Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2016-135 (genetically modified soybean MON 87708 x MON 89788 x A5547-127) from Monsanto under Regulation (EC) No. 1829/2003

17 September 2019
Ref. SC/1510/BAC/2019_0747

Context

Application EFSA-GMO-NL-2016-135 was submitted by Monsanto for the marketing of genetically modified (GM) soybean MON 87708 x MON 89788 x A5547-127 (Unique Identifier MON-877Ø8-9 x MON-89788-1 x ACSGMØØ6-4), 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 three-event stack soybean MON 87708 x MON 89788 x A5547-127 was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:
- MON 87708, expressing the DMO protein that confers tolerance to herbicide products containing dicamba;
- MON 89788, expressing the CP4 EPSPS protein that confers tolerance to herbicide products containing glyphosate;
- A5547-127, expressing the PAT protein that confers tolerance to herbicide products containing glufosinate-ammonium.

The application was validated by EFSA on 19 January 2017. A formal three-month consultation period of the Member States was started, lasting until 27 April 2017, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC designated by each Member State in the case of genetically modified organisms being part of the products).

Within the framework of this consultation, the Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts to evaluate the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). Eight experts answered positively to this request, and formulated a number of comments to the dossier. See Annex I for an overview of all the comments and the comments forwarded to EFSA.

The opinion of the EFSA Scientific Panel on GMOs was published on 5 July 2019 (EFSA Journal 2019;17(7):5733[2]). The responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period were published on 2 July 2019. On 18 July 2019 these two documents were forwarded to the Belgian experts. They were invited to give comments and to react if needed.

[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.2019.5733

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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-2016-135;
- The opinion 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, and one of the lower-order stacks, were as follows:

Event	Application number	BAC advice	Conclusions
MON 87708	EFSA-GMO-NL-2011-93	BAC/2014/0325 (21/05/2014)	No conclusion on the food safety of the event. No risk identified for 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.
A5547-127	EFSA-GMO-NL-2008-52	BAC/2011/0553 (16/06/2011)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.
MON 87708 x MON 89788	EFSA-GMO-NL-2012-108	BAC/2015/0811	No conclusion on the food safety of the stacked event. No risk identified for the European environment.

All GM soybean events mentioned in the table above are authorised in the EU for food and feed uses[3].

Scientific evaluation

1. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of soybean MON 87708 x MON 89788 x A5547-127 (i.e. during transport and/or processing) into the European environment[4] will lead to environmental harm.

2. 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.

3. Assessment of food/feed safety and nutritional value

3.1. Assessment of compositional analysis

Taking into account the previous assessment of the single events and the new data on the composition of the three-stacked event provided by the applicant, the Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM soybean MON 87708 x MON 89788 x A5547-127, when compared with the composition of its conventional counterpart, do not raise safety concerns.

3.2. 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 safety concerns were identified. In its advice on the single event MON 87708, expressing the DMO protein, the Council had expressed some concerns regarding the results of the sub-chronic 90-day rat feeding study with the whole GM soybean: some significant differences in clinical pathology parameters were observed between male rats fed diets containing soybean MON 87708 and control animals. The Council concluded that without further investigation it was not convinced that these differences were incidental. Since no new information has been provided in the current application in relation with the toxicological assessment of the whole food derived from GM soybean MON 87708 or MON 87708 x MON 89788 x A5547-127, the concerns

[3] See EU register of GM food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
[4] As the application doesn't imply cultivation of the GM crop in the EU, a full environmental assessment is as in the case of a cultivation file is not warranted.

expressed above are still valid. As a consequence, the Biosafety Advisory Council is unable to determine whether GM soybean MON 87708 x MON 89788 x A5547-127 is as safe as conventional soybean from a toxicological perspective.

3.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed DMO, CP4 EPSPS and PAT proteins in the context of previous applications, and no allergenicity 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.

3.4. Nutritional value

The Biosafety Advisory Council is of the opinion that the information provided is sufficient to conclude that the nutritional characteristics of soybean MON 87708 x MON 89788 x A5547-127-derived food and feed are not expected to differ from those of conventional maize varieties.

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 MON 87708 x MON 89788 x A5547-127 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the opinion 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 three single events, the Biosafety Advisory Council is of the opinion that as a result of remaining uncertainties concerning the toxicity of the whole food derived from the GM plant, it is not possible to draw a final conclusion on the food safety of soybean MON 87708 x MON 89788 x A5547-127.

Given the scope of the application of the GM soybean (no cultivation in the EU) and the fact that the establishment of volunteer plants would be unlikely (soybean does not survive without human assistance, nor as a weed in Europe), the potential environmental release of soybean MON 87708 x MON 89788 x A5547-127 is unlikely to pose any threat to the European environment.

Dr. Corinne Vander Wauven
President of the Belgian Biosafety Advisory Council

Annex I: Compilation of comments of experts in charge of evaluating the application EFSA-GMO-NL-2016-135 and Comments submitted on the EFSAnet on mandate of the Biosafety Council (ref. BAC_2017_0262)

Bioveiligheidsraad
Conseil de Biosécurité

26/04/2017

Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC_2017_0262
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Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2016/135
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 2 February 2017.
Coordinator: Dhr René Custers
Experts: Eddy Decuypere (KUL), Jacques Dommes (ULg), Patrick du Jardin (ULg-Gembloux), Johan Grooten (UGent), André Huyghebaert (UGent), Peter Smet (Consultant), Frank Van Breusegem (UGent), Jan Van Doorsselaere (KATHO),

Domains of expertise of experts involved: Molecular characterisation, DNA/RNA/protein analysis, herbicide tolerance, animal and human nutrition, food/feed processing, toxicology, general biochemistry, statistics, immunology, alimentary allergology, plant allergens, agronomy, ecology, oilseed rape, breeding techniques, plant biology.

SBB: Didier Breyer, Fanny Coppens, Katia Pauwels.

- **INTRODUCTION**

Dossier **EFSA/GMO/NL/2016/135** concerns an application submitted by the company **Monsanto** for authorisation to place on the market genetically modified Soybean MON87708 x MON 89788 x A5547-127 in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed.
The application has been officially acknowledged by EFSA on 27 January 2017.

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.
It should be noted that all the comments received from the experts are considered in the evaluation of this dossier and in formulating the final advice of the Biosafety Advisory Council. Comments placed on the EFSAnet are indicated in grey.

List of comments/questions received from the experts

GENERAL COMMENTS

Comment 1
No comments

Comment 2
No comments, adequate information was provided

Comment 3
MON 87708 x MON 89788 x A5547-127 will be further referred to as 135 soybean.

Comment 4
No comments

A. HAZARD IDENTIFICATION AND CHARACTERISATION

A.1. INFORMATION RELATED TO THE RECIPIENT OR (WHERE APPROPRIATE) THE PARENTAL PLANT

Comment 1
No questions

Comment 2
No comments, adequate information was provided

Comment 3
Evaluated, no comments

Comment 4
No comments

A.2. MOLECULAR CHARACTERISATION

A.2.1. INFORMATION RELATING TO THE GENETIC MODIFICATION Including:

- Description of the methods used for the genetic modification
- Source and characterization of nucleic acid used for transformation
- Nature and source of vector(s) used

Comment 1
No questions

Comment 2
No comments, adequate information was provided

Comment 3

1. In the bioinformatic searches for similarity of the newly expressed proteins with proteins of potential adverse biological activity using general protein databases (see e.g. section 6.1.3 page 9 in Hileman and Silvanovich 2016d, Table 4 and Appendix 1), the top alignments logically correspond to the intended proteins (here DMO and the chloroplast transit peptides). It does not make sense that the applicant comments on these (expected) top alignments only but he should comment on the best alignments after exclusion of the intended proteins. I tried to find the next best alignments in the Appendix 1 by myself but it seems that only the 50 best alignments are displayed (for 'frame 3' corresponding to the DMO encoding sequence) which all correspond to the intended protein. Conclusion: the applicant should be asked to remove the intended proteins from the displayed alignments in such analyses. I do not consider that there is a safety concern here but my suggestion aims at improving the quality of the assessment.
2. In this dossier, integrity of the inserts in the stack as compared to the single events is show by the sequence analysis of each event in the stack (required by the updated bioinformatic analysis), as reported in Vest and Silvanovich (2016). No Southern blot analysis is provided comparing the stack and the single events side by side. However, genetic stability of the events is inferred from the data obtained in the single events and from the complex breeding tree indicating the successful inheritance of each event throughout the sexual generations leading to the commercialized stack. A theoretical discussion on why no mitotic or meiotic recombination is expected between the common sequences in the inserts is presented in section 1.2.2.4 (page 28 of main dossier). Altogether, the empirical ad theoretical elements provided by the applicant are sufficient to conclude on the integrity and on the stability of the events combined on the stack.

Comment 4

No comments.

Comment 5

No comments

A.2.2. INFORMATION RELATING TO THE GM PLANT Including:

- Description of the trait(s) and characteristics which have been introduced or modified
- Information on the sequences actually inserted or deleted
- Information on the expression of the insert
- Genetic stability of the inserted/modified sequence and phenotypic stability of the GM plant

Comment 1

Expression levels of DMO (dicamba mono-oxygenase), CP4 EPSPS,and PAT proteins leads to herbicide tolerance. Horizontal gene transfer to bacteria, plasmid, virus or human or animal cells is extremely unlikely if not impossible. Inserts are on different chromosomes in soybean, therefore very low possibility of homologous recombination.

No questions.

Comment 2

The molecular characterisation does not rise any safety concern.

Comment 3

No comments. The GM plant is a combination of previous approved transformation events. The inserts are stably inherited.

Comment 4
No comments

A.3. COMPARATIVE ASSESSMENT

A.3.1. CRITERIA FOR THE SELECTION OF COMPARATOR(S)

Comment 1
No questions

Comment 2
As a conventional counterpart A3555 soybean, with a similar genetic background, was used for the comparison with 135 soybean.
As it is usually the case other commercial varieties were included as well.

Comment 3
The values for stachyose, daidzein and genistein, are statistically significant different from those of the conventional counterpart. (treated)
The mean value of each of the test substances (treated) is always located within the range of the reference lines.

The values for trypsin inhibitor, daidzein and genistein, are statistically significant different from those of the conventional counterpart. (non-treated)
The mean value of each of the test substances (non-treated) is always located within the range of the reference lines.

A.3.2. FIELD TRIALS: EXPERIMENTAL DESIGN AND STATISTICAL ANALYSIS

Comment 1
The stacked event , A3555 as near isogenic control and 16 commercial reference varieties are used on 8 field sites; no questions

Comment 2
The statistical analysis was conducted according to the EFSA guidance.
No particular remarks on the experimental design and the statistical analysis.

A.3.3. COMPOSITIONAL ANALYSIS

Comment 1
In table 7 and 8: glycinin (an allergen!) is not categorized for equivalence category due to no equivalent limits due to lack of variation in references: any idea or explanation why?

Comment 2
The selection of the analytes was performed according to the OECD guidelines.
I focus my comments on beans and not on forage.

Fibre compounds are assessed as NDF and ADF. Total dietary fibre is not considered.

Carbohydrates are determined by calculation. Carbohydrates “by difference” are not accepted in human nutrition.
As already mentioned in previous applications, this approach according to the OECD is adequate for comparative purposes. Is not accepted as a source of information on nutrients.
On the other hand some compounds are studied in detail such as amino acids, fatty acids, vitamins as vitamin K1 (of growing importance) anti-nutrients and isoflavones.

To my knowledge allergens in soybeans were considered for the first time in an application. Allergens are not included in the OECD list but required for comparative testing according to recent EU regulations.

This is a major step forwards that illustrates that the OECD guidelines have to be adapted regularly to the up to date scientific knowledge. There is indeed growing concern about the presence of allergens in foods and their impact on human health.
In this part it is mentioned that allergens with fifty percent of observations below the limit of quantification (LOQ) were assigned a value equal to half the LOQ.
This is a well accepted approach in risk assessment calculations: medium bound contrary to the upper bound or the LOQ value or the lower bound or zero value.
Results of the statistical analysis are categorized according to the degree of equivalence and presented in tables.

The applicant concludes that the differences observed are categorized as being of no compositional relevance.

One allergen glycinin is not categorized due to a lack of variation in reference substance genotypes. No data are included to explain this conclusion. A further explanation is welcome.

A.3.4. AGRONOMIC AND PHENOTYPIC CHARACTERISTICS

Comment 1
No questions

Comment 2
Evaluated, no comments

Comment 3
No particular remarks.

A.3.5. EFFECTS OF PROCESSING

Comment 1
No questions

Comment 2
Any effect on processing characteristics is not to be expected.

A.4. TOXICOLOGICAL ASSESSMENT

A.4.1. METHODOLOGY USED FOR TOXICITY TESTS

Comment 1
No questions

A.4.2. ASSESSMENT OF NEWLY EXPRESSED PROTEINS including:

- Molecular and biochemical characterisation of the newly expressed proteins
- Up-to-date bioinformatic search for homology
- Information on the stability of the protein under the relevant processing and storage conditions for the food and feed derived from the GM plant
- Data concerning the resistance of the newly expressed protein to proteolytic enzymes
- Repeated dose toxicity studies using laboratory animals

Comment 1
These data do not rise any safety concern.

Comment 2
Evaluated, no comments

Comment 3
The amounts of DMO, PAT and CP4 EPSPS protein are comparable to those in their respective single event comparator.

Based on earlier information, it is likely that DMO, CP4 EPSPS and PAT proteins are degraded rapidly in the mammalian digestive tract.

28 Day Repeat Dose Toxicity Study by Oral Gavage in Rats.

Not performed. No further testing is needed.
Homology searches: all studies date from 2016. No matches with possible toxins were found

A.4.3. ASSESSMENT OF NEW CONSTITUENTS OTHER THAN PROTEINS

Comment 1
Not applicable

A.4.4. ASSESSMENT OF ALTERED LEVELS OF FOOD AND FEED CONSTITUENTS

Comment 1
Not applicable

A.4.5. ASSESSMENT OF THE WHOLE FOOD AND/OR FEED DERIVED FROM GM PLANTS

Comment 1
No questions

Comment 2

90-Day rat feeding study.
Not performed. No further testing is needed.

A.5. ALLERGENICITY ASSESSMENT

A.5.1. ASSESSMENT OF ALLERGENICITY OF THE NEWLY EXPRESSED PROTEIN including:

- Amino acid sequence homology comparison between the newly expressed protein and known allergens using a comprehensive database
- Specific serum screening
- Pepsin resistance and in vitro digestibility tests
- Additional tests

Comment 1
No questions

Comment 2
No safety concern

Comment 3
Evaluated, no comments

Comment 4
The lack of allergenic potential of the newly expressed proteins has been addressed individually in previous EFSA applications. An updated bioinformatics analysis for amino acid sequence homology with known allergens has been performed by the applicant using the Allergen AD_2016 database. No relevant sequence homologies were observed.
The specificity of the DMO, CP4 EPSPS and PAT proteins make it unlikely that in the stacked event, the proteins would have synergistic or antagonistic effects to each other or modify each other chemically resulting in allergenicity.
Accordingly, I agree with the applicant's conclusion that no concerns in relation to allergenicity of the (stacked) newly expressed proteins were identified.

A.5.2. ASSESSMENT OF ALLERGENICITY OF THE WHOLE GM PLANT

Comment 1
No questions

Comment 2
No safety concern

Comment 3
I agree with the applicant that at the level of the whole plant no indications of potential adverse effects have been identified. I find it nevertheless a pity and lost opportunity regarding the establishment of safety that a 90-day feeding study with whole food and feed in rodents has not been performed. Considering the multiplicity of introduced events, the multiple pathways that may be affected and the

fact that biological pathways are intricate, often interconnected and therefore not always behave as expected, such a feeding study provides in my opinion the best evidence for safety of the stacked GM maize.
The applicant frequently refers in the dossier to “the history of safe use of the introduced proteins”. However no reference to this statement is provided. The applicant should indicate on what data this statement is based on, such as scientific papers or health monitoring reports.
I have no other remarks.

A.5.3. ADJUVANTICITY

Comment 1
No questions

Comment 2
No safety concern

Comment 3
No remarks

A.6. NUTRITIONAL ASSESSMENT

A.6.1. NUTRITIONAL ASSESSMENT OF FOOD DERIVED FROM GM PLANTS

Comment 1
No questions

A.6.2. NUTRITIONAL ASSESSMENT OF FEED DERIVED FROM GM PLANTS

Comment 1
No questions

B. EXPOSURE ASSESSMENT - ANTICIPATED INTAKE/EXTENT OF USE

Comment 1
No questions; I agree with the conclusions on p58 of the report

C. RISK CHARACTERISATION

Comment 1
No comments

D. POST MARKET MONITORING (PMM) OF FOOD AND FEED DERIVED FROM GM PLANTS

Comment 1
No questions

Comment 2
Evaluated, no comments

E. ENVIRONMENTAL RISK ASSESSMENT

E.1. INTRODUCTION

Comment 1
No comments

Comment 2
No comment, adequate information was provided

Comment 3
Evaluated, no comments

E.2. GENERAL APPROACH OF THE ERA

Comment 1
No different from the near isogenic control A555 and equivalent to soybean varieties in commerce; no unintended effects of the genetic modifications

Comment 2
No comment, adequate information was provided

Comment 3
Evaluated, no comments

E.3. SPECIFIC AREAS OF RISK

As stated in the EFSA guidance on the environmental risk assessment of genetically modified plants (EFSA Journal 2010, 8(11):1879) the objective of the ERA is on a case-by-case basis to identify and evaluate potential adverse effects of the GM plant, direct and indirect, immediate or delayed (including cumulative long-term effects) on the receiving environment(s) where the GM plant will be released. For each specific risk the ERA consists of the six steps described in Directive 2001/18/EC:
1. Problem formulation including hazard identification,
2. Hazard characterisation,
3. Exposure characterisation,
4. Risk characterisation,
5. Risk management strategies,
6. Overall risk evaluation and conclusions.

E.3.1. PERSISTENCE AND INVASIVENESS INCLUDING PLANT-TO-PLANT GENE FLOW

Comment 1
No questions

Comment 2
No safety concern

Comment 3
Evaluated, no comments

E.3.2. PLANT TO MICRO-ORGANISMS GENE TRANSFER

Comment 1
No questions

Comment 2
No safety concern

Comment 3
Evaluated, no comments

E.3.3. INTERACTION BETWEEN THE GM PLANT AND TARGET ORGANISMS

Comment 1
Not applicable

Comment 2
No safety concern

E.3.4. INTERACTION BETWEEN THE GM PLANT AND NON-TARGET ORGANISMS (NTOS)

Comment 1
Negligible

Comment 2
I was confused with the two first paragraphs under "5.3.4.1. Step 1: Problem formulation". This part of the ERA discusses the biosafety of the Cry1A, Cry2Ab2 and Cry1Ac proteins! As far as I know, the genes coding these proteins are not present in MON87708 x MON89788 x A5547-127. I suppose that this mistake comes from an inadequate cut and paste from another dossier.

Rephrased by coordinator :
"The two first paragraphs under "5.3.4.1. Step 1: Problem formulation" describe the potential toxicity of newly expressed Cry1.105, Cry2Ab2 and Cry1Ac proteins of MON 87751 × MON 87701 × MON 87708 × MON 89788 instead of MON87708 x MON89788 x A5547-127. It is supposed that this mistake reflects an inadequate copy and paste from another soybean dossier."

Comment 3
Evaluated, no comments

E.3.5. IMPACTS OF SPECIFIC CULTIVATION AND MANAGEMENT AND HARVESTING TECHNIQUES

Comment 1
Not applicable

Comment 2
Not relevant (no cultivation in EU)

Comment 3
Evaluated, no comments

E.3.6. EFFECTS ON BIOGEOCHEMICAL PROCESSES

Comment 1
Not applicable

Comment 2
No safety concern

Comment 3
Evaluated, no comments

E.3.7. EFFECTS ON HUMAN AND ANIMAL HEALTH

Comment 1
No questions

Comment 2
No safety concern

E.3.8. OVERALL RISK EVALUATION AND CONCLUSIONS

Comment 1
No question

Comment 2
No safety concern

Comment 3
Evaluated, no comments

E.4. POST MARKET ENVIRONMENTAL MONITORING PLAN

E.4.1. INTERPLAY BETWEEN ENVIRONMENTAL RISK ASSESSMENT AND MONITORING

Comment 1

No questions

Comment 2
Evaluated, no comments

E.4.2. CASE-SPECIFIC GM PLANT MONITORING

Comment 1
No comments

Comment 2
Evaluated, no comments

E.4.3. GENERAL SURVEILLANCE FOR UNANTICIPATED ADVERSE EFFECTS

Comment 1
No comments

Comment 2
Evaluated, no comments

E.4.4. REPORTING THE RESULTS OF MONITORING

Comment 1
No comments

Comment 2
In the literature survey as part of the monitoring exercise, the applicant performs a bibliographic search using as query terms the combination of the terms MON 87708 AND MON 89788 AND A5547-127 (or the combination of the newly expressed proteins), and concludes that no articles are relevant for the assessment of the potential effects of the MON 87708 × MON 89788 × A5547-127 soybean stack. However, any articles on the single events, which would not be spotted by the search, are potentially relevant. Restricting the search to the combined events thus appears to be too restrictive and a suggestion could be to ask the applicant to expand the search to the single events.