Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2019-159 (maize DP202216) from Pioneer under Regulation (EC) No. 1829/2003

30 April 2024
Ref. SC/1510/BAC/2024_0636

Context

Application EFSA-GMO-NL-2019-159 was submitted by Pioneer Hi-Bred International Inc. for the authorisation for the marketing of genetically modified (GM) maize DP202216 (Unique Identifier DP-2Ø2216-6) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

DP202216 contains a single insert consisting of one copy of the *zmm28* and *pat* cassettes, expressing the endogenous ZMM28 maize transcription factor (to enhance yield) and the PAT protein (tolerance to glufosinate), respectively.

The application was validated by EFSA on 23 September 2019 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 Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts to evaluate the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). One expert answered positively to this request. No comments to the dossier were formulated.

The opinion of the EFSA Scientific Panel on GMOs was published on 20 March 2024 (EFSA Journal 2024;22(3):e8455[2]) together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

In delivering the present advice, the BAC considered the expert feedback on application EFSA-GMO-NL-2019-163 and the opinion of EFSA.

[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.2024.8655

Biosafety Advisory Council - Secretariat • Service Biosafety and Biotechnology (SBB)
Sciensano • Rue Juliette Wytsmanstraat 14 • B-1050 Brussels • Belgium
T + 32 2 642 52 93 • bac@sciensano.be • www.bio-council.be

Scientific evaluation

1. 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.

2. Assessment of food/feed safety and nutritional value

2.1. Assessment of compositional analysis

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM maize DP202216, in comparison with its conventional counterpart, do not raise safety concerns.

2.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed PAT protein in the context of previous applications, and no concerns with respect to toxicity were identified. Since no new information on the potential toxicity of this protein has become available, the Council is of the opinion that its previous conclusions remain valid.

As the ZMM28 protein produced is an endogenous maize protein with no significant similarities to known toxins, the Biosafety Advisory Council considered that there are no safety concerns with respect to toxicity.

The Biosafety Advisory Council is also of the opinion that the combined presence of the PAT and ZMM28 proteins in DP202216 does not raise toxicological concerns.

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed PAT protein in the context of previous applications, and no concerns with respect to allergenicity were identified. Since no new information on allergenicity of this protein has become available, the Council is of the opinion that its previous conclusions remain valid.

As the ZMM28 protein produced is an endogenous maize protein with no significant similarities to known allergens, the Biosafety Advisory Council considered that there are no safety concerns with respect to allergenicity.

The Biosafety Advisory Council is also of the opinion that the combined presence of the PAT and ZMM28 proteins in DP202216 does not raise concerns regarding allergenicity.

2.4. Nutritional value

The Biosafety Advisory Council is of the opinion that the information provided is sufficient to conclude that the nutritional characteristics of maize DP202216-derived food and feed are not expected to differ from those of conventional maize varieties.

3. Environmental risk assessment

Field observations indicate that maize grains can sometimes overwinter and germinate in certain regions of the EU (e.g. Palaudelmàs *et al*., 2009[3]; COGEM, 2011[4]; Pascher, 2016[5]). As a result, volunteer maize plants do sometimes occur in subsequent crops. There is also evidence of the rare occurrence of feral maize plants (e.g. Pascher, 2016; COGEM, 2018[6]). However, volunteer maize has been shown to grow weakly and is not considered an agricultural problem. There are no indications that the occurrence of feral maize plants has resulted in the establishment of self-sustaining populations. This can be explained by the fact that maize is highly domesticated, has no weedy characteristics and is not tolerant to frost. Thus, the occurrence of volunteer and feral maize in the EU is currently limited and transient. In addition, maize has no sexual compatible wild relative in the EU. Therefore, the Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of maize DP202216 (i.e. during transport and/or processing) into the European environment[7] will lead to environmental harm.

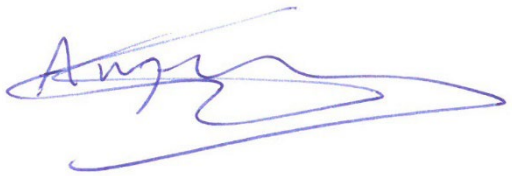
4. Monitoring

With regard to monitoring, the Biosafety Advisory Council is of the opinion that the information provided is sufficient.

Conclusion

Based on the whole set of data on maize DP202216 provided by the applicant, the scientific assessment of the dossier done by the Belgian expert, the scientific opinion of EFSA, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that maize DP202216 would not raise safety concerns in the case of accidental release of viable GM maize grains into the environment;
2) Agrees with the GMO panel of EFSA that in the context of its proposed uses, maize DP202216 is as safe as its conventional counterpart and the tested non-GM reference varieties with respect to potential effects on human and animal health.



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

[3] Palaudelmàs M., *et al*., 2009. Effect of volunteers on maize gene flow. Transgenic Res.18(4):583-594. doi:10.1007/s11248-009-9250-7
[4] COGEM, 2011. Research report "Crop volunteers and climate change. Effects of future climate change on the occurrence of maize, sugar beet and potato volunteers in the Netherlands". https://cogem.net/en/publication/crop-volunteers-and-climate-change-effects-of-future-climate-change-on-the-occurrence-of-maize-sugar-beet-and-potato-volunteers-in-the-netherlands/
[5] Pascher K., 2016. Spread of volunteer and feral maize plants in Central Europe: recent data from Austria. Environ. Sci Eur.28(1):30. doi:10.1186/s12302-016-0098-1
[6] COGEM, 2018. Research report "Are teosinte and feral maize present in the Netherlands?". https://cogem.net/en/publication/are-teosinte-and-feral-maize-present-in-the-netherlands/
[7] As the application doesn't imply cultivation of the GM crop in the EU, a full environmental assessment, as in the case of a cultivation dossier, is not warranted.