

To the Minister for the
Environment
drs. V.L.W.A. Heijnen
Postbus 20901
2500 EX Den Haag


DATE 14 July 2023
REFERENCE CGM/230714-02
SUBJECT Import and processing of GM cotton GHB614 x T304-40 x GHB119 x COT102

Dear Minister,

COGEM was requested to evaluate the environmental risks associated with import of genetically modified (GM) cotton GHB614 x T304-40 x GHB119 x COT102 (EFSA/GMO/ES/2017/147) for use in food and feed, as submitted by Bayer CropScience LP. This stacked event has been created by conventional crossing of four parental GM lines.

COGEM has previously advised positively on the import and processing of all four parental lines,^{1,2,3,4,5} as well as on the import and processing of several stacked events, including GHB614 x T304-40 x GHB119⁶, and other stacked events involving GHB614.^{7,8,9} COGEM has also advised positively on the cultivation of GHB614.¹⁰

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1. COGEM (2008). Import and processing of genetically modified cotton GHB614. COGEM advice CGM/080509-01
 2. COGEM (2020). Renewal of the authorisation for import and processing of genetically modified cotton GHB614 (EFSA/GMO/RX/018). COGEM advice CGM/201022-01
 3. COGEM (2012). Import and processing of cotton T304-40 (EFSA/GMO/NL/2011/97). COGEM advice CGM/120105-01
 4. COGEM (2012). Import of insect resistant and herbicide tolerant GHB119 cotton (EFSA/GMO/UK/2011/96). COGEM advice CGM/120123-01
 5. COGEM (2017). Import and processing of genetically modified cotton COT102 (EFSA/GMO/DE/2017/141). COGEM advice CGM/170929-01
 6. COGEM (2016). Import and processing of genetically modified cotton GHB614 x T304-40 x GHB119 (EFSA/GMO/NL/2014/122). COGEM advice CGM/161124-01
 7. COGEM (2011). Import and processing of cotton GHB614xLLCotton25. COGEM advice CGM/110325-01
 8. COGEM (2015). Import and processing of genetically modified cotton GHB614xLLCotton25xMON15985 and LLCotton25xMON15985. COGEM advice CGM/151008-01
 9. COGEM (2016). Import and processing of GM cotton GHB614xLLCotton25xMON15985 and GM soybean MON87751. COGEM advice CGM/160527-01
 10. COGEM (2013). Cultivation of glyphosate tolerant GHB614 cotton (EFSA/GMO/ES/2012/104). COGEM advice CGM/130321-01



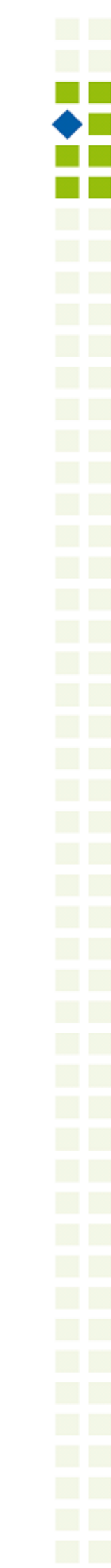
The GM cotton in the present application expresses the *2mepsps*, *bar*, *cry1Ab*, *cry2Ae*, *vip3Aa19*, and *aph4* genes. GHB614 x T304-40 x GHB119 x COT102 is resistant to certain lepidopteran insects, and tolerant to glyphosate and glufosinate-ammonium containing herbicides.

Cotton is highly temperature sensitive and susceptible to frost.^{11,12,13,14} The Dutch climate has a higher number of frost days than optimal for growth and maturation of cotton, and temperatures are consistently lower than required.^{11,14,15,16} Cultivation is not possible in the Netherlands and feral cotton populations do not occur. Moreover, wild relatives of cotton are not present in the Netherlands and hybridisation with other species is thus not possible.

COGEM notes that the *aph4* gene confers resistance to the antibiotic hygromycin B. Hygromycin B has been classified as a group I antibiotic resistance gene, which indicates that it is extremely unlikely that the presence of this gene in cotton will have a negative influence on human or animal health, or that it will impact the already existing spread of antibiotic resistance genes in the environment.¹⁷ Moreover, this application solely concerns the import of GHB614 x T304-40 x GHB119 x COT102. COGEM is of the opinion that the presence of *aph4* in the GM cotton poses a negligible risk to the Dutch environment.^{18,19} However, as mentioned previously, COGEM notes that the presence of antibiotic resistance genes, such as *aph4*, may be considered undesirable in view of public perception.⁵

The bio-informatic analysis of cotton GHB614 x T304-40 x GHB119 x COT102 was performed using the most current databases available at the time of submission of this application. The introduced traits in cotton GHB614 x T304-40 x GHB119 x COT102 will not allow the GM cotton to survive in the Dutch environment. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan^{20,21} but considers the current GS plan adequate for import and processing of GM cotton GHB614 x T304-40 x GHB119 x COT102.

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11. The Organisation for Economic Co-operation and Development (2008). Consensus document on the biology of cotton (*Gossypium spp.*)
 12. Office of the Gene Technology Regulator (2016). The biology of *Gossypium hirsutum* L. and *Gossypium barbadense* L. (cotton)
 13. 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
 14. Reddy KR et al. (1992). Temperature effects on early season cotton growth and development. *Agron. J.* 84: 229-237
 15. Koninklijk Nederlands Meteorologisch Instituut (KNMI). Uitleg over warme dagen. www.knmi.nl/kennis-en-datacentrum/uitleg/warme-dagen (visited: June 29th, 2023) COGEM advice CGM/201022-01 6
 16. Koninklijk Nederlands Meteorologisch Instituut (KNMI). Vorstdagen. www.knmi.nl/kennis-en-datacentrum/uitleg/vorstdagen (visited: June 29th, 2023)
 17. EFSA (2004). Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants. *The EFSA Journal* (2004) 48, 1-18
 18. COGEM (1998). Standpunt van de COGEM ten aanzien van de toelaatbaarheid van het toepassen van antibioticumresistentiegenen in transgene planten. COGEM advice CMG/980929-06 [in Dutch]
 19. COGEM (2000). Het gebruik van antibioticumresistentiegenen als markersysteem tijdens de genetische modificatie van planten. COGEM advice CGM/000918-01 [in Dutch]
 20. COGEM (2010). General Surveillance. COGEM report CGM/100226-01
 21. COGEM (2015). Advice on improving the general surveillance of GM crops. COGEM advice CGM/150601-02



COGEM is of the opinion that import and processing of GM cotton GHB614 x T304-40 x GHB119 x COT102 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,



Prof. dr. ing. Sybe Schaap
Chair of COGEM

- c.c.
- Drs. Y de Keulenaar, Hoofd Bureau ggo
 - Ministerie van IenW, Directie Omgevingsveiligheid en milieurisico's, DG Milieu en Internationaal
 - Ing. M.A.C. Möllers, Food-Feed loket