APHIS Announces Update to Practices for Reviewing Petitions Seeking a Determination of Nonregulated Status for Organisms Altered or Produced Through Genetic Engineering

Media Contact: richard.s.coker@usda.gov

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) is updating its practices for reviewing petitions seeking a determination of nonregulated status for organisms altered or produced through genetic engineering (modified organisms) under 7 C.F.R. part 340. We are making these updates to ensure APHIS' petition process aligns with recent developments related to the National Environmental Policy Act (NEPA) and APHIS' authority in the Plant Protection Act (PPA).

APHIS developed 7 C.F.R. part 340, including the petition process, under its plant pest authority in the PPA. To grant a petition for nonregulated status, APHIS reviews factual and scientific information and must find the modified organism is unlikely to pose a greater plant pest risk relative to an appropriate comparator and, thus, is not subject to regulation as a plant pest under 7 C.F.R. part 340, and the plant pest

provisions of the PPA. *See* 7 C.F.R. § 340.6(b), (c) (detailing information included and considered in a petition). Once APHIS determines a modified organism is not a plant pest subject to the regulations at 7 C.F.R. part 340, the inquiry ends. APHIS has neither discretion to regulate the modified organism nor to impose any conditions on it under 7 C.F.R. part 340. As such, APHIS does not have or retain any jurisdiction of the modified organism as a plant pest under 7 C.F.R. part 340. *See Center for Food Safety v. Vilsack*, 718 F.3d 829, 842 (9th Cir. 2013) ("once APHIS concluded that [the modified organism] was not a plant pest . . . the agency had no jurisdiction to continue regulating the crop" and "deregulation . . . was thus a nondiscretionary act"). APHIS also has no ability under the plant pest provisions of the PPA to consider or mitigate environmental impacts once it has determined that the modified organism does not pose a greater plant pest risk relative to an appropriate comparator and thus not subject to the regulations at 7 C.F.R. part 340. Although APHIS has historically assessed the environmental impacts of granting petitions for nonregulated status as part of its petition process (77 Fed. Reg. 13258 (March 6, 2012)), the agency's practice of conducting NEPA analysis does not mean it is, in fact, obligated to conduct a NEPA analysis.

Recent developments related to NEPA support this view. In 2023, Congress amended NEPA, through the Fiscal Responsibility Act (Pub. L. No. 118-5, § 321(b)), to add a section describing the circumstances under which federal agencies are not required to prepare environmental analyses: "An agency is not required to prepare an environmental document with respect to a proposed agency action if . . . (4) the proposed agency action is a nondiscretionary action with respect to which such agency does not have authority to take environmental factors into consideration in determining whether to take the proposed action." 42 U.S.C. § 4336(a)(4). As stated above, once APHIS determines through the petition process that a modified organism does not pose a greater plant pest risk relative to an appropriate comparator, APHIS must deregulate the modified organism and does not have authority to consider or mitigate environmental impacts.

Even more recently, on May 29, 2025, the U.S. Supreme Court reiterated the "NEPA canon" that "'where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered the legally relevant 'cause' of the effect.'" *Seven Cnty. Infrastructure Coal. v. Eagle Cnty., Colorado,* No. 23-975, 2025 WL 1520964, at *11 (May 29, 2025) (quoting *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 770 (2004)). In other words,

if the statute at issue "precludes consideration of a particular issue, the agency may set it aside for purposes of its NEPA review." *Id.* at *17 (Sotomayor, J., concurring). What follows from this NEPA canon is that "[t]he greater an agency's authority to consider and prevent environmental impacts in its decision-making process, the greater its duty under NEPA to consider those impacts, and vice versa." *Id*. at *17 n.3 (Sotomayor, J., concurring).

Accordingly, in line with the decision from *Seven County*, there is no role for NEPA in the agency's response to a petition for determination of nonregulated status because APHIS has no ability to consider any factors or environmental impacts beyond the factual and scientific information that is relevant to determining whether an article is a "regulated article" under 7 C.F.R. § 340.1. "NEPA requires consideration of environmental impacts only if such consideration would result in information on which the agency could act." *Id*. at *16 (Sotomayor, J., concurring). Here, APHIS only has discretion and authority to act on factual and scientific information related to whether a modified organism is a plant pest. For these reasons, APHIS is announcing that it will no longer prepare a NEPA analysis to accompany its review of petitions seeking a determination of nonregulated status.

Beginning today, when evaluating a petition seeking a determination of nonregulated status that meets the information requirements in 7 C.F.R. § 340.6, APHIS will first determine whether a modified organism is subject to regulation under 7 C.F.R. part 340 and the plant pest provisions in the PPA. If APHIS determines that a modified organism is unlikely to pose a greater plant pest risk relative to its comparator and, as such, is not a plant pest, APHIS will end its review and, because it lacks jurisdiction over the modified organism, APHIS must issue a determination that the modified organism is not subject to 7 C.F.R. part 340. APHIS will continue to publish its draft reviews for petitions in the *Federal Register* for public review and comment before making a final determination about a modified organism's regulatory status.

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