BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0021]

Bayer; Notice of Intent to Prepare an Environmental Impact Statement for Determination of Nonregulated Status for Maize Developed Using Genetic Engineering for Dicamba, Glufosinate, Quizalofop, and 2,4-Dichlorophenoxyacetic Acid Resistance, with Tissue-specific Glyphosate Resistance Facilitating the Production of Hybrid Maize Seed

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) plans to prepare an environmental impact statement (EIS) regarding a request from Bayer seeking a determination of nonregulated status for maize developed using genetic engineering for dicamba, glufosinate, quizalofop, and 2,4-dichlorophenoxyacetic acid resistance with tissue-specific glyphosate resistance facilitating the production of hybrid maize seed. APHIS is requesting public comment to help identify alternatives, and relevant information, studies, and/or analyses APHIS should consider in the EIS.

DATES: We will consider all comments that we receive on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to www.regulations.gov. Enter APHIS-2020-0021 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0021, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The petition and any comments we receive on this docket may be viewed at www.regulations.gov or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; phone (301) 851-3892; email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Need for the Proposed Action

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq*.), the regulations in 7 CFR part 340, "Movement of Organisms Modified or Produced Through Genetic Engineering," regulate, among other things, the importation, interstate movement, or release into the environment of organisms modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.

The petition for nonregulated status described in this notice is being evaluated under the version of the regulations effective at the time that it was received. Animal and Plant Health Inspection Service (APHIS) issued a final rule, published in the *Federal Register* on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034)[1], revising 7 CFR part 340; however, the final rule is being implemented in phases. The new Regulatory Status Review (RSR)

[1]To view the final rule, go to www.regulations.gov and enter APHIS-2018-0034 in the Search field.

process, which replaces the petition for determination of nonregulated status process, became effective on April 5, 2021 for corn, soybean, cotton, potato, tomato, and alfalfa. The RSR process is effective for all crops as of October 1, 2021. However, "[u]ntil RSR is available for a particular crop…APHIS will continue to receive petitions for determination of nonregulated status for the crop in accordance with the [legacy] regulations at 7 CFR 340.6." (85 FR 29815). This petition for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was received by APHIS December 11, 2019.

Bayer has submitted a petition (APHIS Petition Number 19-316-01p) to APHIS seeking a determination of nonregulated status for a maize[2] (identified as MON 87429) which has been developed using genetic engineering for dicamba, glufosinate, quizalofop, and 2,4-dichlorophenoxyacetic acid (2,4-D) resistance with tissue-specific glyphosate resistance facilitating the production of hybrid maize seed. The Bayer petition stated that MON 87429 maize is unlikely to pose a plant pest risk and, therefore, should not be regulated under APHIS' regulations in 7 CFR part 340.

According to our process[3] for soliciting public comment when considering petitions for determination of nonregulated status of regulated organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. On May 8, 2020, APHIS announced the availability of the Bayer petition for public comment in the *Federal Register*[4] (85 FR 27354-27355, Docket No. APHIS-2020-0021). APHIS solicited comments on the petition for 60 days

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[2] Maize is the common botanical term used globally for the cereal plant Zea mays. In the United States, maize is also referred to as corn. Both terms are used interchangeably in this document. For consistency with the common plant name and petition, APHIS uses the term maize, but also refers to corn in certain instances, such as in reference to food products.

[3] On March 6, 2012, APHIS published in the Federal Register (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to www.regulations.gov and enter APHIS-2011-0129 in the Search field.

[4] To view the notice, its supporting documents, or the comments that we received, go to www.regulations.gov and enter APHIS-2020-0021 in the Search field.

ending July 7, 2020, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. We received 4,112 comments by the close of the comment period.

Based on comments received on the petition and new information that APHIS became aware of after our May 8, 2020 *Federal Register* publication, we have determined that an environmental impact statement (EIS), as opposed to an environmental assessment (EA), is the appropriate National Environmental Policy Act (NEPA) analysis for the Bayer petition. Specifically, APHIS became aware of new information regarding potential issues with dicamba spray drift and volatilization and associated potential economic impacts, and the Environmental Protection Agency's (EPA) issuance of a cancellation order on June 8, 2020, for three products (Xtendimax with Vaporgrip Technology, EPA Reg. No. 524-6 17, Engenia, EPA Reg. No. 7969-345, and FeXapan, EPA Reg. No. 352-9 13) that contain the active ingredient dicamba. Additionally, on October 27, 2020, EPA approved limited 5-year registrations for two end-use dicamba products and the extension of the registration for one dicamba product (EPA Reg. Nos. 100-1623, 264-1210, and 7969-472).

As part of our evaluation of Bayer's petition, we are planning to prepare an EIS to consider the potential impacts of a determination of nonregulated status for MON 87429 maize on the human environment.[5]

The EIS is being prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq*.), (2) the Council on Environmental Quality's NEPA-implementing regulations (40 CFR parts 1500-1508), (3) USDA's NEPA-implementing regulations (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

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[5] Human environment means comprehensively the natural and physical environment and the relationship of present and future generations of Americans with that environment. Impacts/effects include ecological (such as effects on natural resources, and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic (such as the effects on employment), social, or health effects (see 40 CFR 1508.1).

Proposed Action and Alternative the EIS will Consider

The EIS will analyze both the preferred alternative—approve Bayer's petition for a determination of nonregulated status for MON 87429 maize—and the no action alternative—deny the petition for nonregulated status—both of which will be fully considered. APHIS has developed a list of topics for analysis in the EIS based on issues identified in prior public comments on the petition, prior EAs/EISs for maize varieties developed using genetic engineering, public comments submitted for other EAs/EISs evaluating petitions for nonregulated status, the scientific literature on agricultural biotechnology, and issues identified by APHIS specific to wild and cultivated *Zea mays* (maize) and *Tripsacum* species. The following topics were identified as relevant to the scope of analysis: Agricultural production (acreage and areas of U.S. corn production, agronomic practices and inputs); physical environment (soils, water resources, air quality); biological resources (soil biota, animal communities, plant communities, herbicide-resistant weeds, gene flow and weediness, biodiversity); public health and worker safety; animal health and welfare; and socioeconomic considerations. In addition, potential impacts on threatened and endangered species will be evaluated.

Summary of Potential Impacts

APHIS anticipates the primary potential impacts of the proposed action will be on agronomic practices and inputs. Agronomic impacts may include changes in: Herbicide use in U.S. corn crops, weed and herbicide resistant (HR) weed management practices, and the control of HR weeds. In recent years, the use of dicamba-based herbicides has resulted in instances of significant economic impact on neighboring crop and orchard fields because of unintended drift and volatilization of the herbicide. Potential economic impacts associated with the use of dicamba-based herbicides will also be considered.

Anticipated Permits and Authorizations

MON 87429 maize, if deregulated, could be cultivated to produce food, feed, fuel, and industrial products, subject to any EPA and/or U.S. Food and Drug Administration (FDA) requirements under the Coordinated Framework.[6] For example, any pesticide registration and use with MON 87429 maize would be subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and EPA requirements. Any human or animal food derived from MON 87429 maize would be subject to the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq*.) and FDA requirements. Bayer may voluntarily consult with the FDA to ensure compliance with the FFDCA.

Public Scoping Process

As previously discussed, APHIS seeks public comment on petitions deemed complete through notices published in the *Federal Register*. In accordance with our process, on May 8, 2020, APHIS solicited comments on the petition for 60 days ending July 7, 2020. We received 4,112 comments on the petition by the close of the comment period from the academic sector, farmers, non-governmental organizations, nonprofit organizations, industry, private citizens, and a tribal nation.

APHIS is seeking additional public comment on this notice of intent to prepare an EIS to help identify potential alternatives, and relevant information, studies, and/or analyses that APHIS should consider in evaluating the potential impacts of the proposed action on the quality of the human environment. Those who have already submitted comments on the Bayer petition need not resubmit—APHIS will consider these comments in development of the EIS. To promote informed NEPA analysis and decision-making, comments should be as specific as possible and explain why the issues raised are important for consideration in the EIS. Comments should include, where possible, references and data sources supporting the information provided in the

[6] See Coordinated Framework. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Biotechnology Regulatory Services, https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/.

comment. We encourage the submission of scientific data, studies, or research to support your comments.

APHIS will accept written comments regarding the EIS for the Bayer petition for a period of 30 days from the date of this notice. The petition is available for public review, and copies are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

Schedule for the Decision-making Process

As part of the decision-making process in responding to the petition, APHIS is preparing an EIS and a Plant Pest Risk Assessment (PPRA). APHIS plans to complete the PPRA within 6 months, and the EIS and record of decision within 2 years of the date of this notice. Note that this schedule is tentative, and the time frame could be extended.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 23rd day of April 2021.

Michael Watson,

Acting Administrator,

Animal and Plant Health Inspection Service.

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