Advice on the second renewal of the authorisation for import and processing of genetically modified oilseed rape MS8, RF3 and MS8xRF3

COGEM advice CGM/220124-01

COGEM is requested to advise on the second renewal of the authorisation for import and processing of genetically modified (GM) oilseed rape MS8, RF3 and MS8xRF3 (EFSA/GMO/RX/024), filed by BASF Agricultural Solution Seeds US LLC.

1. Aspects of oilseed rape

Conventional oilseed rape (*Brassica napus*) is cultivated in the Netherlands and its seeds are imported for oil production. *B. napus* is able to form volunteers and grow in disturbed environments amongst others near roadsides, railways and handling areas. *B. napus* reproduces by self- and cross-pollination with *B. napus* plants, with its more common wild relative *B. rapa* and to a lesser extend with *B. juncea* and *B. oleracea*.[1]

2. GM oilseed rape events MS8, RF3 and MS8xRF3

GM oilseed rape MS8 is a male sterile line, and expresses the inserted *barnase* gene in the tapetum cells, resulting in a lack of viable pollen. The male sterility of MS8 oilseed rape prevents self-pollination. GM oilseed rape RF3 is a fertility restoring line, and expresses the inserted *barstar* gene, resulting in the production of the tapetal-cell-specific Barstar protein. The Barstar protein is an inhibitor of the Barnase protein and restores male fertility. The Barnase-Barstar interaction causes GM oilseed rape MS8xRF3, the crossbreeding product of MS8 and RF3, to be fertile and capable of seed production. Both GM oilseed events MS8 and RF3, and thereby MS8xRF3, also contain the *bar* gene. Expression of the *bar* gene produces the PAT (phosphinothricin N-acetyltransferase) enzyme that confers tolerance to glufosinate-ammonium herbicides.

3. Authorisation of GM oilseed rape events

Since 2007, GM oilseed rape events MS8, RF3 and MS8xRF3 have been authorised for placing on the market in the European Union.[2] The COGEM has multiple times been requested for advise on these GM oilseed rape events.[3,4,5] As the proposed monitoring plan for these GM oilseed rape events did not include monitoring along transport routes and transshipment areas, COGEM advised to not authorise import and processing until the monitoring plan was adapted. The present request for renewal concerns the authorisation for the use of MS8, RF3 and MS8xRF3 as feed and food uses, import and processing.

The application for renewal of the authorisation contains an updated molecular characterization and bioinformatic analyses, a systemic literature search to evaluate all new available information with regard to the safety of the GM oilseed events, and annual monitoring reports. As this application is submitted under Regulation (EC) 1829/2003, a food and/or feed assessment is carried out by the EFSA and Wageningen Food Safety Research (WFSR). The outcome of the assessments by these organisations was not known when this advice was completed.

4. Updated analyses and reports

In 2017, the sequences of MS8 and RF3 have been confirmed by resequencing the original material.[6] For the current renewal application no update on these sequences has been provided. The applicant did update the bioinformatic analyses for the renewal application. The analyses of the putative open reading frames (ORF) translations identified in the transgenic locus, crossing a junction or overlapping the inserted DNA sequences of MS8 and RF3, including the Barnase, Barstar or PAT proteins, did not reveal homology with known toxins.

The applicant has performed a scoping review on literature from June 1st 2013 to July 31 2021, to evaluate studies about the inserted genes of MS8, RF3 and MS8xRF3 *B. napus* and on the effect of these GM oilseed rape events on food, feed or environmental safety. Seven publications were considered relevant by the applicant. The applicant states that these publications support the safe status of MS8, RF3 and MS8xRF3 *B. napus*. No publications were found that contained new data on the inserted genes and the newly expressed proteins in GM oilseed rape MS8xRF3.

5. Post market environmental monitoring

The annual Post Market Environmental Monitoring (PMEM) reports for GM oilseed rape MS8, RF3 and MS8xRF3 were provided from June 2013 until June 2020. Based on the PMEM reports, the applicant states that no adverse health or environmental effects are associated with the import or use of MS8, RF3 and MS8xRF3 oilseed rape. Furthermore, the applicant states that revisions or changes to the monitoring measures are not considered necessary.

COGEM notes that the PMEM reports are general descriptions and provide no information on the number of volunteer plants identified and whether eradication was successful. Furthermore, in all PMEM reports (2013 until 2020) is stated that transport of imported oilseed rape to inland crushing plants is highly unlikely. Instead, crushing plants located at ports are the only facilities likely to process imports of oilseed rape, according to the applicant. COGEM notes that in the Netherlands, a number of small oilseed rape presses are scattered around the country and very likely obtain their seed supply form a nearby harbour via road traffic.[7] Feral GM oilseed rape plants have already been detected along railway lines and at transshipment areas in Switzerland.[8,9,10,11] Presence of feral GM oilseed rape could result in potential gene flow. COGEM remains of the opinion that monitoring along transport routes and transshipment areas should be included in the monitoring plan.

6. Conclusion

Based on the above, COGEM is of the opinion that the molecular characterization and bioinformatic analysis are adequate and there are no indications that MS8, RF3 or MS8xRF3 pose a risk to human health or the environment.

COGEM remains of the opinion that the PMEM plan for GM oilseed rape MS8, RF3 and MS8xRF3 needs to be adapted.[4,5,12] Feral oilseed rape populations can arise from GM oilseed rape seeds spilled during transshipment and transport. The establishment of feral GM oilseed rape can result in potential gene flow between different feral GM oilseed rape events. This process is accelerated if the GM trait provides a selective advantage, but can also occur under natural conditions. Subsequently gene flow can lead to new combinations of GM traits, of which potential adverse effects on the environment cannot

be evaluated in advance. In order to prevent the first steps in this scenario, monitoring along transport routes (including roadsides and railway beddings) and transshipment areas should be included in the monitoring plan. COGEM is of the opinion that the PMEM plan of MS8, RF3 and MS8xRF3 needs to be adapted before a market authorisation for the renewal is granted.

References

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