BIOTECHNOLOGY RULE ON PIPs & E.O. 14081

ISSUE SUMMARY:

EPA regulates pesticides created through biotechnology as a part of its jurisdiction over all pesticides sold or distributed in the United States. As such, EPA has developed rules to facilitate the regulation of genetically engineered biological pesticides. EPA's authority to regulate pesticides and pesticide residues falls under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). Plant-incorporated protectants (PIPs) are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance.

Biotech developers requested that EPA more clearly focus its interpretation of PIPs on those that prevent, destroy, repel, or mitigate a pest and consider exempting additional categories of PIPs beyond those identified in the May 2023 final rule. To that end, EPA provided technical assistance to Congress for its proposed changes to FIFRA, which were captured in the House mark-up of the draft farm bill (May 2024). EPA plans to issue future guidance and/or rulemaking consistent with the proposed changes.

Executive Order 14081 directed EPA, FDA, and USDA to improve how they implement the Coordinated Framework for the Regulation of Biotechnology products. In December 2023, the National Security Commission on Emerging Biotechnology (NSCEB) issued an interim report with additional recommendations. In response, on May 8, 2024, EPA, FDA, and USDA issued a joint regulatory plan to update, streamline, and clarify their regulations and oversight for biotechnology products. Among the first goals, EPA and USDA plan to clarify the regulatory oversight and data requirements and, where possible, reduce duplicative review for modified microbes used for agricultural purposes. One deliverable of this effort, made on October 2, 2024, is a single point of entry web-based tool that informs developers which agency may regulate a given product category based on a series of product-specific questions, Interactive Tool for Genetically Modified Microorganisms.

UPCOMING MILESTONES:

- Implementation of Executive Order (E.O.) 14081 – Ongoing
- PIP guidance and/or rulemaking preparation – Ongoing

BACKGROUND:

- The federal government established the Coordinated Framework for the Regulation of Biotechnology in 1986 and most recently updated it in 2017. It describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology products, including how EPA, the FDA, and USDA share responsibility for regulating many of the products of biotechnology in the United States.
- In May 2023, EPA released a final rule exempting two categories of plant-incorporated protectants (PIPs) created using genetic engineering from registration requirements under FIFRA and from the food or feed residue tolerance requirements under FFDCA.
- Under section 8 of E.O. 14081, EPA, FDA, and USDA issued three reports: 1) *Report on Stakeholder Outreach Related to the Ambiguities, Gaps, Uncertainties in Regulation of Biotechnology Under the Coordinated Framework* (March 2023), 2) a report on plain-language information on agency roles, responsibilities, and processes for the regulation of products of biotechnology (November 2023), and 3) *Plan for Regulatory Reform under the Coordinated Framework for the Regulation of Biotechnology* (May 2024).
- Congress's National Security Commission on Emerging Biotechnology (NSCEB) Interim Report issued in December 2023 recommended creating an office to coordinate biotechnology product review at the federal

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level. EPA, FDA, and USDA provided feedback that this was unnecessary and would slow down the coordination.

KEY EXTERNAL STAKEHOLDERS:

☒ Congress ☒ Industry ☒States ☐ Tribes ☒ Media ☒ Other Federal Agency
☒ NGO ☐ Local Government ☐ Other:_____

Stakeholder interest has focused on support for regulatory relief.

MOVING FORWARD:

LEAD OFFICE/REGION: OCSPP OTHER KEY OFFICES/REGIONS: OGC, OECA, OP