UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

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Rebecca L. Stankiewicz Gabel, Ph.D
Biotechnology Regulatory Services
U.S. Department of Agriculture
4700 River Road, Unit 147
Riverdale, MD 20737-1236

Dear Dr. Gabel:

In accordance with our responsibilities under Section 309 of the Clea Air Act and Section 102(2) (c) of the National Environmental Policy Act (NEPA), the En ironmental Protection Agency (EPA) has reviewed the U.S. Department of Agriculture's (USDA), Animal and Plant Health Inspection Service (APHIS) final environmental impact stat ment (EIS) for *"Glyphosate-Tolerant (GT) Alfalfa Events J101 and J163: Request for Nonre gulated Status."*

APHIS prepared this EIS to comply with an order from the U.S. Distr ct Court for the Northern District of California to prepare an EIS before deciding whether to rant nonregulated status to alfalfa lines J101 and J163, genetically engineered (GE) for toleranc to the herbicide glyphosate. The final EIS examined three alternatives: (1) a No Action Alter ative to maintain the status of GT alfalfa lines J101 and J163 as regulated articles; (2) a Dereg lation Alternative to grant nonregulated status to GT alfalfa lines J101 and J163; and (3) an Isol tion/Geographic Restrictions Alternative that takes into account mandatory measures to provi e for isolation distances, geographical restrictions and best management practices. The fina EIS identified alternatives 2 and 3 as Preferred Action Alternatives.

While EPA does not object to the two preferred action alternatives, w request that statements and conclusions made in the final EIS to support the selection of t e preferred alternatives be carefully reviewed prior to the issuance of the Record of Deci ion. Towards that end, the enclosure identifies areas EPA believes warrant further consideratio

We appreciate the opportunity to review this final EIS. Please contact me or Arthur Totten, at (202) 564-5400 or -7164, respectively, if you have any questions about our review.

Sincerely,

Susan E. Bromm
Director
Office of Federal Activities

Enclosure

ENCLOSURE

EPA's Detailed Comments on USDA's Final Environmental Impa t Statement
Glyphosate-Tolerant Alfalfa Events (GT) J101 and J163: Request for No regulated Status

The Environmental Protection Agency (EPA) is submitting comments on the Final Environmental Impact Statement (EIS) issued by the U.S. Department of Agr culture's Animal Plant Health Inspection Service (APHIS) on December 16, 2010[1]. The final I IS proposes to grant the petition in whole or in part to genetically engineered glyphosate-tole ant (GT) alfalfa lines J101 and J163 based on the USDA analysis and conclusions that these g netically engineered alfalfa lines are unlikely to pose plant pest risks. EPA has several concerns with this final EIS, as detailed in this note. Our two key issues concern resistance man gement and gene flow:

- Resistance Management: As developers produce increasing numbers of novel transgenic herbicide tolerant crops (HTCs), it is becoming increasingly impor ant to give greater consideration to prevention of weed resistance. Failure to do so could significantly impact our ability to preserve HTCs, as well as the associated her bicides. EPA will propose this issue as an agenda topic for the Agricultural Biotechnolc gy Work Group, so that it receives sufficient attention at high levels in the managen ent of the biotech regulatory agencies.

- Gene Flow: The final EIS proposed third action alternative, to allow t ne commercialization of GT alfalfa using restrictions on hay and seed pr duction designed to promote coexistence, constitutes a significant departure from EPA's longstanding approach to addressing potential gene flow concerns under FIFRA. W e anticipate that, should USDA decide to seriously consider implementing the propose third action alternative, it would engage in consultation with EPA, as contemplate under the Coordinated Framework for the Regulation of Biotechnology.

EPA was not given adequate time to review in depth the substance in t ne final EIS or to analyze the science detailed in the appendices, particularly in light of the sign ficant differences in content and volume between the draft and final documents. Given the limi ed time to review a much larger final EIS (more than 2000 pages of material), the bulk of EPA's r esponse attempts to highlight some of the major areas that we believe need to be addressed pric to making a final decision. Many of the corrections and clarifications are technical in nature an l pertain to EPA's science, policy, and practices. USDA's interpretation of these issues was use to support the reasoning behind the alternative approaches that they considered and the pref rred alternative that they ultimately selected. We believe that addressing EPA's corrections a nd clarifications should precede the proposed deregulation of glyphosate tolerant alfalfa.

It has been the practice over the years for APHIS Biotechnology Regu ator Services (BRS) to consult with and solicit comments from EPA's Office of Pesticide P ograms at various stages of their projects. Continuing this collaborative practice, in early 2010, EPA provided

[1] The final EIS package, consisting of the main final EIS document (246 pages) and Appendi es A-W (2204 pages) can be found at: http://www.regulations.gov/#!documentDetail;D=APHIS-2007-0044-12532

scoping comments to APHIS/BRS regarding the deregulation of glyphosate t lerant alfalfa. EPA commented and provided corrections and clarification on the draft EIS f r this project through numerous exchanges in the spring and summer of 2010. We appreci te the opportunities we have had for consulting with USDA during the scoping of this project, an to provide comments on the draft EIS. In addition, we acknowledge and appreciate whe e USDA has adequately addressed concerns we raised over the draft EIS. However, sever l comments we provided detailing inconsistencies and inaccuracies in USDA's characterizati n and conclusions regarding science and policy issues have not been thoroughly addressed in thi final EIS, and explanations for not addressing these concerns have not been provided.

In particular, EPA provided comments regarding changes to specific l nguage found in the draft EIS and subsequently discussed with representatives of BRS the nee l to include a discussion of glyphosate resistant and tolerant weeds, as well as the need for detailed discussion of resistance management or stewardship. Along with these chang s were discussions that elaborated on one of the themes established by these changes, resistance nanagement. EPA stated that it was important that the final EIS include a discussion regarding h rbicide resistant and tolerant weeds with respect to the introduction of glyphosate tolerant alfa fa and the increased use of glyphosate with this crop. It was our understanding that USI A would incorporate and consider these comments in their final EIS. EPA remains co cerned about these issues, as detailed below.

Herbicide Resistant Weeds

- EPA's comment on weed resistance and tolerance with respect to weed sh fts and biotype selection. The primary concern here was the statement "*...glyphosate-res stant weeds would be slow to develop, if they develop at all, due to GT alfalfa.*"

  Text from the draft EIS: (p. iv) Weeds in Alfalfa Section of the Execu ive Summary - *Biology/ecology of alfalfa (perennial status) and production practices (mowing, less glyphosate used compared to other crops) in alfalfa farming suggest t at glyphosate-resistant weeds would be slow to develop, if they develop at all, due to GT alfalfa. . Weed shifts to glyphosate resistant biotypes will likely occur faster than dev lopment of new weed resistance.*"

  EPA Comment on draft EIS: *Suggested change...The perennial nature of alfalfa and the practices used in producing the crop (e.g., mowing) are antagonistic t the selection of many herbicide-resistant weed species found in row crops. If alfalfa v ere to displace other crops, the fields in which the alfalfa is established would experi nce weed shifts and as a result there may be selection pressure placed on a completel different spectrum of weed species.*

  Text from the final EIS: page v, Alfalfa Biology section. *"Biology/ec logy of alfalfa (perennial status) and production practices (mowing, less glyphosate sed compared to other crops) in alfalfa farming suggest that glyphosate-resistant weed would be slow to develop in GT alfalfa stands. Weeds which have already developed re istant to*

glyphosate or are tolerant to glyphosate are more likely to occur in al alfa (weed shifts to glyphosate-resistant or glyphosate tolerant weeds) than is the develop nent of novel glyphosate resistant biotypes."

Conclusion: Changes to the Final EIS are not consistent with EPA's omments on the EIS. The two sentences listed above in the final EIS are confusing. T ıe text in the final EIS does not clearly convey the interrelationship between weed shifts, selection, and resistance development.

Using weed science convention, selection of resistant weeds is not in i self a weed shift. A weed shift is the movement from one spectrum of weed species to a different composition of weed species. Weed shifts are most common when m ving from one crop type to another (e.g. corn to alfalfa). Generally, these weed shift are a result of a favorable ecology in one crop and/or cropping system over another an l to some extent the types of herbicides available for use in different crops. When weec shifts occur, it is natural that biotypes of a weed species which are resistant to a specifi herbicide would occur or be selected, before any novel resistant weed biotypes would (evelop from herbicide use. It is important to clarify that weed shifts, selection, and resistance development are not separate and distinct issues but under certain circ mstances they occur in fields concomitantly.

- EPA is also concerned about confusion surrounding weed resistance.

Text from the draft EIS: *(p.45 [document p. 30])* Glyphosate Resistar ce in Weeds - *Weeds can develop resistance to herbicides for the following reasons: frequent exposure to a particular herbicide, the spread of naturally resistant weed seeds, and the outcrossing of herbicide-tolerant genes from plants, either GE plants r plants that naturally have herbicide tolerance genes, to weedy relatives."*

EPA Comment on the draft EIS: *Suggested change..."Herbicide resis ant weeds are most often due to the spread of seeds from resistant weed biotypes and/or v a frequent exposure of the population to a specific herbicide(s) resulting in the se lection of resistant biotypes. Weeds can develop resistance to herbicides through outcros sing of herbicide-tolerant genes from either GE plants or plants that naturally have her icide tolerance genes."*

Text from the final EIS: (p.34) *Weeds can develop resistance to herbi ides for the following reasons: frequent exposure to a particular herbicide, the spi ead of naturally resistant weed seeds, and the outcrossing of herbicide-tolerant genes j om plants—either GE plants or plants that naturally have herbicide tolerance genes—to weedy relatives.*

Conclusion: Changes to the Final EIS are not consistent with EPA's omments on the EIS.

The characterization in the final EIS of the "*...frequent exposure to a particular herbicide...*" needs to be clarified by adding the word, "selection," as follows: "*Weeds can develop resistance to herbicides for the following reasons: frequent exposure to a particular herbicide* selection..."

- **Specific Comments**

1. In conversations with BRS, EPA stated that it was important that the final EIS include a discussion regarding herbicide resistance management with respect to the introduction of GTA and the increased use of glyphosate with this crop. The changes reflected in the final EIS are consistent with EPA's comments in that they include many of the components of a resistance management plan.

2. Overall, the Executive Summary contains some information that needs context to clarify terms or concepts. While we recognize that this information is contained in the appendices, some of the terms are imprecise on their own (e.g. see the terms in #3).

3. In section 4.2, Appendix G, there is a discussion of weed shifts and the development of resistant weeds in GTA. In this section, several terms are used that may be confused, such as "weed shifts", "resistance development", "evolution of resistant", "confer resistance", "evolved resistance", and "selection of resistance". There is a need to define and contrast these terms in a single introductory paragraph.

4. In section 4.1, Appendix G, first paragraph - there is a definition of herbicide resistance followed along by a brief discussion of glyphosate resistant weeds. Following this paragraph is a different definition, one that is the Weed Science Society of America (WSSA) definition. It would be less confusing to use only the official WSSA definition.

5. In section 4.1, Appendix G - the WSSA definition of herbicide tolerance is given with no context or discussion. Because the entire document is about an herbicide-tolerant crop, a discussion is needed on why the definition is given and why herbicide tolerance is important in weed control.

6. The comment regarding the use of alfalfa as a habitat for wildlife - "*Because it is widespread and is typically grown as a perennial crop, alfalfa also provides important habitat for wildlife (Hubbard 2008).*" (FEIS, pg.iv). The document should clarify that pesticide use practices in agronomic production often vary from pesticide use practices in crops used to support wildlife habitat. An example would be a pre-harvest restriction. In this case, a farmer would need to consider this restriction and the timing of application with respect to harvesting a crop: a rather straight-forward label interpretation. However, a person using alfalfa forage as a wildlife food source (e.g. QDM – quality deer management programs) would need to consider that an animal could be grazing the forage within a very short period following an herbicide application.

7. On p. G-20, section 4.0, a statement is made that "*Fields with a histo y of perennial weed infestation are not well suited for alfalfa (Canevari et al. 2007).*" Wl ile this statement does not indicate what constitutes a "*perennial weed infestation*" or ' *well suited*", there are sufficient herbicides and herbicide mixes that allow for the produ tion of alfalfa in fields with varying degrees of perennial weed infestations. It would ot be possible to avoid perennial weeds, even infestations, in some agricultural systen

Gene Flow

The US Environmental Protection Agency concurs with APHIS' find ngs that gene flow between naturalized or feral species within the genus *Medicago* and Roundu Ready ® alfalfa is unlikely to result in transfer of the GT (glyphosate tolerance) trait to these ot ıer species. But, the potential for gene flow from GT alfalfa, as grown for hay or seed production to conventional and organic (trait-sensitive) growers is a realistic potential outcome based up ɔn the proposed co-existence practices outlined in the EIS. Moreover, the proposed third action ılternative is a significant departure from the way that EPA has consistently addressed gene flow issues under its statutory mandates. Under the regulatory process outlined in the Coordin ted Framework for the Regulation of Biotechnology EPA expects that, prior to USDA reaching ts final decision, the agencies will engage in a robust consultation on an issue of such importance

On a technical basis, there are several areas where the stipulated requ rements of cultivation for GT alfalfa, intended to reduce or eliminate gene flow to trait-s ensitive alfalfa fields, may fall short of this goal. The final EIS assumes a limitation such tha growers of Roundup Ready ® alfalfa will cut for hay production at no greater than 10% lowering. While this clearly would reduce pollen movement from such fields, the presence of lowers and suitable pollinators may in fact concentrate the pollinators on the limited flowers ava able, thereby enhancing the contact with viable pollen grains. Further, in many areas of the country, during the first year of alfalfa cultivation, growers often forego cutting the crop, or do s no more than once, to enhance stand establishment. To alleviate this significant pollen sou ce, growers would need to significantly alter their agronomic practices, preferably under a grow r agreement with the seed seller, to ensure pollinators are not carrying pollen to neighboring fi lds. If mitigation of gene flow is the preferred outcome, then cutting at full bud, prior to flowe ing, is a more effective approach.

Fields destined for hay production only do not appear to have a prede ermined isolation distance and flowering is allowed between 0 and 100% at cutting. It does not seem that this scheme will lead to a true mitigation of gene flow between GT alfalfa and tra t-sensitive crops, (we note that its efficacy is heavily dependent in part on pollinators available .

In the third action alternative, gene flow isolation distances are propo ed to be established based upon the presence of specific pollinator species (e.g., leaf cutter bees, a lkalai bees, honeybees) and will require constant monitoring to determine the presence o absence of said pollinators if this measure is to be effective. While honeybee hives are prohil ited from deployment near seed production fields of GT alfalfa, growers of other crops that require honeybee pollination, especially in California, may be problematic to manag .

The widespread occurrence of feral alfalfa plants in areas where seed and hay production are significant may constitute a source of GT pollen that is largely outside regulatory scrutiny as it may occur outside the immediate agro-ecosystem. Hard seed from GT and other alfalfa varieties are known to germinate after considerable time in the soil and can also represent sources of pollen, particularly in the absence of field monitoring post termination. The final EIS appears to rely upon growers mowing feral plant populations to preclude gene flow, but this is not always the case as witnessed by the prevalence of feral alfalfa in roadside ditches.

The logistical maze proposed by the various requirements on grower, based in large part on the geography of their production fields, may lead to significant difficulties for EPA as we can easily contemplate the development of an alfalfa plant-incorporated protectant requiring regulation under FIFRA. Experimental Use Permits (EUPs) granted under FIFRA are done so with a food / feed tolerance or an exemption from the requirement of a tolerance such that gene flow (outcrossing) between crops is not a consideration of our risk assessment. Deregulation by APHIS under the conditions contemplated by the third action alternative of the final EIS is inconsistent with the regulatory approach followed by EPA since the advent of our PIP regulatory process.

Pesticide Registration Review with Respect to Endangered Species and Critical Habitat

The final EIS makes an erroneous assumption in several places regarding EPA's safety finding about glyphosate products. Specifically, the document states that since EPA has granted registration to glyphosate products, EPA has determined, according to its statute (FIFRA) that those glyphosate products pose no unreasonable environmental risk to federally listed threatened and endangered species if the user adheres to the labeled directions. This is an erroneous assumption because EPA has not completed an assessment of the effect of glyphosate on threatened and endangered species. Examples of this statement can be found on page vi of the executive summary and page 149 of the text of the final EIS, but there may be other such statements throughout.

The text should be clarified to state that EPA has not yet conducted a complete, national-level threatened and endangered species assessment for glyphosate, and that EPA intends to conduct a national-level Endangered Species Assessment as part of its registration review for glyphosate. The registration review of glyphosate began in 2009; the preliminary risk assessment is expected to be published and open for public comment in early 2014, with a final registration review decision in 2015.

Exception to Aquatic Use Restrictions of the Surfactant POEA

The final EIS states that formulations containing the surfactant POEA are not allowed for use over or near surface water. It further concludes that "Adoption of GT alfalfa, however, is unlikely to adversely affect amphibians, because none of the glyphosate formulations that contain surfactants are approved for use over or near surface waters." This statement was correct

as of the time of submission of this final EIS. However, since December 20 2010, EPA has amended one registered product (EPA Reg. No. 71368-25) to add aquatic us s.

Surface Water Purification Process

EPA's letter in response to the draft EIS (comments offered last sumı ıer) suggested inclusion of an expanded discussion of expected levels of glyphosate in drin ing water in areas where water treatment with chlorination or ozonation is not conducted. We vere unable to find such an expanded discussion in the document.

Human Health

AMPA was eliminated as a residue of concern for tolerance enforcen ent and risk assessment as part of the 1993 RED; therefore, the mention of AMPA on pa e 180 of the final FEIS should be eliminated (should be eliminated everywhere).

Page 180 and elsewhere in the document and attachments it is stated hat "EPA determined that non-nursing infants under 1-year of age were at the highest ı sk of adverse effects associated with glyphosate exposure." The Agency believes the mor accurate statement would be to say that "non-nursing infants appeared to have the highest expos ıre to glyphosate." In general, since the Agency may not have a sufficient sample size represent ıg non-nursing infants, EPA is careful about drawing conclusions about non-nursing infants compared to other infant populations.

- **Specific Comments**

1. Section 3.1.1 and 3.1.6 of attachment L need to be altered because EI A is now requesting from registrant's acute/subchronic neurotoxicity and immunotoxicity studies.

2. On page L-23, the document states that glyphosate is listed as categoı y III for oral and dermal toxicity. In EPA's last risk assessment glyphosate was listed a s category IV **(practically non-toxic)** for those two routes of exposure.