

Renewal of the authorisation for import and processing of genetically modified cotton GHB614

COGEM advice CGM/201022-01

- The present application (EFSA/GMO/RX/018) concerns the renewal of the authorisation for import and processing of genetically modified (GM) cotton GHB614;
- GM cotton GHB614 was previously authorised for import and processing in 2011;
- COGEM advised positively on import and processing of GM cotton GHB614 in 2008;
- The GM cotton expresses the gene *2mepsps*, which confers tolerance to glyphosate containing herbicides;

- 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 bioinformatic analyses of GM cotton GHB614 has been updated and meets the criteria of COGEM;
- The updated bioinformatics analyses, 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 GM cotton GHB614 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 present application (EFSA/GMO/RX/018), filed by BASF Agricultural Solutions Seed US LLC, concerns the renewal of the authorisation for import and processing of GM cotton GHB614. This authorisation was granted in 2011 (2011/354/EU).¹ Since authorisations remain valid for a period of 10 years, the applicant filed an application for the renewal of the authorisation. The application contains amongst others monitoring reports, updated bioinformatic analyses and an updated literature search.

2. Previous COGEM advices

In 2008 COGEM advised positively on import and processing of cotton GHB614,² and in later years on import and processing of several stacked events containing GHB614: GM cotton GHB614 x T304-40 x GHB119,³ GHB614 x LLCotton25 x MON15985,^{4,5} and GHB614 x LLCotton25⁶.

COGEM also concluded that the environmental risk of cultivation of GM cotton GHB614 is negligible.⁷

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*, followed by *Gossypium barbadense*, and in lesser amounts *Gossypium arboreum* and *Gossypium herbaceum*.^{8,9,10} The only cultivated cotton species in Europe is *G. hirsutum*, which is grown in Greece, Spain and Bulgaria.^{11,12}

Cotton requires at least 500 mm of rainfall during the growing season, or can be grown as irrigated crop.⁹ Cotton is highly sensitive to temperature, and susceptible to frost.^{9,10,13,14} Seed germination and plant development cease below a temperature of 12°C and delay when the temperature rises above 38°C.^{9,10} The optimal daytime temperature for *G. hirsutum* ranges between 30 and 35°C.^{9,14} *G. hirsutum* requires 180 to 200 frost-free days of uniformly high temperatures (averaging 21-22°C) after planting.^{10,15} From the time of planting to 60% boll opening (i.e., when seed is mature), a minimum of 2050 day degrees¹ is required.^{10,16} In the Netherlands, there are on average 85 days with a daily maximum temperature of $\geq 20^{\circ}\text{C}$ per year.¹⁷ Frost days in the Netherlands generally occur from October up to and including April,¹⁸ and it is not uncommon for frost days to occur in early summer. In the summer (June, July and August), when temperatures are highest, the daily temperature averages 17°C.¹⁹ This corresponds to an accumulated average of 436 day degrees. 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. Considering the above, the Dutch climate conditions are unsuitable for the life cycle of cotton.

Cotton plants reproduce sexually.¹⁰ Cotton is predominantly a self-pollinating species, but cross-pollination may occur.²⁰ Dissemination of pollen by wind is (almost) absent.^{9,10} Outcrossing rates for cotton are strongly influenced by the presence of insects. Cotton seeds can remain dormant for 2-3 months, but this trait is reduced or eliminated by selective breeding. Seeds from modern cotton cultivars do not possess dormancy.⁹ Cotton seeds from cultivars usually do not survive in humid soil and the formation of seed banks is unlikely.^{10,20} Seedlings are also sensitive to competition from weeds.⁹

Cotton volunteers occur in areas where cotton is cultivated and may occur due to spilling during transport or when feeding cattle.¹⁰ There are reports that *G. hirsutum* and *G. herbaceum* are naturalised in some Southern European countries, e.g. Greece and Spain.^{21,22} COGEM is not aware of any reports on feral cotton populations in Northwestern Europe. Because wild relatives of cotton (*Gossypium* spp.) do not occur in North-western Europe, and the COGEM is not aware of any reports

¹ 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°C): [(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.

on feral cotton populations in this region, hybridisation of GM cotton with wild relatives cannot occur in North-western Europe.⁹

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 genes, traits and regulatory elements

GM cotton GHB614 was developed using *Agrobacterium tumefaciens* mediated transformation. A description of the inserted genetic elements is listed in the table below. The list is limited to information on the introduced genes, corresponding traits, and regulatory elements (promoters and terminators).

Introduced genes	Encoded proteins	Traits	Regulatory elements
<i>2mepsps</i>	A modified 5-enolpyruvyl-shikimate-3-phosphate synthase (EPSPS) enzyme originating from maize (<i>Zea mays</i>) ^{7,23}	Tolerance to glyphosate containing herbicides ^{7,23}	Ph4a748At (histone H4, gene promoter derived from <i>Arabidopsis thaliana</i> and 3'histon At, terminator derived from <i>A. thaliana</i>) ^{2,24}
<i>See references for a detailed description of the trait</i>			

3.3 Updated bioinformatic analyses

The COGEM notes that the insert was not resequenced in the current application. The applicant states that the sequence is assumed to be identical to the sequence originally provided, which is supported by a compliance check (performed by the EC's Joint Research Centre in the context of validation of the detection method) of the GBH614 sequence in the stacked event GHB614 x T304-40 x GHB119 x COT102.

The bioinformatic analyses have been reconducted using updated databases. Using the original sequence and recent databases, the applicant updated the bioinformatic analyses of the inserted element and the sequences spanning the 5' and 3' junctions of the insert and its flanking regions. 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, no essential endogenous genes are disrupted at the insertion sites and the putative products of the ORFs do not generate any protein sequence similarities with known allergens or toxins. Similarly, the amino acid sequence of the newly expressed protein (2mEPSPS) also does not show similarity to known allergens or toxins. According to the applicant no new elements that would invalidate the conclusions of the initial risk assessment were identified.

COGEM is of the opinion that the molecular characterisation of cotton GHB614 has been performed correctly and meets the requirements of COGEM.²⁵

Conclusion: The bioinformatic analyses of GM cotton GHB614 has been updated and is adequate. The molecular characterisation meets the requirements of COGEM.

3.4 Annual monitoring reports and literature review

The applicant supplied annual reports on the monitoring carried out between 2011 and 2019. Monitoring was performed by operators involved in import, handling and processing of viable cotton GHB614 i.e., COCERAL, UNISTOCK and FEDIOL. As part of the monitoring reports, the applicant performed a yearly review of scientific publications to monitor the safety of cotton GHB614. In addition, the applicant performed a scoping review of the scientific literature within the period of 10 years prior to the date of submission of this renewal application (between June 1st 2011 to November 30th 2019). In addition, an overview was provided of unpublished studies (produced, controlled or sponsored by the applicant or provided to the applicant by a third party) for GHB614 cotton and the 2mPEPSPS protein. The monitoring reports, studies and scientific publications contained no indications of adverse effects or incidents.

Conclusion: The information in the annual monitoring reports, the literature review and unpublished studies performed by the applicant do not contain any indication of potential environmental risks or incidents resulting from import and/or processing of cotton GHB614.

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/feed safety. In the Netherlands, a food and/or feed assessment for Regulation (EC) 1829/2003 applications is carried out by Wageningen Food Safety Research (WFSR). The outcome of the assessment by other organisations (EFSA, WFSR) was not known when this advice was completed.

5. Post-market environmental monitoring (PMEM)

The applicant did not propose any changes to the existing post-market environmental monitoring (PMEM) plan for GM cotton GHB614, with the exception of changes in format and updated links to webpages. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan^{26,27} but considers the current GS plan adequate for import and processing of GM cotton GHB614.

6. Overall conclusion

COGEM is of the opinion that import and processing of cotton GHB614 poses a negligible risk to the environment in the Netherlands.

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