A Shifting Biotechnology Policy: Federal and Industry Initiatives

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At first glance, the domestic regulatory structure for agro-biotechnology appears to function adequately as new genetically modified (GM) crops regularly receive government approval. While the current 20-year old system has led to a few trade disruptions and litigation, changes on the horizon present uncertainty to the regulated community. Unfortunately, these proposals, particularly regarding the presence of unapproved GM crops, could hamstring coexistence efforts and complicate international trade. The biotech industry, however, is attempting to fill this regulatory gap.

In three consecutive cases, USDA’s Animal and Plant Health Inspection Service (APHIS) lost court challenges to its biotech regulatory policy. The most important case involved the deregulation of genetically engineered alfalfa (Geertson Seed Farms v. Johanns). APHIS’s decision to deregulate GM alfalfa hinged, in part, on its determination that responsibility for preserving genetic purity for both domestic and export markets rested solely on the non-GM producer. The court disagreed, noting that the Government’s deregulation analysis failed to identify a single method that a farmer could employ to protect his crop from GM contamination. In sum, the court found APHIS’s analysis “simply not convincing” and permanently enjoined additional planting of Roundup Ready Alfalfa pending APHIS’s completion of a full Environmental Impact Statement.

In mid-2007, USDA released proposed revisions to its biotech regulatory strategy. Although a full discussion of the proposal is beyond the scope of this article, at least one aspect warrants mentioning—the low level presence of unapproved genetic events in seed. Current domestic regulations (as well as rules in most other countries) set a zero tolerance for the presence of these unapproved varieties. APHIS has proposed the establishment of safety criteria under which such occurrences would be non-actionable—in other words, allowed. Although APHIS speculates that in the majority of cases such “low-level presence” (LLP) of regulated articles may be of minimal risk to health and safety, the economic implications of this policy could be severe as U.S. trading partners are unlikely to adopt this permissive strategy of adventitious presence. Although one could argue that prior APHIS policy never truly concerned itself with coexistence, the proposed rule is a clear abdication of responsibility for the genetic purity of the nation’s harvests and industry’s ability to maintain export markets.

Recognizing the critical nature of genetic surety to the international commodity trade, the biotech industry has proposed industry-wide, non-binding guidance to avoid LLP trade disruption. The guidance requests companies to (1) to identify key product-specific import markets and (2) receive regulatory approval in those key markets prior to commercialization of any new biotechnology products. Seed developers would
determine key markets on a crop-by-crop basis. It remains to be seen whether pressures for immediate return on investment at the individual company level will override the inevitable commercialization delay when waiting for the complete alignment of export market approvals that would result from the new guidance. Failure to wait, however, would jeopardize the delicate nature of export markets in this era of biotechnology.

Regardless of whether USDA eventually backs away from its proposed LLP policy, all segments of the agricultural supply chain should implement coexistence strategies appropriate for their particular segment to meet the genetic purity demands of the world market.