Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application GMFF-2023-14732 (sugar beet KWS20-1) from Bayer and KWS under Regulation (EC) No. 1829/2003

2 July 2025
Ref. SC/1510/BAC/2025_0845

Context

Application GMFF-2023-14732 was submitted by Bayer CropScience and KWS SAAT for the authorisation for the marketing of genetically modified (GM) KWS20-1 (Unique Identifier KB-KWS2Ø1-6) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

KWS20-1 sugar beet expresses the *dmo, pat* and *cp4 epsps* cassettes, conferring tolerance to dicamba, glufosinate- and glyphosate-based herbicides.

The application was validated by EFSA on 27 October 2023 and a formal three-month consultation period of the Member States was started, lasting until 27 January 2024, 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 for an overview of all the comments and the comments sent to EFSA on 24 January 2024.

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 12 May 2025 (EFSA Journal 2025;23(5):e9381[2]). On 15 May 2025 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 GMFF-2023-14732 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.2025.9381

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Scientific evaluation

1. Molecular characterisation

KWS20-1 sugar beet contains a single insert consisting of one copy of the *dmo, pat* and *cp4 epsps* cassettes. The PAT and CP4 EPSPS proteins expressed in KWS20-1 are identical to PAT and CP4 EPSPS proteins already reviewed and assessed positively by the Biosafety Advisory Council. The DMO protein is highly homologous to DMO protein already reviewed and assessed positively by the Council. 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 sugar beet KWS20-1, in comparison with its conventional counterpart, do not raise safety concerns.

2.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety with respect to toxicity of the DMO, PAT and CP4 EPSPS proteins in the context of a previous applications (e.g. maize MON 87429[3] expressing the *dmo*, *pat* and *epsps* gene) and concluded that there were no safety concerns.

As the amino acid sequence of the DMO protein of KWS20-1 differs from previously assessed DMO proteins, the functional equivalence of the DMO protein of KWS20-1 with the already assessed DMO protein of MON 87429 (identical to the amino acid sequence of KWS20-1 with the exception of N-terminal 27 amino acid region) was demonstrated.

Taking into account the information in the current application, the Biosafety Advisory Council is of the opinion that its previous conclusions on the safety of the DMO, PAT and CP4 EPSPS remain valid.

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of GM sugar beet KWS20-1, 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 KWS20-1 does not raise concerns regarding toxicity.

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed DMO, PAT and CP4 EPSPS 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 KWS20-1 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 sugar beet KWS20-1-derived food and feed are not expected to differ from those of conventional sugar beet varieties.

[3] Final advice of the Biosafety Advisory Council on application EFSA-GMO-NL-2019-161

3. Environmental risk assessment

Whole sugar beet or viable parts will not be imported. Hence, in line with the EU GMO Regulation, the Biosafety Advisory Council is of the opinion no environmental risk assessment is needed for the import of food and feed produced from sugar beet KWS20-1.

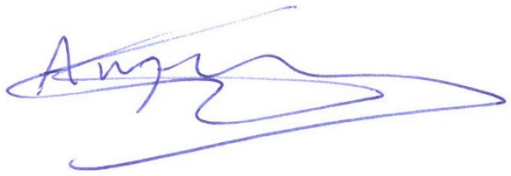
4. Monitoring

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 sugar beet KWS20-1 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 impacts of sugar beet KWS20-1 would not differ from those of conventional sugar beet;
2) Agrees with the GMO panel of EFSA that in the context of its proposed uses, sugar beet KWS20-1 is as safe as the conventional counterpart and the non-GM reference varieties tested with respect to potential effects on human and animal health.



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

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

Annex: Outcome of the assessment of application GMFF-2023-14732 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: René Custers
Experts: Henri Batoko (UCL), Dimitri Gilis (ULB), André Huyghebaert (UGent), Frank van Breusegem (VIB-Ugent), Erik Van Miert (DSM-Firmenich)
SBB: Adinda De Schrijver

Application: **GMFF-2023-14732**
Applicant: **Bayer CropScience and KWS SAAT**
GMO: **sugar beet KWS20-1**
Validated by EFSA: **23 October 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 (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
material for cultivation in the EU

The experts were asked to evaluate whether the information provided in the application is sufficient in order to state that the marketing of the genetically modified plant for its intended uses will not raise any problems for the environment or human or animal health. If information is lacking, the expert was asked to indicate which information should be provided and what the scientifically reasoning is behind this demand.

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

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

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

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

GENERAL COMMENTS

- In document "Summary_AP184", sections 1.3(a) and (b), the boxes "Food/Feed containing or consisting of GM plants" are not ticked, whereas they are in this document. The authors of the KWS20-1 application have not completed section 5 "Environmental assessment", as there is no import of "Food/Feed containing or consisting of GM plants". If the error is in the Summary_AP184 document, then the authors should carry out the study requested in section 5 "Environmental assessment".

  Note SBB: An environmental risk assessment only needs to be carried out in case plant material able to reproduce is imported.

- In several parts of the dossier, the results are not summarised in the "results" sections of the parts of the dossier, leaving us to analyse in detail the additional reports or the annexes to the dossier - which are sometimes very numerous. This is perhaps linked to the fact that the proteins corresponding to the genetic modifications have already been the subject of older dossiers and have already obtained approvals. However, this makes the main dossier lack detail (in certain sections), which explains some of my comments.

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: 2 experts

Comment:
Section 1.1.5 as a whole is poorly documented and lacks detail. The assertions made in this section should be supported by scientific references.

GMO Panel response: In section 1.1.5 are detailed the information relating to the recipient or parental plants required for the environmental safety aspects. This information was considered as adequate by the GMO Panel.

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:

- The sequence of the DMO protein expressed in this GM sugar beet is given in Fig 1 of the report M-832018-01. This DMO protein is from *Stenotrophomonas maltophilia*. When I do a Blast search, the 27 first amino acid of the sequence provided in this report are not present in the sequence from *Stenotrophomonas maltophilia*. I evaluated previously another EFSA dossier (MON94313), where a DMO protein from *Stenotrophomonas maltophilia* was also added in a host genome. And the first amino acids of this sequence were also different compared to the sequence provided in the MON94313 application file (GMFF-2022-6595; AP176). The differences in the DMO sequence are finally discussed in section 1.2.2. Writing in the report M-832018-01 (section 3), cited in section 1.2.1.3c, that "The KWS20-1 sugar beet-produced DMO sequence (Figure 1) used in this analysis was the same as that used previously (Gu, 2022)." is therefore not quite correct. Moreover, in the report M-832018-01, references are made to other technical reports produced by Bayer (Gu 2022, Skottke 2022), but not provided in this application file.

  GMO Panel response: The GMO Panel takes note of the comment but clarifies that the dossier does not contain a report M-832018- 01. The report containing the mentioned information is M-823018-01. The safety assessment of the DMO protein as expressed in this GM sugar beet is described in sections 3.3.3 and 3.5.1.2 of the scientific opinion. The other Technical Reports mentioned were provided in the application file: M-822495-01 2022 (Gu, 2022) and M-822058-01 2022 (Stottke, 2022).

- On the other hand, the bioinformatics analyses were carried out correctly. No significant similarities with known toxins or allergens are found using bioinformatics tools.

1.2.2. Information relating to the genetically modified plant

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

Comment 1:

Analysis of the genomic DNA sequences flanking the insertion site of KWS20-1 sugar beet reveals that the T-DNA did not disrupt any endogenous Open Reading Frames (ORFs). Moreover, no ORFs from the sugar beet genome were found in the neighbouring genomic DNA surrounding the inserted T-DNA. However, it remains unclear whether the analysed flanking DNA, adjacent to the T-DNA, underwent scrutiny for the presence of repetitive sequences, as stipulated by the requirement (Directive 2001/18/EC). If such an examination was conducted, it is essential to provide a clear statement and a detailed description of the methodology used, as outlined in documents M-823013-01 and M-823015-01.

Note SBB & coordinator: The assessment of whether or not the (T-DNA) insert is located in a repetitive region, is not a requirement mentioned in GMO Regulation. However, care should be taken that repetitive sequences do not jeopardise DNA sequencing (EFSA, 2018). The reports in the dossier on the analysis of the genomic DNA flanking regions of the KWS20-1 insert do not indicate there were issues with DNA sequencing due to repetitive sequences (KWS2203_2022).

Comment 2:

- The mode of action of the newly expressed proteins is lacking. What is the mode of action of resistance to the 3 herbicides (dicamba, glufosinate and glyphosate)? Are these 3 proteins specific to their substrate? For instance, a study of Christ et al. (2017) show that transgenic BAR protein (very similar to PAT) converts endogenous aminoadipate and tryptophan to their respective N-acetylated products in several plant species. This study suggests that a similar genetic modification could alter the plant's metabolism.

  Note SBB: Whether or not the production of the BAR protein affects the plant at the level of its composition, is assessed and covered in Section 1.3.

- In section 1.2.2.2f, the authors analyse whether the sequences corresponding to the ORFs show similarities with the sequences in the AD_2022, TOX_2022 and PRT_2022 databases. Detailed

results are presented in report M-823019-01. However, the authors do not specify which ORFs were identified (number, etc.), whether all these ORFs were tested or only those larger than a threshold size.

GMO Panel response: The detailed information on the used methodology is in section M-823019-01 (2022) 4.0 Sequence Database Searches. The detailed description of the obtained results is reported in section 6.0 Results. The GMO Panel requested (see ADR-2) specific clarifications on the analysis to identify whether any open reading frame (ORF) within the insert shows significant similarities to allergens (study ID M-823019-01-1).

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: 2 experts

Comment:
See 1.2.2

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: 1 expert

1.3.3. Selection of material and compounds for analysis

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

Comment:
As always the case in these type of applications the OECD guidelines are followed. As well tops and roots were analysed. I concentrated in my report on roots.

Compounds analysed in roots: protein, fat, moisture, amino acids (18 compounds), sucrose, carbohydrates by calculation, fibre, pectin, minerals (P, K, Na). Important amino acids are *included, also the essential ones. They are important during the valorisation of pulp as animal* feed.

There has been interest in the valorisation of pectin, extracted from sugar beets. The choice of pectin is fully justified.

Oleanolc acid is the only secondary metabolite, given attention. It is a pentacylic triterpenoid and can be considered as an indicator of secondary metabolites. Sugar beets contain a broad range of secondary metabolites such as phenolic acids (caffeic acid, syringic acid, ferulic acid) flavanoids (quercitine, rutine,myricetine) betalaines (betanin, isobetanin), betacyanines, betaxanthines among others.
It cannot be the objective to cover all these compounds in a comparative analysis. However, I find it important that attention is given to a particular representative of these compounds, oleanolic acid. It confirms the conclusion of compositional equivalence.

A substance not present in the review is phytic acid. It is a powerful anti-nutrient in actual human nutrition. Once again I have no doubt that a major effect on the level of phytic acid is not expected, but some attention to a major anti-nutrient would further confirm the conclusion.

1.3.4. Comparative analysis of composition

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

Comment:
The applicant studied in detail the composition of sugar beet KWS-12 and concluded that there is for most compounds no statistical difference between sugar beet KWS-12 and the reference.
If a statistical difference is observed, it is concluded that the differences are small and that they will not contribute to the natural biological variation in composition.

1.3.5. Comparative analysis of agronomic and phenotypic characteristics

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

Comment:
I did not evaluate this section in detail. No particular remarks.

1.3.6. Effects of processing

Comment:
The applicant concludes that the processing of sugar beet KWS20-1 is not expected to be any different from the conventional sugar beet. This conclusion is based upon the comparative analysis of composition.

1.3.7. Conclusion

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

Comment:
The applicant concludes that sugarbeet KWS 20-1 is compositionally equivalent to the reference sugar beet.
I agree with the applicant that the introduction of sugar beet KWS20-1 will not contribute to the biological variability of sugar beets.

1.4. TOXICOLOGY

1.4.1. Testing of newly expressed proteins

Comment 1:
In section 1.4.1.3. it is stated that "*The stability of the DMO (M-820284-01, 2022), PAT[36] and CP4 EPSPS[37] proteins was assessed at different pH conditions during their characterisation and safety assessments.*" However, I could not retrieve this information on DMO in the report M-820284-01, 2022. Could it be that the claimed stability of DMO in different pHs is based on data on the DMO from MON 87429 which is considered equivalent? If so, this should be clearer indicated. The authors rely on the results obtained from bioinformatics analyses and on the fact that the proteins expressed in KWS20-1 are identical or very similar to proteins expressed in other crops that have been approved. In the M-825983-01 report, the authors show the similarity between the DMO used in the MON 87429 dossier and the DMO of this dossier (the two DMOs differ by 27 amino acids in the N-terminal region). They use this to justify the use of the 28-day oral toxicity study performed in the MON 87429 dossier, instead of repeating the study for this dossier. We want to draw EFSA' s attention to this point, but we think it could be acceptable.

GMO Panel response: The GMO Panel thanks Belgium and takes note of the comment. The applicant provided information on the newly expressed proteins aligned with current requirements. Following a weight-of-evidence approach, the GMO Panel considered information on the newly expressed proteins and source organisms, bioinformatics analysis, protein stability and additional experience from the GMO Panel on the safety assessment of these newly expressed proteins, also considering previous assessments by the GMO Panel. The GMO Panel concluded that the proteins CP4 EPSPS, DMO and PAT newly expressed in sugar beet KWS20-1 do not raise safety concerns for human and animal health. No interactions between the newly expressed proteins relevant for food and feed safety were identified.

Comment 2:
The "Repeated-dose 28-day oral toxicity study with the newly expressed proteins in rodents" was not conducted. The authors rely on the results obtained from bioinformatics analyses and on the fact that the proteins expressed in KWS20-1 are identical or very similar to proteins expressed in other crops that have been approved. In the M-825983-01 report, the authors show the similarity between the DMO used in the MON87429 dossier and the DMO of this dossier (the two DMOs differ by 27 amino acids in the N-terminal region). They use this to justify the use of the 28-day oral toxicity study performed in the MON87429 dossier, instead of repeating the study for this dossier. I would draw the committee's attention to this point, but I think it could be acceptable.

GMO Panel response: The GMO Panel thanks Belgium and takes note of the comment. The applicant provided information on the newly expressed proteins aligned with current requirements. Following a weight-of-evidence approach, the GMO Panel considered information on the newly expressed proteins and source organisms, bioinformatics analysis, protein stability and additional experience from the GMO Panel on the safety assessment of these newly expressed proteins, also considering previous assessments by the GMO Panel. The GMO Panel concluded that the proteins CP4 EPSPS, DMO and PAT newly expressed in sugar beet KWS20-1 do not raise safety concerns for human and animal health. No interactions between the newly expressed proteins relevant for food and feed safety were identified.

1.4.2. Testing of new constituents other than proteins

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

1.4.3. Information on natural food and feed constituents

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

1.4.4. Testing of the whole genetically modified food or feed

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

Comment:
Albeit that I agree with the comment about the utility and the conclusions of the 90-day study, I would have liked a more elaborate/clearer justification of the dose levels (2.5 and 5%).

In the report section 3.7.2. it is stated that: "*Incorporation levels up to 5% (w/w) sugar beet pulp in the test and control diets were considered to be appropriate without causing nutritional imbalance.*" I also noted in the report M-815901-01 (2022) in section 2.0: " *Since there was not an OECD recommendation (OECD, 2009) for feeding sugar beet to broiler, a 5% inclusion of sugar beet pulp was used in broiler diets as a conservative approach."* I could however find little information on how these incorporation levels relate to the levels typically used in actual food/feed applications. A quick internet search yielded*: "Dried beet pulp and molassed beet pulp are fed*

mostly to dairy cattle, for which they are very suitable. Dried beet pulp can be up to 30% of the diet on a DM basis" (source: https://gavdeo.com/sugar-beet-pulp/#1523276203428-16a1818b-65ac1e87-c16ab381-1cbfc658-26a6). At first sight this latter information suggests that a 5% incorporation level is not that conservative, so a more elaborate justification of the (conservative) dose levels seems justified.

(very minor comment) Albeit that I agree with the conclusions drawn from the thyroid related findings (sections 7.13. and 7.15.), the tables shown (Text Table 22 and Text Table 23) seem to "struggle" with the number of decimals shown which makes them more difficult to interpret.

GMO Panel response: It is noted that no reference value for the maximum incorporation rate of sugar beet pulp is reported in the explanatory statement published by EFSA (2014). However, EFSA indicated that the choice of inclusion rates should be justified by the applicant, with reference to the best knowledge of the formulator and to the available literature. The applicant provided additional information on this topic in December 2024 (please see ADR-4). Based on the current knowledge, the GMO Panel considers that a rate of 5% can be considered acceptable in the context of this application. If, in the future, additional information becomes available on the maximum level of sugar beet pulp that is suitable for use in rodent diets the acceptability of an incorporation rate of 5% will be reviewed and any new studies submitted to support 'GM sugar beet uses' will be considered against the additional information.

1.4.5. Conclusion of the toxicological assessment

Comment:
I agree with the overall conclusions of the toxicology assessment

1.5. ALLERGENICITY

1.5.1. Assessment of allergenicity of the newly expressed protein

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

Comment:
The bioinformatics study of the allergenicity of the proteins was carried out correctly (according to the EFSA protocols) and did not show any identity with known allergens. The results of the digestibility tests are convincing to me.

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. Adjuvanticity

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

1.5.4. 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

No comments received

3. RISK CHARACTERISATION

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

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

No comments received

5. ENVIRONMENTAL RISK ASSESSMENT (ERA)

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

Comment:
See general comment.

6. POST-MARKET ENVIRONMENTAL MONITORING PLAN (PMEM)

No comments received

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

No comments received

8. REFERENCES

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Benbrook, Charles M. How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides?. Environmental Sciences Europe 2019;31: 1-16.

Bøhn et al. Compositional differences in soybeans on the market: glyphosate accumulates in Roundup Ready GM soybeans. Food Chem. 2014;153:207-15.

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Christ et al. Non-specific activities of the major herbicide-resistance gene BAR. Nat Plants. 2017;3(12):937-945.

Cuhra M. Review of GMO safety assessment studies: gkyphosate residues in Roudup Ready crops is an ignored issue. Environ. Sci. Europe 2015;27: 20.

Duke et al. Isoflavone, glyphosate, and aminomethylphosphonic acid levels in seeds of glyphosate-treated, glyphosate-resistant soybean. J Agric Food Chem. 2003;51:340-344.

Guyton et al. International Agency for Research on Cancer Monograph Working Group ILF. Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. Lancet Oncol. 2015;16:490-491.

Myers et al. Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement. Environ Health. 2016;15:19.

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

GENERAL COMMENTS

Comment:

- The use of glufosinate has been banned in Europe since 2018. At the same time, an opinion is being sought on the import of this transgenic sugar beet which is glufosinate resistant - and therefore grown in the presence of glufosinate. It is not for me to assess the environmental aspects for the place of cultivation, if it is outside Europe. But isn't it schizophrenic to import this GM sugar beet, which is grown in the presence of a herbicide banned in Europe?

1.3.6. Effects of processing

Comment:
It is very well known that the yield of extraction of sucrose during processing is affected by particular substances. In addition to some ions, particular alpha-amino nitrogen is known to affect the yield of sucrose extraction. They are difficult to separate from molasses. I have the impression that this aspect is no included in the study.

Note SBB: The assessment under GM Food/Feed Regulation is restricted to the evaluation of the effects of potential changes of processing on food/feed safety. The yield of extraction of a certain substance is an economic issue that is not covered under the GMO Regulation.

1.4.5. Conclusion of the toxicological assessment

Comment:

The genetic construct gives sugar beet resistance to glyphosate. Does the plant accumulate the sprayed glyphosate in this case?
Studies on glyphosate-resistant soybeans show higher glyphosate residues in the harvested GM plants than in non GM plants (Arregui et al. 2003, Duke et al. 2003, Bøhn et al. 2014, Bøhn et al. 2019). Other studies show the potential toxicity of glyphosate (Myers et al. 2016), and the World Health Organization's International Agency for Research on Cancer re-classified glyphosate as "probably carcinogenic to humans" (Guyton et al. 2015) (although the US EPA reached a different conclusion about the possible carcinogenicity of glyphosate – see Benbrook 2019 for an analysis of this). In this context, measuring glyphosate residues in the GM plants seems to me relevant in a toxicological analysis (Cuhra 2015). This is not done in the toxicology assessment for KWS20-1.