Import and processing of insect resistant and herbicide tolerant cotton 281-24-236x3006-210-23xMON88913

COGEM advisory report CGM/131107-01

Summary

The present application (EFSA/GMO/NL/2009/68) concerns import and processing for use in feed and food of the genetically modified cotton event 281-24-236x3006-210-23xMON88913 Cultivation is not part of this application.

Cotton line 281-24-236x3006-210-23xMON88913 expresses the Cry1F, Cry1Ac PAT and CP4 EPSPS proteins, conferring resistance to certain lepidopteran insect pests and tolerance to glufosinate-ammonium and glyphosate containing herbicides.

281-24-236x3006-210-23xMON88913 was produced by means of conventional breeding of two genetically modified parental cotton lines. Previously, COGEM issued positive opinions on the import and processing of the parental lines 281-24-236x3006-210-23 and MON88913.

In Northwestern Europe, no wild relatives of cotton are present. Modern cotton cultivars do not possess any of the attributes commonly associated with problematic weeds. Cotton cannot survive in Northwestern Europe due to the climate. The introduced traits will not introduce a potential to establish feral populations. Therefore, COGEM is of the opinion that incidental spillage of 281-24-236x3006-210-23xMON88913 seeds will not pose a risk to the environment in Northwestern Europe.

In view of the above, COGEM is of the opinion that import and processing of cotton line 281-24-236x3006-210-23xMON88913 poses a negligible risk to man and the environment. A food/feed safety assessment is carried out by other organisations. Therefore, COGEM abstains from advice on the potential risks of incidental consumption.

Introduction

The scope of the present application (EFSA/GMO/NL/2009/68) submitted by Agrigenetics, Inc. d/b/a Mycogen Seeds, concerns import and processing of cotton line 281-24-236x3006-210-23xMON88913. This line was produced by conventional crossbreeding of the genetically modified parental cotton lines 281-24-236x3006-210-23 and MON88913. It expresses the Cry1F and Cry1Ac proteins conferring resistance to certain lepidopteran insect pests. It also expresses the PAT and CP4 EPSPS proteins, conferring tolerance to glufosinate-ammonium and glyphosate herbicides. The applicant states that glufosinate-ammonium will only be used during the selection stages of the genetic modification.

Previous COGEM advisory reports

In 2004, COGEM issued a positive opinion on the import and processing of parental line 281-24-236x3006-210-23.[1,2] In 2007, COGEM also issued a positive opinion on the import and processing of parental line MON88913.[3]

Aspects of the crop

Cotton is a member of the genus *Gossypium* and belongs to the *Malvaceae* family. The majority of cultivated cotton is *Gossypium hirsutum* (90%) and *Gossypium barbadense* (5%), while *Gossypium arboreum* and *Gossypium herbaceum* are cultivated as well.[4,5,6] The only cultivated cotton species in Europe is *G. hirsutum*, which is grown in Greece, Spain and Bulgaria.[7]

Cotton plants reproduce sexually.[6] Cotton is predominantly a self-pollinating species, but cross-pollination may occur. Dissemination of pollen by wind is (almost) absent.[5,6] The pollen of cotton is large, heavy and somewhat sticky.[5,6] Outcrossing rates for cotton are strongly influenced by the presence of insects. Pollinators of cotton flowers include bumblebees (*Bombus* spp.), honeybees (*Apis* spp.) and other bee species (*Anthophora* spp., *Melissodes* spp. and *Halictus* spp.).[5,8] Hybridisation between *G. hirsutum* and *G. barbadense* may occur and can lead to viable progeny (F1). Hybrid F2 progeny contain either depauperate types or plants that closely resemble one of the parents.[8] Wild relatives of cotton (*Gossypium* spp.) do not occur in Northwestern Europe. Therefore, hybridisation with wild relatives cannot occur in Northwestern Europe.[5]

Cotton is highly sensitive to temperature and susceptible to frost. Temperature is the main factor that determines the geographic range in which cotton can be grown. Plant development ceases below a temperature of 12 ºC and delays when the temperature rises above 38 ºC.[5,6] *G. hirsutum* needs a period of 180 to 200 frost-free days for normal maturation, with an average of 150 days of suitable temperatures (averaging 21-22 ºC). The optimal temperature for growth is between 30 and 35 ºC.[9] *G. barbadense* has a longer growing season and needs 200-250 frost-free days and a lower optimum temperature for growth (25-30°C).[5,10] In places where cotton is cultivated as a rain-fed crop the average rainfall is 800-1200 mm.[4] In areas where the rainfall is less than 500 mm a year, irrigation is necessary.[5]

Cottonseed can be dispersed by wind, water, during transport or when feeding cattle.[6] In addition, cottonseed can be transported by birds or rodents. Seeds from cotton cultivars do not possess dormancy and will germinate directly if conditions are favourable.[5,6] Seeds usually do not survive in humid soil.[6] In regions with mild and dry winters, cottonseeds may overwinter and germinate in spring. Seedlings are sensitive to competition from weeds.[5]

Modern cotton cultivars do not possess any of the attributes commonly associated with problematic weeds, such as dormancy, persistence in seed banks, germination under adverse environmental conditions, rapid vegetative growth, a short life cycle, very high seed output, high seed dispersal and long-distance dispersal of seeds. Cotton volunteers occur in cotton growing areas and may occur when cottonseed is used as livestock feed. The presence of volunteer cotton is limited by soil moisture content and frost.[6] There are reports that *G. hirsutum* and *G. herbaceum* cotton are naturalised in some Southern European countries, e.g. Greece and Spain.[11,12]

Molecular characterization

281-24-236x3006-210-23xMON88913 cotton is the result of a conventional breeding cross between the two genetically modified cotton lines 281-24-236x3006-210-23 and MON88913. COGEM evaluated the molecular characterization of the genetically modified parental lines in previous applications concerning import and processing and concluded that the molecular characterization of the individual parental lines is adequate.[1,2,3] The bioinformatics analyses of cotton line 281-24-236x3006-210-23xMON88913 were performed using up-to-date databases.

Properties of the introduced genes conferring insect resistance

Cotton line 281-24-236x3006-210-23xMON88913 contains the *cry1F* and *cry1Ac* genes. These *cry* genes encode delta-endotoxins (δ-endotoxin), which target lepidopteran insects such as the Tobacco Budworm (*Heliothis virescens*) and Pink Bollworm (*Pectinophora gossypella* Sanders).
δ-endotoxins are solubilised in the midgut of susceptible insects and are activated by midgut proteases to release a toxin fragment. This toxin fragment binds to specific receptors on the epithelial surface of the midgut, which causes pores to open. This leads to disruption of the movement of solutes across the gut epithelium and allows gut bacteria to escape the midgut and enter the hemolymph where they cause septicaemia and death.[13,14]

Properties of the introduced genes conferring herbicide tolerance

281-24-236x3006-210-23xMON88913 expresses the phosphinothricin acetyltransferase (PAT) and CP4 EPSPS proteins. The *cp4 epsps* gene encodes the CP4 EPSPS protein. EPSPS is an enzyme involved in the biosynthesis of aromatic amino acids. Glyphosate inhibits EPSPS, resulting in a lack of amino acids essential for growth and development of plants. In contrast to EPSPS, the CP4 EPSPS protein is not inhibited by glyphosate and therefore the plant is tolerant to glyphosate containing herbicides.[15]

PAT confers tolerance to glufosinate-ammonium containing herbicides.[16] The active ingredient in glufosinate-ammonium is L-phosphinothricin (L-PPT), which binds to glutamine synthetase in plants. The detoxification of ammonia is thereby prevented, leading to plant death. The PAT enzyme catalyses the conversion of L-PPT to an inactive form, which does not bind glutamine synthetase.[17] The applicant states that glufosinate-ammonium will only be used during the selection stages of the genetic modification.

Environmental risk assessment

Cotton is predominantly a self-pollinating species, but cross-pollination may occur. Wild relatives of cotton (*G. hirsutum and G. barbadense*) are not present in Northwestern Europe and therefore, hybridisation with wild relatives is excluded.[5]

Cotton plants are susceptible to frost. A reasonably high temperature (optimally 25-30 ºC for *G. barbadense* and 30-35 ºC for *G. hirsutum*) is required in all stages of development. For normal maturation, a period of 200 to 250 frost-free days is needed for *G. barbadense* and 180 to 200 days

for *G. hirsutum*. In addition, this period needs to have on average 150 days of suitable temperatures, averaging 21-22 ºC. In the Netherlands, the summer months of May, June, July, August and September (in total 153 days) have average monthly temperatures above 12 ºC, but below 18 ºC.[18] In addition, in areas where rainfall is less than 500 mm a year, irrigation should be applied for cotton growth. In the months of May through September in the Netherlands, the average monthly precipitation does not exceed 100 mm.[18] Based on the above, the current Dutch climate is unsuited for cotton growth.

There is no indication that the introduced traits, which confer resistance to certain lepidopteran insects and tolerance to gluphosinate-ammonium and glyphosate containing herbicides, will introduce an ability of cotton to survive in the environment. The applicant carried out an agronomic assessment for 281-24-236x3006-210-23xMON88913. The agronomic assessment does not give any indication to assume that 281-24-236x3006-210-23xMON88913 has an increased fitness compared to conventional varieties.

In view of the above, there are no reasons to assume that 281-24-236x3006-210-23xMON88913 has an increased potential for the establishment of feral populations in case of incidental spillage of cottonseed because the climate in Northwestern Europe is not suited for cotton growth.

Since 2008 COGEM abstains from giving advice on the potential risks of incidental consumption in case a food/feed assessment is already carried out by other organisations.[19] This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed assessment is carried out by EFSA. Other organisations who advise the competent authorities can perform an additional assessment on food safety although this is not obligatory. In the Netherlands a food and/or feed assessment for Regulation (EC) 1829/2003 applications is carried out by RIKILT. Regarding the risks for food and feed, the outcome of the assessment by other organisations (EFSA, RIKILT) was not known at the moment of the completion of this advice.

General surveillance plan

General surveillance (GS) has been introduced to be able to observe unexpected adverse effects of genetically modified (GM) crops on the environment. The applicant's general surveillance plan is in line with the criteria COGEM formulated in 2010. [20]

COGEM notes that the GS plan of cotton line 281-24-236x3006-210-23xMON88913 could be improved by a statement that raw data and analysis of monitoring data will be made available to the Competent Authorities and the European Commission.[21] A similar remark in general has been made by EFSA in its guidance document on the Post-Market Environmental Monitoring of genetically modified plants.[22]

Advice

The present application concerns import and processing for feed and food purposes of the genetically modified cotton line 281-24-236x3006-210-23xMON88913. Cultivation is not part of the application. Therefore, the risk assessment focuses on the accidental spillage of cottonseeds.

Cotton plants are very sensitive to temperature. The Northwestern European climate is unsuited for cotton growth. There is no indication that the introduced traits, which confer resistance to certain lepidopteran insects and tolerance to gluphosinate-ammonium and glyphosate containing herbicides, will introduce an ability to survive in the environment. Therefore, incidental spillage of cottonseeds will not lead to feral cotton populations in Northwestern Europe. COGEM considers the current GS plan sufficient for this application concerning import and processing of cotton line 281-24-236x3006-210-23xMON88913.

In view of the above, COGEM is of the opinion that the risks for man and the environment associated with import and processing of cotton line 281-24-236x3006-210-23xMON88913 are negligible. A food/feed safety assessment is carried out by other organisations. Therefore, COGEM abstains from advice on potential risks of incidental consumption.

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