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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 96-080-1]

Calgene, Inc.; Addition of One Genetically Engineered Tomato Line to Determination of Nonregulated Status

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Animal and Plant Health Inspection Service is announcing that it has added one additional genetically engineered tomato line to those subject to its October 19, 1992, interpretive ruling that the subject FLAVR SAVR™ lines need no longer be regulated. The effect of this action is that one additional delayed softening tomato line, which has been modified by the incorporation of genetic material described by Calgene, Inc., in its initial request for an interpretive ruling, will no longer be subject to regulation under 7 CFR part 340.

FOR FURTHER INFORMATION CONTACT: Dr. Subhash Gupta, Biotechnologist, Biotechnology Permits, BBEP, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1237; (301) 734-7612.

SUPPLEMENTARY INFORMATION: On October 19, 1992, the Animal and Plant Health Inspection Service (APHIS) published in the Federal Register (57 FR 47608-47616, Docket No. 92-087-2) a notice announcing the issuance of an interpretive ruling that previously field tested lines of the Calgene, Inc., FLAVR SAVR™ tomato do not present a plant pest risk and are not regulated articles under the regulations contained in 7 CFR part 340. This action was in response to a petition submitted by Calgene seeking a determination from APHIS that its FLAVR SAVR™ tomato no longer be deemed a regulated article, based on an absence of plant pest risk.

The effect of that action was that previously field tested lines of the FLAVR SAVR™ tomato and their progeny would no longer be regulated under these regulations.

FLAVR SAVR™ tomatoes were defined by Calgene in its initial petition to include any tomatoes transformed with one of seven identified plasmid vectors that all carry an antisense copy of the tomato polygalacturonase gene and a bacterial neomycin phosphotransferase gene with associated regulatory sequences. Calgene's initial request to APHIS in 1992 was for a determination pertaining to all FLAVR SAVR™ transformants produced in tomatoes using any one of the seven plasmid vectors. Calgene indicated in its petition that data provided to the Agency were representative of the data gathered for all lines tested up to that time. The initial determination announced by APHIS on October 19, 1992, only applied to those lines that had already been field tested. However, APHIS indicated that new lines were likely to exhibit properties similar to those of lines already field tested under permit. The determination also allowed for cross-breeding of the identified FLAVR SAVR™ tomato lines with any other lines or cultivars of tomato without a permit. Since the publication of the October 19, 1992, determination, a total of 32 additional FLAVR SAVR™ tomato lines have been added to the original determination. Those additions were announced in notices published in the Federal Register on October 3, 1994 (59 FR 50220, Docket No. 94-096-1); November 18, 1994 (59 FR 59746, Docket No. 94-125-1); March 23, 1995 (60 FR 15284, Docket No. 95-015-1); and July 28, 1995 (60 FR 38788-38789, Docket No. 95-056-1).

The additional FLAVR SAVR™ tomato line that is the subject of this notice was constructed using the plasmid vector pCGN4109, which was one of the seven included in Calgene's initial petition to APHIS. In our determination of October 19, 1992, the lines using these vectors were not deregulated because they had not been field tested. These lines have since been field tested in accordance with APHIS regulations at 7 CFR part 340, and data provided to APHIS indicate that the new transformant, produced in a manner identical to the earlier

transformant lines, behaves similarly to those earlier FLAVR SAVR™ tomato lines to which the determination initially applied. Reports from field trials and other data indicate that the new tomato line grows normally, exhibits the expected morphological, reproductive, and physiological properties, and does not have unexpected pest or disease susceptibility or symptoms. Therefore, the APHIS determination of nonregulated status of October 19, 1992, applies as well to this new transformed line.

Done in Washington, DC, this 4th day of October 1996.

Terry L. Medley,
Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96-25933 Filed 10-8-96; 8:45 am]

BILLING CODE 3410-34-P

[Docket No. 96-073-1]

Availability of Environmental Assessments and Findings of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that three environmental assessments and findings of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of permits to allow the release into the environment of nonindigenous biological control agents. The environmental assessments provide a basis for our conclusion that the release into the environment of the biological control agents will not present a risk of introducing plant pests into the United States or disseminating plant pests within the United States and will not have a significant impact on the quality of the human environment. Based on its findings of no significant impact, the Animal and Plant Health Inspection Service has determined that environmental impact statements need not be prepared.

ADDRESSES: Copies of the environmental assessments and findings of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and