INDUSTRY ASKS USDA TO CLARIFY BROAD POWER TO REGULATE GE CROPS

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The Biotechnology Industry Organization (BIO) is asking the U.S. Department of Agriculture (USDA) to clarify its authority to regulate genetically engineered (GE) corn and other biotech crops due to widespread confusion prompted by recent suggestions from USDAs Animal Plant Health Inspection Service (APHIS) that it lacks authority to regulate at least one variety.

The groups call is also aimed at ensuring the department continues to play the lead role regulating the plants in the wake of suggestions from some activists that EPA should oversee the issue if APHIS would not. At issue is a June 4 notice APHIS published in the Federal Register seeking additional comment on an application by Syngenta Seeds Inc. to deregulate, and thus commercialize, a GE corn, known as Event 3272, that is designed to ease ethanol production.

In the notice, APHIS said it had determined that it lacks regulatory and statutory authority under the Plant Protection Act (PPA) to regulate the corn, agreeing with Syngenta that neither the enzyme injected into the corn nor the corn itself are living organisms subject to PPA oversight.

That assertion prompted broad concern among environmentalists that APHIS was dramatically ceding its authority to regulate many GE crops entirely, and they suggested that EPA may need to step in and regulate under the Toxic Substances Control Act (Inside EPA, June 19).

Now BIO -- the main trade association for the biotech industry -- is also urging APHIS to clarify its earlier statement. In July 6 comments, BIO tells APHIS that its 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. Relevant documents are available on InsideEPA.com.

BIO says the PPA provides expansive authority for the regulation of plant pests and potential plant pests, including [GE] plants.

The group adds that clarification of APHIS authority would help preserve its designation as the lead agency for regulation of biotechnology-derived plants under a framework that dates back to 1986.

Environmentalists are also formally raising their concerns about the APHIS shift in their formal comments. For example, the Union of Concerned Scientists in July 6 comments says APHIS rationale offered a new interpretation of PPA authority that excludes practically all GE plants from PPA jurisdiction . . . The agencys argument that GE ethanol corn is not a plant pest because it is not a parasitic plant applies to most, if not all, GE plants.

If APHIS decides to proceed with this application under PPA authority, the agency should withdraw its new interpretation of GE crop jurisdiction and return to the interpretation established more than two decades ago.

The agencys shift in position on such a weighty matter throws the industry into chaos and undermined confidence in the oversight of GE crops.

However, Syngenta in its own supplemental July 6 comments strongly agrees with APHIS conclusion, noting the APHIS notice fully responds to comments made by corn refiners arguing that the alpha-amylase enzyme is . . . a plant pest if misdirected to corn wet milling production facilities . . . Both the legal and factual analyses conclude that the alpha-amylase enzyme is not a plant pest within the meaning of the statute. We agree . . . The injury that commenters allege may result indirectly from deregulation of Event 3272 corn is simply not a plant pest injury a nd therefore provides no basis for continued regulation.

In a statement to Inside EPA, APHIS defends its broad PPA authority to regulate GE crops and study the safety of their introduction into the market. APHIS says during the initial public comment period on the Syngenta application, the agency received substantive comments questioning whether Event 3272 met the standard of the plant pest. . . . In response, APHIS reopened the public comment period in June . . . and concluded that Syngenta-developed GE corn is unlikely to pose a plant pest risk. APHIS will review all of these comments before making a determination in response to Syngentas request . . . Even if APHIS deregulates a particular biotechnology product, the company must still comply with applicable [Food & Drug Administration] or EPA requirements.