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

Date prepared: 05-09-2008
Permit #:08-051-101r
Institution: Kentucky Bioprocessing LLC
Organism: TMV
Category: Enhanced protease inhibitor enzyme activity
Gene(s): Aprotinin

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	x		
Comment*	*Determined that confinement conditions are adequate according to their performance standards of their design protocol.*			
	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?		x	
Comment*	*The only past, present, and reasonably foreseeable actions associated with the location for the proposed release are those related to agricultural production. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources (soil, water, ecosystem quality, biodiversity, etc.) associated with the release site or the ecosystem in which it is situated. No resources will be significantly impacted due to cumulative impacts resulting from the proposed action. The field used for this release testing is been in production for numerous years.*			
	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?		x	
Comment*	*Not a biologic*			
	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?		x	
Comment*	*Not a vet biologic*			
	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	X		
Comment*	*There have been 15 releases of tobacco that has been inoculated with TMV.* http://www.aphis.usda.gov/brs/aphisdocs/04_12101r_ea.pdf .			
	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	X		
Comment*	*7 field trials have been approved using Aprotinin*			
	Plant Pollination			
	Primarily bee or insect pollinated crop			X
	Primarily wind pollinated food or feed crop			X
	Primarily self fertilized food or feed crop			X
	Primarily self fertilized non-food or feed crop			X
	Primarily wind pollinated non-food or feed crop			X

Comment*	*TMV is only transferred by mechanical transmission*			
	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	x		
Comment*	*Tobacco is not a food or feed crop.*			
	Isolation Distance			
	AOSCA Foundation seed standard for crop	NA		
	Proposed isolation distance	300ft		
Comment*	No plants susceptible to TMV will be grown within 300 feet of the field test site**.** *It is only transmissible by direct contact.*			
	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	x		
Comment*	*[ ]*			
	Effects (positive or negative) on other species			
	Significant effects expected/observed			
	Minimal, non-cumulative effects expected/observed			
	No effects expected/observed	x		
Comment*	*No effects expected/observed on species*			
	Sexually Compatible Relatives			
	Relatives within pollen dispersal distance			
	Relatives not within pollen dispersal distance	x		
Comment*	*Relatives are not within 300 ft from the regulated article. Not spread by seed or pollen.*			
	Seed Dormancy			
	>3 years			x
	3 years			x
	2 years			x
	<2 years			x
Comment*	*TMV is only spread mechanically; it is not spread by seed.*			
	Persistence in environment			
	Crop can naturalize			
	Crop can persist 3-5 years without human intervention			
	Crop does not persist without intervention	x		
Comment*	TMV does not persist in fields. The following crop planted in this field will be a TMV-resistant crop			
	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?			x
Comment				
	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?			X
Comment				
	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?			x
Comment				
	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*	**Yes, eligible for categorical exclusion**			
	NEPA Summary 2: Do any of the exceptions to categorical exclusion apply?		x	
Comment*	**No exceptions to categorical exclusions apply- EA (see above) has been prepared describing the adequacy of confinement measures regarding the production of aprotinin protein by TMV infection of tobacco.**			
ESA assessment:				
	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. Document in summary.			
Summary*	The gene products do not pose a threat to nontarget organisms, including TES. Natureserve (http://www.natureserve.org/explorer/servlet/NatureServe?loadTemplate=tabular_report.wmt&paging=home&save=all&sourceTemplate=reviewMiddle.wmt, accessed on 5/09/08) only two animals and no plants are listed in Daviess county, Kentucky as threatened and endangered, the animals include: *Nerodia erythrogaster neglecta* (copper belly water snake) and *Myotis sodalis* (Indiana bat). Neither of these animals feed on tobacco nor have habitats in agricultural fields.			
	Step 2: Determine what federally listed threatened or endangered species or species proposed for listing are in the action area. Resources available for this are: 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 Document in summary.			
	Step 3: Determine if designated critical habitat or proposed critical habitat is within the action area. The FWS website (http://crithab.fws.gov) can be used to obtain information at the county level. Document in summary.			
Summary*	http://ecos.fws.gov/tess_public/StateListing.do?status=listed&state=KY http://crithab.fws.gov/ All were accessed on June 18, 2007 TES in the state of Kentucky were 34 animals and 8 plants. None of the animals forage on tobacco or live in agricultural fields. None of the plants cross with tobacco. There is no critical habitat where the field site is listed. The only animal know to forage on tobacco is skunk.			
	Step 4: Use the following key 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?		x	
	Is there designated critical habitat or habitat proposed for designation in the action area? If either of the answers are yes, proceed to step 1b.		x	
	a. 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 in summary. Analysis is complete.			
	b. 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" critical habitat, it will be necessary to			

	informally consult with FWS. If it is determined that the action "may affect, likely to adversely affect" critical habitat, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If the evaluation determines that consultation with FWS is needed, document here when the consultation process starts. Further documentation of this process will be done outside of this document. If the evaluation determines there is "no effect," document in summary. Then proceed to 1c.			
Summary*	No TES or proposed TES in the action area. No designated critical habitat in action area.			
	c. 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 effects 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" threatened or endangered species, it will be necessary to informally consult with FWS. If it is determined that the action "may affect, likely to adversely affect" threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If the evaluation determines that consultation with FWS is needed, document here when the consultation process starts. Further documentation of this process will be done outside of this document. If the evaluation determines there is "no effect", document in summary. Then proceed to 3.		x	
Analysis				
	3. Is the engineered plant sexually compatible with a federally listed threatened or endangered species or species proposed for listing that could be found in the area? • If no, go to 5. • If yes, go to 4.		x	
	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 effects to those species that are sexually compatible. If it is determined that the action "may affect, not likely to adversely affect" threatened or endangered species, it will be necessary to informally consult with FWS. If it is determined that the action "may affect, likely to adversely affect" threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If the evaluation determines that consultation with FWS is needed, document here when the consultation process starts. Further documentation of this process will be done outside of this document. If the evaluation determines there is "no effect", document in summary. 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.			
Summary				
	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 in summary: • If yes, analyze the effects 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" threatened or endangered species, it will be necessary to informally consult with FWS. If it is determined that the action "may affect, likely to adversely affect" threatened or endangered species, it will be necessary to prepare a Biological Evaluation and formally consult with FWS. If the evaluation determines that consultation with FWS is needed, document here when the consultation process starts. Further documentation of this process will be done outside of this document. If the evaluation determines there is no effect, document in summary.		x	
Summary	The aprotinin protein is a natural serine proteinase inhibitor consisting of 58 amino acid residues in a single chain, cross-linked by 3 disulphide bridges with a total molecular weight of 6,152 daltons. Aprotinin is			

	produced in bovine tissues and is consumed by humans and animals without any adverse effects. [ ]			
	Threatened or Endangered Species or their habitat			
	▪ may affect, likely to adversely affect federally listed, threatened and endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation.			
	▪ may affect, not likely to adversely affect federally listed threatened and endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation.			
	▪ would have no effect on federally listed threatened and endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation.	x		
Comment				
	ESA SUMMARY: Has APHIS reached a determination that this field release would have no effect on listed (or proposed) species and therefore a written concurrence or formal consultation with Fish and Wildlife Service is not required?	x		
Comment*	*For the above reasons, and those documented on the NEPA/ESA decision document, APHIS has determined that this permit involves contained movement and confined field trails of genetically engineered organisms or products that do NOT involve a new species or organism or novel modification that raises new issues. APHIS has determined that the actions authorized under this permit do NOT have the potential to significantly affect the quality of the human environment. Therefore, approval of this permit is properly categorically excluded from the need to prepare an EA (or EIS) pursuant to 7 CFR 372.5., and none of the exceptions to this categorical exclusion apply.*			

Additional Comments	

Prepared by: Aimee Hyten

Form updated: 8/09/07