Notices

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[Docket No. 92-127-4]

Availability of Determination of Nonregulated Status for Virus Resistant Squash

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a genetically

engineered, virus resistant yellow crookneck squash line designated ZW-20 squash 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 the Upjohn Company in its petition for a determination of the regulatory status of ZW-20 squash, an analysis of other scientific data, and our review of comments received from the public regarding the Upjohn petition. This notice also announces the availability of the written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATES: December 7, 1994.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, the petition, and all written comments received regarding the petition may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are requested to call in advance of visiting at (202) 690–2817.

FOR FURTHER INFORMATION CONTACT: Dr. James White, Chief, Plants Branch, Biotechnology Permits, BBEP, APHIS, USDA, P.O. Drawer 810, Riverdale, MD 20738. The telephone number for the agency contact will change when agency offices in Hyattsville, MD, move to Riverdale, MD, during January. Telephone: (301) 436-7612 (Hyattsville); (301) 734-7612 (Riverdale). To obtain a copy of the Upjohn determination or the accompanying environmental documents, contact Ms. Kay Peterson at (301) 436-7601 (Hyattsville) or (301) 734-7601 (Riverdale).

SUPPLEMENTARY INFORMATION:

Background

On July 13, 1992, the Animal and Plant Health Inspection Service (APHIS) received a petition from the Upjohn Company (Upjohn) and its subsidiary, Asgrow Seed Company, of Kalamazoo, MI, seeking a determination that the ZW-20 virus resistant squash line no longer be considered a regulated article under APHIS' regulations in 7 CFR part 340.

On September 4, 1992, APHIS announced the receipt of the Upjohn petition in the Federal Register (57 FR 40632-40633, Docket No. 92-127-1) and announced its intent to issue an interpretive ruling that the ZW-20 virus

resistant squash does not present a plant pest risk and, therefore, would no longer be considered a regulated article. That notice also requested comments on APHIS' proposed interpretive ruling. After considering the 17 comments submitted during the 45-day comment period, of which 7 were in support of the petition and 10 in opposition. APHIS determined that it was in the public interest to reopen the comment period to seek additional comment on several scientific and technical issues raised by the commenters. The commenters expressed concerns in three major areas: (1) Will the introduction of the two viral coat protein genes increase the likelihood of the creation of new plant viruses: (2) could the introduction of two virus resistance genes cause squash to become a weed; and (3) would the virus resistance genes move to wild squash relatives and would this have a detrimental impact on these wild plants? A notice was published in the Federal Register on March 22, 1993 (58 FR 15323, Docket No. 92-127-2), to reopen the comment period for an additional 60 days. Twelve comments were received, of which 10 were in support and 2 were in opposition. The same major areas of concern expressed during the first comment period were again reflected in the two comments in opposition to the petition, with the addition of a statement that an . environmental impact statement should be prepared in connection with commercial scale growth of the ZW-20

Since the date of the original submission of Upjohn's petition, APHIS has formalized, under a "Petition for Determination of Nonregulated Status" (See 58 FR 17044-17059, Docket No. 92-156-2), the interpretive ruling procedure that was in place when the original petition for the ZW-20 squash was submitted.

On May 23, 1994, APHIS published a third notice in the Federal Register (59 FR 26619-26620, Docket No. 92-127-3) to announce the availability of an environmental assessment (EA) and preliminary finding of no significant impact (FONSI) related to the proposed determination of nonregulated status for the ZW-20 squash, a public meeting in Washington, DC, on July 21, 1994, and a 45-day comment period ending July 7, 1994. The notice included the text of the preliminary FONSI that had been prepared by APHIS.

At the public meeting on June 21, 1994, two speakers presented comments. One commenter supported the EA and preliminary FONSI; the other did not support the EA and preliminary FONSI. Both speakers also

submitted written comments. During the 45-day comment period, APHIS received an additional 52 written comments from private individuals. universities, agricultural experiment stations, the cooperative extension service, public interest groups, industry, a trade association, and a Federal research laboratory. Twenty-three comments supported APHIS' findings in the EA and preliminary FONSI. Twentynine comments disagreed with APHIS' proposal to approve the Upjohn petition, while 23 were in favor of approval. The commenters in opposition to the petition again stressed concerns about the ecological safety of commercial scale growth of the ZW-20 squash, citing such risks as gene glow to wild squash, potential impacts on squash centers of diversity, the potential for increased weediness in wild squash, and the risk of creating new viruses. APHIS has prepared a detailed technical analysis of, and response to, those comments in the determination document, which is available upon request from the individual listed under FOR FURTHER INFORMATION CONTACT.

Analysis

The crookneck squash (Cucurbita pepo L. cultivar YC77E ZW-20) (ZW-20) developed by Upjohn resists infection by two plant viruses, zucchini yellow mosaic virus (ZYMV) and watermelon mosaic virus, type II (WMV2). ZW-20 squash was developed by engineering two plant virus genes. the coat protein (CP) genes of ZYMV and WMV2, into a line of yellow crookneck squash. In addition, the vector system used to transier the viral CP genes into the recipient squasn was derived from the bacterial plant pathogen Agrobacterium tumefaciens. Certain noncoding regulatory sequences were derived from plant pathogens, i.e. from A. tumefaciens and from cauliflower mosaic virus and cucumber mosaic virus.

The ZW-20 squash has been considered a regulated article under the APHIS regulations in 7 CFR part 340 in part because of the use of CP genes, in part because of the derivation of the vector system, and in part because of use of noncoding regulatory sequences from plant pathogens. Field testing of the ZW-20 squash has been conducted since 1990 at approximately 46 field sites in 10 States under 14 permits issued by APHIS. All field trials have been performed under conditions of reproductive confinement. Field data reports indicate no deleterious effects on plants, nontarget organisms, or the environment from these field tests.

Determination

Based on an analysis of the information and data submitted by Upjohn, a review of scientific literature. and comments received from the public, APHIS has concluded that the ZW-20 squash is as safe to grow as traditionally bred virus resistant squash. The available evidence indicates that ZW-20 squash: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than a virus resistant squash plant developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated plant or native wild species with which it can interbreed; (4) should not cause damage to processed agricultural commodities; (5) should not increase the likelihood of the emergence of new plant viruses; and (6) is unlikely to harm other organisms, such as bees. which are beneficial to agriculture. The basic findings of the preliminary FONSI are therefore adopted in support of the determination that Upjohn's ZW-20 squash does not present a plant pest risk and therefore will no longer be considered a regulated article under APHIS' regulations in 7 CFR part 340. The effect of this determination is that the permit requirements of 7 CFR part 340 will no longer apply to the field testing, importation, or interstate movement of ZW-20 squash or its progeny. Importation of ZW-20 squash and nursery stock or seeds capable of propagation is still, however, subject to any restrictions found in the Foreign Quarantine Notice regulations at 7 CFR part 319.

National Environmental Policy Act

The EA has been prepared in accordance with: (1) The National Environmental Policy Act (NEPA) of 1969 (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 Guidelines Implementing NEPA (44 FR 50381-50384, August 28, 1979, and 44 FR 51272-51274, August 31, 1979). Based on that EA, APHIS reached a FONSI with regard to its determination that the virus resistant squash line designated as ZW-20 and its progeny are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and FONSI are available upon request from the individual listed under FOR FURTHER INFORMATION CONTACT.

Done in Washington, DC, this 7th day of December 1994.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 94-30570 Filed 12-12-94; 8:45 am]

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