Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2010-85 (genetically modified soybean MON 87769 x MON 89788) from Monsanto under Regulation (EC) No. 1829/2003

7 July 2021
Ref. SC/1510/BAC/2021_0684

Context

Application EFSA-GMO-NL-2010-85 was submitted by Monsanto for the marketing of genetically modified (GM) soybean MON 87769 x MON 89788 (Unique Identifier MON-87769-7 × MON-89788-1), for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

The two-event stack soybean MON 87769 x MON 89788 was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:
- MON 87769, expressing two desaturase genes, *Primulae juliae* Δ6 desaturase (Pj.D6D) and *Neurospora crassa* Δ15 desaturase (Nc.Fad3). These proteins desaturate certain endogenous fatty acids resulting in the production of stearidonic acid at approximately 20-30% of total fatty acids.
- MON 89788, expressing CP4 EPSPS protein, conferring glyphosate tolerance.

The application was validated by EFSA on 26 November 2010. A formal three-month consultation period of the Member States was started, lasting from 21 May 2014 until 21 August 2014, 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). Seven experts answered positively to this request, and formulated a number of comments to the dossier. See Annex I for an overview of all the comments and the comments forwarded to EFSA on 5 August 2014.

The opinion of the EFSA Scientific Panel on GMOs was published on 8 October 2015 (EFSA Journal 2015;13(10):4256[2]). This opinion was inconclusive as the Panel could not perform a full assessment on the possible impact of MON 87769 × MON 89788 soybean oil on health and nutrition, because of the lack of data on dietary exposure to refined bleached deodorised (RBD) oil from MON 87769 × MON 89788 soybean. EFSA was mandated in 2019 by the European Commission to assess additional information received from the applicant on the human nutritional assessment of RBD oil from genetically modified soybean MON 87769 × MON 89788, and published on 12 May 2021 a statement complementing its opinion from 2015 (EFSA Journal 2021;19(5):6589[3]). One expert in the field of nutrition was requested to assess the additional information and the Panel's overall conclusion.

[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://www.efsa.europa.eu/en/efsajournal/pub/4256
[3] See https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6589

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In delivering the present advice the BAC considered in particular the following information:
- The comments formulated by the experts on application EFSA-GMO-NL-2010-85;
- The opinion and complementing statement of EFSA;
- The advices already adopted by the BAC on the single events. The conclusions of the BAC for the most recent applications for the single events were as follows:

Event	Application number	BAC advice	Conclusions
MON 87769	EFSA-GMO-UK-2009-76	BAC/2014/0427 (24/06/2014)	Unlikely to pose any risk to human and animal health. Unlikely to pose any threat to the European environment.
MON 89788	EFSA-GMO-RX-011	BAC/2018/1090 (11/12/2018)	Unlikely to pose any risk to human and animal health and the environment.

All GM soybean events mentioned in the table above are authorised in the EU for food and feed uses[4].

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

Taking into account the previous assessment of the single events and the new data on compositional analysis provided by the applicant for the two-stacked event, the Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM soybean MON 87769 x MON 89788, 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 PjΔ6D, NcΔ15D and CP4 EPSPS proteins in the context of previous applications, and no safety concerns were identified. Taking into account the updated information considered in the current application, the Council is of the opinion that its previous conclusions remain valid.
The Biosafety Advisory Council is also of the opinion that the combined expression of the newly expressed proteins in the stacked event does not raise toxicological concerns.

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed PjΔ6D, NcΔ15D and CP4 EPSPS proteins in the context of previous applications, and no concerns 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 expression of the newly expressed proteins in the stacked event does not raise concerns regarding the allergenicity.

2.4. Nutritional value

The Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise any concern.

3. Environmental risk assessment

[4] See EU register of GM food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of soybean MON 87769 x MON 89788 (i.e. during transport and/or processing) into the European environment [5] will lead to environmental harm.

4. Monitoring

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

Conclusion

Based on the whole set of data on soybean MON 87769 x MON 89788 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the opinion and complementing statement of EFSA, the answers of the EFSA GMO panel to the questions raised by the Belgian experts, and the advices already adopted by the BAC on the two single events, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that the potential environmental release of soybean MON 87769 x MON 89788 is unlikely to pose any threat to the European environment;
2) Agrees with the GMO panel of EFSA that there is no reason to expect interactions between the newly expressed proteins that could impact on the food or feed safety;
3) Agrees with the GMO panel of EFSA that in the context of its proposed uses, soybean MON 87769 x MON 89788 is unlikely to pose any risk to human and animal health;

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

Annex I: Compilation of comments of experts in charge of evaluating the application EFSA-GMO-NL-2010-85 and comments submitted to EFSA on mandate of the Biosafety Council

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

Annex I: Compilation of comments of experts in charge of evaluating the application EFSA-GMO-NL-2010-85 and answers from the EFSA GMO Panel

Coordinator: René Custers
Experts: Eddy Decuypere (KUL), Jacques Dommes (ULg), Leo Fiems (ILVO), Johan Grooten (UGent), André Huyghebaert (UGent), Frank Van Breusegem (VIB), Hadewijch Vanhooren (KUL).
SBB: Fanny Coppens

Application: EFSA/GMO/NL/2010/85
Applicant: Monsanto
GMO: Soybean MON 87769 x MON 89788
Validation of dossier by EFSA: 26 November 2011

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 highlighted in grey, with the answers from the GMO Panel from EFSA provided underneath.

List of comments/questions received from the experts

PART I - GENERAL COMMENTS

Comment 1
Mon 87769 has been developed for the expression of 2 desaturases, hence production of stearonic acid. And Mon89788 has been developed for tolerance against the herbicide glyphosate by the expression of a glyphosate tolerant 5-enolpyruvyl shikimate-3-phosphate synthase. The Mon87769xMon89788 was obtained by traditional breeding of the 2 individual transgene plants. Clearly explained, no comments.

Comment 2
Soybean MON 89788 has already been approved for import, processing, and food and feed use in the
EU (Anonymous, 2008). Furthermore, the EFSA GMO Panel considered that soybean MON 87769 is
as safe as its conventional counterpart and is unlikely to have adverse effects on human and animal health and the environment (EFSA, 2014). Because soybean MON 87769 × MON 89788 is obtained
by traditional breeding of MON 87769 and MON 89788, and if GM traits are not likely to interact in a manner affecting safety (Pilacinski et al., 2011), the potential toxic effects of soybean MON 87769 x MON 89788 to humans and animals can be considered as negligible.
However, because some trans fatty acids are increased in MON 87769 × MON 89788 soybean, and because of the potential negative effect of some trans fatty acids on human health, more details are desirable with regard to the presence of these trans fatty in animal tissues destined for human consumption.

Comment 3
No comments/questions.

A. GENERAL INFORMATION

Comments/Questions of the expert

Comment 1
No comment, adequate information is provided.

Comment 2
No comments/questions.

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

Comments/Questions of the expert:

Comment 1
No questions.

Comment 2
No comment, adequate information is provided.

Comment 3
No comments/questions.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No comment, adequate information is provided.

Comment 3
No comments/questions.

D. INFORMATION RELATING TO THE GM PLANT

D.1 DESCRIPTION OF THE TRAIT(S) AND CHARACTERISTICS WHICH HAVE BEEN INTRODUCED OR MODIFIED

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No comment, adequate information is provided.

Comment 3
No comments/questions.

D.2. INFORMATION ON THE SEQUENCES ACTUALLY INSERTED OR DELETED

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
Data provided in applications for the single events as well as data presented in this application support the conclusion that the molecular characterization was done adequately and does not rise any safety concern.

Comment 3
No comments/questions.

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No comment, adequate information is provided.

Comment 3
No comments/questions.

D.4. Information on how the GM plant differs from the recipient plant in: reproduction, dissemination, survivability

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No comment, adequate information is provided.

Comment 3
No comments/questions.

D.5. Genetic stability of the insert and phenotypic stability of the GM plant

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No comment, adequate information is provided.

Comment 3
No comments/questions.

D.6. Any change to the ability of the GM plant to transfer genetic material to other organisms

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No comment, adequate information is provided.

Comment 3
No comments/questions.

D.7. Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed

D.7.1 Comparative assessment

Comments/Questions of the expert

Comment 1
p 63 of the technical dossier , the levels of genistein and daidzin in Mon87769xMon89788 were within ther 99% tolerance intervals establisherd from conventional soybean varieties and within the literature database range: however this is not for daidzin in the control group (see also literature range on p92): why are the values for the control mean at all locations so high for daidzin and genistein ? (p78)

Answer from the EFSA GMO Panel: The statistical analysis of the compositional and agronomic and phenotypic characteristics of was done based on the applicable EFSA guidances valid at the time of submission of this application (EFSA, 2007) and includes only the statistical comparison of soybean MON 87769 x MON 89788 with its comparator.

Comment 2
Except fatty acids, most other components in MON 87769 × MON 89788 soybean seed were compositionally equivalent to conventional soybean seed. However, trans-ALA (0.20% total fatty acid
on average) and trans-SDA (0.14% total fatty acid) were detected in MON 87769 × MON 89788 soybean, whereas trans-SDA was not present, and trans-ALA was not regularly detected in conventional soybean. Trans fatty acids from industrial processes and natural sources have different
effects on the risk of cardiovascular disease (Chardigny et al., 2008). In case of MON 87769 × MON 89788 soybean trans-SDA and trans-ALA may not be due to the genetic modification of soybean, but
they were a secondary effect, due to the process of soybean extraction and oil processing (Technical
dossier, P.125).
Significant differences occurred between MON 87769 × MON 89788 and conventional soybean for alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, total fat, vitamin E, daidzein and genistein, but differences were within commercial ranges.
The phytic acid in soybean MON 87769 x MON 89788 was increased compared to control soybean (P
= 0.048). Phytic acid is important, especially in monogastric nutrition, as it makes dietary phosphorus
less soluble, resulting in an increased phosphorus emission into the environment. However, this drawback can be remediated by adding extra phytase to the diets of monogastric animals.

Comment 3
MON 67769 and MON 89788 are already evaluated before. MON 67769 x MON 89788 is obtained by traditional breeding. Comments are focussed on potential effects due to the combination of both stacked events.
Mon 67769 x MON89788 is further referred to as MON Breed.

The OECD consensus document of 2001 is used as a guideline. In the meantime there is a revised consensus document of 2012. Taking into account the time schedule, this revised document could probably not be followed in this evaluation.

The approach followed was similar to previous applications.
The compositional analysis of soybeans included proximates, ADF, NDF, amino acids, fatty acids, trypysin inhibitors, phytic acid, lectin, isoflavones, vit E, raffinose and stachyose.
The relevant nutrients, anti-nutrients and toxicants are covered.
As mentioned before I have some remarks about the selection of the constituents and the analysis methods used. However hese remarks are not relevant for this particular application.

The analyses confirmed that MON Breed was compositionally equivalent to conventional soybean seed with the exception of the expected changes in fatty acids SDA (18:4 stearidonic acid) and GLA (gamma-linolenic acid).
Particular attention is given to potential isomerisation products.
It is very well known that SDA and ALA (alpha-linolenic acid) are sensitive to spontaneous isomerisation leading to the formation of trans isomers. Taking into account the actual discussion on trans fatty acids, particularly the effects on CVD and also the regulatory aspects, this is an important issue.
The levels of trans fatty acids is quite low: trans SDA (0,14 %) and trans-ALA (0,20 %) on total fatty acids and below the general accepted levels for trans fatty acids. In several member states of the EU legislation limits of < 2g TFA /100 g fat are applied. (TFA = trans fatty acids)

The applicant concludes that MON Breed is compositionally equivalent to conventional soybeans with exception of the intended fatty acids.

I agree with this conclusion.

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No particular comments.

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No further comments.

D.7.4 Agronomic traits

Comments/Questions of the expert

Comment 1
No comments.

D.7.5 Product specification

Comments/Questions of the expert

Comment 1
No comments.

D.7.6 Effect of processing

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
An overview of the processes applied to soybeans and the products obtained is given.
No particular effects have to be expected on the technology and the obtained products with the exception of the changes in the fatty acid composition.

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert

Comment 1
No comments.

D.7.8 Toxicology

Comments/Questions of the expert

Comment 1
No comments.

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
MON 87769 x MON 897888 is produced by traditional breeding of MON 87769 and MON 89788.
The safety of the newly expressed proteins PjΔ6D and NcΔ15D (from MON 87769) and CP4 EPSPS (from MON 89788) were already discussed in depth in the applications of MON 87769 and MON 89788. Both applications got a positive Opinion of the EFSA Scientific Panel.
For the application EFSA-GMO-NL-2010-85, updated bioinformatics were provided for the proteins PjΔ6D, NcΔ15D and CP4 EPSPS (2010, 2013).
Adverse effects by combined expression of the 3 proteins are not expected because of the different modes of action and sites of biological activity. No safety concerns were observed in a broiler chicken feeding study using soybean meal.
No further questions.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert

Comment 1

No questions.

Comment 2
No further questions.

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
As was expected from application EFSA-GMO-UK-2009-76 (MON 87769), MON 87769 x MON 89788 contains SDA, GLA, trans-ALA and trans-SDA, increased levels of ALA, and reduced levels of LA. The safety and nutritional impact was already discussed in application EFSA-GMO-UK-2009-76, which got a positive Scientific Opinion (EFSA Journal 2014; 12(5):3644). The expected changes in fatty acid composition of the forage and seed was confirmed in the compositional analysis of MON 87769 x MON 89788. No further questions.

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
A 42-day feeding study in broiler chickens using soybean meal was conducted.
Unfortunately no confirming 90-day rat feeding study was conducted using soybean oil and checking much more parameters.

Comment SBB and coordinator: The data from the single events and the updated bioinformatics studies for the stacked event do not indicate the need to perform a 90-day rat feeding study.

D.7.9 Allergenicity

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
Based on the weight of evidence in this dossier:
- PjΔ6D, NcΔ15D and the CP4 EPSPS proteins were obtained from non-allergenic sources
- PjΔ6D, NcΔ15D and the CP4 EPSPS proteins lack structural similarity to known allergens, as demonstrated by bioinformatics analyses
- PjΔ6D, NcΔ15D and the CP4 EPSPS proteins are rapidly digested in simulated digestive fluid
- PjΔ6D, NcΔ15D and the CP4 EPSPS proteins constitute a very small portion of the total protein present in the seed of MON 87769 × MON 89788

- updated bioinformatics using FASTA
we can assume that MON 87769 × MON 89788 soybean does not pose a serious allergenic risk, and
that it is comparable with conventional soybean with regard to allergenicity.

Comment 3
All three proteins, PjΔ6D, NcΔ15D, and CP4 EPSPS, that are heterologous expressed in MON 87769 × MON 89788 GM plant have been the subject of previous separate evaluations. In these previous dossiers a weight-of-evidence analysis was performed with regard to allergenic potential of the respective proteins, leading to the authorization in 2008 of MON 89788 for import, processing, and food and feed use in the EU. Specifically regarding the new expression of CP4 EPSPS, the allergenic risk was previously also evaluated by undersigned as "The analysis of multiple parameters associated with or indicative of allergenic potential does not indicate (individually or combined) an increased risk for allergenicity". In addition, an updated bioinformatics analysis by the applicant using 2013 databases did not reveal structural similarity of the PjΔ6D and NcΔ15D proteins to known allergens. Based on this historical and further updated weight-of-evidence analyses, the applicant correctly concludes that the PjΔ6D, NcΔ15D and CP4 EPSPS proteins are unlikely to have any allergenic potential, and MON 87769 × MON 89788 expressing these proteins is to be considered as as safe as conventional soybean with regards to allergenicity risk.

In terms of allergenicity of the whole GM plant, the applicant did not present additional supportive data besides referring to the data already presented in the separate dossiers of the parental GM plants. The argument hereto is based on the fact that MON 87769 × MON 89788 is produced by traditional breeding of MON 87769 and MON 89788. However, being an allergenic plant, the introduction of a combination of new traits may affect overall allergenicity of the plant. I therefore recommend to perform a 2-dimensional IgE immunoblot analysis with sera of allergic individuals in order to ascertain the absence of an increased allergenicity of the whole plant.

No consequences with regard to adjuvancy are to be expected from the introduced traits.

Coordinator comment: If both events were proven not to be more allergenic than conventional soybean, then I see no reason why a conventional cross between them would trigger additional analyses. This is also never done for any approved single events which can be conventionally bred with conventional varieties without any further assessment.

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert

Comment 1
The safety of the desaturases (p121) is well established on the 5 points listed on p121: no questions

Comment 2
The increased phytic acid concentration in MON 87769 x MON 89788 soybeans, compared to conventional soybeans, may have consequences for animal nutrition: phosphorus digestibility and utilisation may be decreased in monogastric animals.
A performance study referred to in the Technical Dossier, and conducted in rapidly growing broiler chickens fed MON 87769 × MON 89788 derived soybean meal showed no toxic effect of the stacked
events. Similarly, no negative effect of SDA-enhanced soybean oil from genetically modified soybeans
on performance and health of dairy cows (Bernal-Santos et al., 2010) and broilers (Rymer et al., 2011)
have been reported.
Feeding SDA-enriched soybean oil to broilers had some negative effects on the sensory quality of the meat (Rymer et al., 2011). It is not clear from the Technical Dossier if there was any effect of

MON 87769 x MON 89788 soybean on the sensory quality of broilers meat from the performance study.
Because of the presence of trans-SDA and trans-ALA in MON 87769 x MON 89788 soybeans, these trans fatty acids may also be present in animal tissues that will be used for human consumption. It is not clear if these trans fatty acids are concentrated in animal tissues or metabolised by the animals, because no mention was made of trans fatty acid in the broiler meat originating from the performance study referred to in the Technical Dossier (Table 28). More details are desirable with regard to this aspect.

Answer from the EFSA GMO Panel: In the context of this application, the applicant provided a dietary exposure and nutritional assessment based on data derived from the single event MON 87769 but not on soybean MON 87769 x MON 89788. Therefore, the applicant was asked to provide a dietary exposure assessment based on the compositional analysis of the RBD oil from soybean MON 87769 x MON 89788 taking into account different exposure scenarios, covering low and high consumer groups. However, the applicant did not provide such data. The EFSA GMO Panel therefore cannot complete the assessment on possible impact of the MON 87769 x MON 89788 soybean oil on human health and nutrition.

Note SBB: In June 2021 the expert who formulated the above comment reviewed the additional nutritional data and the EFSA GMO Panel overall conclusion following the publication of its complementing statement, and agreed with EFSA's conclusion.

D.7.11 Post-market monitoring of GM food/feed

Comments/Questions of the expert

Comment 1
No questions.

D.8. Mechanism of interaction between the GM plant and target organisms (if applicable)

Comments/Questions of the expert

Comment 1
No comments.

D.9. Potential changes in the interactions between the GM plant with the biotic environment resulting from the genetic modification

D.9.1. Persistence and invasiveness

Comments/Questions of the expert

Comment 1
No comments.

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert

Comment 1
No comments.

D.9.3 Potential for gene transfer

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
No comment, adequate information is provided.

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert

Comment 1
No comments.

D.9.5 Interactions of the GM plant with non-target organism

Comments/Questions of the expert

Comment 1
No comments.

D.9.6 Effects on human health

Comments/Questions of the expert

Comment 1
No potential adverse effect as for its changed composition as well as for the new proteins expressed.

Comment 2
EFSA (2008 and 2014) reported that MON 89788 soybean is as safe as conventional soybean with respect to potential effects on human or animal health.
Assessment of toxicity and allergenicity, the compositional equivalence and the performance study with broilers suggest that MON 87769 × MON 89788 soybean has no impact on human and animal health. Omega-3 fatty acids have been reported to have a variety of cardiovascular and neuropsychiatric benefits. Stearidonic acid is a metabolic precursor of eicosapentaenoic acid that can
be provided by SDA-enhanced soybean oil (Harris, 2012), which is an advantage of MON 87769 × MON 89788 soybean.
No negative effect of SDA-enhanced soybean oil has been reported for dairy cows and broilers (Bernal-Santos et al., 2010; Rymer et al., 2011). No significant effects of treatment with SDA enriched
soybean oil on total adverse events or within adverse event organ class were observed in 210 nonsmoking
men or women, aged between 21-70 years, with a body mass index between 25 and 35, and generally in good health (Lemke et al., 2010).
However, increased concentrations of trans-ALA and trans-SDA were found as a secondary effect of
the SDA-enrichment. Some trans fatty acids have potential negative effects on human health. EFSA

(2010) stated that trans fatty acid intake should be as low as possible. Based on a soybean consumption of approximately 39.2 g/person/day (Technical Dossier, Table 25) with 17.95% fat (Technical Dossier, Table 11) and a mean concentration of 0.34% trans fatty acids in Total fatty acids
(Technical Dossier, P.61), a trans fatty acid intake from MON 87769 × MON 89788 soybean can be estimated at 0.022g/d. This is considerably lower than the trans fatty acids intake of 11-12 g/d mentioned by Chardigny et al. (2008)

D.9.7 Effects on animal health

Comments/Questions of the expert

Comment 1
No potential adverse effect as for its changed composition as well as for the new proteins expressed.

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert

Comment 1
No comments.

D.9.9 Impacts of the specific cultivation, management and harvesting techniques

Comments/Questions of the expert

Comment 1
No comments.

D.10. Potential interactions with the abiotic environment

Comments/Questions of the expert

Comment 1
No comments.

D.11. Environmental monitoring plan

D.11.1 General

Comments/Questions of the expert

Comment 1
No comments.

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert

Comment 1
No comments.

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert

Comment 1
No comments.

D.11.4 General surveillance of the impact of the GM plant

Comments/Questions of the expert

Comment 1
No comments.

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert

Comment 1
No comments.

References

Anonymous, 2008. Commission decision of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Off. J. Eur. Communities Legis. 333: 7-10.

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Bernal-Santos, G., O'Donnell, A.M., Vicini, J L., Hartnell, G.F., Bauman, D.E. 2010. Enhancing omega-3 fatty acids in milk fat of dairy cows by using stearidonic acid-enriched soybean oil from genetically modified soybeans. J. Dairy Sci. 93, 32-37.

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