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KENMERK CGM/161124-01

ONDERWERP Advies import en verwerking gg-katoenlijn GHB614 x T304-40 x GHB119

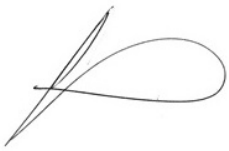
Geachte mevrouw Dijksma,

Naar aanleiding van de adviesvraag over de milieurisico's van import en verwerking van de genetisch gemodificeerde katoen kruisingslijn GHB614 x T304-40 x GHB119 (EFSA/GMO/NL/2014/122) deelt de COGEM u het volgende mee.

Samenvatting:
De COGEM is gevraagd te adviseren over import en verwerking van de genetisch gemodificeerde (gg-) katoenlijn GHB614 x T304-40 x GHB119. Deze lijn brengt de *cry1Ab*, *cry2Ae*, *2mepsps* en *bar* genen tot expressie. Hierdoor is het gewas resistent tegen bepaalde plaaginsecten uit de orde van de Lepidoptera (vlinderachtigen) en tolerant voor glyfosaat en glufosinaat-ammonium bevattende herbiciden.
De katoenlijn GHB614 x T304-40 x GHB119 is tot stand gekomen door kruisingen met drie gg-ouderlijnen. De COGEM heeft eerder positief geadviseerd over import en verwerking van al deze drie gg-ouderlijnen.
In Europa komen geen wilde verwanten van katoen voor, waardoor de ingebrachte sequenties zich niet naar andere soorten kunnen verspreiden. Katoen kan niet overleven in Noordwest-Europa vanwege het klimaat. De eigenschappen die in GHB614 x T304-40 x GHB119 zijn ingebracht, veranderen dit niet. Daarom acht de COGEM de kans verwaarloosbaar klein dat het incidenteel morsen van de gg-katoenzaden van GHB614 x T304-40 x GHB119 leidt tot verspreiding of vestiging in Noordwest-Europa van de gg-katoenlijn.
Alle aspecten in overweging nemende, acht de COGEM de milieurisico's voor Nederland bij import en verwerking van gg-katoen GHB614 x T304-40 x GHB119 verwaarloosbaar klein.
Omdat andere instanties een voedselveiligheidsbeoordeling uitvoeren, heeft de COGEM bij deze vergunningaanvraag de risico's van incidentele consumptie niet beoordeeld.

De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,



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Import and processing of genetically modified cotton GHB614 x T304-40 x GHB119

COGEM advice CGM/161124-01

- The present application (EFSA/GMO/NL/2014/122) concerns import and processing of genetically modified (GM) cotton GHB614 x T304-40 x GHB119 for use in feed and food;
- GHB614 x T304-40 x GHB119 was produced by conventional crossbreeding of the parental GM lines GHB614, T304-40 and GHB119;
- COGEM advised positively on import and processing of all three parental lines;
- Cotton GHB614 x T304-40 x GHB119 expresses the *2m epsps*, *bar*, *cry1Ab* and *cry2Ae* genes;
- GHB614 x T304-40 x GHB119 is resistant to certain lepidopteran insects and is tolerant to glyphosate and glufosinate-ammonium containing herbicides;
- The molecular characterisation of parental lines GHB614, T304-40 and GHB119 has been updated and meets the criteria of COGEM;
- In the Netherlands, cultivation of cotton is not possible and feral cotton populations do not occur;
- In the Netherlands, wild relatives of cotton are not present, so hybridisation with other species is not possible;
- There are no reasons to assume that the introduced traits allow GM cotton GHB614 x T304-40 x GHB119 to survive in the Dutch environment;
- Import and processing of GM cotton GHB614 x T304-40 x GHB119 poses a negligible risk to the environment in the Netherlands;
- COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is carried out by other organisations.

1. Introduction

The scope of the present application (EFSA/GMO/NL/2014/122), submitted by Bayer CropScience LP concerns import and processing of cotton GHB614 x T304-40 x GHB119. The application was submitted in 2014, but was only recently declared valid after EFSA published opinions on all parental lines.

Import and processing of the parental lines GHB614 and T304-40 has been authorised in the European Union.[1,2] Import and processing of the parental line GHB119 has not yet been authorised.

COGEM has been asked to advise on the environmental risks of import and processing of GHB614 x T304-40 x GHB119 cotton.

GHB614 x T304-40 x GHB119 expresses the *cry1Ab* and *cry2Ae* genes conferring resistance to certain lepidopteran insects. It also expresses the *pat*/*bar* and *2m epsps* genes resulting in tolerance to herbicides containing glufosinate-ammonium and glyphosate as the active ingredients, respectively. GHB614 x T304-40 x GHB119 was produced by conventional crossbreeding of the genetically modified parental lines.

Previous COGEM advices

COGEM has previously issued positive opinions on import and processing of GHB614, T304-40 and GHB119.[3,4,5] COGEM also advised positively on cultivation of GHB614.[6]

2. Environmental risk assessment

2.1 Aspects of the wild-type 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.[7,8,9] The only cultivated cotton species in Europe is *G. hirsutum*, which is grown in Greece, Spain and Bulgaria.[10,11]

Cotton is highly sensitive to temperature and susceptible to frost.[8,9,12,13] Plant development ceases below a temperature of 12 ºC and delays when the temperature rises above 38 ºC.[8,9] The optimal temperature for growth is between 25 and 35 ºC.[8,14,15] In areas where the rainfall is less than 500 mm a year, irrigation is necessary.[7,8] In the Netherlands, the summer months have average monthly temperatures above 12 ºC, but below 18 ºC, and the average monthly precipitation does not exceed 100 mm.[16] Due to the temperature, the Dutch climate is unsuited for the cultivation of cotton.

Seeds from cotton cultivars do not possess dormancy and will germinate directly if conditions are favourable.[8,9] In regions with mild and dry winters, cottonseeds may overwinter and germinate in spring, but usually do not survive in humid soil.[9] Seedlings are sensitive to competition from weeds.[8] Cotton volunteers occur in cotton growing areas and may occur due to spilling during transport or when feeding cattle.[9] However, COGEM is not aware of any reports on feral cotton populations in Northwestern Europe.

Cotton plants reproduce sexually.[9] Cotton is predominantly a self-pollinating species, but cross-pollination may occur. Dissemination of pollen by wind is (almost) absent.[8,9] Outcrossing rates for cotton are strongly influenced by the presence of insects. There are reports that *G. hirsutum* and *G. herbaceum* cotton are naturalised in some Southern European countries, e.g. Greece and Spain.[17,18] Wild relatives of cotton (*Gossypium* spp.) do not occur in Northwestern Europe. Therefore, hybridisation with wild relatives cannot occur in Northwestern Europe.[8]

Conclusion: The Dutch climate is unsuited for cotton cultivation. In the Netherlands feral cotton populations do not occur, and hybridisation with other species is not possible because no wild relatives of cotton are present.

2.2 Molecular characterisation

Previously, COGEM evaluated the molecular characterisation of each parental line and considered them to be adequate.[3,4,5] For each parental line the applicant updated the bio-informatic analyses of the junctions of the inserts with cotton genomic DNA and included bio-informatic analyses of *in silico* translations of the different T-DNAs in all six reading frames. According to the applicant, no biologically relevant similarities with allergens, toxins or biologically active proteins were observed in these analyses.

In addition, the applicant updated the bio-informatic analyses of each parental line to assess whether coding sequences or regulatory elements were disrupted by the insertion of the inserts in the parental lines. According to the applicant, it is unlikely that genes at or in the flanking genomic DNA of the insertion sites were disrupted.

The molecular characterisation was conducted according to the criteria previously laid down by COGEM.[19]

Conclusion: The molecular characterisation of GHB614 x T304-40 x GHB119 cotton is adequate.

2.3 Description of the introduced genes and traits

Introduced gene	Encoded protein	Trait
2m epsps (GHB614)	A modified 5-enolpyruvyl-shikimate-3-phosphate synthase (EPSPS) enzyme originating from maize (*Zea mays*)[6]	Tolerance to glyphosate containing herbicides, because of a decreased binding affinity for glyphosate[6]
bar (2 copies; T304-40 and GHB119)	A phosphinotricin acetyltransferase (PAT) of *Streptomyces hygroscopicus* [4,5]	Tolerance to glufosinate ammonium containing herbicides, due to the acetylation of glufosinate-ammonium to an inactive acetylated derivate[4,5]
cry1Ab (2 copies; T304-40)	The N-terminal region of the Cry1Ab proprotein from *Bacillus thuringiensis* subsp. Berliner[4]	Tolerance to certain lepidopteran insects[4]
cry2Ae (GHB119)	A codon usage optimized Cry2Ae proprotein from *Bacillus thuringiensis* subsp. Dakota[5]	Tolerance to certain lepidopteran insects[5]
For a detailed description of the traits see references.		

2.4 Phenotypic and agronomic characteristics

Previously, COGEM evaluated the phenotypic and agronomic characteristics and analyses of each parental line of GHB614 x T304-40 x GHB119, and concluded that the introduced genes do not give any indication to assume that the parental lines have an increased survivability compared to conventional cotton lines.[3,4,5,6]

The applicant analysed the phenotypic and agronomic characteristics of GHB614 x T304-40 x GHB119. The COGEM is of the opinion that there are no indications to assume that the introduced traits in GHB614 x T304-40 x GHB119 allow cotton to survive or establish in the Dutch environment.

Conclusion: There are no reasons to assume that GHB614 x T304-40 x GHB119 has an increased potential for the establishment of feral populations in The Netherlands.

2.5 Food/feed assessment

COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is carried out by EFSA and other national organisations. The present application is submitted in the Netherlands under Regulation (EC) 1829/2003, therefore the food and/or feed assessment is carried out by RIKILT. The outcome of the assessment by other organisations (EFSA, RIKILT) was not known when this advice was completed.

3. General Surveillance

COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,[20,21] but considers the current GS plan adequate for the import and processing of GHB614xT304-40xGHB119.

4. Overall conclusion

Import and processing of GHB614 x T304-40 x GHB119 cotton poses a negligible risk to the environment in the Netherlands. COGEM abstains from giving advice on the potential risks of incidental consumption since a food and/or feed assessment is carried out by other organisations.

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