Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-BE-2019-165 (soybean DBN9004) from Beijing DaBeiNong Biotechnology Co., Ltd. under Regulation (EC) No. 1829/2003

8 October 2025
Ref. SC/1510/BAC/2025_1197

Context

Application EFSA-GMO-BE-2019-165 was submitted by Beijing DaBeiNong Biotechnology Co., Ltd. for the authorisation for the marketing of genetically modified (GM) soybean DBN9004 (Unique Identifier DBN-Ø9ØØ4-6) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

Soybean DBN9004 produces the CP4 EPSPS and PAT proteins conferring tolerance to glyphosate and glufosinate-ammonium herbicides, respectively.

The application was validated by EFSA on 12 March 2021 and a formal three-month consultation period of the Member States was started, lasting until 15 June 2021, 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 2 June 2021.

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 7 July 2025 (EFSA Journal 2025;23(7):e9503[2]). On 15 July 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 EFSA-GMO-BE-2019-165 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.2025.9503

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Scientific evaluation

1. Molecular characterisation

Soybean DBN9004 contains a single insert consisting of one copy of the *pat* and *cp4 epsps* cassettes. With regard to the molecular characterisation, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

2. Assessment of food/feed safety and nutritional value

2.1. Assessment of compositional analysis

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM soybean DBN9004, 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 CP4 EPSPS and PAT proteins in the context of previous applications, and no concerns with respect to toxicity were identified. Since no new information on toxicity of these proteins has become available, the Council is of the opinion that its previous conclusions remain valid.

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of GM soybean DBN9004, in comparison with its conventional counterpart, does not raise safety concerns.

The Biosafety Advisory Council is also of the opinion that the combined presence of the newly expressed proteins in soybean DBN9004 does not raise concerns regarding toxicity.

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed CP4 EPSPS and PAT 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 soybean DBN9004 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 soybean DBN9004-derived food and feed are not expected to differ from those of conventional soybean varieties.

3. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of soybean DBN9004 (i.e. during transport and/or processing) into the European environment[3] will lead to environmental harm.

[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.

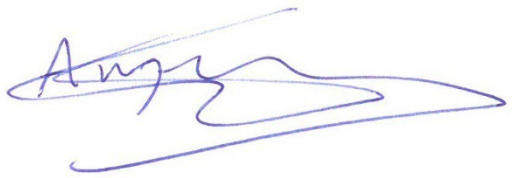
4. Monitoring

With regard to monitoring, the Biosafety Advisory Council is of the opinion that the information provided is sufficient.

Conclusion

Based on the whole set of data on soybean DBN9004 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 soybean DBN9004 is unlikely to pose any threat to the European environment;
2) Agrees with the GMO panel of EFSA that soybean DBN9004 is as safe as its conventional counterpart and the tested non-GM soybean varieties with respect to potential effects on human and animal health.



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

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

Annex: Outcome of the assessment of application EFSA/GMO/BE/2019/165 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: Lieve Gheysen (UGent)
Experts: Eddy Decuypere (KULeuven), André Huyghebaert (UGent), Peter Smet (Consultant), Frank Van Breusegem (VIB), Nicolas Van Larebeke (KULeuven)
SBB: Adinda De Schrijver

Application: **EFSA/GMO/BE/2019/165**
Applicant: **Beijing DaBeiNong Biotechnology Co., Ltd.**
GMO: **soybean DBN9004**
Validated by EFSA: **12 March 2021**

The scope of the application is:
(a) GM food
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
(b) GM feed
☒ Feed containing or consisting of GM plants
☒ Feed produced from GM plants
(c) GM plants for food or feed use
☒ Products other than food and feed containing of consisting of GM plants with the exception of cultivation
☐ Seeds and plant propagating 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

PART I - GENERAL INFORMATION

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

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: 1 expert

Comment 1:

On p22: phytoestrogens are mentioned as health promoting compounds based on facts that estrogens act against oxidation of DNA, increase the anti-oxidant enzymes and are inhibiting tyrosine-kinases, and phytoestrogens bind to human Estrogen Receptor (ER).
However, there is a long list of activities of estrogens and dysfunctional activities if overdosed (including the risk of carcinoma's) (see e.g. in the classical textbook of Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 7th edition, McMillan publ.co., 1839pp).
Moreover, binding activity to ER is not indicating its biological activity, as binding affinity and duration can be longer or shorter, and therefore the activity of phytoestrogens as found in soybean is expressed in 17-beta-estradiol equivalents. These are known to be sometimes 10.000 higher on molar basis, for soybean phytoestrogens (e.g. Hoffman & Evers (1986); Anabolic Agents with sex-hormone-like activities: problems of Residues, in: Drug Residues in Animals, 111-146).
Therefore, it is not fair to mention only the anti-oxidant activity and hence to conclude of a health promoting effect of soy products. This is one-sidedness, biased or partial information.
I am well aware that this discussion is beyond the scope of this dossier on soybean DBN9004, but I think it is therefore better to discard this part on health promoting effects on p 22.

GMO Panel response: The GMO Panel thanks Belgium and takes note of the comment. This application has been submitted under Regulation (EC) No 1829/2003 on genetically modified food and feed. The assessment of health claims is not in the remit of the GMO Panel.

Comment 2:

I think we cannot conclude that outcrossing with cultivated or wild soybean varieties is not an issue. Also, survival for longer periods cannot be excluded, especially in southern Europe, certainly not under the changing climatic conditions. I think the anti-nutritional components might pose problems in animal feed if no heat treatment is used in preparation of the feed. Humans should avoid using soybeans that are not cooked. Allergic reactions can certainly disappear with age, but they can also start or become more prominent with advancing age.

Note SBB & coordinator: We agree that outcrossing may occur. We would like to note that the wild soybean species are endemic in China, Korea, Japan, Taiwan and the Far East of the Russian Federation, but do not naturally exist in Europe (JRC, 2015)[4].

1.2. MOLECULAR CHARACTERISATION

1.2.1. Information relating to the genetic modification

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

Comment 1:

I wonder whether the aminoglycoside-3'-adenylyltransferase giving resistance against a series of antibiotics can get in the plant. Could the sequences used for cloning have any biological effect?

[4] https://ec.europa.eu/jrc/sites/jrcsh/files/ecob_best_practice_soybean.pdf

Note SBB & coordinator: The *aad* gene lies on the vector backbone region of the plasmid used for transformation. It may occur that DNA outside the T-DNA gets integrated. However, for this GM soybean event it has been shown that no vector backbone sequences have been inserted.

Comment 2:
- What is meant with "re-arranged sequence" on p9 (Summary) when describing the genetic elements present in the plasmid?
- There is a discrepancy in the description (length) of the sequences proximal to the Right border in Table 2 in Main text and the Summary. And as well between Table 2 and 3 in the Main text. Most likely, these are typos that should be corrected.

Note coordinator: In the main text, Table 2 lists the sequences in the plasmid and Table 3 lists the integrated sequences. The sequences at the ends of the T-DNA are therefore slightly different and the rearranged sequences were caused by the integration process. These are not typo's. The Table in the summary says "source of DNA" which should refer to the plasmid and therefore what is shown in Table 2. However, the information in this table corresponds to Table 3.

1.2.2. Information relating to the genetically modified plant

Comment 1:
The information that DBN9004 soybean has tolerance to glyphosate due to the CP4-EPSPS protein, and to glufosinate-ammonium herbicide due to the PAT protein, as well as their mechanisms of action, is very well explained in detail. As for the expression of PAT and CP4-EPSPS proteins in different parts of the plant, why is the expression of PAT relatively low in seeds compared to leaf tissue (ratio 1/80-100) while for CP4-EPSPS this ratio is 1/3-4? Is this linked to the different promotors of both genes?

Note SBB & coordinator: We do not consider these questions on difference in expression levels between PAT and EPSPS proteins relevant to come to a risk assessment conclusion.

Comment 2:
I wonder which statistically significant differences between the transgenic plants and controls are found, and how we can be certain that they are not in relation with the PAT enzyme. As to the CP4 EPSPS enzyme, it is difficult to be certain that the changed affinity or changes in its level of expression cannot have other metabolic consequences. Something that might give rise to unexpected problems are the 273 open reading frames present in the T DNA and the 12 open reading frames present at the insertion sites.

Note SBB & coordinator: The issue of differences between the transgenic plant and controls at the composition, agronomic and phenotypic level is addressed in section 1.3 of the Technical Dossier. The open reading frames are being discussed in section 1.2.2.3. of the Technical dossier.

Comment 3:
On p206 of Technical Dossier - Subcellular location of the construct: To avoid any confusion, I suggest to make the conclusion that based on the segregation analysis, the construct is present in the NUCLEAR genome.

Note SBB: Proposals for textual changes are not considered at this stage of the evaluation process.

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

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

Comment:
The statements "The corresponding amino acid sequences of putative ORFs located within the T-DNA insert and genome-to-insert junction sites were not found to match those of putative or known toxins and allergens and if expressed are unlikely to represent a potential safety concern." and "The deletion of a short fragment of soybean genomic DNA was not found to be of significance." are probably impossible to prove, but I agree that they are likely.

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: 3 experts

Comment:
As in other similar applications, a detailed compositional study of soybean DBN is presented. The general approach includes a comparison of soybean DBN with the parental non-transgenic line and also a set of traditional commercial varieties. It applies for DBN 9004, DBN 8002 and DBN 9004 x 8002.

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:
The document contains a list of components, that have been analyzed. It is a long list, according to the OECD recommendations. I have the following comments for the analyses of seeds particularly:

- Proximates: carbohydrates by difference is not acceptable from a human nutrition point: There is no differentiation in carbohydrates such sugars, starch, cellulose and others with the exception of the anti-nutrients raffinose and stachyose.
- Fibre: the methods applied are generally accepted for animal feed, but are not appropriate for human foods; results cannot be used, for instance, in food composition tables. For instance the application contains no data for dietary fibre.

  Note SBB & coordinator: The way fibre should be analysed is a recurrent comment. The Council decided not to send these comments to EFSA as this is an issue that would be better addressed within the context of the OECD.

- Minerals are limited to calcium and phosphorous.

  Note SBB & coordinator: This is in accordance with the OECD recommendations (ENV-JM-MONO(2012)24)

- Amino acids: no comments as the essential amino acids are included.
- Fatty acids: the relevant fatty acids have been analyzed.
- Vitamins: within the tocopherols only α-tocopherol is analyzed; other tocopherols and tocotrienols are not mentioned; they are important as antioxidants. The chromatographic method used, gives information about the presence of other tocopherols and even tocotrienols.
- Anti-nutrients: no remark

- Allergens: a series of allergens is mentioned; this is a positive sign as allergenicity, also for soybeans, is of growing importance in society. The methods used are well described.

1.3.4. Comparative analysis of composition

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

Comment 1:
Why only alpha-tocopherol measured and not gamma-tocopherol, since the latter is more common or widespread in soybean oil?

Note SBB & coordinator: The components analysed by the applicants, is based on the crop documents of the OECD. γ-tocopherol is not included in the list of components to be analysed for soybean according to the OECD (ENV-JM-MONO(2012)24) and are therefore most likely not considered by the applicant. A quick search on the internet reveals that also γ-tocopherol occurs in soybean, but less predominantly than α-tocopherol (https://aocs.onlinelibrary.wiley.com/doi/abs/10.1007/s11746-007-1040-x). We consider this is an issue that is better addressed within the OECD.

Comment 2:
Analysis results of the statistical evaluation, are summarized. The usual statistical method is followed. In most cases equivalence category I and II is found.

As an important conclusion of the statistical analysis it is stated that although statistical differences are found between soybean DBN and the non-transgenic counterpart, these differences fall within the range of commercial non-GMO varieties. As a general conclusion it is stated that the soybeans' DBN are unlikely to pose any adverse health effect risk to humans and animals.

I basically agree with this conclusion. I have some comments on the selection of constituents see 1.3.3. It is indeed very unlikely that the soybean DBN would cause an important health effect, due to one of the not studied constituents. My main concern is that the data obtained cannot be used for further studies as they are not in line with the actual scientific insights, for example composition of carbohydrates, dietary fibre, antioxidative stability and others.

Note SBB & coordinator: The components analysed by the applicants, is based on the crop documents of the OECD. Any comments on the way and type of components to be analysed would better be raised in the context of the revision of these crop documents.

1.3.5. Comparative analysis of agronomic and phenotypic characteristics

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

1.3.6. Effects of processing

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

Comment:
The applicant gives a short overview of the processing steps, applied to soybeans. He concludes that it is not expected that soybean DBN will be different from conventional soybeans. In my opninion this is a valid conclusion.

1.3.7. Conclusion

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

Comment 1:
I agree with the conclusion that the components of DBN9004 or products derived, are unlikely to pose any adverse health risk to animals or humans compared to those of conventional soybean.

Comment 2:
It is certain that there are no important observed changes between DBN9004 and Jack, but some differences were observed, and it is difficult to exclude any significant changes in a parameter that might be relevant for health, possibly of health significance.

Note SBB & coordinator: Significant changes that fall outside the range observed for the references varieties need to be assessed for their possible impact on health. However, in this case, no such changes at compositional level were found.

1.4. TOXICOLOGY

1.4.1. Testing of newly expressed proteins

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

Comment:
How are the differences in peptide fragments between microbial- and plant-derived proteins explained? When it is stated that "the amino acid sequence of the *E. coli*-derived PAT protein is equivalent to that of the DBN9004-derived PAT protein" does that mean that the sequences are identical? The same question arises with respect to the CP4 EPSPS Protein, and the statement "The sequence identity between the DBN9004- and *E. coli*-derived proteins for a major portion of the internal sequence indicate sequence equivalence between the two", does not respond to the question of the complete identity.

Note SBB & coordinator: As the genes for microbial-derived PAT & EPSPS have been adapted in their sequence to ensure expression in plants, the sequences are not identical. Hence the statements that the sequences are equivalent, but not identical.

1.4.2. Testing of new constituents other than proteins

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

Comment 1:
Not relevant since no other constituents than the PAT & CP4-EPSPS proteins are newly expressed or produced.

Comment 2:
A problem that is difficult to assess with certainty is that of the open reading frames that might, *in vivo*, give rise to proteins with unexpected properties.

Note SBB & coordinator: Section 1.4.2 deals with constituents other than proteins. Hence, this comment is not considered relevant for this Section.

1.4.3. Information on natural food and feed constituents

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

1.4.4. Testing of the whole genetically modified food or feed

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

Comment:
In view of the importance of cancer and atheroma's in the developed countries, an assessment of genotoxic effects seems as important as the evaluation of more acute short term health effects. A test for DNA damage or micronuclei would give valuable information.

Note SBB & coordinator: Studies that need to be provided to assess the food/feed safety are described in the Commission Implementing Regulation 503/2013. Testing of DNA damage and micronuclei do not belong to the preset requirements.

1.4.5. Conclusion of the toxicological assessment

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

Comment:
I agree that the available data indicate that DBN9004 is non-toxic, but I regret that no effort was made to exclude genotoxic effects.

See comment SBB & coordinator on point 1.4.4.

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

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: 1 expert

1.6. NUTRITIONAL ASSESSMENT

1.6.1. Nutritional assessment of the genetically modified food

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

1.6.2. Nutritional assessment of the genetically modified feed

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

Comment:
More information on differences in composition between DBN9004 and conventional soybeans would be interesting. The statement that the only difference is the presence of the two proteins is in fact not correct.

Note SBB & coordinator: Differences in composition between DBN9004 and conventional soybeans are addressed in Section 1.3.4. of the Technical Dossier.

1.6.3. Conclusion of the nutritional assessment

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

2. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE OR EXTENT OF USE

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

Comment:
Alpha-tocopherol is the main source in VitE supplementation in olive oil & sunflower oil, but gamma-tocopherol is more prevalent in soybean- and corn oil. Why then only alpha-tocopherol was measured in this study of DBN9004?? (see table 18, p194).

Note SBB & coordinator: see feedback above to address this within the OECD context.

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

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

5. ENVIRONMENTAL RISK ASSESSMENT (ERA)

5.1. INTRODUCTION

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

5.2. GENERAL APPROACH OF THE ERA

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

Comment:
As the genetic material of DBN9004 might be present in faeces of animals fed with feed containing DBN9004, it is not appropriate to consider only ports, processing facilities and transportation routes as receiving environments in the EU.

Note SBB & coordinator: both faeces of animals and ports, processing facilities and transportation routes are considered as pathways of exposure in the ERA (see p.214 Technical Dossier – General approach of the ERA).

5.3. SPECIFIC AREAS OF RISK

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

Comment 1:
I do not see the need of table 40 (p224) to support the statements given in this section.

Comment 2:
The potential movement of the *pat* gene to wild relatives in the transgenic plants might lead to these plants being more resistant to a herbicide and thus have an impact on treatment plans concerning use of herbicide.
I wonder how the " seven statistically significant differences were reported between the transgenic CP4 EPSPS plants and the non-transgenic controls." can be explained if the only difference between transgenic plants and controls consists of the introduced gene.
It seems to me that in the south of the EU DBN9004 seed could well succeed in overwintering.
It seems to me that, where it is unlikely that the hybridisation potential of DBN9004 soybean differs from that of Jack, DBN9004 soybean could well be capable of reproducing with soybean cultivated in the EU. So I think that figure 63 is not adequate.

Note SBB & coordinator: While soybean seeds usually do not survive during winter (OECD, 2000; Owen, 2005), it may occur that soybean some seeds will. However, germination of these seeds to mature plants is considered to be unlikely due to a combination of absence of a dormancy phase, susceptibility to pathogens and cold climatic conditions, and low competitiveness with other plants.

5.3.2. Plant to micro-organisms gene transfer

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

Comment:
I consider that horizontal gene transfer to bacteria is unavoidable, in view of the quantities of genetic material and bacteria involved. Hopefully and probably the impacts are not very dangerous. I find the text on the interaction of GMP with soil properties very instructive.

It seems to me however evident that HGT between DBN9004 soybean DNA and bacteria in soil and human intestines will occur very frequently, due to the millions of applications and persons involved. But I consider that the ensuing risks are probably not important, HGT occurs probably constantly.

5.3.3. Interactions of the GM plant with target organisms

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

Comment:
Not relevant

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

Comment:
Not relevant for this application

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

5.3.8. Overall risk evaluation and conclusions

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

6. POST-MARKET ENVIRONMENTAL MONITORING PLAN (PMEM)

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

Comment:
It is clear, in my view, that a genetically modified plant such as DBN9004 soybean has been subject to far more testing concerning toxicity or allergenicity than any natural food product. I only regret that insufficient attention is paid to genotoxicity because of the central role of genotoxicity in the causation of cancer and atheroma's which are of huge importance for the morbidity and mortality in the developed nations.

Note SBB & coordinator: See feedback given on 1.4.4.

REFERENCES

OECD (Organisation for Economic Co-operation and Development), 2000. Series on Harmonization of Regulatory Oversight in Biotechnology No. 15. Consensus document on the biology of *Glycine max* (L.) merr. (soybean). OECD Environmental Health and Safety Publications, Paris, France, 22 pp.

OECD (Organisation for Economic Co-operation and Development), 2012. Revised Consensus Document on Compositional Considerations for New Varieties of Soybean [Glycine max (L.) Merr.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens. ENV/JM/MONO(2012)24.

Owen, 2005. Maize and soybeans – controllable volunteerism without ferality? In: Gressel J (ed.). Crop Ferality and Volunteerism. OECD and Taylor & Francis, pp. 149–165

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

PART I - GENERAL INFORMATION

Comment:
This is in fact a commentary on the introduction. I think that the import of DBN9004 soybean into the European union is probably not in the interest of the member states. Indeed, the genetic modifications introduced into DBN9004 soybean only serve to facilitate weed management, whereas DBN9004 soybean will not be cultivated in the European union. So DBN9004 soybean is only intent to differ from other soybean types in that it harbors two proteins that do not add to the nutritional value of the soybean and hopefully (and probably) do not pose risks to European livestock or citizens.

3. RISK CHARACTERISATION

Comment:
In terms of human health, the problem associated with glyfosate resistant crops resides mainly in the increased use of glyphosate resulting in increased contamination of feed and food with glyphosate, resulting in an increased internal exposure of humans to glyphosate, a substance that has been classified by IARC as probably carcinogenic to humans, and also has endocrine disrupting, genotoxic and microbiome disrupting properties. In its advice 9561 the Belgian Superior Health Council has stated; "The advice of the Superior Health Counsel is as follows: Based on the available information, and being aware of possible bias, the SHC considers that there is enough evidence to ban glyphosate. Carcinogenicity might not be the most significant toxic effect: other effects may be more important.
The use of glyphosate should stop in 2022 according to the current permission period. Prolongation of the use of glyphosate will depend on a clear plan, set up and coordinated by the appropriate authorities and leading to the planned, progressive abandon of glyphosate.
Any ban on glyphosate should be implemented very carefully, taking into consideration not only the medical arguments, but ecological and economic elements also.
If the precautionary principle is applied, it should be done with great care."

5.3.7. Effects on human and animal health

Comment:
As already pointed out above, I agree that the available data indicate that DBN9004 is non-toxic, but I regret that no effort was made to exclude genotoxic effects. However, as also pointed out above, In terms of human health, the problem associated with glyphosate resistant crops resides mainly in the increased use of glyphosate resulting in increased contamination of feed and food with glyphosate, resulting in an increased internal exposure of humans to glyphosate, a substance that has been classified by IARC as probably carcinogenic to humans, and also has endocrine disrupting, genotoxic and microbiome disrupting properties. In its advice 9561 the Belgian Superior Health Council has stated: "The advice of the Superior Health Counsel is as follows: Based on the available information, and being aware of possible bias, the SHC considers that there is enough evidence to ban glyphosate. Carcinogenicity might not be the most significant toxic effect: other effects may be more important.
The use of glyphosate should stop in 2022 according to the current permission period. Prolongation of the use of glyphosate will depend on a clear plan, set up and coordinated by the appropriate authorities and leading to the planned, progressive abandon of glyphosate.
Any ban on glyphosate should be implemented very carefully, taking into consideration not only the medical arguments, but ecological and economic elements also.
If the precautionary principle is applied, it should be done with great care."

The fact that huge quantities of DBN9004 soybean will be handled by many persons in the European union certainly adds at least to a certain degree to the risk of a series of diseases of civilization. In terms of Physical-chemical hygiene, the use of glyphosate resistant plants is to be avoided.

5.3.8. Overall risk evaluation and conclusions

Comment:
The main problem resides in the problems associated with the resistance to herbicides and the ensuing more intensive use of herbicides.