Thursday, November 9, 2017

As previously covered on this blog, on January 19, 2017, the U.S. Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) published a proposed rule to update its regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered (GE) organisms in response to advances in genetic engineering and the Agency’s understanding of the plant pest and noxious weed risk posed by genetically engineered organisms. These requirements have not been comprehensively revised since they were established in 1987.

On November 7, 2017, APHIS published a notice in the Federal Register (82 Fed. Reg. 51582) announcing its withdrawal of the January 19th proposed rule. In withdrawing the proposed rule, APHIS cited stakeholder feedback critical of the proposed revisions. As previously covered on our blog this summer, in comments submitted to APHIS, industry stakeholders applauded the Agency’s proposed rule as underscoring the need to promote innovation in biotechnology and for proposing to ease regulation of gene-edited products. But at the same time, industry called out a number of proposed revisions as improperly expanding USDA’s review process in certain respects which could effectively hamstring developers before they can even begin testing products.

In its November 7th withdrawal of the proposed rule, APHIS stated that it is committed to exploring “a full range of policy alternatives” and that the Agency will “re-engage with stakeholders to determine the most effective, science-based approach for regulating the products of modern biotechnology while protecting plant health.” Now that APHIS has decided to go back to the drawing
board, industry has an opportunity to work with APHIS to develop revised requirements to facilitate a regulatory framework that promotes innovation in biotechnology.

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