

ARTICLE

USDA Animal and Plant Health Inspection Service Modernizes Its Approach to GE Organisms

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This month, the USDA Animal and Plant Health Inspection Service (APHIS) published a final rule revising the 7 C.F.R. Part 340 regulations that implement APHIS's statutory authority under the Plant Protection Act to regulate the importation, interstate movement, and environmental release of genetically engineered organisms that are or may be plant pests. Publication of this final Part 340 final rule completes an extended rulemaking process that began during the George W. Bush administration and involved three separate proposed rules, the last published on June 6, 2019.

In its June 6, 2019 proposal APHIS stated that its revised proposed rule would better able it to "focus its resources on regulating genetically engineered (GE) organisms that may pose plant pest or noxious weed risks, and will enhance regulatory flexibilities that foster innovation." This, of course, is ideally what biotech regulations should do – (1) focus on products that may pose actual risks, and (2) not impose unnecessary burdens that inhibit or hinder innovation. As promulgated, the final Part 340 rule may accomplish those goals.

APHIS regulates the importation, interstate movement, and environmental release of genetically engineered organisms that are, or may be, plant pests under the Plant Protection Act (7 U.S.C. 7701 – 7786). The Part 340 regulations were promulgated in 1987 and this final rule is the first comprehensive revision of the Part 340 regulations.

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As APHIS notes in its final rule, it now has over three decades of experience regulating such products and during that time, the scientific advances in biotechnology have been astronomical. Since the publication of the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) by the Office of Science and Technology Policy (OSTP) in 1986, the stated policy of the U.S. Government has been that the products of agricultural biotechnology should be regulated on the basis of an assessment of risk of a product, not on the method by which the product was developed. Notwithstanding this policy, affirmed in an update to the Coordinated Framework in 1992, the three Coordinated Framework agencies have, as a matter of course, imposed heightened regulatory burdens on agricultural biotechnology. APHIS's revised Part 340 regulations are a well overdue effort to bring the risk-regulatory burden equation in the context of products under its jurisdiction into some semblance of balance.

APHIS now has new exemptions for GE plants are intended to bring the regulation of the specified categories of potentially regulated GE products more in line with the regulation of conventionally bred crops, which while not "risk free" have been determined to have risks that are "manageable by accepted standards." While the exemptions in the rule are somewhat narrowly circumscribed, the possibility hopefully exists that APHIS will consider amending the rule to expand the scope of the exemptions in the future. While the actual benefits of this altered approach to regulating GE products under Part 340 will become apparent when APHIS implements the new regulations, as promulgated, they are clearly an improvement over the old Part 340. For more information on the scope of the rule, specific changes and timelines for implementation you can access our legal summary of the new rule [here](#).