

Determination of Nonregulated Status for H7-1 Sugar Beet

In response to petition 03-323-01p from Monsanto Company and KWS SAAT AG (KWS), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has evaluated and determined that H7-1 sugar beet and progeny derived from it are unlikely to pose a plant pest risk and is not a plant pest and thereby are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). APHIS' Biotechnology Regulations only regulate genetically engineered articles that are or may be plant pests causing plant pest harms. If APHIS concludes that a genetically engineered plant is unlikely to pose a plant pest risk, APHIS does not have plant pest authority to continue to regulate it.

Since APHIS has determined that H7-1 sugar beet is unlikely to pose a plant pest risk and is not a plant pest, APHIS has decided that H7-1 sugar beet should have nonregulated status. Therefore, APHIS permits or acknowledged notifications that were previously required for the environmental release, interstate movement, or importation under those regulations will no longer be required for H7-1 sugar beet and its progeny. Importation of H7-1 sugar beet seeds and other propagative material will still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201.

This Determination of Nonregulated Status for H7-1 sugar beet is based on APHIS' analyses of field and laboratory data submitted by Monsanto/KWS, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Final Plant Pest Risk Assessment (PPRA) for H7-1 sugar beet and in this Determination.

The Final PPRA conducted on H7-1 sugar beet concluded that it is unlikely to pose a plant pest risk and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 for the following reasons:

(1) agronomic performance and disease and pest susceptibility of H7-1 sugar beet is similar to that of its non-genetically engineered sugar beet counterparts and/or other sugar beet cultivars grown in the U.S.; (2) the new gene product is not known to cause greater changes to the plant metabolism or seed composition (except for the intended changes in the resistance to the herbicide glyphosate) than conventional sugar beet; (3) gene introgression from H7-1 sugar beet 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 the genetic diversity of related plants any more than would cultivation of traditional or other specialty sugar beet varieties; (4) they exhibit no characteristics that would cause them to be weedier or more difficult to control as weeds than non-genetically engineered sugar beet or any other cultivated sugar beet; (5) horizontal gene transfer is unlikely to occur between H7-1 sugar beet and organisms with which they cannot interbreed.

In addition to our finding in the Final PPRA that H7-1 sugar beet is unlikely to pose a plant pest risk, APHIS has evaluated and determined that H7-1 sugar beet and progeny derived from it are not plant pests since they do not meet the Plant Protection Act's (PPA) definition of a plant pest. APHIS has evaluated and concluded that H7-1 sugar beet, the introduced DNA sequences in H7-1 sugar beet, and the EPSPS enzyme H7-1 sugar beet produces, are not the living stage(s) of any article listed in any of the subparagraphs of the PPA's plant pest definition. Accordingly, since APHIS has determined that H7-1 sugar beet and progeny derived from it are unlikely to pose a

plant pest risk and are not plant pests, they should have Nonregulated Status and thus should no longer be subject to the plant pest provisions of the Plant Protection Act and the 7 CFR part 340 regulations.

APHIS has also completed a Final Environmental Impact Statement (EIS) (http://www.aphis.usda.gov/biotechnology/not_reg.html) that assesses the possible impacts of a determination of non-regulated status of glyphosate-tolerant sugar beet event H7-1 on the quality of the human environment consistent with APHIS obligations under the National Environmental Policy Act (NEPA) of 1969 as amended, Council on Environmental Quality (CEQ) regulations for implementing NEPA, the USDA regulations implementing NEPA, and the APHIS regulations implementing NEPA (7 CFR part 372). The Final EIS also included an analysis of the effects, if any, of H7-1 sugar beet on Federally-listed and proposed threatened and endangered species and their designated critical habitat and habitat proposed for designation consistent with our obligations under the Endangered Species Act (ESA) of 1973, as amended. APHIS has issued a Record of Decision for the Final EIS.

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the Final PPRA, the Final EIS, the agency's Response to Public Comments received in reference to the Draft EIS, the Record of Decision, other relevant information in this Determination, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this Determination of Nonregulated Status for H7-1 sugar beet is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

7-19-2012

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date