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New Regulatory Pathways for Genetically Engineered Plants

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Recent USDA approval for the commercialization of a Kentucky Bluegrass (*Poa pratensis* L.) genetically engineered (GE) for tolerance to glyphosate has the potential to drastically alter the exiting regulatory framework for USDA's review of new GE plants. This may be especially true in the context of new GE bioenergy crops that do not have a residual use for food and/or animal feed. A potential easing of federal review, however, could prompt increased scrutiny at the state/local level under existing noxious weed laws, leading to an even more complex regulatory system.

Crafted in 1986, the Coordinated Framework for the Regulation of Biotechnology created a multi-agency system in which the USDA's Animal and Plant Health Inspection Service (APHIS) reviews GE varieties under its authority to regulate potential "plant pests." The Plant Protection Act (PPA) generally defines a plant pest as any organism that can directly or indirectly injure any plant. With the development of GE plants, APHIS assumed regulatory oversight under the premise that GE plants are potential plant pests.

Under the Coordinated Framework/PPA regime, APHIS requires plant developers to conduct field trials of new varieties and subsequently petition for a deregulation determination based on field test results that demonstrate the plant is not a potential plant pest. The deregulation petition also triggers an environmental review under the National Environmental Policy Act (NEPA)—the process that engendered the litigation surrounding GE alfalfa and sugar beets and forced APHIS to re-consider the cumulative impact of glyphosate use and impacts on non-GE markets.

APHIS's authority, however, hinges on whether the new GE variety is a potential plant pest. A novel GE plant would fall under APHIS's PPA jurisdiction if the donor, recipient, vector or vector agent used in the genetic engineering is listed as a plant pest in USDA regulations. The regulations do not list conventional Kentucky Bluegrass, nor the organisms used as the source for the transferred genetic material, as plant pests. Because the developer used no plant pests or unclassified organisms to perform the genetic engineering, APHIS concluded that it had no reason to believe the resulting GE product was a plant pest and, therefore, the agency lacked jurisdiction under the statute to regulate the plant. Thus the herbicide resistant Kentucky Bluegrass side-stepped APHIS's review under the Coordinated Framework. Moreover, as the plant did not have an intended use as food or animal feed, it avoided FDA review, as well.

There may be, however, a potential downside to less federal oversight as battles may shift to the state and local level, which have authority independent from the federal government to declare plants as "noxious weeds." With the exception of a few California counties, most states have deferred regulatory action regarding GE plants in reliance on a comprehensive review at the federal level. But if multiple GE plants circumvent APHIS review, states may decide to assert

previously dormant regulatory authority. Moreover, absent the protective cover of federal "approval," a single environmental or safety incident could shift a still uncertain public perception against the biotech industry, prompting additional state regulation. The result could be more complex barriers and approval regimes that vary between states along with additional marketing restrictions. In sum, circumventing the Coordinated Framework may have some short run benefits, but the potential exists to replace regulatory delays embedded in the Coordinated Framework with regulatory chaos at the state level.