Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2022-6595 (AP176, soybean MON 94313) from Bayer CropScience under Regulation (EC) No. 1829/2003

24 March 2026
Ref. SC/1510/BAC/2026_0323

Context

Application EFSA-GMFF-2022-6595 (AP176) was submitted by Bayer CropScience for the authorisation for the marketing of genetically modified (GM) soybean MON 94313 (Unique Identifier MON-94313-8) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

Soybean MON 94313 produces the dicamba mono-oxygenase (DMO) protein, the phosphinothricin acetyltransferase (PAT) protein, the 2,4-D dioxygenase protein (FT_T.1) and the triketone dioxygenase (TDO) protein, to confer tolerance to dicamba, glufosinate, 2,4-D and mesotrione-based herbicides, respectively.

The application was validated by EFSA on 6 December 2022 and a formal three-month consultation period of the Member States was started, lasting until 5 March 2023, 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, invited experts from the common list of experts established jointly by the BAC and the Service Biosafety and Biotechnology (SBB) to evaluate the dossier. Six experts accepted the invitation, and formulated a number of comments to the dossier. See Annex for an overview of all the comments and the comments sent to EFSA on 3 March 2023.

The scientific opinion of EFSA's GMO Panel, including the responses from the Panel to comments submitted by the Member States during the three-month consultation period, was published on 21 January 2026 (EFSA Journal 2026;24:e9843[2]). On 11 February 2026 these two documents were forwarded to the Belgian experts. They were invited to give comments and to react if needed. One expert indicated agreement with the Panel's answer.

In delivering the present advice, the BAC considered in particular the comments formulated by the experts on application EFSA-GMFF-2022-6595 (AP176), the opinion of EFSA, their answers to the expert's comments, and the expert's assessment of these answers.

[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.2026.9843

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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 soybean MON 94313, in comparison with its conventional counterpart, do not raise safety concerns.

2.2. Assessment of toxicity

The Biosafety Advisory Council evaluated the safety of the newly produced PAT and DMO proteins in the context of previous applications and no food and feed safety concerns with respect to toxicity were identified. The safety of the FT_T.1 and TDO proteins was evaluated in this application, including additional studies performed following a question submitted by the Council.

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of the GM soybean MON 94313, in comparison with its conventional counterpart, does not raise food and feed safety concerns regarding toxicity.

The Biosafety Advisory Council is also of the opinion that the combined presence of the newly produced PAT, DMO, FT_T.1 and TDO proteins in soybean MON 94313 does not raise food and feed safety concerns regarding toxicity.

2.3. Assessment of allergenicity

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the allergenicity of the GM soybean MON 94313, in comparison with its conventional counterpart, does not raise safety concerns regarding allergenicity.

The Biosafety Advisory Council is also of the opinion that the combined presence of the newly produced PAT, DMO, FT_T.1 and TDO proteins in soybean MON 94313 does not raise safety concerns regarding allergenicity, nor that the genetic modification substantially alters the overall allergenicity of soybean MON 94313.

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 soybean MON 94313-derived food and feed are not expected to differ from those of conventional soybean varieties.

3. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of soybean MON 94313 (i.e. during transport and/or processing) into the European environment[3] 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 soybean MON 94313 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, EFSA's opinion, and the answers of the EFSA GMO panel to the questions raised by the Belgian experts, the Biosafety Advisory Council agrees with the GMO panel of EFSA that soybean MON 94313 is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment.

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

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

[3] As the scope of the application does not include the cultivation of the GM crop within the EU, a comprehensive environmental assessment, such as that required for a cultivation dossier, is not necessary.

Annex : Outcome of the assessment of application EFSA-GMO-NL-2022-176 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

Coordinator: Prof. P. Baret
Experts: Leo Fiems (ILVO), Dimitri Gilis (ULB), André Huyghebaert (UGent), Frank Van Breusegem (UGent), Jan Van Doorsselaere (Vives), Erik Van Miert (Sciensano)
SBB: Fanny Coppens

Application: EFSA-GMO-NL-2022-176
Applicant: Bayer
GMO: Soybean MON 94313
Validation of dossier by EFSA: 6 December 2022

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 indicated in grey. 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
In my opinion Soybean MON 94313 may be as safe for human and animal health as conventional soybean. The newly inserted proteins (DMO, PAT, FT_T.1 and TDO) have been tested and showed no adverse effect on human and animal health. These proteins are now collectively embedded in the MON 94313 soybean.

Comment 2
The information provided is adequate. I do not see issues dealing with molecular characterization, toxicity.

Comment 3
Traditional approach in line with previous applications.

Comment 4
Some additional genes introduced in this GM soybean MON94313 have been also introduced in GM maize MON87429, which has been approved in 2022 by the EFSA (EFSA panel Mullins et al. 2022). Work on the characterisation of common proteins was also done as part of this application.

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
Section 1.1.5.2: it is questionable whether a few % of cross pollination at a certain distance is satisfactory; this is not negligible. In the study of Yook et al. (2021), they report a distance of 37.7m for minimising the gene flow between GM and wild soybean.

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
Bioinformatics analysis of the allergenicity and toxicity are partly done in section 1.2.1.3, but also in sections 1.4 and 1.5. I will give all my comment in these sections.

1.2.2. Information relating to the genetically modified plant

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

Comment 1
Section 1.2.2.1, substrate specificity of the TDO protein. The authors identify in silico 59 possible substrates for the TDO protein (see Table 1, page 44). But they test only 32 of them in vitro. Why? If there is no good reason, the authors should test them all, even if the result was negative for all 32 molecules tested.
Page 44, figure 11: the authors should give more details about the protocol used. What criteria are used to assess similarity to mesotrione? As presented, the protocol is too vague to be verified.

SBB comment: From 1.2.2.1, p. 43: those 32 compounds are commercially available.

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

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

1.2.4. Conclusions of the molecular characterisation

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

1.3. COMPARATIVE ANALYSIS

1.3.1. Choice of the conventional counterpart and additional comparators

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

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

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

1.3.3. Selection of material and compounds for analysis

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

1.3.4. Comparative analysis of composition

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

Comment 1
The applicants concludes that based upon the comparison between MON 94313 with other commercial soybeans, there is no contribution to variability of soybeans. Nutrients, antinutrients and isoflavones have been evaluated in detail according the OECD guidelines.

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: 2 experts

1.3.7. Conclusion

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

Comment 1
I agree with the conclusion of the applicant.

1.4. TOXICOLOGY

1.4.1. Testing of newly expressed proteins

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

Comment 1
Overall I agree with the conclusions made. I have some comments on (a few of the) statements in the dossier.

Statement: The protein has a demonstrated history of safe use;
Verification: Section 1.2.1.3 b) elaborates on the source of the genes and corresponding proteins, demonstrating their safety
Conclusion: agree

Statement: No biologically relevant sequence similarities were observed between the MON 94313 DMO, PAT, FT_T.1 and TDO proteins and allergen, toxin, or other biologically active proteins that could be harmful to human or animal health.
Verification: Section 1.2.1.3 c) The results from the bioinformatic analyses indicated that no biologically relevant sequence similarities were observed between the DMO, PAT, FT_T.1 and TDO
protein sequences and the allergens or biologically active proteins associated with adverse effects for human or animal health (TRR0001380, 2022; TRR0000842, 2021; TRR0001385, 2022). The results of previous assessment for PAT, cited in TRR0000842 (2021) can be found in M-787376-01-1 (2020).
Conclusion: agree

Statement: The low concentrations of the MON 94313 DMO, PAT, FT_T.1 and TDO proteins in tissues that are consumed provide additional assurance of their safety.
Verification: Study TRR0001507 provides the determination of the protein expression levels determined by immunoassay. The highest level determined was 150 µg/g dw of DMO protein in forage from treated MON 94313, i.e. 150 µg/g dw, **i.e 0.015 %.** The levels in other locations and of other proteins were about an order of magnitude lower. Thus confirming the low concentrations.
Conclusion: agree

Statement: the MON 94313 DMO, PAT, FT_T.1 and TDO proteins behave with a predictable tendency toward protein denaturation and loss of functional activity at elevated temperatures.
Verification: The reports TRR0001399 (2022), MSL0023584 (2011), TRR0001512 (2022) and TRR0001400 (2022) were checked and the results/conclusions provided corroborate the statement.
Conclusion: agree

Statement: The data indicate that the MON 94313 DMO, PAT, FT_T.1 and TDO proteins remain intact at neutral, basic and acidic pH conditions.

Verification: The reports TRR0001533 (2022), MSL0023567 (2011); TRR0000874 (2021) and TRR0001573 (2022) demonstrate the stability of the proteins at aprox. pH 1.2 (pepsin test conditions) and 7.5 (pancreatin test conditions). It is however unclear into what respect this fully covers that statement about intact proteins at neutral, basic and acidic pH. The reports do not provide a formal conclusion about the pH stability, this information is only provided in the results section.
Conclusion: partially agree

Statement: E. coli-produced DMO, PAT, FT_T.1 and TDO proteins are suitable surrogates for evaluating the safety of the DMO, PAT, FT_T.1 and TDO proteins expressed in MON 94313.
Verification: The reports TRR0001304, TRR0001300, TRR0001291 and TRR0001392 do indicate that the E.coli produced proteins are indeed suitable surrogates for safety evaluation.
Conclusion: agree

Statement: in vitro experiments conducted with MON 94313 DMO, PAT, FT_T.1 and TDO proteins demonstrate that all the proteins are rapidly digested by proteases.
Verification: The reports TRR0001533 (2022), MSL0023567 (2011); TRR0000874 (2021) and TRR0001573 (2022) were checked and the results/conclusions provided corroborate the statement.
Conclusion: agree

Statement: The MON 94313 DMO, PAT, FT_T.1 and TDO proteins have no synergistic or antagonistic effects to each other.
Verification: This was not formally tested but inferred based on the knowledge of their modes of action and/or sites of biological activity which are clearly different. No data in the experimental dataset provided suggests the contrary.
Conclusion: agree

Statement: The safety assessments support the conclusion that exposure to the proteins derived from MON 94313 would not pose any meaningful risk to human or animal health or the environment. Based on the weight of evidence described in this application there is no testable hypothesis to justify using experimental animals to conduct 28-day oral toxicity studies with the MON 94313 DMO, PAT, FT_T.1 and TDO proteins.
Verification: Although the statement that a 28-day study is scientifically of limited value in the current case is valid in my view, the application included in vivo data as specified by Regulation (EU) No 503/2013, 1.4.1. e). For DMO reference was made to a 28-day study with a DMO protein from another GMO; equivalence of the 2 DMO proteins was confirmed in study M-815644-01-1 (2022) and this is thus considered a valid "read-across approach". New 28-day studies were included for the FT_T.1 and TDO proteins. For the PAT protein, no new in vivo study or "read-across" to an analogous PAT protein is provided although it is stated in the application that "*Furthermore, the DMO and PAT proteins expressed in MON 94313 are identical or highly homologous to DMO and PAT proteins expressed in several other crops [see Section 1.2.1.3(b)] that were reviewed and considered safe by several global regulatory agencies[36] including the EFSA[37]"*. As such, it is unclear why a different approach for PAT was chosen rendering the approach seemingly incoherent.
Conclusion: partially agree

Statement: the results of those studies confirmed that oral (gavage) administration of FT_T.1 and TDO proteins to Crl:CD1(ICR) mice at dose levels of 10, 100, and 1000 mg/kg/day for 28 days had no effects on survival and no adverse effects on the growth or health of the mice.
Verification: The study on FT_T/1 protein (TRR0001405, 2022a) was reviewed. The results and conclusion are in line with the above statement.
Albeit that I do not interpret the study with the TDO protein as an indication of an intrinsic toxicity of the TDO protein, the study (CR0-2021-0030, 2022a) is not "clean" and this aspect is in my view insufficiently addressed. A number of observations occur in the high dose group; all unscheduled deaths (4) in the

study were found in the high dose group, the body weight (gain) of the male high dose group is significantly lower and outside the historical range on study day 21 and the lung and nasal findings in primarily the high dose groups. Although that the report mentions and elaborates on the findings, no trace of it can be found in the conclusion. The pattern of findings would suggest some technical issue related to the gavage protocol (gavage-related reflux) of the TDO protein solution/suspension. In the absence of a plausible cause, the absence of TDO-related effects can't be unequivocally claimed.
Conclusion: partially agree

SBB and coordinator's comment: The above comment was sent to EFSA as follows:
Although our expert does not interpret the study with the TDO protein as an indication of an intrinsic toxicity of the TDO protein, the study (CR0-2021-0030, 2022a) is not "clean" and this aspect is insufficiently addressed. A number of observations occur in the high dose group; all unscheduled deaths (4) in the study were found in the high dose group, the body weight (gain) of the male high dose group is significantly lower and outside the historical range on study day 21 and the lung and nasal findings in primarily the high dose groups. Although that the report mentions and elaborates on the findings, no trace of it can be found in the conclusion. The pattern of findings would suggest some technical issue related to the gavage protocol (gavage-related reflux) of the TDO protein solution/suspension. In the absence of a plausible cause, the absence of TDO-related effects can't be unequivocally claimed. We therefore would like more explanation on this study explaining the issues identified above.

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium and takes note of the comment. The applicant was requested to clarify the toxicological profile of the TDO protein in ADR 8. In response, the applicant submitted a position paper addressing the nature of the findings observed in the 28-day gavage study and chose to perform and submit a new 28-day dietary study as additional information in response to ADR 14. No adverse effects were observed in mice in the dietary 28-day toxicity study on E. coli-produced TDO protein, at nominal dietary exposures up to 1000 mg/kg bw per day. This new study did not replicate the adverse finding observed in the gavage study and supported the interpretation that the gavage effects represent a local, route-specific event rather than a systemic toxic property of TDO.
Furthermore, in the context of ADRs 15, 16, 17, 18 and in the spontaneous information received on November 16th, the applicant provided mechanistic and experimental observation providing a plausible explanation by which mid/high-concentration gavage formulations of TDO could rapidly form persistent aggregates under acidic conditions. These aggregates could delay gastric emptying and thereby promote gastro-oesophageal reflux and secondary aspiration of the gastric content, which would be consistent with the observed respiratory tract lesions.
For detailed information, please refer to section 3.5.2.1 of the Scientific Opinion.

Expert's assessment of EFSA's feedback: The 28-day study (OECD 407) in which TDO protein was dosed via oral gavage showed lesions in the respiratory tract of the mid and high dose groups. In the high dose group, 2 male and 2 female mice died before the end of the study. No systemic effects were observed in the study. The applicant provided additional information clarifying the physico-chemical behaviour of the TDO protein which leads to its higher propensity to precipitate out of solution. Based on the information provided, the hypothesis that TDO, when dosed as a high concentration gavage solution, precipitates and influences gastric emptying, thus promoting gastro-oesophageal reflux and secondary aspiration of the gastric content, is convincing. As such, I agree that the findings (lethality and lesions in the respiratory tract) in the oral gavage study are not relevant for the safety assessment of TDO. This conclusion is supported by the absence of relevant findings in the 28-day study in which TDO was dosed via diet.
As such, I agree with the conclusions of the EFSA GMO panel.

Comment 2
Section 1.4.1.3: influence of the t° and the pH on the newly expressed proteins. The PAT protein analyses date from 2011 (documents MSL0023584 and MSL0023567). I assume that the behaviour of this protein has not changed in 10 years, but I am surprised that the analysis has not been done recently, as for the other proteins introduced in MON 94313. It might be useful to ask for a recent analysis, unless the panel feels that it is not necessary.

SBB and coordinator's comment: The above comment was sent to EFSA as follows:
The PAT protein analyses date from 2011 (documents MSL0023584 and MSL0023567). We assume that the behaviour of this protein has not changed in 10 years, but are surprised that the analysis has not been done recently, as for the other proteins introduced in MON 94313. Is any more recent analysis available?

Feedback from the EFSA GMO Panel: Regarding the safety assessment of the PAT protein, the protein was previously assessed by the GMO Panel in the context of other applications and no safety concerns for humans and animals (i.e. farmed and companion animals) were identified (EFSA GMO Panel, 2017a, 2017b, 2022). Furthermore, the GMO Panel is not aware of any new information that would change the previous conclusion on the safety 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: 3 experts

1.4.4. Testing of the whole genetically modified food or feed

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

Comment 1
Overall, I agree with the assessment and conclusions of the applicant

Statement: Taken together, there is no evidence of any adverse effects of the MON 94313 DMO, PAT, FT_T.1 and TDO proteins expressed in MON 94313 on human or animal health.
Verification: Although the 28-day study on the TDO protein was not completely “clean”, the total dataset strongly suggest that the levels of the newly expressed DMO, PAT, FT_T.1 and TDO proteins in MON94313 don’t pose a safety concern for human and animal health.
Conclusion: agree

Statement: Based on the weight of evidence, no more data are required to demonstrate that MON 94313 is as safe as conventional soybean from a food and feed perspective.
Verification: based on the previous point.
Conclusion: agree

As anticipated, the results of this study show that dietary administration of MON 94313 by incorporation into standard rodent chow at 15% (w/w) and 30% (w/w) for at least 90 consecutive days had no adverse effects on the growth or health of Sprague Dawley (Crl:CD[SD]) rats

Verification: Study TRR0001223, 2022, was reviewed and the results and conclusions are coherent with the statement above.
Conclusion: agree

Statement: As a result, there is no reason to expect reproductive, developmental or chronic toxicity, and consequently additional studies on these particular aspects are not scientifically justified.
Verification: based on the previous points.
Conclusion: agree

Statement: There is no reason to expect the occurrence of adverse effects or any nutritional impact of an intentional, substantial or compositional modification of the genetically modified plant, and therefore additional animal studies on these particular aspects are not scientifically justified.
Verification: based on the previous points.
Conclusion: agree

1.4.5. Conclusion of the toxicological assessment

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

1.5. ALLERGENICITY

1.5.1. Assessment of allergenicity of the newly expressed protein

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

Comment 1
The data about the possible relationship of the gene products with known toxins, allergens, … are detailed in section 1.2.1., the analysis of the protein digestion is presented in section 1.4.1.4. I will summarise my remarks here.

- No significant similarities with known toxins or allergens are found using bioinformatics tools.
- In general, the bioinformatics analyses were carried out correctly.
- In section 1.2.1.3, the authors use the classical protocol to evaluate the similarities with known allergens. They have built 2 allergen databases, AD_2021 and AOL_2021 (see TRR0000689), but only use AD_2021. What is the difference in the composition of the 2 DBs and why choose AD_2021?
- The authors could be clearer about the sequence of the DMO protein to be used. A sequence is given in section 1.2.1.3a. In the allergenicity analysis (TRR00001380) of this protein, the first 68 residues are missing. This seems to be explained on page 36 of the application file: the protein expressed in MON 94313 would not contain these first 68 residues. And finally, the sequence used for the allergenicity analysis starts with MLTF, and the one given in Figure 6 page 24 with MATF. I assume that this amino acid difference at position 2 will not be decisive for the allergenicity analysis.
- The PAT protein analyses date from 2011 (same remark as in section 1.4.1).

The results of the digestibility tests seem convincing to me – the results are provided in section 1.4.1.4.

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

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

3. RISK CHARACTERISATION

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

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

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

5. ENVIRONMENTAL RISK ASSESSMENT (ERA)

5.1. INTRODUCTION

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

5.2. GENERAL APPROACH OF THE ERA

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

5.3. SPECIFIC AREAS OF RISK

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

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

5.3.2. Plant to micro-organisms gene transfer

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

5.3.3. Interactions of the GM plant with target organisms

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

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

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

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

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

5.3.6. Effects on biogeochemical processes

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

5.3.7. Effects on human and animal health

Comment 1
The EFSA panel on GMOs had no safety concerns with regard to DMO, PAT, and FT_T proteins expressed in maize MON 87429 (EFSA, 2022). With regard to TDO protein, Dreesen et al. (2018) reported no safety problems and no adverse metabolic effects of 4-hydroxyphenylpyruvate dioxygenase enzyme in genetically modified soybeans to confer tolerance to triketone type of herbicides (including mesotrione, as used in the culture of MON 94313 soybean). Furthermore, stacked genetically modified plants seems to be as safe as conventional plants (Kok et al., 2014; Goodwin et al., 2021).

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

References

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