BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

July 6, 2009

Submitted via Federal eRulemaking Portal

Docket No. APHIS-2007-0016

Regulatory Analysis and Development
Plant Protection Division
Animal and Plant Health Inspection Service
United States Department of Agriculture
Station 3A03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: Docket No. APHIS-2007-0016, "Syngenta Seeds, Inc.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Corn Genetically Engineered to Produce an Enzyme That Facilitates Ethanol Production"

To whom it may concern:

These comments are submitted by the Biotechnology Industry Organization (BIO) in response to the June 4, 2009 announcement (the Notice) by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS or the Agency) of the reopening of the comment period for a petition submitted by Syngenta Seeds, Inc. (Syngenta), seeking a determination of nonregulated status for corn designated as transformation Event 3272 and its associated environmental assessment prepared by APHIS under 7 CFR Part 340. 74 Fed. Reg. 26832. These comments supplement BIO's comments submitted on this same docket on January 20, 2009. BIO appreciates this opportunity to provide these additional comments.

BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multinationals. We also represent state and regional biotechnology-derived associations, service providers to the industry, and academic centers. Based on certain statements made in the Notice regarding the scope of the Agency's authority to regulate products of biotechnology and confusion that has arisen regarding those statements, we have determined that BIO and its Food and Agriculture Section members have a general interest in addressing the issue because of its importance to the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) under which our industry has operated since 1986.

In the Notice, APHIS described the authority that it exercises for the regulation of biotechnology-derived plants under the Plant Protection Act (PPA) and implementing Agency regulations at 7 CFR Part 340 (Part 340). Unfortunately, the Notice has resulted in considerable confusion amongst stakeholders regarding the scope of APHIS' authority and BIO urges the Agency to clarify that issue at the earliest possible time. BIO's detailed comments follow.

The PPA provides expansive authority for the regulation of plant pests and potential plant pests, including genetically engineered (GE) plants. When APHIS indicates in the Notice's discussion of the Syngenta corn amylase petition that the Agency "cannot regulate GE plants that are outside the PPA's plant pest definition," that statement must be read in the context of Syngenta's pending petition for a "determination of nonregulated status" and the definition of "regulated article" under Part 340. In that context, the statement simply recognizes that Event 3272 corn has successfully progressed far enough through the rigorous regulatory process that APHIS applies to all GE plants – a process the Agency refers to in the Notice as its "safeguarding" approach – to allow a determination that the plant does not pose a plant pest risk.

Part 340 provides for the regulation of any GE organism which APHIS "determines is a plant pest or has reason to believe is a plant pest," creating a rebuttable presumption that a new GE organism has the potential to be a plant pest until proven otherwise. Prior to introduction (i.e., field testing, movement, or importation) of a GE plant or other regulated article, applicants are required to submit information for review by regulatory scientists who evaluate the potential risks posed by the introduction and the procedures that the applicant will use to minimize those risks. Depending on the nature of the GE organism, an applicant applies for either a permit or a notification. APHIS authorizes introductions only after considering the donor and recipient organisms and vector agents; the function, nature and expression level of introduced genetic material; the nature of the genetically engineered trait; the ways in which the GE organism is likely to interact with the environment; and numerous other factors.

Permits and notifications are designed to ensure the safe introduction of any GE organism over which APHIS has authority. Conditions are required to maintain confinement of the GE organism throughout the course of the introduction so that, for example, GE plants are grown in a way that maintains confinement of the plant to the area of a field test, with additional precautions taken designed to prevent the movement of pollen, seeds, or plant parts from the field test site.

APHIS works to ensure that notification and permit holders maintain regulatory compliance by providing guidance and violation-prevention efforts and by implementing verification and enforcement procedures that include site audits and inspections, documentation of compliance infractions, and mitigation and enforcement actions to address any infractions. APHIS also requires the submission of field reports which, in addition to providing other information, must inform the Agency if any adverse effects are noted during any introduction of GE organisms.

Over the course of the regulatory process, the developer gathers information on potential plant pest characteristics based, among other things, on the results of APHIS-regulated field tests. After a GE

organism has been field tested extensively and the developer can show that the organism is not a plant pest and can safely be removed from APHIS oversight, the developer may request the deregulation of the organism by filing a petition for a determination of nonregulated status based on all relevant data and information. As Part 340 makes clear, information is to be provided in the petition to address such factors as plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information that APHIS believes to be relevant.

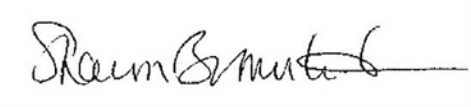
The Agency's statements in this Notice cannot reasonably be read as any type of departure from its well-established role as a cornerstone of the framework for regulation of biotechnology-derived plants in the United States. APHIS made these statements while sharing its preliminary opinion that, following extensive field testing and the submission of data very similar to that accompanying dozens of other petitions for nonregulated status, there is no evidence that Syngenta's corn plant poses a plant pest risk. The process followed here is no different than that followed under the Part 340 regulations for every GE plant since establishment of the petition process in1993.

APHIS has not said that it lacks authority to regulate biotechnology-derived plants such as Event 3272 under Part 340 – the Agency has been actively regulating these plants for over 20 years. Rather, it has refused to compromise the science-based nature of its decisionmaking process to regulate what appears to be a safe product based on purely economic or marketing concerns. This is consistent with the process through which APHIS exercises its noxious weed authority over plants not developed through biotechnology. This approach is also consistent with the designation of APHIS as the lead agency for regulation of biotechnology-derived plants under the Coordinated Framework in 1986.

Finally, with regard to the definition of "plant pest," the PPA defines that term, in relevant part, as "**any living stage**" of certain organisms "that can directly or indirectly **injure, cause damage to, or cause disease in** any plant or plant product." 7 U.S.C. § 7702(14) (emphasis added). The statutory requirement for actual injury, damage or disease to a plant or plant product would preclude a plant pest determination based purely on commercial impacts. Moreover, the requirement for actual harm to plants is consistent with longstanding APHIS interpretations of its authority under the PPA and its predecessor statutes and with international standards for plant pest identification as established by the International Plant Protection Convention (IPPC), to which the United States is a signatory. Reading the "plant pest" definition in its entirety, the Agency would need to determine that the plant or other organism in question is at a "living stage" at the point at which it poses the potential to "injure, cause damage to, or cause disease in" plants or plants products. The fact that a specialty crop expresses an enzyme or other substance that may render the harvested crop unsuitable for certain commodity processing uses does not in any way make that crop a plant pest.

BIO appreciates the opportunity to provide these additional comments in response to the Agency's Notice.

Sincerely,



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