Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-DE-2011-103 (genetically modified maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21) from Syngenta under Regulation (EC) No. 1829/2003

13 May 2019
Ref. SC/1510/BAC/2019_0393

Context

Application EFSA-GMO-DE-2011-103 was submitted by Bayer CropScience N.V. for the marketing of genetically modified (GM) maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 (Unique Identifier SYNBTØ111 x SYNIR162-4 x SYNIR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9), for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

The six-event stack maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:
- Bt11, expressing the Cry1Ab and PAT proteins for insect resistance and herbicide tolerance respectively;
- MIR162, expressing the Vip3Aa20 and the PMI proteins that confer insect resistance and act as a selectable marker respectively;
- MIR604, expressing a modified Cry3A (mCry3A) and the PMI proteins that confer resistance to certain insects and act as a selectable marker respectively;
- 1507, expressing the Cry1F and the PAT proteins for insect resistance and herbicide tolerance respectively;
- 5307, expressing the eCry3.1Ab and PMI proteins for insect resistance and for selection by acting as a selectable marker respectively;
- GA21, expressing the mEPSPS protein for herbicide tolerance.

The application was validated by EFSA on 18 August 2014. A formal three-month consultation period of the Member States was started on 9 March 2018, lasting until 11 June 2018, 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 Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts to evaluate the molecular characterisation aspects the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). Two experts answered positively to this request, and did not have any comments on the dossier.

The opinion of the EFSA Scientific Panel on GMOs was published on 5 April 2019 (EFSA Journal 2019;17(4):5635, 36[2]), along with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period. It covers the six-event stack maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21, as well as the 34 subcombinations that have not been

[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] See https://doi.org/10.2903/j.efsa.2019.5635

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previously assessed (the single events and 22 subcombinations have previously been assessed by EFSA). Subcombinations occur as segregating progeny in the harvested grains of Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21, and refer also to any combination of up to five of the events Bt11, MIR162, MIR604, 1507, 5307 or GA21 that has either been or could be produced by conventional crossing, through targeted breeding approaches. These are maize stacks that can be bred, produced and marketed independently of the six-event stack Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21. The applicant provided data on three of the 34 previously unassessed subcombinations.

In delivering the present advice the BAC considered the opinion of EFSA as well as the advices already adopted by the BAC on the single and lower-order stacked events. The conclusions of the BAC for the most recent applications for the single events were as follows:

Event	Application number	BAC advice	Conclusions
Bt11	EFSA-GMO-RX-Bt11	BAC/2009/1510 (17/03/2009)	No major risks for human and animal health or concerning the environment were identified.
MIR162	EFSA-GMO-DE-2010-82	BAC/2012/0785 (29/08/2012)	No major risks for animal health or concerning the environment were identified, no conclusion on human health; the PMI protein has since been positively assessed.
MIR604	EFSA-GMO-UK-2005-11	BAC/2009/1365 (02/10/2009)	No major risks for animal health or concerning the environment were identified, no conclusion on human health; the PMI protein has since been positively assessed.
1507	EFSA-GMO-RX-001	BAC/2017/0186 (21/03/2017)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.
5307	EFSA-GMO-DE-2011-95	BAC/2018/0327 (29/05/2018)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.
GA21	EFSA-GMO-RX-005	BAC/2018/0058 (30/01/2018)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.

All GM maize events mentioned in the table above are authorised in the EU for food and feed uses[3], except maize 5307, which has been positively assessed by the EFSA GMO Panel on 07/03/2018 and is awaiting marketing authorization as of the writing of this document.

Scientific evaluation

1. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 (i.e. during transport and/or processing) into the European environment[4] will lead to environmental harm.

2. Molecular characterisation

With regard to the molecular characterisation, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

3. Assessment of food/feed safety and nutritional value

3.1. Assessment of compositional analysis

Taking into account the previous assessment of the single events and the new data on compositional analysis provided by the applicant for the six-stacked event, the Biosafety Advisory Council agrees with

[3] See EU register of GM food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
[4] As the application doesn't imply cultivation of the GM crop in the EU, a full environmental assessment is as in the case of a cultivation file is not warranted.

the GMO panel of EFSA that the compositional data of GM maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21, in comparison with its conventional counterpart, do not raise safety concerns.

3.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed Cry1Ab, Vip3Aa20, PAT, mCry3A, PMI, Cry1F, eCry3.1Ab and mEPSPS proteins in the context of previous applications, and no safety concerns were identified. Taking into account the updated information considered in the current application, the Council is of the opinion that its previous conclusions remain valid.
The Biosafety Advisory Council is also of the opinion that the combined expression of the newly expressed proteins in the stacked event does not raise toxicological concerns.

3.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed Cry1Ab, Vip3Aa20, PAT, mCry3A, PMI, Cry1F, eCry3.1Ab and mEPSPS proteins in the context of previous applications, and no concerns were identified. Since these previous evaluations no new information on potential allergenicity of these proteins has emerged, therefore the Council is of the opinion that its previous conclusions remain valid.
The Biosafety Advisory Council is also of the opinion that the combined expression of the newly expressed proteins in the stacked event does not raise concerns regarding the allergenicity.

3.4. Nutritional value

The Biosafety Advisory Council is of the opinion that the information provided is sufficient to conclude that the nutritional characteristics of maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21-derived food and feed are not expected to differ from those of conventional maize varieties.

4. Monitoring

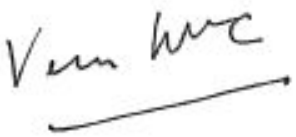
Since the allergenicity of the whole GM maize has not been fully assessed, it is recommended to take up monitoring of allergenicity as part of the general surveillance.

Conclusion

Based on the whole set of data on maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the opinion of EFSA and the advices already adopted by the BAC on the six single events and lower order subcombinations that have already been assessed, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that the potential environmental release of maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 and its subcombinations is unlikely to pose any threat to the European environment;
2) Agrees with the GMO panel of EFSA that there is no reason to expect interactions between the newly expressed proteins that could impact on the food or feed safety;
3) Agrees with the GMO panel of EFSA that in the context of its proposed uses, maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 and its subcombinations is unlikely to pose any risk to human and animal health;
4) Considers that the conclusions of the Biosafety Advisory Council on the single events that have been assessed previously (see table on page 2) remain unchanged.

In addition, the Biosafety Advisory Council recommends following up any unanticipated allergenicity aspects of the GM maize in monitoring systems.



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