

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2023-21220 (RX-031) (genetically modified oilseed rape MON 88302) from Bayer CropScience under Regulation (EC) No. 1829/2003

17 October 2025
Ref. SC/1510/BAC/2025_1228

Context

Application EFSA-GMFF-2023-21220 (RX-031) was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) oilseed rape MON 88302 (UI: MON-88302-9) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003¹.

Oilseed rape MON 88302 expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides. The placing on the market of MON 88302 for food and feed uses, excluding cultivation, is currently authorised, following a positive opinion of EFSA (<https://doi.org/10.2903/j.efsa.2014.3701>).

The renewal application was validated by EFSA on 10 June 2024 and a formal three-month consultation period of the Member States was started, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC designated by each Member State in the case of genetically modified organisms being part of the products).

Within the framework of this consultation, the coordinator for this dossier, on behalf of the Belgian Biosafety Advisory Council (BAC), decided not to request external experts to assess this dossier.

The scientific opinion of EFSA's GMO Panel, including the responses from the Panel to comments submitted by the Member States during the three-month consultation period, was published on 13 May 2025 (EFSA Journal 2025;23:e9378)².

The contents of the renewal application, the previous positive advice of the BAC on oilseed rape MON 88302, and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMFF-2023-21220 (RX-031).

¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p.1).

² <https://www.efsa.europa.eu/en/efsajournal/pub/9378>

Scientific evaluation

The data for application EFSA-GMFF-2023-21220 (RX-031) provided by the applicant included:

- the annual post-market environmental monitoring (PMEM) reports covering the period from July 2014 to June 2023,
- scoping reviews covering the period from January 2014 to September 2024,
- an updated bioinformatic package including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins and of all possible open reading frames within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer, and a safety assessment of the newly expressed protein CP4 EPSPS regarding its potential capacity to trigger celiac disease symptoms,
- reports of additional studies performed by the applicant over the course of the authorisation period.

The members of the Biosafety Advisory Council considered a number of papers part of the literature review by the applicant that refer to the occurrence of (GM) feral oilseed plants along roadsides and in ports (Hecht *et al.*, 2014³ and Schulze *et al.*, 2014⁴). They considered the information presented in these papers not to constitute new information that would invalidate the original risk assessment.

Conclusion

The Biosafety Advisory Council is of the opinion that a continued market authorisation of oilseed rape MON 88302 is unlikely to pose any risk to human and animal health and the European environment.



Dr. ir. Geert Angenon
President of the Belgian Biosafety Advisory Council

Annex: Minority declaration by Philippe Baret, Véronique Fontaine and Nicolas Van Larebeke

³ <https://doi.org/10.1007/s11356-013-1881-9>

⁴ <https://doi.org/10.1371/journal.pone.0114477>

Minority advice on GMFF-2023-21220 (RX-031)

Philippe Baret – 26.09.2025

On June, 17, 2014, EFSA (2014) published an advice on MON88302 mentioning in the environmental assessment :

- Demographic studies and surveys (source type 3, above) have shown the ability of oilseed rape to establish self-perpetuating populations outside agricultural areas, mainly in semi-natural and ruderal habitats in different countries (reviewed by Devos et al., 2012; Bauer-Panskus et al., 2013; COGEM, 2013; Hecht et al., 2014), but overall revealed that feral oilseed rape is confined to ruderal habitats and that feral GMHT oilseed rape does not behave as an ecologically hazardous invasive species (see Appendix D and references therein of EFSA, 2013b, c). Oilseed rape is generally regarded as an opportunistic species, which can take advantage of disturbed sites due to its potential to germinate and capture resources rapidly. In undisturbed natural habitats, oilseed rape lacks the ability to establish stable populations, possibly due to the absence of competition-free germination sites (Crawley et al., 1993, 2001; Warwick et al., 1999; Hails et al., 2006; Sutherland et al., 2006; Damgaard and Kjaer, 2009). Moreover, in controlled sowings into road verges, field margins and wasteland, very few seedlings survived to maturity due to grazing (e.g. by molluscs) and abiotic stress (Charters et al., 1999). Kos et al. (2012) postulated that the low glucosinolate content in current oilseed rape varieties renders the plants more susceptible to leaf and seed herbivory, reducing seed production (see also COGEM, 2013).

On September 9, 2014, the Belgian Biosafety Council delivered a positive advice but a minority declaration was attached to this advice

Minority Declaration of P. Baret, M. Lateur and D. Perreux

Uncontrolled spread of GM oilseed rape in the environment already occurred in Europe and can realistically not be avoided. Risk assessment as reported does not sufficiently take into consideration long term effects of feral GM plants, as the probable introgression of the genetic modification into wild populations of related species (stability of the transgene for example).

Should environmental problems be detected in the future, it will likely be impossible to retrieve GM plants from the environment. Moreover, risks related to the marketing of conventional grain or seed produced in EU (outside of the scope of coexistence regulation) are not taken into consideration. Beside those considerations, GM plants developed to withstand “higher rate” of herbicide are likely to cause environmental problems, wherever they are grown and those problems cannot be ignored. The Biosafety Advisory Council should then give a negative advice regarding the environmental safety of this event.

In June 2014, Hecht et al. (2014) and Schulze et al. (2014) published paper demonstrating the establishment of feral populations of GM rapeseed in Switzerland, contradicting the initial advice of EFSA (see above : “oilseed rape lacks the ability to establish stable populations”). To our understanding, this is clearly **new elements** that should have triggered a reassessment of the environmental risk.

This reassessment was not achieved by the notifier, neither by EFSA and the proposition of the Belgian Safety Council is that ““The comprehensive literature search for publications relevant to the food, feed, and environmental safety of MON 88302 found no new information that would invalidate the conclusions of the risk assessment for MON 88302”. The paper of Schulze was cited in 62 papers and the paper by Hecht was cited by 61 papers. These two papers and the related literature are clearly a new element in the environmental assessment.

In these circumstances, the advice of the Belgian Biosafety Council violates the rationale of the renewal procedure. Indeed, the renewal should take into consideration new relevant elements.

In conclusion, the environmental assessment of the rapeseed MON88302 is inconsistent and the Biosafety Council should publish a negative advice.

References

- EFSA Panel on Genetically Modified Organisms (GMO). 2014. "Scientific Opinion on Application (EFSA-GMO-BE-2011-101) for the Placing on the Market of Herbicide-tolerant Genetically Modified Oilseed Rape MON 88302 for Food and Feed Uses, Import and Processing under Regulation (EC) No 1829/2003 from Monsanto." *EFSA Journal* 12 (6).
<https://doi.org/10.2903/j.efsa.2014.3701>.
- Hecht, Mirco, Bernadette Oehen, Jürg Schulze, Peter Brodmann, and Claudia Bagutti. 2014. "Detection of Feral GT73 Transgenic Oilseed Rape (*Brassica Napus*) along Railway Lines on Entry Routes to Oilseed Factories in Switzerland." *Environmental Science and Pollution Research* 21 (2): 1455–65. <https://doi.org/10.1007/s11356-013-1881-9>.
- Schulze, Juerg, Tina Frauenknecht, Peter Brodmann, and Claudia Bagutti. 2014. "Unexpected Diversity of Feral Genetically Modified Oilseed Rape (*Brassica Napus* L.) despite a Cultivation and Import Ban in Switzerland." *PloS One* 9 (12): e114477.