

Voorzitter: prof.dr.ir. B.C.J. Zoeteman

Aan de Staatssecretaris van
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en Milieubeheer
De heer drs. P.L.B.A. van Geel
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Uw kenmerk	Uw brief van	Kenmerk	Datum
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Onderwerp
Advies Marktdossier EFSA/GMO/NL/2005/13
Herbicidentolerante katoen LLCotton25

Geachte heer Van Geel,

Naar aanleiding van de adviesvraag betreffende het dossier EFSA/GMO/NL/2005/13, getiteld 'Glufosinate ammonium-tolerant Cotton, LLCotton25' voor de import en verwerking van genetisch gemodificeerde katoen door Bayer CropScience GmbH. adviseert de COGEM als volgt.

Samenvatting:

De COGEM is gevraagd te adviseren over import van genetisch gemodificeerde katoenzaden. Onderhavige katoenlijn is voorzien van het *bar* gen waardoor de planten tolerant zijn geworden voor toediening van herbiciden met als werkzame stof glufosinaat-ammonium.

In Europa komen geen wilde verwanten van katoen voor en katoen bezit niet de eigenschappen om te kunnen verwilderen. Katoen is sterk koudegevoelig, heeft hoge temperaturen nodig voor kieming en ontwikkeling van de plant. Daarbij is irrigatie of hoge neerslag gedurende het hele jaar noodzakelijk voor de teelt van katoen. Er zijn geen redenen om aan te nemen dat de modificatie het verwilderingspotentieel vergroot. De COGEM acht derhalve de kans verwaarloosbaar klein dat incidenteel morsen van de katoenzaden leidt tot verspreiding van deze genetisch gemodificeerde katoen binnen Europa.

Concluderend heeft de COGEM geen bezwaar tegen import en verwerking van onderhavige katoenlijn en worden de risico's voor mens en milieu verwaarloosbaar klein geacht.

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

Hoogachtend,

A handwritten signature in black ink, consisting of a large, stylized loop followed by a horizontal line that ends in a small hook.

Prof. dr. ir. Bastiaan C.J. Zoeteman
Voorzitter COGEM

c.c. Dr. ir. B.P. Loos
Dr. I. van der Leij

Title: Import and processing of herbicide tolerant cotton LLCotton25

COGEM advice: CGM/051031-01

The present application by Bayer CropScience GmbH concerning file EFSA/GMO/NL/2005/13, 'Glufosinate ammonium-tolerant Cotton, LLCotton25' refers to the commercial import and processing for use in feed and food of a genetically modified cotton line. Cultivation is not part of this application.

The recombinant cotton line is genetically modified by insertion of the bar gene. As a result, LLCotton25 confers tolerance to herbicides containing the active ingredient glufosinate ammonium. The cotton line is already commercially grown in the United States of America and Canada.

In Europe, no wild relatives of cotton are present and modern cotton cultivars do not possess any of the attributes commonly associated with problematic weeds. There are no reasons to assume that the inserted genes will increase the potential of the cotton to run wild. Furthermore, establishment of feral populations in cotton producing countries is never observed. Cotton can not survive the climatological conditions in North-West Europe. COGEM is of the opinion that without irrigation, cotton volunteers can not survive and establish themselves in the wild. Therefore, COGEM is of the opinion that incidental spillage of seeds of the cotton line will pose no risk to the environment in the Netherlands nor in Europe.

As the present application does not concern cultivation of LLCotton25 and incidental spillage will pose a negligible risk to the environment in North-West Europe. COGEM is of the opinion that an assessment by the COGEM of the molecular analysis does not contribute to the risk analysis. The risk of consumption of cotton seeds is already assessed by both the European Food Safety Authority (EFSA) and the national food safety authorities.

In view of these considerations, COGEM is of the opinion that the proposed import and processing of cotton line LLCotton25 does not pose a significant risk for human health and the environment in the Netherlands.

Introduction

The present application by Bayer CropScience GmbH concerning file EFSA/GMO/NL/2005/13, 'Glufosinate ammonium-tolerant Cotton, LLCotton25' refers to the commercial import and processing for use in feed and food of genetically modified cotton (*Gossypium hirsutum*). Cotton is mainly cultivated for the use of cotton lint. Cottonseeds are harvested as rest products and used for feeding purposes, or for the production of cottonseed oil for human consumption.

The cotton line (LLCotton25) is genetically modified by the introduction and expression of the *bar* gene which confers tolerance to herbicides containing the active ingredient glufosinate ammonium.

LLCotton25 has been previously approved for commercial import, processing and cultivation in the United States of America and Canada (1). There is a history of safe use e.g. no adverse health effects concerning handling and consuming of products and derivatives of this line have been reported.

Previous COGEM advices

In the past COGEM has advised positively on the genetically modified cotton line containing 2 *Cry* genes (insect resistance) in combination with a *pat* gene (herbicide tolerance) for import and processing (CGM/040504-01 and CGM/040427-05). The *pat* gene is comparable with the *bar* gene. Both genes are coding for phosphinothricin acetyl transferase.

Aspects of the crop

Cotton is a member of the genus *Gossypium* and belongs to the *Malvacea* family (2). More than 95% of commercial cotton is upland cotton, *G. hirsutum*, while long staple cotton, *G. barbadense*, occupies a small area of <5% (3).

In 2004, cotton was grown commercially in 86 countries, with a combined production of 67.3 million metric tonnes of seed cotton and 23.0 million metric tonnes of cotton lint. The major producers of seed cotton and lint are China, United States of America, Pakistan, India and Uzbekistan. Together, these countries are responsible for 80% of the total cotton production (2). Within the European Union, cotton is grown on a small scale in Greece, Cyprus, France and Spain (7). It should be noted that only non-gmo cotton is grown in Europe.

Depending on cultivar and climate, the growth period can range from 160 to 220 days. The crop will flower about eight weeks after planting. In the following two months, a cottonboll will develop and will finally open. The time taken for the cotton fibers to reach full length and cellulose content, is about eight weeks later. After this, the cotton can be harvested (2).

Cotton is highly sensitive to temperature. It does not start its vegetative activity until the temperature reaches 15°C and the activity is delayed when temperature rises above 38°C. For normal development, cotton needs an average of 150 days with temperatures between these values (5). The optimum temperature for germination is 34°C, for the growth of seedlings 24-29°C and for later continuous growth 34°C. When the crop is grown at lower temperatures, the production of the vegetative branches increases and the cropping period will be extended. Reduced light intensity will retard flowering and fruiting. Because cotton is susceptible to frost, the whole growth period of six months has to be free of frost (3,5).

In areas where the rainfall is less than 500 mm a year, irrigation should be applied (4). In places where cotton is grown as a rain-fed crop, the average rainfall is 800-1200 mm (2).

Cultivated cotton is a self-pollinating species. But the prevalence of insects strongly influences outcrossing rates for cotton. Many field-based assessments estimate outcrossing rates at 10% or less, although rates up to 80% have been found. The pollen remain viable up to a period of twelve hours (4).

Cotton has a couple of wild-relatives, however, they are not found in Europe. Besides, many wild relatives are diploid ($2n = 26$) making them incompatible with the cultivated species *G. hirsutum* and *G. barbadense* which are tetraploid ($4n = 52$) (3).

Cotton is a domesticated crop. Modern cotton cultivars do not possess any of the attributes commonly associated with problematic weeds, such as dormancy, persistence in soil 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 (4). Cotton volunteers occur in cotton growing areas and are relatively common where cotton seed is used as livestock feed. There is no indication, however, that these volunteers establish feral populations. Seeds that do not germinate are likely to be removed by seed predators or rot, rather than become incorporated into a persistent soil seed bank (4).

Molecular and biological aspects of the GM-plant

Origin and function of the introduced genes

Cotton line LLCotton25 is genetically modified by means of *Agrobacterium tumefaciens* transformation. A gene fragment containing the *bar* expression cassette was inserted into the cotton. The *bar* gene confers tolerance to herbicides containing the active ingredient glufosinate ammonium.

An overview of the introduced sequences is given below:

- P35S3, promoter derived from the *Cauliflower mosaic virus* (CaMV); associated with constitutive high protein expression;
- *bar*, from *Streptomyces hygroscopicus*; confers resistance to glufosinate ammonium. The N-terminal two codons of the wild type *bar* coding region have been substituted for the codons ATG and GAC respectively;
- 3' nos, terminator derived from *Agrobacterium tumefaciens*.

Properties of the introduced genes conferring herbicide tolerance

The cotton line was genetically modified with a *bar* gene encoding phosphinothricin acetyltransferase. As a result, tolerance was obtained to glufosinate ammonium containing herbicides. Applying glufosinate ammonium to plants results in a decline in glutamine and an increase in ammonia levels by inhibiting glutamine synthetase activity. As a result photosynthesis will stop and the plant dies within a couple of days (1). By insertion of the *bar* gene, the genetically modified cotton plant confers tolerance to the herbicide. The *bar* gene is coding for the PAT protein, which catalyzes the conversion of L-phosphinothricine (L-PPT), the active part of the herbicide glufosinate ammonium, to N-acetyl-L-PPT. This results in survival of the plant in case the herbicide is applied.

Advice

The present application concerns the import, processing and feed and food use of a cotton line. Cultivation of the present line is not part of the application. The risk assessment therefore focuses on the accidental spillage of cottonseeds. As stated above, cotton growth is very sensitive to temperature. A reasonably high temperature is required in all stages of development. The Dutch climate is far from ideal for growing cotton. During the warmest months (April to October), the average temperature is around 16°C. The average rainfall for spring and summer is 368 mm and is below the required 500 mm (6). Moreover, the fact that the Netherlands are known for their frost periods in winter, makes it impossible for cotton to survive and to establish itself in the Netherlands.

Climate conditions in other parts of the European Union are more suitable for growing cotton. At the moment cotton is grown in Cyprus, France, Greece and Spain (7). However, it is not to be expected that the spillage of cottonseeds can lead to the establishment of feral populations. All European cotton is irrigated due to the lack of rainfall in the growing season. Furthermore as stated above, modern cotton cultivars do not possess any of the attributes commonly associated with problematic weeds and there are no reasons to assume that the inserted genes will increase the potential of the cotton to run wild. Furthermore, establishment of feral populations in cotton producing European countries is never observed.

In view of the above, COGEM is of the opinion that there is a zero risk that incidental spillage of cottonseeds will lead to the spread of cotton within the European Union. Potential risks of consumption of cottonseeds are already assessed by both the EFSA and the national food safety authorities, including an elaborate assessment of the molecular analysis. Furthermore, there are no wild relatives of cotton present in Europe and therefore outcrossing is impossible. Considering the above, COGEM is of the opinion that an assessment by the COGEM of the molecular analysis does not contribute to the risk analysis.

COGEM is of the opinion that the proposed import and processing of cotton line LLCotton25 does not pose a significant risk for human health and the environment in the Netherlands.

References

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