

To the State Secretary for Public Transport and
the Environment
Ch. A. Jansen
P.O. box 20901
2500 EX The Hague

DATE 28 augustus 2024
REFERENCE CGM/240828-02
SUBJECT Advice on the renewal of import and processing of GM cotton MON15985

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 MON15985 (GMFF-2023-21233, commercial name: Bollgard II™ Cotton) for use in food and feed, as submitted by Bayer Agriculture BV on behalf of Bayer CropScience LP.

This GM cotton was produced by particle bombardment of the genetically modified cotton line MON531, which was previously produced by *Agrobacterium* mediated transformation. MON15985 expresses the *cry1Ac* and *cry2Ab2* genes, both of which confer resistance to Lepidopteran pests. In addition, MON15985 cotton contains the *nptII* and *uidA* marker genes, which allow easy selection of transformed cotton cells. COGEM has previously advised positively on the import and processing of this GM cotton in 2008,¹ 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

-
1. COGEM (2008). Import and processing of MON15985. COGEM advise CGM/081020-01
 2. Commission Implementing Decision (EU) 2015/685 of 24 April 2015 authorising the placing on the market of genetically modified cotton MON 15985 (MON-15985-7) and renewing the authorisation for existing genetically modified cotton MON 15985 (MON-15985-7) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 112/11
 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. Agricult.* 10: 74-79
 6. Reddy KR *et al.* (1992). Temperature effects on early season cotton growth and development. *Agron. J.* 84: 229-237

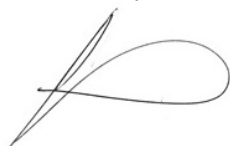
consistently lower than required.^{3,6,7,8} Cultivation is not possible in the Netherlands and feral cotton populations do not occur. Moreover, there are no wild relatives of cotton present in the Netherlands with which hybridisation could occur.⁹

The bio-informatic analysis of the inserted elements and its 3' and 5' junctions in GM cotton 15985 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 MON15985 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 2014 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 MON15985.

COGEM is of the opinion that renewal of the market authorisation for import and processing of GM cotton MON15985 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 4th, 2024)

8. Koninklijk Nederlands Meteorologisch Instituut (KNMI). Vorstdagen. www.knmi.nl/kennis-en-datacentrum/uitleg/vorstdagen (visited: July 4th, 2024)

9. Bourgou 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