

To the State Secretary for Public Transport and
the Environment

Ch. A. Jansen
P.O. box 20901
2500 EX The Hague

DATE 19 September 2024
REFERENCE CGM/240919-02
SUBJECT Advice on the renewal of import and processing of GM cotton GHB614xLLCotton25

Dear Mr Jansen,

COGEM was requested to evaluate the environmental risks associated with the renewal of the authorisation for import of genetically modified (GM) cotton GHB614xLLCotton25 (GMFF-2023-21890) for use in food and feed, as submitted by BASF Agricultural Solutions Seed US LLC, represented in the EU by BASF SE.

This GM cotton was produced by crossing the two parental cotton lines GHB614 and LLCotton25 using traditional breeding methods. These parental cotton lines were previously produced by *Agrobacterium* mediated transformation. GHB614xLLCotton25 expresses the *2mepsps* and *bar* genes, which confer tolerance to glyphosate and glufosinate ammonium containing herbicides respectively. COGEM has previously advised positively on the import and processing of this GM cotton in 2011,¹ and this GM cotton was authorised for placement on the market in the European Union in 2015.²

Cotton is highly temperature sensitive and susceptible to frost.^{3,4,5,6} The Dutch climate has a higher number of frost days than optimal for growth and maturation of cotton, and temperatures are

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1. COGEM (2011). Import and processing of cotton GHB614xLLCotton25. COGEM advice CGM/110325-01
 2. Commission Implementing Decision (EU) 2015/690 of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614xLLCotton25 (BCS-GHØØ2-5xACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 112/35
 3. The Organisation for Economic Co-operation and Development (OECD, 2010). Safety Assessment of Transgenic Organisms, Volume 4. Consensus document on the biology of crops, Section 1 - Cotton (*Gossypium* spp.)
 4. Office of the Gene Technology Regulator (OGTR 2024). The biology of *Gossypium hirsutum* L. and *Gossypium barbadense* L. (cotton)
 5. Unruh BL & Silvertooth JC (1997). Planting and irrigation termination timing effects on the yield of Upland and Pima cotton. J. Product. Agric. 10: 74-79
 6. Reddy KR *et al.* (1992). Temperature effects on early season cotton growth and development. Agron. J. 84: 229-237

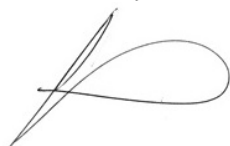
consistently lower than required.^{3,6,7,8} Cultivation is not possible in the Netherlands and feral cotton populations do not occur. Moreover, there are no wild relatives of cotton present in the Netherlands with which hybridisation could occur.⁹

The bio-informatic analysis of the inserted elements and its 3' and 5' junctions in GM cotton GHB614xLLCotton25 were updated, using up-to-date databases of allergens, toxins, and general proteins to assess protein sequence similarities. No indications for potential environmental risks were identified. The introduced traits in GM cotton GHB614xLLCotton25 will not allow the GM cotton to survive in the Dutch environment. In addition, the applicant performed a systematic literature search using a broad collection of bibliographic databases, covering the period from 2015 to 2023. No publications were identified that would invalidate the conclusions of the previous risk assessment.

A post-market environmental monitoring (PMEM) plan is provided in the application. The applicant supplied annual reports on the monitoring carried out between 2015 and 2023. The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and processing of GM cotton GHB614xLLCotton25.

COGEM is of the opinion that renewal of the market authorisation for import and processing of GM cotton GHB614xLLCotton25 poses a negligible risk to the Dutch environment. COGEM abstains from giving advice on the potential risks of incidental consumption, as a food/feed assessment is carried out by other organisations.

Yours sincerely,



Professor Sybe Schaap
Chair of COGEM

c.c.

- Y. de Keulenaar, MA, Head of the GMO Office
- Ministry of Infrastructure and Water Management, Environmental Safety and Risks
Directorate, Directorate-General for the Environment and International Affairs
- M.A.C. Möllers, Food-Feed desk

7. Koninklijk Nederlands Meteorologisch Instituut (KNMI). Uitleg over warme dagen. www.knmi.nl/kennis-en-datacentrum/uitleg/warme-dagen (visited: July 23rd, 2024)

8. Koninklijk Nederlands Meteorologisch Instituut (KNMI). Vorstdagen. www.knmi.nl/kennis-en-datacentrum/uitleg/vorstdagen (visited: July 23rd, 2024)

9. Bourguou L *et al.* (2013). Assessment of possible hybridization between Bt cotton (*Gossypium hirsutum* L.) and other Malvaceae species (*Abelmoschus* spp. and *Hibiscus* spp.) cultivated in Burkina Faso. *Afr. J. Biotechnol.* 12: 1609-1616