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VIA REGULATIONS.GOV

Ms. Katherine Harrigan
Division of Natural Resources and Conservation Planning
National Wildlife Refuge System
U.S. Fish and Wildlife Service
Katherine_harrigan@fws.gov
703-358-2440

RE: Proposed Rule, Docket No. 2022-HQ-HWRS-2022-0106 “National Wildlife Refuge System: Biological Integrity, Diversity, and Environmental Health.”

Dear Ms. Harrigan,

The Biotechnology Innovation Organization (BIO) is pleased to comment on the U.S. Fish and Wildlife Service’s (“FWS”) proposed rulemaking and proposed policy update, “National Wildlife Refuge System: Biological Integrity, Diversity, and Environmental Health” (“BIDEH Proposed Rule” or “Proposed Rule”).

BIO represents more than 1,000 members in a biotech ecosystem with a central mission—to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the agriculture, energy, manufacturing, and health sectors to improve the lives of people and the health of the planet. BIO members are involved in the research and development of innovative agricultural, industrial, and environmental biotechnology products. BIO is committed to speaking up for the millions of families around the globe who depend on our success. BIO promotes the safety and benefits of genetically engineered (“GE”) organisms developed through agricultural biotechnology, advocates for scientifically-based regulatory approaches for these organisms, and supports the concurrent cultivation of both conventional and organic crops.

FWS manages more than 150 million acres of public lands and waters dedicated to habitat and wildlife conservation. A goal of FWS is to restore national refuge lands to their natural state, but many national refuges have had infestations of invasive weeds and/or other undesirable non-native plants that, left unchecked, would outcompete native plants and frustrate habitat restoration efforts. To address that problem, FWS has long implemented a targeted effort for



certain refuges allowing row crop farming (known as “cooperative farming”) prior to restoration, which makes the land hospitable to native plant species by controlling weeds and other undesirable plants. The National Wildlife Refuge System Administration Act, as amended (“Refuge Act”) allows FWS to authorize cooperative farming on refuges. In multiple circumstances, professional refuge managers have determined that successful habitat restoration depends on planting certain GE plants that facilitate the use of highly effective herbicides with a more benign environmental profile approved for use in refuges to control weeds.

GE organisms have been widely grown in the United States and globally for nearly three decades, and their benefits have been thoroughly studied. Currently, more than 90% of U.S. acres of corn, soy, and cotton are planted to genetically engineered varieties—a percentage consistent since the late 1990’s.¹

Among the many documented² benefits of these products are:

- Increased use of conservation tillage, reduction in soil erosion, and improved water quality
- More effective weed control
- Significant reduction in the application of insecticides and increased use of integrated pest management
- Increased farmer income and worker safety
- Increased insect biodiversity in and around fields
- Increased food and feed safety due to reduced presence of fungal toxins.

The research, development, and widespread commercialization of agricultural biotechnology products in the United States occurs under the auspices of the Coordinated Framework for the Regulation of Biotechnology.³ This science-based regulatory framework, most recently updated in 2017, provides robust and appropriate oversight of these products by the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), helping encourage innovation while ensuring safety to human and animal health

¹ <https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>

² See for example, the review conducted by the U.S. National Academies of Sciences, Engineering, and Medicine (NASEM). 2016. *Genetically Engineered Crops: Experiences and Prospects*.

³ *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*, 51 Fed. Reg. 23,352 at 23,366 (June 26, 1986).



and the environment, including the issues of importance to FWS as it makes decisions on how to manage refuge lands.⁴ These sister agencies, recognized as the relevant expert agencies under the Coordinated Framework, have already undertaken rigorous science-based rulemakings and analyses of the health and safety of GE organisms on the market today. Based on years of experience and science-based evaluation, GE organisms have been found to be as safe as their conventional counterparts.

Indeed, the Proposed Rule recognizes the very principles established in the Coordinated Framework, namely, that decisions be science-based:

G. Use best available science. Refuge Managers must use the best available scientific information to inform their sound professional judgment, in accordance with the Department of the Interior’s Scientific Integrity Policy (305 DM 3), Service policy on Scientific Integrity and Scholarly Conduct (212 FW 7) and Data Management (274 FW 1), and the Service’s Information Quality Guidelines. Evidence-based decisions guided by the best available science and data, as well as Indigenous Knowledge and peer review as prescribed in this policy, help ensure management actions benefit wildlife conservation.

BIDEH Proposed Rule at 7. Unfortunately, FWS then directly contradicts the scientifically supported policies and decisions of USDA, EPA and FDA by contending without any scientific support that “[GE organisms] can have unpredictable and unintended effects on species and ecosystems....” BIO strongly encourages FWS to revisit its approach.

It is incumbent on FWS to base its management decisions—including those related to cooperative farming—on science-based, peer-reviewed evidence and consistent with the policies and decisions of the expert Federal agencies charged with reviewing GE organisms for safety: EPA , USDA and FDA. FWS cites no evidence, let alone information that could be

⁴ *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23,302 (June 26, 1986) (“1986 Coordinated Framework”); *Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment*, 57 Fed. Reg. 6,753 (Feb. 27, 1992) (“1992 Update to Coordinated Framework”); *Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology* (Jan. 2017) (“2017 Update to Coordinated Framework”) (available at https://usbiotechnologyregulation.mrp.usda.gov/2017_coordinated_framework_update.pdf) (collectively “Coordinated Framework”).



considered the best available science, to substantiate its claim that GE organisms can have “unpredictable and unintended effects on species and ecosystems.” On the contrary, the Federal agencies charged with reviewing the safety of GE organisms have not found unintended or unpredictable effects after 30 years of experience reviewing these products, and these crops are currently planted on millions of acres in the United States.

FWS’s Proposed Rule would upset both the robust regulatory framework already in place for GE organisms under the Coordinated Framework and the flexibility that refuge managers have historically utilized to enable planting of GE organisms where beneficial. A national policy that can lead to prohibiting use of GE organisms upends the applicable regulatory framework and undermines the health and safety assessments undertaken by FWS’s sister agencies, fostering the kind of regulatory inconsistency the Coordinated Framework was specifically designed to prevent.⁵

Indeed, FWS recognizes “that scientific advances in genetic engineering may provide vital management tools to improve species conservation and ecosystem health, particularly in response to climate change or other anthropogenic change, invasive species, and other stressors.” These findings are consistent with the FWS National Wildlife Refuges in the Southeast Region finalization of a “Programmatic Environmental Assessment for use of Genetically Engineered Agricultural Crops for Natural Resource Management on National Wildlife Refuges in the Southeastern United States.” The 2020 PEA provided a thorough analysis of the potential environmental consequences of the proposed alternative (allow the use of GE organisms on NWRs) and the no action alternative based on an extensive collection of current scientific literature, and they concluded that the proposed alternative met the Services’ purpose and needs. The PEA describes the environmental impact of each alternative and the ability to meet wildlife management objectives, North American Waterfowl Management Plan objectives, and NWR comprehensive Conservation Plans and Habitat Management Plans, among others. FWS fails to square these prior detailed findings with its current Proposed Rule.

The Proposed Rule is further untethered from Executive Order 14081 and the National Security Commission on Emerging Biotechnology Interim Report,⁶ which encourages a science- and risk-

⁵ See 1986 Coordinated Framework (explaining that “a common scientific approach is essential to a coordinated federal regulatory framework”).

⁶ Exec. Order No. 14081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, 87 Fed. Reg. 56,849 (Sept. 15, 2022), *available at*



based regulatory scheme that supports advances in biotechnology. Specifically, the EO aims to “streamline regulations in service of a science- and risk-based, predictable, efficient, and transparent system to support the safe use of products of biotechnology.” The EO further reaffirmed that “biotechnology and biomanufacturing can also be used to achieve our climate and energy goals, improve food security and sustainability, secure our supply chains, and grow the economy across all of America.”⁷ The NSC Interim Report likewise recognized that “[f]ederal coordination is increasingly imperative as biotechnology advances,” and aims to improve coordination among federal agencies and with the research community alike, to support continued research and development in biotechnology and reduce unnecessary regulatory barriers.⁸ A policy that can lead to prohibitions on use of GE organisms is neither science- nor risk-based and contradicts the ubiquitous adoption of GE organisms in modern agriculture over the last three decades. It also perpetuates the misinformation and mistrust of science that undermines collective decision-making important to human health, the environment, and a sustainable and equitable future. FWS and its sister agencies should present a united front on the regulation and undisputed safety of authorized products created through biotechnology for use in agriculture. Any rule updating the Refuge System regulations should maintain the current policy flexibility for refuge managers to make case-by-case evaluations while assuring compliance with other relevant legal authorities. If finalized, the rule should also reinforce—not undermine—the unanimous conclusions reached by the expert federal agencies that GE plants are not inherently riskier than plants created through conventional breeding methods.⁹

The Proposed Rule is particularly inappropriate in light of its stated purpose of providing flexibility to refuge managers to address threats affecting refuge fish, wildlife, plants, and habitats. Despite the widely held scientific consensus that GE organisms are no riskier than their conventional counterparts, the Proposed Rule needlessly hamstring the ability of refuge

<https://www.govinfo.gov/content/pkg/FR-2022-09-15/pdf/2022-20167.pdf>; Nat’l Security Comm’n on Emerging Biotechnology Interim Report (Dec. 2023), available at <https://www.biotech.senate.gov/wp-content/uploads/2024/01/Biotech-Commission-Dec2023-Report.pdf>

⁷ *Id.*

⁸ NSC Interim Report at 21-22.

⁹ See 1992 Update to Coordinated Framework (“Exercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that [a biotechnology product] has been modified by a particular process or technique.”); 2017 Update to Coordinated Framework (explaining that “the current Federal regulatory system for biotechnology products effectively protects health and the environment” and “[e]xercise of agency oversight within the scope afforded by statutes should be commensurate with the risk posed by the introduction of the biotechnology product and should not turn on the fact that it was created or has been altered by a particular process or technique.”).



managers to use the best available science to the fullest extent, without any scientific basis for doing so.¹⁰ For instance, the Proposed Rule directs refuge managers to “promote and maintain soil health” as “vital for sustaining and restoring refuge habits,” yet the Proposed Rule would inhibit refuge managers from utilizing federally approved microbial products that are specifically designed to promote soil health. Rather than “empower refuge managers to uphold the Refuge System’s conservation mission and achieve refuge purposes in the face of complex threats to wildlife and their habitat,”¹¹ the Proposed Rule would impose unnecessary rigidity that is contradicted by the comprehensive risk-based scientific analyses conducted by other federal agencies and limits refuge managers’ options to use all resources at their disposal to preserve National Wildlife Refuge Lands. We therefore urge FWS to pursue a different course with respect to its Proposed Rule by enabling a robust toolkit for refuge managers in making decisions regarding conservation and preservation.

Thank you for the opportunity to provide comments on this proposed rule. Please feel free to contact me directly if you have any questions about our comments.

Sincerely,

A handwritten signature in black ink that reads "Leah Buchman". The signature is written in a cursive, flowing style.

Leah Buchman, Ph.D.
Regulatory Policy, Agriculture & Environment
Biotechnology Innovation Organization

¹⁰ See, e.g., *Movement of Certain Genetically Engineered Organisms*, 85 Fed. Reg. 29,790 (May 18, 2020) (“ A key conclusion from [National Resource Council] reports, taken together, is that it is not the process of genetic engineering per se that imparts the risk[.]”).

¹¹ *National Wildlife Refuge System; Biological Integrity, Diversity, and Environmental Health*, 89 Fed. Reg. 7,345 at 7,346 (February 2, 2024).