



FB to execs: Now is the time to address biotech seed issues

Compiled by Staff

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Washington, March 5. The American Farm Bureau Federation says now is the time to address the transition of Roundup Ready soybeans (Roundup Ready1™ soybeans) to a generic product, even though the patent does not expire for nearly four years. AFBF President Bob Stallman says in a letter to the chief executives of the world's six largest seed companies that "significant hurdles must be overcome for any generic agricultural biotech product to be available to producers."

"Farm Bureau understands that these are enormous challenges to tackle, and we believe that they will be best resolved if technology providers, the U.S. government and farm organizations are working together on a solution. The administration and Congress are clearly interested in this issue as well, but we believe it's best for all parties to work together to find solutions before the government is forced to dictate one. How this first major agricultural biotech product is handled as it goes off-patent will be precedent-setting for other products, and with less than four years to find resolution on such a complicated issue, discussion must begin soon," Stallman wrote in a letter to chief executives at Monsanto, Syngenta, Pioneer, Dow, BASF, and Bayer.

Stallman says the means for maintaining international regulatory approvals post-patent must be found. And, he says, a process that allows for a seamless transition to generic products after patent expiration will have to be established for those products that are still regulated within the United States.

While some agricultural biotech products are de-regulated in the United States and do not require further regulatory action to be grown and utilized in domestic markets, many foreign markets will maintain re-registration processes in order for shipments containing a particular trait can be traded and exported, the nation's largest farm organization pointed out in the letter, which was obtained by *Agri-Pulse*.

"Given the prevalence of many agricultural biotech traits in U.S. agriculture, allowing these international registrations to lapse would amount to catastrophic losses in export markets for U.S. commodities," Stallman says, noting that approximately 20 percent of the corn and 50 percent of the soybeans grown in the United States end up abroad.

The Farm Bureau president says that while continuing the registration of some products requires data packages to be submitted to the appropriate regulatory agencies, the data can often take years to accumulate. He says that over this time, companies have a de facto extension of their patents on a given product while other companies work to recreate a set of data that already exists. “This is particularly problematic given that agricultural biotech companies are precluded from beginning the data collection process until after the expiration of an agricultural biotech patent for fear of legal action against them.” Stallman says some adjustments must be made to the regulatory and/or patent processes to facilitate a smooth and efficient transition.

Stallman says there are a number of number of complicating factors unique to the agricultural biotech industry that will be relevant in addressing the hurdles he cited, including the fact that each individual country has a different approval process and that not all ag biotech crops will face the same challenges post-patent. He also notes that herbicide tolerant traits and insect-resistant traits will face different regulatory environments, and that single-trait products and stacked products are often not treated the same throughout the global regulatory process.

Stallman says farmers are increasingly enthusiastic about the opportunity for generic products to enter the market, noting that while producers praise the agricultural biotech products that they use on their farms, they are also frustrated by the steep yearly price increases that are often associated with the products.

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