National Sustainable Agriculture Coalition

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.

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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 AgroScienes "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

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[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 Unversity 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.

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[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 potential[8]; 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

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[8] *See* Purdue Extension, 2,4-D- and Dicamba-tolerant Crops – Some Facs 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

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[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, *avilable 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 USDA[20] and EPA[21] 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

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[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 a* 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/oppfead1/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.