April 8, 2015

Improving Regulations Docket
Environmental Protection Agency
EPA Docket Center, Mailcode:2822T
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Washington, D.C. 20460-0001

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RE: Comments on Improving EPA Regulations, 80 Fed.Reg. 12372 (March 9, 2015); Docket ID No. EPA-HQ-OA-2011-0156 (Improving Regulations: General)

To whom it may concern:

We are pleased to submit these comments in response to the U.S. Environmental Protection Agency's (EPA) request for public input on the Agency's regulatory review, which will be carried out in response to President Obama's January 18, 2011 Executive Order (EO) 13563, "Improving Regulation and Regulatory Review." Our organizations represent a broad coalition of grower groups, farm organizations, and technology providers who share a common interest in efficient, predictable and non-duplicative regulation of agricultural biotechnology products. We commend the Agency for its efforts to date in streamlining and modernizing regulations, and we note that our previous comments to the docket (Comment ID EPA-HQ-OA-2011-0156-0105) are still valid.

Biotechnology in US agriculture and economy

Biotechnology-driven innovation in agriculture is central to many of this 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*[1] and the annual *Science and Technology Priorities* budget memoranda are among the White House documents that acknowledge, explicitly and implicitly, biotechnology's crucial role as a tool for achieving the President's priorities. Recent White House documents also acknowledge the role the federal regulatory system plays in impeding the development of agricultural biotechnology[2].

EPA regulation of plant-incorporated protectants (PIPs) and the Coordinated Framework

The process of natural selection has provided many plants with endogenous chemicals that protect the plant from pests, such as insects and viruses. For centuries, plant breeders have mimicked nature and used the methods of artificial selection, including wide crosses with wild relatives and mutagenesis, to provide crops with similar, built-in means of pest

[1] https://www.whitehouse.gov/sites/default/files/uploads/InnovationStrategy.pdf ; http://www.feedthefuture.gov/ ; https://www.whitehouse.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf; https://www.whitehouse.gov/sites/default/files/microsites/20091216-maunfacturing-framework.pdf; https://www.whitehouse.gov/sites/default/files/rss_viewer/growing_americas_fuels.PDF; http://www.whitehouse.gov/omb/factsheet/an-economy-built-to-last-for-rural-america

[2] *National Bioeconomy Blueprint* , April 2012; *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; March 2011 Memo- *Principles for Regulation and Oversight of Emerging Technologies*.

protection. For 30 years, plant breeders have used the new tools of modern biotechnology to identify genes in nature and insert them into crops through "genetic engineering," leading to the development of crops with novel endogenous protective substances. These chemical substances, referred to as "plant-incorporated protectants" or "PIPs," are typically proteins that originate in nature and are harmful only to a narrow range of crop pests. Because these substances are proteins that are biodegradable and do not accumulate in the soil[3], they serve EPA's goal of reducing the need for exogenous chemical applications while simultaneously providing an effective means of highly-targeted pest control.

In 1986, the United States unveiled the Coordinated Framework for Regulation of Biotechnology (the "Coordinated Framework"); it outlines a strong, science-based regulatory system for the oversight of genetically engineered (GE) organisms. Using existing statutes, regulatory oversight of agricultural biotechnology product development and commercial use was divided among three U.S. federal agencies— the Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Working effectively and efficiently within this structure, U.S. regulatory agencies oversaw the deployment of new innovations that generated beneficial products, without a single instance of product harm to human or animal health or to the environment. As a result, the U.S. regulatory system was viewed rightfully as the international gold standard for oversight of GE organisms.

The division of regulatory responsibility established by the Coordinated Framework has functioned well for nearly 30 years. Millions of plants expressing pesticidal substances designed to target specific pests have been safely field tested under EPA and USDA permits since 1986, and to date 39 PIP products[4] have been cleared for commercial use following review by EPA, USDA and FDA. U.S. growers, as well as consumers and the environment, have been the beneficiaries of safe, biotechnology-derived crops with built-in pest protection. Biotechnology-derived PIPs have provided multiple benefits, including decreased productions costs[5,6], increased crop yields due to reduced pest damage, and improved food safety. A recent study showed that the some of the greatest beneficiaries of corn PIPs are growers who opt to grow conventional corn varieties in the same geographic area due to the suppression of some insect pest populations from growers who use PIP-containing corn.[7]

In spite of the significant contributions of biotech crops in the nation's agricultural economy[8], a history of safe use, and increased scientific understanding of molecular genetics, genetically engineered crops continue to be subjected to burdensome regulation. Even as evidence of their safety has accumulated, data requirements have increased. This places unnecessary burdens on both regulatory agencies and product developers, while offering no compensatory improvements in environmental quality or human health. Therefore, we are very interested in EPA's efforts to modernize regulations, and are responding to two of the questions raised in EPA's March 9, 2015 FR notice.

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[3] Mendelsohn, M., J. Kough, Z. Vaituzis and K. Matthews. 2003. *Nature Biotechnology* 21:1003-109.

[4] http://www.epa.gov/oppbppd1/biopesticides/pips/pip_list.htm

[5] National Research Council. 2010. *Impact of Genetically Engineered Crops on Farm Sustainability in the United States.*

[6] National Council for Food and Agricultural Policy.2008. *Quantification of the Impacts on US Agriculture of Biotechnology-Derived Crops Planted in 2006.*

[7] Hutchinson, et.al., 2010. *Areawide Suppression of European Corn Borer with Bt Maize Reaps Savings to Non-Bt Maize Growers.* Science 330:222-226

[8] The US is estimated to have enhanced farm income from biotech crops by $53.1 billion in the period 1996 to 2012. Brookes, G. and P. Barfoot. 2014. GM Crops: Global Socio-economic and Environmental Impacts 1996-2012. PG Economics Ltd, UK. pp 1-189.

Question: How can the EPA reduce duplicative reporting requirements in existing regulations that may overlap other federal requirements?

Duplicative efforts at EPA and USDA

- USDA-APHIS was designated as the lead agency for genetically engineered plants.[9] Consistent with this principle, EPA should make clear that it will not exercise its plant growth regulator authority to regulate GE crops with no "-cidal" properties (i.e., that are not intended for preventing, destroying, repelling, or mitigating a pest).

  EPA has recently moved to expand its oversight to encompass traits in biotech crops that are not intended for control of pests. For example, in 2008 EPA claimed regulatory jurisdiction over a biotechnology-derived melon developed by the University of Florida that ripens more slowly and, in 2010, a plum tree developed by USDA scientists that is resistant to a devastating disease. Any attempt to regulate these products will not only be "redundant, inconsistent and overlapping," as developers of these crops would end up submitting essentially the same data to both USDA and EPA for review, it will also run counter to other principles outlined in Executive Order 13563 and the March 11, 2011 memo on regulation of emerging technologies. Not only do these changes impose an increasing regulatory oversight that is not proportionate to risk, but they also create oversight duplicative with the other agencies across the Coordinated Framework and a serious barrier to the development of valuable new plant varieties by universities, research institutes and small companies, particularly with respect to so-called minor use and specialty crops.

  We urge the Agency to be consistent in its interpretations of oversight. Recent Agency actions on products that could be interpreted as plant growth regulators, and therefore regulated as "biochemical pesticides," may have implications for the regulation of non-pesticidal substances expressed in the plant that function to improve plant productivity under adverse conditions, such as drought or nitrogen deficiency.

- EPA should eliminate the requirement for an EUP for PIPs that are planted under USDA-APHIS notification or permit. The intent of the EUP regulations in 40CFR172.3 was to ensure that use of an experimental pesticide product did not result in unreasonable adverse effects to human health or the environment. USDA-APHIS regulated field trials ensure that experimental PIPs are contained and not lost during transport, do not escape the trial site, pose a risk to threatened and endangered species and do not enter food/feed streams. Therefore, an EUP should not be required regardless of acreage as long all PIP field trials are conducted under USDA-APHIS authorization. There is no logical reason for the current duplication of USDA-APHIS regulation by EPA when PIP field testing exceeds 10 acres per pest species.
  - The 10-acre rule is not in Section 5 of FIFRA; it is only in 40CFR172.3(c)(1).
  - EUP rules were written for large-scale testing of traditional chemical pesticides in which USDA has no authority under 7CFR340 to provide oversight.
  - USDA and its state partners have an adequate number of inspectors to verify compliance at PIP trial sites that are under notification or permit.

[9] 51 *Fed. Reg*. 23304.

- EPA should also eliminate EUPs for stacked products that have already been individually deregulated by the USDA and registered at EPA.

- We urge EPA to accept petitions for broader PIP tolerances and tolerance exemptions, rather than establishing a tolerance or a tolerance exemption for a certain PIP in a specific crop. EPA's process for PIPs should mirror FDA's early food safety evaluation of new, non-pesticidal proteins produced by new plant varieties intended for food use[10].

Duplicative reporting requirements are found even within EPA: PIPs undergo re-registration every 5 – 10 years. This year, multiple registered *Bt* products expire in September, the same year that these products are scheduled for registration review. EPA should consider consolidation of re-registration activities with registration reviews where appropriate, as authorized under 40 C.F.R. 155.44.

Question: Is the same information being collected in multiple places, either across different regulations, or across different levels of government (Federal, State, Tribal and local)?

- State registrations of pesticide products require registrants to provide copies of Federal EPA registration information. The information required varies by state, but could include the final label, the approval letter, etc. This information could be made easily accessible through EPA's proposed E-Portal system, and no longer collected at multiple levels of government.

A number of technology companies that belong to the Biotechnology Industry Organization (BIO) have been selected to work with EPA on the E-Portal Pilot. They view the portal as an important tool to modernize business processes and help efficiently obtain access to and interact with both EPA, state and tribal environmental programs and resources.

Regulatory systems function most effectively when they are predictable, risk-proportionate, flexible and outcome-oriented. These attributes have characterized the U.S. regulatory system for many years, and we appreciate the opportunity to provide comments on EPA's regulatory review process in order to continue this system. We look forward to working with EPA on how to improve regulatory efficiencies.

Sincerely,

American Farm Bureau Federation
American Seed Trade Association
American Soybean Association
American Sugarbeet Growers Association
Beet Sugar Development Foundation
Biotechnology Industry Organization
National Corn Growers Association
National Cotton Council
U.S. Beet Sugar Association
U.S. Canola Association

[10] www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096156.htm