

AMERICAN SEED TRADE ASSOCIATION

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July 16, 2013

Docket No. APHIS-2013-0042
Docket No. APHIS-2013-0043
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: Notice of Intent to Prepare an Environmental Impact Statement for Determination of Nonregulated Status of Herbicide Resistant Corn and Soybeans – Dow AgroSciences LLC;
Notice of Intent to Prepare an Environmental Impact Statement for Determination of Nonregulated Status of Herbicide Resistant Soybeans and Cotton – Monsanto Company;
78 Fed. Reg. 28798 and 28796 (May 16, 2013)

To whom it may concern:

The American Seed Trade Association (“ASTA”) appreciates this opportunity to comment on the above-captioned Notices of Intent to prepare Environmental Impact Statements (“EISs”) under the National Environmental Policy Act (“NEPA”) issued by the Animal and Plant Health Inspection Service (“APHIS”) of the U.S. Department of Agriculture with respect to herbicide-tolerant crops developed by Dow AgroSciences LLC and Monsanto Company, two ASTA members.

Founded in 1883, ASTA’s mission is to enhance the development and movement of quality seed worldwide. ASTA’s diverse membership consists of over 700 companies involved in seed production, distribution, plant breeding and related industries in North America. ASTA represents all varieties of seeds, including grasses, forages, flowers, vegetables, row crops and cereals. Many ASTA members are research-intensive companies engaged in the discovery, development and marketing of seed varieties with enhanced agronomic and end-use quality characteristics.

The Notices of Intent published on May 16 identify two issues that led APHIS to conclude that EISs were required by NEPA – the development of herbicide-resistant weeds (i.e., weed resistance) and increased herbicide use. Both of these issues relate solely to the herbicides, such as 2,4-D and Dicamba, that would be available for use in conjunction with the crops modified to tolerate their application. As such, these issues are subject to the exclusive jurisdiction of the U.S. Environmental Protection Agency (“EPA”) under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) and are decidedly *not* subject to APHIS’s jurisdiction under the Plant Protection Act (“PPA”).

The U.S. government recognized the respective statutory mandates of APHIS and EPA in the Coordinated Framework for Regulation of Biotechnology (“Coordinated Framework”) issued under the auspices of the White House Office of Science and Technology Policy in 1986.¹ The federal courts have also recognized the clear divisions of responsibility established by Congress for different types of agricultural products. Seeds and plants, for example, belong to USDA while herbicides and other pesticides belong to EPA.

¹ 51 Fed. Reg. 23,302 (June 26, 1986).

The day after APHIS published its Notices of Intent, the U.S. Court of Appeals for the Ninth Circuit released a decision that analyzed these regulatory distinctions in a case challenging APHIS's determination of nonregulated status ("deregulation") of another herbicide tolerant crop, Roundup Ready® Alfalfa ("RRA"). *Center for Food Safety v. Vilsack*.² Following APHIS's release of its final EIS for RRA and unconditional deregulation of that crop, plaintiffs filed suit alleging: (i) that RRA is a plant pest under the PPA; (ii) that APHIS violated the Endangered Species Act ("ESA") by failing to consult with the Fish and Wildlife Service ("FWS") on its deregulation decision; and (iii) that APHIS violated NEPA by unconditionally deregulating RRA without considering the option of partial deregulation.

The district court granted summary judgment to APHIS and the industry intervenor-defendants. The district court's decision was appealed by plaintiffs and subsequently affirmed by the Ninth Circuit. The Ninth Circuit upheld APHIS's decision that RRA is not a plant pest and squarely rejected plaintiffs' unfounded theory that so-called "transgenic contamination" and increased herbicide use are plant pest harms under the PPA. The court also noted that the possible adverse economic and environmental effects alleged by plaintiffs "are not the result of plant pest harms as defined under the PPA" and that the alleged environmental harms relate to "the application of herbicides to fields of RRA, not the RRA plant." Citing the Coordinated Framework, FIFRA and Supreme Court precedent,³ the Court concluded that regulating herbicide use was EPA's job under FIFRA. The Ninth Circuit and other federal courts have long recognized that it is EPA's responsibility to assess the potential environmental impacts of pesticide use under the specific environmental standards set forth in FIFRA and, further, that "NEPA does not apply to pesticides registered under FIFRA."⁴

In upholding the positions taken by the Government in the case, the Ninth Circuit held that once APHIS concluded that RRA was not a plant pest, "it no longer had jurisdiction to continue regulating the plant." And citing Supreme Court precedent,⁵ the Court held that "APHIS's lack of jurisdiction over RRA obviated the need for the agency to consult with the FWS under the ESA and to consider alternatives to unconditional deregulation under NEPA" in the EIS that APHIS had already prepared. The Ninth Circuit's decision stated unequivocally that, "[i]f APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, **APHIS must deregulate it** since the agency does not have jurisdiction to regulate organisms that are not plant pests." (emphasis added.)

Other potential environmental effects beyond the presence or absence of a legally defined plant pest risk cannot change APHIS's obligation to issue a deregulation decision, and to the extent APHIS considers it necessary to conduct any additional review under NEPA, that analysis must exclude any further discussion of potential effects associated with the herbicides. That responsibility rests solely with the EPA under FIFRA.

ASTA and its members support a science-based, federal environmental review process for new biotechnology seed products. That process must recognize the distinct products, federal actions, and

² *Center for Food Safety v. Vilsack*, No. 12-15052, 2013 WL 2128324 (9th Cir., May 17, 2013) (petition for rehearing en banc filed July 1, 2013).

³ See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984).

⁴ See, e.g., *Merrell v. Thomas*, 807 F.2d 776, 777-781 (9th Cir. 1986); *Douglas Cnty. V. Babbitt*, 48 F.3d 1495, 1502-03 (9th Cir. 1995).

⁵ See *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 665 (2007).

statutory mandates of the regulatory agencies involved. We are concerned, however, that by basing its decision to prepare EISs on the potential environmental effects of the herbicides rather than the associated herbicide tolerant crops, APHIS has failed to recognize those distinctions. Moreover, the EIS preparation process will unnecessarily delay issuance of determinations of nonregulated status for these crops with no additional benefit to the environment.


America's farmers require the very best available methods to combat weed resistance problems. Weed resistance is a well understood scientific phenomenon that is not unique to biotechnology or any other form of agriculture.⁶ Different herbicides attack weeds by different methods or "modes of action." The delay that will result from preparation of the EISs as proposed by APHIS will deny growers the tools they need to prevent and combat weed resistance and maximize yields through the use of herbicides that have been shown to operate with differing modes of action. The proposed use of these herbicides in conjunction with the associated herbicide tolerant plants also supports the continued use of environmentally sustainable practices such as no-till and low-till farming.

Our farmers will also be at a further disadvantage to corn, soybean and cotton growers in other nations that are now completing their regulatory reviews for biotechnology-derived crops on a far more timely basis than the United States. Any further delay is unacceptable, particularly when APHIS's own regulations require the agency to respond to a petition for determination of nonregulated status within 180 days of the Agency's receipt of the petition.⁷ Moreover, the resulting harm to growers and seed developers is irreparable.

For all of these reasons, we respectfully ask APHIS to reconsider its decision to prepare EISs for the herbicide tolerant crops identified in the Notices of Intent and to act expeditiously to finalize the deregulation process for these crops in keeping with the limited scope of APHIS's authority under the PPA, the Ninth Circuit's recent RRA decision, relevant Supreme Court precedent, the division of responsibility set out in the Coordinated Framework and the APHIS regulations governing deregulation petitions.

We appreciate the opportunity to provide comments on APHIS's recent Notices of Intent and would be pleased to discuss these topics further at your convenience.

Sincerely,



Andrew W. LaVigne
President & CEO

cc: Council on Environmental Quality

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⁶ The resistance of any plant to the effects of an herbicide results, in large part, from repeated exposure of the plant to the herbicide. *See, e.g.*, <http://www.ncga.com/topics/biotechnology/weed-and-insect-resistance-management> (National Corn Growers Association, Weed and Insect Resistance Management); [http://www.hracglobal.com/\(Herbicide Resistance Action Committee\)](http://www.hracglobal.com/(Herbicide%20Resistance%20Action%20Committee)).

⁷ 7 C.F.R. § 340.6(d)(3).