Application EFSA-GMO-NL-2010-85 (soybean MON 87769 x MON 89788) **Comments and opinions submitted by Member States during the three-months consultation period**				
Comments from National Competent Authorities under Directive 2001/18/EC				
Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Austria	Federal Ministry of Health	General comments	The notification for GM soybean MON87769xMON89788 was submitted in 2010, however the assessment of this notification started only recently after finalisation of the risk assessment of both single events involved in the construction of GM soybean MON87769xMON89788. Therefore, the notification at hands is structured according to guidance which was revised since (e.g. according to EFSA 2004, which was replaced by EFSA 2010 in the meantime). Thus, the notification for GM soybean MON87769xMON89788 does not fully take into account the updated requirements and standards concerning the structure and content of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003 included in current legislation and guidance (e.g. EFSA 2010; EFSA 2011; EC 2013; EFSA 2013). Furthermore, the notification contains outdated information and references (including a number of non-functional URLs linking to relevant information). Therefore, EFSA needs to assess the respective shortcomings of the notification at hands and - where appropriate and necessary - request updated information according to the existing requirements and standards. [EC, 2013. Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. Official Journal of the European Union. L 157/1: 1-48.	The EFSA GMO Panel has the task to evaluate whether the risk assessment performed by the applicant for soybean MON 87769 x MON 89788 is adequate. In order to guide the applicant on how to present their risk assessment the EFSA GMO Panel regularly updates its guidance. The applicant has followed the guidance applicable when they supplied their application. In case the EFSA GMO Panel finds it necessary to have additional information, it has the possibility to request more data or information from the

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			EFSA, 2004. Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal 99: 1-94. EFSA, 2010. Guidance of the GMO Panel on the environmental risk assessment of genetically modified plants. The EFSA Journal 8(11):1879: 1-111. EFSA, 2011. Guidance of the GMO Panel on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. The EFSA Journal 9(8):2316: 1-40. EFSA, 2013. Guidance on the submission of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003. The EFSA Journal 11(12):3491: 1-133.]	applicant.
Austria	Federal Ministry of Health	D, 02 Information on the sequences actually inserted or deleted	D.2 (a) The size of the copy number of all detectable inserts, both complete and partial: The molecular description provided by the notifier for the transgene inserts present in GM Soybean MON87769xMON89788 is based on an analysis by Southern blot to assess the integrity of inserts in GM soybean MON87769xMON89788 compared with the respective inserts in the parental GM lines GM Soybean MON87769 and MON89788 (Technical Dossier p. 32ff, FROM CBI: REG-08-383 MSL0022285). However, this analysis cannot establish a detailed characterisation of the transgenic inserts present in the stacked event, but allows for a coarse comparison with the parental events only. Furthermore, the notifier does not indicate how many plant individuals were checked for	The GMO Panel considers that the restriction enzyme/probes combination used are sufficient to conclude that the integrity of the inidivual inserts is conserved in the stacked GM line. The stability of the single inserts was demonstrated in the respective single applications (*see* Section D.2.a of Application EFSA-GMO-UK-2009-76 (Monsanto Company, 2009), Page 46 and in Application EFSA-GMO-NL-2006-36 (Monsanto Company, 2006), Page 29, for

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			preservation of insert integrity in these experiments. In our view, additional data should be submitted to establish the molecular identity of the inserts present in GM soybean MON87769xMON89788 and the parental GM lines. The available data cannot identify minor alterations in the inserts and provide evidence to support the assumption of the notifier that no interaction is to be expected between inserts in GM soybean MON87769xMON89788. The notifier is, therefore, requested to submit further data to assess this issue. Additional data are also necessary to provide evidence that the inserts are stably inherited. [Paul S, Girault RL, Tian Q, 2010. Southern blot analysis to confirm the presence of MON 87769 and MON 89788 in the combined trait soybean product MON 87769 x MON 89788. Dossier EFSA/GMO/NL/2010/85.]	MON 87769 and MON 89788, respectively). The molecular characterisation of the events has been assessed in the frame of the single events. The maintenance of the structure of the singles in the stacks has been analysed with Southern blots, which is in line with the EFSA Guidance document (EFSA, 2007). As the stacked event was achieved by conventional crossing, no changes in the molecular structure of the single events are expected to occur. There is no particular reason for increased instability in the cross between the two soybean events. The Southern analysis is enough to confirm these assumptions.
Austria	Federal Ministry of Health	D, 02 Information on the sequences actually inserted or deleted	D.2 (a) The size of the copy number of all detectable inserts, both complete and partial: Specific comments: The applicant maintains that "MON 87769 × MON 89788 contains: The single DNA insert from the genome of MON 87769 (Table 3 and Figure 2), containing the Pj.D6D and Nc.Fad3 expression cassettes consisting of: the 7Sα' promoter and leader, the Pj.D6D coding sequence, tml transcript termination sequence, the 7Sα promoter and leader, the Nc.Fad3 coding sequence and the E9 transcript termination sequence." (see page 33 of the Technical Dossier). This conclusion is not supported by the presented	The GMO Panel considers that the restriction enzyme/probes combination allows to verify the integrity of the flanking regions and the whole insert in line with EFSA Guidance documents (EFSA, 2007).

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			data. According to the relevant EFSA guidance (EFSA 2007, page 3), the applicant is requested to "ensure that probe-restriction enzyme combinations used are sufficient to prove intactness and stability of the insert and including the flanking regions." For characterisation of the transgenic insert of MON87769 in the double stack the applicant applies a single probe covering - according to Figure 2 of the Technical Dossier - roughly the coding region of the NC.FAD3 gene. The applicant is, thus, providing only information about the status of the FAD3 gene senso strictu. There is no probe-based information available about the intactness of the remaining genetic elements (i.e. 7S alpha', Pj.D6D, tml, E9 and the left and right T-DNA border sequences). Information about the flanking regions is missing completely. Moreover, the upper band in Figure 5, lane 5, is distinctly retarded, the lower band shifted compared to the single event displayed in lane 4. Interestingly, the banding pattern for the second event MON89788 displayed in Figure 6 (Technical Dossier, page 35, Lanes 5 and 6) is correct. The presented banding pattern in Figure 5 is indicative only for the presence of a single transgenic MON87769 insert of approximately the expected size but does not per se provide exact information about its intactness in the double stack. Additionally, we would like to mention that the probes used for the detection of MON89788 cover the Tsf1 promoter, the Tsf1 leader, the CTP2 transit peptide and the epsps coding sequence. The Tsf1 intron and the E9 terminator sequences	Southern analysis has its advantages, limitations and sources of error which should be understood when designing experiments and interpreting the results (Southern, 2006, Nature Protocols 1, 518-525). Overall, the Southern analyses presented in the dossier are fit for purpose and properly performed. The GMO Panel considers that the restriction enzyme/probes combination used are sufficient to conclude that the integrity of the inidivual inserts is conserved in the stacked GM line.

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			and the genomic flanking regions are not covered. As the applicant provide only two Southern blots for the molecular characterisation of the double stack a restrictive approach is indicated. Exact Southern blot banding patterns are mandatory in this case. Band shifts are not to be accepted. The EFSA GMO Panel is, therefore, asked to request new Southern blot data using probes covering the whole transgenic insert of MON87769 and producing a correct banding pattern or, preferably, ask for sequence information covering the insert and the flanking genomic regions in the double stack to exclude any uncertainties about the intactness of the transgenic insert. [EFSA, 2007. Guidance document of the GMO Panel for the risk assessment of genetically modified plants containing stacked transformation events. The EFSA Journal 512: 1-5.]	
Austria	Federal Ministry of Health	D, 02 Information on the sequences actually inserted or deleted	D.2 (b) The organisation of the inserted genetic material at the insertion site and methods used for the characterisation: i) Updated bioinformatic analysis of the MON 87769 flanking sequences: The applicant maintains that an "E-score cut-off of less than or equal to 1e-6 (for BLASTn) or 1e-8 (for BLASTx) provides the best compromise between search sensitivity while still minimizing the number of false positives" (Technical Dossier, page 36). We would like to indicate that these are completely arbitrary numbers without any scientific evidence provided by the applicant why these numbers should be chosen as cut-	The applicant initially used the rather stringent E-score cut-offs of 1e-6 (for BLASTn against EST and NT databases) and 1e-8 (for BLASTx against NR database). As no alignments were obtained, all searches were repeated with less stringent E-score cut-off of 10. These outputs are reported and discussed in RAR-10-203. This is in line with the recommendations of the GMO Panel, who asks applicants to provide the best hits regardless of applied E-value

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			offs. Interestingly, the applicant itself refers to a completely different number. "Typically, alignments between two sequences will need to have an E-score of 1e-5 (1×10-5) or smaller to be considered to have significant homology" (FROM CBI: RAR-10-203, page 8) in his report on bioinformatic evaluation of MON87769. We would like to ask the EFSA GMO Panel to request a scientific reference (or statistical calculations) indicating 1e-6 to be the optimal cut-off value for the purpose envisioned. Technical Dossier, page 38: The applicant maintains that "it is unlikely that genes or ORFs were disrupted by the T-DNA insertion in MON 89788, or that the T-DNA insert in MON 89788, within the limits of the query sequence, is not adjacent to endogenous ORFs or genes." That is not correct. The correct sentence is: "it is unlikely that genes or ORFs were disrupted by the T-DNA insertion in MON 89788, or that the T-DNA insert in MON 89788, within the limits of the query sequence, is adjacent to endogenous ORFs or genes." D.2 (c) In the case of deletion(s), size and function of the deleted region(s): The applicant maintains that "…the characteristics of the insertions and the 5' and 3' flanking sequences should be conserved in this combined-trait product." We would like to ask the EFSA GMO Panel to request the relevant sequence information for the double stack to exclude any uncertainties.	thresholds. The GMO Panel takes note of this comment. Resequencing of the stacked GM line is not required in the EFSA guidance document (EFSA GMO Panel, 2007). In addition, the restriction enzyme/probes combination used are sufficient to conclude that the integrity of the inidivual inserts is conserved in the stacked GM line. The cost-effectiveness of the techniques used for data generation supporting the risk assessment is not a factor that is taken into account by the GMO Panel.

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			Sequencing would require a reasonable additional expenditure of mere several hundred dollars for the applicant and should nowadays be no obstacle for providing confidence in food/feed safety anymore. D.2 (e) All sequence information (in electronic format) including the location of primers used for detection: We would like to point to the fact that there is no sequence information available from the double stacked event. Sequence information obtained for the single event is only an indirect - surrogate - marker for the intactness of the transgenic inserts in the double stack. We would like to ask the EFSA GMO Panel to request the relevant sequence information using DNA isolated from MON87769xMON89788 plants to exclude any uncertainties about the intactness of the recombinant DNA inserts and the genomic flanking regions. [RAR-10-203. Dossier EFSA/GMO/NL/2010/85.]	
Austria	Federal Ministry of Health	D, 03 Information on the expression of the insert	For the assessment of the developmental expression of the transgenic inserts tissues were collected from field trials at five locations in the US grown in 2007. At each trial plant tissues from the stacked GM soybean MON87769xMON89788, two positive controls (i.e. the parental lines MON87769 and MON89788) as well as a negative control (conventional soybean A3525) were collected (Technical Dossier, p. 39). The levels of the desaturase enzymes (PjΔ6D & NcΔ15D) as well as the CP4 EPSPS protein levels were assessed in four different plant	

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			tissues (leaf, root, forage and seed). Leaf material was tested at various development stages (V3-V4, V6-V8, V10-V12 and V14-V16) and immature as well as mature seeds were tested. Means, standard deviations and ranges were presented for each tissue type across sites (FROM CBI: REG-08-553 MSL0022224). According to the production plan 07-01-83-27 (FROM CBI: referred to as 07-01-83-27 MSL0021807 in MSL 0021916), two entries, namely the stacked soybean MON87769xMON89788 and the parental herbicide tolerant control MON89788, were treated with glyphosate while the other parent, MON87769, and the control received conventional herbicide treatments (FROM CBI: 07-01-83-27 MSL0021807, p. 5 and Tab. 8). However, the EFSA Opinion on statistical considerations states that three test materials are to be compared (EFSA 2010): treated GM plant, the untreated GM plant and the conventional control. This requirement for the experimental design used in food & feed risk assessment of herbicide tolerant plants has meanwhile been confirmed in the EFSA Opinion on the selection of comparators (EFSA 2011). The data presented do not include an untreated GM soybean MON87769xMON89788 as comparator and thus also lack a respective statistical comparison. Thus in this application the basic EFSA requirements - with respect to the trial design for the food & feed risk assessment of GM herbicide tolerant plants are not fulfilled. While the levels of CP4 EPSPS protein were assessed by ELISA, the levels of the PjΔ6D & NcΔ15D proteins were	The comparison of the expression levels of the newly expressed proteins in the singles and the stack has be performed in accordance with the applicable guidance document (EFSA, 2007).The GMO panel acknowledges that the herbicide treatments were different for the stack and for MON 87769. However, the plants were treated at a stage early in flower development, whereas the desaturase proteins are designed to be expressed in the seeds. In addition, considering the nature of the promoter used to express the desaturase genes, there is no reason to expect an effect of glyphosate their expression levels. The guidance for risk assessment of food and feed from genetically

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			assessed by western blot. The latter method is associated with technical uncertainties as regards quantification, and is consequently regarded as "semi-quantitative" by EFSA (2014). However, the level of uncertainty associated with the assessment of expression of PjΔ6D & NcΔ15D proteins in GM soybean MON87769xMON89788 and its significance for the assessment of exposure levels is not discussed by the notifier. Such a discussion should be provided by the notifier. [MSL 0021916. Dossier EFSA/GMO/NL/2010/85]. [07-01-83-27 MSL0021807. Dossier EFSA/GMO/NL/2010/85]. EFSA, 2010. Scientific opinion of the GMO Panel on statistical considerations for the safety evaluation of GMOs. The EFSA Journal 8(1):1250: 1-59. EFSA, 2011. Guidance of the GMO Panel on selection of comparators for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal 9(5):2149: 1-21. EFSA, 2014. Scientific Opinion of the GMO Panel on application (EFSA-GMO-UK-2009-76) for the placing on the market of soybean MON 87769 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal 12(5):3644: 1-41. REG-08-553 MSL0022224. Dossier EFSA/GMO/NL/2010/85.]	modified plants (2011) gives freedom to the applicant in terms of the method used for expression analysis. PjΔ6D and NcΔ15D are membrane proteins that are expressed in very low amounts even in the GM plant. This poses particular challenges compared to soluble proteins such as EPSPS, for which it is reasonable to develop an ELISA method. The problematics is discussed in detail in the dossier for MON 87769 (EFSA-GMO-UK-2009-76).
Austria	Federal Ministry of	D, 03 Information	D.3 (c) Expression of potential fusion proteins:	

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	Health	on the expression of the insert	The applicant maintains that "as supported by the Southern blot analysis of MON 87769 × MON 89788, the molecular structure of the inserts has been conserved in the combined-trait product, including the junctions of the inserts." We would like to refer again to the shortcomings of the only two Southern blots supplied for the molecular characterisation of the double stack MON87769xMON89788 (see comments in Section 2a). Without any additional (sequence-) information the provided Southern blot information is insufficient to exclude small genetic rearrangements in the double stack.	The GMO Panel considers that the restriction enzyme/probes combination used are sufficient to conclude that the integrity of the inidivual inserts is conserved in the stacked GM line.
Austria	Federal Ministry of Health	D, 04 Information on how the GM plant differs from the recipient plant in:	D.4. Information on how the GM plant differs from the recipient plant in: reproduction, dissemination, survivability: For the assessment of differences in reproduction, dissemination and survivability of GM soybean stack MON87769xMON89788 compared to the conventional control phenotypic, agronomic and ecological interactions data (i.e. abiotic stress response, disease damage, and arthropod damage data) were assessed in field trials in Argentina in 2007/08 at five locations (Technical Dossier, p. 48ff). At each site four commercially available reference varieties were grown (Two of them were grown at each site which amounts to all in all twelve reference varieties) (FROM CBI: Study # REG-07-300 MSL0022215). The notifier concludes that there were "no unexpected changes in the phenotype or ecological interactions of GM soybean MON87769xMON89788 as a result of the inherited traits that could indicate increased pest or weed potential" (Technical Dossier, p.51). However, the data basis provided has several weak points: * In our view, the selected phenotypic and agronomic characteristics are not specific enough to assess ecological	Considering the scope of application EFSA-GMO-NL-2010-85, special attention is paid to those agronomic and phenotypic characteristics (for further details, see Section 4.2) which may be indicative of changes in the survival of soybean MON 87769 x MON 89788 grains which could be accidentally released into the environment, as well as in the establishment and fitness of GM soybean plants: e.g. early and final stand count, yield, seedling vigour and 100 seed weight. In this respect, the EFSA GMO Panel was satisfied with the data package provided by the applicant. As described in Section 4.2, all these agronomic and phenotypic characteristics, except plant height, of soybean MON 87769 x MON 89788 did not differ from those of its comparator. Soybean MON 87769 x MON 89788 not treated with glyphosate-based herbicides had a higher plant height than its comparator in the across-site analysis. The measured values for this characteristic fell within the natural range set by a set of reference varieties. The observed difference in plant height is unlikely to be biologically relevant in terms of increased persistence and invasiveness potential. Against this background, and considering the submission date of application EFSA-GMO-NL-2010-85, data on seed germination were

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			behaviour like persistence and invasiveness. Irrespective of the scope a basic set of information, including for instance specific seed dormancy and germination studies and volunteer assessments, should be presented to thoroughly check for unintended effects. * The notifier states that GM soybean MON87769xMON89788 was grown under agronomic practices characteristic for the region (FROM CBI: Study # REG-07-300 MSL0022215). As the production plan is missing it remains unclear what kind of maintenance applications of herbicides and/or other plant protection products this implied. However, agronomic control practices may suppress insect and disease infestations to a level at which no differences between the treatments are observed any longer. * Three of the five trial sites were located in the same province (i.e. Buenos Aires), which share the same soil characteristics, crops history and similar historical weather data. As no rationale for the selection of the trials sites is presented the notifier's claim that the field trials represent "a range of environmental and agronomic conditions representative of the Argentinian soybean growing regions" is not substantiated. * The plot size used in this experimental design is not comparable to common agricultural practice and most of all not adequate for the assessment of differences in arthropod abundance. Therefore, we request the notifier to submit the production plan of the field trials conducted in Argentina in 2007/08 and to evaluate if the insect and disease control practices applied	not systematically required. Instead the EFSA GMO Panel followed a rationale considering the seed germination data on the two parental lines as well as the data provided on the early stand count of soybean MON 87769 x MON 89788. No statistically significant difference was observed in seed germination of soybean MON 87769 and soybean MON 89788 compared to their respective conventional counterparts across all sites. In addition, the early stand count data on soybean MON 87769 x MON 89788 indicated that changes in seed germination are unlikely. The EFSA GMO Panel considered the description of the field trial sites and the design provided in Study # REG-07-300 MSL0022215, sufficient to conclude on the agronomic and phenotypic characteristics ofsoybean MON 87769 x MON 89788.

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			may have interfered with the assessments of insect and disease infestation. In this respect, clarification is needed whether the expected agricultural condition (i.e. the application of the complementary herbicide glyphosate) has been taken into account. Moreover we request a rationale for the selection of the different test sites as well as evidence for their representativeness for geographic regions, where soybean is commercially grown. [Study # REG-07-300 MSL0022215. Dossier EFSA/GMO/NL/2010/85.]	
Austria	Federal Ministry of Health	D, 04 Information on how the GM plant differs from the recipient plant in:	Additional comment on missing reproductive studies: With respect to potential alterations of reproductive biology of soybean MON87769xMON89788, the safety of the GM plant is entirely based on risk assessment data of the single events. It would be satisfying if data for a comparative assessment of dormancy, germination and the pollen viability characteristics of the stacked event compared to its non-GM counterpart were submitted. Both single event studies on reproductive biology (MON87769, MON89788) revealed weaknesses: The control seed samples (non-GM comparators) contained levels up to ≤3.05% of GM material (FROM CBI: MSL-20187; MSL0020773). EFSA (2007) guidance for GM stacked events points out "changes to agronomic and phenotypic characteristics may be indicative of unintended effects…". With regard to the evaluation of potential unintended effects, it is unclear and	Considering the scope of application EFSA-GMO-NL-2010-85, special attention is paid to those agronomic and phenotypic characteristics (for further details, see Section 4.2) which may be indicative of changes in the survival of soybean MON 87769 x MON 89788 grains which could be accidentally released into the environment, as well as in the establishment and fitness of GM soybean plants: e.g. early and final stand count, yield, seedling vigour and 100 seed weight. In this respect, the EFSA GMO Panel was satisfied with the data package provided by the applicant. As described in Section 4.2, all these agronomic and phenotypic characteristics, except plant height, of soybean MON 87769 x MON 89788 did not differ from those of its comparator. Soybean MON 87769 x MON 89788 not treated with glyphosate-based herbicides had a higher plant height than its comparator in the across-site analysis. The measured values for this characteristic fell within the natural range set by a set of reference varieties. The observed difference in plant height is unlikely to be biologically relevant in terms of increased persistence and invasiveness potential. Against this background, and considering the submission date of

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			needs to be clarified why reproductive characteristics are not part of the comparative assessment of MON87769xMON89788 provided by the applicant. [MSL0020773. Dossier EFSA/GMO/UK/2009/76, Monsanto Company]. [MSL-20187. Dossier EFSA/GMO/NL/2006/36.]	application EFSA-GMO-NL-2010-85, data on seed germination were not systematically required. Instead the EFSA GMO Panel followed a rationale considering the seed germination data on the two parental lines as well as the data provided on the early stand count of soybean MON 87769 x MON 89788. No statistically significant difference was observed in seed germination of soybean MON 87769 and soybean MON 89788 compared to their respective conventional counterparts across all sites. In addition, the early stand count data on soybean MON 87769 x MON 89788 indicated that changes in seed germination are unlikely.
Austria	Federal Ministry of Health	D, 05 Genetic stability of the insert and phenotypic stability of the GM plant	The following data are not sufficiently presented: The selection of probes used for the molecular analysis does not show the integrity of events sufficiently. The original single events were analysed using different combinations of probes. The choice of generations should be explained. Southern blot analysis may only provide a rough characterisation of the inserts and thus, by no means, show the integrity of events. This constraint is aggravated by the fact that the molecular characterisation does not cover the whole insert although adequate probes are available from the experimental setups for the initial characterisation of the single events. According to EFSA guidance, the notifier should show the retained integrity of events used for generating the stack (EFSA 2011, p. 11). The Technical Dossier does not provide detailed characterisation of the stacked event itself, and a detailed assessment of molecular identity with the modifications present in the parental GM lines to support the assumption by the notifier that the inserts are genetically stable is not given.	The GMO Panel considers that the restriction enzyme/probes combination is sufficient to verify the integrity of the flanking regions and the whole insert in line with EFSA Guidance documents (EFSA, 2007). The choice of generations is provided in the technical dossier p. 40 (Figure 7). The molecular analyses were carried out with F4 plants. The stability of the events was shown in their single context over several generations. The confirmation of the integrity of the events in the stacked GM line, which has been crossed and backcrossed, also indicates their stability in this case.

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			In Figure 5 and Figure 6 (Technical Dossier, pp. 34f), the hybridisation signals between the single and the stacked events do not correspond exactly, for which no explanation is given. The analysis of more samples would show whether this is due to technical reasons or inherent to the analysed plants. Southern blots may indeed only verify the presence of the two parental single events but may not show the integrity of the insert sequences sufficiently. Accordingly, the notifier states that "it is highly likely that the insert sequences of MON 87769 and MON 89788 are conserved with their inherent properties", and further reasons for this assumption are given on a theoretical basis. A detailed characterisation of the inserts, e.g. by sequencing, would clarify whether the inserts are conserved. It is also not adequate to refer to the detailed molecular characterisation of the single events as the single events have been analysed using different combinations of restriction enzymes. Using the same probes as for the single events would facilitate comparisons. For stacked events it is required to use plant materials representative of those aimed for commercial production, and the applicant should provide adequate justification for the plant material used. According to the Technical Dossier, p. 40, generation F4 (of the stack) was used for the molecular analysis. For the single events the specification of the generations shown in the comparative molecular analysis is missing. It would furthermore be useful to include more than one generation in the analysis for better comparison. The notifier is requested to give sufficient explanation for the choice of material used in the analysis.	Considering the power and limitations of Southern analyses, the results are sufficient and their interpretation is correct. The expected fragment sizes were detected with the Southern blot for the stacked events These data add to the interpretation that the structure of the inserts in the stacked event is the same as in the respective single events. Stability of the single events was indicated in the previous EFSA GMO Panel scientific opinions. Therefore, which generation is used for comparison with the stack is of no relevance.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			[EFSA, 2011. Guidance of the GMO Panel for risk assessment of food and feed from genetically modified plants. The EFSA Journal 9(5):2150: 1-37.]	
Austria	Federal Ministry of Health	D, 06 Any change to the ability of the GM plant to transfer genetic material to	D.6 (a) Plant to bacteria gene transfer: The applicant maintains, "None of the genetic elements in MON 87769 and MON 89788 has a genetic transfer function. Therefore, no changes are expected in the ability of these soybeans or MON 87769 × MON 89788 to transfer genetic material to bacteria." This conclusion is invalid. In his considerations the applicant ignores gene transfer by natural genetic transformation, which does not rely on special genetic transfer functions. MON87769xMON89788 contains the following genetic elements of bacterial orgin: 1) C4 epsps gene (1367 bp) 2) 3' non-translated region of the tml gene from Agrobacterium tumefaciens octopine-type Ti plasmid (949 bp) 3) right border sequence of T-DNA (43 bp) 4) left border sequence of T-DNA (274 bp) These bacterial sequences increase the; indeed low; probability of recombination of plant-derived DNA with genomic DNA of competent environmental bacteria. Taking this observation into account the probability of gene transfer from plant to bacteria is slightly increased with MON87769xMON89788 compared to plant DNA from conventional soybean.	The potential for horizontal gene transfer of the single events was assessed in previous opinions (EFSA, 2008, 2014) and no concern for an unlikely, but theoretically possible, horizontal gene transfer of the recombinant genes to bacteria in the gut or other receiving environments was identified. Synergistic effects of the recombinant genes, for instance due to combinations of recombinogenic sequences, which would cause an increase in the likelihood for horizontal gene transfer or a selective advantage were not identified. For more information, please consult section 4.4.2.2(a) of the scientific opinion.

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			D.6 (b) Plant to plant gene transfer: Technical Dossier, p. 56: Concerning "reproductive morphology" the notifier provides data on "days to 50% flowering" and eventually "pod shattering". These data do not characterise "reproductive morphology" sufficiently, as, for example, data on flowering time (duration) or pollen viability (see also EFSA guidance) are not presented. Additional data complementing the risk assessment on reproductive biology of GM soybean MON87769xMON89788 are requested. (Please see also comments in Section D.4)	The EFSA GMO Panel was satisfied with the data package on agronomic and phenotypic characteristics provided by the applicant. In accordance with the scope of this application and the biology of soybean, the EFSA GMO Panel considered the possible pathway of gene dispersal through seed from accidental seed spillage during transportation and/or processing and pollen from feral GM soybean plants. As soybean MON 87769 x MON 89788 has no altered survival, multiplication or dissemination characteristics (see Section 4.4.2.1), the EFSA GMO Panel is of the opinion that the likelihood of environmental effects as a consequence of spread of genes from this GM soybean in Europe will not differ from that of conventional soybean varieties.
Austria	Federal Ministry of Health	D, 07.01 Comparative assessment	The compositional analysis of harvested seeds indicates a substantial amount of statistically significant differences between the GM soybean stack MON87769xMON89788 and the control. The statistical analyses of compositional parameters other than fatty acids, which were intentionally altered, revealed 23 significant differences out of 34 comparisons (Technical Dossier, p. 62). Differences were also identified in quite some parameters in the individual site analyses (Technical Dossier, tab. 11). As the compositional values obtained from GM soybean stack MON87769xMON89788, for which statistically significant differences were identified, were always within the calculated 99% tolerance intervals for the population of conventional varieties assessed in trials ("conventional reference"	According to the applicable EFSA guidance on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events (EFSA, 2007) at the date of submission of this application, the field trials need to be carried out at least during one season, however the number of sites were not predefined. The EFSA GMO Panel was in the position to conclude based on the data provided.

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			according to the notifier) and/or within the range of values found in literature, the notifier concluded on the compositional equivalence of the GM soybean stack (Technical Dossier, p. 64). In this respect, we notice that according to the production plan field trials were conducted at eight sites in the US in 2007 (FROM CBI: 07-01-83-27 MSL0021807, p. 8), while in the study reports and the Technical Dossier only data from five locations are presented (Technical Dossier. p. 56ff, FROM CBI: MSL 0021916). Additionally, the EFSA Opinion on statistical considerations requires field trials to be replicated at a minimum of eight sites representative for the receiving environments (EFSA 2010). As no data were gained in another year, the EFSA requirements are not fulfilled with respect to the number of sites used in field trials. Moreover the notifier did include the GM parental lines in the field trials, but did not present a statistical analysis of the data obtained. We therefore request the notifier to provide information on why these data (i.e. data from three more locations and from concurrently grown parental lines) have not been used to substantiate the compositional equivalence of the GM soybean stack MON87769xMON89788 against the background of the many statistically significant differences identified in the compositional parameters between the GM soybean stack and the control. We ask EFSA to insist on the analysis of all data obtained in order to broaden the data basis used for the risk assessment and to contribute to the reduction of uncertainty. Moreover, the scope of the comparative analysis concerning	The application on soybean MON 87769 x MON 89788 was assessed according to the Regulation (EC) no 1829/2003. The herbicide assessment is outside the remit of this regulation.

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			the food and feed risk assessment of GM soybean stack MON87769xMON89788 is too narrow with a view to the characteristics of the application in question as residual levels of the complementary herbicide applied during production of GM soybean MON87769xMON89788 as well as metabolites generated from this herbicide were not subject to analysis. MSL 0021916. Dossier EFSA/GMO/NL/2010/85. 07-01-83-27 MSL0021807. Dossier EFSA/GMO/NL/2010/85. EFSA, 2010. Scientific opinion of the GMO Panel on statistical considerations for the safety evaluation of GMOs. The EFSA Journal 8(1):1250: 1-59.]	
Austria	Federal Ministry of Health	D, 07.01 Comparative assessment	Additional comments on the compositional analysis: Statistical methodology: The compositional analysis of MON87769xMON89788 is based on an outdated statistical methodology: the use of 99% tolerance intervals for testing equivalence with the population of commercial varieties. FROM CBI: MSL 0021916, "… for each compositional component, 99% tolerance intervals were calculated that are expected to contain, with 95% confidence, 99% of the quantities expressed in the population of commercial conventional substances." The current statistical methodology as outlined in EFSA (2010b) has more statistical power with respect to the compositional assessment. Without much effort, the (already available) data could be re calculated on the basis of current statistical methodology using equivalence limits with 95%	The 99% tolerance interval established by the reference varieties grown along wit hthe test material was not used for the compositional analysis of soybean MON 87769 x MON 89788. The statistical analysis of the compositional and agronomic and phenotypic characteristics of soybean MON 87769 x MON 89788 was done based on the applicable guidances valid at the time of submission of this application.

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			confidence level. The 2006 EFSA Guidance noted that "field trial data should be presented separately, as well as pooled, and should be analysed statistically, using appropriate statistical tools". The use of 99% tolerance intervals, often used by applicants in the past, are no more considered appropriate statistical tools. This fact is well known since the publication of the new guidance on statistical considerations in February 2010. It is, therefore, requested that the applicant provides a statistical analysis of the (already existing) field data using state-of-the-art methodology. Significant differences: The compositional analysis resulted in statistically significant differences (p-value 0.05) of 33 of 46 endpoints (a remarkable high number), of which 18 were significantly different at more than one of the individual sites. Except for the fatty acid profile - which is affected by the intended expression of the desaturase transgenes - significant differences were found for 23 for 34: carbohydrates, protein, total fat, amino acids (16), vitamin E, phytic acid, daidzein, genistein (FROM CBI: MSL 0021916, p. 30ff). Many of the differences showed high significances at p-values <0.005: • Carbohydrates (p<0.001; significantly lower in the GM soybean)	The 99% tolerance interval established by the reference varieties grown along wit hthe test material was not used for the

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			• Protein (p=0.003; significantly higher in the GM soybean) • Total fat (p<0.001; significantly higher in the GM soybean) • The amino acids arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, leucine, lysine, phenylalanine, proline (all at p<0.005; significantly higher in the GM soybean) • Vitamin E (p<0.001; significantly higher in the GM soybean) • daidzein, genistein (both at p<0.001; significantly lower in the GM soybean) The applicant only presents an analysis regarding the 99% tolerance interval arguing that the differences are always within the variation of the soybean reference varieties. But, the individual site analysis indicate correlations with the overall compositional results (23 endpoints differences were observed that showed correlations). These results are not sufficiently discussed and the weaknesses attributed to the test design (99% tolerance intervals, five sites, three replicates only, etc.) not adequately taken into consideration. In summary, additional field tests providing sufficient statistical power are needed for drawing final conclusions on the compositional characteristics of the GM soybean MON87769xMON89788. A re calculation using 95% equivalence intervals is a minimum requirement and could be the starting point for a systematic analysis of potential unintended effects in soybean MON87769xMON89788.	compositional analysis of soybean MON 87769 x MON 89788.

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			[MSL 0021916. Dossier EFSA/GMO/NL/2010/85.]	
Austria	Federal Ministry of Health	D, 07.02 Field trials	D.7.2. Production of material for comparative assessment: Data for the compositional analysis were assessed in forage and seed samples from field trials in the US in 2007 at five locations (Technical Dossier, p.58ff). Three reference varieties were grown at each site amounting to all in all fifteen reference varieties (FROM CBI: MSL 0021916). In these field trials obviously also the material for the expression analysis was sampled as MSL 0021916 REG-08-553 MSL0022224 (FROM CBI) both refer to the same production plan, i.e. 07-01-83-27 (also referred to as 07-01-83-27 MSL0021807 (FROM CBI)). According to 07-01-83-27 MSL0021807 (FROM CBI), glyphosate was applied to the stacked soybean MON87769xMON89788 as well as the parental herbicide tolerant control MON87769, while the other parent, MON89788, and the control received conventional herbicide treatments (FROM CBI: 07-01-83-27 MSL0021807, p. 5 and Tab. 8). However, according to the EFSA Opinion on the selection of comparators the experimental design used in food & feed risk assessment of herbicide tolerant plants should include the treated GM plant, the untreated GM plant and the conventional control (EFSA 2011). In addition, the EFSA Opinion on statistical considerations states that these three test materials are to be compared (EFSA 2010). The data presented do not include an untreated GM soybean MON87769xMON89788 as comparator and thus also lack a	The application of the intended herbicide represents the most realistic scenario in commercial use of soybean MON 87769 x MON 89788. Beside the modified fatty acid profile, none of the other differences identified in the composition of grain and forage obtained from the intended herbicide treated soybean MON 87769 × MON 89788 required further assessment regarding food and feed safety. Therefore, the EFSA GMO Panel was in the absence of compositional data obtained from conventional herbicide treated soybean MON 87769 × MON 89788 able to conclude on the comparative assessment. The EFSA GMO Panel noted this comment.

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			respective statistical comparison. Thus, in this application the basic EFSA requirements - with respect to the trial design - for the food & feed risk assessment of GM herbicide tolerant plants are not fulfilled. Moreover, we would like to critically note that the basic aspects of the experimental design, in this case the treatment variations (i.e. the applications of complementary herbicides) are only available from the production plan and not from the information provided in the Technical Dossier or in the respective study reports. Basic information like this ought to be readily visible in the Technical Dossier. [MSL 0021916. Dossier EFSA/GMO/NL/2010/85]. [07-01-83-27 MSL0021807. Dossier EFSA/GMO/NL/2010/85]. EFSA, 2010. Scientific opinion of the GMO Panel on statistical considerations for the safety evaluation of GMOs. The EFSA Journal 8(1):1250: 1-59. EFSA, 2011. Guidance of the GMO Panel on selection of comparators for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal 9(5):2149: 1-21. [REG-08-553 MSL0022224. Dossier EFSA/GMO/NL/2010/85.]	
Austria	Federal Ministry of Health	D, 07.04 Agronomic traits	Additonal Comments on the field trials with MON87769xMON89788 and the set of agronomic observations discussed also in Chapter D.4: Conclusions concerning differences between test an control	The statistical analysis of the compositional and agronomic and phenotypic characteristics of was done based on the applicable EFSA guidances valid at the time of submission of this application (EFSA, 2007).

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			substances in agronomic and phenotypic characteristics are based on results of the agronomic study carried out by Study # REG-07-300 MSL0022215 (FROM CBI). Comments on the phenotypic evaluation (FROM CBI: Study # REG-07-300 MSL0022215): Trial substances (test, control and reference substances): On bases of EFSA-Guidance on the environmental risk assessment of GM plants (EFSA 2010a) a more detailed justification of the choice of the reference substances (e.g. distribution in practical agriculture), should be given as their variation in the phenotypic and agronomic characteristics is relevant for the result of the comparison with reference varieties. Trial sites and trial design: The number of only five trial sites is too low. According to the EFSA-opinion on statistical considerations for the safety evaluation of GMOs (EFSA 2010b) at least eight trial sites are to be included. Furthermore, with only three replications in the RCB-design and eight trial substances, as reported in the field trials results (FROM CBI: Study # REG-07-300 MSL0022215) including the crossing partners MON87769 and MON89788 the number of degrees of freedom (df) for the residual error falls below the recommended limit of 15 df ((24 -1)total -7trial substances -2reps = 14; see also the statistical model on page 46 in Study # REG-07-300 MSL0022215) (FROM CBI). The number of four out of twelve reference varieties on each	The European Food Safety Authority (EFSA) guidance applicable to this application establishes that "Where all single events have been assessed, the risk assessment of stacked events should focus mainly on issues related to a) stability, b) expression of the events and c) potential interactions between the events" (EFSA, 2006, 2007). Additional information received after May 2011 was assessed in accordance with the EFSA 2011 guidance (EFSA GMO Panel, 2011a). Considering the scope of application EFSA-GMO-NL-2010-85, special attention is paid to those agronomic and phenotypic characteristics (for further details, see Section 4.2) which may be indicative of changes in the survival of soybean MON 87769 x MON 89788 grains which could be accidentally released into the environment, as well as in the establishment and fitness of GM soybean plants: e.g. early and final stand count, yield, seedling vigour and 100 seed weight. In this respect, the EFSA GMO Panel was satisfied with the data package provided by the applicant. As described in Section 4.2, all these agronomic and phenotypic characteristics, except plant height, of soybean MON 87769 x MON 89788 did not differ from those of its comparator. Soybean MON 87769 x MON 89788 not treated with glyphosate-based herbicides had a higher plant height than its comparator in the across-site analysis. The measured values for this characteristic fell within the natural range set by a set of reference varieties. The observed difference in plant height is unlikely to be biologically relevant in terms of increased persistence and invasiveness potential.

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			site meets the corresponding requirements in EFSA (2010b). Agronomic and phenotypic characteristics: The phenotypic characteristics recorded in the study are useful, however, the observations of "days to maturity" are lacking. Maturity behaviour of varieties is a crucial character in soybean cultivation. Growth stage monitoring has been done, but its results are not as accurate as observing the date of maturity. The applicant should be requested to provide the missing information. (Plot data: The complete information about single plot data and randomisation of all trial sites is given.) Conclusion (Technical Dossier, p. 51): The conclusion about field phenotypic, agronomic and environmental interaction is founded on a too small database as three sites are lacking. To strengthen the agronomic risk assessment additional information should be submitted. [Study # REG-07-300 MSL0022215]. EFSA, 2010a. Guidance of the GMO Panel on the environmental risk assessment of genetically modified plants. The EFSA Journal 8(11):1879: 1-111. EFSA, 2010b. Scientific opinion of the GMO Panel on statistical considerations for the safety evaluation of GMOs. The EFSA Journal 8(1):1250: 1-59.]	

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Austria	Federal Ministry of Health	D, 07.08 Toxicology	The comparative data have shown that the (carbohydrate, protein and fatty acid) composition profile of the GM soybean MON87769xMON89788 has changed as compared to the non-GM counterpart. The presence of unintended effects and potential consequences for the food and feed safety needs to be adequately assessed. The argument of the applicant (Technical Dossier, page 126), "The safety for humans and animals of the PjΔ6D, NcΔ15D and CP4 EPSPS proteins has been demonstrated on the basis of extensive characterisation, history of safe use, lack of structural similarities with known protein toxins and allergens, absence of acute toxicity in oral gavage studies in rodents and rapid digestion in simulated digestive fluids", misses the fact that repeated dose studies are needed to test for potential effects resulting from continuous additional loading of metabolic or effector systems which can lead to pathologic mechanisms. 28-day toxicity studies were requested by the EFSA GMO Panel, but it was not possible to generate sufficient PjΔ6D and NcΔ15D proteins preparations of suitable quality. No 28 day toxicity study is presented on the CP4 EPSPS protein, too. Thus, none of the transproteins expressed in the GM soybean MON87769xMON89788 were subjected to adequate toxicological investigations as demanded in current guidelines (EFSA 2011b; EC 2013). The approach used by the applicant on the 90-day toxicity study with the single event MON87769 is also questionable: The maximum dosages in the diet fed to rats were only 15%	Results of the comparative analysis were assessed by the EFSA GMO Panel as regards the potential consequences for the food and feed safety, both as regards the intended and unintended effects. Specifically addressing the Member State comment, unintended changes in fatty acids were considered to do not need further assessment for food and feed safety, as these were falling within the variability of these constituents in the conventional soybeans grown in the same field trials or, specifically for linolenic acid, levels were within the range reported in literature (Padgette et al., 1996). Furthermore the EFSA GMO Panel considered that the observed variations in levels of these fatty acids would have no nutritional consequences and didn't need further assessment for food and feed safety. Changes in protein, carbohydrate, isoflavones levels in GM soybean were thoroughly discussed by the EFSA GMO panel and found not to be relevant for food and feed safety. In fact, the differences observed were within the range of the commercial non-GM soybean varieties included in the field trials (protein, isoflavones); or would have no nutritional consequences (arginine), or are a consequence of the altered levels of other constituents, being a calculated parameter (carbohydrate). Please refer to 4.2.1 of the Scientific Opinion for further details. The proteins PjΔ6D and NcΔ15D newly expressed in soybean MON87769xMON89788 were already assessed by the EFSA GMO Panel as regard their safety in the context of the single event MON 87769 (EFSA-GMO-NL-2008-76). As indicated by the Member State, the EFSA GMO Panel asked 28-day studies on these newly expressed proteins to confirm their safety in the absence of a documented history of consumption of these specific proteins (in accordance to EFSA, 2011). The technical reasons provided by the applicant indicating that it was not possible to obtain these proteins in sufficient quality and quantity to run a 28-day study in

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			GM soybean meal. There are examples of GM soybean events (e.g. MON87701) that were tested preparing diets with 30% GM soybean meal. So far, no satisfying answer has been presented on the low dosages of the 90-day study. (The problems to generate sufficient protein preparations are not valid for a 90-day study with soybean meal.) The applicant is requested to justify the choice of the test design (5% and 15%), and if - and on what basis - the applicant considered levels higher than 15% soybean meal to cause nutritional imbalance. The remaining uncertainties should be addressed by generating significant data on toxicology: a 90 day toxicity animal feeding study with stacked event MON87769xMON89788 based on current standards (OECD 1998; EFSA 2011a). [EC, 2013. Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. Official Journal of the European Union. L 157/1: 1-48. EFSA, 2011a. Guidance of the EFSA Scientific Committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. The EFSA Journal 9(12):2438: 1-21. EFSA, 2011b. Guidance of the GMO Panel for risk assessment of food and feed from genetically modified plants. The EFSA	rodents was accepted by the EFSA GMO Panel. The Panel was able to reach its conclusions on the safety of these proteins according to a weight-of-evidence approach. This took into account all the available data (bioinformatics analysis results; literature indicating that no known toxic proteins have such desaturase activity as a component of their biological activity; other desaturases are consumed by humans and animals daily with no reported adverse effects; PjΔ6D and NcΔ15D were rapidly degraded by pepsin in vitro). The EFSA GMO Panel considered that this information reduces the uncertainty raised by the lack of 28-day repeated dose toxicity studies on these newly expressed proteins and concluded that there are no reasons to suppose that these specific desaturases would introduce safety concerns. These considerations were considered applicable to this GM soybean MON87769xMON89788. Please refer to EFSA, 2014 for further details. As regards the comment on the 90-day study provided in the context of EFSA-GMO-NL-2008-76, it is highlighted that the EFSA GMO panel did not identify changes at comparative assessment that would have needed a 90-day study to support the risk assessment of the single event MON87769. Please refer to EFSA 2014 for further details.

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			Journal 9(5):2150: 1-37. OECD, 1998. Guideline for the testing of chemicals - Test No. 408: Repeated dose 90-day oral toxicity study in rodents. 1-10.]	
Austria	Federal Ministry of Health	D, 07.09 Allergenicity	The applicant proposes that the evaluation of reactivity of MON87769 or MON89788 protein extracts with sera from soybean allergic individuals showed no differences as compared to conventional soybean, and that the assessment of the allergenicity of the whole MON87769xMON89788 plant, therefore, is not considered necessary (Technical Dossier, p. 129). With regard to the single events, the IgE tests of the GM soybean MON87769 showed variations in gel patterns and protein spots intensity indicating different reactions to allergenic sera. These variations should be quantitatively assessed by LC-MS/MS. The IgE immunoblot analysis of the single event MON89788 also raised concerns as one sera (#25) showed no reaction with the control line A3244 but a strong reaction with the GMO line (54.779 ng/ml). Additional tests and data were requested from the applicant by EFSA, but without elucidating the specific characteristics of serum #25 (comments referring to Rice and Bannon 2006 (FROM CBI)). These findings show that the conclusions that both MON87769 and MON89788 are comparable to conventional soybean in terms of allergenicity potential need to be further verified. Immunological studies (e.g. IgE binding studies) with plant material derived from the GM soybean stacked	For the assessment of the allergenicity of the whole GM plant, the EFSA GMO Panel requested the applicant for additional experimental studies to address the endogenous allergenicity of soybean MON 87769 x MON 89788. The EFSA GMO Panel considers that there is no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON 87769 x MON 89788 when compared with that of its non-GM comparator. Please see Section 4.3.4.2 of the scientific opinion on application EFSA-GMO-NL-2010-85.

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			event (MON87769xMON89788) are requested to exclude any uncertainties and should, at best, include the serum #25 (comments referring to Rice and Bannon 2006 (FROM CBI)). [Rice EA, Bannon GA, 2006. Assessment of human IgE binding to glyphosate-tolerant second generation soybean MON89788, control, and reference soy extracts. Dossier EFSA/GMO/NL/2006/36, Monsanto Company.]	
Austria	Federal Ministry of Health	D, 12.01 General	The general comment addressing the issue that the dossier at hands is not meeting some of the current standards and requirements for risk assessment is also relevant for the proposed environmental monitoring plan. The plan for environmental monitoring is not fully in line with the requirements of current guidance according to EFSA (2011). In addition the monitoring plan contains outdated information (e.g. information on institutions of the monitoring network proposed to be involved as well as several URLs linking to relevant information sources). Furthermore, the proposed monitoring plan is subject to the same shortcomings as found with most other notifications of GM plants for a similar scope of application. The current monitoring plan is very general in nature and important details are missing which are crucial for implementation of the monitoring. Among others the proposed plan is lacking adequate information on the following issues: • description of the specific parameters addressed by the proposed monitoring • detailed description of the methods used for monitoring and analysis of data	The EFSA GMO Panel gives its opinion on the scientific quality of the post-market environmental plan (PMEM) activities proposed by the applicant. The PMEM plan currently submitted by the applicant for GM soybean is the standard PMEM plan developed jointly by applicants and risk managers and submitted as part of marketing applications for import and processing of GM plants in the EU. The EFSA GMO Panel agrees that the present PMEM plan and in particular the supporting methodology needs to be further detailed by the applicant. However, in accordance with its guidance documents on PMEM of GM plants (EFSA, 2006, 2011), the EFSA GMO Panel recognises that all parties (e.g. applicants, Member States) have to consider their roles in the PMEM of GM plants. Therefore, considering that the definite and final endorsement of the PMEM plan is with risk managers, the EFSA GMO Panel is of the opinion that further discussion on the practical implementation of the PMEM plan (e.g. involvement of existing monitoring systems) is needed between the applicant and risk managers at the time of approval of the GM soybean.

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			• specifics on the proposed involvement of third parties and on the data provided by these institutions • measures to identify relevant receiving environments, i.e. monitoring to establish data on the EU regions where import, storage, processing and use of GM soybean MON87769xMON89788 will commence as well as on the amounts of GM soybean MON87769xMON89788 which are imported, stored, processed and used. [EFSA, 2011. Guidance of the GMO Panel on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. The EFSA Journal 9(8):2316: 1-40.]	
Austria	Federal Ministry of Health	D, 12.03 General Surveillance of the impact of the GM plant	D.11.4. General Surveillance for unanticipated adverse effects: According to the submitted monitoring plan, General Surveillance will involve European trade associations representing relevant operators, dealing with the import, handling and processing of viable GM soybean MON87769xMON89788 (COCERAL, UNISTOCK and FEDIOL). However, it should be clear which existing national organisations will be involved in individual Member States in order to ensure that different import volumes of GM soybean into individual Member States can be taken into consideration. The conduct of General Surveillance will be substantially influenced by the availability, extent and composition of existing networks in the individual EU Member States. The active involvement of these organisations and their assistance to the notifier are essential elements in order to ensure a meaningful monitoring.	The EFSA GMO Panel gives its opinion on the scientific quality of the post-market environmental plan (PMEM) activities proposed by the applicant. The PMEM plan currently submitted by the applicant for GM soybean is the standard PMEM plan developed jointly by applicants and risk managers and submitted as part of marketing applications for import and processing of GM plants in the EU. The EFSA GMO Panel agrees that the present PMEM plan and in particular the supporting methodology needs to be further detailed by the applicant. However, in accordance with its guidance documents on PMEM of GM plants (EFSA, 2006, 2011), the EFSA GMO Panel recognises that all parties (e.g. applicants, Member States) have to consider their roles in the PMEM of GM plants. Therefore, considering that the definite and final endorsement of the PMEM plan is with risk managers, the EFSA GMO Panel is of

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			However the tasks are not appropriately specified in detail, which need to be addressed by the consent holder and the involved trade associations. No specification is given regarding the kind of data which should be collected. The proposed surveillance primarily relies on passively collecting information of unspecified nature. The notifier should apply a more proactive approach of General Surveillance including specific activities for monitoring grain loss at different locations (e.g. ports, silos, processing facilities) and provides additional information with regard to the parameters that are going to be monitored, as well as on the methodological approaches implemented for monitoring. Additionally, the notifier is not providing a justification why the monitoring is exclusively focused on operators handling and using viable GM material. As stated in the introduction by the notifier the monitoring should also address the potential occurrence of unanticipated adverse effects on human and animal health of the use of the GMO (cf. monitoring plan p. 3). Therefore further operators further down the feed or food chain should be involved in the monitoring, e.g. national veterinary networks and services should be involved in the General Surveillance of unanticipated effects on animal health. Thus the monitoring plan at hands fails to address relevant questions with regard to surveillance of animal health. The notifier states that "the baseline and controls for general surveillance will rely on the historical knowledge and experience with non-GM soybean as comparable reference where necessary" (monitoring plan, p. 3). We request that the notifier provides more information with regard to this	the opinion that further discussion on the practical implementation of the PMEM plan (e.g. involvement of existing monitoring systems) is needed between the applicant and risk managers at the time of approval of the GM soybean. As a full assessment on possible health and nutritional impact of the MON 87769 x MON 89788 soybean oil was not made, the EFSA GMO Panel is not in the position to comment on the post-market monitoring plan.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			baseline.	
Austria	Federal Ministry of Health	D, 12.03 General Surveillance of the impact of the GM plant	D.11.4. General Surveillance for unanticipated adverse effects (cont.): The proposed surveillance plan makes reference to the HACCP principles (Monitoring Plan, p. 4 and Annex I). The notifier should further outline how these HACCP principles are specifically implemented to match with the requirements of a comprehensive environmental monitoring plan. Furthermore, it is not clear how unintended release of GM soybean MON87769xMON89788 to the environment via accidental spillage of viable material during transport will be addressed. To address this issue the proposed monitoring needs to be revised to establish data on the actual volumes of GM soybean MON87769xMON89788 imported into the EU, the routes of transport of GM soybean MON87769xMON89788 and mixed commodities containing GM soybean MON87769xMON89788, as well as the places of processing and use of GM soybean MON87769xMON89788. Such information would be required according to the current guidance for submission of applications, which is requiring a consideration of the level of exposure (EFSA 2013, Table for Part II: Scientific information). In conclusion, the proposed monitoring plan falls short of providing a detailed monitoring methodology laying down responsibilities and assigning concrete tasks to each party involved as well as addressing relevant questions for the monitoring of accidental spillage of GM soybean MON87769xMON89788. [EFSA, 2013. Guidance on the submission of applications for	The EFSA GMO Panel takes into account that this application does not include cultivation of the GM 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 87769 x MON 89788 entering cultivation as this would require specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003. Please also consider the response to the above Austrian comments.

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			authorisation of genetically modified plants under Regulation (EC) No 1829/2003. The EFSA Journal 11(12):3491: 1-133.]	
Belgium	BAC	D, 07.01 Comparative assessment	On page 63 of the technical dossier, the levels of genistein and daidzin in MON87769xMON89788 were within their 99% tolerance intervals established from conventional soybean varieties and within the literature database range: however this is not for daidzin in the control group (see also literature range on page 92): why are the values for the control mean at all locations so high for daidzin and genistein ? (page 78)	The statistical analysis of the compositional and agronomic and phenotypic characteristics of was done based on the applicable EFSA guidances valid at the time of submission of this application (EFSA, 2007) and includes only the statistical comparison of soybean MON 87769 x MON 89788 with its comparator.

Application EFSA-GMO-NL-2010-85 (soybean MON 87769 x MON 89788) **Comments and opinions submitted by Member States during the three-months consultation period**				
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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Belgium	BAC	D, 07.10 Nutritional assessment of GM food/feed	The increased phytic acid concentration in MON 87769 x MON 89788 soybeans, compared to conventional soybeans, may have consequences for animal nutrition: phosphorus digestibility and utilisation may be decreased in monogastric animals. Feeding SDA-enriched soybean oil to broilers had some negative effects on the sensory quality of the meat (Rymer et al., 2011). It is not clear from the Technical Dossier if there was any effect of MON87769 x MON89788 soybean on the sensory quality of broilers meat from the performance study. Because of the presence of trans-SDA and trans-ALA in MON 87769 x MON 89788 soybeans, these trans fatty acids may also be present in animal tissues that will be used for human consumption. It is not clear if these trans fatty acids are concentrated in animal tissues or metabolised by the animals, because no mention was made of trans fatty acid in the broiler meat originating from the performance study referred to in the Technical Dossier (Table 28). More details are desirable with regard to this aspect. References: Rymer, C., Hartnell, G.F., Givens, D.I. 2011. The effect of feeding modified soyabean oil enriched with C18 : 4n3 to broilers on the deposition of n3 fatty acids in chicken meat. Br. J. Nutr 105, 866-878.	In the context of this application, the applicant provided a dietary exposure and nutritional assessment based on data derived from the single event MON 87769 but not on soybean MON 87769 x MON 89788. Therefore, the applicant was asked to provide a dietary exposure assessment based on the compositional analysis of the RBD oil from soybean MON 87769 x MON 89788 taking into account different exposure scenarios, covering low and high consumer groups. However, the applicant did not provide such data. The EFSA GMO Panel therefore cannot complete the assessment on possible impact of the MON 87769 x MON 89788 soybean oil on human health and nutrition.
Finland	Board for Gene Technology	General comments	The Finnish Board for Gene Technology stresses the importance of using appropriate management systems for restricting soybean seeds from entering cultivation.	Outside the remit of the EFSA GMO Panel.

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France	Ministère de l'Economie (Consommation)	C. Information relating to the genetic modification	Caractérisation moléculaire Conclusions Les éléments présentés dans le dossier relatifs à la caractérisation moléculaire du soja génétiquement modifié MON87769 x MON89788 ne soulèvent pas de problème particulier lié à la consommation de ce soja. **ENGLISH TRANSLATION** Molecular characterisation Concluding points The items presented in the dossier relating to molecular characterisation of genetically modified soya MON87769 x MON89788 do not raise any particular problems associated with consumption of the soya.	The EFSA GMO Panel took note of this comment.
France	Ministère de l'Economie (Consommation)	D, 07.02 Field trials	Evaluation comparative Dispositif expérimental Pour l'analyse de composition, le soja MON87769 x MON89788 et la variété A3525 ont été cultivés sur 5 sites aux USA en 2007, de même que les 15 variétés commerciales (3 variétés par site). Le soja génétiquement modifié a été traité avec du glyphosate. Chaque modalité (variété témoin, variétés commerciales et variété génétiquement modifiée traitée avec du glyphosate) a été répétée trois fois sur chaque site selon un plan d'expérience en blocs randomisés.	For compositional analysis of soybean MON 87769 x MON 89788, the application of the intended herbicide represents the most realistic scenario in commercial use of soybean MON 87769 x MON 89788. Beside the modified fatty acid profile, none of the other differences identified in the composition of grain and forage obtained from the intended herbicide treated soybean MON 87769 × MON 89788 required further assessment regarding food and feed safety. Therefore, the EFSA GMO Panel was in the absence of compositional data obtained from conventional herbicide treated soybean MON 87769 × MON 89788 able to conclude on the compositional analysis.

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			Les caractéristiques de ce plan d'expérience, qui ne comporte pas la modalité "variété génétiquement modifiée non traitée avec du glyphosate", ne respectent pas les recommandations de l'EFSA (2006) en vigueur pour ce dossier. Pour l'analyse des caractéristiques agronomiques et phénotypiques, le soja MON87769 x MON89788 et la variété A3525 ont été cultivés sur 5 sites en Argentine en 2007-2008, de même que les 12 variétés commerciales (4 variétés par site). Le soja génétiquement modifié a été cultivé sans traitement avec du glyphosate. Chaque modalité (variété témoin, variétés commerciales et variété génétiquement modifiée non traitée avec du glyphosate) a été répétée trois fois sur chaque site selon un plan d'expérience en blocs randomisés. Les caractéristiques de ce plan d'expérience, qui ne comporte pas la modalité "variété génétiquement modifiée traitée avec du glyphosate", ne respectent pas les recommandations de l'EFSA (2006) en vigueur pour ce dossier. **ENGLISH TRANSLATION** Comparative assessment Experimental set-up To investigate its composition, soya MON87769 x MON89788 and variety A3525 were grown at 5 sites in the USA in 2007, as were 15 commercial varieties (3 varieties on each site). The genetically modified soya was treated with glyphosate. Each arrangement (control variety, commercial varieties and the genetically modified variety treated with glyphosate) was	

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			carried out in three locations at each site, following an experimental plan of random blocks. The characteristics of that experimental plan, which did not include an arrangement of the genetically modified variety NOT treated with glyphosate, did not accord with EFSA's recommendations (2006) applying to this dossier. To investigate the agronomic and phenotypical characteristics, soya MON87769 x MON89788 and variety A3525 were grown at 5 sites in Argentina in 2007-08, as were 12 commercial varieties (4 varieties on each site). The genetically modified soya was grown without being treated with glyphosate. Each arrangement (control variety, commercial varieties and the genetically modified variety untreated with glyphosate) was carried out in three locations at each site, following an experimental plan of random blocks. The characteristics of that experimental plan, which did not include an arrangement of the genetically modified variety TREATED with glyphosate, did not accord with EFSA's recommendations (2006) applying to this dossier.	
France	Ministère de l'Economie (Consommation)	D, 07.01 Comparative assessment	Evaluation comparative Analyse statistique Les caractéristiques phénotypiques, agronomiques et de composition sont comparées à l'aide d'analyses de variance réalisées site par site puis en regroupant les résultats de tous les sites expérimentaux. Le soja MON87769 x MON89788 est comparé à la variété témoin A3525 par des tests de	The applicable EFSA Guidance at the date of submission didn't require the test of difference and the test of equivalence. Neither the 99% tolerance interval as suggested by the applicant nor the ILSI database was used by the EFSA GMO Panel for the safety assessment of soybean MON 87769 x MON 89788.

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			différence. Une ANOVA à effets mixtes est réalisée, incluant : - un effet fixe "génotype" (indiquant s'il s'agit du soja MON87769 x MON89788, de la variété témoin ou des variétés commerciales), - des effets aléatoires : "site", "bloc dans le site", et "interaction génotype/site". L'erreur de type 1 retenue par le pétitionnaire est de 5 %. Le pétitionnaire ne réalise pas de tests d'équivalence mais compare les valeurs obtenues pour le soja MON87769 x MON89788 avec des plages de valeurs obtenues sur les variétés commerciales : - pour l'analyse de composition, les variétés commerciales sont utilisées pour calculer un intervalle de confiance pour chaque paramètre, qui comprend 99 % des données avec une confiance de 95 %. - pour l'analyse des caractéristiques agronomiques et phénotypiques, les variétés commerciales sont utilisées pour calculer une plage (minimum-maximum) pour chaque paramètre. Les données sont aussi comparées à celles de la littérature et de la base de données de composition de l'ILSI (2008). L'EFSA préconise depuis 2011 l'utilisation d'un modèle statistique incluant un effet aléatoire « variété commerciale » et la réalisation de tests d'équivalence. Les études, antérieures à 2011, ne répondent pas à ces	

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			recommandations. **ENGLISH TRANSLATION** Comparative assessment Statistical analysis The agronomic, phenotypical and composition characteristics were compared, using analysis of variance (ANOVA), carried out for each site and then combining the results from all the experimentation sites. Soya MON87769 x MON89788 was compared with control variety A3525 using difference tests. Mixed-effects ANOVA was carried out, including: - a 'genotype' fixed effect (showing whether it was MON87769 x MON89788 soya, the control variety or the commercial varieties), - random 'site', 'block within the site' and 'genotype-site interaction' effects. The type-1 error level chosen by the applicant was 5%. The applicant did not carry out equivalence tests, but compared the values obtained for MON87769 x MON89788 soya with the ranges of values obtained from the commercial varieties, as indicated below. • For the analysis of composition, the commercial varieties were used to calculate a confidence interval for each parameter; this accounted for 99% of the data with a confidence level of 95%.	

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			• For the analysis of agronomic and phenotypical characteristics, the commercial varieties were used to calculate a range (minimum and maximum values) for each parameter. The data were also compared with those in the literature and in ILSI's database of composition (2008). EFSA has, since 2011, advocated use of a statistical model including a random commercial-variety effect, and recommended that equivalence tests be carried out. The studies reported in the dossier, earlier than 2011, did not accord with these recommendations.	
France	Ministère de l'Economie (Consommation)	D, 07.06 Effect of the production and processing	Effets de la transformation de la plante en sous-produits Le pétitionnaire affirme que les produits issus du soja MON87769 x MON89788 ne devraient pas être différents de ceux issus de soja conventionnel mais ne présente aucune analyse des produits transformés. **ENGLISH TRANSLATION** Effects of converting the plant into sub-products The applicant asserted that the products derived from MON87769 x MON89788 soya should not differ from those derived from conventional soya, but has not presented any investigation of the converted products.	Seeds of soybean MON 87769 × MON 89788 collected from the 2007 USA field trials were processed into refined bleached deodorised (RBD) oil and analysed for fatty acid composition. The applicant indicated that the intended effects of the genetic modification on the fatty acid pattern already seen in the analysis of unprocessed soybean seeds were also reflected in the composition of RBD oil obtained from soybean MON 87769 × MON 89788. For further details please refer to section 4.3.1 of the scientific opinion.
France	Ministère de	D, 07.01	Conclusion Ananalyse Comparative	The EFSA GMO Panel confirms that soybean MON 87769 ×

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
	l'Economie (Consommation)	Comparative assessment	L'analyse de composition du soja MON87769 x MON89788 traité avec du glyphosate ne met pas en évidence de différence significative entre ce soja et les variétés conventionnelles pour le fourrage. Il existe par contre des différences significatives de composition des graines sur plusieurs composés en plus de ceux attendus du fait de la transformation génétique. Aucune analyse n'a été réalisée sur les produits issus du soja MON87769 x MON89788. La caractérisation phénotypique et agronomique du soja MON87769 x MON89788, réalisée sans traitement avec du glyphosate, ne met pas en évidence de différence significative entre ce soja et les variétés conventionnelles. **ENGLISH TRANSLATION** Concluding points regarding the Comparative Analysis Investigation of the composition of MON87769 x MON89788 soya treated with glyphosate did not reveal any significant difference between that soya and the conventional varieties used as forage. There are, however, significant differences in composition of the beans, in terms of a number of compounds, in addition to those expected as a result of the genetic modification. No investigation was carried out of the products derived from MON87769 x MON89788 soya. The agronomic and phenotypical characterisation of MON87769 x MON89788 soya, carried out without the plants being treated with glyphosate, did not reveal any significant difference between that soya and the conventional varieties.	MON 89788 differs from its comparator and other non-GM soybean reference varieties by having an altered fatty acid profile and a higher level of SDA, as addressed in Section 4.3. None of the other differences identified in the composition of grain and forage obtained from soybean MON 87769 × MON 89788 requires further assessment with regard to food and feed safety. The difference in plant height between soybean MON 87769 × MON 89788 and the comparator were within the natural range established using a set of reference varieties. The observed difference in plant height is unlikely to be biologically relevant in terms of increased persistence and invasiveness potential.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
France	Ministère de l'Economie (Consommation)	D, 07.08 Toxicology	Evaluation toxicologique 1) Lignes directrices normalisées des tests de toxicité La toxicité potentielle du soja génétiquement modifié MON87769 x MON89788 n'a été évaluée qu'à partir d'analyses et de tests réalisés sur les protéines PjD6D, NcD15D et CP4 EPSPS. 2) Evaluation des nouveaux constituants L'analyse de composition du soja MON87769 x MON89788 n'a pas mis en évidence de nouveaux constituants exceptés les acides gras GLA, SDA, trans-ALA et trans-SDA, qui n'ont pas fait l'objet d'une évaluation toxicologique. 3) Evaluation des constituants des denrées alimentaires et aliments pour animaux dont les niveaux sont altérés Aucune analyse n'a été réalisée sur les produits issus du soja MON87769 x MON89788. 4) Evaluation de l'aliment dérivé de plante GM (denrées alimentaires et/ou aliments pour animaux) Aucune étude de toxicité sub-chronique de 90 jours sur rongeur n'a été réalisée sur le soja MON87769 x MON89788. 5) Conclusion Le dossier présenté par le pétitionnaire pour le soja génétiquement modifié MON87769 x MON89788 ne comporte pas d'étude de toxicité sub-chronique de 90 jours sur	The toxicological assessemnt on the newly expressed protein in MON 87769 x MON 89788 has been performed by the EFSA GMO Panel (please see 4.3.2.1 of the Scientific Opinion) The assessment of the altered fatty acid profile has been performed in the context of nutritional assessemnt (human and animal) (please see 4.3.5 of the Scientific Opinion). Please note that the applicant did not provide a dietary exposure assessment based on the compositional analysis of the RBD oil from MON 87769 x MON 89788 soybean taking into account different exposure scenarios, covering low and high consumer groups, as asked by the EFSA GMO Panel. The EFSA GMO Panel therefore cannot complete the assessment on possible impact of the MON 87769 x MON 89788 soybean oil on human health and nutrition. A chicken for fattening study on defatted toasted meals has been provided by the applicant and it has been assessed by the EFSA GMO Panel. This has contributed to conclude that defatted soybean meal from soybean MON 87769 x MON 89788 is expected to deliver the same nutrition as its comparator and other non-GM commercial varieties. (please see 4.3.3. and 4.3.5.2 of the Scientific Opinion). As regards a 90-day study on food/feed derived from MON 87769 x MON 89788, the EFSA GMO Panel did not consider this study necessary, on the basis of preceding analyses (compartive assessemnt). In particular, the altered fatty acid profile of soybean MON 87769 x MON 89788 was assessed by human exposure assessmnt.

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			rongeur. Ceci est conforme aux recommandations de l'EFSA (2006) si l'équivalence de composition est démontrée par rapport à la variété témoin, ce qui n'est pas le cas dans ce dossier. Des études de toxicité sub-chronique de 90 jours avaient été réalisées sur chacun des deux sojas parentaux. Toutefois, ces études portaient sur le tourteau délipidé, ce qui ne permet pas de documenter la sécurité de l'huile, dont la composition est modifiée. Le pétitionnaire a présenté un argumentaire sur l'absence d'interactions entre les protéines nouvellement exprimées dans le soja MON87769 x MON89788, aux niveaux génomique et protéique. **ENGLISH TRANSLATION** Toxicological assessment 1) Standardised guidelines for toxicity tests The potential toxicity of genetically modified MON87769 x MON89788 soya has been assessed only from investigations and tests carried out on proteins PjD6D, NcD15D and CP4 EPSPS. 2) Assessment of new constituents Investigation of the composition of MON87769 x MON89788 soya did not reveal any new constituents except for fatty acids GLA, SDA, trans-ALA and trans-SDA, which were not subjected to toxicological assessment.	

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			3) Assessment of the constituents of foodstuffs and of animal feed for which the levels were altered No investigation has been carried out of the products derived from MON87769 x MON89788 soya. 4) Assessment of food/feed derived from the GM plants (foodstuffs and animal feed) No 90-day study of sub-chronic toxicity has been carried out on rodents using MON87769 x MON89788 soya. 5) Concluding points The dossier presented by the applicant for genetically modified soya MON87769 x MON89788 does not include a 90-day study of sub-chronic toxicity carried out on rodents. This accords with EFSA's recommendations (2006) if equivalent composition has been shown in a comparison with the control variety, which is not the case in this dossier. Studies of sub-chronic (90-day) toxicity had been carried out on each of the two parent soya varieties. Nevertheless, those studies made use of lipid-reduced oil cake, which did not allow documentation of the safety of the oil, which had a modified composition. The applicant put forward an argument based on the absence of interactions between the proteins newly expressed in MON87769 x MON89788 soya, in terms of genomics and protein content.	
France	Ministère de	D, 07.09	Evaluation de l'allergénicité	For the assessment of the allergenicity of the whole GM plant, the

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
	l'Economie (Consommation)	Allergenicity	Conclusion Sur la base des éléments fournis dans le dossier, le potentiel allergénique des protéines PjD6D, NcD15D et CP4 EPSPS exprimées dans le soja MON87769 x MON89788 paraît extrêmement faible. Leur expression dans ce soja ne modifie apparemment pas l'allergénicité de ses graines par rapport à l'allergénicité naturelle des graines de soja. Les protéines PjD6D, NcD15D et CP4 EPSPS ne partagent aucune homologie de séquence avec des protéines à propriétés adjuvantes (toxines) et des propriétés adjuvantes n'ont jamais été rapportées pour ces trois protéines. Enfin, l'huile, préparée à chaud, blanchie et désodorisée, ne renferme pratiquement aucune trace de protéines. **ENGLISH TRANSLATION** Assessment of allergenicity Concluding points Based on the items in the dossier submitted, the allergenic potential of proteins PjD6D, NcD15D and CP4 EPSPS expressed in MON87769 x MON89788 soya appears to be extremely weak. Expression of the proteins in this soya apparently does not alter the soya beans' allergenicity from that of natural soya beans. Proteins PjD6D, NcD15D and CP4 EPSPS have no sequence in common with strains giving rise to proteins with adjuvant (toxic) properties, and adjuvant properties have never been reported for these three proteins. Lastly, the oil, prepared by a warm process and then bleached and deodorised, contains almost no trace of	EFSA GMO Panel requested the applicant for additional experimental studies to address the endogenous allergenicity of soybean MON 87769 x MON 89788. The EFSA GMO Panel considers that there is no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON 87769 x MON 89788 when compared with that of its non-GM comparator. Please see Section 4.3.4.2 of the scientific opinion on application EFSA-GMO-NL-2010-85.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			proteins.	
France	Ministère de l'Economie (Consommation)	D, 07.10 Nutritional assessment of GM food/feed	Evaluation nutritionnelle 1) Evaluation nutritionnelle des denrées alimentaires dérivées de PGM Le pétitionnaire n'a pas réalisé d'évaluation nutritionnelle des denrées alimentaires dérivées du soja MON87769 x MON89788, estimant avoir démontré l'équivalence de composition de ce soja avec la variété témoin A3525. Il rapporte plusieurs études de consommation de différentes quantités de SDA et GLA sans apparition d'effets délétères chez l'homme et les animaux. Cependant, il n'y a pas d'étude concernant la consommation de trans-SDA et des effets négatifs sur le métabolisme lipidique ont été observés chez l'homme lorsque l'apport de trans-ALA dépasse 0,6 % de l'apport énergétique total (EFSA, 2014, avis relatif au dossier EFSA-GMO-UK-2009-76). 2) Evaluation nutritionnelle des aliments pour animaux dérivés de PGM Une étude d'alimentarité a été réalisée sur 800 poulets Cobb 500 (400 mâles et 400 femelles) nourris pendant 42 jours avec deux régimes successifs (démarrage et croissance-finition) contenant 33 et 30 % de tourteaux de soja respectivement. Le soja MON87769 x MON89788 a été comparé avec la variété A3525 et 6 variétés commerciales. Aucun effet significatif n'est observé. Cependant, il n'est pas précisé si le soja a été traité avec du glyphosate. 3) Conclusions de l'évaluation nutritionnelle	The altered fatty acid profile of MON 87769 x MON 89788 soybean was assessed as regards human nutrition and safety. The applicant did not provide a dietary exposure assessment based on the compositional analysis of the RBD oil from MON 87769 x MON 89788 soybean taking into account different exposure scenarios, covering low and high consumer groups, as asked by the EFSA GMO Panel. The EFSA GMO Panel therefore cannot complete the assessment on possible impact of the MON 87769 x MON 89788 soybean oil on human health and nutrition. No information about the treatment of the particular lot used in the feed trial was reported in the dossier. EFSA guidances (2006, 2011) do not require such information on the test material.

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			Pour le poulet de type standard en croissance, le tourteau issu du soja MON87769 x MON89788 a les mêmes qualités nutritionnelles que ceux issus du soja A3525 et des variétés de soja conventionnelles testées dans cette étude. Etant donné que le soja MON87769 x MON89788 a été modifié pour sa composition en acides gras, une étude comparant l'effet de l'origine des huiles sur la croissance des poulets et leur rendement carcasse avec une analyse de la composition en acides gras de la viande aurait été la bienvenue, car l'huile de soja est également utilisée pour l'alimentation animale. **ENGLISH TRANSLATION** Nutritional assessment 1) Nutritional assessment of foodstuffs derived from genetically modified products The applicant has not carried out a nutritional assessment of foodstuffs derived from MON87769 x MON89788 soya, considering that equivalent composition of this soya with the control variety, A3525, had been demonstrated. The applicant reported a number of studies of consumption of various quantities of SDA and GLA, with no adverse effects appearing in humans or other animals. There was, however, no study relating to consumption of trans-SDA, while adverse effects on lipid metabolism have been observed in humans in cases where the intake of trans-ALA accounted for more than 0.6% of the subjects' total energy intake (EFSA, 2014, Opinion relating to the dossier EFSA-GMO-UK-2009-76). 2) Nutritional assessment of animal feedstuffs derived from genetically modified products	

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			A study of suitability for feed was carried out using 800 Cobb 500 chickens (400 males and 400 females) fed for 42 days on two successive diets (a starter diet, and a growth-and-finishing diet) containing 33% and 30% respectively of soya oil cake. Soya MON87769 x MON89788 was compared with variety A3525 and with six commercial varieties. No significant effects were observed. However, it was not specified whether the soya had been treated with glyphosate. 3) Concluding points regarding nutritional assessment For the standard type of chicken in the growth phase, the oil cake derived from MON87769 x MON89788 soya showed the same nutritional qualities as oil cakes tested in this study that were derived from soya A3525 or from conventional soya varieties. Given that MON87769 x MON89788 soya had been given a modified composition of fatty acids, a study comparing the effect of the oils' origins on the chickens' growth and their carcass yields, with an investigation of the fatty-acid composition in the meat, would have been welcome, as soya oil is also used for animal feed.	
France	Ministère de l'Economie (Consommation)	D, 07.07 Anticipated intake/extent of use	Evaluation de l'exposition – consommation prévue/extension d'emploi Le pétitionnaire présente une estimation de la consommation maximale de soja MON87769 x MON89788 par l'Homme en se basant sur le programme GEMS/Food 2011 de l'OMS, en considérant que cette variété est la seule représentée et en utilisant les teneurs en PjD6D, NcD15D et CP4 EPSPS mesurées dans la graine entière du soja MON87769 x MON89788. Chez les enfants de moins de 6 ans, la	The altered fatty acid profile of soybean MON 87769 x MON 89788 was assessed as regards human nutrition and safety. The applicant did not provide a dietary exposure assessment based on the compositional analysis of the RBD oil from soybean MON 87769 x MON 89788 taking into account different exposure scenarios, covering low and high consumer groups, as asked by the EFSA GMO Panel. The EFSA GMO Panel therefore cannot complete the assessment on possible impact of the soybean MON 87769 x MON 89788 oil on human health and nutrition.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			consommation maximale estimée serait de 25,5 et 71,9 mg/kg/j de PjD6D et NcD15D, respectivement et de 899 mg/kg/j de CP4 EPSPS. Pour la population générale, la consommation maximale estimée serait de 13,9 et 39 mg/kg/j de PjD6D et NcD15D, respectivement et de 491 mg/kg/j de CP4 EPSPS. **ENGLISH TRANSLATION** Assessment of exposure – consumption envisaged/extent of use The applicant presented an estimated maximum human consumption of MON87769 x MON89788 soya, based on the WHO's GEMS/Food 2011 programme, considering this variety to be the only soya variety consumed, and using the PjD6D, NcD15D and CP4 EPSPS content values measured in whole MON87769 x MON89788 soya beans. For children under the age of 6, the estimated maximum consumption was shown as 25.5 and 71.9 mg/kg/day for PjD6D and NcD15D, respectively, and 899 mg/kg/day for CP4 EPSPS. For the general population, estimated maximum consumption was shown as 13.9 and 39 mg/kg/day for PjD6D and NcD15D, respectively, and 491 mg/kg/day for CP4 EPSPS.	

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Comments from National Competent Authorities under Directive 2001/18/EC				
Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
France	Ministère de l'Economie (Consommation)	D, 07 Information on any toxic, allergenic or other harmful effects on human or	Caractérisation des risques Le pétitionnaire présente également un calcul des marges de sécurité pour la population générale et les enfants de moins de 6 ans. Le GT considère que la démarche utilisée par le pétitionnaire n'est pas adaptée, car elle s'appuie sur une étude de toxicité aiguë par administration unique. **ENGLISH TRANSLATION** Characterisation of hazards The applicant also presented calculations of safety margins for the general population and for children under the age of 6. The Biotechnology Working Group considers the procedure used by the applicant to be unsuitable, as it depended on a study of acute toxicity involving administration on a single occasion.	Please see the reply above made on a similar aspect.
France	Ministère de l'Economie (Consommation)	General comments	Conclusions du Groupe de travail « Biotechnologie » de l'ANSES Le soja MON87769 x MON89788 est issu du croisement conventionnel entre les sojas MON87769 et MON89788. Les informations moléculaires présentées dans le dossier ne sont pas évocatrices d'un risque pour la santé des hommes et des animaux qui en consommeraient. L'expression des protéines PjD6D, NcD15D et CP4 EPSPS dans ce soja ne modifie apparemment pas l'allergénicité de ses graines par rapport à l'allergénicité naturelle des graines de soja. Sur la base des éléments présentés dans le dossier, le potentiel allergénique des produits dérivés du soja MON87769 x MON89788 paraît extrêmement faible.	The EFSA GMO Panel took note of the comments made. Please consider the replies made already on similar aspects.

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			La caractérisation phénotypique et agronomique du soja MON87769 x MON89788 a été réalisée à partir de cultures non traitées avec du glyphosate. L'analyse de composition n'a été réalisée qu'avec du soja traité avec du glyphosate. Cela ne suit pas les recommandations de l'EFSA (2006). L'équivalence de composition du soja MON87769 x MON89788 avec des variétés conventionnelles n'est pas démontrée. La valeur nutritionnelle de la fraction délipidée (tourteau) de ce soja en alimentation animale n'est pas différente de celle des variétés de soja conventionnelles. Etant donné que le soja MON87769 x MON89788 a été modifié pour sa composition en acides gras, une étude comparant l'effet de l'origine des huiles sur la croissance des poulets et leur rendement carcasse avec une analyse de la composition en acides gras de la viande aurait été la bienvenue, car l'huile de soja est également utilisée pour l'alimentation animale. Le pétitionnaire ne fournit pas d'études de toxicité sub-chronique de 90 jours concernant cet OGM. Par conséquent, le GT « Biotechnologie » ne peut statuer sur les risques liés à l'utilisation de cet OGM dans l'alimentation humaine et animale. CONCLUSIONS ET RECOMMANDATIONS de L'ANSES L'Agence nationale de la sécurité sanitaire de l'alimentation, de l'environnement et du travail adopte les conclusions du Groupe de travail « Biotechnologie ». Sur la base du dossier initial disponible dans les délais prévus, l'Agence émet un avis défavorable à la demande d'autorisation de mise sur le	

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			marché, au titre du règlement (CE) n°1829/2003, du soja génétiquement modifié MON87769 x MON89788. **ENGLISH TRANSLATION** Concluding points from the ANSES Biotechnology Working Group Soya MON87769 x MON89788 is the result of a conventional cross between soya varieties MON87769 and MON89788. The molecular information presented in the dossier does not suggest any health risk to humans or to animals that would eat it. The expression in this soya variety of proteins PjD6D, NcD15D and CP4 EPSPS apparently does not change the soya beans' allergenicity as compared with the natural allergenicity of soya beans. Based on the items presented in the dossier, the allergenic potential of products derived from MON87769 x MON89788 soya appears to be extremely low. The agronomic and phenotypical characterisation of MON87769 x MON89788 soya was carried out using crops not treated with glyphosate. The investigation of composition was carried out using only soya plants that HAD been treated with glyphosate. This does not accord with EFSA's recommendations (2006). Equivalent composition has not been demonstrated for MON87769 x MON89788 soya in comparison with the conventional varieties. The nutritional value in animal feed of this soya's lipid-reduced fraction (in the oil cake) does not differ from that of conventional soya varieties. Given that MON87769 x MON89788 soya was modified to change the fatty-acid composition, a study comparing the effects of the	

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			oils' origins on the growth of chickens and on their carcass yields would have been welcome. This should have included an investigation of the meat's fatty-acid composition, as soya oil is also used in animal feed. The applicant has not supplied 90-day studies of sub-chronic toxicity for this GMO. Consequently, the Biotechnology Working Group cannot rule on the risks associated with use of this GMO in the diets of humans or other animals. CONCLUDING POINTS AND RECOMMENDATIONS FROM ANSES ANSES, France's Agency for Food, Environmental and Occupational Health & Safety, is adopting the concluding points of its Biotechnology Working Group. Based on the initial dossier provided within the period envisaged, ANSES is issuing an Opinion that does not, for the purposes of Regulation (EC) No. 1829/2003, favour the request for a marketing authorisation for genetically modified soya variety MON87769 x MON89788.	

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Comments from National Competent Authorities under Directive 2001/18/EC				
Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	A. General information	The scope of application EFSA-GMO-NL-2010-85 covers import and processing of soybean MON 87769 x MON 89788 including all feed and food products containing, consisting of, or produced from the genetically modified soybean MON 87769 x MON 89788. Cultivation is not covered by this application. MON 87769 x MON 89788 was obtained by traditional breeding of two inbred lines, one derived from MON 87769 and the other one derived from MON 89788. Both single events have previously been risk assessed by EFSA and, beyond that, MON 89788 has already been approved in the EU (import and processing). In line with the risk assessment of soybean MON 87769 x MON 89788 the applicant refers to data given in the respective applications for authorization of the single events MON 87769 (see EFSA-GMO-UK-2009-76) and MON 89788 (see EFSA-GMO-NL-2006-36), respectively. Concerning this matter, we would like to refer to the German comments which we have already submitted in conjunction with the risk assessment of these applications. The Federal Office of Consumer Protection and Food Safety (BVL) as German CA is of the opinion, that the entirety of available data supports the conclusion that soybean MON 87769 x MON 89788 is unlikely to have adverse effects on human and animal health or on the environment in the context of its intended use. Nevertheless, completion and/or clarification on some points of the dossier are recommended.	The EFSA GMO Panel notes the comment.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	A, 07 Where appropriate, the conditions for placing on the market the food(s) or	The import documents should indicate that soybean MON 87769 x MON 89788 has not been approved for cultivation by the EC. In addition to the intended GM labelling a clear labelling of soybean MON 87769 x MON 89788 indicating the tolerance to glyphosate is recommended. Furthermore, appropriate measures have to be taken during transport, storage, and processing to avoid unintended release of viable soybean seed into the environment. In this context, the applicant should inform all parties involved in the handling and processing of soybean MON 87769 x MON 89788 about avoidance and control of spillage. Soybean MON 87769 x MON 89788 and soybean oil derived thereof differ from conventional soybean and soybean oil with respect to their content of stearidonic acid (SDA), an omega-3 fatty acid not present in conventional soybean. In addition gamma-linolenic acid is formed. Further, the level of nutritionally undesirable trans-fatty acids (trans-SDA and trans-alpha-linolenic acid) is higher in SDA-rich MON 87769 x MON 89788 soybean oil compared to conventional soybean oil which contains only traces of trans-alpha-linolenic acid. As no definite conclusion can be drawn to date on the effects of an elevated consumption of SDA, the German CA suggests (as already proposed for single event MON 87769) imposing conditions for the use of SDA-rich soybean oil in food which are equivalent to those laid down in Commission Decision 2008/558/EC for the use of refined Echium oil which is naturally high in SDA. In analogy to refined Echium oil, the maximum content of trans-fatty acids in SDA-rich soybean oil should be limited to 2% of total fatty acids.	Outside the remit of the EFSA GMO Panel.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.01 Comparative assessment	Compositional analysis: For the compositional analysis of soybean MON 87769 x MON 89788, the applicant performed field trials at five different US American field sites in 2007. All MON 87769 x MON 89788 test plots providing the basis for the compositional analysis received applications of glyphosate, however, no data on the GM soybean MON 87769 x MON 89788 non-treated with glyphosate (treated with conventional pesticides only) were supplied. This design is not fully in line with the recommendation of EFSA, according to which the experimental design of field trials should include the herbicide-tolerant GM plant exposed to the intended herbicide (in the present case: glyphosate), the comparator treated with conventional herbicide management regimes, and the GM plant treated with the same conventional herbicide management regimes. This design would allow assessment of whether the expected agricultural condition might influence the expression of the studied parameters within the compositional analysis. Therefore, the applicant should be requested to demonstrate that the composition of forage and seed from soybean MON 87769 x MON 89788 do not raise any safety concerns independent of glyphosate treatment.	The application of the intended herbicide represents the most realistic scenario in commercial use of soybean MON 87769 x MON 89788. Beside the modified fatty acid profile, none of the other differences identified in the composition of grain and forage obtained from the intended herbicide treated soybean MON 87769 × MON 89788 required further assessment regarding food and feed safety. Therefore, the EFSA GMO Panel was in the absence of compositional data obtained from conventional herbicide treated soybean MON 87769 × MON 89788 able to conclude on the comparative assessment.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.02 Field trials	According to Production Plan Number 07-01-83-27 (FROM CBI: 07-01-83-27 MSL0021807) field trials were conducted in 2007 in the United States at a total of eight field sites. However, the compositional analysis was carried out for only five of the eight originally planned locations (FROM CBI: MSL 0021916). The restriction to five sites is not clearly comprehensible on the basis of the application documents and, therefore, should be explained by the applicant.	According to the applicable EFSA guidance on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events (EFSA, 2007) at the date of submission of this application, the field trials need to be carried out at least during one season, however the the number of sites were not predefined. The EFSA GMO Panel was in the position to conclude based on the data provided from five locations.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.03 Selection of compounds for analysis	Compositional analysis was performed on 68 parameters in seed and 7 parameters in forage. The range of analytical components was in line with the OECD consensus document for soybean in the 2001 version (OECD, 2001) which was valid at that time. Nevertheless, the German CA would like to point out that the OECD published a revised consensus document in 2012 (OECD, 2012). As a result, three newly recommended analytes were not considered in the original compositional analysis: phosphorus and calcium (for feed use) as well as vitamin K (for food use). OECD (2001) Consensus document on compositional considerations for new varieties of soybean: key food and feed nutrients and anti-nutrients. Series on the Safety of Novel Foods and Feeds No.2, ENV/JM/MONO (2001)15. OECD (2012) Revised consensus document on compositional considerations for new varieties of soybean [Glycine max (L.) Merr.]: key food and feed nutrients, anti-nutrients, toxicants and allergens. Series on the Safety of Novel Foods and Feeds No.25, ENV/JM/MONO (2012)24.	The EFSA GMO Panel notes the comment. Field trials performed for compositional studies of plant tissues from year 2012 onwards should include the constituents mentioned by the Member State.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.04 Agronomic traits	The provided data suggest that no relevant changes to agronomic and phenotypic characteristics occurred in soybean MON 87769 x MON 89788. Even so, the German CA would like to point out that the performed agronomic and phenotypic characterisation is not fully in line with the recommendation of EFSA because only MON 87769 x MON 89788 test material not treated with glyphosate was considered. However, data volume as well as performance and results of the agronomic study do not give cause for concern. This applies particularly in view of the scope of the present application (import and processing, not cultivation) and the existing data regarding the single soybean events which have already been risk assessed. Nevertheless, in order to meet the recommendations of EFSA, the applicant would do well to explain about the used line of action and the adequacy of the obtained data in more detail.	The EFSA GMO Panel agrees with the German viewpoint as the data package on agronomic and phenotypic characteristics of the GM soybean was considered satisfactory according to the guidance document in application.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.10 Nutritional assessment of GM food/feed	With regard to the conducted broiler feeding study (FROM CBI: CQR-08-034 2009), it should be noted that specifications on the preparation of the diets are missing. The performed analysis of the soybean meal suggests the usage of meal from defatted soybeans. However, it is noticeable that the total fat content of the diverse test materials differs from each other. According to page 11 of the study report, information on the production of the test materials is available at Monsanto Company, however, these data were not part of the application documents and, therefore, should be delivered in addition. Furthermore, according to the tables on the diet formulation, the diets also contain a proportion of soybean oil in addition to the incorporated soybean meal. However, information on the fatty acid composition, which may have an influence on the results, is not given. Without the information on the fatty acid profile in the rations, the described results on the	The EFSA GMO Panel concluded that in the 42-day study on chicken for fattening, diets containing toasted soybean meal derived from MON 87769 × MON 89788 were as nutritious as those containing the comparator and non-GM commercial varieties.

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			performance parameters of broilers can not be adequately evaluated. Therefore, the applicant should be requested to provide the missing information on the preparation of test materials and composition of the diets.	
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 07.07 Anticipated intake/extent of use	The applicant should specify whether and, if so, which impacts on the food (e.g. meat or milk) derived from animals which were fed on materials derived from soybean MON 87769 x MON 89788 are expected and consider this in the exposure assessment.	The EFSA GMO Panel was not in the position to conclude on the nutritional assessment because a dietary exposure assessment on oil derived from soybean MON 87769 x MON 89788 was not provided by the applicant.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 08 Post-market monitoring of GM food/feed	Since the use of oil derived from soybean MON 87769 x MON 89788 will result in a higher intake of stearidonic acid, the applicant should be requested to propose a post-market monitoring plan to confirm the exposure assessment using realistic consumption data for the European population (corresponding to the procedure applied to single event MON 87769).	As a full assessment on possible health and nutritional impact of the MON 87769 x MON 89788 soybean oil was not made, the EFSA GMO Panel is not in the position to comment on the post-market monitoring plan and labelling.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 12 Environmental Monitoring Plan	The monitoring plan is basically acceptable, but needs further elaboration for implementation. Therefore, the applicant is recommended to revise the monitoring plan during the initial implementation phase (after consent is given) and present this revised monitoring plan together with a first report one year after consent is given to be reassessed.	The EFSA GMO Panel agrees with the German comment. Considering that the definite and final endorsement of the PMEM plan is with risk managers, the EFSA GMO Panel is of the opinion that further discussion on the practical implementation of the PMEM plan (e.g. involvement of existing monitoring systems) is needed between the applicant and risk managers at the time of approval of the GM soybean.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 12.02 Case-specific GM plant monitoring	According to the risk assessment no adverse effects on the environment or human health were identified or were expected. Therefore, there is no necessity for a case-specific monitoring.	The EFSA GMO Panel fully agrees with the German comment. As no potential adverse environmental effects were identified, case-specific monitoring was not considered necessary.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 12.03 General Surveillance of the impact of the GM plant	The monitoring plan does not relate the monitoring activities to relevant protection goals. Even more, it is not described which routine observations (including parameters or monitoring characters) are carried out in relation to the protection goals. Only reporting on 'any unanticipated effect' is solely not an appropriate parameter, because it already anticipates an evaluation. This evaluation process should be based on a distinct set of parameters and a scientific sound data analysis. It is requested that the applicant specifies in detail, how and which information will be pro-actively queried, gathered and how they will be evaluated. In addition, it might be useful to integrate food and feed surveillance in coordination with the competent authorities. Information about the use of the product in food and feed could deliver supplementary helpful data (of exposure to consumers and animals) for general surveillance. Therefore, the applicant should specify monitoring activities in the field of human and animal health. It should be described in detail how animal and human health surveillance is integrated in the monitoring plan. Farmers' survey (for cultivation) and operators' survey (for import and processing): The strategy of General Surveillance is mainly based on the involvement of importers, traders, silo operators, and processors coordinated by EuropaBio. The applicant will inform the selected networks of operators about market release of GM plant products and will remind them to report on 'any unanticipated adverse effect'. It is stated that these third parties have to follow legal obligations of food and feed hygiene (HACCP). Nevertheless, the role and interplay of all	The EFSA GMO Panel gives its opinion on the scientific quality of the post-market environmental plan (PMEM) activities proposed by the applicant. The PMEM plan currently submitted by the applicant for GM soybean is the standard PMEM plan developed jointly by applicants and risk managers and submitted as part of marketing applications for import and processing of GM plants in the EU. The EFSA GMO Panel agrees that the present PMEM plan and in particular the supporting methodology needs to be further detailed by the applicant. However, in accordance with its guidance documents on PMEM of GM plants (EFSA, 2006, 2011), the EFSA GMO Panel recognises that all parties (e.g. applicants, Member States) have to consider their roles in the PMEM of GM plants. Therefore, considering that the definite and final endorsement of the PMEM plan is with risk managers, the EFSA GMO Panel is of the opinion that further discussion on the practical implementation of the PMEM plan (e.g. involvement of existing monitoring systems) is needed between the applicant and risk managers at the time of approval of the GM soybe

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			actors on behalf of recording, analysis, and evaluation of monitoring data needs more transparency. Identification of existing networks: The applicant should consider whether other existing monitoring networks might be used in particular in the field of human and animal health. In such a case the selection and evaluation process should be described in detail. Review of ongoing research and development activities and literature review In general other sources of information, e.g. peer-reviewed publications or on going research should be taken into account. However, the applicant should describe in detail how he will consider this information within General Surveillance.	
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	D, 12.06 Reporting the results of monitoring	A report on General Surveillance activities on an annual basis is sufficient. Reporting should refer to the format introduced by the Commission Decision 2009/770/EC.	The EFSA GMO Panel agrees with the German comment. The reporting on general surveillance activities is essential on an annual basis. The EFSA 2011 guidance on the PMEM of GM plants also recommends applicants to submit their PMEM reports periodically (e.g. every third year) covering longer periods in which observations and data collected are reported and analysed in detail and which therefore provide more comprehensive reports that are important for a longer term feedback on the environmental risk assessment ('comprehensive report'). The final decision on reporting frequency is left in the hands of risk

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				managers.
Germany	Federal Agency for Nature Conservation (BfN)	A. General information	The Federal Agency for Nature Conservation (BfN) considers that further information is required before the risk assessment of MON 87769 x MON 89788 soybean can be finalised (see specific comments). In particular the environmental risk assessment and the monitoring plan should be amended. Information (data and data analyses) provided on phenotypic evaluation, composition, and toxicology is insufficient and conclusions of equivalence of MON 87769 x MON 89788 soybean and conventional soybean and on food and feed safety based on this information are premature. The environmental risk assessment cannot be finalised because a study in rodents on the effect of the GM soybean on human and animal health is missing (cf. comments under D, 07.08). The applicant submitted only a short-term toxicity study of delta-6 desaturase and delta-15 desaturase following a single oral gavage to mice. This study is not sufficient to show the safety of MON 87769 x MON 89788 soybean on human and animal health. In accordance with EFSA (2011) at least a 90-day toxicity study in rodents should be included. The applicant's proposal for an environmental monitoring plan does not meet the objectives defined in Annex VII of Directive 2001/18/EC and the supplementing guidance notes (2002/811/EC) and therefore should be amended. EFSA (2011). Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified	This organization has given more detailed comments on the specific issues raised when addressing subject by subject. The EFSA GMO Panel gives its response to these more specific comments.

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			plants. EFSA Journal 2011; 9(5): 2150.	
Germany	Federal Agency for Nature Conservation (BfN)	D, 02 Information on the sequences actually inserted or deleted	The data submitted for the molecular characterisation of MON 87769 x MON 89788 consist of Southern blot analyses to demonstrate the presence of introduced traits (NcΔ15D and CP4-EPSPS) and the intactness of the inserts (FROM CBI: REG-08-383 MSL0022285). We would like to point out that the use of Southern blot analyses only allows a rough estimation of the intactness of the inserts. Rearrangements of the magnitude up to 50 bp cannot be detected by this method. In light of ever cheaper and easier to perform sequencing methods, it would not be inappropriate to request new sequencing data on the stacked event of the applicant. The new sequence data should be compared to the single events and the sequences used in the creation of the single events in order to make a qualified and definitive statement on the intactness of the insertions. Only with this method will it be possible to detect smaller changes (e.g. SNPs) that could affect the detectability of the event using commonly applied screening methods (cf. Morriset et al., 2009) or even on the function of the encoded proteins. Morriset, D., Demšar, T., Gruden, K., Vojovoda, J., Štebih, D. and Žel J. (2009) Detection of genetically modified organisms – closing the gaps, Nature Biotechnology 27 (8), 700-701.	The molecular characterisation of the events has been assessed in the frame of the single events. The maintenance of the structure of the singles in the stacks has been analysed with Southern blots, which is in line with the EFSA Guidance document (EFSA, 2007). The cost-effectiveness of the techniques used for data generation supporting the risk assessment is not a factor that is taken into account by the GMO Panel.
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.02 Field trials	Field trials for compositional analysis, US- field trials: Field trials for the compositional analyses were conducted at five locations in the USA in 2007 (FROM CBI: MSL 0021916; 07-01-83-27 MSL0021807). At each field site, the test (MON 87769 × MON 89788), A3525 (control) and reference seeds	Please consider the replies made already on similar aspects above.

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			were planted in a randomised complete block design with three replicates per block. The GMO was treated with the complementary herbicide. The experimental design has got several weak points: i. Although the field trial sites are located in the major soybean growing region in the United States, it is uncertain if the locations chosen are representative of the range of receiving environments. The notifier should clearly indicate whether the cultivation and environmental conditions of the test sites in the USA are representative of the range of receiving environments (cf. EFSA 2011, p.14). ii. The complementary herbicide glyphosate was applied to all replicates of MON 87769 × MON 89788 and MON 89788 at all sites. A control without application of the herbicide is missing, therefore the influence of the herbicide on the composition cannot be analysed. iii. The purity of starting material was not sufficiently tested. Starting material was analysed for the presence of MON 89788 and MON 87769 events, but not for contamination with other GM soybean varieties. iv. The trial site description contains some relevant information, but history of pest management, present pest and disease infestation is missing. v. Interactions between environmental factors (climate, soil or agricultural practices) and the GMO were not analysed.	

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.02 Field trials	Field trials for phenotypic and agronomic analysis, Argentinian field trials: Field trials for phenotypic and ecological data were conducted at 5 locations in Argentina in 2008. At each site, three replicated plots of MON 87769 × MON 89788, a conventional soybean variety with a similar genetic background to the test plant, and four non-GM references were planted using a randomized complete block design. The experimental design has got several weak points: i. The complementary herbicide glyphosate was not applied for the production of MON 87769 × MON 89788 material that was assessed for agronomic parameters as suggested by EFSA (2011). ii. The parental lines (single events) were not tested in the same study. The comparison to the parental single events allows the analysis of potential interactions which may impact on safety, thus suggesting the parental events as ideal additional comparators. iii. The purity of starting material was not sufficiently tested. The starting material of the test was analysed for the presence and the control for the absence of MON 87769 × MON 89788 but not for contamination with other GM soybean varieties. Nor where the reference lines analysed with regard to the GMO content. iv. The trial site description contains some relevant information, but history of pest management, present pest and disease infestation is missing.	According to the applicable EFSA guidance on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events (EFSA, 2007) at the date of submission of this application, the field trials need to be carried out at least during one season, however the the number of sites were not predefined. The EFSA GMO Panel was in the position to conclude based on the data provided by the applicant. According to the applicable EFSA guidance on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events (EFSA, 2007) at the date of submission of this application, it was not obligatory to cultivate along with the two-event stack the single events. In the absence of defined criteria, the EFSA GMO Panel was satisfied with the purity testing of the starting material and was in the position to conclude on the comparative assessment. Please, see the comment above.

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			v. Interactions between environmental factors (climate, soil or agricultural practices) and the GMO were not analyzed. The experimental design of field trials should be devoid of the above listed deficits. We recommend including data from field experiments from several years for the analysis to include climatic variation between years. These should – in accordance with the step-by-step principle – be supplemented by data from greenhouse studies, e.g. those already collected during breeding of MON 87769 × MON 89788 soybean, which allows simulation of well-defined abiotic and biotic conditions. The field trials should be representative of the climate range of the main soybean cultivation areas. According to the likely use of glyphosate as complementary herbicide during cultivation of MON 87769 × MON 89788 soybean, field study design needs to include application in comparison to non-application of glyphosate. EFSA (2011). Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011; 9(5): 2150.	

Application EFSA-GMO-NL-2010-85 (soybean MON 87769 x MON 89788) Comments and opinions submitted by Member States during the three-months consultation period				
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Germany	Federal Agency for Nature Conservation (BfN)	D, 07.04 Agronomic traits	The deficits listed under D, 07.02 also apply here, namely the applicant is asked (i) to demonstrate the representativeness of the selected trial sites, (ii) to include glyphosate treated MON 87769 x MON 89788 and MON 89788 in the analysis, (iii) to consider site-by-genotype interactions adequately in individual-site analyses and (iv) to provide information and data about the identity and purity of the starting material (test, control and references). Further deficits of the phenotypic and ecological assessment are: i. The selected agronomic characteristics provide only limited information on ecological effects of the GMO and cannot sufficiently indicate differences in reproduction, dissemination, and survivability of MON 87769 × MON 89788 compared to conventional soybean as data on pollen viability and dormancy were not assessed and results about volunteers from field releases performed in various countries are not provided. ii. Pesticides were applied rarely or frequently depending on the site. It cannot be excluded that both aspects interfered with the collection of ecological interaction data (e.g. arthropod abundance). iii. Comparing information and data on biotic stress (prevailing pest and disease pressure) are missing for the locations (cf. comment under D, 07.02). Information about the abiotic stressors and diseases which were actively causing plant injury and which were likely to occur was not given.	Please, see the comment above. Considering the scope of application EFSA-GMO-NL-2010-85, special attention is paid to those agronomic and phenotypic characteristics (for further details, see Section 4.2) which may be indicative of changes in the survival of soybean MON 87769 x MON 89788 grains which could be accidentally released into the environment, as well as in the establishment and fitness of GM soybean plants: e.g. early and final stand count, yield, seedling vigour and 100 seed weight. In this respect, the EFSA GMO Panel was satisfied with the data package provided by the applicant. As described in Section 4.2, all these agronomic and phenotypic characteristics, except plant height, of soybean MON 87769 x MON 89788 did not differ from those of its comparator. Soybean MON 87769 x MON 89788 not treated with glyphosate-based herbicides had a higher plant height than its comparator in the across-site analysis. The measured values for this characteristic fell within the natural range set by a set of reference varieties. The observed difference in plant height is unlikely to be biologically relevant in terms of increased persistence and invasiveness potential.

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Germany	Federal Agency for Nature Conservation (BfN)	D, 07.08 Toxicology	The increased feed intake, bird weight and carcass yield parameters in male birds found in the 42-day feed performance study in broiler chickens (FROM CBI: CQR-08-2) (s. D, 07.10) may be attributed to an increased nutritional value of soybean meal from MON 87769 x MON 89788. However, to exclude adverse effects from the consumption of MON 87769 x MON 89788 a toxicity study, particular a 90-day feeding study in rats with MON 87769 x MON 89788 should be performed. So far compositional analysis as well as nutritional and toxicological assessment did neither address herbicide residues or metabolites nor potential unintended effects deriving there from. However, this has to be taken into account while performing a toxicological risk assessment. To assess the risk of toxic effects from herbicide residues or metabolites or from transformation in general, we recommend the performing of a chronic toxicity study (according to OECD test guideline 414) in rodents with MON 87769 x MON 89788 soybean plant material that was treated with the complementary herbicide during production (according to OECD test guideline 408). Alternatively a two-generation reproductive toxicity study (according to OECD test guideline 416) could be taken into consideration. OECD (1998) Prenatal Development Toxicity Study, http://www.oecd-ilibrary.org/environment/test-no-414-prenatal-development-toxicity-study_9789264070820-en OECD (1998) Guideline for the Testing of Chemicals – Repeated Dose 90-day Oral Toxicity Study in Rodents, 408. http://browse.oecdbookshop.org/oecd/pdfs/free/9740801e.pdf	The EFSA GMO Panel concluded that in the 42-day study on chicken for fattening, diets containing toasted soybean meal derived from MON 87769 × MON 89788 were as nutritious as those containing the comparator and non-GM commercial varieties. The EFSA GMO panel did not consider necessary a 90-day study (or other toxicological studies in rodents) for the risk assessment of MON 87769 x MON 89788 on the basis of the assessment of preceding analyses (comparative assessment and molecular characterisation). Regarding the assessment of herbicide residues or metabolites by toxicological studies, this is outside th remit of the EFSA GMO Panel.

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			OECD (2001) Two-Generation Reproduction Toxicity, 416. http://www.oecd-ilibrary.org/environment/test-no-416-two-generation-reproduction-toxicity_9789264070868-en Assessment of the whole food and/or feed derived from GM plants: So far, the 42-day broiler feeding study (CQR-08-2) is the sole feeding study with material from the whole GM soybean MON 87769 x MON 89788 that has been provided by the applicant. Seeing the statistically significant differences between test and control for male birds by gender analysis and the mentioned deficiencies, a 90-day rat feeding study with MON 87769 x MON 89788 should be requested. Design and performance of a 90-day feeding study in rodents: In light of uncertainties and in accordance with EFSA (2011), at least a 90-day toxicity study in rodents should be included. In addition, we advise to carry out long-term chronic studies and supplemental studies with ruminants and swine which differ with respect to their digestive systems and which will be substantially exposed to feed derived from MON 87769 x MON 89788 soybean. EFSA (2011). Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011; 9(5): 2150.	

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.10 Nutritional assessment of GM food/feed	The 42-day feed performance study in broiler chickens (FROM CBI: CQR-08-034) showed seven statistically significant differences ($p < 0.05$) between test and control for male birds by gender analysis (FROM CBI: RAR-10-168). These differences have been observed in performance as well as carcass parameters. The genetically modification of MON 87769 x MON 89788 soybean results in increased levels of the omega-3 fatty acid, i.e. stearidonic acid as well as gamma-linolenic acid. The increased feed intake, bird weight and carcass yield parameters in male birds may be attributed to an increased nutritional value of soybean meal from MON 87769 x MON 89788. However, to exclude adverse effects from the consumption of MON 87769 x MON 89788 a toxicity study, particular a 90-day feeding study in rats with MON 87769 x MON 89788 should be performed. Furthermore, the 42-day broiler feeding study has got a couple of weak points: (i) the study did not test and compare soybean meal from MON 87769 x MON 89788 grown with and without glyphosate. Also, information is missing about which herbicides were applied during production of the test material. (ii) Reference varieties were produced at different locations than the test and control varieties. (iii) Neither the test material (test, control and reference varieties) nor the basal diet, which contained about 60 % corn as main ingredient, were analysed for contamination with GM material. The only conducted test was to check the test and control variety for MON 87769 and MON 89788. The respective analytical report (COA-2008-164) was not provided and should be requested. (iv) Diets were supplemented with salinomycin, which is a regular feed supplement in industrial poultry farming. Salinomycin is effective not only against protozoa and gram-positive	The EFSA GMO Panel identified no evidence of unintended effects introduced by the genetic modification into soybean MON 87769 x MON 89788 was detected in the tested chicken study. The Panel concluded that toasted soybean meal derived from MON 87769 × MON 89788 is as nutritious as the comparator and non-GM commercial varieties. However, the EFSA GMO Panel could not complete a full assessment on possible impact of the MON 87769 x MON 89788 soybean oil on human health and nutrition. There are no concerns regarding the use of feeding stuffs derived from defatted toasted soybean meal MON 87769 x MON 89788.

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			bacteria, but also kill or inhibits human cancer stem cells and breast cancer cells in mice (Naujokat et al. 2010 http://www.spandidos-publications.com/mmr/3/4/555). Therefore, this compound may well suppress the development of cancer in the fast growing broiler chicks or cover any related adverse effects. Because of the mentioned deficiencies the broiler feeding study is not suited to support the conclusion that MON 87769 x MON 89788 is as safe as conventional soybean in terms of food and feed safety nor does it support the applicant's claim of the absence of any pleiotropic or toxic effects linked to the transgenic protein or the genetic modification. CQR-08-034, 2009. Comparison of broiler performance and carcass parameters when fed diets containing soybean meal produced from MON 87769 × MON 89788, control, or reference soybean. Study No. CQR-08-034, 1-125 Naujokat C., Fuchs D. and G. Opelz. (2010): Salinomycin in cancer: A new mission for an old agent Molecular Medicine REREPORORTS 3: 555-559. RAR-10-168. Comparison of broiler performance and carcass parameters when fed diets containing soybean meal produced from MON 87769 × MON 89788, control, or reference soybean. By Gender Analysis. Study No. RAR-10-168, 1-5	

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	Federal Agency for Nature Conservation (BfN)	D, 08 Post-market monitoring of GM food/feed	The data provided to show the human and animal safety of MON 87769 x MON 89788 soybean on the basis of its substantial equivalence to conventional soybean (except for the introduced traits) are not sufficient. Therefore, a post-market monitoring for food and feed is required. The applicant is further requested to explain how the PMM of MON 87769 x MON 89788 soybean in mixed GMO commodities imported, processed or used for food/feed is realized. This is requested because the monitoring of a GMO must be carried out on a case-by-case basis (Directive 2001/18/EC) with regard to species characteristics, modified traits, the intended use and the degree of exposure. Specific GM product quantities should be provided to estimate the degree of exposure. In case of mixed commodities, according to the precautionary principle, each imported and processed commodity must be assumed to contain any in the EU approved GM soybean and consequently all parameters identified for the different GM soybean products should then be monitored.	As a full assessment on possible health and nutritional impact of the MON 87769 x MON 89788 soybean oil was not made, the EFSA GMO Panel is not in the position to comment on the post-market monitoring plan.
Germany	Federal Agency for Nature Conservation (BfN)	D, 10 Potential changes in the interactions of the GM plant with the biotic	Environmental risk assessment: The Federal Agency for Nature Conservation (BfN) considers that further information is required before the risk assessment of MON 87769 x MON 89788 can be finalised. The environmental risk assessment (e.r.a.) should be amended subjected to the required further information.	Considering the scope of application EFSA-GMO-NL-2010-85, the absence of target organisms and the low level of exposure to the environment, potential interactions of the GM soybean with the biotic environment were not considered a relevant issue by the EFSA GMO Panel.

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Germany	Federal Agency for Nature Conservation (BfN)	D, 12 Environmental Monitoring Plan	Interplay between Environmental Risk Assessment and PMEM: The information necessary to conclude on the ERA is partly missing. Thus, the safety of MON 87769 x MON 89788 soybean cannot be fully assessed. Depending on those results the conclusions concerning case-specific monitoring may need to be revised.	No safety concern to the environment were identified from the import and processing of soybean MON 87769 x MON 89788. There are no indications of an increased likelihood of establishment and spread of feral soybean MON 87769 x MON 89788 plants in the case of accidental release into the environment of viable GM soybean seeds. The unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87769 x MON 89788 to bacteria does not raise a safety concern for these bacteria owing to the lack of a selective advantage. Potential interactions of soybean MON 87769 x MON 89788 with the biotic and abiotic environment were not considered a relevant issue by the EFSA GMO Panel. The EFSA GMO Panel therefore concludes that, as no potential adverse environmental effects were identified, case-specific monitoring was not considered necessary.
Germany	Federal Agency for Nature Conservation (BfN)	D, 12.01 General	The scope of this application is for import, processing, and all uses for food and feed. The applicant provides an environmental monitoring plan, which remains very general. The structure of the monitoring plan has to be provided in accordance with EFSA (2011). The monitoring plan has to be elaborated in more detail in order to meet the following requirements: • Provision of a fully specified list of monitoring parameters. • Application of standardised sampling methodologies: A basic prerequisite for comparing GMO monitoring data is the use of appropriate standard detection or analytical methods. Several standards specific for GMO monitoring are provided by the Association of German Engineers (VDI). They are	The EFSA GMO Panel gives its opinion on the scientific quality of the post-market environmental plan (PMEM) activities proposed by the applicant. The PMEM plan currently submitted by the applicant for GM soybean is the standard PMEM plan developed jointly by applicants and risk managers and submitted as part of marketing applications for import and processing of GM plants in the EU. The EFSA GMO Panel agrees that the present PMEM plan and in particular the supporting methodology needs to be further detailed by the applicant. However, in accordance with its guidance documents on PMEM of GM plants (EFSA, 2006, 2011), the EFSA GMO Panel recognises that all parties (e.g. applicants, Member States) have to consider their roles in the PMEM of GM plants. Therefore, considering that the definite and final endorsement of

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			available under http://www.vdi.eu/engineering/vdi-standards/. • Elaboration of a sampling concept. • In case of monitoring data being collected by external persons or institutions other than the applicant, binding agreements/contracts with third parties are requested which clearly determine what data are provided and how these data are made available. • Elaboration of the methods of data analysis including the statistical methods. • Application of the concept of adverse effects and environmental damages: Adverse environmental effects can only be determined if they are related to certain relevant subjects of protection (Bartz et al. 2009). The subject of protection is damaged if it is significantly adversely affected. The identification of a significant adverse effect should consider both its intensity (e.g. extent of loss) and the value of the impaired subject of protection (e.g. high value of protected species). The monitoring should be run in regions, where MON 87769 x MON 89788 soybean will be transported, stored, packaged, processed or used for feed/food. In case of substantial losses and spread of MON 87769 x MON 89788 soybean, all receiving environments need to be monitored. The time period of monitoring needs to be sufficient to detect delayed or long-term adverse effects. Therefore it may be necessary to extend the monitoring regarding certain	the PMEM plan is with risk managers, the EFSA GMO Panel is of the opinion that further discussion on the practical implementation of the PMEM plan (e.g. involvement of existing monitoring systems) is needed between the applicant and risk managers at the time of approval of the GM soybean.

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			parameters beyond the period of consent. Since traders may commingle MON 87769 x MON 89788 soybean with other commercial GM soybean imported, processed or used for food/feed, the applicant is requested to explain how the monitoring will be designed to distinguish between potential adverse effects caused by MON 87769 x MON 89788 soybean and those caused by other GM soybean. The Federal Agency for Nature Conservation is of the opinion that a detailed monitoring plan has to be provided before consent may be given. Bartz, R., Heink, U. and Kowarik, I. (2009). Proposed Definition of Environmental Damage Illustrated by the Cases of Genetically Modified Crops and Invasive Species. Conservation Biology 24 (3): 675–681. DOI: 10.1111/j.1523-1739.2009.01385.x EFSA Journal (2011). Scientific opinion guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 9, 2150	
Germany	Federal Agency for Nature Conservation (BfN)	D, 12.02 Case-specific GM plant monitoring	We do not share the opinion of the applicant that a case-specific monitoring is not necessary. Case-specific monitoring has to focus on pathways, where MON 87769 x MON 89788 soybean enters the environment. The applicant is requested to provide an appropriate case-specific monitoring plan comprising at least the following elements: i.) spillage or loss of MON 87769 x MON 89788 soybean during transport, storage, packaging, processing and use,	Please see the reply to previous similar comment from BfN. The EFSA GMO Panel takes into account that this application does not include cultivation of the GM 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

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			ii.) potential spread and persistence of MON 87769 x MON 89788 soybean, if spillage or loss of viable MON 87769 xMON 89788 soybean occurs. For these parameters, the use of the following methods is recommended (http://www.vdi.eu/engineering/vdi-standards/): o VDI-Guideline 4330 Part 10 "Floristic mapping of genetically modified plants their crossing partners and their hybrid offspring" o VDI-Guideline 4330 Part 5 "Guideline for the collection and preparation of plant samples for molecular biological analysis" If spread, persistence or accumulation of MON 87769 x MON 89788 soybean in the receiving environment occur, further observations of possible impacts on organisms, food chains and habitats in the specific environment are required. If risk management measures are envisaged, e.g. to minimize incidental spillage during transport, storage, packaging or processing, their efficacy should be monitored during case-specific monitor-ing (EFSA 2011). VDI (2011). VDI Guidelines: monitoring the ecological effects of genetically modified organisms. Genetically modified plants. http://www.vdi.eu/engineering/vdi-standards/ EFSA (2011). Scientific opinion. Guidance on the Post-Market Environmental monitoring (PMEM) of genetically modified	management systems are in place to restrict seeds of soybean MON 87769 x MON 89788 entering cultivation as this would require specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			plants. EFSA Journal, 9(8): 2316, 40 pp.	
Germany	Federal Agency for Nature Conservation (BfN)	D, 12.03 General Surveillance of the impact of the GM plant	The applicant states that the general surveillance will be based on information gathered from the existing networks of COCERAL, UNISTOCK and FEDIOL. Data shall be collected by operators handling and using viable MON 87769 x MON 89788 soybean and reported to the authorisation holder, represented by EuropaBio. It remains unclear, how the authorisation holder/EuropaBio will inform operators about their surveillance function and how it will be assured that operators in duty for general surveillance show the necessary skills to detect environmental impacts of MON 87769 x MON 89788 soybean. Therefore, the applicant is requested • to name the national and local organisations and factories involved in the monitoring, • to prove that a sufficient number of local operators agree to contribute to the general surveillance, to provide a schedule with all relevant observation objects to be monitored, • to explain how local operators will be instructed and trained for conducting the general surveillance, to verify the necessary skills and expertise of local operators to detect adverse environmental impacts. In case the suggested operators are not capable to cover all relevant observation objects, further monitoring systems have to be established. The applicant does not suggest operators further down the food chain to be involved in the process of monitoring. We	Please, see the reply to previous similar comment and consult Section 4.4.3 of the scientific opinion.

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			do not approve this, because processed material may also be a cause of adverse effects. Therefore, the applicant is requested to involve also operators further down the food chain in the process of monitoring. The general surveillance plan has to focus on possible pathways how MON 87769 x MON 89788 soybean can get into the broader environment and how unforeseen adverse effects on human health and the environment can be linked to the dispersal and use of MON 87769 x MON 89788 soybean. Beside the implementation of management and safety standards, the applicant is requested to provide an appropriate general surveillance plan comprising the monitoring of spillage or losses of MON 87769 x MON 89788 soybean, during transport, storage, packaging, processing and use (food and feed) in the environment. MON 87769 x MON 89788 soybean may enter the environment together with other approved GM soybean lines. Therefore, a special focus should be on possible combined effects.	

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Germany	Federal Agency for Nature Conservation (BfN)	D, 12.06 Reporting the results of monitoring	The applicant is required to report on the results of the monitoring including all issues of case-specific monitoring and general surveillance on an annual basis. Raw data have to be made avail-able. The monitoring report should also deliver detailed information on i) actual volumes of MON 87769 x MON 89788 soybean imported into the EU, ii) the ports and silos where shipments of MON 87769 x MON 89788 soybean were unloaded, iii) the processing plants where MON 87769 x MON 89788 soybean was transferred to, iv) the amount of MON 87769 x MON 89788 soybean used on farms for feed, and v) transport routes of MON 87769 x MON 89788 soybean. The applicant is requested to state how the monitoring results will be published.	First of all, as no potential adverse environmental effects were identified, the EFSA GMO Panel is of the opinion that case-specific monitoring is not considered necessary. The EFSA GMO Panel agrees with the German comment pertaining to the reporting of general surveillance activities on an annual basis. According to the EFSA 2011 guidance on PMEM of GM plants, the PMEM results of the deliberate release into the environment of GMOs should be presented in accordance with the standard reporting formats established by Commission Decision 2009/770/EC.
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.01 Comparative assessment	Part I: Compositional analysis: The compositional analysis of MON 87769 x MON 89788 is based on forage and seed material from five sites in the USA over one seasons (2007) (FROM CBI: MSL 0021916; Riordan, 2010). Production of forage and seed material is described in	Please, consider the reply to previous similar comments and consult Section 4.2 of the scientific opinion on application EFSA-GMO-NL-2010-85.

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			the provided production plan (FROM CBI: 07-01-83-27 MSL0021807). According to the applicant, the results support the conclusion that MON 87769 x MON 89788 soybean is, with the exception of the intended effect, substantially equivalent to its parental lines and to conventional soybean. The deficits listed under D, 07.02 also apply here, namely the applicant is asked (i) to demonstrate the representativeness of the selected trial sites, (ii) to include non-glyphosate treated MON 87769 x MON 89788 and MON 89788 in the analysis, (iii) to consider site by genotype interactions adequately in individual-site analyses because the tolerance intervals used were calculated using reference data from all sites and (iv) to provide information and data about the identity and purity of the starting material (test, control and references). Further deficits of the compositional assessment are that (v) minerals and vitamins (apart from vitamin E) were not analysed although soybean is considered a significant source of e.g. potassium and magnesium, of bioavailable iron and water-soluble vitamins in the animal feed diet (Baker, 2000). And that (vi) the compositional analysis did not comprise either residues of the complementary herbicide nor its metabolites. This is of great relevance, because herbicide resistance conferred by genetic modification allows a more intensive use of the complementary herbicide. With regard to a final assessment, further information is required, because the information provided is not considered sufficient to support the conclusion of a substantial equivalence of MON 87769 x MON 89788 soybean and conventional soybean, which is the basis of further	

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			conclusions in application EFSA/GMO/NL/2010/85.	
Germany	Federal Agency for Nature Conservation (BfN)	D, 07.01 Comparative assessment	Part II: The applicant should be asked to provide a robust and reliable data basis for composition to demonstrate substantial equivalence of MON 87769 x MON 89788 soybean and conventional soybean. We recommend including data from field experiments from several years for the analysis to include climatic variation between years. These should – in accordance with the step-by-step principle – be supplemented by data from greenhouse studies, which allows simulation of well-defined abiotic and biotic conditions. Site specific tolerance intervals should be used in the individual-site analyses to account for site by genotype interactions. Criteria on which the representativeness of locations has been established should be given, and the environmental conditions should be documented and provided with the application to assess their possible effects on the considered parameters. Compositional analyses of samples shall include minerals and further vitamins. A summarising statistical analysis should address the between-site variation of all parameters. We recommend following the statistical approach of EFSA in its Scientific Opinion on Statistical considerations for the safety evaluation of GMOs (EFSA 2009). Baker, D.H. (2000) Nutritional constraints to use of soy products by animals. Pp1-12. In Soy in animal nutrition. J. K. Drackley (ed.) Federation of Animal Science Societies, Savoy, IL EFSA Scientific Panel on Genetically Modified Organisms	Please, see the reply to previous similar comments and consult Section 4.2 of the scientific opinion on application EFSA-GMO-NL-2010-85.

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			(GMO) (2009); Scientific Opinion on Statistical considerations for the safety evaluation of GMOs, on request of EFSA. EFSA Journal 2009; 1250. [62 pp.]. Available online: www.efsa.europa.eu Statistical analysis: The detection of no difference in the combined site analysis should not devaluate a statistical significant difference in the individual site analysis as insignificant. Plant characteristics are influenced by the receiving environment. Therefore, differences in certain traits at certain environmental conditions need to be considered.	
Hungary	Ministry of Agriculture	General comments	Although SDA is an omega 3 polyunsaturated fatty acid (PUFA), there is no proof of its health benefits. The Dossier does not contains sufficient information on the stacked soybean event MON 87769 × MON 89788 on which basis we could decide if the product is safe or not as food/feed, since questions remained unanswered with soybean events MON 87769 and MON 89788, as well as the stacks of MON87769. The following question has already been posed by the Hungarian Authority: has the remit of the risk assessment been changed? The original aim was to see if there were any (significant) differences between the GM plant and its conventional counterpart (the parent plant or its near-isogenic line) in composition, or in agronomic/phenotypic characteristics. Reading the Dossiers it appears that the question had been changed. Now the remit appear to be to see if there were any biologically significant differences	Regarding the parental soybeans MON 87769 and MON 89788, the EFSA GMO Panel refers to their opinion on these specific GM events (published in 2014 and 2008, respectively). The applicant has the task to perform a risk assessment of the genetically modified plant they suggest to put on the market according to Regulation (EC) No 1823/2009. In order to guide applicants on how to present such a risk assessment, the EFSA GMO Panel produces guidance documents for risk assessment of GMO plants. These are regularly updated. The applicant has followed the given guidance.

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			between the GM plant and several (unspecified) commercial lines of the same species, grown under different conditions, using different agricultural practises all over a continent/World.	
Hungary	Ministry of Agriculture	A, 05 Designation and specification of the GM plant and/or derived product	Although SDA is an omega-3 fatty acid which can be a metabolic precursor to eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in humans and animals, but it is not considered essential in adults. Though the cardiovascular benefits of long-chain PUFAs are established, there is no experimental evidence for SDA.	The EFSA GMO Panel is requested to consider whether the risk assessment of the applicant is adequate or not, and does not consider any potential benefits of genetically modified organisms and products thereof.
Hungary	Ministry of Agriculture	A, 06 Where applicable, a detailed description of the method of production and	It is stated that, "the MON 87769 × MON 89788 soybean crop will be grown in an identity preserved manner. MON 87769 × MON 89788 will be processed in dedicated oil processing facilities that will also be operated in an identity preserved manner and SDA soybean oil will be sold to food processors for food formulation." Will food processors be informed about the amended fatty acid content, for example as „increased omega 3 fatty acid containing GM soy oil," or something similar?	In order to harvest any possible added value (and get economical benefits), producers of SDA soybean oil need to preserv identity and give correct and suitable information. How this is managed is not within the remit of the EFSA GMO Panel that has considered whether the stacked soybean MON 87769 × MON 89788 can be considered safe.
Hungary	Ministry of Agriculture	A, 07 Where appropriate, the conditions for placing on the market the food(s) or	It is stated that „as demonstrated in this application, MON 87769 × MON 89788 is substantially equivalent to conventional soybean, except for the expected production of SDA and GLA and the associated changes in the levels of other fatty acids and its tolerance to glyphosate, and was shown to be as safe as conventional soybean". However, there were several components (31 out of 42) which were significantly different between the MON 87769 × MON 89788 soybean and the control, such as the16:0 palmitic acid, 18:0 stearic acid, 18:1 oleic acid, 18:2 linoleic acid, 18:3 linolenic	Please, see the reply to previous similar comment and consult Section 4.2 of the scientific opinion on application EFSA-GMO-NL-2010-85.

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			acid, and 20:0 arachidic acid , which were significantly different ($p<0.05$) from the control in the combined-site analysis, as well as were the 22:0 behenic acid and 20:1 11C eicosenoic acids, which were significantly different at most sites. Similarly, alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, methionine, phenylalanine, proline, serine, carbohydrate, protein, total fat, vitamin E, daidzein, and genistein showed significant differences between GM and the control. In addition, statistically significant differences were found for plant height, for days to 50% flowering, lodging, pod shattering, 100 seed weight, test weight, and yield at individual site analysis. Hungary would like to know how the applicant interprets these statistically significant differences. Furthermore, in MON 87769 x MON 89788 soybean oil, the nutritionally undesirable trans-fatty acids' level is higher than in conventional soybean oil. Currently we do not have sufficient evidence on the effects of an increased consumption of SDA. Food processors as well as consumers should be well informed about this fact, as well as a maximum level for trans-fatty acids in SDA-rich soybean oil should be prescribed.	Soybean MON 87769 x MON 89788 not treated with glyphosate-based herbicides had a higher plant height than its comparator in the across-site analysis. The measured values for this characteristic fell within the natural range set by a set of reference varieties. The observed difference in plant height is unlikely to be biologically relevant in terms of increased persistence and invasiveness potential.

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Hungary	Ministry of Agriculture	B, 07 Other potential interactions, relevant to the GM plant, of the plant with	It is stated that soybean „contains several endogenous proteins that have been shown to elicit an allergenic response when ingested". In spite of this, and in case of other soybeans, they are included in food formulas for babies, although we are reassured that „individuals seem to become tolerant to soybean products within 3-5 years after the initial diagnosis".	The EFSA GMO Panel takes note of the comment.
Hungary	Ministry of Agriculture	D, 01 Description of the trait(s) and characteristics which have been introduced	Based on the metabolic pathways described, the amount of essential ALA is being converted to non-essential SDA. Similarly, GLA, which is not an essential fatty acid, but has certain benefit is being converted to SDA, without any proof of benefits.	A benefit assessment is not within the task of the EFSA GMO Panel. The panel has considered issues related to the safety of the stacked soybean MON 87769 × MON 89788.
Hungary	Ministry of Agriculture	D, 02 Information on the sequences actually inserted or deleted	2.a Why are there two bands on Fig. 5, lanes 4 and 5? Similarly, why are there two bands on Fig. 6, lanes 5 and 6? 2.b How can a Southern blot analyses demonstrate the stability of the inserted sequences of MON 87769 and MON 89788, and confirm that no rearrangements of these inserts occurred?	The restriction enzymes used in Figure 5 cut the insert in two fragments. The probe hybridises with both fragments resulting in expected band sizes. In Fig 6, the restriction enzyme used cuts the insert in two fragments. Each of the two probes hybridises with different fragment, resulting in expected band sizes. b) The molecular characterisation of the events has been assessed in the frame of the single events. The maintenance of the structure of the singles in the stacks has been analysed with Southern blots, which is in line with the EFSA Guidance document (EFSA, 2007).

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Hungary	Ministry of Agriculture	D, 03 Information on the expression of the insert	Why was the compositional analysis performed on F3 seeds, while the broiler study and molecular analysis was done on F4 seeds? Was the composition of F4 seeds analysed and compared to F3 seeds? Were there any differences between them?	Based on the EFSA Guidelines, it is not mandatory to use the same generations for all experiments.
Hungary	Minitstry of Agriculture	D, 04 Information on how the GM plant differs from the recipient plant in:	Hungary has always objected to combined site statistical analysis using commercial reference lines. According to our experts to use one commercial line is sufficient to establish natural variation of a variety. The use of several commercial varieties only expands the range without any scientific reason. The question is: is GM similar, or significantly different to its conventional counterpart? It appears now the question is different. What we get the answer for in the Dossier is the following question: is GM different in its composition from all existing varieties of the same species grown at all environment, or to widen the range even further, from all published data, or data in the ILSI database. Those data have nothing to do with the similarity or difference of the GM to its conventional counterpart. The GM and its conventional counterpart should be compared at the same site. If statistical differences were found at one site, or similar differences are observed at other site(s), the differences should be taken very seriously, indeed. Phenotypic and agronomic characteristics were compared in 1 season only. It is stated that „The reference range for each measured phenotypic characteristic and arthropod damage were determined from the minimum and maximum mean values collected from the 12 conventional reference soybean	Based on the EFSA Guidelines it is mandatory to use more than one reference variety in order to establish the natural variation. A single varieties doesn't reflect the whole variability for individual constitutents.

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			varieties planted among the sites. Why? In the individual-site analysis, statistically significant differences were detected for arthropod damage at all sites, for Rachiplusia nu damage, E. aporema damage, for stink bug damage. Statistically significant differences were found for plant height, for days to 50% flowering, lodging, pod shattering, 100 seed weight, test weight, and yield at individual site analysis. This does not suggest agronomic equivalence.	Please, see the reply to previous similar comments and consult Section 4.2 of the scientific opinion on application EFSA-GMO-NL-2010-85.
Hungary	Ministry of Agriculture	D, 05 Genetic stability of the insert and phenotypic stability of the GM plant	The genetic stability of the transgenes has not been checked actually in the MON 87769 × MON 89788 soybean, because it was considered „highly likely that the insert sequences of MON 87769 and MON 89788 are conserved".	The stability of the events was show in their single context over several generations. In line with EFSA Guidance on stack applications (EFSA, 2007), the integrity of the events was confirmed in the stacked GM line, which has been crossed and backcrossed, indicating their stability in this case.
Hungary	Ministry of Agriculture	D, 07.01 Comparative assessment	Trans fatty acids are harmful for humans and animals, except for those naturally occurring in ruminant. The fact is, that two fatty acids, the trans-SDA and trans-ALA, which are present only in MON 87769 × MON 89788 soybean, has not been previously detected in any soybean varieties. Therefore, a very thorough nutritional/toxicological investigation should be performed with this stacked GM soybean, even if MON 89788 soybeans have already been allowed to reach the food chain. Since LA and ALA are the essential fatty acids for humans, and it is their amounts, which has decreased in MON 87769	The EFSA GMO Panel takes note of the comment.

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			× MON 89788 soybean as a result of being converted to GLA and SDA, one cannot see any nutritional benefit of this GM soybeans. Although „spontaneous trans-isomerization of unsaturated fatty acids, at rates that increase with increasing degree of unsaturation has been reported in literature", it does not mean they are safe. Hungarian experts object to the use of the ILSI databases and values published in the scientific literature when deciding compositional similarity or difference of a transgenic plant its parent/conventional comparator, or establishing any tolerance interval. Eight fatty acids in the GM soybeans were significantly different ($p<0.05$) from the control at more than one sites. In the seeds, not treated with glyphpsate, 16:0 palmitic acid, 18:0 stearic acid, 18:1 oleic acid, 18:2 linoleic acid, 18:3 linolenic acid, and 20:0 arachidic acid were significantly different ($p<0.05$) from the control in the combined-site analysis, as well as were the 22:0 behenic acid and 20:1 11C eicosenoic at most sites. Therefore, the conclusion, that MON 87769 × MON 89788 soybean „does not have meaningful differences from conventional soybean from a food and feed safety or nutritional perspective" is not true. In addition, out 42 comparisons made in the combined-site analysis between seed from MON 87769 × MON 89788 and the conventional soybean control, 31 statistically significant differences were found for alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, methionine, phenylalanine, proline, serine, carbohydrate, protein, total fat, vitamin E, daidzein, and genistein.	The EFSA GMO Panel confirms that soybean MON 87769 × MON 89788 differs from its comparator and other non-GM soybean reference varieties by having an altered fatty acid profile and the increased SDA level is addressed in section 4.3. None of the other differences identified in the composition of grain and forage obtained from soybean MON 87769 × MON 89788 that would require further assessment regarding food and feed safety.

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			In the forage, not treated with glyphosate moisture and total fat was significantly different from control at all sites, ADF and protein at one sites. Even if the company does not considers these „biologically meaningful". We do. Hungarian experts do not concur with the conclusion that „ the compositional analyses confirmed that MON 87769 × MON 89788 seed had the intended changes in fatty acid composition. With the exception of these intended changes, the forage and seed from MON 87769 × MON 89788 was considered to be compositionally equivalent to the population of conventional soybeans". In tables 11-15 there are totally unnecessary information listed, the values for „Literature Ranges" and „ILSI Ranges".	
Hungary	Ministry of Agriculture	D, 07.06 Effect of the production and processing	There is another pertinent question. What is the amount of total trans-fatty acids in the processed oils prepared from MON 87769 × MON 89788 and its comparator, the conventional soybeans?	Please, consult Section 4.3.1 of the scientific opinion on application EFSA-GMO-NL-2010-85.

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Hungary	Ministry of Agriculture	D, 07.07 Anticipated intake/extent of use	The estimated consumption of soybeans per capita is approximately 39.2 g/person/day. „This is equivalent to approximately 0.65 g/kg/day if one assumes an average body weight of proximately 60 kg." In Europe, for adults the average weight is 70 kg or more. Please recalculate the data accordingly. The acute consumption of soybean in the general population and in children ≤6 years were 3.03 g/kg and 5.55 g/kg, therefore the compositional differences between MON 87769 × MON 89788 and its comparator seems to be quite significant. As far as the safety assessment is concerned, all 3 proteins are produced from a synthetic version of the transgene under the regulation of „foreign" promoters. Their safety cannot be guaranteed, even if the natural version of these proteins would be safe. However, the donor organisms were never eaten by humans or fed to animals therefore there is no proof of their safety. It is obvious, that the transgenic proteins produced in GM plant are not identical to the wild type of the same proteins, which have not been consumed by human and our domesticated animals. To prove the safety of the newly expressed proteins, an acute dose toxicology test with mice in not sufficient. Please perform a repeated dose toxicological study for at least 90 days with rodents. Rapid degradability of the surrogate protein in vitro in simulated digestive fluids is no guarantee of its safety.	Regarding nutritional assessment, please see comment above. Regarding the safety assessment of the newly expressed proteins, these were thoroughly evaluated by the EFSA GMO Panel in the context of the single events MON 87769 and MON 89788 and no safety concerns for humans and animals were identified. The EFSA GMO Panel is not aware of any new information that would change these conclusions and updated bioinformatic studies confirmed the absence of relevant similarities between these newly expressed proteins to known toxins. It is highlighted that the EFSA Guidance (2011) requires a 28-day study (not a 90-day-study) in rodents if no history of safe consumption can be provided. Please refer to 4.3.2.1 for further details.

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Hungary	Ministry of Agriculture	D, 07.08 Toxicology	In the opinion of Hungarian experts MON 87769 × MON 89788 were not compositionally equivalent to conventional soybeans, and the occurrence of additional trans-fatty acids are worrying. 7.8.3. Where are the published studies to show that SDA has a history of safe consumption in human foods across a range of sources and to show that it is safe? Were those studies performed with SDA or/and SDA soybean oil? Given some proof we might agree that SDA has a history of safe consumption in human foods across a range of sources and safety has been confirmed by several human, as well as animal studies, conducted with SDA and SDA soybean oil, meat and dairy products, but it does not follow that the presence of trans-SDA and trans-ALA in this GM soybean oil does not raise safety concerns. 7.8.4. Since it is the SDA soybean oil which will be consumed by humans, but it was not tested in any form, please perform a 90 day study with the oil in rodents to prove its safety.	Considering the altered fatty acid profile of soybean MON 87769 x MON 89788, the applicant was asked by the EFSA GMO Panel to provide a dietary exposure assessment based on the compositional analysis of the RBD oil from soybean MON 87769 x MON 89788, taking into account different exposure scenarios (covering low and high consumer groups). However, the applicant did not provide such data. The EFSA GMO Panel therefore cannot complete the assessment on possible impact of the soybean MON 87769 x MON 89788 oil on human health and nutrition. 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. As regards defatted soybean meal from soybean MON 87769 x MON 89788, compositional data indicates that would be expected to deliver the same nutrition as its comparator and other non-GM commercial varieties. On this basis, the EFSA GMO panel did not consider necessary a 90-day study (or other toxicological studies in rodents) for the risk assessment of MON 87769 x MON 89788. The results from a feeding study in chickens for fattening confirmed that defatted soybean meal from soybean MON 87769 x MON 89788 would be expected to deliver the same nutrition as its comparator and other non-GM commercial varieties.
Hungary	Ministry of Agriculture	D, 07.09 Allergenicity	The donor organisms have not been consumed by humans, therefore it cannot be said that they are non-allergic. If a protein is present in minute quantities, it can still evoke an allergenic response. The fact that the protein does not demonstrate resistance to digestion by pepsin or other digestive enzymes has no relevance to its allergic potential. Based on these facts, the conclusion that „an assessment of the allergenicity of the whole MON 87769 × MON 89788	The EFSA GMO Panel considered it necessary to obtain experimental data on the endogenous allergenicity of soybean MON 87769 x MON 89788. The EFSA GMO Panel requested the applicant for additional experimental studies to address the endogenous allergenicity of soybean MON 87769 x MON 89788. Based on the information provided, the EFSA GMO Panel considers that there is no evidence that the genetic modification might significantly change the overall allergenicity of soybean MON

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			plant is not considered necessary" is incorrect, in our opinion.	87769 x MON 89788 when compared with that of its non-GM comparator. Please see Section 4.3.4.2 of the scientific opinion on application EFSA-GMO-NL-2010-85. In addition, the EFSA GMO Panel has previously assessment the allergenicity of the newly expressed proteins in the single events and no safety concerns were identified. In the EFSA GMO scientific opinion on application EFSA-GMO-NL-2010-85, the assessment mainly focused on potential interactions. For more information please see Section 4.3.3.1 of the scientific opinion.
Hungary	Ministry of Agriculture	D, 10 Potential changes in the interactions of the GM plant with the biotic	The opinion of Hungarian experts is that „the compositional analyses confirmed that … MON 87769 × MON 89788 were compositionally equivalent to conventional soybean" is incorrect, and a proper 90 days toxicological/nutritional study should be performed to confirm nutritional safety. The broiler study was an industrial study lacking scientific content. Only industrial production parameters were followed and there are no data on inter-organ growth/metabolism, such as heart, liver, bursa, etc. Animals were only weighed on day 0 and 42. In addition, birds have a digestive system which is different from that of humans, monogastric animals or ruminants. Therefore, birds are not the best model to judge human safety. The experiment might give guidance on how to feed MON 87769 × MON 89788 seeds to poultry.	Please, see the reply to previous similar comments and consult Section 4.3.3 and 4.3.5 of the scientific opinion on application EFSA-GMO-NL-2010-85. We agree that the broiler studies are not designed to judge on human safety. Indeed they give supplemental information on the possible occurrence of unintended effects by the comparison of the nutritional value between the GM plant, the comparator and the non-GM commercial varieties with growth studies conducted on young rapidly growing animal species (i.e. broiler) (EFSA 2011). In this particular case the study was not requested by the EFSA GMO Panel but was spontaneously provided by the applicant and assessed by the Panel. This allowed to conclude that toasted soybean meal derived from soybean MON 87769 × MON 89788 is as nutritious as the comparator and non-GM commercial varieties.

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Hungary	Ministry of Agriculture	D, 12.01 General	In our opinion it is not true that „MON 87769 × MON 89788 was shown not to be different from conventional soybean in its agronomic, phenotypic, compositional (except for the expected seed fatty acid changes, particularly the presence of SDA and GLA), nutritional value and safety characteristics, suggesting that any interactions of this soybean with the biotic environment have not been changed compared to conventional soybean", therefore case specific monitoring would be required based on scientific data. In addition, since MON 87769 × MON 89788 soybeans carry the RR® characteristics, it is highly likely that they have increased glyphosate residue levels. Measuring of glyphosate residue for each shipment should be performed to protect human and animal health.	No safety concern to the environment were identified from the import and processing of soybean MON 87769 x MON 89788. There are no indications of an increased likelihood of establishment and spread of feral soybean MON 87769 x MON 89788 plants in the case of accidental release into the environment of viable GM soybean seeds. The unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87769 x MON 89788 to bacteria does not raise a safety concern for these bacteria owing to the lack of a selective advantage. Potential interactions of soybean MON 87769 x MON 89788 with the biotic and abiotic environment were not considered a relevant issue by the EFSA GMO Panel. The EFSA GMO Panel therefore concludes that, as no potential adverse environmental effects were identified, case-specific monitoring was not considered necessary. The assessment and control of the herbicide and its residues is outside the remit of the GMO assessment
Italia	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D, 12.01 General	ERA In different parts of the environmental risk assessment, the applicant states that one way of dispersion of the viable material of MON 87769 × MON 89788 is the accidental loss during the loading/unloading, handling and processing, and analyzes the potential impacts in relation to the receiving environments predictable for these operations (ports, silos, processing facilities). Another possible dispersion route is transport, but the applicant states that the modern containment systems, also used for conventional soybean, ensure the reduction of the potential dispersion. Nowhere in the notification are described these systems: it is therefore required to describe the containment systems for transport, in order to assess their effectiveness; it is suggested also to integrate the PMEM plan (and specifically, general	The EFSA GMO Panel is aware that, owing to the physical characteristics of soybean seeds and methods of transportation, accidental spillage cannot be excluded. Also, it is important that appropriate management systems are in place to restrict seeds of soybean MON 87769 x MON 89788 entering cultivation as this would require specific approval under Directive 2001/18/EC or Regulation (EC) No 1829/2003.

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			surveillance) applying it to the transport.	
Italia	Ministero dell'Ambiente e della tutela del Territorio e del Mare	D, 12 Environmental Monitoring Plan	Monitoring plan for MON 87769 × MON 89788 soybean conforming with Annex VII to Directive 2001/18/EC • According to the applicant, the operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable MON 87769 × MON 89788 soybean: it is required to provide such guidelines to evaluate their effectiveness.	Considering that the definite and final endorsement of the PMEM plan is with risk managers, the EFSA GMO Panel is of the opinion that further discussion on the practical implementation of the PMEM plan (e.g. involvement of existing monitoring systems) is needed between the applicant and risk managers at the time of approval of the GM soybean.
Italia	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D, 12.02 Case-specific GM plant monitoring	The authorization holder is working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio) and trade associations representing the relevant operators in order to implement an harmonised monitoring methodology. Among these there are COCERAL, UNISTOCK and FEDIOL. The links related to COCERAL (http://www.coceral.com/cms/beitrag/10010169/227870) and UNISTOCK (http://www.coceral.com/cms/beitrag/10010260/232602) websites are not working: it is required to update these links. In addition, as a result of control on the official websites of the three associations (http://www.coceral.com/, http://www.unistock.be/, http://www.fediol.be/web/members/1011306087/list1187970073/f1.html), in the Members section, we see that not all European countries are represented within these associations: therefore, it is required to provide a list of Member States not represented and a description of the monitoring methodology adopted in these MS. In addition to the aforementioned existing monitoring systems conducted by third parties, the notifier will perform a screen of peer-reviewed scientific publications relevant to this	The EFSA GMO Panel gives its opinion on the scientific quality of the post-market environmental plan (PMEM) activities proposed by the applicant. The PMEM plan currently submitted by the applicant for GM soybean is the standard PMEM plan developed jointly by applicants and risk managers and submitted as part of marketing applications for import and processing of GM plants in the EU. The EFSA GMO Panel agrees that the present PMEM plan and in particular the supporting methodology needs to be further detailed by the applicant. However, in accordance with its guidance documents on PMEM of GM plants (EFSA, 2006, 2011), the EFSA GMO Panel recognises that all parties (e.g. applicants, Member States) have to consider their roles in the PMEM of GM plants. Therefore, considering that the definite and final endorsement of the PMEM plan is with risk managers, the EFSA GMO Panel is of the opinion that further discussion on the practical implementation of the PMEM plan (e.g. involvement of existing monitoring systems) is needed between the applicant and risk managers at the time of approval of the GM soybean.

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			soybean: it is required to provide a report of this literature search, or to enter it in the annual monitoring report. The link to the EuropaBio website (www.europabio.org/InfoOperators), that should be dedicated to the operators with all the detailed information on the products and at the same time utilized as focal point for the sharing of information on general surveillance, doesn't work: it is required to update and correct the link. The applicant states that the information collected will be evaluated and analyzed in order to assess the relevance: the method is not specified and then it is required to provide it. In the guidance of EFSA on PMEM (chapter 4.2 EFSA Journal 2011;9(8):2316), is established that "In addition, applicants should provide raw data in order to allow different analyses and interrogation of the data and to allow scientific exchange and co-operation between applicants, Member States, the European Commission and EFSA", then it would be appropriate that the applicant provides also the raw data, as well as the analyzes.	

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Italia	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D, 12.03 General Surveillance of the impact of the GM plant	The notifier says that "Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and MON 87769 × MON 89788 can be established": we ask to specify the investigation method. Finally, as described by the same EFSA guidance, "GS plans should include questionnaires to those involved in the handling and processing of the GMP and its products and be designed to monitor whether unanticipated levels of loss, spillage and establishment are occurring and/or if there are any adverse environmental consequences". Nowhere in the PMEM proposed by the applicant are described questionnaires to the operators involved, nor how these questionnaires are structured, which information collect and how this information will be analyzed: it is required to provide this information. In the Annex I, the notifier says that food/feed business operators shall put in place a permanent written procedure based on the Hazard Analysis of Critical Control Point (HACCP) principles to identify any hazards that must be prevented, eliminated or reduced to acceptable levels, to identify the critical control points at the step or steps at which control is essential, etc. It would be useful, in this specific case but in general for the GMOs, that this written procedure is made available.	Please, see the reply to previous similar comments from Italy and consult Section 4.4.3 of the scientific opinion.

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Italia	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	D, 12.06 Reporting the results of monitoring	EFSA, in its recent Scientific Opinion on soybean MON 87769, says that "The PMM plan should include the collection of consumption data for the European population" and again that "Since the use of oil derived from the soybean MON 87769 will result in a higher intake of SDA, a PMM plan is recommended to confirm the exposure assessment using realistic consumption data for the European population". Thereby, this collection should be included also in the PMEM plan for the soybean MON 87769 × MON 89788.	As a full assessment on possible health and nutritional impact of the soybean MON 87769 x MON 89788 oil was not made, the EFSA GMO Panel is not in the position to comment on the post-market monitoring plan and labelling.
Italia	Ministero dell'Ambiente e della Tutela del Territorio e del Mare	General comments	Cartagena Protocol In step k) relating to the "Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate", the applicant refers to appropriate and comprehensive information in the accompanying documents. There are no specifically references to labeling: it is required to integrate this information, extractable from Part IV of the application.	It is outside the remit of the EFSA safety assessment. As a full assessment on possible health and nutritional impact of the soybean MON 87769 x MON 89788 oil was not made, the EFSA GMO Panel is not in the position to comment on the post-market monitoring plan and labelling.

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Netherlands	Ministry of Infrastructure and Environment	D, 12.05 Implementing General Surveillance	- The provided General Surveillance (GS) plan for import and processing of MON87769 x MON89788 soybean could be improved on the following points. - In the present GS plan, the authorization holder states that the operators have agreed to provide information relevant to the monitoring of MON87769 x MON89788 to the authorization holder. The GS plan could be improved by a guarantee that operators will monitor for unanticipated effects. - The GS plan states that if the authorization holder identifies an unexpected adverse effect caused by the GM plants, he will inform the European Commission immediately. The Dutch CA is of the opinion that Member States should also be directly informed of these effects by the authorization holder, to ensure that appropriate measures for protection of humans and the environment can be implemented immediately. - In the EFSA guidance document, EFSA states that raw data and analysis of monitoring data should be made available by the applicant to the Competent Authorities and the European Commission. The Dutch CA agrees with the request and points out that the GS plan of MON87769 x MON89788 soybean could be improved by a statement of the applicant on this point.	The EFSA GMO Panel gives its opinion on the scientific quality of the post-market environmental plan (PMEM) activities proposed by the applicant. The PMEM plan currently submitted by the applicant for GM soybean is the standard PMEM plan developed jointly by applicants and risk managers and submitted as part of marketing applications for import and processing of GM plants in the EU. The EFSA GMO Panel agrees that the present PMEM plan and in particular the supporting methodology needs to be further detailed by the applicant. However, in accordance with its guidance documents on PMEM of GM plants (EFSA, 2006, 2011), the EFSA GMO Panel recognises that all parties (e.g. applicants, Member States) have to consider their roles in the PMEM of GM plants. Therefore, considering that the definite and final endorsement of the PMEM plan is with risk managers, the EFSA GMO Panel is of the opinion that further discussion on the practical implementation of the PMEM plan (e.g. involvement of existing monitoring systems) is needed between the applicant and risk managers at the time of approval of the GM soybean.
Netherlands	Ministry of Agriculture, Nature and Food Quality and Ministry	General comments	The Dutch CA has assessed the dossier with respect to the food and feed safety of event MON87769 x MON89788 and has no comments or requests for additional information in relation to the safety of this GMO event	The EFSA GMO Panel notes the comment.

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	of Health			
Spain	Spanish National Commission on Biosafety	C. Information relating to the genetic modification	The molecular characterization is based in two Southern blots, using the same probes that there used previously to characterize the single events. The design of the probes allows to get fragments of a size appropriate to conclude that both inserts keep the same structure that the single events. So, there can be applied the same insert and flanking sequences that were analysed in the characterization of the single events. We agree with the applicant in his interpretation of the updated bioinformatic analyses; there is no evidence of the interruption of any known endogenous gene in the insertion site. Regarding the stability of the inserts, we also agree that, in the rare case of recombination, it would result in lethal consequences for the progeny. The levels of proteins are in the same range of the level estimated for the single events.	The EFSA GMO Panel notes the comment.
Spain	Spanish National Commission on Biosafety	D, 07.08 Toxicology	For the single event MON 87769, the newly expressed proteins have been tested to in vitro degradation by proteolytic enzymes, heat denaturation and acute toxicity. We agree with the EFSA panel that acute toxicity testing is of little value for the risk assessment of the repeated consumption of food and feed, and more in this case, due to the very low level of protein administered. The applicant also provided a 90-day feeding trial with defatted soybean soybean meal; and 28-day repeated dose toxicity study, 90-day feeding trial and one generation reproductive toxicity study with soybean oil. The results do not show any relevant toxic effect when compare with the	The EFSA GMO panel did not consider necessary animal studies to support the risk assessment of soybean MON 87769 x MON 89788 on the basis of preceding analysis, in particular the comparative assesssment of this stacked event

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			conventional soybean oil. However, there are not animal studies with food / feed derived from the soybean with both transformation events.	
Spain	Spanish National Commission on Biosafety	D, 07.09 Allergenicity	Soybean MON 87769 × MON 89788 is produced by crossing soybean plants containing MON 87769 and MON 89788 by using traditional (conventional) breeding methods. Genetic modifications were used in the development of the parental lines MON 87769 and MON 89788. Soybean MON 87769 contains a single insert consisting of the Pj.D6D gene encoding the Δ6 desaturase protein from Primula juliae and the Nc.Fad3 gene encoding the Δ15 desaturase protein from Neurospora crassa, both involved in the desaturation of endogenous fatty acids into stearidonic acid. Soybean MON89788 was transformed by Agrobacterium tumefaciens-mediated gene transfer technology and expresses the codon-optimized epsps from Agrobacterium sp. strain CP4 encoding CP4 EPSPS that confers glyphosate tolerance to the plant. EFSA previously evaluated the safety of the parental lines (Applications EFSA-GMO-UK-2009-76 and EFSA-GMO-NL-2006-36) and identified no concerns regarding the potential toxicity and allergenicity of the newly introduced proteins (i.e., PjΔ6D, NcΔ15D and CP4 EPSPS proteins) when compared with that of their conventional counterparts. Considering that soybean MON 87769 × MON 89788 results from traditional breeding is not expected to result in adverse effects with regards to allergenicity when compared with those of parental lines.	The EFSA GMO Panel takes note of the comment.