DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service

Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a maize line developed by Pioneer Hi-Bred International, Inc., designated as maize event DP–004114–3, has been genetically engineered to be resistant to certain lepidopteran and coleopteran pests and to the herbicide glufosinate, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Pioneer Hi-Bred International, Inc., in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notice announcing our preliminary determination, and our responses to those comments may be viewed at http://www.regulations.gov/

DATES: Effective Date: June 20, 2013.

ADDRESSSES: Supporting documents, comments we received on our previous notice announcing our preliminary determination, and our responses to those comments may be viewed at http://www.regulations.gov/

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Stankiewicz Gabel, Chief, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3927, email: rebecca.l.stankiewicz-
gabel@aphis.usda.gov. To obtain copies of the documents referred to in this notice, contact Ms. Cindy Eck at (301) 851–3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

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 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. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS received a petition (APHIS Petition Number 11–244–01p) from Pioneer Hi-Bred International, Inc., (Pioneer) of Johnston, IA, seeking a determination of nonregulated status for maize (Zea mays) designated as maize event DP–004114–3 (event 4114), which has been genetically engineered to be resistant to certain lepidopteran pests, including European corn borer (Ostrinia nubilalis), and certain coleopteran pests, including western corn rootworm (Diabrotica virgifera virgifera), as well as to the herbicide glufosinate. The petition stated that this maize is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

In a notice1 published in the Federal Register on February 27, 2013 (78 FR 13312–13313, Docket No. APHIS–2012–0026), APHIS announced the availability of the Pioneer petition, a plant pest risk assessment (PPRA), and a draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition, whether the subject maize is likely to pose a plant pest risk, the draft EA, and the PPRA for 60 days ending on April 29, 2013. APHIS received 12 comments during the comment period: Several of these comments included electronic attachments consisting of a consolidated document of identical letters for a total of 573 comments. Issues raised during the comment period include potential effects on human and animal health and non-target organisms, herbicide resistance, corn rootworm resistance, effects of stacked genes, and the length of the comment period. APHIS has addressed the issues raised during the comment period and has provided responses to comments as an attachment to the finding of no significant impact.

National Environmental Policy Act

To provide the public with documentation of APHIS’ review and analysis of any potential environmental impacts associated with the determination of nonregulated status of Pioneer’s maize event 4114, an EA has been prepared. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (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) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS’ NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent

1 To view the notice, petition, draft EA, the PPRA, and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2012–0026.
scientific data, APHIS has reached a finding of no significant impact with regard to the preferred alternative identified in the EA.

**Determination**

Based on APHIS’ analysis of field and laboratory data submitted by Pioneer, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS’ response to those public comments, APHIS has determined that Pioneer’s maize event 4114 is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain genetically engineered organisms.

Copies of the signed determination document, as well as copies of the petition, PPRA, EA, finding of no significant impact, and response to comments, are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

**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 14th day of June 2013.

Kevin Shea,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013–14705 Filed 6–19–13; 8:45 am]

**BILLING CODE 3410–34–P**

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**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**


**Codex Alimentarius Commission:**

**Meeting of the Codex Committee on Residues of Veterinary Drugs in Food**

**AGENCY:** Office of the Under Secretary for Food Safety, USDA.

**ACTION:** Notice of public meeting and request for comments.

**SUMMARY:** The Office of the Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA) are sponsoring a public meeting on August 5, 2013. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States positions that will be discussed at the 21st Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) of the Codex Alimentarius Commission (Codex), which will be held in Minneapolis, Minnesota from August 26–30, 2013. The Under Secretary for Food Safety and the Food and Drug Administration recognize the importance of providing interested parties the opportunity to obtain background information on the 21st Session of CCRVDF, and to address items on the agenda.

**DATES:** The public meeting is scheduled for Monday, August 5, 2013 from 1:00–4:00 p.m.

**ADDRESSES:** The public meeting will be held at the Jamie L. Whitten Building, United States Department of Agriculture, 1400 Independence Ave. Room 107–A, Washington, DC 20250. Documents related to the 21st Session of CCRVDF will be accessible via the World Wide Web at the following address: http://www.codexalimentarius.org/meetings-reports/en/.

Kevin Greenlees, U.S. Delegate to the 21st Session of the CCRVDF, invites U.S. interested parties to submit their comments electronically to the following email address: Kevin.Greenlees@fda.hhs.gov.

**Call-In Number:** If you wish to participate in the public meeting for the 21st Session of the CCRVDF by conference call, please use the call-in number and participant code listed below:

- Call-in Number: 1–888–858–2144.
- Participant code: 6208658.

**FOR FURTHER INFORMATION ABOUT THE 21ST SESSION OF THE CCRVDF CONTACT:**

Kevin Greenlees, Senior Advisor for Science and Policy, Office of New Animal Drug Evaluation, HFV–100, Food and Drug Administration, Center for Veterinary Medicine, 7520 Standish Place, Rockville, MD 20855, Telephone: (240) 276–8214, Fax: (240) 276–9538, Email: Kevin.Greenlees@fda.hhs.gov.

**FOR FURTHER INFORMATION ABOUT THE PUBLIC MEETING CONTACT:** Kenneth Lowery, U.S. Codex Office, 1400 Independence Ave. SW., Room 4861, Washington, DC 20250, Telephone: (202) 690–4042, Fax: (202) 720–3157, Email: Kenneth.Lowery@fsis.usda.gov.

**SUPPLEMENTARY INFORMATION:**

**Background**

The Codex Alimentarius (Codex) was established in 1963 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade.

The CCRVDF is responsible for determining priorities for the consideration of residues of veterinary drugs in foods, recommending maximum levels of such substances; developing codes of practice as may be required, and considering methods of sampling and analysis for the determination of veterinary drug residues in foods.

The Committee is hosted by the United States of America.

**Issues To Be Discussed at the Public Meeting**

The following items on the Agenda for the 21st Session of the CCRVDF will be discussed during the public meeting:

- Matters referred by the Codex Alimentarius Commission and other Codex Committees and Task Forces
- Matters arising from FAO/WHO and from the Joint FAO/WHO Expert Committee on Food Additives (JECFA)
- Report on World Organization for Animal Health (OIE) activities, including the harmonization of technical requirements for registration of veterinary medicinal products (VICH)
- Draft Maximum Residue Limits (MRLs) for veterinary drugs (at Step 6)
- Proposed draft MRLs for veterinary drugs (at Step 4)
- Risk Management

Recommendations for Residues of Veterinary Drugs for which no ADI and/or MRLs has been recommended by JECFA due to Specific Human Health Concerns

- Proposed draft guidelines on performance characteristics for multi-residue methods
- Risk Analysis Policy on Extrapolation of MRLs of Veterinary Drugs to Additional Species and Tissues
- Proposed “concern form” for the CCRVDF (format and policy procedure for its use)
- Draft priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA
- Database on countries’ needs for MRLs
- Discussion paper on Guidelines on the Establishment of MRLs or other Limits in Honey
- Other business and future work

Each issue listed will be fully described in documents distributed, or to be distributed, by the Secretariat prior to the Meeting. Members of the public may access or request copies of these documents (see ADDRESSES).

**Public Meeting**

At the August 5, 2013 public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to