

**NEPA/ESA Decision Worksheet for Permits
(Authorization of Movement or Release)**

Date prepared:

Prepared by:

Permit #:

Institution:

Organism:

Category:

Gene(s):

Questions		Yes	No	N/A
	Does this document contain CBI? If so, please indicate the information that is CBI using brackets [.....].		X	
NEPA Categorical Exclusion and Exceptions:				
	RELEASE: Is this a confined field release of (a) genetically engineered organism(s)?			
	Confinement and mitigation conditions have been reviewed and determined to be adequate			
Comment*	This permit is for movement only.			
	RELEASE: Does the incremental impact of the proposed release, when added to other past, present, and reasonably foreseeable future actions (regardless of what agency or person undertakes such actions), have a potential for significant environmental impact?			
Comment*				
	RELEASE: Does the proposed release involve a licensed or approved biologic that has been subsequently shown to be unsafe, and will it be used at substantially higher dosage levels or for substantially different applications or circumstances than in the use for which the product was previously approved?			
Comment*				
	RELEASE: Is the proposed release a previously unlicensed veterinary biological product to be shipped for field testing which contains live microorganisms, and will it be used for in vitro diagnostic testing?			
Comment*				
	RELEASE: Do the products involve new species or organisms?			
	New or Novel Species/organism			
	Never used in a field trial			
	Not new but no prior EA			
	Not new and prior EA			
Comment*				
	RELEASE: Are there novel modifications that raise new issues?			
	New or Novel Trait (Is Gene Product unachievable by conventional breeding?)			
	Never used in a field trial			
	Not new but no prior EA			
	Not new and prior EA			
Comment*				
	Plant Pollination			
	Primarily bee or insect pollinated crop			
	Primarily wind pollinated food or feed crop			
	Primarily self fertilized food or feed crop			
	Primarily self fertilized non-food or feed crop			
	Primarily wind pollinated non-food or feed crop			
Comment*				
	Effects on Food/Feed Supply			
	Known allergen, antinutritive, oral toxicant			
	Food safety not established			

	Gene donor includes food or feed crops only			
	GRAS status or approved food additive for native protein			
	GRAS status or approved food additive for plant produced protein			
	Non-food or feed crop			
Comment*				
	Isolation Distance			
	AOSCA Foundation seed standard for crop			
	Proposed isolation distance			
Comment*				
	Scale (the importance of scale varies with the crop/trait combination)			
	>100 acres/trait/crop/institution/year			
	50-99 acres/trait/crop/institution/year			
	10-49 acres/trait/crop/institution/year			
	<10 acres/trait/crop/institution/year			
Comment*				
	Effects (positive or negative) on other species			
	Significant effects expected/observed			
	Minimal, non-cumulative effects expected/observed			
	No effects expected/observed			
Comment*				
	Sexually Compatible Relatives			
	Relatives within pollen dispersal distance			
	Relatives not within pollen dispersal distance			
Comment*				
	Seed Dormancy			
	>3 years			
	3 years			
	2 years			
	<2 years			
Comment*				
	Persistence in environment			
	Crop can naturalize			
	Crop can persist 3-5 years without human intervention			
	Crop does not persist without intervention			
Comment*				
	PROXIMITY TO RESERVATION LANDS OF A FEDERALLY RECOGNIZED TRIBE: Does the action area of the proposed release occur within reservation lands for a Federally Recognized Tribe? If so, was the Tribe contacted and consultation offered? If so, did consultation occur?			
Comment				
	MOVEMENT: Does the incremental impact of the proposed movement, when added to other past, present, and reasonably foreseeable future actions (regardless of what agency or person undertakes such actions), have the potential for significant environmental impact?			
Comment			X	
	MOVEMENT: Does the proposed movement involve a licensed or approved biologic that has been subsequently shown to be unsafe, and will it be used at substantially higher dosage levels or for substantially different applications or circumstances than in the use for which the product was previously approved?			
Comment			X	
	MOVEMENT: Is the proposed movement for a previously unlicensed veterinary biological product to be shipped for field testing which contains live microorganisms, and will it be used for in vitro diagnostic testing?			
Comment			X	
	MOVEMENT: Does the proposed movement have the potential to affect "significantly" the quality of the "human environment" as those terms are defined at 40 CFR §§1508.27 and 1508.14?			
			X	

Comment				
	MOVEMENT: Has APHIS determined that the movement proposed is between contained facilities?	X		
Comment				
	MOVEMENT: Are regulated articles shipped according to 7 CFR § 340.8) or by an approved variance so that viable material is unlikely to be disseminated while in transit and will be stored in such a way that there is no release into the environment. If there is no release into the environment, there can be no environmental impact.)	X		
Comment				
	MOVEMENT All movements of regulated articles are authorized only when measures are used to avoid or minimize impacts to the human environment. Has APHIS determined that these measures are in place?	X		
Comment				
	NEPA Summary 1: Is this eligible for categorical exclusion under NEPA?	X		
Comment*	The regulated article and the proposed action meet the eligibility criteria for categorical exclusion under NEPA.			
	NEPA Summary 2: Do any of the exceptions to categorical exclusion apply?		X	
Comment*	None of the exceptions to the categorical exclusion apply.			
ESA Assessment: Release				
	Step A: 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. In most cases the action area will include the area where the organism is released; any area used for staging activities or storing or processing materials; and any surrounding area subject to monitoring or surveying. When defining the action area, consider the possibility of interrelated and interdependent actions that will occur as part of the release. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification. An example would be construction of an access road to the release site. Interdependent actions are those that would have no independent utility apart from the release. An example would be the construction of a facility to process plant materials generated by the field trial. Document in the summary and proceed to Step B.			
Summary*				
	Step B: Determine the effects on critical habitat. <i>Is the action area within designated critical habitat or habitat proposed for designation?</i> <ul style="list-style-type: none"> If "no," go to Step C. If "yes" analyze the effect on critical habitat. The analysis may have three outcomes: "no effect"; "may affect, not likely to adversely affect"; or "may affect, likely to adversely affect". For proposed critical habitat, a fourth outcome is possible: "Is likely to adversely modify proposed critical habitat". Record the outcome in the summary. If the analysis determines there is "no effect", state the rationale. Once analysis is completed, go to Step C. 			
Summary*				
	Step C. Consider the possible effects the field activities could directly have on federally listed species or species proposed for listing, and how field activities could affect the baseline habitat of those species. <i>Are expected activities (e.g. plowing, removing vegetation, burning) substantially different from activities that historically occur within the action area, thereby possibly affecting a federally listed species or species proposed for listing, or changing their baseline habitat?</i> <ul style="list-style-type: none"> If "no," go to Step D. If "yes," go to Step E and determine what species are in the action area. Analyze the possible effects of the action on species and the baseline habitat of these species. The analysis may have three outcomes: "no effect"; "may affect, not likely to adversely affect"; or "may affect, likely to adversely affect". For proposed species, a fourth outcome is possible: "Is likely to jeopardize the continued existence of proposed species". Record the outcome in the summary. If the analysis determines there is "no effect", state the rationale. Once analysis is completed, go to Step D. 			
Summary*				
	Step D: Determine if the phenotypic properties of the regulated organism could have an effect			

	<p>on a federally listed species or species proposed for listing.</p> <p>If a regulated genetically engineered organism meets the requirements below, the release would be considered to have a “no effect” determination resulting from the organism’s phenotypic properties.</p> <ul style="list-style-type: none"> • 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 non-target 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 species. <ul style="list-style-type: none"> • <i>If the regulated organism does not meet the above criteria, go to Step E.</i> • <i>If there is “no effect” that could result from phenotypic properties, proceed to Step G.</i> 	
Summary*		
	<p>Step E: Determine which federally listed threatened and endangered species and species proposed for listing are in the action area.</p> <p>Resources available for this are: http://ecos.fws.gov/tess_public/StartTESS.do - to search by State and county http://www.fws.gov/offices/ and to search for critical habitat http://criticalhabitat.fws.gov/.</p> <p>Once completed, go to Step F:</p>	
Summary*		
	<p>Step F: The information obtained to this point can now be used to complete the decision tree in order to determine if further analysis under the ESA is required, and also the parameters of the analysis.</p> <p>1. <i>Is the engineered plant sexually compatible with a federally listed species or species proposed for listing that could be found in the action area?</i></p> <ul style="list-style-type: none"> • <i>If “no,” go to 3.</i> • <i>If “yes,” go to 2.</i> 	
Summary*		
	<p>2. <i>Are there measures that can be taken to prevent escape of the genetic material to sexually compatible federally listed species or species proposed for listing?</i></p> <ul style="list-style-type: none"> • <i>If “no,” analyze the effect to those species that are sexually compatible. The analysis may have three outcomes: “no effect”; “may affect, not likely to adversely affect”; or “may affect, likely to adversely affect”. For proposed species, a fourth outcome is possible: “Is likely to jeopardize the continued existence of proposed species”. Record the outcome in the summary. If the analysis determines there is “no effect”, state the rationale. Go to 3.</i> • <i>If “yes,” include the measures in the design protocols. Go to 3.</i> 	
Summary*		
	<p>3. <i>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 an individual of a federally listed species or species proposed for listing?</i></p> <ul style="list-style-type: none"> • <i>If “no,” state the rationale in the analysis for this step. Go to Step G.</i> • <i>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. (See the additional guidance for ESA assessment for plants genetically engineered with toxins.) The analysis may have three outcomes: “no effect”; “may affect, not likely to adversely affect”; and “may affect, likely to adversely affect”. For proposed species, a fourth outcome is possible: “Is likely to jeopardize the continued existence of proposed species”. Record the outcome in the summary. If the analysis determines there is “no effect”, state the rationale. Go to Step G.</i> 	
Summary*		
	<p>Step G: Consider other possible effects.</p> <p><i>Could there be any possible effects from the action on listed species, proposed species, designated critical habitat, or proposed critical habitat that this process has not identified?</i></p>	

	<ul style="list-style-type: none"> If no, the analysis is completed, document the findings in the effects determination section. If yes, conduct the analysis. The analysis may have three outcomes: “no effect”; “may affect, not likely to adversely affect”; and “may affect, likely to adversely affect”. For proposed species and critical habitat, a fourth outcome is possible: “Is likely to jeopardize the continued existence of proposed species/adversely modify proposed critical habitat”. Record the outcome in the summary. If the analysis determines there is “no effect”, state the rationale. 			
Summary*				
	<p>ESA “NO EFFECT” SUMMARY: RELEASE: Has APHIS reached a determination that this release would have no effect on listed species and designated critical habitat, and is unlikely to jeopardize the continued existence of a proposed species or adversely modify proposed critical habitat?</p>			
Summary*				
ESA Assessment: Movement				
	<p>Has APHIS-BRS determined that importation and movement of regulated articles under this permit, following the container requirements specified in §340.8, would have no effect on listed species or species proposed for listing or on designated critical habitat or habitat proposed for designation (APHIS-BRS ESA Memo July 14, 2010)?</p>	??		
	<p>If a variance is requested, has it been evaluated to ensure it will prevent release into the environment and thereby prevent the possibility of exposure to a federally listed species, proposed species, designated critical habitat, or proposed critical habitat? If no, further evaluation and consultation with USFWS/NMFS may be required.</p>	??		
Summary*	<p>As required by the ESA, APHIS-BRS considered the possible effects that importation and interstate movement of regulated articles under APHIS-BRS approved permits could potentially have on threatened or endangered species and their critical habitat. Effect is measured by identifying the potential for exposure, and if exposure is expected, an analysis of the likely response. In consideration of the permit requirements identified in 7 CFR 340.4, 340.7 and 340.8 for a regulated article to be imported or moved interstate, APHIS-BRS has determined that the possibility of exposure from importing or moving a regulated article is negligible to non-existent. This is supported by the fact that since the beginning of the program in 1987, APHIS-BRS has approved many thousands of permits for importation, interstate movement, and movements that were combined with environmental releases, and there have been no reported releases into the environment when following the packaging requirements in §340.8. Therefore, based upon applicant’s adherence to permitting requirements identified in 7 CFR 340 and specifically §340.8, APHIS-BRS has determined that importation and interstate movement of regulated articles under APHIS-BRS approved permits will have no effect on listed species or species proposed for listing, or on designated critical habitat or habitat proposed for designation.</p>			
	<p>Overall ESA Effects Determination for the Action - The overall effects determination for the action will be the “worst” of any individual effects analysis completed above (i.e. if any effects analysis above reached a “may affect, likely to adversely affect” determination, that would be the appropriate determination for the action as a whole.</p>			
	Listed Species/Designated Critical Habitat			
	<ul style="list-style-type: none"> “May affect, likely to adversely affect” federally listed species or designated critical habitat. This determination requires preparation of a Biological Evaluation and <u>formal consultation</u> with USFWS/NMFS. In response to our Biological Evaluation, USFWS/NMFS will develop a Biological Opinion. 			
	<ul style="list-style-type: none"> “May affect, not likely to adversely affect” federally listed species or designated critical habitat. This determination requires an <u>informal consultation</u> with USFWS/NMFS in order to obtain their concurrence. Depending on the complexity, a Biological Evaluation may be necessary. 			
	<ul style="list-style-type: none"> “No effect” on federally listed species or designated critical habitat. This determination requires <u>no further action</u>. 	X		
	Proposed Species/Proposed Critical Habitat			
	<ul style="list-style-type: none"> “Is likely to jeopardize the continued existence of a proposed species or adversely modify proposed critical habitat.” This determination requires a conference with USFWS/NMFS. 			
	<ul style="list-style-type: none"> “Is unlikely to jeopardize the continued existence of a proposed species or 			

	adversely modify proposed critical habitat.” This determination requires <u>no further action.</u>	X		
Comment				

Additional Comments				
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