Renewal of the authorisation for import and processing of genetically modified cotton LLCotton25

COGEM advice CGM/180523-01

- The present application (EFSA/GMO/RX/010) concerns the renewal of the authorisation for import and processing of genetically modified (GM) cotton (*Gossypium hirsutum*) LLCotton25;
- GM cotton LLCotton25 was previously authorised for import and processing in 2008;
- COGEM advised positively on the import and processing of LLCotton25 in 2005, and on import and processing of stacked lines containing LLCotton25 in 2011, 2015 and 2016;
- LLCotton25 expresses the *bar* gene, which confers tolerance to herbicides containing the active ingredient glufosinate ammonium;

- In the Netherlands, cultivation of cotton is not possible and feral cotton populations do not occur;
- Wild relatives of cotton are not present in the Netherlands, therefore hybridisation with other species is not possible;

- The updated bioinformatics analysis of LLCotton25 meets the criteria of COGEM;
- There are no indications that the introduced trait alters the fitness of LLCotton25;
- There is no reason to assume that the introduced trait will allow LLCotton25 to survive in the Dutch environment;
- The updated bioinformatics analysis, literature review and monitoring reports do not give any indication of a potential environmental risk;

- COGEM is of the opinion that import and processing of LLCotton25 pose 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 present application (EFSA/GMO/RX/010), filed by Bayer CropScience LP., concerns the renewal of the authorisation for import and processing of GM cotton LLCotton25. This authorisation was granted in 2008 (2008/837/EC).[1] Since import and processing authorisations remain valid for a period of 10 years, the applicant filed an application for the renewal of the authorisation granted in 2008. The application contains amongst others monitoring reports, an updated molecular characterisation and an updated literature search.

2. Previous COGEM advices

COGEM issued a positive advice on the import and processing of LLCotton25 in 2005.[2] Additionally, COGEM also issued positive advices on import and processing of stacked lines containing LLCotton25 in 2011 (GHB614xLLCotton25)[3], 2015 (LLCotton25xMON15985 and GHB614xLLCotton25xMON15985)[4], and 2016 (GHB614xLLCotton25xMON15985, updated application)[5].

3. Environmental risk assessment

3.1 Characteristics of cotton

Cotton is a member of the genus *Gossypium* and belongs to the *Malvaceae* family. The majority of cultivated cotton is *Gossypium hirsutum* (90%), followed by *Gossypium barbadense* (5%), and *Gossypium arboreum* and *Gossypium herbaceum* (together ≤ 5%).[6,7,8] The only cultivated cotton species in Europe is *G. hirsutum*, which is grown in Greece, Spain and Bulgaria.[9,10]

Cotton requires at least 500 mm of rainfall during the growing season, but can also be grown as irrigated crop.[7] Cotton is highly sensitive to temperature, and susceptible to frost.[7,8,11,12] Seed germination and plant development cease below a temperature of 12 ºC and delay when the temperature rises above 38 ºC.[7,8] The optimal daytime temperature for *G. hirsutum* ranges between 30 and 35 ºC.[7,12] *G. hirsutum* requires 180 to 200 frost-free days of uniformly high temperatures (averaging 21-22 ºC) after planting.[8,13] From planting of cotton to 60% boll opening (i.e., when seed is mature), a minimum of 2050 day degrees[a] is required.[8,14]

The climate in the Netherlands does not fulfil the conditions required for cotton maturation and cultivation. In the Netherlands, there are on average 85 days with a daily maximum temperature of ≥ 20 ºC per year.[15] In the summer (June, July and August), when temperatures are highest, the daily temperature averages 17 ºC.[15,16] Based on the daily maximum and minimum temperatures in summer, the accumulated average day degrees approximates 436. In the remaining months, the temperature is insufficiently high to reach the accumulated amount of day degrees required (2050) for the growth and maturation of cotton. Also, in the Netherlands frost days generally occur from October up to and including April[17], and it is not uncommon for frost days to occur in early summer. Considering the frost sensitivity of cotton, and the requirement of uniformly high temperatures, the Dutch climate conditions are unsuitable for the life cycle of cotton.

Cotton plants reproduce sexually.[8] Cotton is predominantly a self-pollinating species, but cross-pollination may occur.[18] Dissemination of pollen by wind is (almost) absent.[7,8] Outcrossing rates for cotton are strongly influenced by the presence of insects. Cotton seeds can remain dormant for

[a] Day degrees (or heat units) are a measure of time and temperature required to reach a certain plant developmental stage. They are calculated based on the daily minimum and maximum temperature minus the threshold temperature for growth and development of cotton (12 ºC): [(daily max. temperature - 12) + (daily min. temperature - 12)] / 2. The day degrees for each day are summed during the growing season. When the average daily temperature drops below the threshold temperature, the daily increment of day degrees is set to zero.

2-3 months, but this trait is reduced or eliminated by selective breeding. Seeds from modern cotton cultivars do not possess dormancy.[7] Cotton seeds from cultivars usually do not survive in humid soil and the formation of seed banks is unlikely, as seeds become weathered when they do not germinate directly.[8,18] Seedlings are also sensitive to competition from weeds.[7]
Cotton volunteers occur in areas where cotton is cultivated and may occur due to spilling during transport or when feeding cattle.[8] There are reports that *G. hirsutum* and *G. herbaceum* are naturalised in some Southern European countries, e.g. Greece and Spain.[19,20] COGEM is not aware of any reports on feral cotton populations in Northwestern Europe. Wild relatives of cotton (*Gossypium* spp.) do not occur in Northwestern Europe. Therefore, hybridisation with wild relatives cannot occur in Northwestern Europe.[7]

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.

3.2 Description of the introduced gene and trait

LLCotton25 was developed using *Agrobacterium tumefaciens* mediated transformation, using the vector pGSV71. The inserted transgenic sequence consists of the P35S promoter, derived from the *Cauliflower mosaic virus* (CaMV), the *bar* gene, and the 3'nos terminator sequence.

Introduced gene	Encoded protein	Trait
bar	Encodes the phosphinothricin-N-acetyl transferase (PAT) enzyme.[21]	Confers tolerance to glufosinate-ammonium herbicides
For a detailed description of the introduced gene and trait, see reference		

3.3 Updated bioinformatics analyses and molecular characterisation

The current application contains a confirmation of the sequence identity of LLCotton25. Using recent databases, the applicant updated the bioinformatics analyses of the inserted element and the sequences spanning the 5' and 3' junctions of the insert and its flanking regions. The applicant notes that no essential endogenous genes were disrupted at the insertion site. The sequences spanning the insertion site at the 5' and 3' flanking regions and the entire insert were screened to identify all open reading frames (ORFs) between stop codons. According to the applicant, the ORFs do not generate any protein sequence similarities with known allergens or toxins.

According to the applicant, the 2017 LLCotton25 sequence contains a number of sequence differences compared to the sequence submitted in the frame of the EFSA-GMO-NL-2005-13 application, on which the previous COGEM advice is based. The applicant states that the sequence differences can be explained by a lower sequence quality of the previous studies, or the presence of remaining primer sequence. No differences were found when comparing the 2017 sequence with the sequence reported in 2002 and 2010 in frame of the application EFSA-GMO-NL-2010-77.

COGEM is of the opinion that the molecular characterisation of cotton LLCotton25 has been performed correctly and meets the requirements of COGEM.[22] No new elements that would invalidate the conclusions of the initial risk assessment were identified.

Conclusion: The molecular characterisation of cotton LLcotton25 is adequate and no indications for potential environmental risks were identified.

3.4 Systematic literature search

The applicant performed a literature search using a broad collection of bibliographic databases, covering a publication period from January 2007 to August 2017. The scientific publications contained no reports on adverse effects of incidents.

Conclusion: The systematic literature search does not give any indication of potential environmental risks resulting from import and/or processing of cotton LLCotton25.

3.5 Annual monitoring reports

The applicant supplied annual reports on the monitoring carried out between 2009 and 2016. Monitoring was performed by operators involved in the import, handling and processing of viable cotton LLCotton25, i.e., COCERAL, UNISTOCK and FEDIOL. Also, to monitor the safety of LLCotton25, the applicant performed a yearly review of the scientific literature. The monitoring results and literature search did not provide indications of adverse health or environmental effects associated with import or use of cotton LLCotton25.

Conclusion: The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and processing of cotton LLCotton25.

4. Food/feed assessment

This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed assessment is carried out by EFSA and national organisations involved in the assessment of food safety. In the Netherlands, RIKILT carries out a food and/or feed assessment for Regulation (EC) 1829/2003 applications. The outcome of the assessment by other organisations (EFSA, RIKILT) was not known when this advice was completed.

5. Post-market environmental monitoring (PMEM)

The applicant does not consider it necessary to update or change the monitoring post-market environmental monitoring (PMEM) plan of the initial authorisation. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan[23,24] but considers the initial GS plan adequate for import and processing of cotton LLCotton25.

6. Overall conclusion

There are no indications that expression of the introduced trait will alter the fitness of cotton LLCotton25. COGEM is of the opinion that import and processing of cotton LLCotton25 pose a negligible risk to the environment in the Netherlands. COGEM abstains from giving advice on the potential risks of incidental consumption since other organisations carry out a food/feed assessment.

References

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