Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

# Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-ES-2018-154 (Cotton GHB811) from BASF under Regulation (EC) No. 1829/2003

16 September 2021
*Ref. SC/1510/BAC/2021_0877*

## Context

Application EFSA-GMO-ES-2018-154 was submitted by BASF for the authorisation for the marketing of genetically modified (GM) cotton GHB811 for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

Cotton GHB811 contains a single insert with a single copy of the *hppdPfW336-1Pa* and *2mepsps* expression cassettes, producing the 2mEPSPS protein which confers tolerance to glyphosate and HPPD W336, a modified 4-hydroxyphenylpyruvate dioxygenase, conferring tolerance to HPPD-inhibiting herbicides.

The application was validated by EFSA on 16 January 2019 and a formal three-month consultation period of the Member States was started, lasting until 19 April 2019, 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). Eight experts answered positively to this request, and formulated a number of comments to the dossier. See the annex for an overview of all the comments and the comments sent to EFSA on 18 April 2019.

The opinion of the EFSA Scientific Panel on GMOs was published on 16 August 2021 (EFSA Journal 2021;19(8):6781[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 30 August 2021, 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-ES-2018-154 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.2013.3252

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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

After request for more information on the conduct of the field trials, quantification methods for the newly expressed proteins and the statistical analysis of the composition, the Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM cotton GHB811, in comparison with its conventional counterpart, do not raise safety concerns.

2.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed 2mEPSPS and HPPD W336 proteins in the context of previous applications, and no safety concerns were identified.
The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of GM cotton GHB811, 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 2mEPSPS and HPPD W336 proteins in the context of previous applications, and no safety concerns were identified.
The BAC agrees with the GMO panel of EFSA that the available data on the allergenicity of the 2mEPSPS and HPPD W336 proteins, as expressed in soybean GMB151, and on the overall allergenicity of cotton GHB811, do not raise safety concerns.

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 cotton GHB811-derived food and feed are not expected to differ from those of conventional cotton varieties.

### 3. Environmental risk assessment

After request for more information on horizontal gene transfer, the Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of cotton GHB811 (i.e. during transport and/or processing) into the European environment[3] will lead to environmental harm.

### 4. Monitoring

[3] 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.

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 cotton GHB811 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 cotton GHB811 is unlikely to pose any threat to the European environment;
2) Agrees with the GMO panel of EFSA that in the context of its proposed uses, cotton GHB811 is unlikely to pose any risk to 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*

# Annex : Outcome of the assessment of application EFSA-GMO-ES-2018-154 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:** Eddy Decuypere (KUL), Jacques Dommes (ULg), Patrick du Jardin (Ulg), Leo Fiems (ILVO), André Huyghebaert (UGent), Peter Smet (Consultant), Frank Van Breusegem (UGent), Jan Van Doorsselaere (Vives)
**SBB:** Fanny Coppens

Application: **EFSA/GMO/ES/2018/154**
Applicant: **BASF**
GMO: **Cotton GHB811**
Validation of dossier by EFSA: **18 January 2019**

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**

## GENERAL COMMENTS

*Comment 1*
GHB811 cotton may be as safe for human and animal health and the environment as conventional cotton, based on the results of the compositional analysis, and the toxicological and allergenicity assessment.

## PART II - SCIENTIFIC INFORMATION

### 1. HAZARD IDENTIFICATION AND CHARACTERISATION

#### 1.1. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

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

*Comment 1*
P15: EU-cotton production is less than 300.000 t in 2013, but Greece and Spain together are producing in 2014 more or less 540.000 t? Why this discrepancy if source of the information is ec.europe.ev or FAO stat. ?

**SBB comment**: This does not pertain to the safety assessment for animal or human health or the environment of cotton GHB811.

#### 1.2. MOLECULAR CHARACTERISATION

#### 1.2.1. Information relating to the genetic modification

*Have evaluated this section and consider the information adequate: 5 experts*

#### 1.2.2. Information relating to the genetically modified plant

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

*Comment 1*

1- About section "1.2.2.2. Information on the sequences actually inserted/deleted d) Sub-cellular location(s) of insert(s) and methods for its/their determination". I wish to point out that the applicant goes beyond the requested information when ascribing the insertion locus to a specific cotton chromosome (main text page 63 and report 18-RSTHS005). Although the genomic location is requested (insertion in the nuclear vs. cytoplasmic genomes), the guidelines and EC implementing regulation do not ask for the integration locus in the nuclear chromosomes. This is not an issue as long as this information does not become mandatory.
2- About section "1.2.2.3 Information on the expression of the insert". In the report M-574232-01-1 from the Appendices (Study report N°15-RSTHS002 is indicated on the front page of the document itself), the herbicide applications are described, which are needed to conclude on the impact of the treatments on the expression levels of the newly expressed proteins conferring herbicide tolerance. Surprisingly, the IFT (isoxaflutole) treatment was done before plant emergence: "*The IFT application to entry C was made at a rate of 104.9 to 106.6 g ai/ha before emergence (BBCH 00")* (page 14 of

the quoted report). Considering that the engineered herbicide tolerance aims at allowing post-emergence herbicide applications, the applicant should justify the application regime chosen in this trial and indicate whether it is representative of the agronomic conditions of the GM cotton cultivation. How this may impact the conclusions regarding the possible effect of the herbicide on the expression level of the HPPD W336 protein should also be discussed.

3- Regarding the protein extraction for the ELISA quantification of the mEPSPS and HPPD W336 proteins, the extraction buffer can be found in the note of Table A2-1 (page 43 of the report M-574232-01-1, Annex 2). This buffer does not contain protease inhibitors and the applicant did not provide a quantitative assessment of the protein recovery percentages from the different matrices to support the validity of the extraction protocol (at least I could not find such information in the dossier). The applicant should discuss this issue.

**Feedback from the EFSA GMO Panel**: 2) The GMO Panel thanks Belgium for the comment. IFT herbicides, as recommended by the manufacturers, can be applied pre-sowing/pre-emergence and post emergence. IFT is rapidly adsorbed by the shoots and roots that form diketonitrile that is the active HPPD inhibitor (Pallett et al., 1997; 2001). The applicant was requested to justify the dose and timing of the applied herbicides (intended and conventional) and EFSA received additional information on the 17/9/2019.

References:

Pallett, K. E. et al.,1997. Pestic. Sci. 50, 83–84

Pallett, K.E., Cramp, S.M., Little, J.P., Veerasekaran, P., Crudace, A.J. and Slater, A.E. (2001), Isoxaflutole: the background to its discovery and the basis of its herbicidal properties. Pest. Manag. Sci., 57: 133-142.

3) Further information on the method used for the quantification of NEPs was provided in the validation reports STSa-DD0078-01 and STSa-DD0080-01. The GMO Panel is of the opinion that the data on the levels of the newly expressed proteins (NEPs) are sufficient to conclude on the molecular characterization of application 154. The levels of the NEPs were obtained and reported adequately and in accordance with EFSA guidelines (EFSA GMO Panel, 2011) and Regulation (EU) 503/2013.

*Comment 2*

On p62, concrete information on how the transgenic locus sequence was identified/amplified is missing. There is only a vague indication that PCR was used. However, I could not find an accurate description of the methodology. I tried to trace it in the various annexes. Unfortunately I could not find it within the multitude of files.

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

*Have evaluated this section and consider the information adequate: 5 experts*

### 1.2.4. Conclusions of the molecular characterisation

*Have evaluated this section and consider the information adequate: 5 experts*

*Comment 1*

See my comments above.

## 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*

*Comment 1*
In line with the remark made on the protein level assessment, when producing the material for the comparative assessment, the IFT herbicide application regime is described as follows (report M-58563-01, page 25) : "*One application of IFT was made at a rate of 100.3 to 115.2 grams active ingredient per hectare (g ai/ha) before or shortly after emergence (BBCH 00 to 13).*" It is surprising that the herbicide is applied before emergence since the genetic modification aims at allowing post-emergence application. The applicant should confirm that the applied treatments correspond to the intended use of the herbicide on the GHB811 cotton, in order to ensure that the material used for the comparative assessment is appropriate.

**Feedback from the EFSA GMO Panel**: The GMO Panel thanks Belgium for the comment. IFT herbicides, as recommended by the manufacturers, can be applied pre-sowing/pre-emergence and post emergence. IFT is rapidly adsorbed by the shoots and roots that form diketonitrile that is the active HPPD inhibitor (Pallett et al., 1997; 2001). The applicant was requested to justify the dose and timing of the applied herbicides (intended and conventional) and EFSA received additional information on the 17/9/2019.
References:
Pallett, K. E. et al.,1997. Pestic. Sci. 50, 83–84
Pallett, K.E., Cramp, S.M., Little, J.P., Veerasekaran, P., Crudace, A.J. and Slater, A.E. (2001), Isoxaflutole: the background to its discovery and the basis of its herbicidal properties. Pest. Manag. Sci., 57: 133-142.

### 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*
P80-81: is the total rainfall for site (code 03, California) really only 25mm rainfall? Or is it 250 mm? (in the text also 25 is mentioned); therefore it must be irrigated ; but then, which sites have been irrigated and which not? This is not given (only in cotton field production report M-558563-01-1).
Should this not be taken into account in the statistical analysis as well ? Or is this sufficiently covered by including sites in the statistical models as random effects?

**SBB comment**: This does not pertain to the assessment of the safety of the GM cotton.

### 1.3.3. Selection of material and compounds for analysis

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

*Comment 1*
It would be interesting to give analyses of glyphosate and Isoxaflutole and metabolites in the cottonseeds, to verify if there were differences between GHB811 cotton treated with the conventional herbicide management (CHM) or with the intended herbicides (TIH).

**SBB comment**: The assessment of the safety of herbicides is not within the remit of the BAC.

*Comment 2*
See the previous comment.

### 1.3.4. Comparative analysis of composition

*Comment 1*

Some significant differences occurred between GHB811 (treated with CHM and/or TIH) and conventional cotton, but differences were considered of no biological relevance, taking the natural variation into account. However, if differences in one component are consistent amongst locations and have a common trend (always higher or lower) they may be considered as relevant. Did the applicant verify if some differences were consistent among the 15 sites?

**Feedback from the EFSA GMO Panel**: The statistical analysis provided by the applicant was in agreement with the recommendations of EFSA GMO Panel (2011). A site-specific analysis was performed only for those endpoints for which the genotype-by-site interaction was significant: for such endpoints, no relevant pattern was found in the results across sites

*Comment 2*

The OECD document of 2009 was followed. I will not repeat my comments on the selection of compounds for analysis such as the fiber content, the carbohydrates by calculation (or difference). These and other approaches are not at all up to date. A revision of the OECD document is necessary. The approach is however appropriate for comparative purposes.
I agree with the conclusions of this assessment.

*Comment 3*

The table 1.3.7 and following allows also to test possible effects of different herbicide treatments if testCHM versus testTIH would have been compared. I understand that this is not the purpose of the study, but nevertheless worthwhile to look at.

Vit E is considered as alpha-tocopherol: this is indeed the more active form compared to the others, but what is the proportion of alpha vs. beta, gamma and delta tocopherol in cotton seed? What about the four tocotrienols (with unsaturation in the side chain)?
Since VitE is readily oxidized, its supply deteriorates in ground feeds; what will be the effect of treatment on VitE content on cotton seed meal?

*Comment 4*

Compared to dossier 120 the amount of 2mEPSPS is of the same magnitude, but for HPPD W336 this is a factor 100 higher.

Dihydrosterculic acid is classified as non-equivalent (compared to the reference varieties) and different from its isoline. As the mean value in the GMO is lower than in the isoline, this seems to be of no concern.

### 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*

For comparison of 2mEPSPS or HPPD W336 content (expressed per FW or DW) of all components as mentioned in the matrix of table 1.3.17, no differences between not-treated or treated with trait-specific herbicide were observed except for the content of 2mEPSPS as well as of HPPD W336 in untoasted meal non-treated vs. treated, where the contents of both proteins were consistently double or more in toasted meal from treated cotton. Why? This is not mentioned or explained in the text.
I understand that presence of 2mEPSPS and HPPD W336 proteins in these components is of no risk at all in view of relevant processing conditions for the food and feed derived from the GM plant, and/or in view of the rapid degradation of these proteins in SGF and SIF of the gastrointestinal system, but it is just a matter of scientific interest why such differences in treated versus non-treated untoasted meal do occur.

**Feedback from the EFSA GMO Panel**: The GMO Panel took note of the comment. This was considered not a safety concern. Animal dietary exposure to HPPD W336 and 2mEPSPS was estimated via the consumption of cottonseed meal by using a conservative approach; a processing factor of 1.3 was applied to the levels of the two NEPs in cotton fuzzy seeds (see Scientific Opinion, section 3.4.5.2) resulting in highest values than those reported in untoasted meal (both treated and non-treated).

### 1.3.7. Conclusion

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

*Comment 1*
See my comment on the production of the material for the comparative assessment and the herbicide regime applied.

## 1.4. Toxicology

### 1.4.1. Testing of newly expressed proteins

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

*Comment 1*
Two effects attracted my attention:

1) Aminotransferase activity

A lowering in aspartate aminotransferase and alanine aminotransferase activities in **females** were observed (-24%, not statistically significant and -27%, not statistically significant, respectively) when compared to the control (28-day study HPPD W336 dossier 154).
In dossier 98 the same tendency was seen but this time in **males** (28-day study HPPD W336 dossier 98).
Statistically significantly lower mean alanine aminotransferase (ALT) values were noted in the test diet **male** group (90-day study dossier 154).

Since in a study only one sex is effected and the effect is towards a lower activity, this effect seems to be of no direct concern.

2) Prostate weight

Mean absolute and relative prostate weights in the treated group were statistically significantly lower than in males of the control group. These changes were not associated with any relevant macroscopic or microscopic changes (28-day study HPPD W336 dossier 154).
No such an effect was seen in dossier 98.
No effect was seen in the 90-day rat study (90-day study dossier 154).

The lowering in prostate weight seems to be unrelated to the administration of the event.

### 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: 1 expert*

*Comment 1*
The applicant administered HPPD W336 protein by gavage to C57BL/6J mice at 1000 mg/kg/day and did find any treatment-related changes. Dreesen et al. (2018) found no evidence of a systemic toxicity in an acute oral toxicity study in C57BL/6J mice, even with HPPD W336 fed at 2000 mg/kg body weight.

*Comment 2*
See comments above.

No other treatment-related changes were observed.

### 1.4.5. Conclusion of the toxicological assessment

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

### 1.5.2. Assessment of allergenicity of the whole genetically modified plant

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

### 1.5.3. Conclusion of the allergenicity assessment

*Have evaluated this section and consider the information adequate: 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

*Comment 1*
Gossypol can cause a temporary reduction in sperm cell formation in bulls when used at elevated feeding levels. However, it is unlikely that negative consequences for reproduction or health of bulls will occur when feeding cottonseed meal at a dietary incorporation level of 5%, as mentioned for dairy cattle (P. 134 of the Main text).

### 1.6.3. Conclusion of the nutritional assessment

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

## 2. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE OR EXTENT OF USE

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

## 3. RISK CHARACTERISATION

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

*Comment 1*
See my comments on the herbicide treatment of cotton GHB811 for assessing the protein levels and for producing the material for the comparative assessment.

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

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

## 5. ENVIRONMENTAL RISK ASSESSMENT (ERA)

### 5.1. INTRODUCTION

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

### 5.2. GENERAL APPROACH OF THE ERA

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

### 5.3. SPECIFIC AREAS OF RISK

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

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

### 5.3.2. Plant to micro-organisms gene transfer

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

*Comment 1*
The evaluation of horizontal gene transfer from plants to bacteria by the applicant only considers homologous recombination as a theoretical scenario for DNA transfer (see section 5.3.2, page 156 of the main dossier and figure 5.3.1 on page 159). However, the T-DNA contains two *lox* sequences (cfr table 1.2.1 on page 28 of the main dossier), which are aimed at permitting site-specific recombination catalysed by dedicated recombinases (Cre proteins). The applicant does not provide any risk assessment of the possible consequences of these recombinogenic sequences within the inserted T-DNA. I consider that the applicant should be requested to complete the risk assessment of HGT by taking the theoretical possibility of *lox*-mediated site-specific recombination into account.

**Feedback from the EFSA GMO Panel**: The GMO Panel thanks Belgium for the comment and acknowledges the presence in GHB811 event of two lox sites flanking a sequence of about 3800 bp containing the cassette for the expression of the 2mepsps gene. However, as extensively discussed in EFSA (2012), the GMO Panel considers that the stabilisation of the lox flanked fragment due to the Cre recombination system present in bacteria containing a P1 or P1-like bacteriophage is unlikely. Furthermore considering the nature of the recombinant gene and the natural prevalence of glyphosate-resistant bacteria a transfer would not provide a selective advantage to bacterial recipients in the environment.
Reference: EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2012. Scientific Opinion on an application (Reference EFSA-GMO-NL-2009-70) for the placing on the market of genetically modified drought tolerant maize MON 87460 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2012;10(11):2936.

### 5.3.3. Interactions of the GM plant with target organisms

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

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

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

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

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

### 5.3.6. Effects on biogeochemical processes

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

### 5.3.7. Effects on human and animal health

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

### 5.3.8. Overall risk evaluation and conclusions

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

*Comment 1*
See my comment on Horizontal Gene Transfer above.

## 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: 2 experts*

### 6.2. Case-specific GM plant monitoring (strategy, method and analysis)

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

### 6.3. General surveillance for unanticipated adverse effects (strategy, method)

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

### 6.4. Reporting the results of PMEM

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

## 7. ADDITIONAL INFORMATION RELATED TO THE SAFETY OF THE GENETICALLY MODIFIED FOOD OR FEED

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

## References

Dreesen, R., Capt, A., Oberdoerfer, R., Coats, I., Pallet, K. E. 2018. Characterization and safety evaluation of HPPD W336, a modified 4- hydroxyphenylpyruvate dioxygenase protein, and the impact of its expression on plant metabolism in herbicide-tolerant MST-FGØ72-2 soybean. Reg Tox Pharmacol 97, 170-185.