Resuming Federal Register Publications for Petitions for Nonregulated Status of Genetically Engineered Plants in Accordance with USDA’s Biotechnology Regulations

Print

Under the authority of the Plant Protection Act, the Animal and Plant Health Inspection Service (APHIS) regulates the introduction of organisms altered or produced through genetic engineering (modified organisms) that are plant pests or that there is reason to believe are plant pests. USDA’s biotechnology regulations (7 CFR part 340) allow any person to submit a petition to APHIS seeking a determination that a modified plant should not be subject to the regulations. The regulations state that when APHIS receives a complete petition, it will publish a notice in the *Federal Register* informing the public that it is accepting written comments on the petition for 60 days from the date of the notice. The regulations also state that after receiving comments, APHIS will make its decision available in the *Federal Register*. Following these regulations, APHIS historically published its draft plant pest risk assessment and a draft environmental document along with the petition for the first *Federal Register* posting, and its final plant pest risk assessment and environmental document with APHIS’ determination in the second *Federal Register* posting.

On March 6, 2012, APHIS adjusted its practice for publishing petitions and supporting documents in the *Federal Register* and began publishing as many as three *Federal Register* notices for certain petitions depending on whether the petition raised substantive new issues. *See* 77 Fed. Reg. 13,258 (March 6, 2012) ("Biotechnology Regulatory Services; Changes Regarding the Solicitation of Public Comment for Petitions for Determinations of Nonregulated Status for Genetically Engineered Organisms"). At that time, APHIS anticipated that enabling earlier public engagement on the petition would help scope the subsequent analyses, including whether the petition raised substantive new issues. APHIS has now evaluated the 34 petitions reviewed under the process announced in 2012 and found that the first comment period has not yielded comments that significantly impacted the scoping for APHIS' evaluation.

Given this experience, APHIS will not use the process outlined in the March 6, 2012 *Federal Register* notice (77 Fed. Reg. 13258). APHIS will institute the following process consistent with USDA's biotechnology regulations. Once APHIS deems a petition to be complete, it will publish a notice in the *Federal Register* making the petition and APHIS' draft evaluation documents available for public comment for 60 days. After the comment period closes, APHIS will review the comments and any other relevant information it receives during the comment period, complete its evaluation documents and make a final determination. APHIS will respond to the petitioner either approving or denying the petition and publish a notice in the *Federal Register* announcing the regulatory status of the modified plant, along with the availability of the regulatory determination and final supporting documents.