



July 17, 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

To whom it may concern:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the above-captioned Notices of Intent (Notices) to prepare Environmental Impact Statements (EISs) for herbicide tolerant crops under the National Environmental Policy Act (NEPA) issued by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), 78 Fed. Reg. 28,798 and 28,796 (May 16, 2013). BIO respectfully submits that these EISs are not required under the law, are an unnecessary expenditure of scarce government resources, will not advance or assist APHIS's decision-making, and will only delay unnecessarily the availability of these crops that, under APHIS's governing statute and regulations, are strong candidates for determinations of nonregulated status or "deregulation."

BIO is a national trade organization, based in Washington, D.C., representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO represents the overwhelming majority of the biotechnology-derived seed and plant developers in North America and, as such, has a substantial and long-standing interest in federal regulatory policy that impacts the pre-commercialization review and approval process for the valuable agricultural products developed by its members on an ongoing basis.

BIO and the members of its Food and Agriculture Section have a substantial interest in ensuring the integrity of the science-based regulatory process that was developed under the auspices of the White House Office of Science and Technology Policy in 1986, and issued as the U.S. Coordinated Framework for Regulation of Biotechnology (Coordinated Framework).¹ The key statutes over which APHIS, the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) have jurisdiction to regulate products of biotechnology are the same statutes that constitute the legal and scientific foundation of the Coordinated

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

Framework. The three agencies collectively have used their respective authorities to independently review and clear nearly a hundred beneficial products, ensuring in the process that crops enhanced through agricultural biotechnology are as safe to grow and as safe to eat as any other crops.

In developing its implementing biotechnology regulations under the Federal Plant Pest Act and Plant Quarantine Act,² APHIS acknowledged that its oversight of the introduction of genetically engineered (GE) plants and other organisms would be in accordance with NEPA.³ The assessment of potential environmental effects has always been an important element of the federal regulatory process for products of biotechnology, whether for plants and other organisms under NEPA at APHIS or for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) at EPA. The basis for the APHIS Notices, however, was not any potential environmental impacts associated with the plants under review. Rather, the Notices identify two issues for consideration in an EIS - the potential selection of herbicide resistant weeds and increased herbicide use. As discussed in greater detail herein, the law is clear that potential impacts associated with herbicide use are EPA's responsibility under FIFRA and are neither subject to APHIS's jurisdiction under the Plant Protection Act (PPA) nor an appropriate basis for preparation of an EIS for an action proposed under the PPA.

BIO and its members are also concerned that the decision to prepare EISs for the crops identified by APHIS will unnecessarily delay issuance of determinations of nonregulated status, causing significant harm to American farmers and the developers of the crops without any additional environmental benefit. APHIS's regulations require a petition for determination of nonregulated status to either be approved in whole or in part or denied within 180 days of the Agency's receipt of the completed petition.⁴ Yet, the earliest deregulation petition for the subject crops was filed with APHIS nearly four years ago and declared complete shortly thereafter, and none of the pending petitions for which an EIS would be prepared has yet to be resolved. APHIS estimates completing the two EISs in the summer of 2014 at the earliest, nearly five years after the earliest deregulation petition was filed with APHIS and over four years after APHIS's own regulatory deadline.

The delay that will result from preparation of the EISs will deny American farmers the new tools they need to prevent and combat herbicide-resistant weeds and maximize yields. BIO members have submitted applications to EPA that would authorize use of their herbicides on the associated herbicide tolerant crops identified in the APHIS Notices. These herbicides have differing modes of action, enhancing the ability of growers to address weed problems and supporting the continued use of environmentally sustainable practices such as no-till farming.

Delays inherent in the EIS process will also put U.S. corn, soybean and cotton growers at a particular disadvantage in relation to their counterparts in other nations that are now completing their review processes for GE crops on a far more timely basis than the United States. In addition, the developers of these crops will suffer further delay in commercializing and offering valuable new products for sale and other developers of innovative products may reconsider whether to invest in the U.S. market. Because the APHIS Notices failed to provide a satisfactory legal or scientific justification for opting to prepare an EIS for the subject products, developers of future products also lack predictability as to whether APHIS will opt to prepare an EA or an EIS, which significantly affects the deregulation timeline and product development decisions.

² These statutes were consolidated by Congress in 2000 in the Plant Protection Act, 7 U.S.C. § 7701 et seq.

³ 51 Fed. Reg. at 23,359; *see also* 7 C.F.R. Part 372.

⁴ 7 C.F.R. § 340.6(d)(3).

Finally, impeding innovation runs counter to this Administration's priorities.⁵ Biotechnology-driven innovation in agriculture is central to a number of the Administration's initiatives. The *Strategy for American Innovation, Feed the Future Initiative, National Bioeconomy Blueprint, A Framework for Revitalizing American Manufacturing, Growing American's Fuels Strategy, Revitalizing Rural America Initiative*, and the annual *Science and Technology Priorities* budget memoranda are among the White House documents that acknowledge, explicitly and implicitly, plant biotechnology's crucial role as a tool for achieving the President's objectives.⁶

APHIS's Notices of Intent Under NEPA

APHIS announced on May 10, 2013, that it plans to prepare two separate EISs "to better inform decision-making regarding the regulatory status of crops genetically engineered (GE) to be resistant to the herbicides known as" 2,4-D and Dicamba.⁷ On May 16, 2013, APHIS published a Notice of Intent to prepare an EIS for an herbicide tolerant corn plant and two herbicide tolerant soybean plants developed by Dow AgroSciences LLC (DAS) and a separate Notice for herbicide tolerant soybean and cotton plants developed by Monsanto Company (Monsanto). Each of the five crops has been tested in the field under APHIS permits and is now the subject of a pending petition submitted for a determination of nonregulated status under the applicable APHIS regulations.⁸ As noted above, in some cases these deregulation petitions have been pending for nearly four years.

The Notices identify two issues for consideration in an EIS— potential selection of herbicide resistant weeds or "weed resistance" and increased herbicide use – both of which fall squarely within EPA's statutory mandate under FIFRA, not APHIS's jurisdiction under the PPA. Importantly, the Notices do not identify these issues as relevant to APHIS's plant pest determinations, nor could they properly do so either as a matter of fact or law. Instead, the Notices acknowledge that "[w]hile the EIS's will look more broadly at potential impacts to the environment as a whole, APHIS' regulatory authority is based on The Plant Protection Act and the Agency's oversight is specific to evaluating the potential for the GE plants to pose a plant pest risk to crops or other plants."⁹

As discussed below, to the extent the EISs do not pertain to potential environmental impacts that might be associated with the deregulated plants and would delay deregulation of plants unlikely to pose a plant pest risk, the EISs are contrary to law and constitute an unnecessary expenditure of scarce public resources.

⁵ EO 13563 (January 18, 2011) *Improving Regulation and Regulatory Review* <http://www.whitehouse.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review>; EO 13610 (May 10, 2012) *Identifying and Reducing Regulatory Burdens* <http://www.whitehouse.gov/the-press-office/2012/05/10/executive-order-identifying-and-reducing-regulatory-burdens>; Memorandum (March 11, 2011) *Principles for Regulation and Oversight of Emerging Technologies* <http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf>

⁶ <http://www.whitehouse.gov/omb/factsheet/an-economy-built-to-last-for-rural-america>; <http://www.feedthefuture.gov/article/growing-innovation-harvesting-results-feed-future%E2%80%99s-progress-2012>; http://www.whitehouse.gov/sites/default/files/rss_viewer/growing_american_fuels.PDF; http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-30.pdf; http://www.whitehouse.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf; *Report to the President on Agricultural Preparedness and the Agricultural Research Enterprise*, December 2012. http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_agriculture_20121207.pdf

⁷ May 10, 2013 USDA News Release.

⁸ 7 C.F.R. § 340.6.

⁹ May 10, 2013 USDA News Release.

APHIS's PPA Authority

Under both the PPA and its implementing regulations, APHIS's authority to regulate organisms such as herbicide tolerant plants depends upon the existence of a plant pest risk. The PPA provides that the Secretary may regulate any plant or plant product if he or she determines that "prohibition or restriction" is necessary to prevent the introduction into the United States or the dissemination within the United States of a plant pest. APHIS's regulations further provide that in order to seek discontinuance of APHIS oversight of a regulated article, including a GE plant, any party may petition APHIS for a determination of nonregulated status. The petition must set forth the scientific data and other information supporting the petitioner's request that the organism no longer be treated as a regulated article.

APHIS must then conduct a very targeted inquiry in order to determine, based on the data and other information submitted, whether the GE organism "is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived."¹⁰ There is nothing in the PPA or APHIS's regulations that requires a determination of nonregulated status to be held in abeyance pending the outcome of an analysis under NEPA. To the contrary, those regulations require APHIS to either approve a petition for determination of nonregulated status in whole or in part or deny the petition within 180 days of the Agency's receipt of a completed petition.¹¹

As discussed below, upon APHIS's finding that a regulated article is unlikely to pose a plant pest risk, APHIS does not have jurisdiction to continue regulating that article. Other potential environmental effects beyond the presence or absence of a legally defined plant pest risk cannot change this determination. Nor should potential environmental effects related to the use of pesticides be used as a basis for a NEPA analysis that duplicates the statutorily mandated role of the EPA under FIFRA. Under the current circumstances, in which the sole purpose identified by APHIS for conducting the EISs is to examine potential environmental effects of pesticides under EPA's exclusive jurisdiction, and where such further NEPA analysis cannot affect any APHIS discretion, NEPA's purpose is not implicated and EISs are not required. Any further NEPA analysis that APHIS deems necessary must be limited to the potential environmental effects of the plants themselves.

Ninth Circuit's Roundup Ready® Alfalfa Decision

The day after APHIS's Notices were published in the Federal Register, the U.S. Court of Appeals for the Ninth Circuit issued its decision in a case challenging APHIS's deregulation of another herbicide tolerant crop, Roundup Ready Alfalfa (RRA). *Center for Food Safety v. Vilsack*.¹² Following APHIS's release of its final EIS and unconditional deregulation of RRA, plaintiffs, including the Center for Food Safety, 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 deregulation; and (iii) that APHIS violated NEPA by unconditionally deregulating RRA without considering the option of partial deregulation.

¹⁰ 7 C.F.R. § 340.6(c).

¹¹ 7 C.F.R. § 340.6(d)(3); see also "Biotechnology Regulatory Overview" (August 23, 2011), available at http://www.usbiomassboard.gov/pdfs/gregoire_tac_q3_2011.pdf.

¹² *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).

The district court granted summary judgment to APHIS and the industry intervenor-defendants. Plaintiffs appealed, and the Ninth Circuit affirmed. The Ninth Circuit upheld APHIS's decision that RRA is not a plant pest and squarely rejected plaintiffs' wholly unfounded theory that so-called "transgenic contamination" and increased herbicide use are plant pest harms under the PPA, noting that the adverse environmental effects alleged by plaintiffs were related to "the application of herbicides to fields of RRA, not the RRA plant." Slip. Op. at 26. Citing the Coordinated Framework, the Court concluded that regulating herbicide use was EPA's job under FIFRA. *Id.* The Ninth Circuit has long recognized EPA's unique role in assessing the environmental impacts of pesticide use under FIFRA.¹³

The Court held that once APHIS concluded that RRA was not a plant pest, "it no longer had jurisdiction to continue regulating the plant. 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." *Id.* at 8. Indeed, the Ninth Circuit 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." *Id.* at 14 (emphasis added). This conclusion is completely consistent with the position taken by APHIS in the brief filed by the Department of Justice in the case.

The Court further held that deregulation of RRA was "a nondiscretionary act that did not trigger the agency's duty to consult under the ESA." *Id.* at 28. Finally, the Court found that APHIS was under no duty to conduct a separate noxious weed analysis as part of the review of a petition for deregulation of a GE plant in a situation where no party petitioned APHIS to list the plant as a noxious weed under the PPA. *Id.* at 30-31.

The district and circuit court decisions in the RRA case are founded on Supreme Court precedent. In *Department of Transportation v. Public Citizen*, 541 U.S. 752 (2004), the Supreme Court held that, since the Department of Transportation (DOT) lacked statutory discretion to prevent cross-border operations of Mexican motor carriers, it did not need to consider the environmental impacts of those operations in its analysis under NEPA. In *National Association of Homebuilders v. Defenders of Wildlife*, 551 U.S. 644 (2007), the Supreme Court held that EPA had no duty to consult with the FWS on the potential effects of its permitting decision on threatened and endangered species because EPA's act was nondiscretionary: "an agency cannot be considered the legal 'cause' of an action that it has no statutory discretion *not* to take."

As in these cases, the scope of APHIS's relevant inquiry is limited to whether a plant pest risk exists, and that decision must be made within 180 days. APHIS's review under NEPA of the potential environmental impacts of its deregulation action must be limited to the plant over which it has jurisdiction. Actions on petitions for nonregulated status should not be delayed for months or years pending completion of time-consuming, expensive and unnecessary EISs that ultimately have no bearing on the scope of APHIS's discretion.

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For the foregoing reasons, BIO respectfully requests APHIS to reconsider its decision to prepare EISs for the crops identified in the Notices and to expeditiously finalize the deregulation process for these crops as contemplated by the Ninth Circuit and applicable APHIS regulations.

¹³ See *Merrell v. Thomas*, 807 F.2d 776 (9th Cir. 1986); *Douglas Cnty. V. Babbitt*, 48 F.3d 1495, 1502-03 (9th Cir. 1995).

BIO appreciates this opportunity to provide comment on APHIS's recent Notices of Intent and would be pleased to provide any additional information that might be useful to APHIS in its consideration of the critical policy and procedural issues raised by these Notices and the federal court decisions discussed herein.

Sincerely,



Cathleen Enright Ph.D.
Executive Vice President, Food & Agriculture

cc: Honorable Thomas J. Vilsack, Secretary, U.S. Department of Agriculture
Honorable Debbie Stabenow, U.S. Senate
Honorable Thad Cochran, U.S. Senate
Honorable Frank D. Lucas, U.S. House of Representatives
Honorable Collin C. Peterson, U.S. House of Representatives
Ramona Romero, General Counsel, U.S. Department of Agriculture
Sylvia Mathews Burwell, Director, Office of Management and Budget
Nancy Sutley, Chair, Council on Environmental Quality
Jim Jones, Acting Asst. Administrator, OCSPP, U.S. Environmental Protection Agency