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To the Minister for the Environment and Public Transport
Mr Ch.A. Jansen
P.O. Box 20901
2500 EX The Hague

DATE 19 February 2025
REFERENCE CGM/250219-01
SUBJECT Advice on the renewal of import and processing of GM soybean MON 87705

Dear Mr Jansen,

COGEM was requested[1] to evaluate the environmental risks associated with the renewal of the authorisation for import of genetically modified (GM) soybean MON 87705 (GMFF-2023-21236, RX037) for use in food and feed, as submitted by Bayer Agriculture BV on behalf of Bayer CropScience LP.

GM soybean MON 87705 was produced by *Agrobacterium*-mediated transformation and expresses the CP4 EPSPS protein which confers tolerance to glyphosate-based herbicides. In addition, MON87705 contains a FAD2-1A/FATB1A suppression cassette that generates double-stranded RNA (dsRNA). Via the RNA interference (RNAi) pathway, the dsRNA mediates suppression of the endogenous *FATB* and *FAD2* RNA levels in soybean seeds resulting in decreased levels of palmitic, stearic, and linoleic acid, and increased levels of oleic acid.[2]

COGEM has previously advised positively on the import and processing of this GM soybean in 2010,[3] and this GM soybean was authorised for placement on the market in the European Union in 2015.[4]

1. At the request of the Dutch portal for European market applications (the Food-Feed-portal), this advisory letter is written in English.
2. European Food Safety Authority (EFSA, 2012). Scientific Opinion on application (EFSA-GMO-NL-2010-78) for the placing on the market of herbicide-tolerant, increased oleic acid genetically modified soybean MON 87705 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 10: 2909
3. COGEM (2010) Import and processing of genetically modified glyphosate tolerant soybean MON87705 with an altered fatty acid profile. COGEM advice CGM/101013-03
4. Commission Implementing Decision (EU) 2015/696 of 24 April 2015authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87705 (MON-877Ø5-6)

Soybean (*Glycine max*) is cultivated worldwide, from equatorial to temperate zones. It is a predominantly self-pollinating species. Natural outcrossing rates are generally low.[5,6] For growth, soybean requires an optimum temperature between 25 °C and 30 °C. It is sensitive to frost and does not survive freezing conditions.[5,6] Although the Dutch climate is not optimal for soybean cultivation, it is cultivated on a small scale in the Netherlands (442 hectares in 2023).[7] Soybean volunteers are very uncommon in the Netherlands and have never resulted in establishment of wild populations. To the best of COGEM's knowledge, there are no reports of feral soybean populations in Europe. Additionally, hybridisation with other species is not possible in Europe because there are no wild relatives of soybean.[5,6]

In the application for renewal the bio-informatic analysis of the inserted elements and its 3' and 5' junctions in GM soybean MON 87705 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 safety assessment also included a screening on the *FATB* and *FAD2* siRNA sequences against endogenous soybean transcripts, to identify possible off-target effects. A low number of potential off-target transcripts were identified that were not perfectly matched, indicating a very low potential of off-target gene suppression. In addition, the applicant performed a systematic literature search using a broad collection of bibliographic databases, covering the period from January 2014 to November 2023. No publications were identified that would invalidate the conclusions of the previous risk assessment. There is no indication that the introduced traits in GM soybean MON 87705 will allow the GM soybean to survive or establish in the Dutch environment.

A post-market environmental monitoring (PMEM) plan is provided in the application. The applicant also 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 soybean MON 87705. The applicant did not propose any changes to the existing (PMEM) plan for soybean MON 87705. COGEM has published several recommendations for further improvement of the general surveillance (GS) plan[8,9] – which is part of a PMEM plan – but considers the current GS plan adequate for import and processing of GM soybean MON 87705.

COGEM is of the opinion that renewal of the market authorisation for import and processing of GM soybean MON 87705 poses a negligible risk to the Dutch environment. COGEM abstains from

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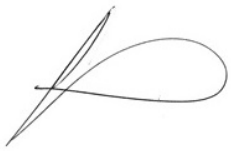
pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 112/60-65

5. OECD (2006), "Section 2 - Soybean (GLYCINE MAX (L.) MARR.)", in Safety Assessment of Transgenic Organisms, Volume 1: OECD Consensus Documents, OECD Publishing, Paris
6. Andersson MS & de Vicente MC (2010). Soybean (Glycine max (L.) Merr.). In: Gene flow between crops and their wild relatives. Eds: Andersson MS et al., The Johns Hopkins University Press, Baltimore
7. Centraal Bureau voor de Statistiek (CBS). Landbouw; gewassen, dieren en grondgebruik naar regio. https://opendata.cbs.nl/#/CBS/nl/dataset/80780ned/table [in Dutch] (visited: 23rd January 2025)
8. COGEM (2010). General Surveillance. COGEM report CGM/100226-01
9. COGEM (2015). Advice on improving the general surveillance of GM crops. COGEM advice CGM/150601-02

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.

- Y. de Keulenaar, MA, Head of the GMO Office
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