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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. FDA-2015-N-3403

Submitted electronically via www.regulations.gov

Re: NSAC Comments on “Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology”

On behalf of the represented member organizations of the National Sustainable Agriculture Coalition (NSAC),¹ we submit the following comments on the Office of Science and Technology Policy (OSTP) request for stakeholder input on the Coordinated Framework for the Regulation of Biotechnology and the Long-Term Strategy for the Regulation of the Products of Biotechnology. NSAC is a grassroots alliance that advocates for federal policy reform that supports the long-term social, economic, and environmental sustainability of agriculture, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainability. These include certified organic, sustainable, non-genetically engineered, and farm identity-preserved products, systems, and supply chains that are impacted by the regulation of genetically engineered (GE) organisms, or lack thereof.

¹ Agriculture and Land Based Training Association, Salina, CA; Alternative Energy Resources Organization, Helena, MT; California Certified Organic Farmers, Santa Cruz, CA; California FarmLink, Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture), Hereford, TX; Catholic Rural Life, Des Moines, IA; Center for Rural Affairs, Lyons, NE; Clagett Farm/Chesapeake Bay Foundation, Upper Marlboro, MD; Community Alliance with Family Farmers, Davis, CA; Dakota Rural Action, Brookings, SD; Delta Land and Community, Almyra, AR; Ecological Farming Association, Soquel, CA; Farmer-Veteran Coalition, Davis, CA; Flats Mentor Farm, Lancaster, PA; Florida Organic Growers, Gainesville, FL; GrassWorks, New Holstein, WI; Hmong National Development, St. Paul, MN; Illinois Stewardship Alliance, Springfield, IL; Institute for Agriculture and Trade Policy, Minneapolis, MN; Interfaith Sustainable Food Collaborative, Sebastopol, CA; Iowa Natural Heritage Foundation, Des Moines, IA; Izaak Walton League of America, St. Paul, MN; Kansas Rural Center, Whiting, KS; Kerr Center for Sustainable Agriculture, Poteau, OK; Land Stewardship Project, Minneapolis, MN; MAFO, St. Cloud, MN; Michael Fields Agricultural Institute, East Troy, WI; Michigan Integrated Farm and Food Systems, East Lansing, MI; Michigan Organic Food and Farm Alliance, Lansing, MI; Midwest Organic and Sustainable Education Service, Spring Valley, WI; National Center for Appropriate Technology, Butte, MT; Nebraska Sustainable Agriculture Society, Ceresco, NE; Northeast Organic Dairy Producers Alliance, Deerfield, MA; Northern Plains Sustainable Agriculture Society, LaMoure, ND; Northwest Center for Alternatives to Pesticides, Ohio Ecological Food and Farm Association, Oregon Tilth, Eugene, OR; Organic Farming Research Foundation, Santa Cruz, CA; Rural Advancement Foundation International – USA, Pittsboro, NC; Union of Concerned Scientists Food and Environment Program, Cambridge, MA; Virginia Association for Biological Farming, Lexington, VA; Wild Farm Alliance, Watsonville, CA.

Many of the farmers that NSAC works with and represents choose to grow only non-GE crop varieties because the markets they serve demand GE-free products; because they have concerns about potential adverse health, environmental, or agronomic impacts of GE crop technologies; or because they are USDA certified organic and not allowed to grow GE crops. These producers sustain substantial economic losses when their products contain unintended GE material at levels exceeding market or organic certifier specifications.


In addition, exposure of organic or non-GE fields to GE pollen, pesticides, and herbicides from neighboring farms using GE crop technology packages can lead to adverse ecological and agronomic consequences for the non-GE producer, as well as tensions among farmers. Thus, the outcomes of biotechnology regulation directly impact the economic, environmental, and social sustainability of our nation's agriculture and rural communities, and are therefore of great concern for NSAC.

NSAC welcomes the opportunity to submit comments to OSTP on the Coordinated Framework for the Regulation of Biotechnology and the long-term strategy for the regulation of the products of biotechnology. This is a very important opportunity for OSTP, USDA, FDA and EPA to improve the coordination of biotechnology regulations.

We believe the current Coordinated Framework does not address the risks and concerns that biotechnology poses for non-GE farmers and the environment. As we discuss in our comments, there is significant need for a comprehensive regulatory framework that addresses the secondary environmental and socioeconomic impacts of biotechnology and ensures that the diverse sectors of American agriculture can thrive.

Thank you for your consideration of our views.

Sincerely,


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GENERAL COMMENTS

- 1. Provide clear information to the public regarding the various Administrative actions recently taken on biotechnology and their relation to one another, including an overarching process by which the comments received on and impacts of each action will be considered comprehensively.**

The Office of Science and Technology Policy's (OSTP) request for information on the regulatory framework for biotechnology comes on the heels of a number of related requests from the agencies OSTP aims to coordinate. For example, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) solicited comments on the withdrawal of the biotechnology regulation proposed rule in June 2015, and included questions related to the Coordinated Framework. And APHIS' Biotechnology Regulatory Services will be holding a stakeholder meeting next week to discuss and solicit input on a new proposed rule. USDA also recently solicited comments on the issue of agricultural "coexistence" through several dockets in the past two years. Lastly, we note that USDA continues to move forward with plans to deregulate or field-test more varieties of GE plants and insects despite the fact that the agency is reconsidering aspects of its regulatory system. We are deeply concerned by this lack of coordination.

While we appreciate agencies seeking public comment and asking stakeholders to engage on these important issues, the multiple requests for information from different agencies on overlapping topics makes the biotechnology framework seem fragmented and rather uncoordinated.

Biotechnology products and their regulatory frameworks are incredibly complex, and the agencies should do as much as they can to facilitate public understanding and engagement around these issues. As a general recommendation, we encourage OSTP to foster a more transparent, streamlined approach to the discussion of biotechnology regulation, with clear information in one place providing a bigger-picture understanding of the various ways in which the Federal government is tackling this issue. A timeline, for example, explaining how and when each of these requests for comment will be considered in relation to one other, could help the public remain informed about and engaged in the efforts of various agencies to regulate biotechnology. We encourage OSTP and the coordinating agencies to provide the public with this kind of explanatory information post haste.

- 2. Develop a comprehensive and robust regulatory framework for biotechnology.**

In our previous comments on biotechnology regulations to the USDA, we have advocated for a comprehensive regulatory framework for biotechnology and encouraged USDA to take specific actions to ensure such a robust framework. We believe these considerations are crucial to OSTP's consideration of long-term strategies to ensure the coordinated, streamlined, predictable, and effective regulatory oversight of biotechnology. They include recommendations to:

- Develop a regulatory process that is transparent and informed by independent science;

- Include farmers and other stakeholders throughout the regulatory and review process;
- Build into the process the authority to take into consideration the social, environmental, and economic risks that each new biotechnology product and process pose;
- Implement a rigorous post-commercialization monitoring system of biotechnology products that informs future regulatory decisions;
- Develop regulations that improve oversight and tracking on experimental field trials of biotechnology products;
- Require implementation of contamination prevention practices for GE crop producers and users to safeguard organic and non-GE producers;
- Create robust compensation mechanisms for farmers affected by GE contamination resulting in harm, including but not limited to economic losses; and
- Support non-regulatory actions that bolster research and education for non-GE seed and crop production.

We believe these considerations are equally important to OSTP as it updates the Coordinated Framework and develops a long-term strategy for the regulation of the products of biotechnology.

NSAC also offers the following recommendations to OSTP, focusing our comments on the question posed by the agencies in Question 5. While our first two recommendations relate to the Coordinated Framework, the remaining recommendations aim to inform the development of a long-term strategy for the regulation of the products of biotechnology.

RESPONSES TO QUESTION 5

Question 5 asks, “are there specific issues that should be addressed in the update of the CF or in the long-term strategy in order to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?” Below, we provide five specific issues that should be addressed in the long-term strategy of the agencies to improve upon the biotechnology regulatory system, and then – once undertaken – be duly reflected in the updated Coordinated Framework.

- 1. Ensure the combined impacts of crop technology packages are fully assessed by better coordinating the agency review processes.**

A comprehensive biotechnology regulatory system must address the full technology packages that comprise new products (e.g. Enlist™ Corn and Soybeans and Enlist Duo™ herbicide). Under the current framework, USDA approves the traits and EPA approves the corresponding herbicide, with APHIS’ decision to deregulate a new variety typically occurring before EPA can review the associated changes to the herbicide label. This dual-agency review process is problematic, because GE crops and herbicides may not seem as harmful when their impacts are reviewed separately. Furthermore, the current uncoordinated process creates significant industry pressure to also approve the label without

adequate review. This, in turn, creates markets for new GE technologies that rely on applications of more toxic herbicides, resulting in herbicide-resistant weeds, reduced crop productivity, and millions of dollars in losses for farmers.

We urge OSTP to ensure that herbicide labels are regulated in close coordination with the deregulation of the trait. As we indicated in our June 2015² and October 2015³ comments to APHIS, the Plant Protection Act gives APHIS broad noxious weed authority that allows USDA to regulate for the indirect impacts of herbicide resistant weeds. As a result, APHIS can and should consider the associated implications of changes in herbicide use that are part of the same technology package as the GE variety seeking deregulation. A more unified review process would help to prevent herbicide drift, nontarget crop losses, further increases in herbicide resistant weeds, and other negative effects on the environment and public health.

Recommendation: The Coordinated Framework should require agencies to coordinate their evaluations of the environmental, social, ecological, and economic impacts of the full crop technology package prior to deregulation.

2. Reconsider the product-based approach in the Coordinated Framework.

NSAC supports a fully informed regulatory process driven by the identification of risk, the evaluation of products and processes through independent science and research, and the assessment of scientific uncertainty on various biotechnology issues.

The current regulatory criteria developed under the Coordinated Framework of 1986 uses a solely product-based approach and assumes that the process of biotechnology itself poses no unique risks.⁴ However, a National Academy of Sciences report states that genetic engineering itself should be the trigger for regulatory review. They specifically write, “even if the risks of all conventionally bred crops are considered to be ‘acceptable,’ there is still a logical scientific justification for GE crops to enter into regulatory oversight.”⁵ The product-based approach to regulating biotechnology fails to address the higher rates of potentially harmful and unintended effects that genetic engineering poses when compared to conventional plant breeding.⁶ Furthermore, the methods and processes used to create new biotechnology products are rapidly evolving, and the consequences of a process-based approach may be just as harmful as a product-based approach.

There does not seem to be consensus among the agencies that the current product-based approach is working. In June 2015, while soliciting stakeholder input on the withdrawal of the biotechnology regulation proposed rule, the first question APHIS posed was, “Should

² See Appendix I, NSAC Comments at 4-5.

³ See Appendix II, NSAC Comments at 5.

⁴ The Pew Charitable Trust. *Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products*. The Pew Initiative on Food and Biotechnology. Washington, DC. 2001.

⁵ National Academy of Sciences, Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants, Board on Agriculture and Natural Resources. *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* (2002), p. 79, 83.

⁶ National Academy of Sciences, National Research Council. *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (2004), p. 64.

APHIS regulate based on the characteristics of biotechnology products and the potential risks they may pose, or by the process by which they were created? In either case, what criteria should be used to determine what APHIS regulates? Are there products and processes APHIS should not regulate?” It seems poorly coordinated for OSTP to simply invite comments on how to “increase the transparency, coordination, predictability, and efficiency of the regulatory system,” rather than question whether or acknowledge that changes to the approach may be warranted, particularly as APHIS seems to be contemplating that very question.

As we recommended to APHIS when they solicited comments on this issue,⁷ we believe that the decision to take any approach – whether product, process, or a hybrid approach– must be preceded by significant research, risk assessment, and public education on each of the options under consideration, and the various hazards and benefits associated with each. OSTP should consider the comments submitted to the docket on that issue, particularly with respect to any necessary research and education, before updating the Coordinated Framework. In order for the public to properly consider and provide feedback on a product- vs. process-based approach, there must be significant and comprehensive research and public education on the topic to allow for informed public input into this incredibly complex topic. This research and analysis should be conducted immediately, as the current product-based regulatory system has many shortcomings; unintended effects from existing GE products are well documented.⁸

Recommendation: The Coordinated Framework should charge OSTP with researching and evaluating the various options for the regulation of biotechnology – including product, process, hybrid, or alternative approaches. As part of that process, OSTP, USDA, EPA, and FDA should provide the public with clear, objective information assessing the relative risks and benefits of each approach, followed by another opportunity to provide comment.

3. Improve data collection and analysis on the long-term direct and indirect environmental and economic implications.

A comprehensive regulatory framework addresses not only the regulation of the technology and products, but also the secondary environmental and socioeconomic impacts of the full technology package’s use in the field. Research is specifically needed to inform contamination prevention strategies.

The agencies should fully analyze the long-term direct and indirect environmental effects of GE contamination and the implications of managing GE crops, including the increased risk of pesticide drift, the development of pest resistances, and the scope of contamination. For example, as we noted in our comments on coexistence to USDA in May 2015:⁹

Roundup Ready crops entail a greatly increased use of glyphosate, which could potentially increase risk of herbicide drift as well as the documented evolution of weeds resistant to glyphosate. While the spread of glyphosate-resistant weeds onto

⁷ See Appendix I, NSAC Comments at 3-4.

⁸ See Appendix I for our full comments to APHIS.

⁹ See Appendix III for our full comments to USDA.

organic farms may have little impact (since USDA certified organic does not allow this herbicide), other non-GE identity preserved producers who rely on judicious use of glyphosate as part of their management systems may be forced to switch to older, more toxic herbicides.

As part of this inquiry, the agencies should compile sound, research-based information on effective contamination prevention strategies for each crop for which commercially available GE varieties are being produced. These strategies may include isolation distances, buffers, modifications of planting date, and other measures.

Recommendation: As part of a long-term strategy, the agencies should prioritize and coordinate research on the environmental impacts of biotechnology, including effective contamination prevention strategies. By collecting, compiling, and analyzing data, the agencies will better understand the scope of GE contamination and best practices for preventing contamination in the future. OSTP could serve a vital role in the compilation and dissemination of this data.

4. Develop stronger GMO regulations that prevent contamination of organic and other non-GE farm products and crop seed with unintended GE content.

Once the agencies have a better understanding of the environmental implications of GE contamination, the agencies should require best practices to prevent GE contamination by farmers who use GE seed. GE contamination includes both genetic contamination and contamination from chemical drift used in GE crop production.

We should not expect non-GE farmers who do not use or benefit from this technology to bear the brunt of the responsibility for preventing GE contamination. The burden of preventing contamination must be tied to ownership. Mandatory measures are necessary to prevent GE contamination, because voluntary solutions to contamination have proven insufficient. Furthermore, it costs more money to clean up contamination than it does to prevent it.

We need stronger GMO regulations that ensure shared responsibility for contamination prevention. This may be accomplished by relying on existing legal authorities to regulate the products of biotechnology. For example, as we discussed in our June 2015 comments to USDA's request for stakeholder input on the withdrawal of the biotechnology regulation proposed rule:¹⁰

USDA has the authority to protect the USDA Organic Seal and implement the National Organic Program (NOP). NOP's mission is "ensuring the integrity of USDA organic products in the U.S. and throughout the world." NOP standards prohibit the use of GE inputs in products sold or labeled as organic. Consumers and foreign buyers look to the organic seal as an indicator of GE-free production methods. Therefore, to ensure the integrity of organic production, USDA must develop regulations that minimize the likelihood that organic products are inadvertently contaminated by GE inputs.

¹⁰ See Appendix III for our full comments to USDA.

Recommendation: As part of a long-term strategy, the agencies should mandate best practices to prevent GE contamination by farmers who use GE seed and require concrete contamination prevention measures on those farms to supplement measures already used by organic and other non-GMO producers.

5. Establish a fair compensation mechanism for economic losses due to GE contamination.

Those who patent, promote, and profit from GE products should not only be responsible for preventing contamination, but also for covering damage when prevention fails.

As we have noted in previous comments, crop insurance is not a good model for compensation. Unlike events that farmers usually insure against, GE contamination is a man-made occurrence that is not inevitable. Furthermore, GE contamination is often not an isolated incident that is linked to one instance or pathway of contamination. Agencies should not place the burden on non-GE producers who do not stand to benefit from the technology, or on taxpayers (through insurance subsidies). As a result, the crop insurance model is not an ideal method of addressing compensation issues arising from GE contamination of non-GE seeds, crops, and harvests.

Instead, those who enjoy the economic gains from the use of GE crop technologies – the patent holders themselves – should also bear the onus of compensating non-GE producers for losses related to unintended trespass of GE material into their fields or crop seeds. While GE producers do profit from the sale of these crops, it is the GE technology patent holders who make the majority of profits related to GE technology. Thus, they should bear the primary responsibility, both for preventing GE contamination of non-GE crops, and for compensating non-GE farmers adversely affected by such compensation.

We recommend the establishment of a general compensation fund that is primarily funded by GE crop technology patent holders. Patent holders retain effective ownership of GE seed, and therefore should accept the responsibility of adequate stewardship of the technology and compensation of those harmed by contamination. The exact form and size of the general compensation fund will need to be determined based on the outcome of the agencies' research into the extent of GE contamination and associated economic impacts to organic, IP, and other non-GE producers.

Recommendation: As part of a long-term strategy, the agencies should develop a compensation mechanism based on a fund model and should rely on GE patent holders to provide the majority of funds to compensate for losses of GE contamination.

CONCLUSION

We appreciate the opportunity to present our views on how the current biotechnology regulatory framework fails to fully assess the combined impacts of crop technology packages and protect all farmers from economic losses due to the unintended presence of GE material

in farm products. We believe that all producers should feel secure that their choices of production system and markets will not be compromised or foreclosed due to the impacts of contrasting production systems employed by other producers. Robust regulatory improvements are necessary to prevent contamination to begin with and place responsibility with the patent holders, not the farmers affected by contamination.

NSAC and the farm, food, and rural organizations we represent wish to remain engaged in the conversation as OSTP, USDA, FDA and EPA work together to improve the Coordinated Framework and create a long-term strategy. We thank you for giving serious consideration to our recommendations, and we look forward to working with you to ensure the Coordinated Framework allows the diverse sectors of American agriculture to thrive.



June 22, 2015

Biotechnology Regulatory Services
Animal Plant Health Inspection Service
United States Department of Agriculture
4700 River Road Unit 146
Riverdale, MD 20737-1236

Docket No. APHIS-2008-0023
RIN 0579-AC31

Submitted electronically via www.regulations.gov

Re: NSAC Comments on the Withdrawal of the Proposed Rule Regarding the Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms.

On behalf of the represented member organizations of the National Sustainable Agriculture Coalition (NSAC),¹ we submit the following comments on the U.S. Department of Agriculture's (USDA) request for stakeholder input on the withdrawal of the biotechnology regulation proposed rule. NSAC is a grassroots alliance that advocates for federal policy reform that supports the long-term social, economic, and environmental sustainability of agriculture, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainability. These include certified organic, sustainable, non-genetically engineered, and farm identity-preserved products, systems, and supply chains that are impacted by the regulation of genetically engineered (GE) organisms, or lack thereof.

Many of the farmers that NSAC works with and represents choose to grow only non-GE crop

¹ Agriculture and Land-Based Training Association - Salinas, CA; Alternative Energy Resources Organization - Helena, MT; California Certified Organic Farmers - Santa Cruz, CA; California FarmLink - Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture) - Hereford, TX; Center for Rural Affairs - Lyons, NE; Claggett Farm/Chesapeake Bay Foundation - Upper Marlboro, MD; Community Alliance with Family Farmers - Davis, CA; Dakota Rural Action - Brookings, SD; Delta Land and Community, Inc. - Almyra, AR; Ecological Farming Association - Soquel, CA; Farmer-Veteran Coalition - Davis, CA; Flats Mentor Farm - Lancaster, MA; Florida Organic Growers - Gainesville, FL; GrassWorks - New Holstein, WI; Hmong National Development, Inc. - St. Paul, MN and Washington, DC; Illinois Stewardship Alliance - Springfield, IL; Institute for Agriculture and Trade Policy - Minneapolis, MN; Interfaith Sustainable Food Collaborative - Sebastopol, CA; Iowa Natural Heritage Foundation - Des Moines, IA; Izaak Walton League of America - St. Paul, MN/Gaithersburg, MD; Kansas Rural Center - Whiting, KS; The Kerr Center for Sustainable Agriculture - Poteau, OK; Land Stewardship Project - Minneapolis, MN; Michael Fields Agricultural Institute - East Troy, WI; Michigan Food & Farming Systems - East Lansing, MI; Michigan Organic Food and Farm Alliance - Lansing, MI; Midwest Organic and Sustainable Education Service - Spring Valley, WI; National Catholic Rural Life Conference - Des Moines, IA; The National Center for Appropriate Technology - Butte, MT; Nebraska Sustainable Agriculture Society - Ceresco, NE; Northeast Organic Dairy Producers Alliance - Deerfield, MA; Northern Plains Sustainable Agriculture Society - LaMoure, ND; Northwest Center for Alternatives to Pesticides - Eugene, OR; Ohio Ecological Food & Farm Association - Columbus, OH; Oregon Tilth - Corvallis, OR; Organic Farming Research Foundation - Santa Cruz, CA; Rural Advancement Foundation International - USA - Pittsboro, NC; Union of Concerned Scientists Food and Environment Program - Cambridge, MA; Virginia Association for Biological Farming - Lexington, VA; Wild Farm Alliance - Watsonville, CA.


varieties because the markets they serve demand GE-free products; because they have concerns about potential adverse health, environmental, or agronomic impacts of GE crop technologies; or because they are USDA certified organic and not allowed to grow GE crops. These producers sustain substantial economic losses when their products contain unintended GE material at levels exceeding market or organic certifier specifications.

In addition, exposure of organic or non-GE fields to GE pollen, pesticides, and herbicides from neighboring farms utilizing GE crop technology packages can lead to adverse ecological and agronomic consequences for the non-GE producer, as well as tensions among farmers. Thus, the outcomes of biotechnology regulation directly impact the economic, environmental, and social sustainability of our nation's agriculture and rural communities, and are therefore of great concern for NSAC.

NSAC welcomes the opportunity to submit comments on the Animal Plant Health Inspection Service's (APHIS) questions regarding the regulation of GE organisms. NSAC believes that stronger regulations can and should be implemented pursuant to USDA's existing regulatory authority under the Plant Protection Act. This is a very important opportunity for APHIS to improve biotechnology regulations that advance the complementary goals of public health, environmental sustainability, and economic viability for farmers and rural communities.

Our comments focus on the four specific questions APHIS has raised for stakeholder engagement to identify solutions and offer input to the future regulatory activities of APHIS, as well as USDA's current regulatory authority to address this issue. We appreciate your consideration of our views.

Sincerely,


Sophia Kruszewski
Policy Specialist


Carla Curle
Policy Intern

GENERAL COMMENTS

To ensure a robust GE regulatory framework, NSAC recommends that USDA:

- Develop a regulatory process that is transparent and informed by independent science;
- Include farmers and other stakeholders throughout the regulatory and review process;
- Build into the process the authority to take into consideration the social, environmental, and economic risks that each new biotechnology product and process pose;
- Implement a rigorous post-commercialization monitoring system of biotechnology products that informs future regulatory decisions;
- Develop regulations that improve oversight and tracking on experimental field trials of biotechnology products;
- Require implementation of contamination prevention practices for GE crop producers and users to safeguard organic and non-GE producers;
- Create robust compensation mechanisms for farmers affected by GE contamination resulting in harm, including but not limited to economic losses; and
- Support non-regulatory actions that bolster research and education for non-GE seed and crop production.

With these considerations in mind, NSAC offers the following recommendations and responses to APHIS's questions regarding GE regulations.

Question 1: Should APHIS regulate based on the characteristics of biotechnology products and the potential risks they may pose, or by the process by which they were created? In either case, what criteria should be used to determine what APHIS regulates? Are there products and processes APHIS should not regulate?

NSAC supports a fully informed regulatory process driven by the identification of risk, the evaluation of products and processes through independent science and research, and the assessment of scientific uncertainty on various biotechnology issues. We therefore are not convinced that the question APHIS poses is a simple “either/or” question.

The current regulatory criteria developed under the Coordinated Framework of 1986 uses a solely product based approach and assumes that the process of biotechnology itself poses no unique risks.² However, a National Academy of Sciences report states that genetic engineering itself should be the trigger for regulatory review. They specifically write, “even if the risks of all conventionally bred crops are considered to be ‘acceptable,’ there is still a logical scientific justification for GE crops to enter into regulatory oversight.”³ The product-based approach to regulating biotechnology fails to address the higher rates of potentially harmful and unintended effects that genetic engineering poses when compared to conventional plant breeding.⁴

² The Pew Charitable Trust. *Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products*. The Pew Initiative on Food and Biotechnology. Washington, DC. 2001.

³ National Academy of Sciences, Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants, Board on Agriculture and Natural Resources. *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* (2002), p. 79, 83.

⁴ National Academy of Sciences, National Research Council. *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (2004), p. 64.

Given the rapidly changing methods and processes used to create new biotechnology products, a process-based approach to regulation could present challenges as concerning as those posed by a product-based approach. We therefore believe that the decision to take any approach – whether product, process, or a hybrid approach– must be preceded by significant research, risk assessment, and public education on each of the options under consideration, and the various hazards and benefits associated with each.

In order for the public to properly consider and provide feedback on a product- vs. process-based approach, we believe there must be significant and comprehensive research and public education on the topic to allow for informed public input into this incredibly complex topic. Given the significant impacts any approach will have on the farming community – particularly those that choose not to use biotechnology or products produced with biotechnology – we believe that there is a strong need for more information and independent studies evaluating the environmental and socio-economic risks associated with biotechnology products and processes before we can provide adequate input.

NSAC is very concerned with the secondary risks to farmers that accompany the usage of GE crops on neighboring farms. Therefore, it is crucial that the regulatory method APHIS utilizes fully assesses and takes into consideration the risks – including environmental, social, and economic – and impacts of genetic contamination.

Recommendation: USDA should research and evaluate the various options under consideration for the regulation of biotechnology – including product, process, hybrid, or alternative approaches – and should provide the public with clear, objective information assessing the relative risks and benefits of each approach, followed by another opportunity to weigh in. This research and analysis should be conducted without delay, as the current product-based regulatory system has many shortcomings; unintended effects from existing GE products are well documented. USDA should also ensure that the approach to biotechnology regulation under consideration at APHIS takes into account the need for a comprehensive regulatory framework that addresses not only the regulation of the technology and products, but also the secondary environmental and socioeconomic impacts of the full technology package’s use in the field.

Question 2: The Plant Protection Act gives APHIS the authority to protect plant health through regulatory programs. APHIS has implemented the plant pest authority as part of their biotechnology regulations. Should APHIS add noxious weed provisions to their to biotechnology regulations and if so, how? What protection goals should APHIS consider?

We support the application of APHIS’ noxious weed authority to the regulation of biotechnology under the Plant Protection Act. It is crucial to organic and other non-GE producers, including specialty crop producers, that this broad noxious weed authority be applied to biotechnology products because of the inherent risks of contamination.

The term “noxious weed” refers to any plant or plant product that can directly or indirectly cause damage to crops and other interests of agriculture, natural resources, the public health, or the environment.⁵ Applying the noxious weed provision to the regulation of biotechnology is crucial

⁵ Public Law 106-224. Plant Protection Act. Commerce and trade. Exports and imports. *Title IV-Plant Protection Act*. 2000.

under APHIS authority, as the Plant Protection Act gives USDA the responsibility of preventing the spread of noxious weeds.

By incorporating the noxious weed authority in its biotechnology regulations, APHIS should consider developing provisions that will prevent against:

- Crop and seed contamination through gene flow, pollen drift, and other modes;
- Increased pesticide and herbicide usage and the associated development of pest and weed resistance;
- Increased weediness of GE crops already being grown;
- Economic harm to farmers and producers in other agricultural markets (non-GE, organic); and
- Impacts on non-target organisms and on the biodiversity of a region.

It is crucial that the biotechnology regulatory system addresses the full technology package that comprise new products (i.e. Enlist™ Corn and Soybeans and Enlist Duo™ herbicide), as the unintended effects may not be as powerful in isolation. This has been well documented with the case of Roundup Ready® soybeans, cotton, and corn and the widespread reliance on Roundup® resulting in weed resistance.⁶ Not only has this created herbicide-resistant weeds that infest fields, reduce crop productivity, and cause farmers millions of dollars in losses, it has continued the pesticide treadmill by creating markets for new GE technologies that rely on applications of more noxious herbicides and mixtures of herbicides. The use of these new herbicides will have harmful effects on ecological systems, human health, and farmers' livelihoods.

Recommendation: Herbicide resistance in weeds can cause real and lasting problems for farmers, whether they use the technology or not. APHIS must use its authority under the Plant Protection Act to protect the livelihoods of farmers, public health, and our natural resources from the spread of noxious weeds and the associated damages from these GE crop-herbicide technology packages.

Question 3: Are there legal authorities given to USDA outside the Plant Protection Act that APHIS should examine to regulate or oversee the products of biotechnology? What are they, and how would they be used?

Aside from the Plant Protection Act, there are several authorities that we recommend USDA examine as it considers its authority to regulate biotechnology.

First, the 2008 Farm Bill directed USDA to take actions on “regulations to improve management and oversight” of biotechnology crop production that would augment the agency’s existing authority under the Plant Protection Act.⁷ Specifically, section 10204(a)(1) directed USDA to take action on each of the “lessons learned” from the Liberty Link rice contamination event in 2006. A critical lesson learned from the Liberty Link event was that GE researchers and developers had to submit a corrective action plan to address contamination. Clearly, USDA found value in and had authority to require GE researchers and developers to establish plans related to contamination. Therefore,

⁶ Owen, Micheal DK, and Ian A. Zelaya. "Herbicide resistant crops and weed resistance to herbicides." *Pest Management Science* 61.3 (2005): 301-311.

⁷ Food, Conservation, and Energy Act of 2008, Pub. L. 110-234, section 10204.

USDA should require prevention plans as well as require corrective action plans to be in place before a GE research and development project is underway.⁸

Second, USDA has authority to protect the USDA Organic Seal and implement the National Organic Program (NOP). NOP's mission is "ensuring the integrity of USDA organic products in the U.S. and throughout the world." NOP standards prohibit the use of GE inputs in products sold or labeled as organic. Consumers and foreign buyers look to the organic seal as an indicator of GE-free production methods. Therefore, to ensure the integrity of organic production, USDA must develop regulations that minimize the likelihood that organic products are inadvertently contaminated by GE inputs. APHIS should review NSAC and our member organizations' numerous comments to USDA regarding steps to prevent contamination of organic products. Any new APHIS regulation should include elements of contamination prevention – focusing on the actions that must be taken by GE users to prevent contamination.

Third, USDA has authority over the purity and quality of seed that is sold and over germplasm resources in this country. The National Plant Germplasm System is a cooperative effort by State and Federal agencies and private organizations to safeguard the genetic diversity of agricultural and other plant varieties. APHIS should consider programs such as this and others that promote diversity within our agricultural system when overseeing products of biotechnology.

Finally, it is important to remember that the existing Coordinated Framework of 1986 gives regulatory authority to three different agencies: USDA, FDA, and EPA. NSAC stresses the significance of a coordinated and comprehensive regulatory process for biotechnology with transparent communications between all agencies and stakeholders. FDA and EPA should adopt this opportunity for stakeholder engagement to improve their own biotechnology regulations to ensure human, environmental, and economic viability.

Question 4: What non-regulatory solutions or policy alternatives could or should be considered to complement APHIS's regulatory program?

While non-regulatory approaches are important complementary actions to regulation, NSAC strongly believes that those efforts should not replace any existing or future biotechnology regulatory program. As we stated in our comments on the "coexistence" docket: a robust federal regulatory program that considers and addresses the risks GE crops present to farmers' choices and socioeconomic and environmental health is of the utmost importance to ensuring all sectors of agriculture can thrive. Accordingly, the agencies involved in biotechnology regulation must be comprehensive and coordinated in their efforts, and any non-regulatory actions must complement, and not supplant, regulatory requirements and oversight.

There are a number of non-regulatory or policy approaches that can complement a more rigorous framework for GE regulation.

1. Increasing funding for public sector, non-GE breeding and research efforts to increase biodiversity and resiliency within our agricultural system.

⁸ See Lessons Learned and Revisions Under Consideration for APHIS' Biotechnology Framework, *available at* <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/LessonsLearned10-2007.pdf>

2. There is also a need to educate all agricultural sectors on the risks surrounding biotechnology products and the actions required to continue on a path towards coexistence. The new regulatory authority should mandate contamination prevention and ensure that benefits exceed the risks presented by these new biotechnology products. We raised this issue in our comments on the “coexistence” docket, and believe they are equally relevant here:⁹

We are supportive of the reestablishment of the National Genetic Resources Advisory Council (NGRAC) and its charge to develop a plan for how USDA should work with industry and other stakeholders to evaluate the pool of commercially available non-GE and organic seed varieties and identify market needs for producers serving GE-sensitive markets.

In addition, USDA should commit to increasing departmental resource prioritization to ensure more organic, non-GE, and public cultivar development more generally. NSAC has long advocated for increased federal support for public plant and animal breeding programs in order to reverse the dangerous trends of diminishing numbers of public plant breeders, loss of biodiversity, and the narrowing of crop and livestock genetic resources. Reprioritizing USDA resources to support this type of research is critical to ensure a diverse stock of plant and animal genetics in order to meet future challenges related to food security and resiliency to the impacts of a changing climate.

We also strongly support independent risk assessment of current and proposed biotech crops for economic and environmental harms through the Biotechnology Risk Assessment Grant (BRAG) program.

3. USDA should level the playing field so that the burden of preventing contamination is not solely placed on organic and other non-GMO operations. Responsibility must be tied to ownership. Those who patent, promote, and profit from GE products should be responsible for preventing contamination and covering damage in cases where prevention fails.

USDA should more fully analyze the specific environmental implications of GE contamination and the implications of managing GE crops, including the increased risk of pesticide drift or development of pest resistances. For example, Roundup Ready crops entail a greatly increased use of glyphosate, which could potentially increase risk of herbicide drift as well as the documented evolution of weeds resistant to glyphosate. While the spread of glyphosate-resistant weeds onto organic farms may have little impact (since USDA certified organic does not allow this herbicide), other non-GE identity preserved producers who rely on judicious use of glyphosate as part of their management systems may be forced to switch to older, more toxic herbicides.

Recommendation: USDA should continue to pursue non-regulatory actions, such as research and education, but these actions should be complementary to, and should not supplant, a robust regulatory framework. We have included our comments to the coexistence docket, which provide more detail on what such a robust regulatory framework should look like as an appendix to these comments.

⁹ See the attached Appendix for our full comments to the coexistence dockets in both 2014 and 2015.

CONCLUSION

In closing, we believe that the current regulatory process and authority given to APHIS under the Plant Protection Act is severely lacking and actions must be taken to protect the viability and vitality of farmers and the environment from the impacts that can result from poorly- or under-regulated agricultural biotechnology. The various agencies involved in biotechnology regulation must be comprehensive and coordinated in their efforts, and any non-regulatory actions must serve as complementary, and not supplant, regulatory action in order to most effectively protect all stakeholders.

NSAC and the farm, food, and rural organizations we represent wish to remain engaged in the conversation as APHIS continues this process. We thank you for giving serious consideration to our recommendations, and we look forward to working with you to establish a transparent and robust regulatory framework for biotechnology that allows the diverse sectors of American agriculture to thrive.



October 13, 2015

Regulatory Analysis and Development
Animal Plant Health Inspection Service
United States Department of Agriculture
4700 River Road Unit 118
Riverdale, MD 20737-1236

Docket No. APHIS-2015-0048

Submitted electronically via www.regulations.gov

RE: NSAC Comments on the Petition for Determination of Nonregulated Status: Monsanto Company; Maize Genetically Engineered for Resistance to Dicamba and Glufosinate

On behalf of the represented member organizations of the National Sustainable Agriculture Coalition (NSAC),¹ we submit the following comments on the U.S. Department of Agriculture Animal and Plant Health Inspection Service's (APHIS) request for comment on a petition by Monsanto requesting nonregulated status for a variety of maize (MON 87419), which has been genetically engineered for resistance to the herbicides dicamba and glufosinate. APHIS has made the petition available for public review, and is specifically requesting comments to help the agency "identify potential issues and impacts that APHIS should be considering" in evaluating the petition.

NSAC is a grassroots alliance that advocates for federal policy reform that supports the long-term social, economic, and environmental sustainability of agriculture, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainability. These include certified organic, sustainable, non-genetically engineered, and farm identity-preserved products, systems, and supply

¹ Agriculture and Land Based Training Association, Salina, CA; Alternative Energy Resources Organization, Helena, MT; California Certified Organic Farmers, Santa Cruz, CA; California FarmLink, Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture), Hereford, TX; Catholic Rural Life, Des Moines, IA; Center for Rural Affairs, Lyons, NE; Clagett Farm/Chesapeake Bay Foundation, Upper Marlboro, MD; Community Alliance with Family Farmers, Davis, CA; Dakota Rural Action, Brookings, SD; Delta Land and Community, Almyra, AR; Ecological Farming Association, Soquel, CA; Farmer-Veteran Coalition, Davis, CA; Flats Mentor Farm, Lancaster, PA; Florida Organic Growers, Gainesville, FL; GrassWorks, New Holstein, WI; Hmong National Development, St. Paul, MN; Illinois Stewardship Alliance, Springfield, IL; Institute for Agriculture and Trade Policy, Minneapolis, MN; Interfaith Sustainable Food Collaborative, Sebastopol, CA; Iowa Natural Heritage Foundation, Des Moines, IA; Izaak Walton League of America, St. Paul, MN; Kansas Rural Center, Whiting, KS; Kerr Center for Sustainable Agriculture, Poteau, OK; Land Stewardship Project, Minneapolis, MN; MAFO, St. Cloud, MN; Michael Fields Agricultural Institute, East Troy, WI; Michigan Integrated Farm and Food Systems, East Lansing, MI; Michigan Organic Food and Farm Alliance, Lansing, MI; Midwest Organic and Sustainable Education Service, Spring Valley, WI; National Center for Appropriate Technology, Butte, MT; Nebraska Sustainable Agriculture Society, Ceresco, NE; Northeast Organic Dairy Producers Alliance, Deerfield, MA; Northern Plains Sustainable Agriculture Society, LaMoure, ND; Northwest Center for Alternatives to Pesticides, Ohio Ecological Food and Farm Association, Oregon Tilth, Eugene, OR; Organic Farming Research Foundation, Santa Cruz, CA; Rural Advancement Foundation International – USA, Pittsboro, NC; Union of Concerned Scientists Food and Environment Program, Cambridge, MA; Virginia Association for Biological Farming, Lexington, VA; Wild Farm Alliance, Watsonville, CA. The Pennsylvania Association for Sustainable Agriculture – a participating NSAC member – also contributed significantly to these comments.

chains that are impacted by the regulation of genetically engineered (GE) organisms, or lack thereof. Many of the farmers that NSAC works with and represents choose to grow only non-GE crop varieties because the markets they serve demand GE-free products; because they have concerns about potential adverse health, environmental, or agronomic impacts of GE crop technologies; or because they are USDA certified organic and not allowed to grow GE crops. These producers sustain substantial economic losses when their products contain unintended GE material at levels exceeding market or organic certifier specifications.

In addition, exposure of organic or non-GE fields to GE pollen, pesticides, and herbicides from neighboring farms utilizing GE crop technology packages can lead to adverse ecological and agronomic consequences for the non-GE producer, as well as tensions among farmers. Thus, the outcomes of biotechnology regulation decisions directly impact the economic, environmental, and social sustainability of our nation's agriculture and rural communities, and are therefore of great concern for NSAC.

NSAC has submitted comments to USDA's requests for comment on the issue of agricultural coexistence (in March 2014 and April 2015), as well as the recent request for comments on biotechnology regulations more broadly (June 2015), in response to the agency's decision to withdraw the 2008 proposed rule regarding biotechnology regulations. We appreciate the opportunity to submit comments on this petition, and believe these comments and APHIS' decision on this petition should be considered broadly within the context of USDA's current efforts to understand the issues surrounding current biotechnology regulation, and the need to provide a stronger regulatory framework to ensure all American farmers can thrive.

Our comments address these broader, foundational elements of the biotechnology regulatory framework, as well as issues specific to the petition APHIS is considering. We appreciate your consideration of our views.

Sincerely,



Sophia Kruszewski
Policy Specialist



Ferd Hoefner
Policy Director

I. GENERAL COMMENTS ON BIOTECHNOLOGY REGULATORY OVERSIGHT

This petition must be considered within the broader context of USDA's current rethinking of its regulatory structure. NSAC strongly believes that USDA must establish a robust regulatory framework to oversee the biotechnology approval process. USDA has solicited information from stakeholders recently on this issue through multiple venues, including the decision to withdraw the 2008 GE proposed rule (February 2015), the recent "coexistence" docket (March 2014), and the recent coexistence workshops (April 2015). Clearly, USDA is evaluating its approach to biotechnology regulation, and - given this period of reconsideration - it is prudent for the agency to wait until more certainty has been established regarding the direction the agency will be taking - informed by stakeholder input and a careful and complete consideration of the risks and benefits posed by GE crop technology packages - prior to fully deregulating any new GE crop varieties.

As NSAC has stated to APHIS in the past, USDA must develop a robust regulatory framework for biotechnology. To do so, USDA must:

- Develop a regulatory process that is transparent and informed by independent science;
- Include farmers and other stakeholders throughout the regulatory and review process;
- Build into the process the authority to take into consideration the social, environmental, and economic risks that each new biotechnology product and process pose;
- Implement a rigorous post-commercialization monitoring system of biotechnology products that informs future regulatory decisions;
- Develop regulations that improve oversight and tracking on experimental field trials of biotechnology products;
- Require implementation of contamination prevention practices for GE crop producers and users to safeguard organic and non-GE producers;
- Create robust compensation mechanisms for farmers affected by GE contamination resulting in harm, including but not limited to economic losses; and
- Support non-regulatory actions that bolster research and education for non-GE seed and crop production.

With these considerations in mind, NSAC offers the following recommendations and responses to APHIS's questions regarding the petition to grant nonregulated status to MON 87419.

II. BIOLOGICAL, CULTURAL, AND ECOLOGICAL CONCERNS

We commend APHIS for requesting comments on potential environmental and interrelated economic issues and impacts that APHIS should consider in evaluating the petition. In particular, the request for comments on cultural concerns - as well as biological and ecological issues - demonstrates a sensitivity to the concerns that many public interest, including sustainable agriculture and conservation organizations, have been raising for some time on this issue. We strongly support the consideration of such concerns in APHIS' determination of whether to grant nonregulated status to a biotech variety, because it recognizes the broader socio-economic context within which these decisions are made. It is our fervent hope that this request is not merely to appease a certain segment of stakeholders, and that these concerns will be considered as seriously as any others.

USDA's latest Organic Production Survey documented that from 2011-2014, 92 organic operations reported total losses over \$6.1 million in crop losses from GE contamination, equaling about \$66,000 per farm affected.² That is a substantial increase from 13 farms with average losses of about \$6,000 from 2006-2010.³ The inability to keep GE traits contained and the lack of structure in place to assign liability has led to a culture whereby the non-GE producer must bear the costs associated with GE contamination, relieving the industry of any incentive to improve the technology or its management to avoid this outcome. This is an unfair and untenable system, and should be considered in evaluating the deregulation of new GE varieties.

We also believe that reverting to old chemicals and mixing more and more chemicals together to combat problems resulting from the overuse of chemicals – and yet considering this “progress” – is a cultural concern. Technology should be helping farmers move forward, away from outdated practices that merely stack more and different herbicides in an effort to “protect the technology.”⁴

The steady deregulation of herbicide tolerant crops is also leading us down a path that commits our food system to low-diversity, highly homogenized cropping systems. The ongoing crises with glyphosate-resistant weeds has been a valuable opportunity to reinvigorate investment in diversified cropping systems and integrated weed management practices that have multiple benefits for soil health, environmental quality, and a healthier food supply.

In fact, the USDA has itself recently supplied good evidence that herbicide resistant crops are a significant obstacle to the development of more diversified and sustainable agriculture systems. In a 2013 ERS report, MacDonald et al. show that by reducing the time and labor costs of weed management for well-capitalized farms, glyphosate-resistant crops were a key factor in the latest surge of farm consolidation and increasing farm size that has occurred over recent decades.⁵ This process deprives rural areas of a skilled workforce, and very large farms without skilled labor resources can only consider very simple and time efficient approaches to weed management. Thus, when an outbreak of herbicide-resistant weeds occurs, large farmers simply do not have the time, labor, or management ability to integrate cover crops, inter-row cultivation, or perennial forages for weed control. Instead, they look anxiously to the commercialization of a new herbicide-resistance trait/herbicide package as a short-term solution.

In their Environmental Impact Statement review of Dow AgroSciences “Enlist” corn and soybeans, USDA acknowledged this phenomenon when they wrote that as a result of the failure of glyphosate:

Cover cropping and crop rotation, both of which have shown promise in reducing weed pressure, may increase under the No Action Alternative . . . Crop rotation also may become

² See 2014 NASS Organic Production Survey, Table 19

http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Organics/organics_1_019_019.pdf

³ *Id.*

⁴ See the recent article in the Delta Farm Press by Bob Scott of the University of Arkansas

<http://deltafarmpress.com/soybeans/libertylink-acres-increase-protect-technology?page=1> (September 23, 2015).

⁵ Macdonald, J.M., Korb, P., Hoppe, R.A., 2013. Farm Size and the Organization of U.S. Crop Farming. USDA Economic Research Service, Washington D.C.

more diverse to leverage differences in crop ecology to shift the dominant weed species and thereby lessen the size of the resistant weed seed bank.⁶

Clearly, APHIS is aware that not deregulating a new herbicide tolerant variety would result in more sustainable practices. If USDA has a mandate to evaluate the full social, economic, cultural, and environmental impacts of new biotechnologies, these biotechnologies therefore must be evaluated in light of impacts on the viability of family-scale farms. New HR traits will likely have the effect of accelerating farm consolidation and the further loss of family-scale farms with skilled managers with the motivation and ability to build diversified, sustainable cropping systems.

These cultural concerns provide important context for APHIS' decision, and should help determine whether any conditions should be established prior to the release of this GE variety - or any others - into commerce, in addition to a science-based risk assessment of the full technology package.

III. THE PETITION SIGNIFICANTLY UNDERESTIMATES THE IMPACTS OF HERBICIDES

It is crucial that the biotechnology regulatory system addresses the full technology packages that comprise new products (i.e. Enlist™ Corn and Soybeans and Enlist Duo™ herbicide), as the unintended effects may not be as powerful in isolation. This has been well documented with the case of Roundup Ready® soybeans, cotton, and corn and the widespread reliance on Roundup® resulting in weed resistance.⁷ Not only has this created herbicide-resistant weeds that infest fields, reduce crop productivity, and cause farmers millions of dollars in losses, it has continued the pesticide treadmill by creating markets for new GE technologies that rely on applications of more toxic herbicides and mixtures of herbicides.

As we discussed in our June 2015 comments, APHIS has the legal authority to regulate GE crops on the basis of whether they pose a plant pest risk, as well as broad noxious weed authority that would allow USDA to regulate for the indirect impacts of herbicide resistant weeds. Therefore, as part of this responsibility, APHIS can and should consider the associated implications of changes in herbicide use that are part of the same technology package as the GE variety seeking deregulation. APHIS' decision to deregulate a new variety typically occurs before EPA can review the associated changes to the herbicide label. This dual-agency review process should be coordinated so that potential plant pest risks are evaluated before changes to the chemical label are completed. The current uncoordinated process creates significant industry pressure to also approve the label without adequate review.

As we discuss below – and the petition acknowledges - herbicide use patterns fostered by these GE traits will almost certainly create new herbicide resistant weed varieties. That is, unless herbicide labels are regulated in close coordination with the deregulation of the trait. We strongly urge APHIS and EPA to coordinate their evaluations of the environmental, social, ecological, and economic impacts of the full crop technology package prior to deregulation to avoid this outcome.

⁶ United States Department of Agriculture-Animal and Plant Health Inspection Service. 2014. Dow AgroSciences petitions (09-233-01p, 09-349-01p, and 11-234-01p) for determinations of Nonregulated status for 2,4-D-resistant corn and soybean varieties, Final Environmental Impact Statement.

⁷ Owen, Micheal DK, and Ian A. Zelaya. "Herbicide resistant crops and weed resistance to herbicides." *Pest Management Science* 61.3 (2005): 301-311.

Without a coordinated and thorough evaluation of the full technology package, and a meaningful analysis of impacts, adding yet another new crop/herbicide package will continue adding to the existing harmful effects on herbicides on ecological systems, human health, and farmers' livelihoods through herbicide drift and nontarget crop losses; the widespread increase in herbicide resistant weeds; and environmental and public health impacts. Yet, the petition either overlooks or underestimates these impacts.

A. Herbicide Drift

Dicamba is a notoriously volatile herbicide with great drift potential⁸; yet the petition cursorily dismisses these concerns by claiming that there are no expected changes in farmers' management decisions that will result from this new GE variety, and because both dicamba and glufosinate are already allowed for use, there is no cause for concern. Yet, elsewhere in the petition, Monsanto notes that they have also applied to EPA for approval to at least double the application rates of dicamba.⁹ How can Monsanto justify the claim that management decisions will not change, if they are also expecting that the rates of dicamba application could double? This is a troubling inconsistency, and cannot justify the claims that there will be no changes in the amount of herbicides applied.

Moreover, even though chemical companies have developed newer formulations of the herbicide to combat some of the volatility concerns, lower cost dicamba is still readily available, and growers are likely to turn to those stocks of existing dicamba as a way to save money.¹⁰ In fact, some experts are so concerned about the resultant harm from growers applying older formulations of dicamba, that they "strongly recommend that the U.S. Environmental Protection Agency restrict, by label, the use of higher volatile formulations on any Roundup Ready® crops and that record-keeping requirements (similar to those in place for restricted use (RUP) products) makes sense to help in any investigation of off-target movement."¹¹ The petition does not acknowledge this issue. Clearly, more analysis is required on the impacts of increased application of dicamba, and the petition's claim that management decisions will be unaffected cannot and should not justify a deregulation decision.

Particle drift will likely be an even more significant problem. Some crops, especially tomatoes and soybeans, are particularly sensitive to low-dose exposures of dicamba, and the potential for yield loss is quite real. Non-target crop loss is especially likely in regions where horticultural crops are grown in close proximity to row crops, and could impact areas where local and regional markets are developing and growing.

For vegetable farmers, an even bigger problem is that EPA does not have approved dicamba tolerances for human exposure via ingestion for many horticultural crops. This means that legal tolerance is essentially zero, such that if a fruiting tomato plant is exposed to dicamba drift, even at a dose too low to cause any observable damage or yield loss to the plant, it is illegal for the farmer to market the crop for human consumption. With a high value crop like tomatoes, economic losses under this situation can be very severe. Given these potential economic losses, we believe it is

⁸ See Purdue Extension, 2,4-D- and Dicamba-tolerant Crops – Some Facts to Consider (Nov. 2012), *available at* <https://www.extension.purdue.edu/extmedia/id/id-453-w.pdf> ("Purdue Extension").

⁹ Petition from the Monsanto Company, APHIS-2015-0048-0002 at 340 ("Petition").

¹⁰ Purdue Extension at 5.

¹¹ *Id.* at 7.

irresponsible for USDA to consider deregulating MON 87419 before EPA has approved dicamba tolerances for horticultural crops.

B. Herbicide Resistant Weeds

The petition also makes light of the growing epidemic of herbicide resistant weeds. It notes that there are already four species with known resistant biotypes to dicamba in the U.S. and Canada, and two species resistant to glufosinate (one of which is in the U.S.).¹² The petition fully acknowledges that “like other herbicides, the use of dicamba may lead to the development of dicamba-resistant weed species.”¹³ Yet, it still concludes that these concerns regarding herbicide resistance are insignificant, focusing on grower management to combat any concerns with herbicide resistance. Given the fact that glyphosate-resistance has reached “epidemic” levels, this concern cannot be so summarily dismissed.¹⁴

The petition also downplays a rather startling suggestion of cross-resistance – that a weed species that can be resistant to glyphosate could also develop resistance to glufosinate.¹⁵ If the point of this technology is to slow resistance to glyphosate in weeds, then the implication that glufosinate could actually lead to resistance in glyphosate-resistant weeds must be further studied before this variety’s nonregulated status can be justified.

C. Public and Environmental Health

Both new and older science provides evidence for the harm caused by these chemicals, yet the petition overlooks potential public and environmental health impacts in its assessment.

In one particular example, the petition notes that one of the reaction products when MON 87419 is treated with dicamba is formaldehyde, yet concludes that – because formaldehyde is commonly produced in nature, and it is produced at “sufficiently” low levels in the MON 87419 cropping system – it does not raise a plant pest risk.

However, the petition does not consider the cumulative impact of widespread adoption of GE corn varieties and how that may impact the concentration of formaldehyde, and what corresponding effects on the surrounding ecology may occur as a result. While a single plant may produce a minimal quantity of formaldehyde, the impact may become significant when compounded across millions of planted acres.¹⁶ APHIS should consider these cumulative impacts in a complete environmental impact statement prior to making any decisions about deregulating MON 87419.

Both older and new science provides evidence for the public health and environmental harm caused by these chemicals. The World Health Organization’s International Agency for Research on Cancer recently classified glyphosate as “probably carcinogenic to humans,” based on positive studies

¹² See Petition at 339.

¹³ *Id.* at 338.

¹⁴ See Evans, JA et al, “Managing the Evolution of Herbicide Resistance” *Pest Management Science* (May 11, 2015) <http://onlinelibrary.wiley.com/doi/10.1002/ps.4009/pdf>. See also Mortensen, DA et al, “Navigating a Critical Juncture for Sustainable Weed Management,” *BioScience* 62:1, p75-84 (Jan 2012).

¹⁵ See Petition at 339.

¹⁶ See National Agricultural Statistics Service, Corn Acres: United States, *available at* http://www.nass.usda.gov/Charts_and_Maps/Field_Crops/cornac.asp (last accessed Oct. 9, 2015).

concluding there was “sufficient evidence of carcinogenicity in experimental animals.”¹⁷ The New England Journal of Medicine recently published an article suggesting that GE foods and the herbicides applied to them may pose hazards to human health that have not been sufficiently examined in previous assessments.¹⁸ Studies have strongly linked glyphosate use to declining habitat for monarch butterflies,¹⁹ and both USDA²⁰ and EPA²¹ have taken steps to support monarch habitat, yet the petition does not acknowledge the relationship between increased herbicide use and public or environmental health concerns. Changes in crop resistance and herbicide labels to allow postemergence applications of dicamba and glufosinate will only accelerate the loss of milkweed and monarch caterpillar habitat. Failure to consider this fact puts USDA and EPA commitments – as well as the taxpayer dollars that have supported them – at risk.

IV. APHIS SHOULD CONDUCT A FULL ENVIRONMENTAL IMPACT ANALYSIS

In light of the comments provided above, and considering the cursory discussion of environmental impacts contained within the petition itself, APHIS must undertake a full environmental impact analysis under NEPA, and release a draft environmental impact statement for public review, before making any decision regarding the status of MON 87419.

NEPA requires federal agencies to take a hard look at the impacts of any federal action that could have a significant impact on the environment. At the very least, APHIS must consider the likelihood that this corn variety will increase the use of dicamba (particularly given Monsanto’s pending request with EPA to double the application rate); that farmers may rely on cheaper, more volatile dicamba formulations than the petition assumes, and the related impacts on nontarget species (whether pollinator habitat or neighboring specialty crops) due to herbicide drift; the cumulative impacts of increased concentrations of formaldehyde on environmental health; and the possibility of cross-resistance between glufosinate and glyphosate resistant weed species. This analysis must be in the form of a robust environmental impact statement; an environmental assessment that relies on the petition’s conclusory statements cannot suffice.

V. REGIONAL CONCERNS

As discussed above, some crops are particularly sensitive to low-dose exposures of dicamba and the potential for yield loss is quite real. Non-target crop loss is especially likely in regions where horticultural crops are grown in close proximity to row crops (such as southeastern Pennsylvania), but in other regions as well. APHIS is therefore right to request comments on regional concerns, and should analyze the impacts with particular focus on regions where horticultural crops are grown in close proximity to row crops, as well as the implications for states and regions where row crop

¹⁷ See World Health Organization International Agency for Research on Cancer. “IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides (Mar. 20, 2015), available at <http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf>.

¹⁸ See Landrigan, PJ and C. Benbrook. N Engl J Med 2015; 373:693-695 (Aug. 20, 2015), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1505660>.

¹⁹ See Pleasants, JM and KS Oberhauser. “Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population.” *Insect Conservation and Diversity* (2012), available at http://www.mlmp.org/results/findings/pleasants_and_oberhauser_2012_milkweed_loss_in_ag_fields.pdf

²⁰ See e.g. <http://www.nrcs.usda.gov/wps/portal/nrcs/detail/plantmaterials/home/?cid=STELPRDB1256245>

²¹ See e.g. http://www.epa.gov/oppead1/cb/csb_page/updates/2015/protecting-monarch-butterfly.html

growers are diversifying into horticultural crops, and/or where local and regional markets are developing and growing.

VI. CONCLUSION

We appreciate that APHIS is requesting input from stakeholders on specific issues to consider while the agency reviews the petition for deregulating MON 87419. In particular, and given USDA's recent efforts to engage stakeholders in discussions surrounding the biotechnology regulatory process, it is imperative that the decision on this petition be considered within the full context of social, cultural, economic, environmental, and public health concerns that are implicated by the use of biotechnology. Thank you for considering our views.



May 11, 2015

Regulatory Analysis and Development
USDA, PPD, APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Submitted electronically via www.regulations.gov

Re: Public Comments on Docket No. APHIS-2013-0047

On behalf of the represented member organizations¹ of the National Sustainable Agriculture Coalition (NSAC), we submit the following comments on the U.S. Department of Agriculture's (USDA) request for public input on enhancing agricultural coexistence (Docket No. APHIS-2013-0047).

NSAC is a grassroots alliance that advocates for federal policy reform that supports the long-term social, economic, and environmental sustainability of agriculture, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainability. These include certified organic, sustainable, non-genetically engineered (GE), and identity-preserved systems and supply chains that are impacted by a coexistence framework.

Many of the farmers that NSAC works with and represents choose to grow only non-GE crop varieties because the markets they serve demand GE-free products; because they have concerns about potential adverse health, environmental, or agronomic impacts of GE crop technologies; or because they are USDA certified organic. These producers sustain substantial economic losses

¹ Agriculture and Land-Based Training Association - Salinas, CA; Alternative Energy Resources Organization - Helena, MT; California Certified Organic Farmers - Santa Cruz, CA; California FarmLink - Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture) - Hereford, TX; Center for Rural Affairs - Lyons, NE; Clagett Farm/Chesapeake Bay Foundation - Upper Marlboro, MD; Community Alliance with Family Farmers - Davis, CA; Dakota Rural Action - Brookings, SD; Delta Land and Community, Inc. - Almyra, AR; Ecological Farming Association - Soquel, CA; Farmer-Veteran Coalition - Davis, CA; Fay-Penn Economic Development Council - Lemont Furnace, PA; Flats Mentor Farm - Lancaster, MA; Florida Organic Growers - Gainesville, FL; GrassWorks - New Holstein, WI; Hmong National Development, Inc. - St. Paul, MN and Washington, DC; Illinois Stewardship Alliance - Springfield, IL; Institute for Agriculture and Trade Policy - Minneapolis, MN; Iowa Natural Heritage Foundation - Des Moines, IA; Izaak Walton League of America - St. Paul, MN/Gaithersburg, MD; Kansas Rural Center - Whiting, KS; The Kerr Center for Sustainable Agriculture - Poteau, OK; Land Stewardship Project - Minneapolis, MN; Michael Fields Agricultural Institute - East Troy, WI; Michigan Food & Farming Systems (MIFFS) - East Lansing, MI; Michigan Organic Food and Farm Alliance - Lansing, MI; Midwest Organic and Sustainable Education Service - Spring Valley, WI; National Catholic Rural Life Conference - Des Moines, IA; The National Center for Appropriate Technology - Butte, MT; Nebraska Sustainable Agriculture Society - Ceresco, NE; Northeast Organic Dairy Producers Alliance - Deerfield, MA; Northern Plains Sustainable Agriculture Society - LaMoure, ND; Northwest Center for Alternatives to Pesticides - Eugene, OR; Ohio Ecological Food & Farm Association - Columbus, OH; Organic Farming Research Foundation - Santa Cruz, CA; Rural Advancement Foundation International - USA - Pittsboro, NC; Union of Concerned Scientists Food and Environment Program - Cambridge, MA; Virginia Association for Biological Farming - Lexington, VA; Wild Farm Alliance - Watsonville, CA.

when their products contain unintended GE material at levels exceeding market or organic certifier specifications. In addition, exposure of organic or non-GE fields to GE pollen, pesticides, and herbicides from neighboring farms utilizing GE crop technology packages can lead to adverse ecological and agronomic consequences for the non-GE producer, as well as tensions among farmers. Thus, the challenges of coexistence among contrasting farming systems directly impact the economic, environmental, and social sustainability of our nation's agriculture and rural communities, and are therefore of great concern for NSAC.

To our disappointment, NSAC was not invited to attend the USDA Stakeholder Workshop held in Raleigh, NC on March 12 and 13th. Therefore our comments here are formed based on feedback we received from some of our members who were in attendance, and from our review of the documents that followed the workshop. Particularly, the documents detailing USDA's actions already underway and new or proposed actions related to the topic, which we address below.

Our comments focus on the specific questions raised in the Federal Register notice regarding the stakeholder meeting and next steps in bringing stakeholders together to identify solutions, as well as USDA's proposed and current activities to address this issue.

Sincerely,



Juli Obudzinski, Senior Policy Specialist
National Sustainable Agriculture Coalition



Sophia Kruszewski, Policy Specialist
National Sustainable Agriculture Coalition

I. General Coexistence Comments

In March 2014, NSAC submitted comments to the coexistence docket APHIS-2013-0047, attached as an Appendix below. Our comments today continue to draw from that same foundational premise: that any attempts to discuss or advance notions of “coexistence” across all sectors of agriculture first requires a robust framework to ensure that the diverse sectors of American agriculture can thrive. This framework must include:

- Sound, science-based information that empowers farmers to make good decisions regarding their production systems and to implement stewardship practices that enhance coexistence;
- Effective measures to prevent contamination of organic and other non-GE farm products and crop seed with unintended GE content;
- A fair and workable system of compensation in the event that GE contamination leads to economic losses for organic and non-GE producers; and
- Mechanisms for preventing and responding to problems associated with drift of agricultural chemicals associated with GE crops onto neighboring farms, including concerns related to damage to crops and natural resources such as pollinator and beneficial insect habitat.

A viable coexistence framework must also include the following critical aspects:

- The need to use existing authority to update and revise the existing regulatory framework on GE crop technologies;
- The need to establish a strong contamination prevention framework;
- The need for a fair compensation mechanism when contamination occurs; and
- The need for addressing pressing research needs related to coexistence and the use of GE products.

We note that some of these aspects were present in the coexistence stakeholder meeting, but not all. For example, from what we have seen and heard, discussions did not adequately address compensation for loss; mechanisms to prevent and respond to problems with chemical drift (in addition to genetic drift); and the need to update agency authority and revise the existing regulatory framework on GE crop technologies.

We appreciate the Administration moving forward with convening a stakeholder meeting on the topic of coexistence. However, we are troubled by the shortage of stakeholder representation from the sustainable agriculture community, including organic and non-GE representation.

USDA needs broad feedback on its activities related to coexistence, and hence this comment period is particularly important. We hope that it leads to constructive discussion at USDA and in future stakeholder and advisory committee meetings.

NSAC is generally supportive of many of the current and proposed new actions by the Department to take some critical, but practical next steps, such as a dedicated focus on our national germplasm collection, research on economic harm from GE contamination on non-GE markets, and the development of a baseline for the availability of suitable improved cultivars for organic and non GE markets.

However, we still believe that these recommendations and proposed activities fall short on proposing a long-term solution to this serious issue facing our nation's agricultural sector. We therefore submit the following recommendations on the current activities already underway or completed by the Department.

II. Comments on USDA's Activities Already Underway or Completed

1. Establish a Fair Compensation Proposal and Level Playing Field

While we are supportive of strengthening crop insurance options for organic and diversified farming systems -- including the development of additional organic price elections and the refinement and promotion of the whole-farm revenue protection (WFRP) policy -- we continue to oppose the use of crop insurance as the mechanism to compensate producers who suffer economic losses due to GMO contamination. Crop insurance is not a workable model for compensation, as outlined in our previous comments (see Appendix A). We would instead urge USDA to establish a fair compensation proposal, in which the patent holder is responsible for segregation and traceability from seed to plate and is held responsible for the economic and market harm their products cause.

Additionally, USDA should level the playing field so that the burden of preventing contamination is not solely placed on organic and other non-GMO operations. Responsibility must be tied to ownership. Those who patent, promote, and profit from GE products should be responsible for preventing contamination and covering damage in cases where prevention fails.

2. Increase Seed Availability for Organic and Diversified Producers

We support the development of the Organic Seed Finder to better understand the availability and accessibility of organic seeds throughout the county, and identify gaps in seed diversity, quality, or appropriateness for specific production systems. We are also supportive of the reestablishment of the National Genetic Resources Advisory Council (NGRAC) and its charge to develop a plan for how USDA should work with industry and other stakeholders to evaluate the pool of commercially available non-GE and organic seed varieties and identify market needs for producers serving GE-sensitive markets.

In addition, USDA should commit to increasing departmental resource prioritization to ensure more organic, non-GE, and public cultivar development more generally. NSAC has long advocated for increased federal support for public plant and animal breeding programs in order to reverse the dangerous trends of diminishing numbers of public plant breeders, loss of biodiversity, and the narrowing of crop and livestock genetic resources. Reprioritizing USDA resources to support this type of research is critical to ensure a diverse stock of plant and animal genetics in order to meet future challenges related to food security and resiliency to the impacts of a changing climate.

We also strongly support independent risk assessment of current and proposed biotech crops for economic and environmental harms through the Biotechnology Risk Assessment Grant (BRAG) program.

III. Comments on USDA's Planned or New Activities

In addition to the activities that USDA is currently pursuing, we also recommend that stronger steps be taken in the future to reach a viable and long-term strategy to ensure that farmers of all kinds are able to pursue a diversity of production methods without fear of economic loss from contamination. We therefore propose the following recommendations on future activities of the Department:

1. Improved Data Collection and Analysis on Environmental and Economic Implications

We are supportive of the proposed new initiatives to better understand the economic implications of coexistence, including the Economic Research Service report examining these issues and the collection of data on economic losses faced by organic farmers related to GE contamination.

However, USDA should more fully analyze the specific environmental implications of GE contamination and the implications of managing GE crops, including the increased risk of pesticide drift or development of pest resistances. For example, Roundup Ready crops entail a greatly increased use of glyphosate, which could potentially increase risk of herbicide drift as well as the documented evolution of weeds resistant to glyphosate. While the spread of glyphosate-resistant weeds onto organic farms may have little impact (since USDA certified organic does not allow this herbicide), other non-GE identity preserved producers who rely on judicious use of glyphosate as part of their management systems may be forced to switch to older, more toxic herbicides.

These economic and environmental impacts are of critical importance to the ideas underpinning “coexistence” – how one system of agriculture can directly and indirectly impact the viability of the other.

2. USDA Outreach and Education Strategy

We have previously commented on the proposed USDA Coexistence Education and Outreach Strategy, and maintain that while this strategy may prove useful, in order to be effective it must be based on sound scientific evidence, and communicate prevention strategies that include actions and accountability on behalf of technology providers and users, and not solely the producer who suffers losses due to contamination. For example, USDA should work with seed companies in order to educate farmers at the point of sale on best production practices to avoid contamination and drift.

In addition, USDA cannot rely solely on communication and outreach to farmers – this isn't enough to prevent contamination. USDA proposes to increase education, collaboration, and outreach on the topic of coexistence. Communication between neighboring farmers is a good thing, but communication alone is not a viable solution to preventing and dealing with contamination. The last thing we need is to pit farmers against each other when communication and prevention fails. To avoid this result, we again emphasize the need for a comprehensive, meaningful coexistence framework that includes, as just one example, the much-needed mechanism to provide fair compensation for contamination-related loss.

3. Update GMO Regulations and Establish Mandatory Measures that Prevent GE Contamination

Finally, as USDA begins the process of updating regulations that govern its oversight of GE crops, we urge the agency to develop stronger GMO regulations that ensure shared responsibility for contamination prevention. Updated regulations should mandate prevention practices on the part of both owners and users of GE crops, establish a fair compensation mechanism for those harmed by contamination events, and address the broader economic and environmental issues related to GMOs.

USDA should establish mandatory measures that prevent GE contamination. Voluntary solutions to contamination are insufficient – it's what we have now and it isn't working. USDA must mandate best practices to prevent GE contamination by farmers who use GE seed and require concrete contamination prevention measures on those farms to supplement measures already used by organic and other non-GMO producers. It costs more money to clean up contamination than it does to prevent it, and USDA should be leading the way in support of this common-sense maxim.

V. Conclusion

In closing, while we support the efforts currently underway or proposed by the Administration as it relates to coexistence, we believe that, in sum, these activities do not provide the necessary comprehensive framework to protect all farmers from economic losses due to unintended presence of GE material in farm products. The proposed measures fail to include robust regulatory improvements for preventing contamination to begin with and placing responsibility where it belongs: with the patent holders.

NSAC and the farm, food, and rural organizations we represent wish to remain engaged in the conversation as the Department works to find a way forward on this pressing issue. We thank you for giving serious consideration to our recommendations, and we look forward to working with you to establish a workable and robust coexistence framework that allows for the diverse sectors of American agriculture to thrive.