conference may be combined with the consultation.

#### ARTICLE 6 – MUTUAL RESPONSIBILITIES

APHIS and the United States Fish and Wildlife Service mutually agree to cooperate fully and perform their required roles as specified in the act and in accordance with regulations found in 50 CFR Part 402, Interagency Cooperation Regulations.

#### ARTICLE 7 - STATEMENT OF NO FINANCIAL OBLIGATION

Signature of this MOU does not constitute a financial obligation on the part of APHIS. Each signatory party is to use and manage its own funds in carrying out the purpose of this MOU. Transfers of funds or items of value is not authorized under this MOU.

#### ARTICLE 8 - LIMITATIONS OF COMMITMENT

This MOU and any continuation thereof shall be contingent upon the availability of funds appropriated by the Congress of the United States. It is understood and agreed that any monies allocated for purposes covered by this MOU shall be expended in accordance

with its terms and the manner prescribed by the fiscal regulations and/or administrative policies of the party making the funds available. If fiscal resources are to transfer, a separate agreement must be developed by the parties.

This MOU is limited solely to the release of regulated GE plants. It does not include the release or regulation of other GE organisms, or a decision to deregulate a regulated article.

#### ARTICLE 9 - CONGRESSIONAL RESTRICTION

Under 41 USC 22, no member of, or delegate to, Congress shall be admitted to any share or part of the MOU or to any benefit to arise therefrom.

#### ARTICLE 10 - AMENDMENTS

This MOU may be amended at any time by mutual agreement of the parties in writing.

#### ARTICLE 11 - TERMINATION

This MOU may be terminated by either party upon sixty (60) days written notice to the other party.

#### ARTICLE 12 - EFFECTIVE DATE AND DURATION

This MOU will be in effect upon date of final signature and will continue in effect for ten years.

UNITED STATES DEPARTMENT OF INTERIOR  
UNITED STATES FISH AND WILDLIFE SERVICE

Bryan Ayco 5/17/07  
Assistant Director for Endangered Species Date  
Acting

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
BIOTECHNOLOGY REGULATORY SERVICES

Robert B. Ball 5/07/07  
Deputy Administrator Date