Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2020-172 (maize DP915635) from Pioneer under Regulation (EC) No. 1829/2003

13 March 2024
Ref. SC/1510/BAC/2024_0350

Context

Application EFSA-GMO-NL-2020-172 was submitted by Pioneer for the authorisation for the marketing of genetically modified (GM) maize DP915635 (Unique Identifier DP-915635-4) 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 DP915635 contains a single insert consisting of one copy of the *ipd079Ea*, *mo-pat*, and *pmi* expression cassettes, expressing the IPD079Ea protein for control of corn rootworm pests, the PAT protein for tolerance to glufosinate-ammonium herbicides, and the PMI protein which was used as a selectable marker.

The application was validated by EFSA on 11 June 2021 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). Six experts answered positively to this request, and formulated a number of comments to the dossier, none of which were selected to be sent to EFSA. See Annex I for an overview of all the comments from the experts.

The opinion of the EFSA Scientific Panel on GMOs was published on 17 January 2024 (https://doi.org/10.2903/j.efsa.2024.8490[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 in particular the comments formulated by the experts on application EFSA-GMO-NL-2020-172 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://www.efsa.europa.eu/en/efsajournal/pub/8490

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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 DP915635, 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 DP915635, 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 is of the opinion that the information provided is sufficient to conclude that there is no indication for allergenicity of the newly expressed DP915635 protein.

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 DP915635-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. The occurrence of feral maize plants has not resulted in the establishment of self-sustaining populations, mainly because 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

[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/

the accidental release of maize DP915635 (i.e. during transport and/or processing) into the European environment[7] will lead to environmental harm.

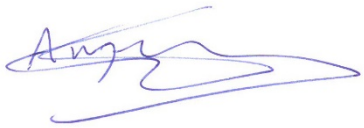
4. Monitoring

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 DP915635 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 DP915635 would not raise environmental safety concerns;
2) Agrees with the GMO panel of EFSA that in the context of its proposed uses, maize DP915635 is as safe as the conventional counterpart and non-GM maize reference varieties tested.



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/2020/172 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)

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Experts: Jacques Dommes (ULg), Leo Fiems (ILVO), Michel Ghanem, André Huyghebaert (UGent), Peter Smet (Consultant), Frank Van Breusegem (UGent),
SBB: Fanny Coppens, Adinda De Schrijver

Application: **EFSA/GMO/NL/2020/172**
Applicant: **Pioneer**
GMO: **Maize DP915635**
Validation of dossier by EFSA: **11 June 2021**

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.

The following was sent to EFSA: "We do not have any comments and we consider all the necessary information is present to conduct a robust risk assessment". It should be noted that all the comments received from the experts are considered in the evaluation of this dossier and in formulating the final advice of the Biosafety Advisory Council.

List of comments/questions received from the experts

PART I - GENERAL COMMENTS

Comment 1
The rationale of the development of this new transgenic line and its advantage compared to other existing GMOs is well explained. Although I would have love to see how this new MOA would be better in terms of resistance compared to that the Bt GMO previously used.
The segregation analysis provided in section 1.2.2.4 across five breeding generations is well documented and confirms a stable Mendelian inheritance pattern.
The SbS analysis provided in the document is well explained and documented and shows that a single copy of the inserted DNA derived from PHP83175 and PHP73878, and that no additional insertions or plasmid backbone sequences are present in its genome. Although this analysis was conducted on the T1 generation only.

The data presented in the document confirm that that there were any endogenous gene or regulatory element disruption or deletion occurred at the integration site in DP915635 maize according to currently available sequence information.

Further evidence and information are needed as specified in the specific comments.

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: 3 experts

Comment 1
"The history of safe use of the PMI protein supports the weight of evidence that the PMI protein expressed in DP915635 maize is unlikely to present significant risks to the environment, human, or animal health." Again this statement needs further references to support that claim.

SBB/coordinator comment: For more details, see p. 90 and section 7.1 of the main file ("A systematic review of studies published in the scientific literature and studies performed by the applicant within the period of 10 years prior to the date of submission of the dossier on the potential effects on human and animal health of the genetically modified food and feed covered by the application").

"The PAT and PMI proteins present in DP915635 maize are found in several approved events that are currently in commercial use." Please detail !

SBB/coordinator comment: While the events that contain PAT & PMI proteins are indeed not specified in the dossier, the information on these two proteins relevant for the RA has been provided; we consider the latter information more informative for risk assessment.

"Therefore, no deliberate release of viable plant material or derived products into the EU environment is expected." This statement is followed by another sentence that says “possible routes of exposure would therefore consist of accidental release of imported viable or organic plant materials, exposure

through manure and faeces following feed consumption or gastrointestinal exposure through food and/or feed consumption". This is a non-negligible risk !

"During the processing of GM plants into feed and food products, there is much degradation of DNA, limiting exposure to plant DNA including intact transgenic DNA. Harsh conditions such as high temperatures, mechanical disruption, and damaging chemicals significantly degrade DNA (Kharazmi et al., 2003)." This is relatively true, but how about fresh consumption ? Isn't it a risk that needs to be evaluated ?

SBB/coordinator comment: The potential risk that may result due to the above-mentioned routes of exposure, including food/feed consumption, have been addressed in the application.

1.2. MOLECULAR CHARACTERISATION

1.2.1. Information relating to the genetic modification

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

Comment 1
The DP9156635 insertion contains two loxP sites bracketing the pmi and the mo-pat genes. The applicant did not address the reason for the presence of these sequences in the inserted DNA. I guessed that these loxP site could be used in the future to eliminate the selection marker and the pat gene by sequence-specific recombination. The presence of these sequences does not raise any safety concern.

Comment 2
Amino Acid Sequence of Microbially Derived IPD079Ea Protein Indicating Chymotryptic Peptides Identified Using LC-MS Analysis shows that (Fig 4) there are some deletions. What are the consequences of that deletion?

SBB/coordinator comment: Fig. 4 does not indicate deletions in the sequence, but the peptides that were identified by LC-MS after chymotryptic digestion.

"Bioactivity analysis demonstrated that the IPD079Ea protein had insecticidal activity toward a target insect, *D. virgifera virgifera."* Details required about how this insecticidal activity was conducted.

SBB/coordinator comment: More details about the assay are provided in annex PHI-2019-187, as mentioned in the first part of the quoted sentence.

Page 31 "The history of safe use of the PAT protein expressed in DP915635 maize supports a weight of evidence that the PAT protein is unlikely to be an allergen or toxin". Supported by what evidence ? Needs clarification here.

Coordinator comment: See page 89.

"The strain *E. coli* K-12 is well-characterised and its safety (non-pathogenicity) has been extensively reviewed (Gorbach, 1978)." This reference is relatively old and needs to be supported by more recent evidence.

SBB/coordinator comment: While the reference is indeed quite old, the information on the IPD079Ea protein is considered more informative for risk assessment.

"The PMI version expressed in DP915635 maize has been found in different *Escherischia coli* strains (including the sequenced K-12) and identical or homologues proteins have been identified in other *Escherichia* species and in most other genera of Enterobacteriaceae (such as genus *Enterobacter*, *Klebsiella*, *Citrobacter*, *Shigella*, *Salmonella, Yersinia, Serratia*)." This statement is quite worrying because of the possibility of transfer to other microorganisms.

SBB/coordinator comment: The possibility of transfer to other microorganisms and the consequences of such a transfer are addressed further in the application (see section 5.3.2).

"The amino acid sequence of the PMI protein present in DP915635 maize was demonstrated to be identical to the PMI protein expressed in MIR162 maize, which is commercialized and has a history of safe use." This statement is not fully supported by the data shown specifically in Figure 7. As there were deletions in the sequence comparison.

SBB/coordinator comment: Fig. 7 does not indicate deletions in the sequence, but the peptides that were identified by LC-MS after tryptic and chymotryptic digestion.

1.2.2. Information relating to the genetically modified plant

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

Comment 1
Sometimes, off-target effects were reported in crops where CRISPR/Cas technology has been applied (Graham et al., 2020; Kawal et al., 2020; Lassoued et al., 2019). Were there undesirable off-target effects in the case of DP915635 maize?

SBB/coordinator comment: CRISPR/Cas is in this case not used for "editing" (such as point mutations). The applicant has checked whether no unintended plasmid-derived sequences were present (p. 38-42 Main text).

Comment 2
"DP-915635-4 maize (referred to as DP915635 maize)." This double referencing is somehow confusing.

SBB/coordinator comment: Proposals for textual changes are not considered at this stage of the evaluation process.

"Reads also aligned to the *pin*II terminator elements located outside of the intended insertion regions in PHP83175, PHP73878, PHP70605, and PHP21875 although these elements were not incorporated into the insertion." How do you explain that ?

Coordinator comment: Is explained later in the text.

“It should be noted that while DNA sequencing provides certain molecular information, the exact nucleotide sequence should not be viewed as static. Spontaneous mutations are a very common phenomenon in plants, presenting a biological mechanism of adaptation to constantly changing environment (Weber et al., 2012)." This statement is true and I would have love to see that analysis conducted on the 5 generation to make sure how stable this is even if the selection pressure over five years may not be enough to produce significant mutations.

SBB/coordinator comment: Genetic stability of the insert over 5 generations is addressed further down in the main text, p 47-52.

"Search of various databases including NCBI (nt), (nr), and EST_others suggests that there is no interruption by the insert of a known maize gene or regulatory element." Further evidence needed on the database searching methods and results. These can be provided in an appendix.

SBB/coordinator comment: This information can be found in the annex referenced in the paragraph from which the quoted phrase was taken.

Plant tissue samples were collected throughout the growing season at various growth developmental stages. Expression in grain is most informative for this risk assessment, in line with the scope of this application." The growth developmental stages reported (R1, R4 and R6) as reported in Table 10. Why these stages were chosen? Justification needed.

SBB/coordinator comment: The protein expression levels reported in Table 10 cover those growth stages from which food/feed are produced.

"Concentrations of the IPD079Ea, PAT, and PMI proteins were determined using quantitative enzyme-linked immunosorbent assays (ELISAs) (Annex PHI-2019-015/701). All assays were internally validated to demonstrate method suitability." ELISA is a relatively old technic that bares several problems that were solved by newer technics. Why was ELISA used ? Second, how the assays were “internally validated”? Please provide details about that ?

SBB/coordinator comment: A summary of the validation of each ELISA assay is provided in Annex PHI-2019-015/701.

"Expression in grain is most informative for this Risk Assessment, in line with the scope of this application." This comes regularly throughout the document. Was the expression grain chosen simply because it was the highest compared to others rather than because it is “more informative” ?

SBB/coordinator comment: As the scope of the application is food and feed (no cultivation), expression in grain is the most informative.

"Genotypic and phenotypic analyses were conducted for five generations of DP915635 maize (F1, T2, T3, T4, and T5 generations)." Maybe I have missed something in the document but I want to know at which site these 5 generations were evaluated ?

SBB/coordinator comment: Information on the sampling can be found in the annex referred to in the main text (Annex PHI-2019-127). Samples for segregation analyses were taken from plants grown in pots under controlled suitable growing conditions.

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: 3 experts

1.2.4. Conclusions of the molecular characterisation

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

Comment 1
I consider it globally adequate and satisfying provided that some elements are addressed as in the above specific comments.

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

Comment 1
"Compositional samples were measured and analysed from 8 of the sites, (Annex PHI-2019-016/022 and Annex PHI-2020-178) whilst agronomic performance and phenotypic characteristics were assessed from all of the 10 locations (PHI-2019-016/003)." Were some sites dropped because of certain problems in field that are not reported here ? Please explain. The statement that “The 8 sites for compositional analysis were selected primarily considering geographic distribution to represent a diversity of environments” is not fully convincing.

SBB/coordinator comment: EFSA guidelines require field trials to be replicated at a minimum of 8 sites, representative of the range of likely receiving environments where the plant will be grown. (https://www.efsa.europa.eu/en/efsajournal/pub/2150). The next sentence in the main text explains that "The additional agronomic sites were mainly intended to ensure that compositional data would be able to be collected from 8 complete sites."

The four reference lines at each site were selected from a set of 20 non-GM commercial reference lines, listed in Table 14. What were the selection criteria of the 4 lines ? and why these lines were selected specifically ? The selection could introduce a bias in the evaluation if not randomly selected or selected based on specific criteria.

SBB/coordinator comment: This selection was done at random for each site (see Annex PHI-2019-016_022).

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
How were 2 of the 10 locations omitted for compositional analysis; what criteria were used? Is this due to low-quality collection methods, inappropriate study designs, or sampling techniques?

SBB/coordinator comment: See above: "The additional agronomic sites were mainly intended to ensure that compositional data would be able to be collected from 8 complete sites."

Comment 2
"The field phase of this study was conducted during the 2019 growing season in commercial maize-growing regions of North America and Canada." The selected regions are of course maize-growing ones but do not cover the entire corn belt of the USA and Canada. Globally this is fine.

In table 15 there is only one site of the 6 that has minimum tillage. Was this site analysed differently as we know that agronomical practices and management influences a lot the plant development and above all the soil health and microbial activity. This would need specific attention in the analysis.

SBB/coordinator comment: All sites were analysed similarly. The current EFSA guidelines do not require a different analysis depending on tillage.

"Each treatment provides control of common weed species and were sprayed at commercially labeled rates and crop growth stages." This statement requires more precision

SBB/coordinator comment: More precision is provided in Table 17 of the main text.

1.3.3. Selection of material and compounds for analysis

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

Comment 1
The OECD document was followed for the selection of compounds. In addition to the compounds mentioned in the document, others are included as well in the assessment.
The whole series of tocopherols is analyzed. This is valuable information in relation to the antioxidative activity of maize.
The dietary fibre issue is also covered according to the actual insights.

No questions

1.3.4. Comparative analysis of composition

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

Comment 1
Results of the compositional analyses are evaluated according to the generally applied system and classified into category I, II, III, IV or not categorized. Most analytes are found in category I and II indicating at a minimum equivalence more likely than not in relation to control maize.

Two analytes, crude protein and carbohydrates in forage are classified in category III and no analytes in category IV or not categorized. It is demonstrated that the results for carbohydrates and crude protein in forage, are within the natural biological variation of maize.

The applicant concludes that the nutrient composition of forage and grain maize derived from maize DP915635 is comparable to that of conventional maize (non-GMO near- isoline control maize and non-GM commercial maize).

I agree with the conclusion of the applicant.

1.3.5. Comparative analysis of agronomic and phenotypic characteristics

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

Comment 1

In the evaluation of the agronomic characteristics by comparison of maize DP915635 and non-GM near-isoline control maize and non-GM commercial maize, comparable results are obtained.

1.3.6. Effects of processing

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

Comment 1
The applicant gives an overview of processes applied to maize and concludes that there are no indications that product derived from maize DP915635 will be different from those obtained from conventional maize.

I agree with this conclusion.

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

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

1.4.5. Conclusion of the toxicological assessment

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

Comment 1
P.83 of Main text, § 1.4.5.: the allergenic potential has not been discussed in this section.

Coordinator comment: Indeed that is the next chapter.

1.5. ALLERGENICITY

1.5.1. Assessment of allergenicity of the newly expressed protein

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

1.5.2. Assessment of allergenicity of the whole genetically modified plant

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

1.5.3. Conclusion of the allergenicity assessment

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

1.6. NUTRITIONAL ASSESSMENT

1.6.1. Nutritional assessment of the genetically modified food

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

1.6.2. Nutritional assessment of the genetically modified feed

Comment 1
The nutritional assessment of DP915635 maize was based on a 42-d feeding study with broilers. The Main text refers to Annex PHI-2020-006 for more details about the experiment. This annex refers to Appendix E for diet composition. However, Appendix E was only mentioned by name, and no details were shown. Some extensification is desirable.

Coordinator comment: Appendix E is present under ERA Appendices.

1.6.3. Conclusion of the nutritional assessment

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

2. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE OR EXTENT OF USE

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

3. RISK CHARACTERISATION

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

Comment 1
The recipient organism for the creation of DP915635 maize is conventional maize (*Zea mays* L.). How is the recipient maize line (non-GMO) cultivated in Europe and how adequate is this line to the European growing conditions?

SBB/coordinator comment: The scope of this application does not include cultivation in the European Union.

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: 3 experts

5.2. GENERAL APPROACH OF THE ERA

Have evaluated this section and consider the information adequate: 3 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

Comment 1
Further evidence is need as to the plant-to-plant gene flow. In my opinion the risk is non-negligible and should be adequately assessed to a possible transfer through pollen and pollinating insects (as the expression was non-negligible in pollen (Table 10 in the document).

SBB/coordinator comment: Plant-to-plant gene transfer is fully addressed on pages 110-115 of the main text. Reproduction, sexual compatibility, survivability and dissemination of maize are addressed on pages 10-14.

5.3.2. Plant to micro-organisms gene transfer

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

Comment 1
A risk of transfer through other E-coli organisms and after use as feed (not dried).

SBB/coordinator comment: This is addressed on pages 115-120 of the main text.

5.3.3. Interactions of the GM plant with target organisms

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

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

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

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

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

Comment 1
As mentioned earlier the no-till/or minimum till (which is a growing practice) needs further attention in the evaluation. The application presents data from one site that has a minimum till agronomic practice.

SBB/coordinator comment: See above.

5.3.6. Effects on biogeochemical processes

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

5.3.7. Effects on human and animal health

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

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: 1 expert

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: 1 expert

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

- Graham, N., Patil, G.B., Bubeck, D.M., Dobert, R.C., Glenn, K.C., Gutsche, A.T., Kumar, S., Lindbo, J.A., Maas, L., May, G.D., Vega-Sanchez, M.E., Stupar, R.M., Morrell, P.L. 2020. Plant genome editing and the relevance of off-target changes. Plant Physiol. 183, 1453-1471.
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