Bioveiligheidsraad
Conseil de Biosécurité

26-09-2008

Secretariaat
Secrétariat

O./ref.: WIV-ISP/BAC/2008_813

Title: Advice of the Belgian Biosafety Advisory Council on the application **EFSA/GMO/NL/2006/36** from Monsanto under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/NL/2006/36 was submitted by Monsanto on 7 November 2006 for the marketing (import and processing) of the glyphosate-tolerant genetically modified soybean MON 89788 for food and feed applications under Regulation (EC) No. 1829/2003[1]. It was officially acknowledged by EFSA on 8 June 2007.

On the same date EFSA started the formal three-month consultation period of the Member States, 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 (GMOs) being part of the products).

Within the framework of this consultation, the Belgian Biosafety Advisory Council, 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 Biosafety Advisory Council and the Division of Biosafety and Biotechnology (SBB). Seven experts answered positively to this request, and formulated a number of comments to the dossier which were edited by the coordinator. See Annex I for an overview of all the comments and for the list of comments actually placed on the EFSAnet on 5 September 2007.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 2 July 2008 (The EFSA Journal, 2008, 758, 1-23)[2], and published together with the responses from the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period.

On 4 August 2008 the opinion of EFSA was forwarded to the Belgian experts. They were invited to give comments and to react if needed to the answers given by the EFSA GMO Panel, in particular in case the comments formulated in their initial assessment of the dossier were not taken into account in the opinion of EFSA.

The comments formulated by the experts together with the opinion of EFSA including the answers of the EFSA GMO Panel form the basis of the advice of the Biosafety Advisory Council given below.

---

[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: <http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1178620787358.htm>

Wetenschappelijk Instituut Volksgezondheid | Institut Scientifique de Santé Publique
Afdeling Bioveiligheid en Biotechnologie | Section Biosécurité et Biotechnologie
Rue Juliette Wytsmanstraat 14 | B-1050 Brussels | Belgium
T + 32 2 642 52 11 | F + 32 2 642 52 92 | bac@sbb.ihe.be | www.bio-council.be

Scientific evaluation

1) According to the Biosafety Advisory Council, no major risks were identified concerning the environment[3].

2) With regard to the molecular characterisation, the Belgian experts noticed missing data about the sequence of the corresponding non-transgenic control and about the design of the primers to perform the PCR analysis. Additional information has been requested by EFSA to the applicant and according to the GMO Panel and the Biosafety Advisory Council the received information is satisfactory.

3) With regard to the compositional analysis it was not clear if the field trials were treated with glyphosate herbicides. On request from the GMO Panel of EFSA the applicant supplied additional data in which some plots of soybean MON89788 were treated with glyphosate herbicides and other plots were untreated with these herbicides. In this additional information the data concerning the comparative assessment in amino acids composition was judged satisfactory by the GMO Panel. There were significant differences in composition between soybean MON89788 sprayed with glyphosate and unsprayed MON89788 for tryptophane and heptadecanoic acid. The significant difference in stachyose was not consistent over the years.
Feeding trials with rats showed no significant differences except for triglyceride composition of the rat tissue. But the dossier is not clear whether the transgene soybean in these trials had been treated with the herbicide. The Biosafety Advisory Council recommends to verify if the feeding trials really have been conducted with GM soybean treated with glyphosate and non-GM soybean treated with conventional herbicides. If yes the Biosafety Advisory Council considers that the feeding trials gave satisfactory results.
Following the comments submitted by the Belgian experts, the Biosafety Advisory Council considers that even if the compositional analysis of the GM food/feed was performed according to the OECD consensus document[4], it lacks the analysis on dietary fibre while this concept is widely accepted in human food studies.

4) With regard to the allergenicity of the whole GM soybean the Belgian experts requested additional data. On request of the GMO Panel further information has been obtained from the applicant on cross-reactivity of sera from soybean allergic patients to extracts of soybean MON89788, its control variety and different soybean varieties. Based on these new data the Panel and the Biosafety Advisory Council conclude that the overall allergenicity of the whole GM soybean MON89788 is unlikely to be different from that of conventional soybeans.

[3] As the application doesn't imply a cultivation of the plant in EU, a full environmental assessment is not required in EFSA procedure and was not achieved.

[4] OECD, 2001. Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-Nutrients. ENV/JM/MONO(2001)15. http://www.olis.oecd.org/olis/2001doc.nsf/c5ce8ffa41835d64c125685d005300b0/

Conclusion

Based on the scientific assessment of the dossier done by the Belgian experts,
taking into account the opinion of EFSA, the answers of the EFSA GMO Panel to the questions raised by the Belgian experts, the answers of the notifier to the EFSA GMO Panel questions and considering the data presently available, the Belgian Biosafety Advisory Council concludes the following:
Provided that the feeding trials have been conducted with GM soybean treated with glyphosate and non-GM soybean treated with conventional herbicides, the Belgian Biosafety Advisory Council agrees with EFSA that it is unlikely that soybean MON89788 will have any adverse effect on human and animal health or on the environment in the context of its proposed uses.

In addition, the Biosafety Advisory Council is of the view that EFSA should advice future applicants to complete the compositional analysis of the food with data on dietary fibre.

Prof. D. Reheul
President of the Belgian Biosafety Advisory Council

Annex : Full comments of experts in charge of evaluating application EFSA/GMO/NL/2006/36 and comments submitted on the EFSAnet (ref: BAC_2007_PT_572)

Bioveiligheidsraad
Conseil de Biosécurité

05/09/2007

Secretariaat
Secrétariat

N./réf. : WIV-ISP/BAC/2007/PT_572
Email. : bac@sbb.ihe.be

Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2006/36
and
Comments submitted on the EFSAnet on mandate of the Biosafety Council

Mandate for the Group of Experts: mandate of the Biosafety Advisory Council (BAC) of 11 June 2007
Coordinator: Prof. Thierry Hance
Experts: Pascal Cadot (Consultant), Armand Christophe (UGent), Eddy Decuypere (KUL), Jacques Dommes (ULg), Godelieve Gheysens (UGent), André Huyghebaert (UGent), Jean-Pierre Maelfait (UGent)
Domains of expertise of experts involved: Genetics, genome analysis, epigenetics, genetic engineering, improvement of plants, transgene integration pattern, transgene expression, GMO traceability, human nutrition, animal nutrition, biochemistry of food/feed, analysis of food/feed, risk analysis, industrial processing, traceability of alimentary chain, toxicology, immunology, alimentary allergology, ecology, plant-insect relations, nature conservation, biosafety research
Secretariat: Didier Breyer, Adinda De Schrijver, Martine Goossens

INTRODUCTION

Dossier **EFSA/GMO/NL/2006/36** concerns an application of the company **Monsanto** for the marketing of the genetically modified **soybean MON89788** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 08 June 2007.
The scope of the application is:

☒ 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)

Depending on their expertise, the experts were asked to evaluate the genetically modified plant considered in the application on its 1) molecular, 2) environmental, 3) allergenicity, 4) toxicity and/or 5) food and feed aspects. It was expected that the expert should evaluate if 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.

The comments are structured as in the "Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA Journal (2004), 99, 1-94). Items are left blank when no comments have been received either because the expert(s) focused on other related aspects, or because for this dossier the panel of experts who accepted to evaluate the dossier didn't have the needed expertise to review this part of the dossier. Comments placed on the EFSAnet are indicated in grey.

List of comments received from the experts

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

Comment 2
MON89788 soybean is tolerant to glyphosate, the active component in Roundup. The phosphonomethyl-glycine blocks the activity of 5-enolpyruvylshikimate-3-phosphate synthase or EPSPS, which is a key enzyme in the shikimic pathway. MON89788 soybean produces the same CP4-EPSPS as Roundup Ready Soybean (40-3-2) but is only different by the way the CP4 EPSPS-gene cassette was introduced in the soybean genome. Since it was introduced into elite soybean germplasm (variety A3244), a higher yield advantage for MON89788 was realized.

Comment 3
A new methodology is used to introduce the same gene in MON89788 as in Roundup Ready soybean 40-3-2. Yet MON89788 is reported to have a yield advantage (Technical report, Part II, Summary, page 5). Is there an explanation why this is so or does this point to an unanticipated property of the new GMO?

Additional comment from coordinator
Point 6 in general info: It is not true that no change in production are anticipated for Mon 89788 as this genetic modification is designed to use Glyphosate herbicide in post emergence. Presence of Glyphosate residues in the seeds may thus be expected due to change in the production process. It is now known that glyphosate and its metabolites (AMPA) may present a toxicity on human beings (Richard *et al.,* 2005).

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

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

D. INFORMATION RELATING TO THE GM PLANT

D.1 DESCRIPTION OF THE TRAITS AND CHARACTERISTICS WHICH HAVE BEEN INTRODUCED OR MODIFIED

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

Comment 2
CP4-EPSPS is structurally similar and functionally identical to endogenous plant EPSPS, but has a much reduced affinity for glyphosate relative to endogenous plant EPSPS. What about other bacterial EPSPS? Are these also not tolerant for glyphosate? Is this also the case for rhizobia that form a symbiosis with soybean for N-fixation? Are they also killed by glyphosate or not? However, because the application is for consent to import and use MON89788 grain and not for seeds and plants propagation, risk on environmental release is minimal, and concern for side effects of glyphosate are not relevant or applicable here.

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

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

Comment 2
a) The southern blot analysis is very complete and the results are of high quality. It is therefore not expected to see that, although in figures 6, 7 and 8 the results clearly fit with one copy inserted, the figures 9 and 10 show a stronger band than the 1-copy control (and even stronger than the 2-copy). Nevertheless, there is no clear evidence from the blots that there could be more than one copy of T-DNA inserted.

b) The applicants claim that a deletion has not happened during T-DNA insertion, but there are no data to support this. They do provide the sequence of the T-DNA insertion and its flanking soybean DNA but I could not find the sequence of the corresponding non-transgenic control in the dossier (and we do not have permission to search the public database for this). Usually (but indeed not always) T-DNA insertion causes a deletion of target DNA (Forsbach et al., 2003; Gheysen et al., 1991; Kumar & Fladung, 2002; Latham et al., 2006; Mayerhofer et al., 1991).

c) PCR-analysis has been performed to check the organization of the T-DNA insert, also using primers flanking the T-DNA insert. It is however not clear how the sequence flanking the T-DNA has been obtained to design these primers.

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

D.4. INFORMATION ON HOW THE GM PLANT DIFFERS FROM THE RECIPIENT PLANT IN: REPRODUCTION, DISSEMINATION, SURVIVABILITY

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

D5. GENETIC STABILITY OF THE INSERT AND PHENOTYPIC STABILITY OF THE GM PLANT

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

D.6. ANY CHANGE TO THE ABILITY OF THE GM PLANT TO TRANSFER GENETIC MATERIAL TO OTHER ORGANISMS

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

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(s)

Comment 1
- No difference found.
- Since glyphosate blocks the activity of the EPSPS which is a key enzyme in the shikimic pathway leading to the formation of aromatic amino acids, I wonder why the seed tyrosine, phenylalanine and tryptophane of MON89788 is not given instead of seed methionine ?
- Are these levels of analytes in MON89788 with or without glyphosate treatment in culture? (this is not described under 7.6 in technical dossier).

- They are compared with A3244 and traditional varieties, which are all cultivated without glyphosate of course. Therefore I wonder whether the comparison with MON89788 is also without glyphosate, and if glyphosate resistance of MON89788 is 100 %?

Comment 2

1. The value reported for seed palmitic acid (%dw) in Table 14 of the Technical Dossier is impossible for soy and does not correspond to values reported in study MLS#20375, amended report for MLS 20162 and should be corrected. Are there no statistical differences observed for linolenic acid for some sites between MON 89788 and A3244 in the Argentine study?

2. The major product of soybean seeds for human use is its oil. From the methodology described in study MSL #20300, page 101, it is clear that the fatty acids are determined on the total fat extract (which is OK) giving the fatty acid composition of the oil which is of nutritional importance. Neither these results nor their statistical evaluation are given however. Rather calculated values taking into account the fatty acid composition AND the fat content are presented (fatty acid values are expressed as percent in the seeds) and statistically evaluated (Table 2). Note that the limit of quantification is reduced by this procedure (that of fat determination is claimed to be 0.1%; that of fatty acid determination 0.003%). As a result, statistical significant differences might occur in minor fatty acids. Although they would not be of nutritional importance, they may point to unanticipated and unintended plant metabolism.
   Q: Are there statistically significant differences in soybean oil fatty acids between MON89788 and the reference oils?

Comment 3

Compositional equivalence was determined by a comparison of MON89788 and traditional soybean varieties, among others a variety with background genetics similar to MON89788, obtained in field trials in 2004 and 2005 in the USA and Argentina.

No further comments.

Additional comments from coordinator

The reason of developing Roundup Ready soybeans is the post-emergence application of the herbicide Roundup (glyphosate) during cultivation. However, no indication is given that seeds used for the tests presented here were well sprayed with glyphosate during cultivation as currently recommended to farmers. No data are given on glyphosate residues (including AMPA) in the seeds after such treatment and on its effects on metabolic pathways in that GM plant. Glyphosate application on plant could modify some of the results presented in the Monsanto study. Consumers will be exposed to seeds harvested from plant that had underwent all the current farming practices, including Glyphosate application. In consequence, I think it is really essential to know if these tests were done with such material (see also comment 1 above)

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

Comment 1

The USA study includes seed and forage of MON89788 and the control A3244, of five sites across the USA during the 2005 season. . (note from coordinator: no indication were given if those sites were treated with glyphosate during cultivation)
A total of 63 analytes were assessed. The compositional data for forage include proximates. The seed analysis covers, in addition to proximates, fibre, amino acids, fatty acids, specific constituents (anti-nutrients), and carbohydrates by difference.
No statistical difference was found in 91% of the within-site comparisons. However any difference found were not confirmed in the across-site comparisons.
In the across-site comparisons four differences were detected among others vit E, daidzein and glycitein. These differences are however small and within the range for traditional soybeans.
I agree with the conclusion that the composition of MON89788 is equivalent to traditional soybeans as far as the studied constituents is concerned.
I have however some comments on the selection of compounds studied: see D.7.3.
In the Argentina study, a similar approach was followed with 60 analytes studied. A similar conclusion is proposed as in the USA study.
As mentioned before I have however some comments on the selection of compounds studied: see D.7.3.

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Comment 1

I have the following questions and/or remarks:

1. No information is available on minerals, relevant in animal or human nutrition. Some essential data on mineral composition are necessary to confirm compositional equivalence.
2. Information on vitamins is limited to vitamin E. Data on other relevant vitamins are needed to conclude that the studied soybean is equivalent to traditional ones.
3. Carbohydrates are assessed by difference. Some further information on carbohydrate composition, in addition to raffinose and stachyose, is needed particularly for soybeans used as a human food.
4. Information on fibre is limited to acid detergent fibre and neutral detergent fibre. This is one of the approaches for animal feed. It is however not appropriate for human nutrition where concepts as dietary fibre, soluble fibre and insoluble fibre are widely used. A more in depth study of fibre composition is even relevant as different fibre constituents may have different functionality in human nutrition.

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

D.7.5 Product specification

Comments/Questions of the expert(s)

D.7.6 Effect of processing

Comments/Questions of the expert(s)

Comment 1
The conclusion by the applicant is based upon an overview of the most relevant processing techniques. It is concluded that it is highly likely that MON89788 and its derived food and feed product are not different from food and feed originating from traditional soybeans.
No further comments on these particular aspect of the dossier.

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

Comment 1
The applicant states that anticipated dietary intake of soybean and soybean derived foods and feed is not expected to be altered upon authorization of MON 89788 for import and use in the EU.
The primary use of soybean is as a heat processed defatted meal for protein supplementation in animal feeds.
Soybean oil, refined or modified, is the main food ingredient derived from soybean. Other soybean derived product are increasingly used in the food industry.
I refer to my comments on the composition of soybean, particularly vitamins and minerals, under D.7.3.
According to OECD soybean is the higher natural source of dietary fibre in food: soy hulls are processed into fibre pan breads, cereals and snacks. The applicant refers to this publication.
Any further information on the dietary fibre composition is lacking, as mentioned above.

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1
No indications for additional toxicity in MON89788 soybean; same level of anti-nutritional factors as in traditional non-GM soybean.

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

Safety assessment of the newly expressed protein was based on:

- safety of the donor organism
- similarity of CP4 EPSPS to other EPSPS's naturally present in food with a long history of safe use
- protein specificity
- no homology with known protein toxins or allergens
- very quickly digestion in vitro and therefore very little chance that intestines would be exposed to food allergen
- no acute toxicity by mice acute gavage studies

Therefore, CP4 EPSPS is safe and poses no concerns for humans or animals; hence soybean MON89788 poses no additional concern compared with non-GM soybean.

Comment 2

Soybean protein isolate is the base of soy-based infant formula. The protein isolate of soy MON89788 is expected to contain the introduced CP4 EPSPS protein.
Q: Is there a history of safe use of MON89788 protein isolate **as a base of baby food?**

Additional comment from coordinator

Acute toxicity tests on rats were carried out using the *E. coli* purified CP4 EPSPS, because that, according to the applicant, extracting sufficient amounts of that protein from soybean is difficult. The test presented assumed the protein expressed in Mon 89788 is similar to *E coli* CP4 EPSPS from which the genetically engineered gene was extracted. This can only be verified when the soybean produced protein is isolated and the amino acid sequence is determined. This was not done here. GM transformation can sometimes result in some changes of amino acid and/or post-translational modification after expression. It was presumed Monsanto had determined the amino acid sequence of the GE soybean but it had sequenced only 15 amino acids from the CP4 EPSPS expressed in *E. coli*. In the same way, antigenic similarity does not mean that amino acid sequences are exactly the same.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

Comment 1

In terms of anti-nutritional factors, the dossier contains information on the most relevant constituents. It is concluded that the level of anti-nutrients in MON89788 is comparable to traditional soybeans.
I have no further remarks in this respect.

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert(s)

Comment 1
The safety of MON89788 is further demonstrated by a 90 day feeding study in rats and a 42 day feeding study in broilers.
I have no particular comments on these aspects.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1
See remarks as for 7.8.1.

Comment 2
Allergenicity of the newly introduced protein.
The applicant has evaluated the likelihood of the CP4 EPSPS protein to be an allergen.
1) The source it originates from is not known as allergenic.
2) The fact that the protein is expressed at low level does not fully warrant absence of allergenicity, as minute amounts might be sufficient for allergic reactions. However, the lower the amount, the lower the probability for an allergic reaction to occur.
3) Resistance to digestion is not strictly indicative of non-allergenicity. As an example, Mal d 1, the major allergen of apple, is known to be very labile.
Those three points together tend to show that the introduced protein is not likely to be an allergen, as mentioned by the applicant. However, point 4 needs some clarification.
4) The bioinformatics analysis revealed some similarity of the sequence of CP4 EPSPS sequence with that of Der f 2, a known dust mite allergen (*Dermatophagoides farinae*). Although the alignment is qualified as of low quality by the applicant, this remains a concern. The fact that the similar stretches of amino-acids are not fully aligned, and gaps are needed for best alignment, does not decrease the value of the match. Indeed, the folding of the protein in its 3-D structure might bring together all common amino-acids to form cross-reactive epitopes between CP4 EPSPS and allergenic Der f 2. For that reason, the reviewer recommends that skin tests with purified Der f 2 and purified CP4 EPSPS be carried out on a limited number of Der f 2-sensitized individuals.

Allergenicity of the whole modified crop.
The applicant has rightly analyzed the possibility of altered endogenous allergenicity of the modified crop, compared to the traditional counterpart.
Some comments, however:
1) The applicant should briefly describe the extraction method that has been used to prepare the protein extracts.
2) Was the negative outcome with serum 16 to probe traditional soybean reproducible? In that case, one should admit that the introduction of the trait has modified the overall allergenicity of the crop, and that this modification might be important for some patients (1/16).

The reviewer recommends that additional studies be carried out: For example, it should be determined whether a newly expressed allergen appears in MON89788, as compared with A3244, which could explain the reactivity of serum 16. For that, SDS-PAGE IgE-immunoblot patterns of MON89788 and A3244 should be determined with the same 16 sera.

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

Comment 1

In view of the weight data (birds, fat pad, breast weight …) on table 19 of the technical dossier I assume only male broilers were used for those data (?). Or is it all broiler pens together for both sexes? Since 8 male and 8 female pens per block (5 in total) were used (or 5 pens per sex per soybean meal (8)), male and female data could be given separately, since statistically and 2-factor analysis of variance under a randomized complete block structure was done with gender & diet as factors.
This could be relevant as for certain measurements (not further specified in technical dossier) a significant treatment x sex interaction was noted, and males & females were compared separately (cfr p108, but not seen in table 19).

Comment 2

Nutritional assessment of MON89788, as a food, is based upon compositional equivalence to traditional soybean. As anticipated intake of soybean derived food is not expected to be altered due to the introduction of MON89788, no nutritional imbalance is expected.
I refer to my comments on minerals, vitamins and dietary fibre. (see D.7.3)
Nutritional assessment as a feed is based upon the 42 days broiler study.
No further comment.

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

Comments/Questions of the expert(s)

None

D.8. MECHANISM OF INTERACTION BETWEEN THE GM PLANT AND TARGET ORGANISMS (IF APPLICABLE)

Comments/Questions of the expert(s)

Comment 1

Indeed, not applicable.

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(s)

Comment 1
Provided information: sufficient.

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1
Provided information: sufficient.

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1
No comments, information adequate.

Comment 2
Provided information: sufficient.

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert(s)

Comment 1
Indeed, not applicable.

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

Comments/Questions of the expert(s)

Comment 1
Provided information: sufficient.

D.9.6 Effects on human health

Comments/Questions of the expert(s)

Comment 1
See comments under D 7.8.1.
Effects on human health of MON89788 soybean are unlikely and also for its specific CP4-EPSPS no effects on human health are expected.

Comment 2
See above.

Additional comment from coordinator
No data are available on a possible synergic negative effect of the association between CP4 EPSPS and Glyphosate residues or its metabolites.

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

Comment 1
No effects on animal health of MON89788.

Comment 2
See above.

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1
Provided information: sufficient.

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

Comments/Questions of the expert(s)

Comment 1
Indeed, not applicable.

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1
No potential impact of MON89788 on biotic or abiotic environment is expected to result from the import, processing or use of this product for food & feed in the EU.
If an impact has to be expected or hypothesized, then it could be the effect of glyphosate used when MON89788 is cultivated.
The widespread use of glyphosate will be made possible and promoted by the use of GM-soybean with CP4-EPSPS like MON89788.
However, since this application is for consent to import MON8978 grain in EU to use it as any other soybean, excluding the cultivation of MON89788 varieties, it also excludes the usage of glyphosate.

Comment 2
Provided information: sufficient.

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

Comments/Questions of the expert(s)

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert(s)

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

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

Comments/Questions of the expert(s)

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

References

Forsbach A, Schubert D, Lechtenberg B, Gils M, Schmidt R. (2003) A comprehensive characterization of single-copy T-DNA insertions in the Arabidopsis thaliana genome. Plant Mol. Biol. 52 (1): 161-176.

Gheysen G, Villaroel R, Van Montagu M. (1991) Illegitimate Recombination in Plants - A model for T-DNA integration. Genes & Development 5 (2): 287-297.

Jonathan R. Latham, Allison K. Wilson, and Ricarda A. Steinbrecher. (2006) The Mutational Consequences of Plant Transformation. J. Biomed. Biotechnol. Volume 2006, Article ID 25376, 7 pages. doi:10.1155/JBB/2006/25376.

Kumar S, Fladung M. (2002). Transgene integration in aspen: structures of integration sites and mechanism of T-DNA integration. Plant J. 31 (4): 543-551.

Mayerhofer R., Konczkalman Z., Nawrath C, et al. (1991) T-DNA integration - A mode of illegitimate recombination in plants. EMBO J. 10 (3): 697-704.

Richard S, Moslemi S, Sipahutar H, Benachour N, Seralini GE, (2005) Differential effects of glyphosate and roundup on human placental cells and aromatase . Environmental Health Perspectives 113 (6).