



ABSAs

INTERNATIONAL

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Draft Environmental Impact Statement and Preliminary Pest Risk Assessment for Permit for Release of Genetically Engineered Citrus tristeza virus

ABSAs International appreciates the opportunity to review the USDA Animal and Plant Health Inspection Service (APHIS) *Draft Environmental Impact Statement and Preliminary Pest Risk Assessment for Permit for Release of Genetically Engineered Citrus tristeza virus*.

Citrus Greening is an acute problem that poses a serious threat to the U.S. (and in particular Florida's) citrus industry. ABSAs International fully supports taking action to curtail this disease. To that end we reviewed the draft risk assessment and the six (6) issues most frequently cited in public comments and have questions for your consideration included in the attached review table.

ABSAs International appreciates the opportunity provided by APHIS to review and comment on the *Draft Environmental Impact Statement and Preliminary Pest Risk Assessment for Permit for Release of Genetically Engineered Citrus tristeza virus*. We recognize and appreciate the work involved in preparing to safely address this significant plant disease. Please contact me with any questions or to request clarification.

Respectfully,

Patrick Condreay, PhD, RBP
President, ABSAs International

**ABSA International Technical Regulatory Review
Document Review**

<p>Notice: "Draft Environmental Impact Statement and Preliminary Pest Risk Assessment for Permit for Release of Genetically Engineered Citrus tristeza virus"</p>		<p>Document Citation/Number: 83 FR 22944 https://www.federalregister.gov/documents/2018/05/17/2018-10490/draft-environmental-impact-statement-and-preliminary-pest-risk-assessment-for-permit-for-release-of</p>	
<p>Deadline: June 25, 2018</p>		<p>PDF: https://www.epo.gov/fdsys/pkg/FR-2018-05-17/pdf/2018-10490.pdf</p>	
<p>Table 1: General Comments</p>			
<p><i>Instructions: Use this section to make general comments about the document content or related issues. Add rows as needed.</i></p>		<p><i>Proposed change</i></p>	
<p>General comment</p>		<p>Proposed to address each comment submitted</p>	
<p>Public perception is a concern in considering the comments submitted at the time of this writing.</p>	<p>Educating the public is an important element of soliciting public review.</p>	<p>The concern about using a virus to introduce a foreign gene into a human food source could be alleviated in part by an improved explanation of the process and safety measures at the outset of the document. Text that would market the concept to the lay public would be a good predecessor to the large and technical supporting documents which may not be read by many of the concerned public.</p>	
<p>The full impact to human health does not appear to be adequately under investigation.</p>		<p>Question: Is there a potential for allergic reactions? There are a few papers on PubMed that indicate that this is a potential. Would the orange juice or other citrus products be labeled as potentially containing the protein?</p>	
<p>The impact on food products does not appear fully assessed.</p>	<p>Information sought was not located in the Risk Assessment.</p>	<p>The impact of the protein expression in food products made from the grafted trees was not located. It is stated that the seeds of the fruit won't contain the protein and that the pests eat young leaves so there should be no risk. Will this be tested?</p>	<p>Provide information on testing the impact of the protein expression in food products.</p>
<p>Study results and related information is missing.</p>	<p>Results from referenced studies and design elements are not presented leaving information gaps.</p>	<p>The background lists that the CTV has already been deployed in field studies in Hendry and Polk Counties; what are the results from these studies? What happened to the fruit from these test trees? Was it analyzed for the presence of the defensin proteins? They do state it isn't in the seeds. What citrus trees are targeted or are all citrus trees potentially going to be inoculated? They performed greenhouse testing on a number of different species.</p>	<p>Provide information in EIS and PPRA documents. Conduct studies to fill in gaps if necessary.</p>
<p>Environmental Issues for Consideration:</p>	<p>Information regarding these environmental questions were not included in the documents nor located during additional review.</p>	<p>Are there any new or greater plant pest or environmental risks or apparent benefits associated with the strategy of using genetically engineered CTV instead of the currently available approaches to manage citrus greening disease?</p> <p>The EIS will focus on the development and use of genetic engineering to offer a novel pest control program. Are there any environmental risks that APHIS should consider in detail for CTV expressing spinach defensin?</p> <p>What are the potential risks of nontarget impacts associated with this technology?</p>	<p>Please respond and explain.</p>
<p>Not enough information about modified CTV in notice statement (dated May 17th)</p>	<p>A summary of the risk assessment for using CTV would be helpful. All of the information is present, but is difficult to read/sort through (especially for lay people who may be commenting)</p>	<p>Add a summary risk assessment that clearly outlines that CTV is already ubiquitous throughout southern Florida and there is a minimal increased risk of using the CTV-defensin vectors (e.g., the Conclusion statement on page 20-21 of risk assessment document-maybe summarize in bullet-point in introduction?). A vector map detailing the engineering of this vector would be helpful. A summary list of the removed CTV virulence genes would be helpful in showing that the risk of CTV occurring or a recombination event occurring in nature is low.</p>	<p>While all of the information is present in the preliminary risk assessment document, it is a 38-page document that may make it difficult for people to understand. More of an emphasis on the safety of using the CTV as a vector in the introduction may help with buy-in.</p>

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Table 2: Specific Comments

Instructions: Use this section to make comments specific to each recommendation in the document. Add rows as needed.			
Section Name or #	Paragraph #/ Figure/Table (e.g., 121.14(f))	Comment Type ge = general te = technical ad = additional	Proposed change
Draft Environmental Impact Statement (EIS): Section 2.2 "Preferred Alternative: Issue the APHIS Permit"	Page 7, Section second paragraph	ge	The renewal process should be described. It should include a progress report with information on efficacy, environmental impact and public health.
EIS: Section 3.4.1 "Environmental Impacts of the Proposed Release of CTV-SoD"	Page 34	te	The renewal process should be described. It should include a progress report with information on efficacy, environmental impact and public health.
Preliminary Pest Risk Assessment (PPRA)	Page 20	te	The RA states that there is a potential for recombination with any of the other strains of CTV co-infecting the tree. Is there a concern for recombination with another strain that can infect other plants?
PPRA Section B - Pest Risk Assessment	Page 21, Paragraph 2	te	It is stated (p. 21, paragraph 2) that the CTV can be transported within aphids but in the RA conclusions bullet point #6 (p. 22) states that the CTV-SoD lacks the ability to be vectored by aphids.

Describe or link to renewal process website and relevant documents.
Recommend adding progress reporting with details listed to permit. Reporting detail was not observed in Title 7 Code of Federal Regulations (CFR) 370.4 cited in EIS text for section 2.2.

Provide response.

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Resolve conflicting information.

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Section Name or #	Paragraph #/ Figure/Table (e.g. 121.14(f))	Comment Type <i>ge = general te = technical ed = editorial</i>	Comment (justification for change)	Proposed change	Proposal to address each comment submitted
PPRA Section D- Supplemental Conditions		te	How will this organism be monitored once released is not clearly described.	Include how the modified organism will be monitored	Add monitoring requirement details to PPRA Section D, to include frequency of monitoring to release and location information.
PPRA Section D- Supplemental Conditions		te	If something unforeseen goes wrong once implemented - what is the reporting requirement/strategy? Would any steps be taken? E.g. stop using the product?	Include the criteria that would require reporting to APHIS.	Clarify and add reporting requirements to those referenced as Standard Permit Conditions, presumably referring to 7 CFR 340.4. Recommend adding pre-determined response strategies in the event of an unforeseen adverse event.
PPRA Section D- Supplemental Conditions	New entry	te	Testing of the crops regularly to confirm that the CTV-SoD variants don't affect the fruits after a prolonged release.	Because of the relative unpredictability of the pest release over time, recommend employing a strategy similar to that used in human clinical trials where the phases (I, II, III) are determined by the number of subjects involved and the expected outcomes.	Add monitoring strategy to include release and testing intervals similar to phased clinical trials.
PPRA Section D- Supplemental Conditions	New entry	ge	Communication to neighboring growers - Community awareness	Notification to the community is critical. For example, it will ensure notification of unexpected adverse effects on other crops	Add communications section to inform community, to include methods of notification to permittee of pertinent observations. The results from regular testing of the crops to confirm that the CTV-SoD variants don't affect the fruits after a prolonged release (see cell D27) could be offered as a service to neighboring growers to alleviate concerns of non-participating farmers. Demonstrating that neighboring crops are unaffected could reduce the negative response many in the public have to anything GMO.