Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127)
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	II.1.3.4 Comparative analysis of composition	3.3 Compositional analysis (cont.) Specific comment on the significant results (Scientific Information, p. 56ff) The field trials for compositional analysis using two control and test lines were performed in 2012 in the USA. From eight sites field data were statistically analysed testing for i) the difference between GMO soybean FG72xA5547-127 and conventional counterpart and ii) the equivalence to natural variation represented by the set of non-GM reference varieties. Two treatment regimes were used, and hence two difference tests were carried out: a) FG72xA5547-127 soybean under conventional herbicide management (CHM analysis). b) FG72xA5547-127 soybean treated with the intended herbicides (TIH analysis). The CHM analysis revealed 27 statistically significant differences between GM soybean FG72xA5547-127 and the conventional counterpart (of 63 assessed parameters). The TIH analysis revealed 39 statistically significant differences between GM soybean FG72xA5547-127 and the conventional counterpart (of 63 assessed parameters). In the TIH analysis more than 60% of the parameters showed a significant difference between the GMO and the control line, and many were categorised even as outcome types 4 meaning that the null hypothesis of no difference must be rejected, and also that the null hypothesis of non-equivalence cannot be rejected, although the appropriate conclusion is that equivalence between the GM and the set of commercial varieties is more likely than not. It is recommended by current EFSA guidance that further evaluation is carried out in such cases (cf. EFSA 2010, p. 27f). The outcome types 4 parameters (TIH analysis) are:	The GMO Panel thanks Austria for their assessment. The GMO Panel concluded that none of the differences identified in seed composition between soybean FG72 × A5547 127 and the non-GM comparator, and none of those identified in the agronomic and phenotypic characteristics, needed further assessment regarding food and feed safety.

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			• grain proximates (NDF, crude protein, carbohydrates) • grain amino acids (glutamic acid, glycine, proline) • grain vitamins (B2) • grain anti-nutrients (daidzin) The CHM analysis confirms the significant findings of the TIH analysis: • grain proximates (crude protein… also significantly lower in the GM, outcome type 2) • grain proximates (NDF… also significantly higher in the GM, type 2) • grain amino acids (glutamic acid… also significantly lower in the GM, type 2) • grain amino acids (glycine… also significantly lower in the GM, type 4) • grain amino acids (proline… also significantly lower in the GM, type 2) • grain anti-nutrients (daidzin… also significantly higher in the GM, type 2) It is important that these results of both the CHM and TIH analysis showing an overall-site effect are further evaluated by conducting within-site analyses. In the discussion provided in the Scientific Information (p. 58f) it is only said that the significant parameters are still within the range of the six soybean reference varieties and the range reported from literature. EFSA guidance mentions, "The statistical analysis of data from the experiments for comparative risk assessment is mainly concerned with studying the average difference and the average equivalence over sites. Nevertheless, applicants should check for possible site-specific effects " (EFSA 2010, p. 28). The notifier is requested to carry out a site-specific analysis and also to provide the p-values in relation to all significantly different findings for accurate interpretation of the data. Scientific Information, p. 58: The notifier says, "The slight increase in the average carbohydrate content of the FG72 x A5547-127 soybean seed (treated with the intended herbicides) compared to the conventional counterpart can be an effect of the slightly higher average crude protein, since the carbohydrate is calculated using protein, fat and ash contents." This comment is incorrect,	Individual-site statistics was provided by the applicant in the comparative analysis report. The GMO Panel was able to conclude on the risk assessment based on the information provided by the applicant. The GMO Panel agrees with this comment: protein levels were lower. Lower (not higher) protein contents do actually explain the increase in carbohydrate content, as carbohydrate content is calculated by subtracting the content of crude

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			as there is a slightly lower average crude protein content in the GM soybean FG72xA5547-127. [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.]	protein, crude fat and ash from the total dry matter content.
Austria	Federal Ministry of Health	II.1.2.1 Information relating to the genetic modification	2.1 Information relating to the genetic modification 2.1.1 Description of the methods used for the genetic modification Scientific Information, p. 24: The applicant states that "FG72 and A5547-127 were developed via direct gene transfer..." Does the applicant mean "directed" gene transfer or is there a possibility to construct transgenic plants by "indirect" gene transfer? Please clarify.	Events FG72 and A5547-127 were developed by particle bombardment (please see GMO Panel scientific opinions on these events: EFSA GMO Panel 2011a, 2015a).
Austria	Federal Ministry of Health	II.1.2.2 Information relating to the genetically modified plant	2.2.2 Information on the sequences actually inserted or deleted The molecular description provided by the notifier for the transgene inserts present in GM soybean FG72xA5547-127 is based on an analysis by Southern blot to assess the integrity of inserts in GM soybean FG72xA5547-127 compared with the respective inserts in the parental GM lines GM soybean FG72 and A5547-127 (Scientific Information CC2, p. 27-39, Study Report M-465846-02-1). However, this analysis cannot establish a detailed characterisation of the transgenic inserts present in the stacked event. It only allows a coarse comparison with both parental events. Furthermore, the notifier did check 20 plant individuals from a single seed lot (seed lot 12QMGM000035-002) for preservation of insert integrity using 2 different Southern approaches. Thus, the available data cannot identify minor alterations in the inserts, like single nucleotide polymorphisms (SNPs). Such alterations can be introduced during the breeding process and can affect the function of transgenic components and/or detectability of the GM construct (Morisset et al. 2009). The notifier is therefore requested to submit further data to assess this issue. Additional data are also necessary to support the conclusion by the notifier	The GMO Panel considers that the information provided by the applicant confirms that the inserts present in the single events are maintained in soybean FG72 x A5547-127.

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			that the results demonstrate convincingly that the inserts are stably inherited. The notifier should also describe the chromosomal site of integration/translocation in reference to the published soybean genomic sequence (Schmutz et al. 2010). Additional remarks Concerning the presented Southern blots we acknowledge the inclusion of 20 individual plants, each, for "structural" stability analysis. However, the applicant does not explain if this sample number is representative for the stack variety nor does he describe the statistical power of this analytic approach. The approach would be optimal if the applicant had also shown the results of 5 generations of the stack. A certain drawback of the analysis is the low discriminatory power of the applied Southern blots due to the large size of the expected DNA fragments and the short runs of the gels. For details please see below. Page 31: The applicant interprets the Southern blot represented in Figure A.8 and explains that "this band of 11430 bp was obtained after hybridisation with the Ph4a748B probe: … it's the faint band right above the 9900 pb band." This maybe or may not be the case. The discriminatory power of the applied Southern blot is significantly too low to draw a final conclusion. This Southern blot in general suffers from the fact that the expected fragments are all extremely long (range: 6-12 kb). For this high molecular weight fragments the resolution of the gel is much too low to draw reliable conclusions. To avoid this ambiguity the gel should have been run for a longer period of time or the agarose concentrations could have been reduced. Another possibility would have been to provide two kinds of Southern blot photos: one representative for a short run (as displayed in Figure A.8) and the other representative for a long run (additional information necessary). Under the present circumstances the indicated 11 430 bp fragment cannot be reliably detected. We would like the EFSA GMO	The GMO Panel considers the provided data of sufficient quality in order to conclude on the molecular characterisation of soybean FG72 x A5547-127. The GMO Panel is aware of the limitations of Southern blot analyses. Having taken that into account, the GMO Panel considers the provided Southern images of sufficient quality to perform the risk assessment.

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			Panel to take this into consideration for their evaluation. Page 32, Table A.2: Restriction of FG72xA5547-127 DNA with EcoRI is indicated. This restriction enzyme is not mentioned in the indicated Figures (A.7, 8) nor in the main body of the accompanying text. Has this genomic DNA been cut with EcoRI or only with ScaI/HindIII. This makes a difference. We would like to ask the EFSA GMO panel to inquire an explanation for this discrepancy. Please explain "secondary structure f" as mentioned in the last line of Table A.8 In all figures restriction with SacI is indicated, however in the main body of the text and in Table A.2 the applicant is referring to ScaI. Please provide a clarification which kind of restriction enzyme was actually used. Figure A.9: Please explain the 1159 bp fragment in lane 10. Figure A.10: The signal of the probe containing lane 12 is extremely faint, and thus, not useful for estimating equimolarity of probe and genomic DNA fragments in this assay. Page 40: The applicant maintains that "New and up-to-date bioinformatics analysis of the flanking regions and within the insert for the single events FG72 and A5547-127 were performed and are presented…". We are a little bit astonished about this proposition. How can one provide an up-to-date bioinformatic analysis when the query sequence has not been determined in the soybean variety under consideration and the proposed and used "surrogate" query sequence (i.e. of the single events) is more than 5 years old? We would like to ask the EFSA GMO Panel to insist up-to-date sequencing data from the genetically modified plant/variety under consideration of this application.	The indication in Table A.2 is most likely a typing error. It can be seen in Table A.3 on page 37 that EcoRI would have generated different fragments when digesting soybean FG72 x A5547-127 DNA. There is no mention of “secondary structure f” in Table A.8. *Sac*I and *Sma*I were used to prepare the digested fragment of pSF10, as explained in Appendix M465846-02-1. *Sca*I and *Hind*III were used to digest the DNA samples. The GMO Panel has evaluated Figure A.9 and is of the opinion that the sample “soybean WT variety JACK – HindIII digested” might have contained an impurity from the processing stage. The GMO Panel agrees with the comment. Following a request of the GMO Panel, the applicant provided updated bioinformatic analyses. However, these analyses are based on the nucleotide sequence determined in the single soybean events FG72 and A5547-127 respectively, not in soybean FG72 x A5547-127. The GMO Panel would like to point out that the Implementing Regulation (EU) No 503/2013 is not applicable to this application, therefor the applicant was not requested to resequence the inserts and flanking regions in the stack.

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			[M-465846-02-1, Stability analysis of soybean FG72 x A5547-127. Dossier EFSA/GMO/NL/2013/120. Morisset D, Demšar T, Gruden K, Vojvoda J, Štebih D, Žel J, 2009. Detection of genetically modified organisms - closing the gaps. Nat Biotechnol 27(8): 700-701. Schmutz J, Cannon SB, Schlueter J, Ma J, Mitros T, Nelson W, Hyten DL, Song Q, Thelen JJ, Cheng J, Xu D, Hellsten U, May GD, Yu Y, Sakurai T, Umezawa T, Bhattacharyya MK, Sandhu D, Valliyodan B, Lindquist E, Peto M, Grant D, Shu S, Goodstein D, Barry K, Futrell-Griggs M, Abernathy B, Du J, Tian Z, Zhu L, Gill N, Joshi T, Libault M, Sethuraman A, Zhang XC, Shinozaki K, Nguyen HT, Wing RA, Cregan P, Specht J, Grimwood J, Rokhsar D, Stacey G, Shoemaker RC, Jackson SA, 2010. Genome sequence of the palaeopolyploid soybean. Nature 463(7278): 178-183.]	
Austria	Federal Ministry of Health	II.1.2.2 Information relating to the genetically modified plant	2.2.3 Information on the expression of the inserted/modified sequence For the assessment of developmental expression of the transgenic insert during the life cycle of GM soybean FG72xA5547-127, data from two different field trials conducted at three sites in Brasil in 2012-2013 and at three sites in USA in 2012 were provided by the notifier (Scientific Information CC2, p. 44ff.). However, the trials are not directly comparable since the parental GM soybean events FG72 and A5547-127 (treated with conventional herbicide management and complementary herbicides, respectively) were only tested in the Brasil trial alongside GM soybean FG72xA5547-127 (again treated with conventional herbicide management and complementary herbicides, respectively). The data submitted in the Scientific Information seem to indicate that expression of transgenic proteins in GM soybean FG72xA5547-127 is influenced by several factors: • the stacking of transgenes in GM soybean FG72xA5547-127 (compare	The study from USA 2012 was not considered by the GMO Panel, as it lacked data on the single events. The levels reported for HPPD W336 in soybean FG72 x A5547-127 in the Brazil 2012-2013 study were below the limit of quantification, therefore they could not be compared with the levels reported for soybean FG72, which were quantifiable. Following a request of the GMO Panel, the applicant provided additional data (7 April 2016), obtained in USA, 2014. The reported expression levels of HPPD W336 in most tissues in the stack were lower than in the single (maximum

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			differences in HPPD W336 expression in GM soybean FG72xA5547-127 vs. GM soybean FG72, Table A.5, p. 45) • the receiving environment (compare HPPD W336 expression in GM soybean FG72xA5547-127 in Brasil trial vs. US trial, Table A.5 and A.8; compare 2m EPSPS expression in Brasil trial vs. US trial, Table A.6 and A.9; compare pat expression Brasil trial vs. US trial, Table A7 and A.10) • the herbicide treatment of GM soybean FG72xA5547-127 (compare PAT expression in Brasil trial, Table A.7) Thus, we request that the notifier provides information to further assess the potential interactions as mentioned above on the expression of transgenes in GM soybean FG72xA5547-127. Furthermore the notifier should provide the necessary information to demonstrate that the trial conditions are indeed representative for conditions encountered during commercial production of GM soybean FG72xA5547-127 and that the trials are representative for the different agricultural environments as used for commercial production. The notifier should also discuss how he considered the quite wide ranges for expression of the transgenic proteins in GM soybean FG72xA5547-127 (c.f. Scientific Information CC2, Table A.5-A.10, p. 45-47) in his assessment of exposure of animals and humans to transgenic material derived from GM soybean FG72xA5547-127. Additional remarks Page 45, Table A.5: The differences in the average dry weight of HPPD W336 between single and stacked event is nearly ten-fold. The same is true for minimally and maximally encountered concentrations. We would like to ask the EFSA GMO Panel to take this observation under special consideration for potential interactions of the transgenic inserts in the stack and for the induction of unintended effects. This is especially interesting if you compare these data with those presented in Tables A.6 and A.7. In the latter tables the	ratio of 2-fold), although with overlapping ranges. Such variation in protein expression levels is not unexpected. The GMO Panel agrees that the receiving environment may affect protein expression levels. This is not unexpected and does not impact outcome the risk assessment. Small variations (up to 1.5-fold) between treated and not-treated plants are not unexpected and do not impact the outcome of the risk assessment. Following a request from the GMO Panel, the applicant provided additional information (7 April 2016) to support the assessment of the newly expressed proteins. For exposure purposes, the GMO Panel took into account the highest mean values of the protein levels (please see section 3.3.3. of the Scientific opinion). The levels reported for HPPD W336 in soybean FG72 x A5547-127 in the Brazil 2012-2013 study were below the limit of quantification, therefore they cannot be compared with the levels reported for soybean FG72, which were quantifiable.

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			expression of the transgenic proteins are rather similar between single event and the stack. Page 48: The applicant uses the following line of argumentation to explain the situation as mentioned above: "Given how low the expression is of HPPD W336 protein, the variability observed in the FG72 x A5547-127 soybean samples of below 0.150 µg/g (LLOQ) to the upper range of 2.14 µg/g in FG72 do not represent significant variability in practical terms as the values are so low and reasonably comparable." In our opinion, this is a crude line of argumentation which is to be rejected. A difference in the obtained concentrations of the tested analytes between single event and stack of up to 20-fold (in the worst case) - without applying any sophisticated statistical methodology - cannot be reasonably interpreted as low variability. If the risk assessment is based upon comparative analysis of single events versus the constructed stack, then the variability of the data between both analysed objects is of predominant interest. The occurrence of variation - if not caused by technical problems with the assay conditions or the device - is an indication for potentially occurring unintended effects in the transgenic stack. The absolute amount may be considered in a second step. We would like to ask the EFSA GMO Panel to request a statistically sound analysis of variation (including some standard parameters as standard deviation and variance) from the applicant.	Following a request of the GMO Panel, the applicant provided additional data (7 April 2016), obtained in USA, 2014. The reported expression levels of HPPD W336 in most tissues in the stack were lower than in the single (maximum ratio of 2-fold), although with overlapping ranges. Such variation in protein expression levels is not unexpected.
Austria	Federal Ministry of Health	II.1.2.1 Information relating to the genetic modification	2.1 Information relating to the genetic modification 2.1.3 Nature and source of vector(s) used including nucleotide sequences intended for insertion Scientific Information, p. 25: The applicant indicates that A5547-127 contains a 400 bp fragment of a ß-lactamase resistance gene. We would like the EFSA GMO Panel to take into account that also antibiotic resistance gene fragments may be taken up by competent bacteria and recombine with similar sequences in the host genome potentially forming new resistance determinants with altered or	As reported in Section 3.6.2.2 an updated bioinformatics analysis has been conducted for event FG72 and A5547-127. The latter revealed two regions with sufficient bacterial sequence identity in the same orientation, thus bearing

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			extended substrate specificities (i.e. mosaic genes). Functional ß-lactamase genes are widely spread in environmental bacterial populations (Demanèche et al. 2008) potentially functioning as recombination partners. Transgenic ß-lactamase gene fragments might be affected by mutations or DNA damage in their environments and may induce mutations in the bacterial receptor sequences of the competent host genome (Overballe-Petersen et al. 2013). We would like to indicate that there is a substantial knowledge gap on the frequency of DNA fragment transfers in natural environments. As far as we know all horizontal gene transfer rates in natural environments have been determined and/or calculated relying on the transfer of full-length, intact genes. Gene fragment transfer rates may, however, actually be lower or significantly higher than those obtained for full length gene transfers. Notwithstanding the above, these HGT rates for DNA fragment will have to be determined empirically. In light of the precautionary principle and facing the current crisis in antibiotic resistance (Martinez and Olivares 2011; Howard et al. 2013; Laxminarayan et al. 2013; Spellberg et al. 2013) we are of the opinion that ARM gene fragments in transgenic plant genomes should be avoided. We would like to ask the EFSA GMO Panel to inquire the necessary empirical data before concluding on this aspect of the molecular risk assessment. The applicant maintains that "Pseudomonas fluorescens, from which the HPPD protein was isolated to obtain the HPPD W336 protein, has a good history of safe use. P. fluorescens is ubiquitous in the environment…". We are not aware of any applications of P. fluorescens in the food or feed sector nor have we ever heard that it was applied deliberately as plant protection agent in agriculture. Quite on the contrary, P. fluorescens is known as one of the most abundant causes for spoilage of milk (Wiedmann et al. 2000). In this context the only argument of the applicant for his conclusion on a "good history of safe use" appears to be a proposed environmental omnipresence of this species. We would like to indicate that with such a line of argumentation all (even highly toxic) substances (like mercury, cadmium, lead etc…) can be defined as having a good history of safe use because they are also ubiquitously present in the environment. We would like the EFSA GMO Panel to take into account that a ubiquitous presence of a	potential for facilitating homologous recombination. Homologous recombination is possible between the 3' and 5' sequences of the *bla* gene with the insertion of the *pat* gene located in between. This homologous recombination could occur with a chromosomally located *bla* gene, leading to insertion of the *pat* gene chromosomally. The GMO Panel assessed this scenario and concluded that no selective advantage to bacterial recipients would be conferred. For the assessment, the GMO Panel used the criteria described in EFSA, 2015. The safety of the newly expressed protein HPPD W336 and of soybean FG72 was evaluated in the context of application EFSA-GMO-BE-2011-98 (please see EFSA GMO Panel, 2015a).

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			substance is not equivalent with a good history of safe use and therefore no eligible argument in support of the view expressed by the applicant. [Demanèche S, Sanguin H, Pote J, Navarro E, Bernillon D, Mavingui P, Wildi W, Vogel TM, Simonet P, 2008. Antibiotic-resistant soil bacteria in transgenic plant fields. Proc Natl Acad Sci U S A 105(10): 3957-3962. Howard SJ, Catchpole M, Watson J, Davies SC, 2013. Antibiotic resistance: global response needed. Lancet Infect Dis 13(12): 1001-1003. Laxminarayan R, Duse A, Wattal C, Zaidi AK, Wertheim HF, Sumpradit N, Vlieghe E, Hara GL, Gould IM, Goossens H, Greko C, So AD, Bigdeli M, Tomson G, Woodhouse W, Ombaka E, Peralta AQ, Qamar FN, Mir F, Kariuki S, Bhutta ZA, Coates A, Bergstrom R, Wright GD, Brown ED, Cars O, 2013. Antibiotic resistance-the need for global solutions. Lancet Infect Dis 13(12): 1057-1098. Martinez JL, Olivares J, 2011. Environmental pollution by antibiotic resistance genes. Antimicrobial Resistance in the Environment, John Wiley & Sons, Inc.: 149-172. Overballe-Petersen S, Harms K, Orlando LA, Mayar JV, Rasmussen S, Dahl TW, Rosing MT, Poole AM, Sicheritz-Ponten T, Brunak S, Inselmann S, de Vries J, Wackernagel W, Pybus OG, Nielsen R, Johnsen PJ, Nielsen KM, Willerslev E, 2013. Bacterial natural transformation by highly fragmented and damaged DNA. Proc Natl Acad Sci U S A 110(49): 19860-19865. Spellberg B, Bartlett JG, Gilbert DN, 2013. The Future of Antibiotics and Resistance. New Engl J Med 368(4): 299-302. Wiedmann M, Weilmeier D, Dineen SS, Ralyea R, Boor KJ, 2000. Molecular and phenotypic characterization of Pseudomonas spp. isolated from milk. Appl Environ Microbiol 66(5): 2085-2095.]	
Austria	Federal	II.1.2.2	2.2.4 Genetic stability of the inserted/modified sequence and phenotypic	

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	Ministry of Health	Information relating to the genetically modified plant	stability of the GM plant As indicated in our comments to Section 2.2.2., the submitted Southern blot analysis is inappropriate to convincingly demonstrate that no rearrangements incl. minor alterations occurred during propagation. The notifier further states that "The results of the analysis of the newly expressed proteins in FG72xA5547-127 soybean showing no biologically relevant differences compared to the expression in the single parental lines FG72 and A5547-127 (M-469896-01-1, M-464491-03-1) confirmed the phenotypic stability of FG72xA5547-127 soybean." (Scientific Information CC2, p. 49). In our opinion the assessment by the notifier is short of providing an appropriate comparison of expression of transgenic proteins in GM soybean FG72xA5547-127 and its parental single events, respectively, which is based on a comparison at an appropriate number of trial sites and years and is representative of all relevant environmental and agricultural conditions commonly encountered during commercial cultivation. The notifier also fails to address the substantial differences of expression of transgenic proteins in GM soybean FG72xA5547-127 in different replications (resulting in quite wide ranges of expression levels measured in different samples). Furthermore he does not assess in detail the differences in expression of specific transgenic components in GM soybean FG72xA5547-127 and the respective single event as noted in our comments to section 2.2.3. (c.f. compare differences in HPPD W336 expression in GM soybean FG72xA5547-127 vs. GM soybean FG72, Table A.5, Scientific Information CC2 p. 45).	The GMO Panel considers the Southern analyses provided to be of sufficient quality in order to conclude on the molecular characterisation of soybean FG72 x A5547-127. The GMO Panel is of the opinion that the data provided by the applicant (in the submitted application and additional information from 7 April 2016) related to the expression of the inserts allow for a proper risk assessment.

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Austria	Federal Ministry of Health	II.1.3.1 Choice of the conventional counterpart and additional comparators	3.1 Criteria for the selection of comparator(s) With respect to the selection of the conventional counterpart for the comparative assessment, the notifier remarks that: • "FG72 x A5547-127 in MST24 genetic background and MST24 conventional counterpart were planted in field locations 01, 03, 04, 05, 07, 08, 09." • "FG72 x A5547-127 in MST39 genetic background and MST39 conventional counterpart were planted in locations 02 and 06." As this approach is not in line with current standard (cf. EFSA 2010 (Chapter 5 - Example illustrating the proposed methodology)), it needs to be proven by the notifier that the use of different test and control lines does not lower the statistical power of the whole test design used in the comparative assessment. Relevant literature data should be provided to support the notifier's view. [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.]	The two stacked events were introgressed into two different genetic backgrounds (soybeans MST24 and MST39). This was done to expand the range of possible receiving environments of soybean FG72 × A5547-127. The applicant documented the process to obtain the two different GM lines (FG72 × A5547-127 in MST24 and FG72 × A5547-127 in MST39). Soybean MST24 and MST39 were used as non-GM comparators accordingly. The GMO Panel considers that these non-GM soybean varieties are appropriate non-GM comparators The statistical analysis was in line with GMO Panel (2011b). For the analysis, the data from the two different genetic backgrounds (MST24 and MST39) were pooled together both for the non-GM comparators and for the GM soybean. Therefore, the statistical power of the tests was not affected.
Austria	Federal Ministry of Health	II.1.5.2 Assessment of allergenicity of the whole genetically modified plant	5.2 Assessment of the allergenicity of the whole GM plant Comment on the Study Report M-458282-01-1 2-d gel electrophoresis analyses of soybean endogenous food allergens This study was conducted to compare the expression level of known endogenous soybean allergens between the FG72xA5547-127 soybean and its non-GM near-isogenic counterpart MST39. The study report says, "The first assay compared FG72xA5547-127 and MST39 seed samples. Six replicates gels were performed per sample. The second assay evaluated the biological variability in the commercial non-GM soybeans. Four replicates gels were performed for each type of commercial samples." Unfortunately, only one representative gel image obtained from a soybean extract is presented in the whole study report (p. 19).	For the assessment of endogenous allergenicity, the applicant performed two-dimensional (2D) electrophoresis of extracts of soybean FG72 × A5547-127, its conventional counterpart and three non-GM soybean commercial varieties followed by Coomassie blue staining. The Member State requests the replicates of the gels to be provided by the applicant. The purpose of the analysis was to compare the intensity of 37 spots representing five known soybean allergens. In table 2 (pages 22 to 27) of the study report M-458282-01-1, the applicant provided values for individual spots of the different test items which was the main information considered for the allergenicity assessment.

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			We would like to request (for matters of traceability) the image of each of the gels evaluated for the allergenicity assessment of GM soybean FG72xA5547-127. This is even more important, since 6 spots (glycinin family allergens GY4B3_8, GY3B1b_11, GY2A2_23, GY1A1a_33, GY1A1a_34 and GY5A3_37) in the GM soybean FG72xA5547-127 supposedly fell outside (below) the natural variability represented by the commercial soybean samples. [M-458282-01-1, FG72xA5547-127 soybean: Two-dimensional gel electrophoresis analyses of soybean endogenous food allergens. Dossier EFSA/GMO/NL/2013/120.]	Please note that the applicant provided only one gel as a representation of the approach followed for the analysis and of how the different spots were identified with a given name. The Member State also refers to 6 spots belonning to the glycinin allergen and supposedly falling outside (below) the natural variability set by the commercial varieties tested. Please note that the applicant analysed 23 spots corresponding to different subunits/isoforms/precursos of the glycinin allergen (Gly m 6), and therefore all contributing to the overall allergenicity of the glycinin allergen. The genetic modification did not induce a significant increase in the intensity of spots raising concerns for any of the five allergens tested. Furthermore, it is also noted that great variability in Gly m 6 allergen content in soybean commercial varieties has been reported (e.g. Stevenson et al 2012; Chen et al 2014). Considering the GMO Panel Guidance Document applicable to this application (2011b), the GMO Panel did not find indications of increase allergenicity in soybean FG72xA5547-127 when compared to that in its conventional counterpart and in non-GM commercial varieties.

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Austria	Federal Ministry of Health	II.1.3.2 Experimental design and statistical analysis of data from field trials for comparative analysis	3.2 Field trials: experimental design and statistical analysis For comparative assessment of composition as well as agronomic and phenotypic characteristics a field trial was conducted in 2012 in the USA at 9 trial sites (see Scientific Information CC2 p. 52ff., Study Report: M-464855-03-1 as amended 2015). From these 9 sites only 8 were used for analysis of samples. This is in contradiction to the recommendation by the EFSA GMO Panel that all available data should be analysed; however, a minimum of 8 complete datasets need to be included to ensure an appropriate power of analysis (J. Perry 2014 at EFSA tech. meeting concerning the draft guidance document on assessment of agronomic and phenotypic characteristics of GMPs). In our opinion, the process of selecting 8 specific sites from the pool of 9 sites cannot be considered unbiased as a random selection was only made from a subset of sites. Furthermore, analysis of all 9 sites would have increased the overall power and representativeness of the trial. Representativeness as regards commercial production furthermore is not demonstrated appropriately as information and justifications to establish representativeness are missing: • The notifier fails to provide evidence for the representativeness of trial sites for all geographic regions where soybean is commercially produced. The trial cannot even be considered representative for all US production regions. • The notifier should also indicate whether the agricultural procedures correspond to those usually applied for soybean crops in the respective	The field trial design was in line with the recommendations of GMO Panel (2011b), including a minimum of eight field trial sites. The applicant provided all the data generated in the field trials; compositional data was only available for eight sites. The sites selected by the applicant are distributed in areas where soybean is commonly cultivated. As documented by the applicant (Studies M-469555-02-1 and M-464855-03-1) the selected sites differ for their maturity zone (II and III) meteorological conditions and agronomic practices. The GMO Panel considered representative the selected sites and is also aware that is not feasible, in practice, to assess GM lines under all possible receiving environments. The applicant introgressed the stacked events FG72 × A5547-127 in two different genetic backgrounds to expand the range of possible receiving environments. Was possible to test soybean FG72 × A5547-127 in two different maturity zones. As reported by the applicant, the crop was grown in typical soybean production areas, using methods typical of commercial practices.

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			regions. • The herbicide management used in the trials cannot be considered representative of the conditions of commercial production: In the trial GM soybean FG72xA5547-127 was treated with the conventional herbicides as well as complementary herbicides; complementary herbicides were applied in a regime that may not be representative of repeated applications of higher doses of herbicides according to the maximum tolerable level. Such a situation is encountered, e.g. with Glyphosate based herbicides under conditions of infestations of weeds, which are resistant or semi-resistant to Glyphosate at the recommended standard level for treatment. • Furthermore, no appropriate justification is provided on whether the conditions of cultivation (e.g. climatic conditions) were representative for the respective sites and for the range of conditions encountered during commercial production. We request that the notfier provides further information on the abovementioned aspects. In particular, we request that the maximum tolerable levels of complementary herbicides are indicated by the notifier and a discussion is provided whether the conditions used during trial reflect the conditions of herbicide treatments which may be used for commercial production, taking into account elevated levels of use due to pressure of resistant or semi-resistant weeds over the next 10 years. Since no sufficient justification is be provided for the representativeness of the selected trial sites and the range of receiving environments covered in the trial, all available data should be analysed for the assessment. [M-464855-03-1, Field production of FG72 x A5547-127 soybean grown in USA, 2012. Dossier EFSA/GMO/NL/2013/120.]	Implementing Regulation (EU) No 503/2013 refers to the conventional counterpart (A) and the GMHT plant (B) treated with the same conventional herbicide regime. The comparison of A and B allows a direct comparison of the GM plant and its conventional counterpart under the same conventional herbicide regimes and enables the detection of unintended effects arising from the genetic transformation (EFSA GMO Panel, 2015b). The application of the intended herbicide in addition to the conventional herbicide regime allows detecting possible unintended effect of the genetic transformation. As mentioned above, the GMO Panel considered that the selected sites were representative, and that the experimental design was in line with the applicable guidance document (EFSA GMO Panel, 2011b).

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Austria	Federal Ministry of Health	II.1.3.4 Comparative analysis of composition	3.3 Compositional analysis The EFSA guidance document for ERA (EFSA 2010) states that a justification shall be provided that the sites and conditions will be representative of commercial production (see above comments to Chapter 3.2.). In particular, further information important to assess the data for the comparative assessment under different environmental conditions is lacking. The notifier should provide 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. The notifier should also indicate whether the agricultural procedures correspond to those usually applied for commercial production of soybean crops like GM soybean FG72xA5547-127. The notifier should also provide an appropriate "environment x genotype" assessment based on the data from all 9 field trial sites. In addition, we consider that the scope of the comparative analysis concerning food and feed risk assessment is too narrow with a view to the characteristics of GM soybean FG72xA5547-127. In particular it remains unclear, why only a limited number of antinutrients were assessed. As soybean contains also a number of known food allergens (see e.g. Batista et al. 2007; EFSA 2010), other relevant soybean allergens should be considered, e.g. as described in Houston et al. (2011), in addition to the analysed parameter trypsin inhibitor. A recent review of compositional analyses and feeding studies conducted with herbicide tolerant crop material demonstrated the need to better take into account current production conditions for herbicide-tolerant crops in the design of field tests (Cuhra 2015). It is necessary to ensure that assessments are representative of commercial cultivation conditions, e.g. as regards increased application rates and frequencies of application of Glyphosate-based herbicides due to increasing weed resistance to broadband-herbicides. The more frequent use and/or higher amounts of herbicides used in commercial cultures may affect herbicide residue levels	The sites selected by the applicant are distributed in areas where soybean is commonly cultivated. As documented by the applicant (Studies M-469555-02-1 and M-464855-03-1) the selected sites differed in the maturity zone (II and III), meteorological conditions and agronomic practices. The GMO Panel considered representative the selected sites, and is also aware that is not feasible, in practice, to assess GM lines under all possible receiving environments. Individual-site statistics was provided by the applicant in the comparative analysis report. The GMO Panel was able to conclude on the risk assessment based on the information provided by the applicant. In relation to the allergens, the GMO Panel performed an assessment of the endogenous allergenicity of the soybean FG72xA5547-127 based on experimental data provided by the applicant (please see Section 3.5.4). The GMO Panel would like to point out that Implementing Regulation (EU) No 503/2013 is not applicable to this application and that measurements of individual relevant allergens following the principles of the comparative compositional analysis is therefore not applicable to application EFSA-GMO-NL-2013-120. The intended herbicides were applied as commercial products (i.e.: Balance Pro®, Ignite® 280SL and WeatherMAX®) at a rate that is in accordance with the recommendation of the producer. Considering the scope of the application, that does

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			in crop material (Benbrook 2012; Heap 2015). Therefore, the notifier needs to justify, why the treatment regime used in the field trials is considered a realistic exposure scenario. [Batista R, Martins I, Jeno P, Ricardo CP, Oliveira MM, 2007. A proteomic study to identify soya allergens - the human response to transgenic versus non-transgenic soya samples. Int Arch Allergy Immunol 144(1): 29-38. Benbrook C, 2012. Impacts of genetically engineered crops on pesticide use in the U.S. - the first sixteen years. Environmental Sciences Europe 24(1): 24. Cuhra M, 2015. Review of GMO safety assessment studies: glyphosate residues in Roundup Ready crops is an ignored issue. Environmental Sciences Europe 27(1): 1-14. EFSA, 2010. Guidance of the GMO Panel on the environmental risk assessment of genetically modified plants. The EFSA Journal 8(11):1879: 1-111. Heap I, 2015. The International Survey of Herbicide Resistant Weeds; www.weedscience.org; (last accessed: 04/11/2015). Houston NL, Lee DG, Stevenson SE, Ladics GS, Bannon GA, McClain S, Privalle L, Stagg N, Herouet-Guicheney C, MacIntosh SC, Thelen JJ, 2011. Quantitation of soybean allergens using tandem mass spectrometry. J Proteome Res 10(2): 763-773.]	not cover cultivation, the GMO Panel considered sufficient the information provided by the applicant in this respect. Assessment of herbicide residues and metabolites is outside the remit of the GMO Panel.

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Austria	Federal Ministry of Health	II.1.3.5 Comparative analysis of agronomic and phenotypic characteristics	3.4 Agronomic and phenotypic characteristics For the assessment of agronomic and phenotypic characteristics material from the field trial discussed above (see comments on Chapter 3.2) was used and analysed. However, relevant information to assess the data provided by the notifier is missing (see comments on the experimental design of the field trials under 3.2) and no rationale is provided whether the sample size and the design of the field trial were sufficient to detect potential differences in agronomic and phenotypic characteristics, particularly effects concerning environmental interaction of GM soybean FG72xA5547-127. The notifier fails to provide a rationale for the selection of the phenotypic and agronomic parameters and whether these characteristics are relevant to his conclusions as regards persistence and invasiveness. The assessment falls short of a demonstration that the data basis is sufficient so assess the characteristics under a range of environmental conditions that would be comparable to standard agronomic conditions. The notifier also does not specifically discuss whether the pesticides used for management of the crop adversely affected the assessment of environmental interaction. Therefore, the data submitted for assessment of environmental interaction of GM soybean FG72xA5547-127 cannot be adequately evaluated. Thus, the conclusions drawn by the notifier are not sufficiently supported by submitted data. We request that the notifier provides further information on the above mentioned aspects. Additionally, an analysis of between-site variation should be made to account for interactions of GM soybean FG72xA5547-127 with the respective environment (environment x genotype interactions). Specific comments on the agronomic assessment - Study Report M-469555-02-1 Trial sites and trial design: The RCB-design with four replicates, the number of eight trial sites and the	The field trials conducted by the applicant are in line with the applicable EFSA guidance documents. Further information was requested to the applicant to support the assessment of the response of GM soybean FG72 x A5547-127 to biotic and abiotic interactions This information was submitted 28 April 2016. Considering the scope of the application, that does not cover cultivation, the GMO Panel considered sufficient the information provided to assess the environmental interaction. In relation to the environmental conditions, it is not feasible, in practice, to assess the GM lines under all possible conditions, and the GMO panel considered the selected sites representative. The sites were selected in regions were soybean is commonly cultivated and the selected sites are spread over different soybean maturity zones with different environmental conditions. Individual-site statistics was provided by the applicant in the comparative analysis report. The GMO Panel was able to conclude on the risk assessment based on the information provided by the applicant.

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			number of three reference varieties on each site out of six reference varieties in total are in accordance with the EFSA-opinion on statistical considerations for the safety evaluation of GMOs (EFSA 2010). Agronomic and phenotypic characteristics: The phenotypic characteristics recorded in the study are useful, however no data for 100-seed-weight are given. The 100-seed-weight is rather genotype specific and a relevant trait in soy-food processing. Plot data: The data information of phenotypic characteristics from single plots for all trial sites is given, however missing for the environmental interaction evaluations. No environmental interactions evaluations are given. Assessment of plant health as a comprising trait cannot reveal differences in reaction to relevant biotic or abiotic stressors. According to EFSA guidance, the comparative assessment should include "response to plant pathogens and insects pests, sensitivity to abiotic stress " (EFSA 2011, Section 3.1.3.4. p. 20). Specific comments on the germination evaluation - Study Report M-506916-01-1 Comparative evaluation of the germination potential of FG72xA5547-127, FG72, A5547-127, and the non-GM conventional counterpart (MST39) soybean: Laboratory tests on germination (warm and cold germination tests) were carried out. Both lines and the crossing itself were tested in comparison to the non-GM conventional counterpart (MST39). Materials, results and discussion: • Test design is very poor, no additional reference varieties were included in the test. The test was carried out once, without replication.	The GMO Panel acknowledges this comment. The 100 seed weight is an endpoint that will be considered mandatory after the full implementation of the GMO Panel guidance document on agronomic and phenotypic characterisation of GM plants (EFSA GMO Panel, 2015b). The agronomic and phenotypic characteristics that were measured and that include the 'plant health rating' were considered sufficient to assess the environmental interaction. More details on how to report biotic interactions are reported in the guidance document on agronomic and phenotypic characterisation of GM plants (EFSA GMO Panel, 2015b), therefore more standardised datasets will be provided by the applicant in future applications. The GMO Panel considered the provided information informative to assess the germination capacity of GM soybean FG72 x A5547-127

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			• It is NOT described were the seed came from, if all the lines were grown on the same site/ different sites or under equal climatic and whether conditions (possible influences on germination!) Methods and experimental design: • Tolerated temperature variation: +/- 5°C more than defined in ISTA rules (+/-2°C tolerated) • Cold germination test is not conform according to ISTA; number of seeds should be 400 instead of 200 for statistical reasons. • The "pure seed definition" is lacking. • Page 21, Figure 1 and 2: observation of seedlings: according to ISTA-rules and the "seedling evaluation-handbook" primary leafs have to be included into the evaluation. Concerning the figures, it seems that primary leafs were ignored, but only the cotyledons were observed. [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 for risk assessment of food and feed from genetically modified plants. The EFSA Journal 9(5):2150: 1-37. M-469555-02-1, Comparative analysis of composition, and agronomic and phenotypic characteristics for glyphosate, isoxaflutole and glufosinate tolerant soybean FG72 X A5547-127. Dossier EFSA/GMO/NL/2013/120. M-506916-01-1, Comparative evaluation f the germination potential of FG72 x A5547-127, FG72, A5547-127, and the non-GM conventional counterpart (MST39) soybean. Dossier EFSA/GMO/NL/2013/120.]	compared to its non-GM counterpart and with its GM parental lines. The selected tested materials were considered appropriate to determine possible unintended effects of the events FG72 and A5547-127, and interactions among them. The seed germination study was conducted on BC3F8 generation and no significant differences in germination potential were identified in the two germination conditions for the tested materials compared to the non-GM counterpart. The germination study was not conducted in accordance with the ISTA rules. The applied methodology to study seed germination was properly described by the applicant. Seed identity of the different used seed lots was verified via PCR.

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Austria	Federal Ministry of Health	II.6 Post-Market Environmental Monitoring Plan (PMEM)	4. Post-Market Environmental Monitoring 4.1 General The submitted monitoring plan is very general and basically identical with the plans submitted for previous notifications of other GM (soybean) applications for a similar scope of use, including the parental single events GM soybean FG72 and GM soybean A5547-127. In line with concerns raised previously to these notifications we find that the submitted monitoring plan does not provide a sufficiently concrete design for meaningful monitoring which is implementing the requirements according to Dir. 2001/18/EC in an appropriate way. Therefore we reiterate our previously notified comments below. We acknowledge the newly introduced amendment concerning requirements for measures, which need to be implemented by the network of operators selected by the notifier. Namely that "in the framework of their management or safety standards (ISO, HACCP, …), procedures must be in place and implemented to limit losses and spillage of viable soybean and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential adverse effects." (PMEM plan CC2 p. 6). We, however, note that the respective requirement is missing in the PMEM section of the scientific dossier (cf. Scientific Information CC2, Chapter 4.4.6, p. 132) and that details how this requirement will be implemented are lacking. We request that the notifier in his revision of the submitted PMEM plan addresses among others the abovementioned shortcomings as well as the issues raised below.	The GMO Panel gives its opinion on the scientific quality of the post-market environmental plan (PMEM) activities proposed by the applicant. The PMEM plan submitted by the applicant for soybean FG72 x A5547-127 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 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 document on PMEM of GM plants (EFSA GMO Panel, 2011c), 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 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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Austria	Federal Ministry of Health	II.6.3 General Surveillance (strategy, method)	4.4 General surveillance for unanticipated adverse effects According to the submitted Monitoring plan, General Surveillance will involve trade associations representing relevant operators, dealing with the import, handling and processing of viable GM soybean FG72xA5547-127 at EU level (COCERAL, UNISTOCK and FEDIOL). However, it should be clear which existing national institutions 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 and such the monitoring is ensured to be proportionate to the extent of imports of GM soybean FG72xA5547-127 as indicated by the notifier. 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. As the main use of GM soybean FG72xA5547-127 will be in feed products, national veterinary networks and services should be involved in the General Surveillance of unanticipated effects on animal health of GM soybean FG72xA5547-127. In the proposed monitoring plan these institutions are not involved in the suggested monitoring network. 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" (PMEM plan CC2, p. 4). We request that the notifier provides more information with regard to this baseline. Furthermore it is not clear how the monitoring will address unintended release to the environment via accidental spillage of viable material during transport. Additionally, the various tasks assigned to the consent holder as well as	Please refer to section 3.7.2 of the scientific opinion where it is concluded that that no data have emerged to indicate that soybean FG72 x A5547-127 is any less safe than its conventional counterpart. In addition, soybean FG72 x A5547-127 is considered as nutritious as conventional soybeans. Therefore, and in line with the guidance document, the GMO Panel is of the opinion that post-market monitoring of the GM food/feed is not necessary. The GMO Panel comments on the scientific quality of the monitoring plan. The final agreement on the monitoring is made at authorisation. EFSA has published guidance and scientific opinion on post-market environmental monitoring (PMEM) (EFSA GMO Panel, 2011c). The GMO Panel is of the opinion that the information supplied by the applicant is in line with the guidance on PMEM.

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			selected trade associations, e.g. distribution of information about the GMO (provided by the consent holder to operators via the website of EuropaBio) and the conduct of monitoring and reporting, are not appropriately specified in detail. No specification is given regarding the kind of data which ought to be collected. The proposed surveillance primarily relies on passively collecting information of unspecified nature. The notifier is requested to 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. The notifier only refers to substantial unintended losses of GM soybean FG72xA5547-127 during loading and unloading as a route for environmental exposure. Other routes of exposure of the environment by (waste) materials from processing or use of GM soybean FG72xA5547-127 are not assessed specifically. However, the requirement that all potential routes of exposure should be addressed is one of the pillars of the EU approach to monitoring. The notifier states that "exposure to the environment will be limited ... Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious soybean plants, such as manual or mechanical removal and the application of herbicides (with the exception of glyphosate, glufosinate and isoxaflutole)" (PMEM plan CC2, p. 3). As no clear responsibilities are assigned in this respect, it remains unclear who actually will be responsible e.g. for clean-up measures in the case of accidental spillage during loading and unloading. 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 FG72xA5547-127.	

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Austria	Federal Ministry of Health	Part I – General information	Detection Method The presented method describes the quantitative detection of GM soybean FG72xA5547-127. The detection method uses TaqMan technology and event specific primers, i.e. one primer resides within the transformed insert and one in the plant genome. The validation method as presented by the notifier is criticised because it uses DNA of the two single events and not the notified stacked event FG72xA5547-127. Providing an event specific detection method for each parental line and a specific reference PCR system is not satisfactory. Generally, a validated event specific detection method for the stacked event should be presented before deciding about the placing on the market of this product. Furthermore, as long as no official (guidance) document on the interpretation of detection results, i.e. how to distinguish between a stacked event and its respective single events, of the described method for stacked events is available, no approval for placing on the market of this product should be given. The detection method for GM soybean FG72xA5547-127 was sent for validation to CRL. The current evaluation status of the method is "Step 2 (scientific assessment) completed" (http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx).	The detection method is outside the remit of the GMO Panel.

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Austria	Federal Ministry of Health	II.1.4 Toxicology	4. Toxicological assessment The toxicological assessment in relation to the active principles in GM soybean FG72xA5547-127 is commented as follows: The modified EPSPS protein There could be some metabolic implications in the plant caused by the genetic modification, as confirmed by OECD Consensus Document on the safety assessment of transgenic organism (OECD 1999): "However, if very high expression levels (note: of EPSPS) result from the insertion, the levels of downstream metabolites might change. " What may be perhaps more perturbing is the fact that this active principle is solely used to create resistance to glyphosate and therefore possibly provoke some overdosing of the herbicide. Therefore also tests with herbicide-treated GM crops should be performed (as done and submitted by other applicants). This fact of non-delivering tests with glyphosate-treated GM plants is all the more serious because of the most recent assessment of glyphosate by the WHO (International Agency for Research on Cancer, IARC) classifying the herbicide glyphosate and the insecticides malathion and diazinon as "probably carcinogenic to humans (Group 2A) " (WHO 2015). For the herbicide glyphosate, there was limited evidence of carcinogenicity in humans for non-Hodgkin lymphoma. The evidence in humans is from studies of exposures, mostly agricultural, in the USA, Canada, and Sweden published since 2001. In addition, there is convincing evidence that glyphosate also can cause cancer in laboratory animals. On the basis of tumours in mice, the United States Environmental Protection Agency (US EPA) originally classified glyphosate as possibly carcinogenic to humans (Group C) in 1985. After a re-evaluation of that mouse study, the US EPA changed its classification to evidence of non-carcinogenicity in humans (Group E) in 1991. The US EPA Scientific Advisory Panel noted that the re-	Replies to each comment are provided below. The three enzymatic proteins catalyse distinct biochemical reactions: PAT acts on glufosinate herbicide; HPPD W336 and 2mEPSPS act on different substrates in the plant. On the basis of the known biological function of the individual newly expressed proteins, there is currently no expectation for possible interactions relevant to the food and feed safety assessment of the two-event stack soybean FG72 × A5547 127. The GMO Panel concludes that there are no safety concerns to human and animal health related to the newly expressed proteins HPPD W336, 2mEPSPS and PAT in the two-event stack soybean FG72 × A5547 127 (section 3.5.2.1). Moreover the safety of the proteins newly expressed in soybean FG72 x A5547-127 was already assessed in the context of the application for authorisation of the single events FG72 and A5547-127 (EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52, respectively), and no safety concerns were identified. No substantial modifications in the composition of the food and feed derived from the two-event stack soybean and no indication of possible unintended effects or interactions between the events were identified during the comparative assessment (Section 3.4.3). Protein expression analyses showed that the levels of the newly expressed proteins are similar in the two-stack soybean and

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			evaluated glyphosate results were still significant using two statistical tests recommended in the IARC Preamble. The IARC Working Group that conducted the evaluation considered the significant findings from the US EPA report and several more recent positive results in concluding that there is sufficient evidence of carcinogenicity in experimental animals. Glyphosate also caused DNA and chromosomal damage in human cells, although it gave negative results in tests using bacteria. One study in community residents reported increases in blood markers of chromosomal damage (micronuclei) after glyphosate formulations were sprayed nearby. The PAT protein WHO/FAO/JMPR states in its 1998 evaluation of Glufosinate-ammonium that information on the metabolism of glufosinate-ammonium and NAG (N-acetyl-L-glufosinate) in laboratory rats, lactating goats and laying hens was reported (FAO/WHO 2013). In summary, most of the administered dose of both compounds is rapidly excreted. NAG may be partially metabolised back to glufosinate. Bremmer and Leist (1997) examined the possible conversion of NAG to glufosinate in rats. Up to 10% deacetylation occurred at a low dose of 3 mg/kg bw as shown by the occurrence of glufosinate in the faeces. The authors concluded however that most of the conversion was caused by bacteria in the colon and rectum although toxicity findings indicate partial bioavailability (Bremmer and Leist 1998). The HPPD W336 protein FG72 soybean is a crop genetically engineered to be resistant to isoxaflutole, or to any herbicide in its class. Isoxaflutole is a relatively new herbicide, first used in the US in 1999, which kills plants by disrupting photosynthesis, resulting in bleaching and then death. Isoxaflutole is a pro-herbicide that is activated when it degrades or is metabolised to DKN (a diketonitrile derivative) within the plant or in the environment. It is classified as an HPPD inhibitor - interfering with the enzyme hydroxyphenolpyruvate dioxygenase.	in the single events (Section 3.3.3). Therefore, no animal studies on the food and feed derived from soybean FG72 × A5547 127 the two-event stack soybean are required (EFSA GMO Panel, 2011b). The potential for increased toxicity of the pesticides and their metabolites produced in the plant is not in the remit of the GMO Panel.

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			Isoxaflutole has been controversial from the start because it is classified by EPA as a "probable human carcinogen", is toxic to some aquatic organisms and to non-target plants, and it and its degradation products and metabolites contaminate water easily. These concerns have resulted in restrictions on its use. It is a federally "Restricted Use Pesticide" (RUP), meaning that it can only be applied by certified applicators, and only in some of the corn growing states (Bayer CropScience 2013). Concluding remarks A potential for increased toxicity to humans and animals or for modified nutritional value due to the stacked event may arise from interactions among the single events with regard to additive, synergistic or antagonistic effects of the gene products or by these produced metabolites. The risk assessment should account for this possibility and consider safety tests of all newly expressed proteins present in the GM soybean FG72xA5547-127 in animal models applied simultaneously and combined. Taking into consideration the weaknesses in the assessment of the individual active principles of the 2mEPSPS, the PAT protein, and the HPPD W336 protein, the testing of the combined trait (for instance by a 90-day toxicity study in rodents) becomes even more important, and should be done. [Bayer CropScience, 2013. Balance Flexx Herbicide; www.cdms.net/LDat/ld8QS010.pdf; (last accessed: 11/11/2015). Bremmer JN, Leist K-H, 1997. Disodium-N-acetyl-L-glufosinate; AE F099730 - Hazard evaluation of L-glufosinate produced intestinally from N-acetyl-L-glufosinate. Safety Evaluation Frankfurt. TOX97/014. A58659. Unpublished. Hoechst Schering AgrEvo GmbH. Bremmer JN, Leist K-H, 1998. Disodium-N-acetyl-L-glufosinate (AE F099730, substance technical) - Toxicity and metabolism studies summary and evaluation. Frankfurt. TOX98/027. A67420. Unpublished. Hoechst Schering AgrEvo GmbH.	

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			FAO/WHO, 2013. Glufosinate-ammonium (175); www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Evaluation98/glufosi.pdf; (last accessed: 11/11/2015). OECD, 1999. Consensus document on general information concerning the genes and their enzymes that confer tolerance to glyphosate herbicide. Series on Harmonization of Regulatory Oversight in Biotechnology. Paris: 1-26. WHO, 2015. IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides; http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf; (last accessed: 26/08/2015).]	
France	DGCCRF	II.1.3.1 Choice of the conventional counterpart and additional comparators	II.1.3.1. Choix de l'équivalent non transgénique et des comparateurs supplémentaires Le soja FG72 x A5547-127 utilisé pour cette analyse était placé dans le fonds génétique MST24 ou MST39 selon les sites d'expérimentation (groupes de maturité différents). Le soja témoin non génétiquement modifiée était MST24 sur les sites où l'événement FG72 x A5547-127 se trouvait dans ce fonds génétique et MST39 sur les sites où il était placé dans ce fonds génétique. Le soja FG72 x A5547-127 a également été comparé à 6 variétés commerciales conventionnelles de soja. **ENGLISH TRANSLATION** II.1.3.1. Choice of the conventional counterpart and additional comparators The soya, FG72 x A5547-127, used for this analysis was placed in the genetic base MST24 or MST39 depending on the experimental sites (different maturity grades). The non-genetically modified control soya was MST24 on the sites where event FG72 x A5547-127 was present in this genetic base and MST39 for sites where it was placed in this genetic base. Soya FG72 x A5547-127 was also compared to six conventional soya varieties.	The GMO Panel thanks France for the summary.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
France	DGCCRF	II.1.5.3 Conclusion of the allergenicity assessment	II.1.5.3. Conclusions de l'évaluation de l'allergénicité Sur la base des données et des commentaires fournis par le pétitionnaire : - le potentiel allergénique des protéines 2mEPSPS, HPPD W336 et PAT exprimées dans le soja FG72 x A5547-127 peut être considéré comme négligeable, - ces protéines n'ont apparemment pas de propriétés adjuvantes, - l'allergénicité du soja FG72 x A5547-127 reste comparable à celle d'un soja conventionnel. **ENGLISH TRANSLATION** II.1.5.3. Conclusion of the allergenicity assessment Based on the information and comments provided by the petitioner: - the allergenic potential of proteins 2mEPSPS, HPPD W336 and PAT expressed in soya FG72 x A5547-127 may be deemed to be negligible, - these proteins do not appear to have adjuvant properties, - the allergenicity of soya FG72 x A5547-127 remains similar to that of a conventional soya.	The GMO Panel takes note of the comment.
France	DGCCRF	II.1.2.4 Conclusions of the molecular characterisation	II.1.2.4. Conclusions de la caractérisation moléculaire La caractérisation moléculaire du soja génétiquement modifié FG72 x A5547-217 doit être complétée par le séquençage de l'insert et des régions flanquantes et par l'analyse de l'expression éventuelle de la cystéine protéase putative. **ENGLISH TRANSLATION** II.1.2.4. Conclusions of the molecular characterisation The molecular characterisation of genetically modified soya FG72 x A5547-217 must be supplemented by sequencing of the insert and flanking regions and by analysis of any expression of the putative cysteine protease.	The GMO Panel would like to point out that the Implementing Regulation (EU) No 503/2013 is not applicable to this application, therefore the resequencing of the inserts and flanking regions in the stack is not required in order to complete the molecular characterisation. Updated bioinformatic analysis of the flanking regions of event FG72 (submitted as additional information on 30 January 2017) indicated that no endogenous genes were interrupted, therefore the GMO Panel considers that the expression analysis of the putative cysteine protease is not needed.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
France	DGCCRF	II.1.3.2 Experimental design and statistical analysis of data from field trials for comparative analysis	II.1.3.2. Dispositif expérimental et analyse statistique des données issues des essais au champ pour l'analyse comparative Les caractéristiques de ce plan d'expérience respectent les recommandations de l'EFSA (2011). Le modèle statistique utilisé, qui inclut un effet fixe "génotype" et un effet aléatoire "variété commerciale", correspond à celui proposé par l'EFSA (2011). Les résultats des tests statistiques sont interprétés selon l'approche décrite par l'EFSA (2010), en classant les variables en 4 catégories selon les résultats du test d'équivalence et 7 types après combinaison avec les résultats des tests de différence. **ENGLISH TRANSLATION** II.1.3.2. Experimental design and statistical analysis of data from field trials for comparative analysis The details of this experimental plan follow the EFSA recommendations (2011). The statistical model used, which includes a fixed 'genotype' effect and a random 'commercial variety' effect is the model proposed by EFSA (2011). The results of the statistical tests are interpreted according to the approach described by EFSA (2010), dividing the variables into four categories depending on the results of the equivalence test and seven types after comparison with the results of the difference tests.	The GMO Panel thanks France for the summary.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
France	DGCCRF	II.1.3.3 Selection of material and compounds for analysis	II.1.3.3. Sélection du matériel et des composés pour analyse Les composés analysés correspondent à ceux du document consensus de l'OCDE (2012), à l'exception des phospholipides. Le pétitionnaire n'explique pas pourquoi ces composés n'ont pas été étudiés, mais les analyses réalisées sont recevables. Tableau C4, pages 177/185 et 178/185 du document "M-469555-02-1" : il semble qu'il y ait une interversion entre acide arachidonique et acide eicosatriénoïque ou entre C20:3 et C20:4. Cette erreur n'a pas d'incidence, car les mesures sont inférieures à la LOQ de la méthode d'analyse dans tous les cas. Néanmoins, ce point devrait être clarifié par le pétitionnaire. **ENGLISH TRANSLATION** II.1.3.3. Selection of material and compounds for analysis The compounds for analysis are those in the OECD consensus document (2012), except for phospholipids. The petitioner does not explain why these compounds have not been studied, although the analyses performed are receivable. Table C4, pages 177/185 and 178/185 of document 'M-469555-02-1': it appears that there is a reversal between arachidonic acid and eicosatrienoic acid, or between C20:3 and C20:4. This error has no impact as the measurements are below the LOQ of the analytical method in all cases. This point should nevertheless be clarified by the petitioner.	In the OECD revised consensus document for soybean (OECD, 2012), phospholipids are discussed but they are not among the suggested compositional parameters for soybean seeds. The GMO Panel considered that the spectrum of compounds chosen by the applicant was adequate for the risk assessment. The GMO Panel takes note of the comment.
France	DGCCRF	Part II – Scientific information	CONCLUSIONS DU GROUPE DE TRAVAIL « BIOTECHNOLOGIE » de l'ANSES La caractérisation moléculaire du soja génétiquement modifié FG72 x A5547-217 doit être complétée par le séquençage de l'insert et des régions flanquantes et par l'analyse de l'expression éventuelle de la cystéine-protéase putative. L'expression des protéines 2mEPSPS, HPPD W336 et PAT 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	

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			présentés dans le dossier, le potentiel allergénique des produits dérivés du soja FG72 x A5547-127 paraît extrêmement faible. La caractérisation phénotypique et agronomique et l'analyse de composition des graines du soja FG72 x A5547-127 montrent que ce soja est équivalent aux variétés conventionnelles. En conséquence et en conformité avec les recommandations de l'EFSA, l'évaluation nutritionnelle de ce soja n'a pas été réalisée. L'argumentaire présenté par le pétitionnaire au sujet des interactions potentielles entre les produits de l'expression des gènes introduits dans le soja FG72 x A5547-127 suit les recommandations de l'EFSA. L'évaluation de la sécurité des protéines 2mEPSPS, HPPD W336 et PAT exprimées dans le soja FG72 x A5547-127 ne met pas en évidence d'éléments permettant de conclure que ces protéines ont un effet toxique sur la santé humaine et animale. En revanche, en l'absence d'une étude de toxicité sub-chronique de 90 jours réalisée avec le soja FG72 x A5547-127 ou avec le soja A5547-127, 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'AGENCE 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 marché, au titre du règlement (CE) n° 1829/2003, du soja génétiquement modifié FG72 x A5547-127. Par ailleurs, l'Anses précise qu'elle regrette que l'analyse comparative de la composition n'ait pas été réalisée sur le fourrage, alors qu'une telle analyse est très fréquemment présentée dans les dossiers, dans la mesure où le fourrage peut être utilisé en alimentation animale. **ENGLISH TRANSLATION** CONCLUSIONS OF THE ANSES 'BIOTECHNOLOGY' WORKING GROUP	The GMO Panel considers that the molecular

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			The molecular characterisation of the genetically modified soya FG72 x A5547-217 should be supplemented by sequencing of the insert and flanking regions and by analysis of any expression of the putative cysteine protease. Expression of the proteins 2mEPSPS, HPPD W336 and PAT in this soya does not appear to modify the allergenicity of its grains compared with the natural allergenicity of soya grains. On the basis of the information provided in the dossier, the allergenic potential of products derived from soya FG72 x A5547-127 appears to be extremely low. The phenotypic and agronomic characterisation and analysis of the composition of soya grains FG72 x A5547-127 show that this soya is equivalent to the conventional varieties. As a result, and consistent with EFSA recommendations, the nutritional assessment of this soya was not performed. The discussion presented by the petitioner about potential interactions between expression of the products of genes introduced into soya FG72 x A5547-127 follows the EFSA recommendations. The safety analysis for the proteins 2mEPSPS, HPPD W336 and PAT expressed in soya FG72 x A5547-127 do not reveal indicators allowing a conclusion to be drawn that these proteins have a toxic effect on human or animal health. However, in the absence of a 90-day subchronic toxicity study on soya FG72 x A5547-127 or on soya A5547-127, the 'Biotechnology' WG cannot draw a conclusion as to the risks of use of this GMO in human and animal feed. CONCLUSIONS AND RECOMMENDATIONS FROM THE AGENCY The French Agency for Food, Environmental and Occupational Health and Safety agrees with the conclusions of the 'Biotechnology' Working Group. Based on the initial dossier available within the stipulated time schedule, the Agency rejects the application for Marketing Authorisation, through regulation (EC) No 1829/2003, for genetically modified soya FG72 x A5547-127. In addition, Anses states that it regrets that the comparative analysis of the composition was not performed on the animal feed, as this type of	characterisation of soybean FG72 x A5547-127 has been properly performed by the applicant. The GMO Panel takes note of the comment on allergenicity assessment.

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			analysis is very commonly presented in the dossiers in so far as the feed may be used for animal nutrition.	
France	DGCCRF	II.1.3.7 Conclusion	II.1.3.7. Conclusions de l'évaluation comparative L'analyse de composition réalisée sur les graines crues, ainsi que la caractérisation agronomique et phénotypique du soja FG72 x A5547-127, traité ou non avec les herbicides glyphosate, glufosinate-ammonium et isoxaflutole, montrent que ce soja est équivalent aux variétés conventionnelles. Aucune analyse n'a été réalisée sur le fourrage ni sur les produits issus du soja FG72 x A5547-127. **ENGLISH TRANSLATION** II.1.3.7. Conclusions of the comparative assessment The composition analysis performed on the raw grains and the agronomic and phenotypic characterization of soya FG72 x A5547-127, whether or not it is treated with glyphosate, glucosulfonate-ammonium and isoxaflutole herbicides, show that this soya is equivalent to the conventional varieties. No analysis was performed on the feed or on the products obtained from soya FG72 x A5547-127.	The GMO Panel takes note of the comment.

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France	DGCCRF	II.1.2.2 Information relating to the genetically modified plant	II.1.2.2. Informations concernant la plante génétiquement modifiée Les caractères agronomiques introduits dans le soja FG72 x A5547-127 sont la tolérance au glyphosate, aux herbicides de type isoxaflutole et au glufosinate-ammonium. Les séquences effectivement insérées dans les lignées parentales ont été analysées précédemment. Une analyse par hybridation de type Southern blot a été réalisée sur l'ADN génomique : - du soja FG72 x A5547-217, - du parent FG72, - du parent A5547-127, - de sojas non génétiquement modifiés, utilisés comme témoins négatifs. Les résultats confirment la présence des insertions des sojas FG72 et A5547-127 dans l'hybride FG72 x A5547-127 et montrent une organisation identique à celle de ces sojas. La translocation observée dans le parent FG72 est donc vraisemblablement présente dans l'hybride, ce qui place une séquence codant une cystéine protéase putative dans un nouvel environnement contenant un promoteur. L'expression éventuelle de cette cystéine protéase devrait être vérifiée. Seules les analyses bioinformatiques des séquences (inserts et jonctions) des sojas parentaux ont été actualisées en utilisant les bases de données de 2013. Pour chaque parent, l'ADN inséré dans le génome ne génère pas de nouveau cadre ouvert de lecture présentant une certaine homologie avec une toxine, un allergène ou une protéine biologiquement active. Aucun gène ou ORF de soja ne semble avoir été interrompu par cette insertion. Cependant, aucune donnée de séquençage n'a été générée sur le soja FG72 x A5547-127, ce qui n'est pas conforme aux exigences du Règlement d'exécution (UE) n° 503/2013. **ENGLISH TRANSLATION** II.1.2.2. Information relating to the genetically modified plant The agronomic features introduced into soya FG72 x A5547-127 are glyphosate tolerance and tolerance to isoxaflutole and glufosinate-	

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			ammonium herbicides. The sequences inserted into the parental lines have been analysed previously. Southern blot hybridisation analysis was performed on the genomic DNA: - of soya FG72 x A5547-217, - of parent FG72, - of parent A5547-127, - of non-genetically modified soyas, used as negative controls. The results confirm the presence of insertions from soyas FG72 and A5547-127 into the hybrid, FG72 x A5547-127, and show identical organization to that of these soyas. The translocation seen in parent FG72 is therefore likely to be present in the hybrid, which places a sequence coding for a putative cysteine protease in a new environment containing a promoter. Any expression of this cysteine protein should be verified. Only the bioinformatics analyses of sequences (inserts and junctions) of parental soyas have been updated using the 2013 database. For each parent, the DNA inserted into the genome does not produce a new open reading frame displaying a degree of homology with a toxin, allergen or biologically active protein. No soya gene or ORF appears to have been interrupted by this insertion. However, no sequencing information has been obtained from soya FG72 x A5547-127. This does not comply with the (EU) No 503/2013 execution regulation requirements).	Following a request of the GMO Panel, the applicant provided updated bioinformatics analyses (additional information 12 August 2016 and 30 January 2017). The GMO Panel would like to point out that the Implementing Regulation (EU) No 503/2013 is not applicable to this application.
France	DGCCRF - Ministère Consommation	II.1.1 Information relating to the recipient or (where appropriate) parental plants	II.1.1. Informations concernant les plantes réceptrices ou (le cas échéant) parentales Le soja génétiquement modifié FG72 x A5547-127, soumis à la présente saisine, est issu du croisement conventionnel entre les sojas FG72 et A5547-127. Différents fonds génétiques ont été utilisés pour la caractérisation de ce soja. Ils sont précisés dans chacun des paragraphes concernés. **ENGLISH TRANSLATION**	

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			II.1.1. Information relating to the recipient or (where appropriate) parental plants Genetically modified soya FG72 x A5547-127, being examined in this instruction, is obtained from conventional crossing between soyas FG72 and A5547-127. Different genetic bases have been used to characterise this soya. These are described in each of the paragraphs concerned.	The GMO Panel takes note of this comment.
France	DGCCRF	II.1.3.4 Comparative analysis of composition	II.1.3.4. Analyse comparative de la composition L'analyse de composition porte uniquement sur la graine crue. Aucune donnée n'est fournie sur le fourrage, ni sur les produits dérivés du soja FG72 x A5547-127. Les mesures de 60 composés parmi les 68 analysés sont utilisables pour les analyses statistiques. Des imprécisions dans le tableau A.13 et dans le 1er paragraphe de la page 57 du document "Main Text EFSA GMO NL 2013 120", ainsi que l'utilisation des abréviations "NA" et "NAf" pour désigner des cas différents dans les tableaux A.14 à A.20 jettent un doute sur les paramètres qui ont effectivement été mesurés et ceux qui ont été utilisés pour les analyses statistiques : - tableau A.13 : la liste des paramètres de composition mesurés comprend l'acide gamma-linolénique (gamma-C18:3), mais aucun résultat concernant ce composé n'est ensuite présenté, ni dans le document "Main Text EFSA GMO NL 2013 120", ni dans le document "M-469555-02-1". - page 57 du document "Main Text EFSA GMO NL 2013 120", 1er paragraphe : "A number of composition parameters had results that were reported to be below the limit of quantification (<LOQ) of the respective analytical method. If this was the case in more than one third of the samples, the analyte (i.e. sodium, the isoflavone aglycones and several fatty acids) was excluded from the statistical analysis. If all results for an analyte were found to be <LOQ, it was assumed that FG72 x A5547-127 soybean is not different to the conventional counterpart and that FG72 x A5547-127 soybean is equivalent to the non-GM soybean reference varieties. This was the case for glycitein and most of the not quantifiable fatty acids with the exception of heptadecenoic (C17:1), eicosadienoic (C20:2) and docosahexaenoic acid (C22:6)." o la glycitéine étant une isoflavoe aglycone, a-t-elle été considérée dans les	

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			composés pour lesquels les résultats de plus du tiers des échantillons étaient < LOQ, comme le suggère l'expression "the isoflavone aglycones", ou bien dans les composés pour lesquels tous les résultats étaient < LOQ ? (ce qui semble être le cas, compte tenu des résultats présentés dans le document "M-469555-02-1"). o plusieurs acides gras (several fatty acids) ou un seul (C22:6) ont-ils été considérés dans les composés pour lesquels les résultats de plus du tiers des échantillons étaient < LOQ ? o l'expression "most of the not quantifiable fatty acids" ne permet pas d'identifier clairement quels acides gras entrent dans cette catégorie. Or, cette information est importante pour comprendre comment on passe des 82 paramètres annoncés dans le tableau A.13 (81 paramètres en réalité, l'acide gamma-linolénique (gamma-C18:3) étant ensuite absent des résultats, Cf. supra) aux 68 présentés dans les tableaux A.14 à A.20. o tableau A.14, paramètre "ADF (% dw)" ; tableau A.15, paramètre "Iron (ppm dw)" et tableau A.20, paramètre "C17:1 Heptadecenoic" : il aurait mieux valu utiliser le terme "Not categorized" (comme dans le tableau B.7 du document "M-469555-02-1") que les abréviations "NA" et "NAf". o tableau A.15, paramètre "Sodium (% dw)" : il aurait mieux valu utiliser une autre abréviation que "NA" pour ce paramètre, car elle est aussi utilisée pour le paramètre "Iron (ppm dw)" dans ce même tableau. Or, le sodium a été exclu des analyses parce que les résultats de plus du tiers des échantillons étaient < LOQ, alors que le fer est non catégorisé (Cf. supra). o tableau A.18 : l'abréviation "NA" renvoie au cas où plus du tiers des échantillons étaient < LOQ, alors que la glycitéine semble faire partie des composés pour lesquels tous les résultats étaient < LOQ (Cf. supra). o tableau A.20, paramètre "C22:6 Docosahexaenoic" : dans l'explication donnée sous le tableau, l'abréviation "NA" ne renvoie qu'à ce paramètre, qui a été exclu des analyses parce que les résultats de plus du tiers des échantillons étaient < LOQ, alors qu'elle est aussi utilisée pour le paramètre "C17:1 Heptadecenoic", qui est non catégorisé (Cf. supra). Ces points nécessitent une vérification et des corrections de la part du pétitionnaire, de manière à lever toute ambiguïté.	

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			L'analyse combinée de l'ensemble des sites d'expérimentation de 2012 montre que la composition des graines du soja FG72 x A5547-127, T et NT, est équivalente à celle des variétés commerciales (catégorie I ou II). Des différences significatives (type 2 ou 4) sont observées entre le soja FG72 x A5547-127 et le témoin (MST24 ou MST39). Toutefois, ces différences sont faibles et les valeurs moyennes mesurées sur le soja FG72 x A5547-127 sont dans tous les cas comprises dans la plage de variation des valeurs mesurées sur les variétés commerciales. Ces différences entre le soja FG72 x A5547-127 et le soja témoin ne sont donc pas évocatrices d'un risque pour une utilisation en alimentation animale et humaine de ce soja. **ENGLISH TRANSLATION** II.1.3.4. Comparative analysis of composition The composition analysis is based only on the raw grain. No information is provided about the feed or about products derived from soya FG72 x A5547-127. Measurements from 60 compounds of the 68 analysed can be used for the statistical analyses. Inaccuracies in Table A.13 and in the 1st paragraph of page 57 of document 'Main Text EFSA GMO NL 2013 120', and the use of the abbreviations 'NA' and 'NAf' to indicate the different cases in Tables A.14 to A.20 cast doubt on the parameters which were actually measured and those which were used in the statistical analyses: - Table A.13: the list of composition parameters measured includes gamma-linolenic acid (gamma-C18:3), but no results on this compound are then presented either in the 'Main Text EFSA GMO NL 2013 120' document or in document 'M-469555-02-1'. - Page 57 of the document 'Main Text EFSA GMO NL 2013 120', 1st paragraph: 'A number of composition parameters had results that were reported to be below the limit of quantification (<LOQ) of the respective analytical method. If this was the case in more than one third of the samples, the analyte (i.e. sodium, the isoflavone aglycones and several fatty acids) was excluded from the statistical analysis. If all results	The GMO Panel takes note of the comment. The GMO Panel considers that γ-linolenic acid was not analysed in the compositional analysis, and that it was mentioned in the list of endpoints most likely because of an editorial mistake. The GMO Panel remarks that γ-linolenic acid is not among the endpoints recommended by OECD (2012); α-linolenic acid (C18:3) is instead recommended and it was fully covered in the application.

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			for an analyte were found to be <LOQ, it was assumed that FG72 x A5547-127 soybean is not different to the conventional counterpart and that FG72 x A5547-127 soybean is equivalent to the non-GM soybean reference varieties. This was the case for glycitein and most of the not quantifiable fatty acids with the exception of heptadecenoic (C17:1), eicosadienoic (C20:2) and docosahexaenoic acid (C22:6).' ○ As glycitein is an aglycone isoflavone, has it been considered amongst the compounds for which the results for more than one third of samples were <LOQ, as suggested by the expression 'the isoflavone aglycones', or amongst the compounds for which all results were <LOQ? (which appears to be the case in view of the results presented in document 'M-469555-02-1'). ○ Several fatty acids or only one (C22:6): were these considered amongst the compounds for which results were <LOQ for more than one third of the samples? ○ The expression 'most of the not quantifiable fatty acids' does not clearly identify which fatty acids were contained in this category. This is important information to understand the change from the 82 parameters reported in Table A.13 (81 parameters in reality, as gamma-linolenic acid (gamma-C18:3) was not contained in the results, Cf. above) to the 68 presented in Tables A.14 to A.20. ○ Table A.14, parameter 'ADF (% dw)'; Table A.15, parameter 'Iron (ppm dw)' and Table A.20, parameter 'C17:1 Heptadecenoic': it would have been better to use the term 'Not categorised' (as in Table B.7 of document 'M-469555-02-1') than the abbreviations 'NA' and 'NAf'. ○ Table A.15, parameter 'Sodium (% dw)': it would have been better to use another abbreviation than 'NA' for this parameter as this is also used for the parameter 'Iron (ppm dw)' in the same table. Sodium was excluded from the analyses because the results for more than one third of samples were <LOQ, whereas iron is not categorised (Cf. above).	The GMO Panel considers that docosahexaenoic acid (C22:6) was wrongly included in the sentence. ○ The tables with raw data in study report M-469555-02-1 show that all the values for glycitein were <LOQ. ○ The fatty acids with values <LOQ are listed in study report M-469555-02-1. Two of those fatty acids (heptadecenoic (C17:1), eicosadienoic (C20:2)) had only a few values <LOQ and were included in the statistical analysis. The other fatty acids (including docosahexaenoic acid (C22:6)) had almost all the values <LOQ and were excluded from the statistical analysis. ○ The GMO Panel considers that γ-linolenic acid was not analysed in the compositional analysis, and that it was included in Table A.13 (see above) most likely because of an editorial mistake. ○ The GMO Panel takes note of the comment on Table A.14 ○ The GMO Panel takes note of the comment on Table A.15. ○ The GMO Panel takes note of the comment on Table A.18. The GMO Panel considers that the results of the compositional analysis were overall clearly presented by the applicant,

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			○ Table A.18: the abbreviation 'NA' refers to cases in which more than one third of the samples were <LOQ, whereas glycitein appears to be included in the compounds for which all of the results were <LOQ (Cf. above). ○ Table A.20, parameter 'C22:6 Docosahexaenoic': in the explanation given in the table, the abbreviation 'NA' only refers to this parameter, which was excluded from the analyses because the results for more than a third of samples were <LOQ, whereas it is also used for the parameter 'C17:1 Heptadecenoic', which is not categorised (Cf. above). These points need to be clarified and corrections made by the petitioner in order to remove any ambiguity. The combined analysis from all of the experimentation sites in 2012 shows that the composition of soya grains FG72 x A5547-127, T and NT, is equivalent to that of the commercial varieties (categories I or II). Significant differences (type 2 or 4) are seen between soya FG72 x A5547-127 and the control (MST24 or MST39). These differences, however, are small and the mean values measured for soya FG72 x A5547-127 are all within the range of variation of the values found in commercial varieties. These differences between soya FG72 x A5547-127 and the control soya are not therefore suggestive of a risk for use of this soya in animal or human feed.	despite minor inconsistencies with notation. ○ The GMO Panel takes note of the comment on Table A.20. The GMO Panel considers that the results of the compositional analysis were overall clearly presented by the applicant, despite minor inconsistencies with notation. The GMO Panel considers that despite minor ambiguities, the results of the compositional analysis were overall clearly presented by the applicant. The GMO Panel takes note of the comment. The GMO Panel concluded that none of the differences identified in seed composition between soybean FG72 × A5547 127 and the non-GM comparator needed further assessment regarding food and feed safety.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
France	DGCCRF	II.1.4.5 Conclusion of the toxicological assessment	II.1.4.5. Conclusions de l'évaluation toxicologique Les précédentes évaluations avaient permis de conclure que l'ingestion de graines de soja portant l'événement de transformation FG72 était sans effet toxique chez le rat exposé pendant 90 jours via l'alimentation. En revanche, dans son avis du 15 octobre 2008, l'Afssa conclut qu'en l'absence d'une étude de toxicité sub-chronique de 90 jours chez le rat nourri avec un produit dérivé de soja A5547-127, traité et non traité par le glufosinate-ammonium, elle ne peut se prononcer sur la sécurité sanitaire des sojas portant l'événement de transformation A5547-127. La situation est inchangée et les réserves émises lors de l'examen du soja A5547-127 demeurent. Enfin, l'argumentaire présenté par le pétitionnaire au sujet des interactions potentielles entre les produits de l'expression des gènes introduits dans le soja FG72 x A5547-127 suit les recommandations de l'EFSA. **ENGLISH TRANSLATION** II.1.4.5. Conclusions of the toxicological assessment It may be concluded from the above assessments that ingestion of soya grains carrying the FG72 transformation event have no toxic effect on the rat exposed through diet for 90 days. Conversely, in its opinion on 15 October 2008, Afssa concluded that because of the lack of a 90-day subchronic toxicity study in the rat fed with a product derived from soya A5547-127, whether or not treated with glufosinate-ammonium, it could not reach a conclusion as to the health safety of soyas carrying transformation event A5547-127. The situation is unchanged and the reservations raised from the examination of soya A5547-127 remain. Finally, the discussion presented by the petitioner about potential interactions between expression products of genes introduced into soya FG72 x A5547-127 follows the EFSA recommendations.	The GMO Panel takes note of the comment and is of the opinion that the newly expressed proteins 2mEPSPS, HPPD W336 and PAT in the two-event stack soybean did not raise safety concerns for human and animal health and no interactions between these proteins, relevant for food and feed safety, were identified. Moreover none of the observed differences identified in seed composition between soybean FG72 × A5547 127 and the non-GM comparator required further assessment. These conclusions are in line with those expressed for the respective single events.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	BVL	II.5.3.1 Persistence and invasiveness including plant-to-plant gene flow	The import documents should indicate that soybean FG72 x A5547-127 has not been approved for cultivation by the EC and that soybean FG72 x A5547-127 is tolerant to glyphosate, glufosinate-ammonium and to isoxaflutole. Furthermore, appropriate measures have to be taken during transport, storage, and processing to avoid unintended release into the environment.	The GMO Panel takes note of the comment.
Germany	BVL	II.6.3 General Surveillance (strategy, method)	II.6.3.2 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.	The GMO Panel took note of this comment.
Germany	BVL	II.1.2.2 Information relating to the genetically modified plant	It is known that HPPD activity is not only inhibited by isoxaflutole but also by β-triketones such as sulcotrione and mesotrione and pyroxazoles such as pyrazolynate, pyrazoxyfen and benzofenap. In the present application nothing is mentioned about the sensitivity/tolerance of the newly introduced HPPD W336 to β-triketone and pyroxazole herbicides. The scope of the application confirms that isoxaflutol will be commercialized as complementary herbicide. However, the applicant should provide further information about the characteristics of the HPPD W336 enzyme concerning potential tolerance to other herbicides than isoxaflutole. The results of the bioinformatic studies should be reconfirmed by using updated databases.	As assessed in EFSA-GMO-BE-2011-98 (GMO Panel, 2015a), data on the functional activity of the HPPD W336 protein has been provided by the applicant on a range of substrates which were considered appropriate by the GMO Panel. Following a request of the GMO Panel, the applicant provided updated bioinformatic analyses (additional information 12 August 2016 and 30 January 2017).
Germany	BVL	II.6 Post-Market Environmental Monitoring Plan (PMEM)	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 point raised by BVL is in the remit of risk managers, and thus not that of the GMO Panel.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	BVL	II.6.3 General Surveillance (strategy, method)	II.6.3.3 Review of ongoing research and development activities and literature review In general, other sources of information e.g. peer-reviewed publications or ongoing research should be taken into account. However, the applicant should describe in detail how he will consider this information within General Surveillance.	A literature search relevant for the application was provided by the applicant on 8 November 2016 upon EFSA's request.
Germany	BfN	II.1 Hazard identification and characterisation	Comments by the Federal Agency for Nature Conservation: The Federal Agency for Nature Conservation (BfN) considers that further information is required before the risk assessment of EFSA/GMO/NL/2013/120 can be finalised. In particular the environmental risk assessment (e.r.a.) and the monitoring plan should be amended. Due to the expression of the HPPD W336 protein, FG72 x A5547-127 and FG72 are resistant not only to isoxaflutole, which belongs to the isoxazoles, but possibly also to other herbicide families, e.g. triketones and pyroxazoles (Matringe et al. 2005; cf. our comments on application EFSA-98). In this respect the transgenic trait has not been described comprehensively and the comparative assessment should possibly consider GM material that has been treated with further herbicides as well (cf. also II.1.3.2 IV). Information (data and data analyses) provided on composition, phenotypic evaluation and toxicology is insufficient and conclusions of equivalence of the GMO and conventional soybean and on food and feed safety based on this information are premature. The range of compounds for the compositional analysis should be broadened (cf. II.1.3.4). To assess the potential for any interaction, FG72 x A5547-127 should be compared to the single events as comparators in the expression analysis and in the comparative assessment. Several of the deficits listed here are valid for the single events FG72 and A5547-127 as well. Therefore, we refer to our previous comments on the corresponding applications EFSA-98 and EFSA-52. Most of them remain also valid after additional information has been provided by the applicant, amongst others because the new field trial study submitted for FG72 (From M482561-02-1, 2014) shares the same deficits as the former one. We want to point out that glufosinate will be phased out in Europe on September 30th 2017 due to its reproductive toxicity (see Annex I of	The GMO Panel took note of the comments. Considering the introduced traits and the outcome of the comparative analysis, the routes of exposure and limited exposure levels, the GMO Panel concluded that the two-event stack soybean would not raise safety concerns in case of accidental release of viable GM seeds into the environment. There are no indications of an increased likelihood of spread and establishment of soybean FG72 x A5547-127 plants unless these plants are exposed to glufosinate-ammonium- and/or glyphosate-and/or isoxaflutole- containing herbicides. The GMO Panel considered that the scope of the post-market environmental monitoring plan provided by the applicant is consistent with the scope of the two-event stack soybean. The GMO Panel agreed with the reporting intervals proposed by the applicant in the PMEM plan. The GMO Panel takes note of this comment. The GMO Panel assessed the two single events in the frame of the respective applications (EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52) and identified no safety concerns. This issue is outside the remit of the GMO Panel.

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			Directive 91/414/EWG). FG72 x A5547-127 soybean expresses the 2mEPSPS protein to confer resistance to glyphosate. We want to point out that the safety of glyphosate is presently under revision by the EU and that glyphosate has been classified by IARC (WHO) as a probable carcinogen (IARC 2015). Information on glyphosate residues within food and feed products from FG72 x A5547-127 soybean should be provided (see also Cuhra 2015). 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 before consent can be given. Cuhra, M. (2015). Review of GMO safety assessment studies: glyphosate residues in Roundup Ready crops is an ignored issue. Environ Sci Eur 27:20; DOI 10.1186/s12302-015-0052-7. International Agency for Research on Cancer World Health Organization (2015). Evaluation of five organophosphate insecticides and herbicides. IARC Monographs, Volume 112, 20 March 2015. Matringe, M., Sailland, A., Pelissier, B., Rolland, A. and Zink O. (2005). p-Hydroxyphenylpyruvate dioxygenase inhibitor-resistant plants. Pest Manag Sci 61: 269–276.	This issue is outside the remit of the GMO Panel.
Germany	BVL	II.1.4 Toxicology	The results of the bioinformatic studies should be reconfirmed by using updated databases.	Following a request of the GMO Panel, the applicant has provided updated bioinformatic analyses (additional information 12 August 2016 and 30 January 2017).

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	BfN	II.1.3.2 Experimental design and statistical analysis of data from field trials for comparative analysis	Comments by the Federal Agency for Nature Conservation: Material for the agronomic and compositional analyses was sampled from eight out of 9 locations in the USA in 2012 (Dharmasri 2015, M-464855-03-1). At each site, four replicated plots of the GMO, a conventional soybean variety with a similar genetic background to the GMO, and three out of a pool of 6 non-GM references were planted using a randomized complete block design. The experimental design has got several weak points: I. Field sites were located in the states of the Midwest in Missouri, Indiana, Nebraska, Illinois and Indiana. A justification is missing, whether locations are "representative of the range of receiving environments where the crop will be grown, thereby reflecting relevant meteorological, soil and agronomic conditions" (EFSA 2011, p.14). Soybean is grown in other areas as well, as reflected by field trials in the North, in the South or the South East of the USA (such as Michigan, Minnesota, Wisconsin, Louisiana, Mississippi, Alabama, Florida and Georgia) which were considered as trial sites for other GM soybeans (applications EFSA-43, EFSA-52, EFSA-76, EFSA-79 and EFSA-91). II. The GMO was either treated or not treated with the three complementary herbicides in combination. As it cannot be excluded that effects of isoxaflutole, glyphosate and glufosinate point in opposite directions and annul each other, studies for comparative assessment should also involve the GMO treated with each of the herbicides separately. III. It should be clarified whether the GMO received treatments with the complementary herbicides and conventional herbicide. According to our interpretation this does not comply with the herbicide treatments foreseen in the EFSA guidance (2011). IV. The complementary herbicides were applied each solely at a uniform rate, not considering regional agronomic conditions. To our understanding rates of the complementary herbicides should also be case-specific and take into account the amount of active ingredients tolerated by a certain GMO. In this respect, data are missing and requested on the amount of the three herbicides tolerated by the GMO. V. Interactions between the recorded environmental factors (climate, soil or agricultural practices) at the various trial sites and the GMO were not	I. The GMO panel considered the selected sites sufficiently representative. It is not feasible, in practice, to assess the GM lines under all possible conditions, and the sites were selected in regions were soybean is commonly cultivated and the selected sites are spread over different soybean maturity zones with different environmental conditions. II. In accordance with the applicable guidance document (EFSA, 2011b), in case of herbicide tolerant GM plant, the applicant is requested to include in the experimental design a plot with the GM plants exposed to the intended herbicide(s). The experimental design is therefore considered acceptable. III. The intended herbicides were applied in addition to the maintenance agrochemicals, and in accordance with the specific requirement of each site (see annex I of the field production study report M-464855-03-1). This was considered in line with the requirements of the GMO Panel guidance (2011b). IV. The three intended herbicides were

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			analysed. VI. Ideally compositional and agronomic studies should be based on a full power analysis, conducted prior to finalising the design. VII. The starting material was not sufficiently characterised. The GMO, the comparator and the references were not tested for contamination with other GM soybean varieties. VIII. To assess the potential for any interactions between the two events, FG72 x A5547-127 should be compared to the single events as well, which were not considered as comparators in the field trial. 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 the GMO, which allows simulation of well-defined abiotic and biotic conditions (cf. 1.3.5). EFSA (2011). Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011; 9(5): 2150.	sequentially applied across the different sites at the same growing phase and at the same rate. This practice was considered acceptable by the GMO Panel because a similar treatment was consistently applied at the different sites. The occurrence of phytotoxic effects on the GM plants was monitored and recorded trough the visual estimation of plant health. V. Individual-site statistics was provided by the applicant in the comparative analysis report. The EFSA GMO Panel was able to conclude on the risk assessment based on the information provided by the applicant. VI. A power analysis is not among the requirements of the applicable guidance document (EFSA GMO Panel, 2011b). VII. The GMO acknowledges the comment. A more clear guidance to the applicant is now provided with the EFSA guidance (EFSA GMO Panel, 2015b) that will be fully implemented in May 2017. VIII. A comparison of the stack with the single events is not among the requirements of the applicable guidance document (EFSA GMO Panel, 2011b). The GMO Panel considered that the field trial design, including the selected comparators, were adequate for the risk assessment.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	BfN	II.6.2 Case Specific Monitoring (strategy, method and analysis)	Comments by the Federal Agency for Nature Conservation: 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 FG72 x A5547-127 soybean or material containing FG72 x A5547-127 soybean enters the environment, which occurs during transport, processing or use of the GMO as food and feed. The applicant is requested to provide an appropriate case-specific monitoring plan comprising at least the following elements: i.) spillage or loss of FG72 x A5547-127 soybean during transport, storage, packaging, processing and use (food and feed); ii.) potential spread and persistence of FG72 x A5547-127 soybean, if spillage or loss of viable grains of the GMO occurs; For measuring these parameters the use of the following standardized 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 or persistence of FG72 x A5547-127 soybean occur, further observations of potential adverse effects on organisms, food chains and habitats 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 plants. EFSA Journal, 9(8): 2316, 40 pp.	The environmental risk assessment did not conclude on a potential risk of FG72 x A5547-127; therefore case-specific monitoring is not required. The GMO Panel comments on the scientific content of the monitoring plan. EFSA has published guidance and scientific opinion on post-market environmental monitoring (PMEM) (EFSA, 2011c). The GMO Panel is of the opinion that the information supplied by the applicant is in line with the guidance documents on PMEM. Please refer also to Section 3.7.2 of the scientific opinion on application EFSA-GMO-NL-2013-120.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Germany	BVL	II.1 Hazard identification and characterisation	The scope of application EFSA-GMO-NL-2013-120 covers import and processing of soybean FG72 x A5547-127 including all feed and food products containing, consisting of, or produced from the genetically modified soybean FG72 x A5547-127. Cultivation is not covered by this application. 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 FG72 x A5547-127 is unlikely to have adverse effects on human and animal health or on the environment in the context of its intended use. However, completion on a few points of the dossier is recommended. The provided monitoring plan is incomplete at this stage and needs further elaboration for implementation.	The GMO Panel takes note of the comment.

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Germany	BfN	II.1.2.2 Information relating to the genetically modified plant	Comments by the Federal Agency for Nature Conservation: Material for the expression analysis was sampled from three locations in Brazil in 2012-2013 (de Araujo 2013, M469554-01-1) and additionally from three locations in the USA in 2012 (Dharmasri 2015, M-464855-03-1). See II.1.3.2 for a description of the field design of Dharmasri and our comments. At the locations in Brazil, four replicated plots of the GMO, a conventional soybean variety with a similar genetic background to the GMO, and of the single events FG72 and A5547-127 were planted using a randomized complete block design. A5547-127 was treated with one, FG72 was treated with two and FG72 x A5547-127 was treated with all three complementary herbicides. The experimental design of both studies has got some weak points (cf. 1.3.2 for comments on Dharmasri): I. A justification is missing, whether locations are representative of typical cultivation practices (cf. EFSA, 2011). To our understanding, the locations should also cover the range of receiving environments where the crop will be grown since both cultivation practice and the environment can influence the expression. A description of the trial sites in Brazil is missing. II. FG72 x A5547-127 was either treated or not treated with the three complementary herbicides in combination. As it cannot be excluded that effects of isoxaflutole, glyphosate and glufosinate point in opposite directions and annul each other, the three herbicides should be applied singly as well. III. It should be clarified whether plots with FG72 x A5547-127 received treatments with the complementary herbicides and conventional herbicide. According to our interpretation this does not comply with the herbicide treatments foreseen in the EFSA guidance (2011). IV. The starting material was not tested for contamination with other GM soybean varieties. V. Only in the Brazil study expression levels of the three transgenic proteins in FG72 x A5547-127 were compared to the expression levels in the single events VI. Interactions between environmental factors (climate, soil or agricultural practices) and the expression of the proteins were not analysed. We do not agree with the applicant's conclusion that – based on the present	I. Brazil and USA are two of the main soybean producing countries worldwide (OECD-FAO, 2015). Nevertheless, the GMO Panel takes note of the comment. II. It can be expected that the "representative conditions of typical cultivation" for soybean FG72 x A5547-127 will include spraying with all three herbicides. III. In the Brazil 2012-2013 field trial, all plots received a conventional herbicide treatment (section 3.0 of M469554-01-1). IV. The GMO Panel takes note of the comment. V. Following a request of the GMO Panel, the applicant submitted additional data (7 April 2016) from a field trial conducted in the USA, where the two-event stack and the singles were grown side by side. VI. The variation of protein expression levels across sites is not unexpected and does not constitute a target of the risk assessment.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			data – there were no relevant differences in the expression of the three proteins in FG72 x A5547-127 (stacked event) compared to expression in the single events FG72 and A5547-127. On the contrary, the present data indicate that the single events interact in the stacked event and that the intended (= complementary) herbicides affect the expression of two of the proteins. a) In the Brazil study mean expression levels (in µg/g d.w) for the HPPD W336 protein were 0.837 with conventional herbicide treatment (= CHM) and 1.14 with treatment with intended herbicides (= TIH) in FG72 and 0.170 (CHM) and 0.186 (TIH) in the stacked event. In the USA study values were 0.795 (CHM) and 0.728 (TIH) in the stacked event and the FG72 was not considered in this study. Taken together, at the locations in Brazil the HPPD W336 protein was expressed in FG72, but not in the stacked event, while at the locations in the USA it was expressed in the stacked event, but not considered in FG72. b) In the Brazil study the expression level of the PAT protein was slightly affected by the herbicide treatment in the single event A5547-127 (13.4 µg/g with CHM and 14.8 µg/g with TIH), but clearly affected in the stacked event (12.9 µg/g with CHM and 19.6 µg/g with TIH, (+ 52%). A similar effect was obtained with the 2mEPSPS in the Brazil study with a plus of 5.5% in the single event and 29.9% in the stacked event. The expression analysis should be based on a field trial which is devoid of the above listed deficits and provide sufficient data in order to demonstrate that there are no interactions between the events in FG72 x A5547-127. The applicant is requested to test the influence (i) of environmental factors such as climate or soil on the expression and (ii) of the complementary herbicides on the expression of the three transgenic proteins. 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-2013-120 (soybean FG72 x A5547-127) 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**
Germany	BfN	II.1.4.4 Testing of the whole genetically modified food or feed	Comments by the Federal Agency for Nature Conservation: We do not agree with the applicant's conclusion that the GMO is substantial equivalent to conventional soybean and as safe as soybean for food and feed use (cf. I.3) nor do we share EFSA's opinions on the single events. To complete the risk assessment we recommend carrying out at least a sound 90-day toxicity study with whole plant material of the GMO in rodents. In addition, we advise to carry out supplemental studies with ruminants and swine which differ with respect to their digestive systems and which will be substantially exposed to feed derived from the GMO. At present, a 90-day feeding study in rodents is available for FG72 (Odin-Feurtet 2010, M-368148-01), but not for A5547-127 or for FG72 x A5547-127. The study of Odin-Feurtet (2010) has got several weak points which compromise the conclusions (cf. our comments on application EFSA-98): (i) the study did not feed GM material treated with and without intended herbicides and herbicide families other than isoxazoles have not been considered yet (cf. our comment under II.1); (ii) the test material used for the studies (GM soybean and control soybean) was not analysed for contamination with other GM material; (iii) the rodent diet A04 Safe was not analysed for contamination with other GM material. Mesnage et al. (2015) analysed several rodent diets on a spot check basis. Although they found only low amounts of GM soybean in rodent diet A04 Safe, it cannot be excluded that the batches used by Odin-Feurtet or in other studies contained higher amounts of foreign GM material. Mesnage, R., Defarge, N., Rocque, L.-M., Spiroux de Vendômois, J. and G.-E. Séralini (2015). Laboratory Rodent Diets Contain Toxic Levels of Environmental Contaminants: Implications for Regulatory Tests. PLoS ONE 10(7): e0128429. doi:10.1371/journal.pone.0128429	The GMO Panel takes note of the comment. No substantial modifications in the composition of the food and feed derived from the two-event stack soybean and no indication of possible unintended effects or interactions between the events were identified during the comparative assessment (Section 3.4.3). Therefore, no animal studies on the food and feed derived from soybean FG72 × A5547 127 are required (EFSA GMO Panel, 2011b). This comment refers to the single events FG72 and A5547-127. The two single events have been previously assessed by the GMO Panel in the context of applications EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52, respectively, and no safety concerns were identified.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) **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**
Germany	BfN	II.6.4 Reporting the results of PMEM	Comments by the Federal Agency for Nature Conservation: 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 FG72 x A5547-127 soybean imported into the EU, ii) the ports and silos where shipments of FG72 x A5547-127 soybean were unloaded, iii) the processing plants where FG72 x A5547-127 soybean was transferred to, iv) the amount of FG72 x A5547-127 soybean used on farms for feed, and v) transport routes of FG72 x A5547-127 soybean.	The publication of the monitoring results is not in the remit of the GMO Panel. In accordance with Regulation (EC) No 1829/2003, the authorisation holder "*shall submit reports to the European Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30*" of Regulation (EC) No 1829/2003.
Germany	BVL	II.6.2 Case Specific Monitoring (strategy, method and analysis)	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 GMO Panel agrees with BVL on this point.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Germany	BVL	II.6.3 General Surveillance (strategy, method)	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.	The GMO Panel took note of this comment, and reminds that the scope of this application is for import/processing for food/feed uses, excluding cultivation. Moreover, monitoring and its practical implementation are related to risk management, and thus a final adoption of the post-market environmental monitoring plan falls outside the mandate of EFSA. No relevant compositional, agronomic and phenotypic changes were identified in soybean FG72 × A5547-127 when compared with its conventional counterpart. Furthermore, the overall intake or exposure is not expected to change because of the introduction of soybean FG72 × A5547-127 into the market. Therefore, the GMO Panel considered that the post-market monitoring of soybean FG72 × A5547-127 is not necessary.
Germany	BVL	II.6.3 General Surveillance (strategy, method)	II.6.3.1. 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 actors on behalf of recording, analysis and evaluation of monitoring data needs more transparency.	Monitoring and its practical implementation are related to risk management, and thus a final adoption of the post-market environmental monitoring plan falls outside the mandate of EFSA.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Germany	BVL	II.6.4 Reporting the results of PMEM	A report on GS activities on an annual basis is sufficient. Reporting should refer to the format introduced by the Commission Decision 2009/770/EC. The applicant is requested to state how the monitoring results will be published.	Monitoring and its practical implementation are related to risk management, and thus a final adoption of the post-market environmental monitoring plan falls outside the mandate of EFSA.
Germany	BfN	II.1.3.5 Comparative analysis of agronomic and phenotypic characteristics	Comments by the Federal Agency for Nature Conservation: For general comments on comparative assessment and the production of material we refer to our comments under II.1.3.2. Agronomic data were analysed by Oberdörfer (2013 M-46955502-1). The agronomic analysis is supplemented by a seed germination test conducted in plant growth chambers (Franklin 2015, M506916-01-1). Results about volunteers from field releases performed in various countries are not provided. Further data and analysis are required before phenotypic and ecological equivalence can be concluded. Next to the weak points of the experimental design (cf. 1.3.2) this is for the following reasons: I. The selected agronomic characteristics cannot sufficiently indicate differences in reproduction, dissemination, and survivability of the GMO compared to conventional soybean. II. Ecological interaction data were not collected, but can indicate the presence of unintended effects in the GMO. However, the field design is – because of the small plot size – not comparable to common agricultural practice. Also, agrochemicals were applied where necessary. It cannot be excluded that both aspects would interfere with the collection of ecological interaction data (e.g. arthropod abundance). III. Information about the production of the starting material is missing. Therefore, it is unclear, where it was produced, whether all material derives from the same field trial, whether GM-material was produced and tested with and without intended herbicides and whether the starting material was tested for the absence of other GM soybean events. The applicant should be asked to provide a robust and reliable data basis for reproduction, dissemination, and survivability to demonstrate substantial equivalence of the GMO and conventional soybean, which is devoid of the above listed deficit and the ones listed under II.1.3.2. Relevant data should	Considering the scope of the application, that does not cover cultivation, the GMO Panel considered sufficient the information provided by the applicant. I. The applicant collected endpoints during early, mid and late season, providing a complete description of the life cycle of the crop during the different growth stages. Considering the scope of the application, that does not cover cultivation, the GMO Panel considered sufficient the information provided II. Additional information were requested by the GMO Panel and submitted on 28 April 2016. III. The GMO Panel acknowledge the comment and clarification on how to describe the starting material is reported in the EFSA guidance on agronomic and phenotypic characterisation of genetically modified plants (EFSA GMO Panel, 2015b). In this specific application the starting material was tested for contamination as described in the study M-464855-03-1.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
			be collected and assessed following the amendments under II.1.3.2. Field studies with ecology-based parameters such as frost tolerance, seed dormancy, time span of pollen emission or duration of pollen viability of the GMO tested under field conditions should be included in the application. We recommend including data on the occurrence of volunteers during cultivation of the GMO at all sites. In agreement with the step-by-step principle field results, including post-release monitoring reports from the releases of the GMO in the USA, Brazil and Argentina, shall be provided. Field data should cover suboptimum growing conditions (cf. II.1.3.4) and be supplemented by data from greenhouse studies, e.g. those already collected during event selection. Unlike field studies, greenhouse studies allow simulation of well-defined abiotic and biotic conditions.	
Germany	BfN	II.6 Post-Market Environmental Monitoring Plan (PMEM)	Comments by the Federal Agency for Nature Conservation: 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 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	Monitoring and its practical implementation are related to risk management, and thus a final adoption of the post-market environmental monitoring plan falls outside the mandate of EFSA. As the environmental risk assessment did not identify potential adverse environmental effects from the two-event stack soybean, the GMO Panel did not require case-specific monitoring.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
			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 the GMO will be transported, stored, packaged, processed or used for feed/food. In case of substantial losses and spread of the GMO, 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 parameters beyond the period of consent. Since traders may commingle the GMO 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 the GMO 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. There are gradual differences in the predictability among effects and therefore gradual transitions between case-specific monitoring and general surveillance. It is therefore necessary to include the option of investigating similar parameters in case-specific monitoring, in general surveillance, or in both simultaneously. Consequently, monitoring requirements are listed under both categories. 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 (2011). Scientific opinion. Guidance on the Post-Market Environmental monitoring (PMEM) of genetically modified plants. EFSA Journal, 9(8): 2316, 40 pp.	

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Germany	BfN	II.6.3 General Surveillance (strategy, method)	Comments by the Federal Agency for Nature Conservation: 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 the viable GMO 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 the GMO. 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 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 FG72 x A5547-127 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 FG72 x A5547-127 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 FG72 x A5547-127 soybean, during transport, storage, packaging, processing and use (food and feed) in the environment.	Monitoring and its practical implementation are related to risk management, and thus a final adoption of the post-market environmental monitoring plan falls outside the mandate of EFSA. As the environmental risk assessment did not identify potential adverse environmental effects from the two-event stack soybean, the GMO Panel did not require case-specific monitoring.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
			FG72 x A5547-127 soybean may enter the environment together with other approved GM lines. Therefore, a special focus should be on possible combined effects.	
Germany	BfN	II.5 Environmental risk assessment	Comments by the Federal Agency for Nature Conservation: The Federal Agency for Nature Conservation (BfN) considers that further information is required before the risk assessment of EFSA/GMO/NL/2013/120 can be finalised. The environmental risk assessment should be amended subjected to the required further information.	The GMO Panel took note of the comments. Considering the introduced traits and the outcome of the comparative analysis, the routes of exposure and limited exposure levels, the GMO Panel concluded that the two-event stack soybean would not raise safety concerns in case of accidental release of viable GM seeds into the environment. There are no indications of an increased likelihood of spread and establishment of soybean FG72 x A5547-127 plants unless these plants are exposed to glufosinate-ammonium- and/or glyphosate- and/or isoxaflutole-containing herbicides. To finalise the environmental risk assessment of GM soybean FG72 x A5547-127 the GMO Panel requested further information to the applicant (add info 20 August 2015; 19 November 2015; 28 April 2016 and 12 August 2016).
Germany	BfN	II.6.1 Interplay between Environmental Risk Assessment, Risk Management and PMEM	Comments by the Federal Agency for Nature Conservation: The information necessary to conclude on the e.r.a. is partly missing. Thus, the safety of FG72 x A5547-127 soybean cannot be fully assessed. Depending on those results the conclusions concerning case-specific monitoring may need to be revised.	Considering that the scope of application EFSA-GMO-NL-2013-120 excludes cultivation, the GMO Panel considers that the information provided relating to the environmental risk assessment is sufficient. The environmental risk assessment did not identify on any potential adverse environmental effects related to soybean FG72 x A5547-127; therefore case-specific monitoring is not required.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) **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**
Germany	BfN	II.1.4.1 Testing of newly expressed proteins	Comments by the Federal Agency for Nature Conservation: The single event FG72 expresses the HPPD W336 protein. With FG72 a 90-day toxicity study in rodents and a 42-day broiler study were performed. The diet of both studies was not assured to be free of GM material. The same is true for the 28-day toxicity study in mice to test the acute toxicity of the HPPD W336 protein (cf. II.1.4.4).	This comment refers to the single events FG72 and A5547-127. The two single events have been previously assessed by the GMO Panel in the context of applications EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52, respectively, and no safety concerns were identified.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Germany	BfN	II.1.3.4 Comparative analysis of composition	Comments by the Federal Agency for Nature Conservation: For general comments on field trial design and comparative assessment we refer to II.1.3.2. Compositional data were analysed by Oberdörfer (2013 M-46955502-1). Further data and analysis are required before compositional equivalence can be concluded. Next to the weak points of the field trial design this is for the following reasons: I. None of the intended herbicides or their possible metabolites were analysed, although the genetic transformation allows that the herbicides are used much more intensively with the GMO than with conventional varieties. Glyphosate-resistant plants can accumulate glyphosate residues at unexpected high levels (reviewed in Cuhra 2015). II. The compounds included in the compositional analysis were selected according to OECD recommendations for key food and feed nutrients for new varieties of soybean. Although several compounds have been analysed, the range of selected substances is still limited. Recent studies hypothesized that genetic transformation itself is stressful to plants and found that parameters traditionally used as indicators of oxidative stress (antioxidant enzymes, malondialdehyde content, hydrogen peroxide level) were higher in GM soybean when compared to non-GM soybean (Arruda et al. 2013; Barbosa et al. 2012). One possible consequence of this metabolic stress could be that the composition of GM plants, when put under further stress e.g. by growing under suboptimum conditions, is more likely to change and differ from the counterpart with respect to further compounds. III. Depending on the specific compound, the impact of the intended herbicides can result in an increase as well as a decrease of their value. Therefore it is justified to group both cases (a) “comparator > GMOCHM > GMOTIH” and (b) “comparator < GMOCHM < GMOTIH” into the category “comparator -> GMOCHM -> GMOTIH”, where -> can mean either increase or decrease. In about 35 of 58 compounds, which were analysed, there was a clear tendency that their values followed the order of “comparator -> GMOCHM -> GMOTIH”, but only 11 cases with a different order (“comparator ->GMOTIH -> GMOCHM”) and another 12 cases without any order or only a weak tendency, meaning that the values were similar or differed only slight; CHM means conventional herbicide treatment and TIH	I. Assessment of herbicide residues and metabolites is outside the remit of the GMO Panel. II. The GMO Panel considered that the spectrum of compounds chosen by the applicant was adequate for the risk assessment. III. The GMO Panel concluded that none of the differences identified in seed composition between soybean FG72 × A5547 127 and the non-GM comparator needed further assessment regarding food and feed safety.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
			means treatment with intended herbicides. Since the distribution of orders is not random, the results should be analysed in terms of a possible impact of the intended herbicides and also compared in this respect with the results of the agro/pheno analysis. The applicant should be asked to provide a robust and reliable data basis for composition to demonstrate equivalence of the GMO and conventional soybean, which is devoid of the deficits listed above and under II.1.3.2. Relevant data should be collected and assessed following the amendments under II.1.3.2. The range of compounds in the compositional analysis should be extended and consider traditional indicators of oxidative stress. The results should be discussed in the light of a recent paper, which integrates C1 metabolism and oxidative stress (Ayyadurai and Deonikar 2015), and should be combined with experiments in the field and in the greenhouse under suboptimum growing conditions (cf. 1.3.5). Arruda, S.C., Barbosa, H.S., Azevedo, R.A. and Arruda, M.A. (2013). Comparative Studies Focusing on Transgenic through cp4EPSPS Gene and Non-Transgenic Soybean Plants: An Analysis of Protein Species and Enzymes. Journal of Proteomics, 93, 107-116. http://dx.doi.org/10.1016/j.jprot.2013.05.039 Ayyadurai, V.A.S. and Deonikar, P. (2015). Do GMOs Accumulate Formaldehyde and Disrupt Molecular Systems Equilibria? Systems Biology May Provide Answers. Agricultural Sciences, 6, 630-662. doi: 10.4236/as.2015.67062. Barbosa, H.S., Arruda, S.C., Azevedo, R.A. and Arruda, M.A. (2012). New Insights on Proteomics of Transgenic Soybean Seeds: Evaluation of Differential Expressions of Enzymes and Proteins. Analytical and Bioanalytical Chemistry, 402, 299-314. http://dx.doi.org/10.1007/s00216-011-5409-1 Cuhra, M. (2015). Review of GMO safety assessment studies: glyphosate residues in Roundup Ready crops is an ignored issue. Environmental Sciences Europe, 27:20. DOI 10.1186/s12302-015-0052-7	The GMO Panel considered the dataset and the comparative analysis adequate for the risk assessment. The GMO Panel considered that the spectrum of compounds chosen by the applicant was adequate for the risk assessment.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Germany	BfN	II.4 Post-market monitoring on the genetically modified food or feed	Comments by the Federal Agency for Nature Conservation: The data provided to show the human and animal safety of FG72 x A5547-127 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 FG72 x A5547-127 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.	No relevant compositional, agronomic and phenotypic changes were identified in soybean FG72 × A5547-127 when compared with its conventional counterpart. Furthermore, the overall intake or exposure is not expected to change because of the introduction of soybean FG72 × A5547-127 into the market. Therefore, the GMO Panel considers that the post-market monitoring of soybean FG72 × A5547-127 is not necessary.
Germany	BfN	II.1.6 Nutritional assessment	Comments by the Federal Agency for Nature Conservation: No feeding study with whole plant material was submitted with FG72 x A5547-127. The 42-day broiler study with FG72 (Stafford 2009) shares the same deficits as the 90-day feeding study in rodents (cf. 1.4.4).	No substantial modifications in the composition of the food and feed derived from the two-event stack soybean and no indication of possible unintended effects or interactions between the events were identified during the comparative assessment (Section 3.4.3). Therefore, no animal studies on the food and feed derived from soybean FG72 × A5547-127 are required (EFSA GMO Panel, 2011b).

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) **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**
Germany	BfN	II.1.4 Toxicology	Comments by the Federal Agency for Nature Conservation: Toxicology assessment of the GMO is mainly focused on the expression of the new proteins, but not on potential unintended effects deriving there from, from herbicide residues (cf. II.1.3.4), from interactions amongst them or from genetic transformation. We recommend carrying out at least a sound 90-day toxicity study in rodents to test for the above mentioned possible effects (cf. 1.4.4).	The GMO Panel takes note of the comment. No substantial modifications in the composition of the food and feed derived from the two-event stack soybean and no indication of possible unintended effects or interactions between the events were identified during the comparative assessment (Section 3.4.3). Therefore, no animal studies on the food and feed derived from soybean FG72 × A5547 127 are required (EFSA GMO Panel, 2011b).
Hungary	Ministry of Agriculture	II.1.2.2 Information relating to the genetically modified plant	a) If the "the overlap between the probe and the fragment is too small for visualization on the autoradiograph", another probes should have been used. b) If "some additional fragments were observed in the digestions of the sample DNA/12-025/38 with the ScaI enzyme (lanes 3 and 4 on Figure A.9 and Figure A.10), due to partial digestion of the sample", new samples should have been run. c) Figure A7.and A11 are messy. d) The possible presence of "a partial (putative) cysteine protease" and "partial Zinc-binding protein" might have biological effect. Was it checked? f) Homology searches of the newly expressed proteins were performed using a window of 8 amino acids, and not 6, as it is recommended by WHO/FAO already in 2001.	The GMO Panel takes note of the comments a)-c). d) Analyses of the pre-insertion locus and the flanking regions of event FG72 did not indicate the deletion or interruption of functional endogenous genes, therefore the GMO Panel considered that further analyses were are not needed. f) Please note that the GMO Panel has published a Scientific Opinion on allergenicity in 2010, highlighting that identity search "*over 6 contiguous amino acids to known allergens is associated with very poor specificity (many false positives)*" (EFSA GMO Panel, 2010a).
Hungary	Ministry of Agriculture	II.1.3.2 Experimental design and statistical analysis of data from field trials for comparative	3.2.1 Field trials were performed in 1 season only. 3.2.2 Hungary objects to changing the remit of risk assessment by comparing the GM with commercial reference lines instead of comparing the GM crop with its comparator.	The field trial design was in line with the recommendations of EFSA GMO Panel (2011b). In the comparative analysis, the GM soybean was compared (test of difference) with the non-GM comparator, and tested for equivalence with the set of non-GM commercial varieties.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
		analysis		
Hungary	Ministry of Agriculture	II.1.3.3 Selection of material and compounds for analysis	3.3 Should be clarify why were all the analyses performed on a logarithmically transformed scale? Statistically significant differences were found between FG72 x A5547-127 soybean (conventional herbicide management) and the conventional counterpart for delta tocopherol and glycine. Comparing FG72 x A5547-127 (treated with the intended herbicides) and the conventional counterpart, the crude protein, carbohydrates, NDF, vitamin B2, daidzin, glutamic acid, glycine and proline were significantly different.	It may happen that a scale transformation is needed to fulfil the assumption of normality. The logarithmic transformation is very commonly used (see also discussion in EFSA GMO Panel, 2010b). The GMO Panel takes note of the comment.
Hungary	Ministry of Agriculture	II.1.6 Nutritional assessment	No nutritional experiment has been carried out with FG72 x A5547-127 soybean (nor with the event A5547-127) which, considering the differences in composition, and the presence of residues and metabolites of 3 different total herbicides, is a major problem for risk assessment.	The intended trait of the two-event stack soybean FG72 × A5547 127 is herbicide tolerance, with no intention to alter nutritional parameters. Comparison of the composition in seeds of soybean FG72 × A5547 127 with the non-GM comparator did not identify differences that would require a nutritional assessment as regards to food and feed (Section 3.5.5). Therefore, no animal studies on the food and feed derived from soybean FG72 × A5547 127 are required (EFSA GMO Panel, 2011b). Assessment of the presence of residues and metabolites of 3 different total herbicides is out of the remit of the EFSA GMO Panel.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) **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**
Hungary	Ministry of Agriculture	II.1.2.3 Additional information relating to the genetically modified plant required for the environmental safety aspects	a) If the "the overlap between the probe and the fragment is too small for visualization on the autoradiograph", another probes should have been used. b) If "some additional fragments were observed in the digestions of the sample DNA/12-025/38 with the ScaI enzyme (lanes 3 and 4 on Figure A.9 and Figure A.10), due to partial digestion of the sample", new samples should have been run. c) Figure A7.and A11 are messy. d) The possible presence of "a partial (putative) cysteine protease" and "partial Zinc-binding protein" might have biological effect. Was it checked? f) Homology searches of the newly expressed proteins were performed using a window of 8 amino acids, and not 6, as it is recommended by WHO/FAO already in 2001.	The GMO Panel takes note of the comments a)-c). d) Analyses of the pre-insertion locus and the flanking regions of event FG72 did not indicate the deletion or interruption of functional endogenous genes, therefore the GMO Panel considered that further analyses were are not needed. f) Please note that the EFSA GMO Panel has published a Scientific Opinion on allergenicity in 2010, highlighting that identity search "*over 6 contiguous amino acids to known allergens is associated with very poor specificity (many false positives)*" (EFSA GMO Panel, 2010a).
Hungary	Ministry of Agriculture	II.1.2.1 Information relating to the genetic modification	Neither Pseudomonas fluorescens, nor Streptomyces viridochromogenes. were consumed as food before, therefore the transgenic proteins have no history of safe use. In any case all transgenic proteins are produced by modified genes, (the 2mepsps gene was generated by introducing mutations into the wild-type epsps (wt epsps) gene from maize; a single amino acid substitution has been made in the wt hppdPf gene), therefore the transgenic proteins in the form as they are present in the GM soy are not present in Nature or in their natural hosts.	The safety of the proteins newly expressed in events FG72 and A5547-127 was assessed in the context of applications EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52 respectively (please see EFSA GMO Panel 2011a, 2015a).

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) **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**
Hungary	Ministry of Agriculture	II.3 Risk characterisation	The risk assessment reflects the views of the understanding of the assessors. If certain risks are ignored, a proper risks assessment cannot be carried out. The risk assessors totally ignore the changes in herbicide use with GM crops. It is necessary to pay attention to the altered residue pattern in imported food/feed. The concern with the current application is that isoxaflutole herbicide has a higher potential for causing health risks than, for example, glyphosate (isoxaflutole ADI: 0.0I, mg/kg bw - glyphosate ADI: 0.3 mg/kg bw). There is no information on residues of glufosinate, although it is known that its metabolites MPP and NAG was shown to be reconverted into the active herbicide by micro-organisms in the digestive tract (Bremmer JN and Leist K-H (1997). Disodium-N-acetyl-L-glufosinate; AE F099730 -Hazard evaluation of Lglufosinate produced intestinally from N-acetyl-L-glufosinate. Hoechst Schering AgrEvo GmbH, Safety Evaluation Frankfurt. TOX97/014. A58659 (www.fao.org/ag/agp/agpp/pesticid/jmpr/Download/98/glufosi3.pdf). Therefore, the use of glufosinate, in GM crops could have implications for consumers. Similarly, since glyphosate is patented as an antibiotic and also as a microbial agent, it affects the microbial balance of the gut of humans and animals. As a minimum, the herbicid-residue/metabolite levels should be measured for each shipment of GM soybeans entering the EU.	The assessment of herbicide residues is not in the remit of the GMO Panel.
Hungary	Ministry of Agriculture	II.1.5 Allergenicity	The allergenic characteristics of soy and GM soy differ [Batista, R., Martins, I., Jeno, P., Ricardo, C. P. and Oliveira, M. M. (2007). A proteomic study to identify soya allergens - the human response to transgenic versus non-transgenic soya samples. Int Arch Allergy Immunol 144(1): 29-38)., and this was not considered in the application).	The GMO Panel is aware of the publication by Batista et al (2007). The authors concluded that "*none of the individuals tested reacted differentially to the transgenic versus non-transgenic samples under study*".

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Comments from National Competent Authorities under Directive 2001/18/EC				
Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Hungary	Ministry of Agriculture	II.1.3.1 Choice of the conventional counterpart and additional comparators	3.1 Should be clarify why is it that 2 the conventional counterparts MT24 and MST39 used in the comparative assessment?	The two stacked events were introgressed into two different genetic backgrounds (soybeans MST24 and MST39). This was done to expand the range of possible receiving environments of soybean FG72 × A5547-127. The applicant documented the process to obtain the two different GM lines (FG72 × A5547-127 in MST24 and FG72 × A5547-127 in MST39). Soybean MST24 and MST39 were uses as non-GM comparators accordingly. The GMO Panel considers that these non-GM soybean varieties are appropriate non-GM comparators.
Hungary	Ministry of Agriculture	II.4 Post-market monitoring on the genetically modified food or feed	In addition to evaluating the potential risks arising from the genetic modification, it is important to address all concerns in connection with the changes in pesticide use and the resulting altered residue/metabolites patterns of imported food/feed. The current application and the presented risk assessment does not consider these aspects. The submitted monitoring plan is very general and unsuitable to find any effects, and does not make it possible to pin them to any specific GMO. The PMM it is short of providing meaningful monitoring requirements according to Dir 2001/18/EC. It is not clear how the general monitoring will address unintended release of GMOs to the environment via accidental spillage of viable material during transport. The time period of monitoring should be longer than the duration of authorisation.	Assessment of herbicide residues and metabolites is outside the remit of the GMO Panel. No relevant compositional, agronomic and phenotypic changes were identified in soybean FG72 × A5547-127 when compared with its conventional counterpart. Furthermore, the overall intake or exposure is not expected to change because of the introduction of soybean FG72 × A5547-127 into the market. Therefore, the GMO Panel considers that the post-market monitoring of soybean FG72 × A5547-127 is not necessary. The unintended release of GMOs to the environment via accidental spillage of viable material during transport is covered in the post market environmental monitoring plan.

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Comments from National Competent Authorities under Directive 2001/18/EC				
Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
Hungary	Ministry of Agriculture	II.1.2.2 Information relating to the genetically modified plant	2.2.3 a) Should be clarify why the E.coli recombinant proteins were used in the ELISA assays to quantify the transgenic proteins instead of the transgenic proteins isolated from the GM plant? b) Should be clarify what is the reason for the changes in the transgenic protein expression upon herbicide(s) treatment (Table A5-7)?	a) The equivalence between the E. coli-produced and the plant-produced newly expressed proteins was demonstrated in the single event applications (EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52). Therefore the described ELISA method is considered sufficient by the GMO Panel. b) Small variations in protein levels between the treated and not-treated plants are not unexpected and do not impact the outcome of the risk assessment.
Hungary	Ministry of Agriculture	II.1.4 Toxicology	Neither the FG72, nor the A5547-127 soybeans are considered safe by Hungarian experts since there are several statistically significant differences in their composition and agronomic characteristics compare to comparators.	The two single events FG72 and A5547-127 have been previously assessed by the GMO Panel in the context of applications EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52, respectively, and no safety concerns were identified.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Hungary	Ministry of Agriculture	II.1.4 Toxicology	4.1 All transgenic proteins in FG72 x A5547-127 soybean are modified and are not present in nature, they have no history of safe use. The toxicological studies were performed with the E. coli bacterial recombinant proteins instead of the ones from the GM plant. The transgenic proteins in the GM soybeans are present in a different matrix, their genes have different regulatory element than that of the original genes. SGF and SIF are irrelevant to protein survival in vivo. It is documented that both glyphosate and glufosinate can affect the microbial flora of humans and animals. No 90 day toxicological/nutritional assessment was carried out with A5547-127 soybean. Based on the above reasons a repeated dose toxicity studies using laboratory animals should have been carried out with FG72 x A5547-127 soybeans. In addition, the concerns in connection with the changes in pesticide management, altered pesticide application scheme, and changed pesticide residue/metabolite patterns in imported food/feed should be part of the toxicological assessment.	The two single events FG72 and A5547-127 have been previously assessed by the GMO Panel in the context of applications EFSA-GMO-BE-2011-98 and EFSA-GMO-NL-2008-52, respectively, and no safety concerns were identified. No substantial modifications in the composition of the food and feed derived from the two-event stack soybean and no indication of possible unintended effects or interactions between the events were identified during the comparative assessment (Section 3.4.3). Therefore, no animal studies on the food and feed derived from soybean FG72 × A5547 127 are required (EFSA GMO Panel, 2011b). The assessment of pesticide management and herbicide residues is not in the remit of the GMO Panel.
Hungary	Ministry of Agriculture	II.2 Exposure assessment — anticipated intake or extent of use	Exposure assessment does not consider the presence of residues and metabolites of the three different herbicides	The assessment of herbicide residues and metabolites is not in the remit of the GMO Panel.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Hungary	Ministry of Agriculture	II.1.5.1 Assessment of allergenicity of the newly expressed protein	5.1 and 2 The source of the transgenes was never consumed as food, the transgenes have no history of safe use. SGF and SIF have no relevance to in vivo digestibility of the proteins. The database homology searches of the newly expressed proteins were performed using a window of 8 amino acids, and not 6, as it is recommended by WHO/FAO already in 2001.	The GMO Panel has previously assessed the single events soybean FG72 and soybean A5547-127 and no indications for safety concern on allergenicity were identified. For the allergenicity assessment of newly expressed proteins, the GMO Panel followed its guidance documents (EFSA GMO Panel, 2011b).The principles of such guidance documents are based on internationally agreed standards by Codex Alimentarius (2009). Information of different nature on the newly expressed protein is taken into consideration under a stepwise, weight-of-evidence approached. For the question on the homology searches and the peptide match of complete identity over 6 contiguous amino acids to known allergens, please note that the GMO Panel has previously published a Scientific Opinion on allergenicity in 2010 highlighting that identity search "*over 6 contiguous amino acids to known allergens is associated with very poor specificity (many false positives)*" (EFSA GMO Panel, 2010a).
Hungary	Ministry of Agriculture	II.1.1 Information relating to the recipient or (where appropriate) parental plants	Soy was cultivated first as a ground covering crop in China, not as food.	The GMO Panel takes note of the comment.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) **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**
Hungary	Ministry of Agriculture	II.1.3.5 Comparative analysis of agronomic and phenotypic characteristics	3.4 The following agronomic and phenotypic characteristics: the stand count recorded in the early season, final stand count and plant height were significantly different between FG72 x A5547-127 soybean and the conventional counterpart. Significant differences are significant, and cannot explained away.	The applicant was requested to provide further information on the significant difference identified on stand count (additional information 12/8/2016). The environmental consequences of these differences are discussed in section 3.6.2 of the scientific opinion.
Hungary	Ministry of Agriculture	II.1.3.6 Effects of processing	3.5 Concerning the effect of processing, the finding of Esdaile (2002) indicates that the PAT protein is not fragmented or modified in by heat treatment at up to 90°C for 60 minutes, and the EPSPS protein was detected in heat treated soybeans. Gonzales-Morales S et al. (2015) describes in Food Science and Technology, that in processed GM soybean the DNA of CaMV 35S can be detected and measured, as well as the protein EPSPS. These DNAs and the protein can be detected in the products after heat- and pH treatment. The presence and activity of the transgenic proteins can be measured experimentally in the final products. These measurements should perform. Therefore the conclusion, that dietary exposure to functionally active proteins in processed food products can be negligible and below levels of any safety concerns" is not justified.	The GMO Panel has previously assessed the effect of processing on the newly expressed proteins 2mEPSPS and HPPD W336 (single-event soybean FG72, application EFSA-GMO-BE-2011-98) and PAT (single-event soybean A5547-127, application EFSA-GMO-NL-2008-52), and no safety concerns were identified.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Hungary	Ministry of Agriculture	Part I – General information	Hungary does not support the authorisation of the placing on the market of the genetically modified herbicide tolerant soybean FG72 x A5547- since Hungarian experts are not convinced that it is safe and it was tested with sufficient scientific vigour to establish its safety. This GM soy contains tolerance to 3 herbicides and 3 gene cassettes. Each of these codes for modified enzymes not present in Nature. It is likely that the FG72 x A5547 genetically modified soybeans will be used with glyphosate, glufosinate, and isoxaflutole herbicides. The combined effects of the residues and metabolites of these herbicides have not been tested at the levels they are likely to be used. The current application and the presented risk assessment data do not sufficiently consider this aspects. The measurement residue and metabolite level on the seeds is not envisaged. Significant differences must be taken into account. All major data should be provided in each application without referring back to previous applications. Hungary objected to the authorisation both of FG72 and A5547 genetically modified herbicide tolerant soybeans on a scientific basis, and those reasons are still valid.	The GMO Panel takes note of the comment. However, the issue of herbicide residues and metabolites is not in the remit of the GMO Panel.
Italy	Ministero dell'Ambiente	II.6.3 General Surveillance (strategy, method)	General surveillance. We agree with the applicant as far as the involvement of the stakeholders with the coordination of EuropaBio. However, specific information related to handling and processing of soybean FG72 x A5547-127 should be provided in order to minimize the unintended losses in the environment and contamination of other similar products. To this purpose, a more effective and direct information system for the operators handling this product instead of the one offered by the sole EuropaBio website should be adopted and described.	The point raised by Italian Ministry of Environment is in the remit of risk managers, and thus not that of the GMO Panel. The 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.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) 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**
Italy	Ministero dell'Ambiente	II.4 Post-market monitoring on the genetically modified food or feed	1. Part E.4 “PMEM” • As indicated by the EFSA guidance on PMEM (EFSA Panel on Genetically Modified Organisms, 2011), "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 proposed PMEM the questionnaires are described and nor how the collected information will be analyzed. The applicant should provide this information. • 4.4.1 “Approach”: the notifier only refers to substantial unintended losses of GM soybean during loading/unloading of the viable commodities as a route for environmental exposure. The applicant should analyze all potential routes of exposure, including transportation. • 4.4.1 “Approach”: the notifier states that "Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious soybean plants, such as manual or mechanical removal and the application of herbicides (with the exception of Isoxaflutole, glyphosate and glufosinate herbicides)”. No clear responsibilities are assigned in case of accidental exposure, so it remains unclear who actually will be responsible for those clean-up measures: we ask to detail more this aspect. • 4.4.1 “Approach”: 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 FG72 X A5547-127: it is required to provide such guidelines to evaluate their effectiveness. 4.4.5 “Existing systems”: 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. As a result of control on the official websites of the three associations COCERAL, UNISTOCK and FEDIOL in the Members section, we see that not all Member States are represented: therefore, it is required to provide a list of these Member States and to describe how the monitoring activities will be conducted there. • 4.4.5 “Existing systems”: in addition to the aforementioned existing	Monitoring and its practical implementation are related to risk management, and thus a final adoption of the post-market environmental monitoring plan falls outside the mandate of EFSA.

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Country	**Organization**	**Reference**	**Comment**	**GMO Panel response**
			monitoring systems conducted by third parties, the notifier will perform a screening of peer-reviewed scientific publications relevant to the specific GMO: it is required to provide the report of literature search within the annual monitoring report. • 4.4.6 "Monitoring Methodology": 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 (EFSA Panel on Genetically Modified Organisms, 2011) 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.	
Italy	Ministero dell'Ambiente	II.6.4 Reporting the results of PMEM	• 4.5 "Reporting": the monitoring report for the FG72 X A5547-127 soybean should also deliver detailed information on: actual volumes imported in the EU specifying final use, the ports and silos where shipments will be unloaded, the location of processing facilities and transportation routes. References: EFSA Panel on Genetically Modified Organisms, 2010. Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879. EFSA Panel on Genetically Modified Organisms, 2011. Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011;9(8):2316.	ERA WG / PMEM The publication of the monitoring results is not in the remit of the EFSA GMO Panel. In accordance with Regulation (EC) No 1829/2003, the authorisation holder "*shall submit reports to the European Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30*" of Regulation (EC) No 1829/2003.
Netherlands	GMO Office	Part I – General information	The Dutch CA has assessed the dossier with respect to the food and feed safety of FG72 x A5547-127 soybean and has no comments or requests for additional information in relation to the safety of this GM event.	The EFSA GMO Panel takes note of this comment.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) **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**
Netherlands	GMO Office	Part I – General information	The Dutch CA under Directive 2001/18/EC has assessed the dossier with respect to the environmental safety of FG72 x A5547-127 soybean and has no comments or requests for additional information in relation to the safety of this GM event.	The GMO Panel takes note of this comment.
Norway	Norwegian Environment Agency	Part I – General information	The Norwegian CA requests the notifier to provide further information that will allow the Norwegian authorities to evaluate the possible contributions of FG72xA5547-127 to a sustainable development, benefit to the society and other ethical considerations regarding the use of the genetically modified crop. These aspects will be addressed in the evaluation of the notification in Norway under the Norwegian Gene Technology Act and in accordance with the Regulations relating to impact assessment pursuant to the Gene Technology Act http://www.regjeringen.no/en/doc/laws/acts/gene-technology-act.html?id=173031 The notifier is reguested to provide information related to the following issues: changes in pesticide use, accumulation of herbicides in the plants, emergence of herbicide resistant weeds, potential of gene flow (in particularly the bla gene) and possible impacts on farmers cultivating soya.	The GMO Panel takes note of this comment.

Application EFSA-GMO-NL-2013-120 (soybean FG72 x A5547-127) **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**
Sweden	National Food Agency	II.1.3.4 Comparative analysis of composition	The applicant has performed field trials, designed according to legal requirements, in order to study agronomic, phenotypic and compositional characteristics of soybean A5547-127 x FG72 (both sprayed and not sprayed with isoxaflutole+glufosinate+glyphosate). The reported outcome of the studies did not raise concern with regard to safety of the newly developed soybean stack. However, it would be interesting to understand why the applicant did not randomized the non-GM soybean reference varieties to locations in the field trials. Although not being important for the safety assessment of soybean A5547-127 x FG72, the applicant should also explain why they not present the data on seed content of C18:3 g-linolenic acid which apparently was included in the set of fatty acids analysed in the soybean materials (C18:3 g-linolenic acid is not in the list of compounds omitted for statistical analysis due to too many data points being below the LOD).	The EFSA GMO Panel takes note of the comment. As explained in the study report (Study ID M-469555), the six reference varieties belonged to different maturity groups, hence they were assigned to the field trial sites in the most appropriate maturity zones. The EFSA GMO Panel agrees with the criteria followed for the assignment. The EFSA GMO Panel considers that γ-linolenic acid was not analysed in the compositional analysis, and that it was mentioned in the list of endpoints most likely because of an editorial mistake. The EFSA GMO Panel remarks that γ-linolenic acid is not among the endpoints recommended by OECD (2012); α-linolenic acid (C18:3) is instead recommended and it was fully covered in the application.

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