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SCIENTIFIC OPINION

Scientific Opinion on an application (Reference EFSA-GMO-NL-2011-100) for the placing on the market of the herbicide-tolerant, increased oleic acid genetically modified soybean MON 87705 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2,3]

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ABSTRACT

The EFSA GMO Panel previously assessed the two single events combined to produce soybean MON 87705 × MON 89788 and did not identify safety concerns. No new data on the single events affecting the previous conclusions were identified. No differences in composition requiring further assessment were observed between soybean MON 87705 × MON 89788 and its comparator, except for the intended trait i.e. an altered fatty acid profile. Nutritional assessment on soybean MON 87705 × MON 89788 oil and oil-containing food products did not identify concerns on human health and nutrition. There are no concerns regarding the use of feedingstuffs from defatted soybean meal MON 87705 × MON 89788. The EFSA GMO Panel is of the opinion that soybean MON 87705 × MON 89788 is as safe, and at least as nutritious, as its comparator and commercial soybean varieties. There is no reason to expect interactions between the single events that could impact on the food and feed safety and the nutritional properties of soybean MON 87705 × MON 89788. There are no indications of an increased likelihood of establishment and spread of feral soybean plants. Potential interactions with the biotic and abiotic environment were not considered to be a relevant issue. The unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87705 × MON 89788 to environmental bacteria does not give rise to any safety concern. The post-market environmental monitoring plan and reporting intervals are in line with the scope of the application. The EFSA GMO Panel considers that the information available for soybean MON 87705 × MON 89788 addresses the scientific comments raised by Member States. The EFSA GMO Panel concludes, considering the scope of the application, that soybean MON 87705 × MON 89788 is as safe as its comparator and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment. The GMO Panel recommends a post-market monitoring plan, focusing on import data and, if needed, on consumption data for the European population, for the marketed foods and feed.

[1] On request from the Competent Authority of the Netherlands on an application (EFSA-GMO-NL-2011-100) submitted by Monsanto, Question No EFSA-Q-2011-00954, adopted on 25 June 2015.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Groups on Molecular Characterisation, Food/Feed safety and Environment on GMO applications for the preparatory work on this scientific opinion, and EFSA staff: Anna Lanzoni, Sylvie Mestdagh, and Irina Olaru, for the support provided to this scientific opinion.

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KEY WORDS

GMO, soybean (*Glycine max* (L.) Merr.), CP4 EPSPS, herbicide tolerant, increased oleic acid, stack

SUMMARY

Following the submission of application EFSA-GMO-NL-2011-100 under Regulation (EC) No 1829/2003 from Monsanto, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the safety of herbicide-tolerant, increased oleic acid genetically modified (GM) soybean MON 87705 × MON 89788 (Unique Identifier MON-877Ø5-6 × MON-89788-1). The scope of application EFSA-GMO-NL-2011-100 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

The soybean single events MON 87705 (expressing CP4 EPSPS and having an altered fatty acid profile) and MON 89788 (expressing CP4 EPSPS) were assessed previously and no concerns were identified. No safety issue was identified by updated bioinformatic analyses, nor reported by the applicant concerning the two single soybean events, since the publication of the respective scientific opinions. Consequently, the EFSA GMO Panel considers that its previous conclusions on the safety of the single soybean events remain valid.

The two-event stack soybean MON 87705 × MON 89788 was produced by conventional crossing to produce soybean tolerant to glyphosate-based herbicides and having an altered fatty acid profile. The EFSA GMO Panel evaluated soybean MON 87705 × MON 89788 with reference to the scope and appropriate principles described in its guidelines for the risk assessment of GM plants and derived food and feed, the environmental risk assessment of GM plants and the post-market environmental monitoring of GM plants. The scientific evaluation of the risk assessment included molecular characterisation of the inserted DNA and analysis of the expression of the CP4 EPSPS protein. An evaluation of the comparative analyses of the compositional, agronomic and phenotypic characteristics was undertaken, and the safety of the newly expressed protein and the whole food/feed was evaluated with respect to potential toxicity, allergenicity and nutritional wholesomeness. An evaluation of environmental impacts and the post-market environmental monitoring plan was also undertaken. In accordance with the EFSA GMO Panel guidance document applicable to this application "*For GM plants containing a combination of transformation events (stacked events) the primary concern for risk assessment is to establish that the combination of events is stable and that no interactions between the stacked events, that may raise safety concerns compared to the single events, occur. The risk assessment of GM plants containing stacked events focuses on issues related to: a) stability of the inserts, b) expression of the introduced genes and their products and c) potential synergistic or antagonistic effects resulting from the combination of the events*".

The molecular data establish that the transformation events stacked in soybean MON 87705 × MON 89788 have the same molecular properties and characteristics as the single transformation events. The presence or absence of interactions that manifest at protein expression level could not be established by comparing the protein levels in the single events and the two-event stack. From the molecular characterisation, no indications of interactions between the events based on the biological functions of the newly expressed proteins were identified.

The EFSA GMO Panel considered the compositional, phenotypic and agronomic data supplied and the observed statistically significant differences between soybean MON 87705 × MON 89788 and its comparator, in the light of the field trial design, measured biological variation and the level of the studied compounds in commercial non-GM soybean reference varieties. No differences in composition requiring further assessment for food/feed safety were observed between soybean MON 87705 × MON 89788 and its comparator, except for the intended trait i.e. altered fatty acid profile (reduced SFAs palmitic acid (C16:0) and stearic acid (C18:0), reduced PUFA linoleic acid (C18:2), and increased MUFA oleic acid (C18:1)).

Nutritional assessment on soybean MON 87705 × MON 89788 oil and oil-containing food products did not identify concerns on human health and nutrition. There are no concerns regarding the use of feedingstuffs derived from defatted soybean meal MON 87705 × MON 89788. The EFSA GMO Panel

is of the opinion that soybean MON 87705 × MON 89788 is as safe, and at least as nutritious, as its comparator and commercial soybean varieties, in the context of its scope.

Considering the intended modified soybean MON 87705 × MON 89788 nutritional composition, a proposal for a post market monitoring (PMM) plan needs to be provided by the applicant. EFSA recommends that the post-market monitoring plan should initially focus on the collection of import data for Europe; in the event of significant import, requiring a new exposure assessment, consumption data for the European population and concentration data for fatty acids in the oils would be needed.

Considering the scope of application EFSA-GMO-NL-2011-100, there is no requirement for scientific information on possible environmental effects associated with the cultivation of soybean MON 87705 × MON 89788 in Europe. There are no indications of an increased likelihood of establishment and spread of feral soybean MON 87705 × MON 89788 plants in case of accidental release into the environment of viable GM soybean seeds. Potential interactions of soybean MON 87705 × MON 89788 with the biotic and abiotic environment were not considered to be a relevant issue by the EFSA GMO Panel. The unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87705 × MON 89788 to environmental bacteria does not give rise to safety concerns owing to the lack of a selective advantage in the context of its intended uses. The post-market environmental monitoring plan provided by the applicant and the reporting intervals are in line with the scope of application EFSA-GMO-NL-2011-100.

In delivering its scientific opinion, the EFSA GMO Panel took into account application EFSA-GMO-NL-2011-100, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications.

In conclusion, the EFSA GMO Panel considers that the information available for soybean MON 87705 × MON 89788 addresses the scientific issues indicated by the Guidance document of the EFSA GMO Panel and the scientific comments raised by the Member States, and that soybean MON 87705 × MON 89788 is as safe as its comparator and is unlikely to have adverse effects on human and animal health and the environment in the context of its intended uses as proposed by the applicant.

Considering the modified composition and nutritional values of soybean MON 87705 × MON 89788, the EFSA GMO Panel considered a specific labelling proposal provided by the applicant in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003. The applicant proposed that food and feed products within the scope of application should be labelled as “genetically modified soybean containing increased oleic acid oil”. The GMO Panel is of the opinion that the compositional data show that the fatty acid composition of seeds of soybean MON 87705 × MON 89788 and derived oil has indeed been changed in relation to the comparator.

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BACKGROUND

On 17 August 2011, the European Food Safety Authority (EFSA) received from the Competent Authority of The Netherlands application EFSA-GMO-NL-2011-100, for authorisation of genetically modified (GM) soybean MON 87705 × MON 89788 submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 for food and feed uses, import and processing.[4]

After receiving the application EFSA-GMO-NL-2011-100 and in accordance with Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed Member States and the European Commission, and made the summary of the application available to the public on the EFSA website.[5] EFSA initiated a formal review of the application to check compliance with the requirements laid down in Articles 5(3) and 17(3) of Regulation (EC) No 1829/2003. On 1 June 2012 and 9 July 2012, EFSA received additional information (requested on 27 September 2011 and 22 June 2012). On 30 July 2012, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003.

EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC[6] following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003 to request their scientific opinion. Member States had three months after the date of receipt of the valid application (from 26 October 2012 to 26 January 2013)[7] to make their opinion known.

The EFSA GMO Panel carried out an evaluation of the scientific risk assessment of soybean MON 87705 × MON 89788 for food and feed uses, import and processing in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. The EFSA GMO Panel took into account the appropriate principles described in its guidelines for the risk assessment of GM plants and derived food and feed (EFSA GMO Panel, 2011a), the environmental risk assessment of GM plants (EFSA GMO Panel, 2010c) and on the post-market environmental monitoring of GM plants (EFSA GMO Panel, 2011b). Furthermore, the EFSA GMO Panel also took into consideration the scientific comments of Member States, the additional information provided by the applicant and the relevant scientific publications.

The EFSA GMO Panel requested additional information from the applicant on 11 February 2013, 10 April 2013, 11 April 2013, 27 June 2013, 5 September 2013, 29 November 2013, 19 February 2014, 25 July 2014, 27 November 2014 and 27 February 2015. The applicant provided the requested information on 22 February 2013, 22 May 2013, 2 July 2013, 7 August 2013, 18 September 2013, 17 February 2014, 12 May 2014, 24 October 2014, 9 April 2015 and 1 June 2015.

In giving its scientific opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003 (EC, 2003), EFSA has endeavoured to respect a time limit of six months from the acknowledgement of the valid application. As additional information was requested by the EFSA GMO Panel, the time limit of six months was extended accordingly, in line with Articles 6(1), 6(2), 18(1), and 18(2) of Regulation (EC) No 1829/2003.

[4] 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. 1–23.

[5] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00954

[6] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38.

[7] Upon validation, application EFSA-GMO-NL-2011-100 was stopped pending the finalisation of application EFSA-GMO-NL-2010-78 (soybean MON 88705). The scientific opinion on application EFSA-GMO-NL-2010-78 was adopted on 28/9/2012.

According to Regulation (EC) No 1829/2003 (EC, 2003), this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

TERMS OF REFERENCE

The EFSA GMO Panel was requested to carry out a scientific assessment of soybean MON 87705 × MON 89788 for food and feed uses, import and processing in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003.

Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. The EFSA GMO Panel did consider if there is a need for specific labelling in accordance with Articles 13(2) (a) and 25(2)(c) of Regulation (EC) No 1829/2003. However, it did not consider proposals for methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

ASSESSMENT

1. Introduction

Application EFSA-GMO-NL-2011-100 covers the two-event stack soybean MON 87705 × MON 89788 produced by conventional crossing of events MON 87705 and MON 89788. The scope of this application is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

European Food Safety Authority (EFSA) guidance establishes the principle that "*For GM plants containing a combination of transformation events (stacked events) the primary concern for risk assessment is to establish that the combination of events is stable and that no interactions between the stacked events, that may raise safety concerns compared to the single events, occur. The risk assessment of GM plants containing stacked events focuses on issues related to: a) stability of the inserts, b) expression of the introduced genes and their products and c) potential synergistic or antagonistic effects resulting from the combination of the events*" (EFSA GMO Panel, 2011a).

Soybean MON 87705 × MON 89788 was developed to confer tolerance to glyphosate (*N*-(phosphonomethyl)glycine)-based herbicides and to have an altered fatty acid profile (increased oleic acid). Tolerance to glyphosate is achieved by expression of the CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS). The increased oleic acid phenotype is achieved by introducing fragments of the soybean *FAD2-1A* and *FATB1-A* genes, under the control of a promoter predominantly active in seeds. The genetic modification results in an inhibition of the expression of the *FAD2-1A* and *FATB1-A* genes by RNA interference (RNAi), resulting in reduced levels of the corresponding fatty acid Δ12-desaturase and palmitoyl acyl carrier protein thioesterase enzymes. The transport of the saturated fatty acid (SFA) out of the plasmid is thus decreased, the conversion of oleic acid to linoleic acid is inhibited (linoleic acid decreases), and the oleic acid level increases.

The two single soybean events MON 87705 and MON 89788 have been previously assessed (see Table 1) on the basis of experimental data. No concerns for human or animal health or environmental safety were identified.

Table 1: Single soybean events already assessed by the EFSA GMO Panel

Events	Application or mandate	EFSA Scientific Opinions
MON 87705	EFSA-GMO-NL-2010-78	EFSA GMO Panel (2012)
MON 89788	EFSA-GMO-NL-2006-36	EFSA (2008)

2. Issues raised by Member States

Issues raised by Member States on soybean MON 87705 × MON 89788 were considered in this scientific opinion and are addressed in detail in Annex G of the EFSA overall opinion.[8]

3. Updated information on single events

Since the publication of the scientific opinions on the single soybean events by the EFSA GMO Panel (EFSA, 2008; EFSA GMO Panel, 2012), no safety issues pertaining to the two single events have been reported by the applicant.

Updated bioinformatic analyses[9] on the junction sites between the genomic DNA and inserts present in the events MON 87705 and MON 89788 confirmed that no known endogenous genes were disrupted by any of the inserts. Updated bioinformatic analyses[10] of the amino acid sequence of the newly

[8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00954
[9] Additional information: 03/03/2015.
[10] Additional information: 03/03/2015.

expressed protein CP4 EPSPS and other Open Reading Frames present within the insert and spanning the junction sites revealed no significant similarities to known toxins or allergens.

In order to conclude on the possibility of horizontal gene transfer (HGT) by homologous recombination (HR), sequence identity analyses of the regions of bacterial origin of MON 87705 and MON 87705 were performed. In soybean MON 87705, a pair of identical sequences of sufficient length (259bp and 275bp) were identified. However, the similarity in the bacterial genome is with a single sequence, and the length of the sequence that could be transferred is more than 10kb. Therefore, double HR is unlikely. In soybean MON 89788, no pairs of sequences with a sufficient length of identity and the correct orientation with bacterial genomes were found to facilitate the transfer of insert sequences to bacterial recipients by double HR. The likelihood and potential consequences of the plant-to-bacteria gene transfer are described in Section 4.4.2.2.

Having assessed the updated information on soybean MON 87705 and MON 89788, the EFSA GMO Panel considers that its previous conclusions on the safety of the single soybean events remain valid.

4. Risk assessment of the two-event stack MON 87705 × MON 89788

4.1. Molecular characterisation

Possible interactions between the known biological functions conferred by the individual inserts and interactions that would manifest at protein expression level are considered.

4.1.1. Genetic elements and their biological functions

Soybean MON 87705 and MON 89788 are combined by conventional crossing to generate soybean MON 87705 × MON 89788. The structure of the inserts present in soybean MON 87705 × MON 89788 are described in detail in the EFSA GMO Panel scientific opinions (EFSA, 2008; EFSA GMO Panel, 2012), and no new genetic modifications were involved. Genetic elements in the expression cassettes of the single events are summarised in Table 2.

Table 2: Genetic elements in the expression cassettes of the events stacked in soybean MON 87705 × MON 89788.

Event	Promoter	5′ UTR	Transit peptide	Coding region	Terminator
MON 87705	*7Sα'* from the *Sphas1* gene (*Glycine max*)	*7Sα'* from the *Sphas1* gene (*G. max*)	no	*FAD2-1A* (partial intron), *FATB1-A* (partial 5'UTR and CTP) *(G. max)*	*H6 (Gossypium barbadense)*
	Enhancer of 35S RNA promoter of *FMV* (*Figwort Mosaic Virus*)/*Tsf1* promoter *(Arabidopsis thaliana)*	5′ UTR and intron from *Tsf1* (*A. thaliana)*	*CTP2* from *ShkG* encoding EPSPS (*A. thaliana*)	CP4 *epsps* (*Agrobacterium tumefaciens sp.* strain CP4)	*E9 (Rbc2)* (*Pisum sativum*)
MON 89788	35S promoter from *FMV* and promoter from *Tsf1* gene (*A. thaliana*)	5′ UTR and intron from *Tsf1* gene (*A. thaliana*)	*ShkG* (*A. thaliana*)	CP4 *epsps* (*A. tumefaciens* strain CP4)	3′ UTR of *RbcS2* (*P. sativum*)

CTP, chloroplast transit peptide
UTR, untranslated region.

Biological functions conferred by the inserts in soybean MON 87705 × MON 89788 are summarised in Table 3. CP4 EPSPS is already present together with the FAD2-1A/FATB1-A suppression cassette in event MON 87705. The addition of another copy of the CP4 EPSPS–coding gene from event

MON 89788 can be expected to increase the total amount of CP4 EPSPS, the ratio of CP4 EPSPS to endogenous EPSPS, and the herbicide tolerance of the stacked event.

Table 3: Biological functions of the events stacked in soybean MON 87705 × MON 89788.

Event	Protein	Function in donor organism	Function in GM plant
MON 87705	CP4 EPSPS	Donor organism: *Agrobacterium* sp. strain CP4 EPSPS) synthase is an enzyme involved in the shikimic acid pathway for aromatic amino acid biosynthesis in plants and microorganisms (Herrmann, 1995)	The bacterial CP4 EPSPS protein confers tolerance to glyphosate-based herbicides as it has a much lower affinity towards glyphosate than the plant endogenous enzyme
	FAD2-1A/ FATB1-A	Donor organism: *Glycine max* FAD2-1A Δ-12 desaturase; FATB1-A palmitoyl acyl carrier protein thioesterase. Both proteins function in fatty acid biosynthesis	The sense and antisense segments of *FAD2-1A* and *FATB1-A* express RNA that contains an inverted repeat of the gene segments. This transcript produces double-stranded RNA that via RNAi leads to the degradation of endogenous FAD2-1A and FATB1-A mRNAs. As a consequence, the oil is higher in oleic acid and lower in saturated and polyunsaturated fatty acids
MON 89788	CP4 EPSPS	Same as above	Same as above

4.1.2. Integrity of the events in soybean MON 87705 × MON 89788[11]

The genetic stability of the inserted DNA over multiple generations in the single soybean events MON 87705 and MON 89788 was demonstrated previously (EFSA, 2008; EFSA GMO Panel, 2012). Integrity of the events in soybean MON 87705 × MON 89788 was demonstrated by Southern analyses.

4.1.3. Information on the expression of the inserts[12]

The levels of the newly expressed CP4 EPSPS protein in soybean MON 87705 × MON 89788 were analysed by enzyme-linked immunosorbent assays (ELISAs). Tissue samples were collected from eight field trial sites in the USA during 2009. The trial included appropriate comparators. Protein levels were determined in forage, seeds, leaves and roots. Data on seed are reported and discussed below (Table 4). The CP4 EPSPS protein levels in the two-event stack were slightly higher than the corresponding levels in the single-event soybean plants.

Table 4: Levels of CP4 EPSPS protein (µg/g dry weight) in seed from soybean MON 87705 × MON 89788 and from single soybean events MON 87705 and MON 89788.

	MON 87705 × MON 89788	MON 87705	MON 89788
Mean ± SD	270 ± 34	240 ± 35	170 ± 28
Range	210-340	190-310	98-220

[11] Dossier: Part II—Section A2.2.2.
[12] Dossier: Part II—Section A2.2.3.

4.1.4. Conclusion

The molecular data establish that the transformation events stacked in soybean MON 87705 × MON 89788 have the same molecular properties and characteristics as the single transformation events. The presence or absence of interactions that manifest at protein expression level could not be established by comparing the protein levels in the single events and the two-event stack. The molecular characterisation revealed no indications of interactions between the events based on the biological functions of the newly expressed proteins.

4.2. Comparative analysis

4.2.1. Evaluation of relevant scientific data

4.2.1.1. Choice of comparator and production of material for the comparative analysis[13]

Field trials for the comparative analysis of agronomic and phenotypic characteristics and compositional data of MON 87705 × MON 89788 were performed in the USA in 2009. In these field trials, soybean MON 87705 × MON 89788 (both untreated and treated with the target herbicide glyphosate) was compared with the control soybean material A3525, which has a genetic background similar to soybean MON 87705 × MON 89788.[14] The Asgrow variety A3525 was the commercial soybean variety used to establish the transformation event MON 87705, and is a progeny (crossed with the A3469 variety) of the soybean variety A3244 used to establish the transformation event MON 89788.

The field trials were performed at nine separate sites within the soybean cultivation areas of the USA. Eight of the nine sites were used for the agronomic and phenotypic comparison,[15] and eight were used for comparative compositional studies of soybean seed and forage.[16] Seven of the nine field trials were used for both compositional and agronomic/phenotypic analysis. At each field trial site, the soybean materials were planted in a randomised complete block design with four replicates per block. The plant materials grown at each site were soybean MON 87705 × MON 89788, the comparator (non-GM soybean A3525) and three different commercial non-GM soybean reference varieties,[17] all treated using typical agricultural practices, as well as soybean MON 87705 × MON 89788 additionally treated with glyphosate-based herbicides.

4.2.1.2. Statistical analysis of field trials data

The statistical analysis of the agronomic, phenotypic and compositional data followed the recommendations by the EFSA GMO Panel (EFSA, 2010a, 2011a). This includes a test of difference to determine whether or not the GM plant is different from its comparator, and a test of equivalence to determine whether or not the GM plant falls within the range of natural variation estimated from the non-GM soybean reference varieties. As described in EFSA GMO Panel (2011a), the result of the equivalence test is categorised into four possible outcomes to facilitate drawing conclusions with respect to the presence or absence of equivalence. These four categories are category I, indicating full

[13] Dossier: Part II—Sections A.3.1–3.2; additional information: 18/9/2013, 17/2/2014 and 12/5/2014.

[14] Using single nucleotide polymorphism (SNP) marker technology, soybean MON 87705 × MON 89788 was shown to be approximately 90% similar to the A3525 genetic background.

[15] A field trial site in Indiana (INRC) was dropped from the agronomic/phenotypic due to sample mishandling during the vegetative stage. As the mishandling did not impact on the resulting forage and grain samples harvested, compositional data on this material was included in the analysis.

[16] A field trial site in Illinois (ILWY) was dropped from the compositional studies due to contamination of three of the four control samples with unintended traits. As this contamination had not influenced the agronomic/phenotypic measurements, the data collected from this field trial site were included in the agronomic/phenotypic analysis.

[17] Altogether, 18 commercial non-GM varieties were used for the compositional analysis: Pioneer 93B15, Schillinger TP31834, Wilken 3316, FS 3591, Hoshea, Garst 3585N, Williams 82, Pioneer 93M52, Croplan HT3596STS, Hoegemeyer 333, Midland 363, Quality Plus 365C, Schillinger 388.TC, Maverick, Lewis 372, Crows C37003N, NK S38-T8, and NK 32Z3. For the assessment of phenotypic/agronomic characteristics, 19 varieties were used: 16 were in common with the compositional analysis (all except Hoegemeyer 333 and Midland 363), and in addition Stewart SB3454, Channel Bio 3461 and Schillinger 348.TC were used.

equivalence; category II, indicating that equivalence is more likely than non-equivalence; category III, indicating that non-equivalence is more likely than equivalence; and category IV, indicating non-equivalence.

4.2.1.3. Agronomic and phenotypic characteristics[18]

The phenotypic and agronomic characteristics evaluated were early stand count, plant vigour, days to 50 % flowering, plant height, lodging, pod shattering[19], final stand count, seed moisture content, 100-seed weight and yield. Growth stage data were also collected but were not analysed statistically.

In the analysis of soybean MON 87705 × MON 89788 not treated with glyphosate, the test of difference of phenotypic and agronomic characteristics identified statistically significant differences between soybean MON 87705 × MON 89788 and the comparator for six endpoints. The test of equivalence showed that four of these endpoints (plant height, final stand count, 100 seed weight, and yield) fell into equivalence category I and two (early stand count and plant vigour) fell into equivalence category II. In all cases plant vigour ratings were in the range excellent to normal for soybean.

In the analysis of soybean MON 87705 × MON 89788 treated with glyphosate, the test of difference identified statistically significant differences between soybean MON 87705 × MON 89788 and its comparator for seven endpoints. The equivalence test showed that five of these endpoints (days to 50% flowering, plant height, final stand count, 100 seed weight, and yield) fell into equivalence category I and two (early stand count and plant vigour) fell into equivalence category II. Also for glyphosate-treated soybean MON 87705 × MON 89788, plant vigour ratings were in the range of excellent to normal for soybean.

As for early stand count and plant vigour, full equivalence with the range of non-GM reference varieties could not be demonstrated (for either of the two spraying regimens). Because these endpoints are relevant for the assessment of possible changes in persistence and invasiveness of the GM soybean, the significant differences observed in early stand count and plant vigour are further assessed for their potential environmental impact in Section 4.4.

The plots used for the ecological studies were those that had not been sprayed with glyphosate. Plant response (damage) to three abiotic stressors, three diseases and three arthropod pests was evaluated four times during the growing season at each field trial site. No differences between soybean MON 87705 × MON 89788 and the comparator were noted in any of the comparisons. These data indicated no difference in environmental interactions between soybean MON 87705 × MON 89788 and the comparator A3525.

[18] Dossier: Part II— Section A3.4; additional information: 18/9/2013 and 17/2/2014.

[19] Pod shattering could not be statistically analysed in the equivalence test because of the variance among the commercial non-GM reference soybean varieties was too small. However, no significant differences were identified between soybean MON 87705 × MON 89788 and the comparator.

4.2.1.4. Compositional analysis[20]

Soybean forage and seeds harvested from the field trials were analysed for 67 constituents (60 in seeds[21] and 7 in forage[22]), including the key constituents recommended by the Organisation for Economic Co-operation and Development (OECD, 2001). Eighteen rarely occurring fatty acids in soybean with more than 50 % of the observations below the limit of quantification were excluded from the statistical analysis,[23] the analysis therefore included 49 compounds (42 in seed and 7 in forage).

The compositional endpoints that are further discussed based on the results of statistical analysis are presented in Table 5.

As expected, statistically significant differences of considerable magnitude between soybean MON 87705 × MON 89788 (both sprayed and not sprayed with the target herbicide) and the comparator were found for several fatty acids, demonstrating the intended effect of event MON 87705. The results for the fatty acid profile composition in seeds of soybean MON 87705 × MON 89788 (Table 5) are therefore discussed separately from those for the other endpoints.

The data in Table 5 confirm the expected decrease in the relative level (% total fatty acid (FA)) of palmitic acid (16:0) (about 80 % relative decrease for both treatments) and stearic acid (18:0) (about 25 %), and the increased level of oleic acid (18:1) (about 240 %) accompanied by a decrease in linoleic acid (18:2) (about 65%); the level of eicosenoic acid (20:1) was also increased (by about 80 %). Less marked changes were detected for the other fatty acids: a decrease in α-linolenic acid (18:3) (about 6 %) and behenic acid (22:0) (about 7 %), and an increase in arachidic acid (20:0) (about 17 %). The relative level of all the fatty acids fell outside the equivalence limits established from the non-GM soybean reference varieties (equivalence category IV), with the exception of α-linolenic acid (18:3) which was found equivalent for both treatments (equivalence category I), and arachidic acid (20:1) which fell into equivalence category III for soybean MON 87705 × MON 89788 sprayed with the target herbicide. For all the eight fatty acids, a significant genotype × environment interaction was identified: this result is associated with the high between-site variability of the fatty acid content of soybean MON 87705 × MON 89788 (e.g. mean linoleic acid content per site ranges approximately from 12 % FA to 28 % FA). The nutritional consequences of this variation are assessed in Section 4.3.4.

With regard to non-fatty acid compounds, the test of difference between soybean MON 87705 × MON 89788 (not sprayed with the intended herbicide) and the comparator identified statistically significant differences for 17 endpoints, one in forage (carbohydrate level) and 16 in seeds.[24] The equivalence test showed that 14 of these endpoints fell into equivalence category I or II and two (arginine and cystine levels) under equivalence category III (Table 5); carbohydrate level in forage fell into equivalence category I. Given the well-known function of arginine and cystine, the differences observed between soybean MON 87705 × MON 89788 and the comparator were

[20] Dossier: Part II— Section A3.3; additional information: 18/9/2013 and 17/2/2014.

[21] Proximates (protein, fat, ash and moisture), carbohydrates by calculation, fibre fractions (acid detergent fibre (ADF) and neutral detergent fibre (NDF)), amino acids (alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine), fatty acids (caprylic acid (C8:0), capric acid (C10:0), lauric acid (C12:0), myristic acid (C14:0), myristoleic acid (C14:1), pentadecylic acid (C15:0), pentadecenoic acid (C15:1), palmitic acid (C16:0), palmitoleic acid (C16:1), heptadecanoic acid (C17:0), heptadecenoic acid (C17:1), stearic acid (C18:0), oleic acid (C18:1), octadecenoic acid (C18:1), linoleic acid (C18:2), (9c,15c) isomer of linoleic acid (C18:2), (6c,9c) isomer of linoleic acid (C18:2), linolenic acid (C18:3), γ-linolenic acid (C18:3), arachidic acid (C20:0), eicosenoic acid (C20:1), eicosadienoic acid (C20:2), eicosatrienoic acid (C20:3), arachidonic acid (C20:4), behenic acid (C22:0), and lignoceric acid (C24:0)), the micronutrient vitamin E, anti-nutrients (phytic acid, trypsin inhibitor, lectin, stachyose and raffinose) and other secondary metabolites (isoflavones: daidzein, genistein, and glycitein).

[22] Proximates, carbohydrates by calculation and fibre fractions (ADF, NDF).

[23] Caprylic acid (C8:0), capric acid (C10:0), lauric acid (C12:0), myristic acid (C14:0), myristoleic acid (C14:1), pentadecylic acid (C15:0), pentadecenoic acid (C15:1), palmitoleic acid (C16:1), heptadecanoic acid (C17:0), heptadecenoic acid (C17:1), octadecenoic acid (C18:1), (9c,15c) isomer of linoleic acid (C18:2), (6c,9c) isomer of linoleic acid (C18:2), γ-linolenic acid (C18:3), eicosadienoic acid (C20:2), eicosatrienoic acid (C20:3), arachidonic acid (C20:4), lignoceric acid (C24:0).

[24] Levels of carbohydrates, protein, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, leucine, lysine, serine, vitamin E, phytic acid, raffinose, trypsin inhibitor and genistein.

considered to be of no relevance for food and feed safety. For arginine, a significant genotype × environment interaction was identified, but the magnitude of individual-site differences between the GM soybean and the comparator was considered of no relevance for food and feed safety.

In the corresponding statistical analysis for soybean MON 87705 × MON 89788 treated with glyphosate compared with the comparator A3525, 11 significant differences (apart from the eight fatty acids) were found for seed constituents,[25] and none for forage constituents. The equivalence test showed that nine of the significantly different endpoints fell into equivalence category I or II, and cystine and methionine levels fell into equivalence category III (Table 5). Given the well-known function of cystine and methionine, the differences observed between glyphosate-treated soybean MON 87705 × MON 89788 and the comparator were considered to be of no relevance for food and feed safety.

Table 5: Compositional endpoints that are further discussed based on the results of the statistical analysis: means (for the comparator and the GM soybean) and equivalence limits (from the non-GM reference varieties) estimated from field trials data collected in 2009. For the GM soybean, significantly different entries are marked with an asterisk, while the outcomes of the test of equivalence are differentiated by greyscale backgrounds: white (equivalence category I or II), light grey (equivalence category III) and dark grey (equivalence category IV).

Endpoint	Comparator (A3525)	Soybean MON 87705 × MON 89788 Untreated [(a)]	Soybean MON 87705 × MON 89788 Treated [(b)]	Equivalence limits from non-GM reference varieties
Fatty acids				
Palmitic acid (16:0) (% FA) [(c)]	11.53	2.49*	2.50*	(9.54, 11.71)
Stearic acid (18:0) (% FA) [(c)]	3.84	2.85*	2.90*	(3.29, 4.31)
Oleic acid (18:1) (% FA) [(c)]	19.15	64.81*	65.04*	(15.05, 25.17)
Linoleic acid (18:2) (% FA) [(c)]	54.74	19.63*	19.4*	(50.65, 59.52)
Linolenic acid (18:3) (% FA) [(c)]	10.01	9.45*	9.38*	(8.68, 10.52)
Arachidic acid (20:0) (% FA) [(c)]	0.29	0.24*	0.24*	(0.25, 0.34)
Eicosenoic acid (20:1) (% FA) [(c)]	0.15	0.27*	0.27*	(0.13, 0.19)
Behenic acid (22:0) (% FA) [(c)]	0.29	0.27*	0.27*	(0.29, 0.35)
Amino acids				
Arginine (% dw)	3.06	3.16*	3.12*	(2.72, 3.15)
Cystine (% dw)	0.62	0.64*	0.64*	(0.57, 0.64)
Methionine (% dw)	0.58	0.59	0.59*	(0.54, 0.59)

(a): Untreated: soybean MON 87705 × MON 89788 not sprayed with the target herbicide (glyphosate).
(b): Treated: soybean MON 87705 × MON 89788 sprayed with the target herbicide (glyphosate).
(c): Fatty acid proportions are given as percentages of total fatty acids.
dw, dry weight.

The EFSA GMO Panel assessed all compositional differences between soybean MON 87705 × MON 89788 and the comparator, the measured biological variation in commercial non-GM soybean varieties, and concluded that soybean MON 87705 × MON 89788 has an altered fatty acid composition as compared with soybean A3525, the modified soybean oil being characterised by a reduced proportion of palmitic acid (16:0) and stearic acid (18:0), and an increase in oleic acid (18:1)

[25] Levels of ash, carbohydrates, arginine, cystine, histidine, lysine, methionine, tyrosine, vitamin E, phytic acid and genistein.

accompanied by a decrease in linoleic acid (18:2) (Table 5). With regard to non-fatty acid constituents, after considering the well-known biological role of the compounds concerned and the magnitudes of the changes observed (Table 5), the EFSA GMO Panel did not identify any need for further assessment with regard to food and feed safety.

4.2.2. Conclusion

The EFSA GMO Panel confirms that soybean MON 87705 × MON 89788 differs from the comparator and the non-GM soybean reference varieties by having an altered fatty acid profile. None of the other differences identified in the composition of grain and forage obtained from soybean MON 87705 × MON 89788 necessitated further assessment regarding food and feed safety.

The differences in agronomic and phenotypic characteristics observed in early stand count and plant vigour between soybean MON 87705 × MON 89788 and the comparator are further assessed for their potential environmental impact in Section 4.4.

4.3. Food and feed safety assessment

4.3.1. Effect of processing[26]

Soybean MON 87705 × MON 89788 will undergo the existing methods of production and processing used for commercial soybean. No novel methods of production and processing are envisaged.

Seeds of soybean MON 87705 × MON 89788 collected from the 2009 USA field trials were processed into refined bleached deodorised (RBD) oil and analysed for fatty acid composition.[27] The EFSA GMO Panel concluded that the intended effects of the genetic modification and the effects on the fatty acid pattern already seen in the analysis of unprocessed soybean seeds (Table 5) were also reflected in the composition of RBD oil obtained from soybean MON 87705 × MON 89788 (Table 6).

Table 6: Fatty acid composition of RBD oil and seed oil of soybean MON 87705 × MON 89788.

Fatty acid	RBD oil (% total FA) [(a)]	Seed oil (% total FA)
Palmitic acid (16:0)	2.46	2.50
Stearic acid (18:0)	2.88	2.90
Oleic acid (18:1)	63.6	65.04
Linoleic acid (18:2)	20.8	19.40
Linolenic acid (18:3)	9.42	9.38
Arachidic acid (20:0)	0.23	0.24
Eicosenoic acid (20:1)	0.30	0.27
Behenic acid (22:0)	0.26	0.27

(a): Average rounded value from duplicate fatty acid analyses of RBD oil.

The influence of the altered fatty acid pattern seen in the unprocessed soybean seeds on the various products obtained after seed processing was described and assessed by the EFSA GMO Panel for soybean MON 87705 (EFSA GMO Panel, 2012). The products studied included RBD oil, isolated soy protein, toasted defatted meal and crude lecithin.

As observed for MON 87705, the altered fatty acid composition of soybean MON 87705 × MON 89788 seeds is also reflected in the composition of the RBD oil.

The oil of soybean MON 87705 × MON 89788 has a fatty acid profile that is more similar to other types of vegetable oil (e.g. olive oil) than conventional soybean. Therefore, the production of food

[26] Dossier: Part II—Section A3.5..
[27] Additional information: 3/6/2015.

quality oil from soybean MON 87705 × MON 89788 (as from MON 87705) is expected to be kept separated from production of oil from conventional soybean varieties.

4.3.2. Toxicology

4.3.2.1. Toxicological assessment of newly expressed proteins[28]

The only newly expressed protein in soybean MON 87705 × MON 89788 is the CP4 EPSPS protein, expressed by both events. The EFSA GMO Panel has previously assessed this protein in the single events (see Table 1), as well as in other GMO applications (e.g. EFSA GMO Panel, 2014) and no safety concern for humans and animals was identified. The EFSA GMO Panel is not aware of any new information that would change these conclusions. The levels of CP4 EPSPS protein observed in seeds of soybean MON 87705 × MON 89788 are not considered to give rise to any concern regarding food and feed safety.

4.3.2.2. Toxicological assessment of components other than newly expressed proteins

The compositional analysis of soybean MON 87705 × MON 89788 identified changes in the fatty acid composition of the seeds (see Table 5).

All of these fatty acids occur naturally in the diet of humans and animals; the safety impact of the altered fatty acid profile is evaluated in Section 4.3.4.

4.3.3. Animal studies with the food/feed derived from GM plants

A report of a 42-day feeding study with a total of 960 male and female chickens for fattening (one-day-old Cobb 500) was provided.[29] The birds were randomly allocated to eight dietary treatments with 120 chickens per treatment (five pens/treatment per gender, initially 12 birds per pen, reduced to 10 on day seven). Soybean MON 87705 × MON 89788 (verified by PCR) was compared with its comparator and to six non-GM commercial varieties (Anand, Jake, Gateway 427, Hoffman HS387, NuPride 3202 and NuTech 315). Soybean MON 87705 × MON 89788 was treated with glyphosate.[30] The comparator and the commercial varieties were grown following local agriculture practice. The diets consisted mainly of corn and soybean meal (about 33 and 29 % in the starter and grower/finisher diets, respectively). Before feed formulation, all toasted defatted soybean meals were analysed for proximates, amino acids, mycotoxins and pesticide residues, corn and corn gluten meal for proximates and amino acids.[31] Toasted defatted soybean meal of MON 87705 × MON 89788 contained residual oil (1 %)[32] with the expected compositional changes in fatty acids profile. The starter diets (given on days 0-21) were calculated to contain 21.7 % crude protein (CP), 1.2 % lysine, 0.6 % methionine and 3090 kcal ME/kg. The grower/finisher diets (given on days 21-42) were calculated to contain 20.0 % CP, 1.1 % lysine, 0.55 % methionine and 3 135 kcal ME/kg. The calculated data were confirmed by analysis. Feed and water were provided for *ad libitum* intake.

Chickens were observed twice daily for clinical signs; deaths were recorded and necropsy performed on all birds found dead. Body weight and feed intake were measured at the start and at day 42. On day 43 and day 44, males and females were processed for carcass evaluation (yield, dressing percentage, and weight of thighs, breast, wings, legs, abdominal fat and whole liver). Data were statistically analysed by a two-factor analysis of variance (ANOVA) (diet and sex), and pair-wise comparison was made by the Fischer's Least Significant Difference test. A mixed linear model was applied to compare the soybean MON 87705 × MON 89788 group with the mean of all non-GM varieties.

[28] Dossier: Part II—Section A4.2.
[29] Dossier: Part II—MSL0022972; additional information: 17/2/2014.
[30] Additional information: 17/2/2014.
[31] Additional information: 17/2/2014.
[32] Dossier: Part I—MSL0022972; additional information: 17/2/2014.

Mortality was low (< 2 % in any treatment group). No significant treatment × sex interaction was detected for performance characteristics. Overall, no significant difference was seen in final body weight (about 2.8 kg), feed intake (about 4.4 kg), or feed to gain ratio (about 1.61) between the soybean MON 87705 × MON 89788 and the comparator, or the soybean MON 87705 × MON 89788 and the mean of the non-GM varieties. Carcass parameters were not significantly different between soybean MON 87705 × MON 89788 and the comparator or the overall mean of all non-GM varieties.

There was no evidence of unintended effects introduced by the genetic modification at the inclusion levels of about 30 % soybean MON 87705 × MON 89788 in complete feed. The EFSA GMO Panel concluded that toasted defatted soybean meal from MON 87705 × MON 89788 is as nutritious as the comparator and six non-GM commercial varieties.

4.3.4. Allergenicity

For the allergenicity assessment, a weight-of-evidence approach is followed, taking into account all of the information obtained on the newly expressed proteins, since no single piece of information or experimental method yields sufficient evidence to predict allergenicity (EFSA GMO Panel, 2011a; Codex Alimentarius, 2009). In addition, when known functional aspects of the newly expressed protein or structural similarity to known adjuvants may indicate an adjuvant activity, the possible role of these proteins as adjuvants is considered (EFSA GMO Panel, 2011a). When newly expressed proteins with a potential adjuvant activity are expressed together, possible interactions increasing adjuvanticity and impacting on the allergenicity of the GM crop are assessed.

4.3.4.1. Assessment of allergenicity of the newly expressed proteins[33]

With regard to allergenicity, the EFSA GMO Panel has previously evaluated the safety of the CP4 EPSPS protein, and no concerns about allergenicity were identified in the context of the applications assessed (e.g. EFSA, 2008; EFSA GMO Panel 2012, 2014). No new information on allergenicity of the newly expressed protein that might change the previous conclusions of the EFSA GMO Panel has become available. As regards adjuvanticity, no information available on the structure or function of the newly expressed CP4 EPSPS protein would suggest an adjuvant effect of the protein in soybean MON 87705 × MON 89788 resulting in or increasing an eventual immunoglobulin E (IgE) response to a bystander protein.

The EFSA GMO Panel considers that there are no indications that the newly expressed CP4 EPSPS protein in soybean MON 87705 × MON 89788 may be allergenic.

4.3.4.2. Assessment of allergenicity of the whole GM plant[34]

Soybean is considered to be a common allergenic food[35] (OECD, 2012). Therefore, any potential change in the endogenous allergenicity of the GM plant when compared with that of its comparator(s) should be assessed (EFSA GMO Panel, 2011a). Such assessments were performed for the single events soybean MON 87705 and soybean MON 89788, and no reasons for concern were identified by the EFSA GMO Panel (EFSA 2008; EFSA GMO Panel. 2012).

At the request of the EFSA GMO Panel, the applicant provided an assessment of the endogenous allergenicity[36] by comparing protein extracts of soybean MON 87705 × MON 89788 and of its comparator as determined by gel electrophoresis followed by mass spectrometry. The intensities of the bands corresponding to specific allergens were analysed. No relevant differences in the allergen

[33] Dossier: Part II—Section A5; additional information: 3/3/2015.
[34] Dossier: Part II—Section A5; additional information: 22/2/2013; 7/8/2013; 17/2/2014.
[35] Directive 2007/68/EC of the European Parliament and of the Council of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. OJ L 310, 27.11.2007, p. 11–14.
[36] Additional information: 22/2/2013; 7/8/2013; 17/2/2014.

content between the protein extracts of soybean MON 87705 × MON 89788 and of its comparator were identified.

The EFSA GMO Panel considers that there is no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON 87705 × MON 89788 compared with that of its comparator.

4.3.5. Nutritional assessment of GM food/feed

4.3.5.1. Human nutritional assessment

The main product for human consumption from soybean is the oil. The nutritional consequences of the modifications to the fatty acid profile were assessed in the context of the previous opinion on the single event MON 87705 (EFSA GMO Panel, 2012). Although high variability between-site was observed (Section 4.2.4), the fatty acid profile of soybean MON 87705 × MON 89788 seeds is similar as that of soybean MON 87705 seeds.[37] The fatty acid profile of the RDB oil of the soybean MON 87705 × MON 89788 is essentially the same as that of the unprocessed seeds.[38] Consequently, the EFSA GMO Panel concludes that the basis for the nutritional assessment made for soybean MON 87705 can be used also for the soybean MON 87705 × MON 89788.

The assessment of dietary exposure[39] covers all possible uses of soybean MON 87705 × MON 89788 oil, including both commercial and domestic uses as well as frying. Consumption data are taken from the UK National Diet and Nutrition Survey 2008-2010 (Bates et al., 2011). The estimated dietary intake (expressed as percentage of energy (E %) of the total diet) of fatty acid groups (saturated fatty acids (SFAs), monounsaturated fatty acids (MUFAs), n-3 polyunsaturated acids (PUFAs) and n-6 PUFAs) was based on fatty acid composition[40] of the unprocessed herbicide-treated soybean seeds MON 87705 × MON 89788,[41] using three substitution levels (100 %, 50 % and 25 %) of vegetable oils[42] with soybean MON 87705 × MON 89788 oil. The EFSA GMO Panel selected the 100 % substitution as the most conservative scenario arising from both domestic and commercial use of the vegetable oils.

Calculations based on the full replacement scenario indicated that fatty acid intakes would be closer to current dietary advice for MUFA and n-3 PUFA intake.

Linoleic acid is the main dietary *cis*-n-6 PUFA. EFSA has proposed an Adequate Intake for linoleic acid of 4 E % (EFSA NDA Panel, 2010). The previous assessment showed that intakes of n-6 PUFA for adults (50th and 97.5th centile) would fall by around 40 %, but it was concluded this was unlikely to be of concern, because linoleic acid deficiency has not been observed at intakes > 1E % (EFSA NDA Panel, 2010) and because the 100 % replacement by soybean MON 87705 × MON 89788 oil of vegetable oils in the diet is unlikely to occur (EFSA GMO Panel, 2013). However, data on low consumers of vegetable oils (*i.e.*, below the 5th centile), who are potentially at the greatest risk of linoleic acid deficiency, were not available at that time.

In the context of this application, an assessment was provided for the low (5th), average (50th) and high (95th) centile adults (Table 3).

[37] Additional information: 24/10/2014 (Table 2).
[38] Additional information: 3/6/2015 (Table 1).
[39] Additional information: 12/5/2014 (Exponet, 2014).
[40] Dossier: Part II— Section A3.3; additional information: 18/9/2013 and 17/2/2014.
[41] These seeds are harvested from the field trial in USA in 2009.
[42] Conventional soybean, rapeseed and sunflower oils. These three oils account for about 80% of vegetable oils available for consumption in the UK.

Table 7: Estimated daily intake (E %) of fatty acid groups before (B) and after (A) the replacement. Predicted changes in the total diet with respect to fatty acid groups (SFAs, MUFAs and PUFAs) are given as percentage of total energy in adults (19-64) years old for the 5th, 50th and 95th centile consumers through replacement of all consumed vegetable oils (soybean, rapeseed and sunflower) by soybean MON 87705 × MON 89788.

Fatty acid group	Males						Females					
	5th %(a)		50th %(b)		95th %(c)		5th %(a)		50th %(b)		95th %(c)	
	B	A	B	A	B	A	B	A	B	A	B	A
SFA	6.6	5.1	12.4	9.3	18.7	14.4	7.1	5.1	12.3	9.3	19.0	15.0
MUFA	7.1	9.7	11.8	16.1	16.5	22.6	7.0	9.6	11.7	16.0	16.0	21.8
n-3 PUFA	0.5	0.6	0.9	1.0	1.8	2.1	0.5	0.6	0.9	1.0	1.9	2.2
n-6 PUFA	2.4	1.7	4.7	3.4	7.3	5.3	2.7	1.9	4.6	3.4	7.8	5.7

(a); see Table 8-B-1 in [Exponent 2014].
(b): see Table 8-C-1 in [Exponent 2014].
(c): see Table 8-D-1 in [Exponent 2014]. [43]

As Table 7 shows that although a decrease in the intake of n-6 PUFA occurs in both males and females, this would still result in intakes of > 1 E %, which is greater than the level below which symptoms of linoleic deficiency may occur.

Although the dietary assessment considers only exposure of adults, the EFSA Dietary Reference Values report on fatty acids (EFSA NDA Panel, 2010) shows that intake data for n-6 PUFA for children from four European countries were similar to those of adults, therefore, the EFSA GMO Panel considers that the exposure assessment made in adults is valid also for children.

In conclusion, the profile of fatty acid intake, after substituting soybean MON 87705 × MON 89788 oil for conventional vegetable oils, is closer to current dietary advice for MUFA and n-3 PUFA intake. Although variability was observed in the fatty acid profile between-site (Section 4.2.1.4), only that affecting the linoleic acid content might give rise to concern, given the proximity of the intake values for low consumers (Table 7) to the level where symptoms of deficiency may occur. However, considering the conservative nature of the full replacement scenario in the exposure assessment, the magnitude of the differences observed would not be expected to introduce adverse effects on human health with respect to n-6 PUFA intake. This was demonstrated when partial replacement scenarios were considered.

Other soybean products for human consumption are not expected to differ in their composition, except for their fatty acid content. The contribution of fatty acids from such products to overall human exposure would be small and is not expected to affect the conclusion on human health and nutrition.

4.3.5.2. Animal nutritional assessment

Defatted toasted soybean meal represents the most common soybean by-product used in animal feed formulations, with around 90 % of the defatted soybean meal entering the feed chain in the European Union mainly for poultry, pig and cattle. Presently, only small amounts of full fat soybeans (1 % of the total soybean feed) are directly fed to food-producing animals. The use of soybean oil in animal feed is limited and only small amounts (0.5-3 %) are added to mixed feed (especially for poultry and pigs) in order to avoid dust, improve the quality/stability of pellets and add energy to the diets.[44]

Compositional data indicate that the defatted soybean meal from soybean MON 87705 × MON 89788 would be expected to deliver the same nutrition as its comparator and other non-GM commercial

[43] Additional information: 12/5/2014.
[44] Personal communication from Deutscher Verband für Tiernahrung, 29 July 2011

varieties. This was confirmed by results of a feeding study in chickens for fattening (see Section 4.3.3).

4.3.6. Post-market monitoring of GM food/feed

A proposal for a post-market monitoring plan needs to be provided by the applicant (EFSA GMO Panel, 2011a). EFSA recommends that the post-market monitoring plan should initially focus on the collection of import data for Europe. In the event of significant import such that a new exposure assessment is required, consumption data for the European population and concentration data for fatty acids in the oils would be needed.

For specific labelling, the applicant proposed that, for example, operators handling products containing or consisting of oil produced from soybean MON 87705 × MON 89788 shall be required to label these products with the words "increased oleic acid oil produced from genetically modified soybean". The EFSA GMO Panel considers that this proposal is consistent with the compositional data of this soybean.

4.3.7. Conclusion

The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly expressed CP4 EPSPS protein, and found no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON 87705 × MON 89788. Nutritional assessment on soybean MON 87705 × MON 89788 oil and oil-containing food products did not identify concerns on human health and nutrition. There are no concerns regarding the use of feedingstuffs derived from defatted soybean meal MON 87705 × MON 89788.

4.4. Environmental risk assessment and monitoring plan

4.4.1. Evaluation of relevant scientific data

Considering the scope of application EFSA-GMO-NL-2011-100, the environmental risk assessment (ERA) of the GM soybean is concerned mainly with: (1) the exposure of bacteria to recombinant DNA in the gastrointestinal tract of animals fed GM material and bacteria present in environments exposed to faecal material; and (2) the accidental release into the environment of viable seeds of soybean MON 87705 × MON 89788 during transport and processing.

As the scope of application EFSA-GMO-NL-2011-100 excludes cultivation, environmental concerns in the EU related to the use of glyphosate-based herbicides on the GM soybean do not apply.

4.4.2. Environmental risk assessment

4.4.2.1. Potential unintended effects on plant fitness due to the genetic modification[45]

Cultivated soybean (*Glycine max* (L.) Merr.) is a species in the subgenus *Soja* of the genus *Glycine*. The species originated from eastern Asia and is a highly domesticated crop (Lu, 2005). The major worldwide soybean producers are Argentina, Brazil, China, North Korea, South Korea and the USA. In the EU,[46] soybean is mainly cultivated in Italy, Romania, France, Hungary, Austria, Slovakia and the Czech Republic (Dorokhov et al., 2004; Krumphuber, 2008). Cultivated soybean seeds rarely display any dormancy characteristics and only under certain environmental conditions grow as volunteers in the year after cultivation. If volunteers occur, they do not compete well with the succeeding crop, and can easily be controlled mechanically or chemically (OECD, 2000). In soybean fields, seeds do not usually survive the winter owing to herbivory, rotting and germination resulting in death, or owing to management practices prior to planting the subsequent crop (Owen, 2005).

[45] Dossier: Part II—Section E3.1 and Appendix D.
[46] http://epp.eurostat.ec.europa.eu/portal/page/portal/agriculture/data/database

The expected changes in seed fatty acid composition in soybean MON 87705 × MON 89788 resulting from the introduced *FAD2-1A/FATB1-A* suppression cassette are not known to provide an agronomic or selective advantages. The herbicide tolerance trait can be regarded as providing only potential agronomic and selective advantages for this GM soybean plant where and when glyphosate-based herbicides are applied. However, survival of soybean plants outside cultivation where glyphosate-based herbicides are applied is limited, mainly by a combination of low competitiveness, absence of a dormancy phase, and susceptibility to plant pathogens and cold climatic conditions. Based on the inserted traits, the EFSA GMO Panel considers that these general characteristics are unchanged in soybean MON 87705 × MON 89788; herbicide tolerance is therefore unlikely to provide a selective advantage outside cultivation. Even if glyphosate-based herbicides are applied to these plants, this will not change their ability to survive over seasons. Therefore, it is considered very unlikely that soybean MON 87705 × MON 89788 will differ from conventional soybean varieties in its ability to survive until subsequent seasons or to establish feral populations under European environmental conditions.

Laboratory tests and field studies have been carried out to assess the phenotypic and agronomic characteristics as well as the environmental interactions of GM soybean as described in Section 4.2.1.3. Phenotypic and agronomic characteristics were evaluated in a field trial across eight locations in the USA in 2009. In addition, environmental interactions, such as soybean MON 87705 × MON 89788 responses to abiotic and biotic stressors, were evaluated in the same trials (i.e. they were not treated with glyphosate-based herbicides; for further details, see Section 4.2.1.3).

Considering the scope of application EFSA-GMO-NL-2011-100, special attention is paid to those agronomic characteristics that may affect the survival, establishment and fitness of soybean MON 87705 × MON 89788 grains which could be accidentally released into the environment: e.g. early and final stand count, plant vigour, 100-seed weight, plant height and yield. As described in Section 4.2.1.3, soybean MON 87705 × MON 89788 treated and not treated with glyphosate-based herbicides had a lower early stand count but a higher plant vigour than its non-GM comparator. Moreover, the equivalence test for the early stand count and plant vigour endpoints indicates that equivalence with non-GM reference varieties is more likely than not. For this reason and because these endpoints are relevant for the assessment of possible changes in persistence and invasiveness of the GM soybean, the significant differences observed in early stand count and plant vigour are further assessed below.

During the ERA of the single soybean transformation event MON 87705 (EFSA GMO Panel, 2012), the EFSA GMO Panel also observed that "*soybean MON 87705 had a lower early and final stand count and a lower 100-seed weight than its conventional counterpart"*. The observed differences in early stand count and plant vigour for soybean MON 87705 × MON 89788 might therefore be an indication of unintended effects due to the genetic modification. Differences in seed lot quality could also explain such observations; however, the information included in the dossier does not indicate such an effect.

Specific data on pollen viability, seed germination and dormancy for soybean MON 87705 × MON 89788 were not provided by the applicant. Therefore, the EFSA GMO Panel asked the applicant to clarify the origin and production conditions of the test materials used, and to justify that the best materials allowed a proper comparative assessment. The applicant did not provide additional data but did provide a rationale[47] relying on seed germination data for the two single soybean events[48] and data on the early stand count for soybean MON 87705 × MON 89788 compared with its comparator. The applicant concluded that "*the use of MON 87705 × MON 89788 and control materials that had similar genetic backgrounds except for the traits of interest, and the seed germination characteristics already provided, demonstrate the suitability of the test and control materials utilized in the comparative assessment*".

[47] Additional information: 08/05/2014.
[48] Section D.4 of EFSA-GMO-NL-2006-36 and Section D.4 of EFSA-GMO-NL-2010-78.

The EFSA GMO Panel therefore considered the data provided by the applicant on seed germination and dormancy of the single soybean events MON 87705 and MON 89788, their comparators and non-GM reference varieties, produced under different environmental conditions (see EFSA, 2008; EFSA GMO Panel, 2012). For soybean MON 89788, there were no differences observed in seed germination compared with its conventional counterpart under all controlled environmental conditions. For soybean MON 87705, differences in seed germination were observed under certain controlled environmental conditions. The observed differences were not associated with the characteristics of the sites from which the seeds were obtained and did not indicate a consistent plant response associated with the herbicide-tolerant event.

Considering the available dataset on soybean MON 87705 × MON 89788, and in the light of the scope of application EFSA-GMO-NL-2011-100, the EFSA GMO Panel did not expect changes in the seed germination characteristics of soybean MON 87705 × MON 89788.

Although the differences observed in early plant count and plant vigour might result from the genetic modification, they more likely indicate a decreased fitness of the GM soybean. The other characteristics of the GM soybean, relevant to persistence and invasiveness, are not changed. The EFSA GMO Panel therefore concludes that there is no indication of increased weediness potential of soybean MON 87705 × MON 89788 in the context of the scope of application EFSA-GMO-NL-2011-100.

Although the differences observed in early plant count and plant vigour might result from the genetic modification, they are unlikely to be biologically relevant in terms of increased weediness potential of soybean MON 87705 × MON 89788 in the context of the scope of application EFSA-GMO-NL-2011-100 and considering that the other characteristics of soybean MON 87705 × MON 89788, relevant to persistence and invasiveness, are not changed.

In addition to the data presented by the applicant, the EFSA GMO Panel is not aware of any scientific report of increased spread and establishment of existing GM soybeans and any change in the survival capacity, including overwintering (Dorokhov et al., 2004; Owen, 2005; Bagavathiannan and Van Acker, 2008; Lee et al., 2009).

Therefore, the EFSA GMO Panel is of the opinion that the likelihood of unintended environmental effects of the soybean MON 87705 × MON 89788 in Europe will not be different from that of conventional soybean varieties.

4.4.2.2. Potential for gene transfer[49]

A prerequisite for any gene transfer is the availability of pathways for the transfer of genetic material, either through horizontal gene transfer (HGT) of DNA or through vertical gene flow via seed dispersal and cross-pollination.

(a) Plant-to-bacteria gene transfer

The potential for HGT of the recombinant DNA of the single events has already been assessed in previous opinions (EFSA, 2008; EFSA GMO Panel, 2012) and no concern for an unlikely, but theoretically possible, HGT of the recombinant genes to bacteria in the gut or other receiving environments was identified.

Bioinformatic analyses revealed, for MON 87705, two left border sequences, one at the 5′-end and one at the 3′-end with perfect identity to the *Agrobacterium tumefaciens* Ti plasmid. The sequence between the borders of the plant insert has a length of 10 530 bp and carries a plant-codon optimized version of the *epsps* gene of *Agrobacterium* sp. CP4. The GMO panel assumes that the sequence identity of these two border sequences has the potential to facilitate double HR with Ti plasmids of

[49] Dossier: Part II—Sections E3.1–3.2.

environmental *A. tumefaciens* strains, resulting in the insertion of this 10 530 bp DNA fragment. The large size of this insert, however, decreases the probability for HGT. Considering the presence of native bacterial *epsps* genes and the codon optimization of the CP4 *epsps* gene, its transfer would not confer a new trait to bacterial recipients present in receiving environments. Recipients receiving a Ti plasmid with such a large DNA insert would also, most likely, be affected in their fitness because of the additional burden of replicating non-functional DNA in their cells during growth.

For the bioinformatic analyses of MON 89788, no sequence identity with bacterial DNA, including the CP4 *epsps* gene, which was plant codon optimized, were identified. Thus, there is no indication for facilitated gene transfer of recombinant DNA from MON 89788 to bacteria.

Synergistic effects of the recombinant genes in increasing the likelihood for HGT, for instance combinations of recombinogenic sequences, were not identified. Since soybean MON 87705 × MON 89788 is produced from conventional crossing, close linkage of the different events is extremely unlikely.

Therefore, in line with its previous assessment of soybean, MON 87705 and MON 89788, and considering the new, additional bioinformatic analyses provided by the applicant, the EFSA GMO Panel concludes that in the context of its intended uses, the unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87705 × MON 89788 to environmental bacteria does not give rise to any safety concern.

(b) Plant-to-plant gene transfer

Considering the scope of application EFSA-GMO-NL-2011-100 and the physical characteristics of soybean seeds, a possible pathway of gene dispersal is from seed spillage and pollen of occasional feral GM soybean plants originating from accidental seed spillage during transport and/or processing.

The genus *Glycine* is divided into two distinct subgenera: *Glycine* and *Soja*. Soybean is in the subgenus *Soja*. The subgenus *Glycine* contains 16 perennial wild species, while the cultivated soybean, *G. max*, and its wild and semi-wild annual relatives, *G. soja* and *G. gracilis*, are classified in the subgenus *Soja* (OECD, 2000). Owing to the low level of genomic similarity among species of the genus *Glycine*, *G. max* can cross only with other members of the *Glycine* subgenus *Soja* (Hymowitz et al., 1998; Lu, 2005). Hence, the three species of the subgenus *Soja* are capable of cross-pollination and the hybrid seed that is produced can germinate normally and produce plants with fertile pollen and seeds (Abe et al., 1999; Nakayama and Yamaguchi, 2002). However, since *G. soja* and *G. gracilis* are indigenous to China, Taiwan, Korea, Japan, the far-eastern region of Russia, Australia, the Philippines and the South Pacific, and since they have not been reported in other parts of the world where the cultivated soybean is grown (Dorokhov et al., 2004; Lu, 2005), the plant-to-plant gene transfer from soybean is restricted to cultivated areas and the occasional soybean plants resulting from seed spillage in the EU.

Soybean is an annual almost completely self-pollinating crop in the field, which has a percentage of cross-pollination of usually less than 1 % (Weber and Hanson, 1961; Caviness, 1966; Ray et al., 2003; Lu, 2005; Yoshimura et al., 2006; Abud et al., 2007). Soybean pollen dispersal is limited because the anthers mature in the bud and directly pollinate the stigma of the same flower (OECD, 2000).

However, cross-pollination rates as high as 6.3 % have been reported for closely spaced plants (Ray et al., 2003), suggesting the potential for some within-crop gene flow in soybean. These results indicate that natural cross-pollination rates can fluctuate significantly among different soybean varieties under particular environmental conditions such as favourable climate for pollination and an abundance of pollinators (Gumisiriza and Rubaihayo, 1978; Kikuchi et al., 1993; Ahrent and Caviness, 1994; Ray et al., 2003; Lu, 2005).

Plant-to-plant gene transfer could therefore occur under the following scenarios: imports of soybean MON 87705 × MON 89788 seeds (although most MON 87705 × MON 89788 grains will be processed in the countries of production), processing outside importing ports, transport in regions of soybean production in Europe, spillage of GM seeds during transport, germination and development of spilled seeds within soybean fields or in very close vicinity to cultivated soybean fields, overlap of flowering periods and environmental conditions favouring cross-pollination. The overall likelihood of cross-pollination between GM soybean plants and cultivated soybean is therefore extremely low. Apart from seed production areas, GM plants and plants derived from out-crossing with this GM soybean will not persist over time. Dispersal of soybean seeds by animals is not expected owing to the characteristics of the seed, but accidental release into the environment of seeds may occur during transport and processing for food, feed and industrial uses. However, cultivated soybean seeds rarely display any dormancy characteristics and only under certain environmental conditions grow as volunteers in the year after cultivation (OECD, 2000). Even in soybean fields, seeds do not usually survive the winter because of predation, rotting or germination resulting in death, or as a result of management practices prior to planting the subsequent crop (Owen, 2005).

The EFSA GMO Panel takes into account that this application does not include cultivation of the soybean within the EU so that the likelihood of cross-pollination between cultivated soybean and occasional soybean plants resulting from seed spillage is considered extremely low. However, in countries cultivating this GM soybean and producing seed for export, there is a potential for admixture in seed production and thus the introduction of GM seeds through this route. Hence, it is important that appropriate management systems are in place to restrict seeds of soybean MON 87705 × MON 89788 entering cultivation as this would require specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

In conclusion, as soybean MON 87705 × MON 89788 has no altered survival, multiplication or dissemination characteristics, the EFSA GMO Panel is of the opinion that the likelihood of unintended environmental effects as a consequence of spread of genes from this GM soybean in Europe will not differ from that of conventional soybean varieties.

4.4.2.3. Potential interactions of the GM plant with target organisms[50]

Considering the scope of application EFSA-GMO-NL-2011-100, and in the absence of target organisms, potential interactions of the GM plant with target organisms were not considered a relevant issue by the EFSA GMO Panel.

4.4.2.4. Potential interactions of the GM plant with non-target organisms[51]

Considering the scope of application EFSA-GMO-NL-2011-100, and the low level of exposure to the environment, potential interactions of the GM plant with non-target organisms were not considered a relevant issue by the EFSA GMO Panel.

4.4.2.5. Potential interactions with the abiotic environment and biogeochemical cycles[52]

Considering the scope of application EFSA-GMO-NL-2011-100, and the low level of exposure to the environment, potential interactions with the abiotic environment and biogeochemical cycles were not considered a relevant issue by the EFSA GMO Panel.

4.4.3. Post-market environmental monitoring[53]

The objectives of a post-market environmental monitoring (PMEM) plan, according to Annex VII of Directive 2001/18/EC, are (1) to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO, or its use, in the ERA are correct; and (2) to identify the

[50] Dossier: Part II—Section E3.3.
[51] Dossier: Part II—Section E3.4.
[52] Dossier: Part II—Section E3.6.
[53] Dossier: Part II—Section E4.

occurrence of adverse effects of the GMO, or its use, on human health or the environment that were not anticipated in the ERA.

Monitoring is related to risk management, and thus a final adoption of the PMEM plan falls outside the mandate of EFSA. However, the EFSA GMO Panel gives its opinion on the scientific content of the PMEM plan provided by the applicant (EFSA, 2006; EFSA GMO Panel, 2011b). The potential exposure to the environment of soybean MON 87705 × MON 89788 would be through faecal material from animals fed the GM soybean or through accidental release into the environment of GM soybean seeds during transport and processing. The EFSA GMO Panel is aware that, owing to the physical characteristics of soybean seeds and the methods of transport used, accidental spillage cannot be excluded. Hence, it is important that appropriate management systems are in place to restrict seeds of soybean MON 87705 × MON 89788 entering cultivation, as this would require specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

The PMEM plan proposed by the applicant includes (1) the description of an approach involving operators (federations involved in soybean import and processing) reporting to the applicant via a centralised system any observed adverse effect(s) of GMOs on human health and the environment; (2) a coordinating system established by EuropaBio for the collection of the information recorded by the various operators; and (3) the use of networks of existing surveillance systems (Lecoq et al., 2007; Windels et al., 2008). The applicant proposes to submit a PMEM report on an annual basis and a final report at the end of the consent.

The EFSA GMO Panel is of the opinion that the PMEM plan proposed by the applicant is in line with the scope of application EFSA-GMO-NL-2011-100, as the ERA did not cover cultivation and identified no potential adverse environmental effects. No case-specific monitoring is necessary. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan.

4.4.4. Conclusion

Considering the scope of application EFSA-GMO-NL-2011-100, there are no indications of an increased likelihood of establishment and spread of feral soybean MON 87705 × MON 89788 plants in the event of accidental release into the environment of viable GM soybean seeds. Potential interactions of soybean MON 87705 × MON 89788 with the biotic and abiotic environment were not considered a relevant issue by the EFSA GMO Panel. The unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87705 × MON 89788 to environmental bacteria does not give rise to a safety concern owing to the lack of a selective advantage in the context of its intended uses. The PMEM plan provided by the applicant and the reporting intervals are in line with the scope of application EFSA-GMO-NL-2011-100.

CONCLUSIONS AND RECOMMENDATIONS

No new data on the single soybean events MON 87705 and MON 89788 that would lead to a modification of the original conclusions on their safety were identified.

The combination of soybean single events MON 87705 and MON 89788 in the two-event stack soybean MON 87705 × MON 89788 did not give rise to issues—relating to molecular, agronomic, phenotypic or compositional characteristics—regarding food and feed safety. The EFSA GMO Panel considers that there is no reason to expect interactions that could impact on the food and feed safety or nutritional properties.

No differences in composition requiring further assessment for food/feed safety were observed between soybean MON 87705 × MON 89788 and its comparator, except for the intended trait i.e. altered fatty acid profile. Nutritional assessment on soybean MON 87705 × MON 89788 oil and oil-containing food products did not identify concerns on human health and nutrition. There are no concerns regarding the use of feedingstuffs derived from defatted soybean meal MON 87705 × MON 89788. The EFSA GMO Panel is of the opinion that soybean MON 87705 × MON 89788 is as safe,

and at least as nutritious, as its comparator and commercial soybean varieties, in the context of the scope of application EFSA-GMO-NL-2011-100.

Considering the scope of application EFSA-GMO-NL-2011-100, there are no indications of an increased likelihood of establishment and spread of feral soybean MON 87705 × MON 89788 plants in the case of accidental release into the environment of viable GM soybean seeds. Potential interactions of soybean MON 87705 × MON 89788 with the biotic and abiotic environment were not considered a relevant issue by the EFSA GMO Panel. The unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87705 × MON 89788 to environmental bacteria does not give rise to any safety concern owing to the lack of a selective advantage in the context of its intended uses. The PMEM plan provided by the applicant and the reporting intervals are in line with the scope of application EFSA-GMO-NL-2011-100.

In conclusion, the EFSA GMO Panel considers that the information available for soybean MON 87705 × MON 89788 addresses the scientific comments raised by Member States and that soybean MON 87705 × MON 89788, as described in this application, is as safe as its non-GM comparator and the non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of the application.

Considering the modified composition and nutritional values of soybean MON 87705 × MON 89788, the EFSA GMO Panel agrees with the specific labelling proposal provided by the applicant, in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the Competent Authority of the Netherlands, received on 17 August 2011 concerning a request for authorisation for placing on the market of genetically modified soybean MON 87705 × MON 89788 submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V. (application reference EFSA-GMO-NL-2011-100)

2. Acknowledgement letter dated 5 September 2011 from EFSA to the Competent Authority of the Netherlands.

3. Letter from EFSA to applicant dated 27 September 2011 requesting additional information under completeness check.

4. Letter from applicant to EFSA received on 1 June 2012 providing additional information under completeness check.

5. Letter from EFSA to applicant dated 22 June 2012 requesting additional information under completeness check.

6. Letter from applicant to EFSA received on 9 July 2012 providing additional information under completeness check.

7. Letter from EFSA to applicant dated 1 August 2012 (effective from 30 July 2012) delivering the "Statement of Validity" of the application for the placing on the market of genetically modified soybean MON 87705 × MON 89788 (EFSA-GMO-NL-2011-100) submitted in accordance with Regulation (EC) No 1829/2003 Monsanto Europe S.A./N.V.

8. Letter from EFSA to applicant dated 2 August 2012 stopping the clock due to the on-going risk assessment of the single event MON 87705 (application EFSA-GMO-NL-2010-78).

9. Letter EFSA to applicant dated 9 October 2012 re-starting the clock due to the finalisation of the risk assessment of the single event MON 87705 (application EFSA-GMO-NL-2010-78).

10. Letter from EFSA to applicant dated 11 February 2013 requesting additional information and stopping the clock.

11. Letter from applicant to EFSA received on 22 February 2013 providing additional information.

12. Letter from EFSA to applicant dated 10 April 2013 requesting additional information and maintaining the clock stopped.

13. Letter from EFSA to applicant dated 11 April 2013 requesting additional information and maintaining the clock stopped.

14. Letter from applicant to EFSA received on 22 May 2013 providing additional information.

15. Letter from EFSA to applicant dated 27 June 2013 requesting additional information and maintaining the clock stopped.

16. Letter from applicant to EFSA received on 2 July 2013 providing additional information.

17. Letter from applicant to EFSA received on 7 August 2013 providing additional information.

18. Letter from EFSA to applicant dated 5 September 2013 requesting additional information and maintaining the clock stopped.

19. Letter from applicant to EFSA received on 18 September 2013 providing additional information.

20. Letter from EFSA to applicant dated 29 November 2013 requesting additional information and maintaining the clock stopped.

21. Letter from applicant to EFSA received on 17 February 2014 providing additional information.

22. Letter from EFSA to applicant dated 19 February 2014 requesting additional information and maintaining the clock stopped.

23. Letter from applicant to EFSA received on 12 May 2014 providing additional information.

24. Letter from EFSA to applicant dated 25 July 2014 requesting additional information and maintaining the clock stopped.

25. Letter from applicant to EFSA received on 24 October 2014 providing additional information.

26. Letter from EFSA to applicant dated 27 November 2014 requesting additional information and maintaining the clock stopped.

27. Letter from EFSA to applicant dated 27 February 2015 requesting additional information and maintaining the clock stopped.

28. Letter from applicant to EFSA received on 9 April 2015 providing additional information.

29. Letter from applicant to EFSA received on 1 June 2015 providing additional information.

30. Letter from EFSA to applicant dated 15 June 2015 re-starting the clock.

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