Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application GMFF-2022-5890 (maize MON 95275) from Bayer under Regulation (EC) No. 1829/2003

24 September 2024
Ref. SC/1510/BAC/2024_1218

Context

Application GMFF-2022-5890 was submitted by Bayer for the authorisation for the marketing of genetically modified (GM) maize MON 95275 (Unique Identifier MON-95275-7) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

MON 95275 contains a single insert consisting of one copy of the *dvSnf7.1* suppression cassette, expressing a double-stranded (ds) RNA transcript, and the *mpp75Aa1.1* and *vpb4Da2* expression cassettes, thereby providing protection against coleopteran insect pests. MON 95275 is going to be used to produce stacked events via conventional breeding and will not be commercialised as a stand-alone product. The assessment and opinion by the Belgian Biosafety Advisory Council (BAC) presented below are therefore for a hypothetical product.

The application was validated by EFSA on 29 August 2022 and a formal three-month consultation period of the Member States was started, lasting until 1 December 2022, 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. See Annex I for an overview of all the comments and the comments sent to EFSA on 1 December 2022.

The opinion of the EFSA Scientific Panel on GMOs was published on 1 August 2024 (EFSA Journal 2024;22:e8886[2]) together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period. Those documents were forwarded to the experts on 6 August 2024, with an invitation to react if needed.

In delivering the present advice, the BAC considered in particular the comments formulated by the experts on application GMFF-2022-5890 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.2024.8886

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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 MON 95275, in comparison with its conventional counterpart, do not raise safety concerns.

2.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety with respect to toxicity of the new constituent DvSnf7 dsRNA and the derived siRNAs in the context of a previous application covering maize event MON 87411 (EFSA/GMO/NL/2015/124)[3] and concluded that there were no safety concerns. Taking into account the information considered in the current application, the Council is of the opinion that its previous conclusion remains valid.

The Biosafety Advisory Council evaluated the safety of the newly produced Mpp75Aa1.1 and Vpb4Da2 proteins and no safety concerns with respect to toxicity were identified. The Biosafety Advisory Council is also of the opinion that the combined presence of these newly expressed proteins in MON 95275 does not raise toxicological concerns.

Further, the Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of GM maize MON 95275, 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 new constituent DvSnf7 dsRNA and the derived siRNAs in the context of a previous application covering maize event MON 87411 (EFSA/GMO/NL/2015/124) and concluded that there were no safety concerns with respect to allergenicity. Taking into account the information considered in the current application, the Council is of the opinion that its previous conclusion remains valid.

The Biosafety Advisory Council evaluated the safety of the newly produced Mpp75Aa1.1 and Vpb4Da2 proteins and no safety concerns with respect to allergenicity were identified.

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 MON 95275-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[4]; COGEM, 2011[5]; Pascher, 2016[6]). As a result, volunteer maize plants do sometimes occur in subsequent crops. There is also evidence of the rare occurrence of feral

[3] Final advice Biosafety Council application EFSA-GMO-NL-2015-124 (bio-council.be)

[4] 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

[5] 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/

[6] 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

maize plants (e.g. Pascher, 2016; COGEM, 2018[7]). 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 MON 95275 (i.e. during transport and/or processing) into the European environment[8] 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 MON 95275 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the scientific opinion of EFSA, and the answers of the EFSA GMO panel to the questions raised by the Belgian experts, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that maize MON 95275 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 MON 95275 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

Annex : Outcome of the assessment of the application and comments sent to EFSA

[7] 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/

[8] 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 GMFF-2022-5890 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: Geert Angenon (VUB)
Experts: Jacques Dommes (ULiege), Leo Fiems (ILVO), Dimitri Gillis (ULB), André Huyghebaert (UGent), Frank Van Breusegem (VIB-UGent), Jan Van Doorsselaere (VIVES)
SBB: Adinda De Schrijver

Application: **GMFF-2022-5890**
Applicant: **Bayer CropScience LP**
GMO: **maize MON 95275**
Validated by EFSA: **29 August 2022**

The scope of the application is:
(a) GM food
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
(b) GM feed
☒ Feed containing or consisting of GM plants
☒ Feed produced from GM plants
(c) GM plants for food or feed use
☒ Products other than food and feed containing of consisting of GM plants with the exception of cultivation
☐ Seeds and plant propagating material for cultivation in the EU

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.

Annex I provides an overview of risk assessment related comments received that fall within the remit of the Biosafety Advisory Council. The comments indicated in grey in Annex I were sent to EFSA. It should

be noted that all the comments mentioned in Annex I were considered in the evaluation of this dossier and in formulating the final advice of the Biosafety Advisory Council.

Annex II provides an overview of other comments received that do not fall within the remit of the work of the Biosafety Advisory Council, such as comments related to the plant protection product used on the GM plant and Maximum Residue Levels of herbicides, and statements on GMOs (e.g. socio-economic considerations) or statements without supporting reasoning or evidence.

Annex I - List of risk assessment related comments/questions received from the experts

PART I - GENERAL COMMENTS

Comment:
General comment with regard to the content of the technical dossier:

- in my opinion maize Mon 95275 may be as safe for human and animal health as conventional maize
- nevertheless, the PMEM should pay special attention to possible consequences of maize Mon 95275 DvSnf7 dsRNA in non-target organisms

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

Comment:
The possible cross-pollinisation is discussed in section 1.1.5.2 where it is stated "The amount of pollen-mediated gene flow is greatest within the first few meters and decreases sharply with increasing distance...". This is probably underestimated. Some of the references cited by the authors themselves speak of more than a few tens of meters before the flow decreases. Other simulations (Hu et al. 2022) even consider more than a few hundred meters. Furthermore, it is also questionable whether 0.1% gene flow at a certain distance is satisfactory; this flow is not negligible.
A large scale study of Fernandes et al. (2022), in Brazil, shows also gene flow between GM and non-GM plants even if the distances legally fixed are respected.

Note SBB and coordinator: While gene flow from maize has been reported at greater distances up to a few hundred meters, it is indeed generally recognised that most of the pollen is deposited within about 30 m from the source (e.g. Devos et al., 2005, Environ. Biosafety Res. 4, 71-78).

Feedback from the EFSA GMO Panel: This application covers the import, processing and all food and feed uses of maize MON 95275, excluding cultivation. Environmental exposure to pollen of this GM maize would be limited to plants rarely occurring after germination and development until sexual maturity of grains resulting from accidental spillage. Therefore, the likelihood/frequency of crosspollination between occasional feral GM maize plants resulting from grain spillage, and weedy or cultivated Zea plants is considered extremely low. Even if cross-pollination occurred, the GMO Panel is of the opinion that environmental effects as a consequence of the spread of genes from occasional feral GM maize plants in Europe will not differ from that of conventional maize varieties for the reasons given in Section 3.6.1.1 of the Scientific Opinion.

1.2. MOLECULAR CHARACTERISATION

1.2.1. Information relating to the genetic modification

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

Comment 1:
Pages 18-19, "history of safe use": the authors rely on the fact that two other proteins (Tpp35Ab1 and mMpp51Aa2) of the same family as the additional proteins in MON95275 (Mpp75Aa1 and Vpb4Da2) are expressed in another commercial GM maize and do not cause adverse effects in human consumption. We keep in mind that this does not constitute proof that Mpp75Aa1 and Vpb4Da2 will not cause adverse effect.

It is also stated that bacteria that naturally produce Mpp75Aa1 and Vpb4Da2 are present in some foods without causing an adverse effect. The authors compare the effects of ingesting a bacteria producing the protein to ingesting maize containing/producing this protein after genetic modification. The protein produced by the 2 different systems is in a different cellular machinery, and the comparison is not relevant (Latham et al. 2017); the protein could be processed differently by the 2 cellular machinery.

Note SBB and coordinator: These are general risk assessment observations. We do not see the relevance of sending these to EFSA as they will not aid in the risk assessment.

Comment 2:
In general, the summary file suffers from some sloppiness. Essential info is missing to allow a swift reading and interpretation. In the summary 3.1c (page 9) the description of the expression cassettes is lacking for both proteins and the dsRNA parts. Also in the summary, the results on the expression of the genes are missing, or at least a reference towards the results. It is first mentioned that expression was done in the “most relevant” organs: forage, grain and pollen. However, I could not find back results or description of the expression in pollen.

Note SBB and coordinator: Proposals for textual changes are not considered at this stage of the evaluation process. TRR0001513 contains the information on the expression of the newly expressed proteins in pollen.

1.2.2. Information relating to the genetically modified plant

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

Comment 1:
The function of the maize genomic sequences interrupted / modified by the insertion is not given in the main text (1.2 Molecular characterization).
Eventually I found this information in documents TRR0001330 2022a and TRR0001436 2022. Insertion occurred in chromosome 3, without disruption of any known gene. Therefore, this does not rise any biosafety concern. This information should have been included in the main text.

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

Comment 2:
It is normally useful to have all essential info present in the main document. In this dossier, the reader is often referred to additional files and to dig there for the information that, according to me should be presented in the main file. E.g. map and table (with different elements) of the expression cassette (p16); p18 “see RR0001330. A short summary/description in the main file would make the assessment more efficient.

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

p13. The argument that the *cp4epsps* selectable marker is eliminated by conventional breeding is not per se the right argument to confirm its absence.

Note SBB and coordinator: Agree. The absence of the *cp4 epsps* selectable marker as well as of the Cre-vector (PV-ZMOO513642) used to remove the selectable marker is verified with next generation sequencing (TRR0001330 section 4.1.2.)

p16. Some indication on the identity/function of the DvSnf7 gene would be useful knowledge to read.

Note SBB and coordinator: Information is available in references cited

p16. Is there a reference to the ABI strain?

Note SBB and coordinator: Reference is missing.

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium for this comment. The GMO Panel considered the provided information sufficient for the risk assessment.

p17 1.2.1.3 The first 5 lines are irrelevant here.

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

What is meant with R5-R6 growth stages?

Note SBB and coordinator: R stands for 'Regeneration'. The R5 is the dent growth stage; R6 the maturity growth stage.

p24 (d) Taxonomic classification: the part on *Agrobacterium* transformation is irrelevant.

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

p38. Results on developmental expression of the transgenes seem to be missing.

Note SBB and coordinator: We do not consider information on developmental expression relevant in case of GM plants solely meant for import as food/feed. In these cases, solely the expression levels of the transgenes in the product to be imported is considered relevant.

p37. Why is there no need to assess the levels of the dsRNA construct?

Note SBB and coordinator: Is explained on p.37: "*Due to rapid degradation of RNAs in digestion tracts, the presence of gastrointestinal barriers that limit RNA uptake and rapid intracellular digestion of absorbed RNAs, expressions are not considered relevant for the risk assessment*".

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: 5 experts

1.2.4. Conclusions of the molecular characterisation

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

Comment:
See remarks of section 1.2.1 about the safety concerns.

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: 2 experts

1.3.3. Selection of material and compounds for analysis

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

Comment:
The OECD document is followed. No further remark.

1.3.4. Comparative analysis of composition

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

Comment 1:
The applicant concludes that maize 173 is compositionaly similar and is not a significant contributor to variability in maize. I agree with this conclusion.

1.3.5. Comparative analysis of agronomic and phenotypic characteristics

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

1.3.6. Effects of processing

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

Comment:
Maize 173 is processed in the same way as conventional maize. It is very unlikely that there will be any effect on processed products.

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: 1 expert

Comment:
The data about the possible relationship of the gene products with known toxins, allergens, … are detailed in section 1.2.1. No significant similarities with known toxins or allergens are found using bioinformatics tools. However, we have to keep in mind that some toxins from the Cry family have been reported to be linked to allergy or toxicity problems (Latham et al. 2017).
For pepsin digestibility tests, a large fragment size is maintained for 2 min for Mpp75Aa1 and 5 min for Vpb4Da2. According to EFSA (2017), these are large but transient fragments and can be considered low risk (also cross-referenced with other bioinformatics analyses). For pancreatin digestibility tests, large fragments are maintained for longer times for Mpp75Aa1 and for Vpb4Da2. But they should not be a problem if the proteins are first exposed to pepsin.

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 L. Fiems:

The safety of maize MON 95275 from a toxicological point of view has been confirmed by Petrick et al. (2016), Edrington et al. (2022) and Wang et al. (2022).

Note SBB and coordinator: Petrik et al. (2016) is mentioned in the dossier and therefore not forwarded to EFSA.

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium for this comment. Edrington et al. (2022) and Wang et al. (2022) were discussed by the applicant in the additional information provided for clock 10.

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

Comment:

The bioinformatics analyses were carried out correctly. See comments in sections 1.2.1 (the bioinformatics results are presented in this section) and 1.4.1 (for the digestibility of the protein).

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: 1 expert

1.6.2. Nutritional assessment of the genetically modified feed

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

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

Comment L. Fiems:

The assessment of the MON 95275 newly expressed proteins, Mpp75Aa1.1 and Vpb4Da2, is discussed in report TRR0001266 (2022). Here, intake was calculated according to OECD (2009), based on the expression levels of Mpp75Aa1.1 and Vpb4Da2 reported by Mozaffar (2021), Bayer Technical Report TRR0000859. I did not find the Bayer Technical Report TRR0000859 among the documents available: did I miss something?

Note SBB and coordinator: Study is indeed missing and will be asked;

Feedback from the EFSA GMO Panel: Regarding human dietary exposure, please refer to section 3.5.4.1 of the GMO Panel Scientific Opinion.

Additional note SBB: The applicant clarified: “The data reported in TRR0000859 were derived from data generated from the GLP study REG-2020-0349 which results are reported in TRR0000635 and already provided to EFSA. Therefore, providing TRR0000859 would not add any value to the risk assessment.”

3. RISK CHARACTERISATION

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

Comment:
See remark in sections 1.2.1, 1.4.1 and 1.5.1.

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

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

Comment:
I am not an expert in post market monitoring, but, even if it is not described in this section, I assume that the obligatory "general surveillance" will be applied.

Note SBB and coordinator: This will indeed be the case as this is an obligatory legal requirement.

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: 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: 3 experts

5.3.2. Plant to micro-organisms gene transfer

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

5.3.3. Interactions of the GM plant with target organisms

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

Comment:
The applicant refers to the possibility of corn rootworm developing resistance to the DvSnf7 dsRNA and the insecticidal proteins, Mpp75Aa1.1 and Vpb4Da2, expressed in MON 95275 (p.27 of this section).
Khajuria et al. (2018) reported resistance of western corn rootworm to DvSnf7 dsRNA.

Note SBB and coordinator: As MON 95275 is only meant for import as food/feed in the EU, development of resistance as a result of cultivation, is not considered relevant in the context of this dossier.

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

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

Comment:
Kulkarni et al. (2006) and Raybould and Burns (2020) reported that externally applied dsRNA-based biocontrol products may lead to off-target degradation of messenger RNA in non-target organisms.

Note SBB and coordinator: Given that MON 95275 is not meant for cultivation, we find this information less relevant in the context of this dossier.

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

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

5.3.6. Effects on biogeochemical processes

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

Comment:
With regard to DvSnf7 dsRNA, Dubelman et al. (2014) reported that it is unlikely to persist or accumulate in the environment.

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium for the comment and took note of the comment.

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: 3 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: 1 expert

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

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Edrington T., Wang R., McKinnon L., Kessenich C., Hodge-Bell K., Li W., Tan J., Brown G., Wang C., Li B., Giddings K. 2022. Food and feed safety of the *Bacillus thuringiensis* derived protein Vpb4Da2, a novel protein for control of western corn rootworm. PLoS ONE 17, e0272311.

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Wang C., Bean G.J., Chen C.J., Kessenich C.R., Peng J., Visconti N.R., Milligan J.S., Moore R.G., Tan J., Edrington T.C., Li B., Giddings K.S., Bowen D., Luo J., Ciche T., Moar W.J. 2022. Safety assessment of Mpp75Aa1.1, a new ETX_MTX2 protein from *Brevibacillus laterosporus* that controls western corn rootworm. PLoS ONE 17, e0274204.

Annex II - List of other comments/questions received from the experts

PART I - GENERAL COMMENTS

Comment 1:

General comment with regard to the lay-out:

- The main text of the technical dossier is not always clear: it cannot be evaluated without consulting the files with supplementary information. This is time-consuming because of searching, opening and closing the appropriate files
- There is some overlapping between the different sections of the technical dossier
- the watermark in the main text of the technical dossier is distracting when reading

Note SBB: We have reported the issues raised related to the new layout of the dossiers to EFSA.

Comment 2:

I have a general comment on the approach taken in section 5.2: an argument put forward in several subsections (5.2, 5.3.1, 5.3.2, ...) is that GM maize MON95725 is imported and not grown in the EU. The authors therefore assess the risks associated with the imported seeds and not the crop itself. This is in line with the EU legislation, and our mandate do not cover the growing risk for the environment. Is it a good thing not to look at the environmental consequences of crops grown outside the EU at all? If a crop should be environmentally unsafe, but is grown under less stringent legislation, importing it encourages this type of crop. This is outside our mandate, but shouldn't we change the legislation on this, and still have information on the environmental risks if the crops are outside the EU? But this is only a general comment, and it is outside the scope of the mandate.

5. ENVIRONMENTAL RISK ASSESSMENT (ERA)

Comment:

The applicant emphasizes that MON 95275 maize will not be cultivated in the EU. This may not be a reason to minimalize the environmental risk assessment. The world belongs to all of us. Therefore, we are all responsible for a good global management.