Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2017-140 (genetically modified maize MON 87419) from Monsanto under Regulation (EC) No. 1829/2003

21 March 2023
Ref. SC/1510/BAC/2023_0272

Context

Application EFSA-GMO-NL-2017-140 was submitted by Monsanto for the authorisation for the marketing of genetically modified (GM) maize MON 87419 (Unique Identifier MON-87419-8) 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 MON 87419 contains a single insert consisting of one copy of the *dmo* and *pat* expression cassettes, expressing two variants of the DMO protein, DMO + 7 and DMO + 12, conferring tolerance to dicamba-based herbicides, and the PAT protein for tolerance to the glufosinate ammonium-containing herbicides.

The application was validated by EFSA on 21 July 2017 and a formal three-month consultation period of the Member States was started, lasting until 23 October 2017, 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). Seven 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 19 October 2017.

The opinion of the EFSA Scientific Panel on GMOs was published on 20 January 2023 (EFSA Journal 2023;21(1):7730[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 22 February 2023, 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 EFSA-GMO-NL-2017-140, EFSA's answers to those questions, 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/7730

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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 87419, 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 MON 87419, 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 DMO and PAT 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.

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 87419-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 MON 87419 (i.e. during transport and/or processing) into the European environment[7] will lead to environmental harm.

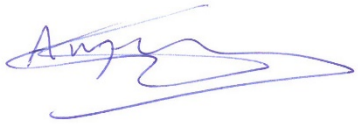
4. Monitoring

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 MON 87419 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the 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 the potential environmental release of maize MON 87419 is unlikely to pose any threat to the European environment;
2) Agrees with the GMO panel of EFSA that maize MON 87419 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 and comments sent to EFSA

[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-2017-140 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) and feedback from the EFSA GMO Panel

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Experts: Patrick du Jardin (Ulg), Leo Fiems (ILVO), Johan Grooten (UGent), André Huyghebaert (UGent), Peter Smet (Consultant), Frank Van Breusegem (UGent), Jan Van Doorsselaere (Vives)
SBB: Fanny Coppens

Application: EFSA-GMO-NL-2017-140
Applicant: Monsanto
GMO: Maize MON 87419
Validation of dossier by EFSA: 21 July 2017

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.

Comments sent to EFSA are highlighted in grey, with the answers from the GMO Panel from EFSA provided underneath.

List of comments/questions received from the experts

PART I - GENERAL INFORMATION

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

Comment 1
MON 87419 maize may be as safe for human and animal health and the environment as conventional maize based on the results of the compositional analysis and the toxicological and allergenicity assessments.
It has been reported that tank-mixing of glufosinate with dicamba showed an additive effect and will be an additional tool with two effective modes of action for the management of glyphosate-resistant giant ragweed (Ganie and Jhala, 2017).

Coordinator comment: Even though this is interesting recent information, it is not related to the safety of the GM crop.

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

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
Regarding the history of safe use of the DMO protein (see main dossier page 25), the wild type protein from *S. maltophila* was modified as follows: a leucine was introduced after the first methionine and an extension of either 7 AA or 12 AA is found at the N-terminus of the plant-expressed proteins, as a result of the partial and inaccurate cleavage of the chloroplast transit peptide. As such, the protein expressed by MON 87419 is very similar to that of MON 88701 (a cotton event), for which a non-conclusive opinion was issued by EFSA on the basis that no 28-day feeding study was performed with the DMO protein (EFSA Journal 2017;15(3):4746, doi: 10.2903/j.efsa.2017.4746). In line with the applicant, I consider that such minor alterations at the N-terminus of the protein are not expected to change the bioactivity and safety of the DMO protein, for which a history of safe use is documented.

SBB comment: This comment was sent as follows to EFSA (altered last sentence):
"Regarding the history of safe use of the DMO protein (see main dossier page 25), the wild type protein from *S. maltophila* was modified as follows: a leucine was introduced after the first methionine and an extension of either 7 AA or 12 AA is found at the N-terminus of the plant-expressed proteins, as a result of the partial and inaccurate cleavage of the chloroplast transit peptide. As such, the protein expressed by MON 87419 is very similar to that of MON 88701 (a cotton event), for which a non-conclusive opinion was issued by EFSA on the basis that no 28-day feeding study was performed

with the DMO protein (EFSA Journal 2017;15(3):4746, doi: 10.2903/j.efsa.2017.4746). Although our expert does not expect this alteration at the N-terminus to affect the safety of the DMO protein, could EFSA comment on this?"

Feedback from the EFSA GMO Panel: The GMO Panel concluded that it is not possible to confirm a documented history for safe consumption of the DMO protein. Based on the information provided by the applicant, the GMO Panel considers that there are no toxicological concerns for the DMO protein newly expressed in maize MON 87419. Please see the assessment performed by the EFSA GMO Panel in Section 3.5.

Comment 2
For sake of clarity: in 1.2.1.1, the use of a double T-DNA vector was not introduced yet. This makes the reading of the text on the unlinked T-DNAs confusing. A short introduction/description of the used vector would be more appropriate and clear.

1.2.2. Information relating to the genetically modified plant

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

Comment 1
1. When looking to the possible interruption of endogenous genes, the applicant performed BlastN and BlastX searches using the 5' and 3' flanks as query sequences, and concludes that there is no interruption of known genes (Hileman and Silvanovich, 2016c). However, the search parameters use E-score cut-offs of 10^{-6} for the BlastN search of EST_2016 and NT_2016 databases, and 10^{-8} for the BlastX search of theNR_2016 database. This seems quite stringent and not complying to existing guidelines of the bioinformatic analysis. Interestingly, the applicant performed in parallel a FASTA search using the putative translation products of the junction ORFS as query sequences and the PRT database, which did identify a hit corresponding to a hypothetical protein ZEAMM (Hileman and Silvanovich, 2016c).
I would suggest that the applicant repeats the BlastN and BlastX searches using less stringent E-score cut-offs, to clarify whether or not some coding region occupies the insertion site. It is worth noting that the sequence analysis of the pre-insertion locus concluded to a 602-bp deletion and it would be interesting to know more about the genes possibly located at the insertion locus, by using appropriate parameters in the bioinformatic search.

Feedback from the EFSA GMO Panel: Molecular characterisation of maize MON 87419 was performed by next generation sequencing (NGS) and junction sequence analysis (JSA). The possible interruption of known endogenous maize genes by the insertion in maize MON 87419 was evaluated by (updated) bioinformatics analyses of the pre-insertion locus and of the genomic sequences flanking the insert. The results of these analyses do not indicate the interruption of any known endogenous gene in maize MON 87419.

2. Similarity of the PAT protein with the GNAT protein (GCN5-related N-acetyltransferase, from toxin-antitoxin system of bacteria, see Hileman and Silvanovich, 2016c, alignment on page 471 and comments on page 12). The applicant comments this hit as follows: "*As expected, these alignments reveal structural similarities between the PAT sequence and the toxin component of the GNAT toxin-antitoxin system of bacteria. Bacterial toxin-antitoxin systems are widespread; they are involved in the maintenance of low copy plasmids (Makarova, et al. 2009) and are only toxic when produced intracellularly in bacteria".*
I do not understand the argument of the applicant, nor the wording "as expected". The quoted reference (Makarova et al. 2009) is missing in the dossier. I would suggest to ask the applicant to elaborate on the arguments and to provide the supporting articles, allowing to substantiate the absence of safety issue.

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium for the comment. New updated bioinformatics analysis was requested and assessed (Stop-the-clock 11; 23/09/2022). The submitted analysis was complete and compliant to the EFSA guidelines and the assessment did not raise any safety issues.

3. Protein expression: in the analysis of PAT and DMO expression in field trials, it seems that the same (2013-) field trials were used, but the herbicide-treated and untreated samples were analysed independently and reported separately: treated samples are found in Chinnadurai 2014a, whilst untreated samples are described in Chinnadurai 2017a. The issue here is that the extraction protocols are not the same - tissue grinding and clarification of the extracts followed different protocols – and that recovery percentages were not calculated. In consequence, comparison of the data from treated and untreated samples can not be rigorously made. However, I consider that no effect of herbicide treatment is expected which would exceed the natural variation due to other environmental factors and I see no safety issue.

SBB comment: This comment was sent as follows to EFSA (altered last sentence):
"Protein expression: in the analysis of PAT and DMO expression in field trials, it seems that the same (2013-) field trials were used, but the herbicide-treated and untreated samples were analysed independently and reported separately: treated samples are found in Chinnadurai 2014a, whilst untreated samples are described in Chinnadurai 2017a. The issue here is that the extraction protocols are not the same - tissue grinding and clarification of the extracts followed different protocols – and that recovery percentages were not calculated. In consequence, comparison of the data from treated and untreated samples can not be rigorously made. Although our expert does not expect the effect of herbicide treatment to exceed the natural variation due to other environmental factors and does not see a safety issue, could EFSA comment on this?"

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium for its comments. Additional information was requested on the extraction protocols used in treated and non-treated samples, and the validation reports used for the protein expression levels. See Stop-the-clock 3 (20/12/2017). The methodology used to quantify the levels of the DMO and PAT proteins was assessed and considered adequate by the GMO Panel.

Comment 2
Dossier 80: 0,59 (0,18) / 0,28 – 0,83
Dossier 92: mean 0.075 / 0.099 (sprayed and non-sprayed)
Dossier 112: ND
Dossier 118: < LOD
Dossier 123: < 0.069

The amounts of PAT (based on dry weight) are significantly higher than in previous dossiers), but since the PAT protein shows no biological effects, this seems of no concern.

Comment 3
For completeness and accuracy: the text on the screening of thousands of events at the molecular, biochemical and phenotypic level to finally select the MON87419 event is not in line with the workflow depicted in Figure 1. The reference to Prado et al., 2014 suggests that the selection procedure is described there. However this is a reference to a general review on GM product development. It is also somehow confusing that the same name (MON87419) is used to describe the primary transgenic event and is used for the final product. The reference Clarke & Carbon, 1976 to indicate the sufficient coverage of the maize genome sequence is not correct. In 1976, no NGS was at hand (at least not publically to my knowledge) and this work describes on the sequencing of an *E.coli* genomic library. I suggest to adapt the text towards a more accurate description and reference.

Feedback from the EFSA GMO Panel: The GMO Panel takes note of the comment.

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: 2 experts

1.2.4. Conclusions of the molecular characterisation

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

Comment 1
I consider that above considerations (see 1.2.2) deserve clarification from the applicant before concluding on this section.

1.3. COMPARATIVE ANALYSIS

1.3.1. Choice of the conventional counterpart and additional comparators

Have evaluated this section and consider the information adequate: 4 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

Comment 1
The experimental design included a treatment with the combined application of glufosinate and dicamba, against which MON 87419 maize is tolerant. This is in agreement with the guidelines of EFSA (2010). Consequently, it is evident to take this experimental design into account for the comparative analysis, including the residue concentrations of glufosinate and dicamba in MON 87419 maize.

Coordinator comment: The comparative analysis has the goal to compare the composition of the GM plant with its non-GM counterpart, and does not look at components that have been externally applied to the crop.

1.3.3. Selection of material and compounds for analysis

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

Comment 1
My comments are in line with previous evaluations and are related to the selection of compounds for analysis. The OECD guidelines are followed but these are out of date:
- there is no information on dietary fiber,
- carbohydrates by calculation is not accepted for human nutrition; carbohydrates have to be differentiated into the main components,
- no information about other carotenoids than beta-carotene; as mentioned before maize is a source of lutein and zeaxanthin in human nutrition; both are important for eye health,

- no information on phytosterols, constituents with a positive effect on cholesterol metabolism in humans,
- no information on tocopherols and tocotrienols; in response to this comment in a previous applications it was stated that information on alpha-tocopherol is adequate as it is the major constituents for vitamin E activity; no doubt about this reaction but the problem is not the vitamin E activity; the question is about the anti-oxidative activity of tocopherols and tocotrienols; it is well known that vitamin activity and anti-oxidative properties are inversely related; maize germ oil is a highly unsaturated oil, stable in maize germs but unstable once isolated from the germs; under normal conditions the oil is protected against oxidation by tocopherols and tocotrienols; data on these constituents would confirm the functionality of maize germ oil in terms of oxidation stability.

I accept that the applicant followed the OECD guidelines from 2002 but the actual knowledge about maize oil and maize in general is more advanced than in 2002. A revision of the guidelines is urgently needed.

In conclusion I agree with the conclusion of the applicant that maize 140 T and NT is compositionally equivalent to conventional maize.

My addition to this conclusion is that maize T and NT is equivalent as far as major constituents are studied according to the OECD guidelines of 2003.

Feedback from the EFSA GMO Panel: The GMO Panel took note of the comment.

Comment 2
Furfural is missing in the analysis. What is the equivalence category and outcome type of the statistical analysis for this product?

1.3.4. Comparative analysis of composition

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

Comment 1
No residue concentrations were given for dicamba and glufosinate in case of MON 87419 maize treated with these herbicides. So, what is the relevance of including treatments with these herbicides in the experimental design if results dealing with the residues of dicamba and glufosinate are omitted? OECD (2009) mentioned the analysis of toxicants, meaning those toxicologically significant compounds known to be inherently present in the species, whose toxic potency and levels may impact human and animal health.

Coordinator comment: The compositional assessment is about the constituents of the plant itself, and not about any substances applied to the crop. The amounts of residues will not be taken into account in the statistical calculations.

Comment 2
See previous paragraph

1.3.5. Comparative analysis of agronomic and phenotypic characteristics

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

Comment 1
I found no information on resistance to infection by moulds.

Maize is by far one the major sources of mycotoxins in human (and animal) nutrition.
Information about this item would be very welcome.

SBB and coordinator comment: This is not required by the applicable EFSA and OECD guidance documents.

1.3.6. Effects of processing

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

1.3.7. Conclusion

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

1.4. TOXICOLOGY

1.4.1. Testing of newly expressed proteins

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

Comment 1
The chance that the new proteins of MON 87419 maize (DMO and PAT) will pose serious risks for toxicity is negligible.
We assume that there is no biological pathway in which the newly-inserted genes would directly or indirectly interact with safety (Kok et al., 2014; Zdziarski et al., 2014). There is no plausible or testable hypothesis for an interaction of the new proteins in MON 87419 maize (Steiner et al., 2013). WHO (1995) stated that, when two plants that are substantially equivalent to conventional varieties are crossed by conventional breeding, the stacked event is expected to be substantially equivalent to the single events.

Comment 2
See MC section above regarding the issue related to the bioinformatic analysis of the PAT protein

1.4.2. Testing of new constituents other than proteins

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

1.4.3. Information on natural food and feed constituents

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

1.4.4. Testing of the whole genetically modified food or feed

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

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

Comment 1
The risk analysis was performed in accordance with the requirements by EFSA. In line with previous risk assessments (EFSA, 2009, 2013a, 2013b, 2013c, 2017a, 2017b), this analysis did not reveal a risk for allergenicity of the newly expressed DMO and PAT proteins. Also the feeding studies performed as part of the toxicological risk assessment did not indicate a health risk.

The studies were well performed and well reported. Accordingly, I comply with the applicant's conclusion that the newly expressed DMO and PAT proteins are unlikely to have any allergenic potential.

I have no further comments.

1.5.2. Assessment of allergenicity of the whole genetically modified plant

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

Comment 1
I comply with the applicant's conclusion that the results of the compositional analyses and rat feeding studies along with the overall allergenic safety profile of maize-derived food make it unlikely that MON 87419 would have an increased allergenic potential as compared to conventional maize.

I have no further comments.

1.5.3. Conclusion of the allergenicity assessment

Have evaluated this section and consider the information adequate: 3 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

Comment 1
Results dealing with residue concentrations of dicamba and glufosinate are lacking. Although the herbicides involved are not directly related to the genetic modification of organisms, they are related to

MON 87419 maize because of its herbicide tolerance. Furthermore, these aspects have been taken into account in the experimental design.

SBB comment: The evaluation of the safety of pesticide residues is not within the remit of the BAC.

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 1
No combined MOE for DMO and PAT proteins, and dicamba and glufosinate residues, as proposed by Wilkinson et al. (2000) and Meek et al. (2011), was presented for the 2 proteins and the 2 herbicides in MON 87419 maize. However, no risk is expected due to the low concentrations.

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: 1 expert

5.2. GENERAL APPROACH OF THE ERA

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

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: 1 expert

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: 1 expert

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

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

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

Comment 1
Although it is not intended to cultivate MON 87419 maize in the EU, the use of dicamba and glufosinate in other regions outside the EU may not prevent herbicide resistance on the long run (Evans et al., 2015). So, the problem is not the genetic modification in itself, but rather the management and the governance of this innovation with regard to the use of some herbicides against which as MON 87419 maize is tolerant.

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
No adverse effects of the new protein (DMO and PAT) in MON 87419 maize on human and animal health are expected.

5.3.8. Overall risk evaluation and conclusions

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

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

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