Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2022-174 (maize DP910521) from Corteva Agriscience under Regulation (EC) No. 1829/2003

25 September 2024
Ref. SC/1510/BAC/2024_1209

Context

Application EFSA-GMO-NL-2022-174 was submitted by Corteva Agriscience for the authorisation for the marketing of genetically modified (GM) maize DP910521 (Unique Identifier DP-91Ø521-2) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

Maize DP910521 contains a single insert consisting of *mo-pat*, *pmi* and *cry1B.34* expression cassettes, expressing the Cry1B.34 protein for resistance against certain lepidopteran insect pests, the PAT protein for tolerance to glufosinate herbicides, and the PMI protein as a selectable marker.

The application was validated by EFSA on 5 January 2023 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). Five experts answered positively to this request, and formulated a number of comments to the dossier. See Annex I for an overview of all the comments.

The scientific opinion of the EFSA Scientific Panel on GMOs was published on 1st August 2024 (EFSA Journal 2024;22:e8887[2]). One external expert was additionally consulted regarding the increased levels of iron of the GM maize. In delivering the present advice, the BAC considered in particular the opinion of EFSA and the comments formulated by the experts on application EFSA-GMO-NL-2022-174 and on 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.2024.8887

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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 DP910521, including the iron levels, in comparison with its conventional counterpart, do not raise safety concerns.

2.2. Assessment of toxicity

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of GM maize DP910521, in comparison with its conventional counterpart, does not raise safety concerns.

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed PAT and PMI proteins in the context of previous applications, and no concerns were identified. Since no new information on allergenicity of these proteins has become available, the Council is of the opinion that its previous conclusions remain valid. The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data does not indicate that the newly expressed Cry1B.34 protein may be allergenic.

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 DP910521-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,

[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/

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.

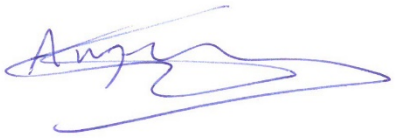
4. Monitoring

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 DP910521 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, and the opinion of EFSA, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that the potential environmental release of maize DP910521 would not raise safety concerns to the European environment;
2) Agrees with the GMO panel of EFSA that maize DP910521 is as safe as its conventional counterpart and the tested non-GM maize reference varieties with respect to potential effects on human and animal health.



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

Annex: Outcome of the assessment of the application

[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.

Annex: Outcome of the assessment of application EFSA-GMO-NL-2022-174 by the Biosafety Advisory Council during the formal consultation of the Member States (3-month commenting period in accordance with Articles 6.4 and 18.4 of Regulation (EC) No 1829/2003)

Coordinator: W. Vanhove
Experts: Henri Batoko (UCL), Leo Fiems (ILVO), Frank Van Breusegem (UGent), Jan Van Doorsselaere (Vives), Erik Van Miert (Sciensano)
SBB: Fanny Coppens

Application: **EFSA-GMO-NL-2022-174**
Applicant: **Corteva Agriscience**
GMO: **Maize DP910521**
Validation of dossier by EFSA: **5 January 2023**

Scope of the application:
☒ GM plants for food use
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
☒ GM plants for feed use
☒ Feed produced from GM plants
☒ Import and processing (Part C of Directive 2001/18/EC)
☐ Seeds and plant propagating material for cultivation in European Union (Part C of Directive 2001/18/EC)

Given the characteristics of the GMO and its intended uses, experts were consulted to cover the following areas of expertise:
☒ Molecular characterization
☒ Environmental aspects
☒ Allergenicity
☒ Toxicology
☒ Food and Feed aspects

The experts were asked to evaluate whether the information provided in the application is sufficient in order to state that the marketing of the genetically modified plant for its intended uses, will not raise any problems for the environment or human or animal health. If information is lacking, the expert was asked to indicate which information should be provided and what the scientifically reasoning is behind this demand.

List of comments/questions received from the experts

PART I - GENERAL COMMENTS

Comment 1
The safety for human and animal health and for the environment of Cry1B.34, PAT and PMI proteins has been previously evaluated. Furthermore, genetically modified plants with stacked traits seem to be as safe as conventional plants. Therefore, in my opinion maize DP 910521 is as safe for human and animal health and for the environment as conventional maize.

PART II - SCIENTIFIC INFORMATION

1. HAZARD IDENTIFICATION AND CHARACTERISATION

1.1. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

Have evaluated this section and consider the information adequate: 4 experts

1.2. MOLECULAR CHARACTERISATION

1.2.1. Information relating to the genetic modification

Have evaluated this section and consider the information adequate: 3 experts

1.2.2. Information relating to the genetically modified plant

Have evaluated this section and consider the information adequate: 3 experts

1.2.3. Additional information relating to the genetically modified plant required for the environmental safety aspects

Have evaluated this section and consider the information adequate: 4 experts

1.2.4. Conclusions of the molecular characterisation

Have evaluated this section and consider the information adequate: 4 experts

1.3. COMPARATIVE ANALYSIS

1.3.1. Choice of the conventional counterpart and additional comparators

Have evaluated this section and consider the information adequate: 2 experts

1.3.2. Experimental design and statistical analysis of data from field trials for comparative analysis

Have evaluated this section and consider the information adequate: 1 expert

Comment 1

Field trials were conducted at 12 sites in North-America, but compositional samples were taken from 8 locations. It is mentioned that additional agronomic sites were intended to ensure 8 complete sites for the analysis of compositional data. It is not clear how the selection of these 8 locations was made, or what criteria were used to eliminate some locations for data collection. Were the sites selected on a random base or was an outlier test applied?

SBB comment: EFSA's "Guidance on the agronomic and phenotypic characterisation of genetically modified plants" (https://www.efsa.europa.eu/en/efsajournal/pub/4128, under 5.1) requests at least eight field trial sites. Annex 15 of the dossier mentions: "Eight sites were selected for composition analysis which represent geographically diverse locations within the crop production areas, including different soil textures and weather characteristics (as described in report PHI-2020-023/002), and capture variability within the set of potential receiving environments in which the test materials can be grown."

1.3.3. Selection of material and compounds for analysis

Have evaluated this section and consider the information adequate: 2 experts

1.3.4. Comparative analysis of composition

Have evaluated this section and consider the information adequate: 1 expert

Comment 1
Proximates of DP 910521 maize were within the reference maize data range or the tolerance interval. So, composition of DP 910521 maize is equivalent with reference maize varieties.

1.3.5. Comparative analysis of agronomic and phenotypic characteristics

Have evaluated this section and consider the information adequate: 2 experts

1.3.6. Effects of processing

Have evaluated this section and consider the information adequate: 1 expert

1.3.7. Conclusion

Have evaluated this section and consider the information adequate: 2 experts

1.4. TOXICOLOGY

1.4.1. Testing of newly expressed proteins

Have evaluated this section and consider the information adequate: 2 experts

Comment 1
Statement: The potential toxicity of the Cry1B.34 protein was assessed by comparison of its sequence to the sequences in a toxin and general database (Annex 11). Bioinformatic analyses support the conclusions that the Cry1B.34 protein is unlikely to be a toxin.

Verification: Annex 11 elaborates on the analyses to identify allergens (COMPARE 2021 database) and toxins (UniProtKB/Swiss-Prot, NCBI protein databases). No significant alerts were observed.
Conclusion: agree

Statement: Lability of the Cry1B.34 Protein in Sequential Digestibility Analysis with Simulated Gastric Fluid (SGF) and Simulated Intestinal Fluid (SIF).
Verification: Annex 18 shows that the Cry1B.34 protein migrating at ~129 kDa was digested within 0.5 minutes in SGF as was evident in both the stained SDS-PAGE gel and western blot. After digestion of the Cry1B.34 protein in SGF, the remaining detectable low molecular weight bands (~2-5 kDa) were digested within 0.5 minutes during sequential SIF digestion (Annex 19).
Conclusion: agree

Statement: The results demonstrated that Cry1B.34 protein heated for approximately 30 minutes at temperatures of 75 °C or higher was inactive against S. frugiperda when incorporated in an artificial insect diet.
Verification: Annex 20 The results demonstrated that Cry1B.34 protein heat-treated for approximately 30 minutes at 75 °C and 95 °C was effectively inactive against S. frugiperda when incorporated in an artificial diet. Statistically significant decreases in protein activity were observed for Cry1B.34 protein heat-treated at temperatures of 75 °C and 95 °C when compared to the unheated control. No statistically significant decreases in protein activity were observed for Cry1B.34 protein heat-treated for approximately 30 minutes at 25 °C and 50 °C when compared to the unheated control.
Conclusion: agree

Statement: Glycosylation was determined to be negative for the DP910521 maize-derived Cry1B.34 protein.
Verification: Annex 1 The DP910521 maize-derived Cry1B.34 protein was determined to be negative for glycosylation using a glycoprotein staining assay.
Conclusion: agree

Statement: The results demonstrated that the Cry1B.34 protein derived from DP910521 maize and the microbially-derived Cry1B.34 protein are of the expected molecular weight, immunoreactivity, amino acid sequence, and had the expected lack of glycosylation. The bioactivity of the microbially-derived Cry1B.34 protein and DP910521 maize-derived Cry1B.34 protein was also verified by insect bioassays. The microbially-derived Cry1B.34 protein was demonstrated to be an appropriate test substance for use in safety studies.
Verification: Annex 2 and Annex 3:

- Cry1B.34 protein migrated as a predominant band consistent with the expected molecular weight of approximately 129 kilodaltons (kDa).
- Western blot analysis demonstrated that the Cry1B.34 protein was immunoreactive to a Cry1B.34 monoclonal antibody
- Protein glycosylation was not detected for the Cry1B.34 protein using a glycoprotein staining assay.
- The matched peptides identified with the LC-MS analysis of the trypsin and chymotrypsin-digested Cry1B.34 protein account for 90.8% (1042/1147) of the expected Cry1B.34 amino acid sequence
- The bioactivity analysis demonstrated that the Cry1B.34 protein had insecticidal activity toward a target insect, Spodoptera frugiperda.

Conclusion: agree

Statement: The acute oral toxicity tolerant dose and the LD501 of Cry1B.34 protein were determined to be greater than 5000 mg/kg body weight.
Verification: Annex 21. Under the conditions of this study, intragastric exposure of Cry1B.34 protein to male and female mice at 5000 mg/kg body weight did not result in mortality or other evidence of acute oral toxicity, based on evaluation of body weight, clinical signs, and gross pathology.
Conclusion: agree

Statement: The no-observed-effect level (NOEL) was 1000 mg/kg of bw/day equivalent to 920 and 1155 mg/kg of bw/day Cry1B.34 protein for males and females, respectively.
Verification: Annex 22. Based on the results of this study, oral (dietary) exposure of CrylB.34 protein to Crl:CDl(ICR) mice at target exposure levels of 300 and 1000 mg/kg of bw/day for at least 28 consecutive days was well-tolerated at all target exposure levels with no test substance-related mortality or adverse findings. The no-observed-effect level (NOEL) was 1000 mg/kg of bw/day equivalent to 920 and 1155 mg/kg of bw/day for males and females, respectively, in the Main Study Group animals.
Conclusion: agree

Statement: the data from these assessments support the conclusion that the Cry1B.34 protein is unlikely to be a toxin to humans or animals.
Verification: The above-mentioned
Conclusion: agree

Statement: The PAT protein expressed in DP910521 maize was characterised to confirm the expected molecular weight, immunoreactivity, amino acid sequence, and absence of glycosylation as observed from prior characterisation.
Verification: Annex 6
- SDS-PAGE analysis to confirm the expected molecular weight;
- Western blot analysis to confirm expected molecular weights and immunoreactivity;
- N-terminal amino acid sequence analysis to confirm the identity of the protein;
- mass determination of tryptic and chymotryptic peptides by LC-MS to confirm the identity of the protein; and
- glycoprotein staining to confirm lack of post-translational modification (glycosylation).

Conclusion: agree

Statement: Updated bioinformatic analyses support the original conclusions that the PAT protein is unlikely to be a toxin
Verification: Annex 11 (updated assessment) Bioinformatics evaluation of the DP910521 insert did not generate biologically relevant amino acid sequence similarities to known allergens, toxins, or other proteins that would be harmful to humans or animals.
Conclusion: agree

Statement: the data from these assessments support the conclusion that the PAT protein is unlikely to be a toxin to humans or animals.
Verification: Reference Table 1.4-1. Toxicological Evaluation of Newly Expressed Protein, provides most of the information as requested by 503/2013, Annex II 1.4.1. No 28-day study with the protein is provided in the document. An acute tox. study is provided/referenced which is not in agreement with 1.4.1 where it is indicated that acute studies have limited value. On the other hand, Annex II, 1.4.1

also states “As regards proteins expressed in the genetically modified plant, in the case where the history of safe use for consumption as food and/or feed of both the plant and the newly expressed proteins is duly documented, specific toxicity testing as provided for in this Section shall not be required. In such case, the applicant shall provide the necessary information regarding the history of safe use of the proteins.” The information provided does indeed suggest that the PAT protein in DP910521 maize is unlikely to be toxic to humans or animals. A more specific statement that/why the available information justifies the omission of a 28-day toxicity study would help transparency. For instance, the applicant states “Several Cry proteins have been deployed as safe and effective pest control agents in microbial Bt formulations for almost 40 years. Several Cry proteins have also been effectively deployed as safe and effective pest control agents and have a history of safe use in genetically modified crops (ISAAA, 2022a).”, yet provides a 28-day tox. study for the latter.
Conclusion: agree, yet more specific documentation would be welcomed

SBB Comment: the presence of all the required studies is already checked by EFSA before the start of the consultation. The safety of the PAT protein has already been assessed in several previous applications (also dating from before the requirement of a 28-day toxicity study), while this is the first application with Cry1B.34 specifically.

Statement: The PMI protein expressed in DP910521 maize was characterised to confirm the expected molecular weight, immunoreactivity, amino acid sequence, and absence of glycosylation as observed from characterisation.
Verification: Annex 7

- SDS-PAGE analysis to confirm the expected molecular weight;
- Western blot analysis to confirm expected molecular weights and immunoreactivity;
- N-terminal amino acid sequence analysis by LC-MS to confirm the identity of the protein;
- mass determination of tryptic and chymotryptic peptides by LC-MS to confirm the identity of the protein; and
- glycoprotein staining to confirm lack of post-translational modification (glycosylation).

Conclusion: agree

Statement: These analyses confirmed that DP910521 maize-derived PMI protein had the expected molecular weight, immunoreactivity, amino acid sequence, and absence of glycosylation as observed from prior characterisation of other registered events. The sequence of the PMI protein matched the respective translated gene sequence. Therefore, the previous safety evaluations on the PMI protein are applicable to DP910521 maize.
Verification: Reference Table 1.4-2 and Annex 11
Annex 11: (updated assessment) Bioinformatics evaluation of the DP910521 insert did not generate biologically relevant amino acid sequence similarities to known allergens, toxins, or other proteins that would be harmful to humans or animals
None of the sequence alignments is related to any known toxic proteins that are harmful to humans or animals; while they do show expected alignments with non-toxic proteins, many are already present in the food and/or feed chain.
Conclusion: agree

Statement: the data from these assessments support the conclusion that the PAT protein is unlikely to be a toxin to humans or animals.
Verification: Reference Table 1.4-2. Toxicological Evaluation of Newly Expressed Protein, provides most of the information as requested by 503/2013, Annex II 1.4.1. No 28-day study with the protein is

provided in the document. An acute tox. study is provided/referenced which is not in agreement with 1.4.1 where it is indicated that acute studies have limited value. On the other hand, Annex II, 1.4.1 also states “As regards proteins expressed in the genetically modified plant, in the case where the history of safe use for consumption as food and/or feed of both the plant and the newly expressed proteins is duly documented, specific toxicity testing as provided for in this Section shall not be required. In such case, the applicant shall provide the necessary information regarding the history of safe use of the proteins.” The information provided does indeed suggest that the PMI protein in DP910521 maize is unlikely to be toxic to humans or animals. A more specific statement that/why the available information justifies the omission of a 28-day toxicity study would help transparency. For instance, the applicant states “Several Cry proteins have been deployed as safe and effective pest control agents in microbial Bt formulations for almost 40 years. Several Cry proteins have also been effectively deployed as safe and effective pest control agents and have a history of safe use in genetically modified crops (ISAAA, 2022a).”, yet provides a 28-day tox. study for the latter.
Conclusion: agree, yet more specific documentation would be welcomed

Statement: These data support the conclusion that the Cry1B.34, PAT, PMI proteins in DP910521 maize are unlikely to be toxic to humans or animals.
Verification: The information provided do indeed confirm the safety of the Cry1B.34, PAT and PMI proteins.
Conclusion: agree

1.4.2. Testing of new constituents other than proteins

Have evaluated this section and consider the information adequate: 2 experts

1.4.3. Information on natural food and feed constituents

Have evaluated this section and consider the information adequate: 2 experts

1.4.4. Testing of the whole genetically modified food or feed

Have evaluated this section and consider the information adequate: 2 experts

Comment 1
Statement: Under the conditions of this study, no diet-related differences were observed in rats fed a diet containing up to 50% of the DP910521 maize grain compared with rats fed diets containing control or reference maize grain. These results support the conclusion that maize grain containing event DP-91Ø521-2 is as safe and nutritious as maize grain that does not contain event DP-91Ø521-2.
Verification: Annex 23: Under the conditions of this study, no diet-related differences were observed in rats fed a diet containing up to 50% of the DP910521 maize grain compared with rats fed diets containing 022 Control or Reference maize grain. These results support the conclusion that maize grain containing event DP-91Ø521-2 is as safe and nutritious as maize grain that does not contain event DP-91Ø521-2.
Conclusion: agree

1.4.5. Conclusion of the toxicological assessment

Have evaluated this section and consider the information adequate: 3 experts

1.5. ALLERGENICITY

1.5.1. Assessment of allergenicity of the newly expressed protein

Have evaluated this section and consider the information adequate: 2 experts

1.5.2. Assessment of allergenicity of the whole genetically modified plant

Have evaluated this section and consider the information adequate: 2 experts

1.5.3. Conclusion of the allergenicity assessment

Have evaluated this section and consider the information adequate: 2 experts

1.6. NUTRITIONAL ASSESSMENT

1.6.1. Nutritional assessment of the genetically modified food

Have evaluated this section and consider the information adequate: 2 experts

1.6.2. Nutritional assessment of the genetically modified feed

Have evaluated this section and consider the information adequate: 2 experts

1.6.3. Conclusion of the nutritional assessment

Have evaluated this section and consider the information adequate: 2 experts

2. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE OR EXTENT OF USE

Have evaluated this section and consider the information adequate: 2 experts

3. RISK CHARACTERISATION

Have evaluated this section and consider the information adequate: 2 experts

4. POST-MARKET MONITORING ON THE GENETICALLY MODIFIED FOOD OR FEED

Have evaluated this section and consider the information adequate: 1 expert

5. ENVIRONMENTAL RISK ASSESSMENT (ERA)

5.1. INTRODUCTION

Have evaluated this section and consider the information adequate: 2 experts

5.2. GENERAL APPROACH OF THE ERA

Have evaluated this section and consider the information adequate: 2 experts

5.3. SPECIFIC AREAS OF RISK

5.3.1. Persistence and invasiveness including plant-to-plant gene flow

Have evaluated this section and consider the information adequate: 2 experts

5.3.2. Plant to micro-organisms gene transfer

Have evaluated this section and consider the information adequate: 2 experts

5.3.3. Interactions of the GM plant with target organisms

Have evaluated this section and consider the information adequate: 2 experts

5.3.4. Interactions of the GM plant with non-target organisms (NTOs)

Have evaluated this section and consider the information adequate: 2 experts

5.3.5. Impacts of the specific cultivation, management and harvesting techniques

Have evaluated this section and consider the information adequate: 1 expert

5.3.6. Effects on biogeochemical processes

Have evaluated this section and consider the information adequate: 1 expert

5.3.7. Effects on human and animal health

Have evaluated this section and consider the information adequate: 1 expert

Comment 1
Three traits were stacked in DP 910521 maize: Cry1B.34, PAT and PMI proteins. It has been previously concluded that maize MON 89034x1507xMIR162xNK603xDAS-40278-9, a five-event stack maize, which also contain Cry, PAT and PMI proteins, among others, is as safe as its non-genetically modified comparator and the tested non-genetically modified maize varieties (EFSA, 2022). Furthermore, stacked genetically modified plants seems to be as safe as conventional plants (Goodwin et al., 2021).

Coordinator comment: Goodwin et al. (2021) rather states "(…) to date, there is no evidence of a higher risk of stacked genetically modified plants compared to the risks of plants with single GM-events which are stacked in the former plants".

5.3.8. Overall risk evaluation and conclusions

Have evaluated this section and consider the information adequate: 2 experts

6. POST-MARKET ENVIRONMENTAL MONITORING PLAN (PMEM)

6.1. INTERPLAY BETWEEN ENVIRONMENTAL RISK ASSESSMENT, RISK MANAGEMENT AND PMEM

Have evaluated this section and consider the information adequate: 2 experts

6.2. CASE-SPECIFIC GM PLANT MONITORING (STRATEGY, METHOD AND ANALYSIS)

Have evaluated this section and consider the information adequate: 1 expert

6.3. GENERAL SURVEILLANCE FOR UNANTICIPATED ADVERSE EFFECTS (STRATEGY, METHOD)

Have evaluated this section and consider the information adequate: 2 experts

6.4. REPORTING THE RESULTS OF PMEM

Have evaluated this section and consider the information adequate: 2 experts

7. ADDITIONAL INFORMATION RELATED TO THE SAFETY OF THE GENETICALLY MODIFIED FOOD OR FEED

Have evaluated this section and consider the information adequate: 1 expert

References

EFSA, 2022. Assessment of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 for food and feed uses, under regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-151). EFSA Journal 20, 7451.

Goodwin, L., Hunst, P., Burzio, L., Rowe, L., Money, S., Chakravarthy, S. 2021. Stacked Trait Products Are As Safe As Non-Genetically Modified (GM) Products Developed By Conventional Breeding Practices. Journal of Regulatory Science 9, 22-25.