

ALERT

USDA Extends Comment Period for APHIS Proposed Rule Revising Regulations on Environmental Release of GE Organisms

February 10, 2017

On February 10, 2017, USDA's Animal and Plant Health Inspection Service (APHIS) extended the comment period for the January 19, 2017, proposed rule that proposes to revise the 7 C.F.R. Part 340 regulations that govern the importation, interstate movement, and environmental release of genetically engineered organisms that may be plant pests. The comment period for the proposed rule will now close on June 19, 2017.

Provisions of the APHIS proposed rule, if promulgated, would impose significant changes in the regulatory scheme for genetically engineered organisms not intended for pesticidal uses. Significant provisions include a (1) a new regulatory risk analysis to evaluate GE organisms for noxious weed potential; (2) elimination of the notification process for certain GE organisms in favor of an affirmative permitting scheme; (3) a process for regulating GE organisms intended for use as biological control agents; (4) new criteria for regulation of plants genetically engineered to produce industrial chemicals and pharmaceuticals; (5) new criteria for regulation of small-scale field testing of new plant-incorporated-protectants (PIPs); and (6) a commitment to work with EPA to try to better coordinate regulatory decisions for herbicide-resistant plants and approvals of new uses for the associated herbicides.

Background

Pursuant to authority under the Plant Protection Act, 7 U.S.C. 7701 – 7786, APHIS regulates the movement in interstate commerce of genetically engineered organisms that are, or may be, plant pests.

Practice Areas

Environment & Product Regulation

This includes importation, interstate movement, and environmental release of such organisms. The APHIS regulations implementing this authority are at 7 C.F.R Part 340, *Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests*. The Part 340 regulations were promulgated in 1987, and have not been comprehensively revised since that initial promulgation.

APHIS first proposed comprehensive revisions to the Part 340 rule in a proposal published on October 9, 2008. That proposal had an almost 9 month comment period during which APHIS received over 5,500 submissions containing 88,000 comments. On March 4, 2015, APHIS withdrew the proposed rule, and stated that the reasons for the withdrawal included substantive issues raised by some of the comments, “experience we have gained over the past 28 years,” and “continuing advances in biotechnology.” As is often the case in matters involving biotechnology, the comments reflected a wide disparity of opinion, e.g., that the proposed regulations were not sufficiently rigorous, and that the proposed regulations were too rigorous; or that the proposal was “supportive” of biotechnology, and that the proposal was likely to inhibit technological innovation. A number of commenters also were concerned that the APHIS proposal would result in a significant expansion of regulatory authority. Thus, APHIS determined to, essentially, start over.

On January 19, 2017, APHIS published its latest proposal to update the Part 340 regulations. The proposal notes that “advances in genetic engineering have occurred” since the regulations were promulgated in 1987 and, importantly, that the evaluations associated with over 43,000 regulatory decisions under the 1987 regulations “have provided evidence that most genetic engineering techniques, even those that use a plant pest as a vector, vector agent, or donor, do not result in a GE organism that presents a plant pest risk.” Notwithstanding this conclusion, the regulatory scheme proposed by APHIS in the January 2017 proposal is wide-ranging and complex. It is fair to say that it also would result in an expansion of APHIS’ regulatory reach over GE plants.

APHIS had initially scheduled a 120-day comment period. The comment period has now been extended 30 days to June 19, 2017.

Need for Action

These changes could result in increased regulatory burden. Individuals and companies that intend to release, move interstate, or import any genetically engineered organism not intended for pesticidal use should carefully review the APHIS proposed rule and consider submitting comments on relevant provisions. It is important to provide APHIS with substantive input, both to possibly influence the final rule, and to preserve important issues for possible judicial challenge.