



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2017-0075]

Verdeca LLC; Availability of a Draft Plant Pest Risk Assessment and a Draft Environmental Assessment for Determination of Nonregulated Status of Soybean Genetically Engineered for Yield Increase and Resistance to Glufosinate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service is making available for public comment a draft plant pest risk assessment (PPRA) and a draft environmental assessment (EA) for the new plant variety HB4 soybean designated as event IND-00410-5, which has been genetically engineered for increased yield and resistance to the herbicide glufosinate. We are making the draft PPRA and draft EA available for public review and comment.

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 <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0075>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2017-0075, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0075> or in our reading room, which is located in room 1141 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.

The petition is also available on the APHIS website at: http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS petition 17-223-01p.

FOR FURTHER INFORMATION CONTACT: Dr. Subray Hegde, Chief, Plants Branch, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3901; email: subray.hegde@usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION: 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, "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," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is

reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 17-223-01p) from Verdeca LLC (Verdeca), seeking a determination of nonregulated status for the new plant variety called HB4 soybean (*Glycine max*) designated as event IND-00410-5 (also OECD unique identifier IND-00410-5), which has been genetically engineered for increased yield. The Verdeca petition states that information collected during field trials and laboratory analyses indicates that HB4 soybean is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process¹ for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice² published in the *Federal Register* on November 15, 2017 (82 FR 52873-52874, Docket No. APHIS-2017-0075), APHIS announced the availability of the Verdeca petition for public comment. APHIS solicited comments on the petition for 60 days ending on January 16, 2018, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine

¹ 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 <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

² To view the notice, the petition, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0075>.

should be considered in our evaluation of the petition. APHIS received five comments on the petition (a sixth comment addressing an entirely different topic was erroneously submitted). Of the five comments, four were opposed to the deregulation and one comment was in support. In May 2018, Verdeca provided supplemental information to APHIS informing us that its HB4 soybean variety also had field-level resistance to the herbicide glufosinate. APHIS reviewed the supplemental information and has included it in its analyses in the draft plant pest risk assessment (PPRA) and draft environmental assessment (EA). We are making the supplemental information available along with the draft PPRA and draft EA for public comment.

After public comments are received on a completed petition, APHIS evaluates those comments and then provides a second opportunity for public involvement in our decisionmaking process. According to our public review process (see footnote 1), the second opportunity for public involvement follows one of two approaches, as described below.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises no substantive new issues, APHIS will follow Approach 1 for public involvement. Under Approach 1, APHIS announces in the *Federal Register* the availability of APHIS' preliminary regulatory determination along with its draft EA, preliminary finding of no significant impact (FONSI), and its draft PPRA for a 30-day public review period. APHIS will evaluate any information received related to the petition and its supporting documents during the 30-day public review period.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues, APHIS will follow Approach 2. Under Approach 2, APHIS first solicits written comments from the public on a draft PPRA and draft EA for a 30-day comment period through the publication of a *Federal Register* notice. Then, after reviewing and evaluating the comments on the draft PPRA and draft EA and other information, APHIS will revise the PPRA as necessary and prepare a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a FONSI or a notice of intent to prepare an environmental impact statement). For this petition, we are using Approach 2.

APHIS has prepared a draft PPRA and has concluded that HB4 soybean designated as event IND-00410-5, which has been genetically engineered for increased yield and resistance to the herbicide glufosinate, is unlikely to pose a plant pest risk. In section 403 of the Plant Protection Act, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has also prepared a draft EA in which we present two alternatives based on our analysis of data submitted by Verdeca, a review of other scientific data, field tests conducted under APHIS oversight, and comments received on the petition. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of HB4 soybean designated as event IND-00410-5, or (2) make a determination of nonregulated status of HB4 soybean designated as event IND-00410-5.

The draft EA was prepared in accordance with (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) U.S. Department of Agriculture regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In accordance with our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments on our draft PPRA and our draft EA regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 30 days from the date of this notice. Copies of the draft PPRA and the draft EA, as well as the previously published petition, are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

After the 30-day comment period closes, APHIS will review and evaluate any information received during the comment period and any other relevant information. After reviewing and evaluating the comments on the draft PPRA and the draft EA and other information, APHIS will revise the PPRA as necessary and prepare a final EA. Based on the final EA, APHIS will prepare a NEPA decision document (either a FONSI or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS will furnish a response to the petitioner, based on APHIS' conclusions in the PPRA, either approving or

denying the petition. APHIS will also publish a notice in the *Federal Register* announcing the regulatory status of the GE organism and the availability of APHIS' final PPRA, EA, FONSI, and our regulatory determination.

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 7th day of March 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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