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Charlene Parker,

Departmental Information Collection Clearance Officer.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–113–2]

Mycogen Seeds/Dow AgroSciences LLC and Pioneer Hi-Bred International Inc.; Availability of Determination of Nonregulated Status for Genetically Engineered Corn

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Mycogen Seeds/Dow AgroSciences LLC and Pioneer Hi-Bred International Inc. corn designated as corn line DAS–59122–7, which has been genetically engineered for resistance to a corn rootworm complex and for tolerance 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 Mycogen Seeds/Dow AgroSciences LLC and Pioneer Hi-Bred International Inc. in their petition for a determination of non-regulated status, our analysis of other scientific data, and comments received from the public in response to a previous notice announcing the availability of the petition for nonregulated status and an environmental assessment. This notice also announces the availability of our written determination and our finding of no significant impact.

DATE: Effective September 23, 2005.

FOR FURTHER INFORMATION CONTACT: Dr. Michael Watson, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–0486; e-mail: *michael.t.watson@aphis.usda.gov*. To obtain copies of the petition or, the determination, the environmental assessment (EA), or the finding of no significant impact (FONSI) contact Ms. Ingrid Berlanger at (301) 734–4885; e-mail: *ingrid.e.berlanger@aphis.usda.gov*. The petition and the EA, including the FONSI and determination, are also available on the Internet at *http://www.aphis.usda.gov/brs/aphisdocs/03_35301p.pdf* and *http://www.aphis.usda.gov/brs/aphisdocs/03_35301p_ea.pdf*.

SUPPLEMENTARY INFORMATION: 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.

On December 19, 2003, APHIS received a petition (APHIS No. 03–353–01p) from Mycogen Seeds/Dow AgroSciences LLC of Indianapolis, IN, and Pioneer Hi-Bred International of Johnston, IA (Dow AgroSciences/Pioneer), requesting a determination of nonregulated status under 7 CFR part 340 for corn (*Zea mays*) designated as corn line DAS–59122–7, which has been genetically engineered for resistance to corn rootworm and for tolerance to the herbicide glufosinate. The Dow AgroSciences/Pioneer petition states that the subject corn should not be regulated by APHIS because it does not present a plant pest risk.

In a notice published in the **Federal Register** on July 1, 2005 (70 FR 38094–38096, Docket No. 04–113–1), APHIS announced the availability of the Dow AgroSciences/Pioneer petition and an environmental assessment (EA). APHIS solicited comments on whether the subject corn would present a plant pest risk and on the environmental assessment. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject corn and products developed from it.

APHIS received two comments by the close of the comment period on August 30, 2005. One comment was from a trade association, which supported the petition. The other comment was from a private individual who did not support the petition. The response to these comments can be found in an attachment to the finding of no significant impact (FONSI).

APHIS has amended the section of the EA titled ''Potential impacts on threatened and endangered arthropods.'' The amended section includes a reference to a process for assessment of impacts on threatened and endangered species that has been mutually agreed upon by the U.S. Fish and Wildlife Service and APHIS. The change in language merely provides clarity to the reader; it is not substantive and did not change the analysis described in the EA.

As described in the petition, corn line DAS–59122–7 has been genetically engineered to express a plant incorporated protectant (PIP) that controls certain corn rootworm. The PIP is an insecticidal crystal protein (ICP) from *Bacillus thuringiensis* strain PS149B1. The ICP is made of two proteins Cry34Ab1, approximately 14 kDa, and Cry35Ab1, approximately 44 kDa in molecular weight. Transcription of the Cry34Ab1 coding sequence is controlled by the maize ubiquitin promoter (UBI1ZM PRO). Transcription of Cry35Ab1 is controlled by a wheat (*Triticum aestivum*) peroxidase (TA Peroxidase) promoter. The termination sequences for these two genes were derived from the potato (*Solanum tuberosum*) proteinase inhibitor II (PINII). The PIP is expressed throughout the plant and confers resistance to northern corn rootworm (nCRW), western corn rootworm (wCRW), and Mexican corn rootworm (mCRW).

Corn line DAS–59122–7 has also been genetically engineered to express the enzyme phosphinothricin acetyltransferase (PAT), which confers tolerance to the herbicide glufosinate. The expression of the *pat* gene, derived from the bacterium *Streptomyces viridochromogenes*, is under the control of the cauliflower mosaic virus (CaMV) 35S RNA promoter and a CaMV termination sequence (CaMV35S TERM). The DAS–59122–7 corn line was generated through Agrobacterium-mediated transformation of the publicly available corn line Hi-II.

Determination

Based on its analysis of the data submitted by Dow AgroSciences/Pioneer, a review of other scientific data, field tests of the subject corn, and the comments submitted by the public, APHIS has determined the following with respect to corn line DAS–59122–7: (1) It exhibits no plant pathogenic properties; although a plant pathogen was used in the development of this

corn, these plants are not infected by this organism, nor do they contain genetic material from this pathogen that can cause plant disease; (2) it exhibits no characteristics that would cause it to be more weedy than the non-transgenic parent corn line or other cultivated corn; (3) gene introgression from DAS–59122–7 corn into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect genetic diversity of related plants any more than would introgression from traditional corn hybrids; (4) disease and insect susceptibility and compositional profiles of the kernel is similar to non-transgenic corn and should have no adverse impact on raw or processed agricultural commodities; (5) it exhibits no potential to have significant adverse impact on organisms beneficial to agriculture; (6) compared to current agricultural practices, cultivation of DAS–59122–7 should not reduce the ability to control pests and weeds in corn or other crops. In addition to our finding of no plant pest risk, there will be no effect on threatened or endangered species resulting from a determination of non-regulated status for DAS–59122–7 and its progeny.

Therefore, APHIS has concluded that the subject corn and any progeny derived from hybrid crosses with other non-transformed corn varieties will be as safe to grow as corn varieties in traditional breeding programs that are not subject to regulation under 7 CFR part 340. The effect of this determination is that Dow AgroSciences/Pioneer corn line DAS–59122–7 is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340.

Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the subject corn or its progeny. However, importation of corn line DAS–59122–7 and seeds capable of propagation are still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319 and imported seed regulations in 7 CFR part 361.

National Environmental Policy Act

An EA was prepared to examine any potential environmental impacts and plant pest risk associated with the determination of nonregulated status for the Dow AgroSciences/Pioneer corn line DAS–59122–7. 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 that EA, APHIS has reached a FONSI with regard to the determination that Dow AgroSciences/Pioneer corn line DAS–59122–7 and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and FONSI are available from the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Authority: 7 U.S.C. 1622n and 7701–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 3rd day of October 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–20194 Filed 10–6–05; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 05–062–2]

University of Kentucky; Availability of an Environmental Assessment and a Finding of No Significant Impact for Field Tests of Genetically Engineered Neotyphodium

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment for a field trial of genetically engineered strains of an endophytic fungus of perennial ryegrass, *Neotyphodium* sp. isolate Lp1. The fungi have been genetically engineered to disrupt the ergovaline synthesis pathway. The environmental assessment provides a basis for our conclusion that these field tests will not present a risk of introducing or disseminating a plant pest and will not have a significant impact on the quality of the human environment. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared for these field tests.

DATES: A permit may be issued on or after October 7, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Blanchette, Biotechnology Regulatory Services, APHIS, 4700 River Road, Unit 147, Riverdale, MD 20737–1236; (301) 734–5141; e-mail: *michael.p.blanchette@aphis.usda.gov.* To obtain copies of the petition, the environmental assessment (EA), or the finding of no significant impact (FONSI), contact Ms. Ingrid Berlanger at (301) 734–4885; e-mail: *ingrid.e.berlanger@aphis.usda.gov.* The EA and FONSI are also available on the Internet at: *http://www.aphis.usda.gov/brs/aphisdocs/05_15201r_ea.pdf.*

SUPPLEMENTARY INFORMATION: 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.'' A permit must be obtained or a notification acknowledged before a regulated article may be introduced. The regulations set forth the permit application requirements and the notification procedures for the importation, interstate movement, or release into the environment of a regulated article.

On June 1, 2005, the Animal and Plant Health Inspection Service (APHIS) received a permit application (APHIS No. 05–152–01r) from the University of Kentucky, Department of Plant Pathology, for a confined field release of two mutant strains of *Neotyphodium* sp isolate Lp1, which is an endophytic fungus of *Lolium perenne* (perennial ryegrass). These two mutants were generated by inserting a gene construct containing a hygromycin phosphotransferase gene (*hph*) into specific genes in the ergovaline synthesis pathway. The literature is obscure regarding the specific donor of the *hph* gene to the plasmid that was used to create this construct. The identical *hph* gene has been identified in three bacterial species, *Klebsiella* sp., *Streptomyces hygroscopicus,* and *Escherichia coli.* Expression of the *hph* gene is regulated by the *Neurospora crassa* cross-pathway control gene (*cpc-1*) promoter and a transcription termination sequence from the *trpC* gene of *Aspergillus nidulans.*

Strain Lp1–4175 results from an insertion of the *hph* construct in the dimethylallyltryptophan synthase