Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2022-179 (GMFF-2021-0071, maize DP51291) from Corteva Agriscience under Regulation (EC) No. 1829/2003

18 December 2024
Ref. SC/1510/BAC/2024_1573

Context

Application EFSA-GMO-NL-2022-179 (GMFF-2021-0071) was submitted by Corteva Agriscience for the authorisation for the marketing of genetically modified (GM) maize DP51291 (Unique Identifier DP-Ø51291-2) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

Maize DP51291 expresses the IPD072Aa, PAT and PMI proteins, for control of susceptible corn rootworm pests, tolerance to glufosinate herbicides, and as a selectable marker, respectively.

The application was validated by EFSA on 5 May 2023 and a formal three-month consultation period of the Member States was started, lasting until 5 August 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, contacted experts to evaluate the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). Five experts answered positively to this request, and formulated a number of comments to the dossier. See Annex I for an overview of all the comments and the comments sent to EFSA.

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 11 November 2024 (EFSA Journal 2024;22:e9059[2]). On 25 November 2024 these two documents were forwarded to the Belgian experts. They were invited to give comments and 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-2022-179 (GMFF-2021-0071) 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.2024.9059

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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 DP51291, 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 DP51291, in comparison with its conventional counterpart, does not raise safety concerns regarding toxicity.

The Biosafety Advisory Council is also of the opinion that the combined presence of the newly expressed proteins in DP51291 does not raise concerns regarding toxicity.

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed IPD072Aa, PAT and PMI proteins in the context of previous applications, and no concerns regarding allergenicity were identified. Since no new information on allergenicity of these proteins has become available, the Council is of the opinion that its previous conclusions remain valid.

The Biosafety Advisory Council is also of the opinion that the combined presence of the newly expressed proteins in DP51291 does not raise concerns regarding allergenicity.

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 DP51291-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

[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/

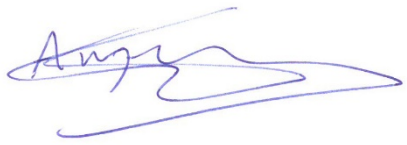
weakly and is not considered an agricultural problem. There are no indications that the occurrence of feral maize plants has resulted in the establishment of self-sustaining populations. This can be explained by the fact that maize is highly domesticated, has no weedy characteristics and is not tolerant 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 DP51291 (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 DP51291 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 agrees with the GMO panel of EFSA that maize DP51291 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 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

[7] As the application doesn't imply cultivation of the GM crop in the EU, a full environmental assessment, as in the case of a cultivation dossier, is not warranted.

Annex : Outcome of the assessment of application EFSA-GMO-NL-2022-179 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: Leo Fiems (ILVO), André Huyghebaert (UGent), Frank Van Breusegem (UGent), Jan Van Doorsselaere (Vives), Nicolas Van Larebeke (UGent)
SBB: Fanny Coppens

Application: **EFSA-GMO-NL-2022-179**
Applicant: **Corteva Agriscience**
GMO: **Maize DP51291**
Validation of dossier by EFSA: **5 May 2023**

Scope of the application:
☒ GM plants for food use
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
☒ GM plants for feed use
☒ Feed produced from GM plants
☒ Import and processing
☐ 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. 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

Maize DP51291 will be further described as maize 179.
The file contains information in line with well-known approaches, applied in previous dossiers.

Comment 2

The safety for human and animal health and for the environment of PAT and PMI proteins has been previously evaluated. These proteins are present in several approved events across several different crops that have been approved for application. Studies indicated that IDP072Aa protein and DP51291 maize are not harmful for human or animal health or the environment. Consequently, the risk of the use of DP51291 maize for food and feed will be negligible.

Comment 3

It was particularly difficult to perform a serious evaluation of this dossier, due to an insufficiently clear or possibly incomplete documentation.

It can be considered that DP51291 maize has on the one hand a genetic characteristic that is unfavorable to human health, that is increased resistance against a pesticide, but has on the other hand a characteristic that is favorable to human health, that is resistance against a pest, lowering the use of pesticides.

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: 1 expert

Comment 1

The applicant refers to an article of Jiménez-Juárez et al. for the insecticidal activity of IPD072Aa. This article is published in the meantime: Jiménez-Juárez, N., Oral, J., Nelson, M.E., Lu, A.L. 2023. IPD072Aa from *Pseudomonas chlororaphis* Targets Midgut Epithelial Cells in Killing Western Corn

Rootworm (Diabrotica virgifera virgifera). Applied and Environmental Microbiology 89, doi/pdf/10.1128/aem.01622-22

Comment 2

The ipd072Aa gene from *P. chlororaphis* encodes the IPD072Aa protein, which confers protection against certain coleopteran pests when expressed in maize plants Tis section refers to Anderson et al. (2018) in relation to toxicity. This paper provides an assessment of the safety of *P. chlororaphis* as a gene source for GM crops. As started in the conclusion of this paper, "This information supports, in part, the safety assessment of potential traits, such as IPD072Aa, derived from *P. chlororaphis*." However, it does not prove that the gene and protein cannot have toxic effects when ingested by human beings. I wonder whether slight modifications to the gene and protein, resulting from recombination events with related sequences, might result in toxic effects to humans

I did not find the Jimenez-Juarez et al. accepted paper. I found a document by Jimenez-Juares et al., Applied and Environmental Microbiology, Edited by Knut Rudi, vol. 89, issue 3, id. e01622-22 stating "Our results show that IPD072Aa binds to receptors in WCR gut that are different than those utilized by current commercial traits and its targeted killing of midgut cells results in larval death."

SBB and coordinator comment: This section concerns the molecular characterization. Concerning toxicity, we have to evaluate the toxicity of the protein as it is present in the maize, and not speculate about the toxicity of possible variations of the protein that are not present in the plant.
In certain cases the insecticidal proteins have been altered to increase their efficacy or for other reasons. If that is the case, then we evaluate the toxicity of this modified version of the insecticidal protein as it is present in the plant.

1.2.2. Information relating to the genetically modified plant

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

Comment 1

"*WCR damage has historically been managed with crop rotation, broad-spectrum soil insecticides, and transgenic crops expressing crystalline (Cry) proteins, such as the Cry3 and Cry34/35 (Gpp34Ab1/Tpp35Ab1) classes of protein, developed from Bacillus thuringiensis (Bt). As adoption of Bt maize has increased, the selection pressure on target insects to develop resistance has become greater (Cullen et al., 2013). Insect resistance to transgenic traits can pose a threat to the long-term durability of Bt crops. Differentiated modes of action (MOA) are important for maintaining sustainable and durable corn rootworm management (Gassmann et al., 2016; Niu et al., 2017)*"

I find this comment interesting and pointing to an issue of concern. Maybe genetic engineering of plants will not lead to a really more sustainable agriculture and food supply, while introducing some changes in the composition of the food in terms of nutrients and anti-nutrients, as reported in the document 1.3 Comparative analysis, where some assessments in terms of "Non-Equivalence More Likely Than Not" and "Non-Equivalence" are reported. The" *long-term durability of Bt crops"* is not a value in itself in terms of the general interest.

Coordinator comment: This dossier relates to the import and placing on the market of food and feed derived from this maize. The issues raised here relate to the issue of management of possible resistance that may arise when using crops that have been modified to produce insecticidal protein.

The scope of our assessment is limited to the safety of the food and feed derived from this maize and environmental issues related to potential spillage of corn seeds during importation and transport within the EU.
Sustainability issues, even though important, are also not within the remit of the current evaluation.

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

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

1.2.4. Conclusions of the molecular characterisation

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

1.3. COMPARATIVE ANALYSIS

1.3.1. Choice of the conventional counterpart and additional comparators

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

Comment 1

No particular remark: the comparison between maize 179 and the conventional counterpart and additional comparators is well described and similar to these type of previous dossiers.

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 four reference lines at each site were selected from a set of 20 non-GM commercial reference lines. What criteria were used to select these four reference lines?

SBB and coordinator comment: The trial was performed with a randomized complete block design, with four blocks at each of the 8 sites. For each block four out of the 20 reference lines were randomly chosen. So no specific criteria were used. The selection was random.

1.3.3. Selection of material and compounds for analysis

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

Comment 1

As could be expected the OECD 2002 guidelines are followed in the selection of compounds.
In addition to the guidelines some compounds are added. There is information about the dietary fiber content and also about the different tocopherols.

1.3.4. Comparative analysis of composition

Comment 1

The results of the statistical evaluation are described in detail.
The applicant concludes that any statistical difference or lack of equivalence is of low relevance.
He concludes that the nutrient composition of maize 179 is comparable to the conventional counterpart and non-GM commercial maize.
I agree with this conclusion.

Comment 2

Analytes are within the tolerance interval or within reference values; consequently, nutrient composition of forage and grain derived from DP51291 maize is similar to that of conventional maize.

Comment 3

I wonder how the observed differences in chemical composition between CHT DP51291 maize or IHT maize and control maize can be explained. I wonder also whether control maize and reference maize show as many differences in chemical composition as CHT DP51291 maize or IHT maize on the one hand and reference maize on the other.

Coordinator comment: There will always be compositional differences between the GM line and the control lines and reference lines. It is very difficult to establish the causes of such changes. Anyhow, there will also always be difference between the control maize and reference maize. The important question is whether any of these changes would require further attention and create a safety concern. The general evaluation is that the observed differences are of low relevance. They are within the tolerance interval or within reference values.

1.3.5. Comparative analysis of agronomic and phenotypic characteristics

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

1.3.6. Effects of processing

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

Comment 1

As maize 179 is compositionally equivalent no particular effect of the wet or dry milling processes are to be expected.

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.

Comment 2

It would be more scientifically correct to state “the compositional characteristics of DP51291 maize are not identical but quite similar compared to those of the conventional counterpart and commercial reference maize lines, taking into account biological variation. “

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium for the comment. Quantitative results for the compositional endpoints showing significant differences between maize DP51291 and its conventional counterpart and falling under category III/IV for phosphorus in forage and manganese, proline, oleic acid (C18:1) and linoleic acid (C18:2) in grain are given in Section 3.4.6 of the Scientific Opinion. These differences were further assessed.

1.4. TOXICOLOGY

1.4.1. Testing of newly expressed proteins

Comment 1

The applicant refers to “IPD072As” in the first paragraph: it is assumed that this is a typing error. The safety evaluation of IPD072Aa protein is largely based on DP23211 maize (EFSA-GMO-NL-163 dossier). However, it is not clear for me if EFSA has published a scientific opinion for DP23211 maize. As far as I am aware, the applicant did not give a relevant reference for his statement. According to Smith et al. (2021) DP23211 maize is comparable with DP51291 maize, except that it also contains DvSSJ1 double-stranded RNA.

SBB comment: EFSA’s scientific opinion on application EFSA-GMO-NL-2019-163 has not yet been published.

Comment 2

I did not find the annexes 22 and 23 provided as "*previously submitted Annex 19, 20, 21, 22, 23 [respectively] in AP163*" in this application on the results of toxicity studies in Mice. I am not convinced that the IPD072Aa protein is indeed not toxic to mammals, although the action of this protein might well be specific to receptors or other molecular structures on the target pest I wonder whether, due to massive cultivation of DP51291 maize, slight modifications to the gene and protein, resulting from recombination events with related sequences, might result in proteins with toxic effects to humans.

As to the PAT protein, which is an acetylating enzyme, Christ et al. (2017) showed that the closely related BAR protein, due to a certain enzyme promiscuity, also acetylates other amino acids. The EFSA (2018) rebuttal of the concern that arises due to the findings of Christ et al. (2017) is certainly

reasonable, but not entirely convincing in relation to a phenomenon that concerns a massive use of food products.

Coordinator comment: Why would one take into account possible modifications to / variations of the protein which are not present in the plant, and which are not likely to occur?
If one would apply the same reasoning to other proteins that have been introduced into the plant like the PMI and the PAT protein, then one could argue that one would also have to consider slight modifications to these genes resulting from recombination events with related sequences.

Feedback from the EFSA GMO Panel: The GMO Panel thanks Belgium for the comment. The study by Christ et al. (2017) has been previously assessed by EFSA in the context of a mandate from the European Commission on public comments on genetically modified oilseed rape Ms8, Rf3 and Ms8×Rf3 under application EFSA-GMO-RX-004 (question number EFSA-Q-2018-00138). EFSA is of the opinion that the results reported in this publication cannot be at present placed in the context of the risk assessment of PAT/bar-expressing genetically modified plants.

1.4.2. Testing of new constituents other than proteins

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

Comment 1

Indeed, most tested constituents were present in similar concentrations with only a few exceptions, which probably do not present any risks. Whether no other constituents could be present could only be ruled out by a non-suspect analytical chemical approach.

SBB comment: The applicant performed all the analyses required by the currently applicable legislation and guidelines.

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: 2 experts

Comment 1

The 90-day feeding tests, although not perfect (some differences were noted, and did only disappear after False discovery rate was applied), are quite reassuring.

1.5. ALLERGENICITY

1.5.1. Assessment of allergenicity of the newly expressed protein

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

1.5.2. Assessment of allergenicity of the whole genetically modified plant

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

1.5.3. Conclusion of the allergenicity assessment

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

1.6. NUTRITIONAL ASSESSMENT

1.6.1. Nutritional assessment of the genetically modified food

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

Comment 1

The 42-day feeding study in Ross 708 broilers indicates that the DP51291 maize is certainly equivalent in energetic terms. Whether DP51291 maize is equivalent in terms of an equilibrated nutrition with sufficient vitamins and other substances that are relevant for human health (also at old age) cannot be deduced from such experiments. However it seems likely that DP51291 maize is equivalent to non-GMO maize.

SBB and coordinator comment: Section 1.3.3. lists all the compounds, including vitamins, that were analyzed and compared to non-GM maize varieties. The GM maize is in terms of composition (except for the presence of the PAT and insecticidal protein) compositionally equivalent to control and reference varieties. This means that there are no reasons to suspect that the GM maize would differ in nutritional terms from the non-GM maize.

1.6.2. Nutritional assessment of the genetically modified feed

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

1.6.3. Conclusion of the nutritional assessment

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

Comment 1

Based on the compositional similarity between DP23211 maize and DP51291 maize on the one hand, and the fact that mortality and performance in broilers fed diets with DP23211 maize grain were not

adversely affected in comparison with broilers fed diets with control maize grain (Smith et al., 2021) on the other hand, DP51291 maize may be nutritional equivalent and as safe as conventional maize.

2. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE OR EXTENT OF USE

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

Comment 1

It is somewhat strange that the applicant apparently tries to minimize the estimated exposure, whereas the applicant will certainly try to maximalize exposure.

SBB and coordinator comment: The following was sent to EFSA: In reading the application, our expert has the impression that the applicant tries to minimize the estimated exposure. Could EFSA comment on this?

Feedback from the EFSA GMO Panel: In line with Regulation (EU) No 503/2013 the applicant provided dietary exposure estimates (Section 3.5.4.1 of the Scientific Opinion). The applicant followed the methodology described in the EFSA Statement 'Human dietary exposure assessment to newly expressed protein in GM foods' to anticipate human dietary exposure making use of summary statistics of consumption (EFSA, 2019a).

3. RISK CHARACTERISATION

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

Comment 1

I think this Risk characterization is essentially correct in scientific terms, but it should be recognized that there are certainly still some uncertainties that remain, for instance in terms of subtle differences in chemical composition, the possible impact of which on human health are difficult to assess.

Coordinator comment: The uncertainties referred to here are not different from uncertainties that arise from subtle or more outspoken changes in chemical composition resulting from the introduction of new conventional varieties. In the case of GMO dossiers we have knowledge about the actual subtle differences and can make an estimation whether they trigger safety related issues. For conventional crops we do not have such knowledge, which means that the level of uncertainties is probably higher for conventionally bred varieties than for GMO crops.

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

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

Comment 1

Post marketing monitoring should test, in an area where the use of DP51291 maize in feed for animals is intensive, whether DP51291 maize can be detected in agricultural fields.

Coordinator comment: This maize is going to be imported and processed into animal compound feed materials that will be fed to animals on a farm. The risk of spread of the maize kernels is prior to the maize being processed into compound feed. That is also why we see some feral populations close to ports where such maize is shipped. The imported maize is not really going to be on farms or on agricultural fields in a form that it could form plants on the field.

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: 1 expert

Comment 1

Concerning the statement "*it was concluded that DP51291 maize is comparable to conventional maize*." Some differences were indeed detected. It would be more scientifically correct to state "the compositional characteristics of DP51291 maize are not identical but quite similar compared to those of the conventional counterpart and commercial reference maize lines, taking into account biological variation. "

Concerning the statement: "*there are no biologically relevant differences between DP51291 maize and a conventional counterpart*". This is not true. The introduced resistances against pesticides and pests are biologically relevant.

SBB and coordinator comment: the phrase "no biologically relevant differences" is used in this section in relation to the compositional analysis and the agro-pheno characteristics, with addition to the phrase "apart from the intended traits".

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

Comment 1

I wonder whether the statement "*There are no indigenous sexually compatible wild relatives of maize in the EU, therefore no cross-hybridisation or introgression is expected*." is correct in scientific terms. **(1)**

The statements

"*DP51291 maize is unlikely to establish without human intervention under EU conditions.*

• *The persistence and invasiveness potential of DP51291 maize is not expected to be different from those of the conventional crop.*

• *Cross-hybridisation with wild indigenous relatives is highly unlikely occur in the EU due to the lack of wild relatives*. "

Do not seem, to be correct to me.

I think that massive use of DP51291 maize as animal, feed might well lead to DP51291 plants surviving in agricultural areas. **(2)**

I think that the intended introduced genetic traits make DP51291 maize more successful in the conditions prevailing in our agricultural areas. **(3)**

I do not understand the point about the lack of "*wild relatives*". I think that maize plants are cultivated in very many areas and that these plants are the relevant ones.

Concerning the statement "*and the nature of the traits, which is unlikely to confer selective advantage*" I think that these traits just aim to give a selective advantage in the conditions prevailing in our agriculture.

Since the conclusion of step 1 is possibly wrong, the statements made in steps 2, 3, 4, 5 and 6 are also possible wrong.

Coordinator comment: **(1)** This is correct in scientific terms. There may some teosinte growing in Spain with which the maize could hybridize, but this is not an indigenous plant. It is an exotic plant that has probably been introduced accidentally or unintentionally.

(2) The amount of maize being imported as animal feed is already substantial, and this amount has not led to establishment of maize in agricultural areas with the exemption of some feral, temporary populations.
And see also comment above that the maize is going to be processed into compound animal feed and is not likely to be on farms in a form that could form plants in field.
The risk of spread is on routes between the import harbour and the animal feed processing factories.

(3) It is not clear on the basis of which arguments the introduced traits would make this maize more successful in our agricultural environments Are there any indications that corn root worms play a role in keeping possible feral populations under control? Glufosinate-ammonium is a herbicide that is not allowed to be used in Europe. Therefore the presence of the PAT protein does not provide any selective advantage in Europe, as this herbicide is not allowed to be used here.

5.3.2. Plant to micro-organisms gene transfer

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

Comment 1

I wonder whether the presence of E coli sequences in the plant DNA could give rise to recombination events and integration of the intended genes into microorganisms.

SBB and coordinator comment: this is addressed in the corresponding section in the application.

5.3.3. Interactions of the GM plant with target organisms

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

Comment 1

Apparently, according to EFSA, this issue is not relevant here.

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

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

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

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

5.3.6. Effects on biogeochemical processes

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

5.3.7. Effects on human and animal health

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

Comment 1

The only possible concerns are the uncertainties concerning possible indirect toxic effects of the IPD072Aa gene and protein.

5.3.8. Overall risk evaluation and conclusions

Comment 1

It is very likely that DP51291 is as safe as conventional maize. This statement has been substantiated by results of Anderson et al. (2018) and Carlson et al. (2019).

Comment 2

I am not convinced that the statement "*that the risk that the import, processing or food and feed use of DP51291 maize in the EU will result in harm to sustainable agricultural production or biodiversity as a result of changes in persistence or invasiveness compared with the conventional crop is negligible*." Is correct.

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

Comment 1

I think that a monitoring of the presence of DP51291 plants in agricultural areas' with intensive use of DP51291 maize containing feed is necessary

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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