REGULATED PRODUCTS SAFETY ASSESSMENT

Assessment of the Safety of Genetically Modified Soybean Used as MON 87705 X MON 87708 X MON 89788 for Food and Feed Uses Under Assimilated Regulation (EC) No. 1829/2003 (RP2149)

Food Standards Agency[1], Food Standards Scotland[2]

[1] Regulated Products Risk Assessment, Food Standards Agency, UK, [2] Risk Assessment, Food Standards Scotland, UK

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FSA Research and Evidence

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) received an application from Bayer CropScience Ltd ("the applicant") under assimilated Regulation (EC) No. 1829/2003 for soybean MON 87705 x MON 87708 x MON 89788 (three-event stack soybean). The FSA and FSS reviewed the submitted evidence, including the 2020 European Food Safety Authority (EFSA) opinion and a 2024 EFSA statement to assess the safety of three-event stack soybean in terms of the UK.

The three-event stack soybean is modified by conventional crossing to combine three single soybean events: MON 87705, MON 87708 and MON89788. This combination is intended to alter the fatty acid profile in the seed, through a FAD2-1A/FATB1-A suppression cassette, increasing the levels of oleic acid. In addition, two proteins are produced to confer tolerance to both dicamba (DMO) and glyphosate-based herbicide (CP4 EPSPS). EFSA previously assessed the three single soybean events whilst the UK was a Member State of the EU, and did not identify safety concerns.

The scope of the application is for the authorisation for import, processing, and food and feed use of soybean MON 87705 x MON 87708 x MON 89788.

The application does not cover cultivation, and no soybean MON 87705 x MON 87708 x MON 89788 will be grown in the UK.

The FSA and FSS agreed with the EFSA Scientific Opinion and the Statement complementing the EFSA Opinion, confirming that soybean MON 87705 x MON 87708 x MON 89788, as described in this application, is as safe as its non-GM comparator and the non-GM reference varieties tested in the context of its intended uses in GB.

This safety assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.

1. Introduction

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) received an application (RP2149) for the authorisation of genetically modified soybean MON 87705 x MON 87708 x MON 89788 (unique identifier: MON-877Ø5-6 x MON-877Ø8-9 x MON-89788-1), submitted by Bayer CropScience Ltd. (230 Cambridge Science Park, Cambridge, United Kingdom) (hereafter referred to as "the applicant"), on behalf of Bayer CropScience LP (800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, USA, according to assimilated Regulation (EC) No. 1829/2003.

To ensure the regulatory systems of the FSA/FSS are risk proportionate, and resources are used effectively, the FSA and FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA Scientific Opinion, to provide a summary assessment of the evidence of safety presented in this report. In carrying out the assessment, the FSA/FSS reviewed the information provided by the EFSA Scientific Opinion and the Statement complementing the EFSA Scientific Opinion, and the dossier submitted by the applicant

The EFSA Scientific Opinion (2020) and the Statement (2024) have been reviewed by the FSA/FSS and it has been verified that the standard approach taken, when compared to the relevant guidance applied in GB, has been followed and the conclusions made are consistent with the data summarised in the opinion. This assessment represents the opinion of the FSA/FSS on the safety of genetically modified soybean MON 87705 x MON 87708 x MON 89788.

This three-event stack soybean was produced by conventional crossing of the single soybean events MON 87705 (containing the soybean FAD2-1A/FATB1-A gene fragments downregulating endogenous FAD2 and FATB enzymes in seeds by RNA interference (RNAi), and expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS protein)), MON 87708 (expressing dicamba mono-oxygenase (DMO protein)) and MON

89788 (expressing CP4 EPSPS protein). This combination is intended to confer an altered fatty acid profile (increased oleic acid content) and tolerance to glyphosate-based and dicamba herbicides.

Each single event and the two-event stack soybeans MON 87705 x MON 89788 and MON 87708 x MON 89788 were previously assessed by EFSA and authorised for use in the EU, while the UK was a Member State (EFSA, 2012, EFSA, 2013b, EFSA, 2013a, EFSA, 2015b, EFSA, 2015a, EFSA, 2018), as shown in Table 1. No concerns for human or animal health or environmental safety were identified. The stacked soybean MON 87705 × MON 87708 × MON 89788 has also been assessed and authorised in the EU, with an EFSA opinion (EFSA-GMO-NL-2015-126) published in 2020 (EFSA, 2020) and implemented with a Statement complementing the EFSA Opinion (EFSA, 2024). The Statement allowed EFSA to finalise the risk assessment of the three-event stack soybean after the applicant provided a 90-day feeding study on GM soybean MON 87705 and a proposal for post-market monitoring considering the altered fatty acid profile of three-event stack soybean.

Table 1. Single soybean events assessed by the European Food Safety Authority (EFSA) when the UK was a Member State of European Union.

Event	Application number or Mandate	EFSA opinion date
MON 87705	EFSA-GMO-NL-2010-78 EFSA-Q-2013-00423	EFSA GMO Panel (2012) EFSA GMO Panel (2013b)
MON 87708	EFSA-GMO-NL-2011-93	EFSA GMO Panel (2013a)
MON 89788	EFSA-GMO-NL-2006-36	EFSA (2008)
MON 89788	EFSA-GMO-RX-011	EFSA GMO Panel (2018)
MON 87705 x MON 89788	EFSA-GMO-NL-2011-100	EFSA GMO Panel (2015b)
MON 87708 x MON 89788	EFSA-GMO-NL-2012-108	EFSA GMO Panel (2015a)

The FSA/FSS reviewed the information in the EFSA Opinion about the composition and agronomic characteristics of the stack, the potential for interactions between the individual events, DNA sequencing and updated bioinformatics analyses, and additional toxicological studies provided by the applicant as part of application RP2149. As the single events were previously safety assessed and authorised, this assessment focusses on the combined transformation events including stability and expression of the transformation events, and potential interactions resulting from the combination of the transformation events as required by Regulation (EU) No 503/2013 (EC, Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on Applications for Authorisation of Genetically Modified Food and Feed in Accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and Amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (Text with EEA Relevance), 2013).

Soybeans have been domesticated for over three millennia and are now grown as a commercial crop in over 90 countries throughout the world. In 2021, over 129,000,000 hectares of soybeans were harvested, producing over 370,000,000 tonnes of soybeans and over 58,000,000 tonnes of oil. The major commodities of soybeans are the grain (used to make traditional soy foods such as miso, soy sauce and tofu as well as other products), oil, and meal, despite the known presence of allergens.

The genetic modification in soybean MON 87705 x MON 87708 x MON 89788 does not impact any production or manufacturing processes currently used for soybean. The scope of the application is for the authorisation for import, processing, and food and feed use of soybean MON 87705 x MON 87708 x MON 89788. The application does not cover cultivation and therefore no soybean MON 87705 x MON 87708 x MON 89788 will be grown in the UK.

This safety assessment represents the opinion of the FSA and FSS.

2. Details of other regulator's opinion

2.1. Molecular characterisation

Soybean MON 87705 x MON 87708 x MON 89788 was obtained by conventional crossing of the GM soybean plants containing single events MON 87705, MON 87708 and MON 89788, and no vector has been used to produce this soybean. The structure of the inserts introduced into three-event stack soybean are described in previous EFSA assessments (Table 1) and no new genetic modifications were involved.

The three events in soybean MON 87705 x MON 87708 x MON 89788, the resultant proteins produced, and the traits conferred are as follows:

- MON 87705 was developed to selectively down-regulate two key enzymes, FATB and FAD2, involved in the soybean seed fatty acid biosynthetic pathway. This was accomplished through *Agrobacterium*-mediated transformation of soybean meristem tissue. The assembled gene transcript has an inverted repeat that produces double stranded RNA (dsRNA) that, via RNA-based suppression, suppresses endogenous *FATB* and *FAD2* genes, thereby producing the desired fatty acid phenotype of decreased saturated (16:0 palmitic acid and 18:0 stearic acid), increased oleic and decreased linoleic fatty acid composition in the oil. As a result, the fatty acid levels in MON 87705 soybean oil are lower for saturated fats and higher for oleic acid. The increase in monounsaturated fatty acid (oleic) in MON 87705 is accompanied by an overall

decrease in polyunsaturated fatty acids (PUFAs). MON 87705 also contains the 5-enolpyruvylshikimate-3-phosphate synthase gene derived from *Agrobacterium* sp. strain CP4 (*cp4 epsps*), which encodes the CP4 EPSPS protein, which was used as a selection marker.

- MON 87708, developed through *Agrobacterium*-mediated transformation of soybean tissues, contains a gene derived from *Stenotrophomonas maltophilia* that expresses DMO, a mono-oxygenase enzyme that rapidly demethylates dicamba (3,6-dichloro-2-methoxybenzoic acid), rendering it inactive, thereby conferring tolerance to dicamba.
- MON 89788, also developed through *Agrobacterium*-mediated transformation of soybean tissues, contains a gene derived from *Agrobacterium* sp. strain CP4 (*cp4 epsps*) that expresses CP4 EPSPS protein conferring tolerance to glyphosate.

The use of soybean MON 87705 x MON 87708 x MON 89788 will enable growers to utilise both dicamba and glyphosate for effective control of weeds.

The applicant demonstrated that the genetic insertions in soybean MON 87705 x MON 87708 x MON 89788 were intact and equivalent to that of the individual events present in the single event GM lines, through Polymerase chain reaction (PCR) and sequence analysis. Updated bioinformatics analyses on the open reading frames (ORFs) and newly expressed proteins in soybean MON 87705 x MON 87708 x MON 89788 provided by the applicant raised no safety concerns.

The applicant determined CP4 EPSPS and DMO protein levels for the three-event stack and the corresponding single events in different parts of the plant (leaves, roots, forage, seeds) harvested from field trials at five locations in Argentina in 2013–2014, and treated with dicamba and glyphosate, using Enzyme-linked immunosorbent assays (ELISA).

The levels of the DMO protein in the three-event stack soybean and the corresponding single soybean event MON 87708 were similar in all tissues. Differences in CP4 EPSPS protein levels were expected because of the combination of soybean events MON 87705 and MON 89788 both producing CP4 EPSPS in the three-event stack soybean. The expression levels of the transgenic proteins were determined by the applicant using suitable methodologies, and no biologically relevant changes in protein expression were observed between soybean MON 87705 x MON 87708 x MON 89788 and the single event soybean lines.

The FSA/FSS agree with EFSA Scientific Opinion that the applicant demonstrated that the single events within soybean MON 87705 x MON 87708 x MON 89788 are equivalent to those already assessed by EFSA while the UK was an EU Member State and remain applicable to the UK.

2.2. Comparative analysis

All individual events in the three-event stack soybean were previously assessed, whereby equivalence with conventional counterpart and non-GM reference varieties was demonstrated for all single events.

In addition to the information already available, the applicant provided a comparative assessment of the three-event stack soybean. The GM soybean was equivalent to the conventional counterpart and to reference varieties for its agronomic characteristics and composition.

For agronomic and compositional analysis, 8 sites in Argentina were tested by the applicant during 2013 and 2014. Each field trial site utilised a randomised complete block design with four blocks, each containing: 1) soybean MON 87705 x MON 87708 x MON 89788 treated with conventional herbicides management regimes; 2) a non-GM comparator (soybean A3525) treated with conventional herbicides management regimes; 3) four non-GM soybean reference varieties (hereafter 'non–GM reference varieties'), treated with conventional herbicides management regimes; 4) soybean MON 87705 x MON 87708 x MON 89788 treated with the intended glyphosate and dicamba containing herbicides in addition to the conventional herbicides.

The FSA/FSS agree with EFSA that the field trials, and the materials used in the field trials, are appropriate for the comparative assessment. The geographical locations, soil conditions, meteorological conditions, and management practices used were all considered typical of the receiving environments where the three-event stack soybean could be grown.

The FSA/FSS agree with EFSA that no differences between the three-event stack soybean and the conventional counterpart or the non-GM reference varieties that would raise safety concerns were observed.

The applicant assessed 9 agronomic and phenotypic endpoints, as well as abiotic stressors, diseases, and pest damage. The applicant observed significant differences between the three-event stack soybean treated with conventional herbicides (days to 50% flowering, seed moisture, 100 seed weight and yield) and the non-GM comparator. Significant differences were observed also between the three-event stack soybean treated with intended herbicides (early stand count, days to 50% flowering, pod shattering, final stand count, seed moisture and 100 seed weight) and the

non-GM comparator. However, the applicant considers these differences not a concern because equivalence with the non-GM reference varieties was demonstrated for all these endpoints.

Seventy-four compositional constituents were analysed; however, statistical analysis was only performed on 60 of these. Statistically significant differences were observed between the three-event stack soybean not treated with the intended herbicides and the non-GM comparator for 35 endpoints (five in forage and 30 in seeds). For soybean treated with the intended herbicides, the test of difference identified statistically significant differences with the non-GM comparator for 33 endpoints (five in forage and 28 in seeds). The changes in the fatty acid profile in seeds (palmitic acid (C16:0), stearic acid (C18:0), oleic acid (C18:1), linoleic acid (C18:2), arachidic acid (C20:0), eicosenoic acid (C20:1), behenic acid (C22:0)) are consistent with the intended trait and further assessed in Section 2.3 (Food/feed safety assessment). In addition, compositional differences between the three-event stack soybean and the non-GM comparator were also identified for Gly m 3 and total fat and are further assessed in Section 2.3 (Food/feed safety assessment).

The FSA and FSS agreed with the EFSA Scientific Opinion, confirming that the three-event stack soybean is equivalent to the conventional counterpart and the non-GM reference varieties.

2.3. Food/feed safety assessment

As the three-event stack soybean will undergo established production processes used for conventional soybean, and considering the outcome of the comparative assessment, processing of the three-event stack soybean into food and feed products is not expected to result in products being different from those of conventional non-GM soybean varieties, except for the intended changes in fatty acid composition and the newly expressed proteins DMO and CP4 EPSPS.

Additional information was provided by the applicant on the fatty acid composition of refined bleached deodorised (RBD) oil extracted from the seeds of the three-event stack soybean, one of the processed commodities, which shows a relatively high content in oleic acid and the relatively low content in linoleic acid. This product results in an oil with higher oxidative stability than the conventional soybean oil, more similar to other types of vegetable oil (e.g. olive oil) than conventional soybean. Therefore, the production of this speciality RBD oil (as described for the single and the double stack, Table 1) is expected to be kept separated from the production of oil from conventional soybean varieties. Moreover, the use of this RBD oil in many different food products (shortenings, bakery,

deep frying) will do without undergoing partial hydrogenation, a process used to stabilise fats but known to be linked to a rise in trans-fatty acids and therefore the risk of coronary heart disease (EFSA NDA Panel, 2010).

The effects of temperature and pH on proteins CP4 EPSPS and DMO newly expressed in this three-event stack soybean have been previously evaluated by the GMO Panel (Table 1).

2.3.1. Toxicological assessment

The dsRNAs produced by the FAD2-1A/FATB1-A suppression cassette and its deriving siRNAs, the interaction between the newly expressed proteins, and *in vitro* protein degradation studies on CP4 EPSPS and DMO proteins have been previously evaluated and assessed by the GMO Panel (EFSA GMO Panel, 2015b, 2015a) in the context of the single soybean events and of the two-event stack soybean MON 87705 x MON 89788 and MON 87708 x MON 89788 (Table 1), and no safety concerns were identified for humans and animals.

For this reason, the EFSA considered that no toxicological studies are necessary on these constituents.

EFSA considered the available literature and the biological characteristics and functions of those compounds (fatty acids (palmitic acid (C16:0), stearic acid (C18:0), oleic acid (C18:1), linoleic acid (C18:2), arachidic acid (C20:0), eicosenoic acid (C20:1), behenic acid (C22:0)), total fat and Gly m 3) whose levels in seeds of MON 87705 x MON 87708 x MON 89788 soybean were significantly different as compared to its conventional counterpart. This information, along with the outcome of the molecular characterisation assessment, comparative analysis and toxicological assessment, allowed it to conclude that these compounds do not raise toxicological concerns. Therefore, animal studies on food/feed derived from the three-event stack soybean are not necessary.

In accordance with Regulation (EU) No 503/2013, the applicant provided a 90-day oral repeated-dose toxicity study in rats on whole food and feed from each of the single soybean events MON 87705, MON 87708 and MON 89788. The three studies had already been provided in the context of the single-event applications and assessed by EFSA; no adverse effects related to the administration of the respective GM diets had been identified (Table 1).

Additional requested information was provided by the applicant on MON 87708 and MON 89788, which were previously assessed by EFSA in the context of another application under Regulation (EU) 503/2013. This information supported the conclusion that there are no indications of

adverse effects related to the 90-day administration to rats of diets including defatted toasted meal from soybean MON 87708 and MON 89788 (EFSA GMO Panel, 2019a, 2019b).

Following a request from EFSA, the applicant provided a further 90-day feeding study on GM soybean MON 87705 (Statement complementing the EFSA Scientific Opinion, 2024) to address deficiencies identified from the previous EFSA scientific opinion issued in 2020. EFSA concluded that the 90-day feeding study on GM soybean MON 87705 is in line with the requirements of Regulation (EU) No 503/2013 and that no treatment-related adverse effects were observed in rats after feeding diets containing soybean MON 87705 meals at 30% or 15% for 90 days.

The FSA and FSS agreed with the EFSA Scientific Opinion and the Statement complementing the EFSA Scientific Opinion, confirming that the three-event stack soybean does not show any toxicological concern for animal and human health.

2.3.2. Allergenicity assessment

A weight-of-evidence approach was also used by the applicant to determine any potential allergenicity. EFSA previously evaluated the safety of CP4 EPSPS and DMO proteins individually, and no concerns on allergenicity were identified in the context of the applications assessed (Table 1). In addition, no information available on the structure or function of the newly expressed CP4 EPSPS and/or DMO proteins would suggest an adjuvant effect of these proteins in the three-event stack soybean.

An assessment provided by the applicant of the newly expressed proteins with respect to coeliac disease also found no indications of safety concerns.

Considering that soybean is a common allergenic food, the applicant included in the comparative analysis specific allergens relevant for soybean measured by specific ELISA methods. The applicant also referred to the Kunitz trypsin inhibitor as a potential soybean allergen, and anti-nutrient. Allergen Gly m 3 levels in soybean MON 87705 x MON 87708 x MON 89788 (treated) were significantly different from those of the non-GM comparator and fell under equivalence category III. EFSA considered that the difference consists of a decrease and for this reason there is no evidence that the genetic modification can cause additional allergenicity concerns.

The FSA and FSS agreed with the EFSA Scientific Opinion, confirming that the three-event stack soybean does not substantially change the overall allergenicity of the three-event stack soybean when compared with that of the non-GM comparator and the non-GM reference varieties tested.

2.3.3. Exposure assessment

The human and animal dietary exposure to CP4 EPSPS and DMO proteins were also estimated by the applicant based on the three-event stack soybean treated with the intended herbicides, the current available consumption data and feed practices, the foods and feeds currently available on the market and the described processing conditions. Human and animal dietary exposure assessment to the dsRNAs and the deriving siRNAs was not conducted because dsRNAs and deriving siRNAs are considered generally not to exert any biological effects once ingested by humans and animals. The main commodity expected to be derived from this three-event stack soybean for human consumption is oil, which was excluded from the assessment since proteins are not expected to be present in it. Consumption figures were evaluated for the relevant commodities (soya bean flour, soya bread, textured soy protein, soya drink, soya-based infant formula, soya-based follow-on formula, tofu etc.). Most relevant food commodities in terms of contribution to the exposure were soya drink and meat imitates (textured soy protein). An ad hoc dietary exposure scenario was carried out considering the consumption of protein-based supplements ('Protein and amino acids supplements' and 'Protein and protein components for sports people'). Consumption data on 'Pollen supplements' might occur but since no data on the presence of newly expressed proteins in pollen were available, dietary exposure from this source was not estimated.

Animal exposure to CP4 EPSPS and DMO proteins was estimated in various animal species using a worst-case scenario with 100% replacement of conventional soybean products by the three-event stack soybean products. EFSA evaluated the human and animal dietary exposure to CP4 EPSPS and DMO proteins and found no safety concerns.

The FSA and FSS agreed with the EFSA Scientific Opinion, confirming that human and animal exposure to the three-event stack soybean does not show any safety concerns for animal and human health.

2.3.4. Nutritional assessment

The levels of all saturated fatty acids (palmitic acid, stearic acid, arachidic acid and behenic acid) decreased in the three-event stack soybean as compared to the non-GM comparator, in particular palmitic acid; this is in line with current nutritional recommendations for saturated fatty acids (EFSA NDA Panel, 2010).

The small decrease in total fat content is not considered nutritionally relevant and was not further assessed by the applicant.

The increase in the levels of two monounsaturated fatty acids (oleic acid and eicosenoic acid), particularly evident for oleic acid, which constitutes the most abundant fatty acid in the RBD oil produced from the three-event stack soybean, do not raise nutritional concerns since these fatty acids are synthesised by the body (EFSA NDA Panel, 2010).

Because the concentration of linoleic acid in RBD oil produced from the three-event stack soybean seeds was lower when compared to the non-GM comparator, dietary intake estimations were considered necessary to assess the effect of introducing RBD oil produced from the three-event stack soybean in the diet. Indeed, linoleic acid is an essential fatty acid required to maintain metabolic integrity and it cannot be synthesised by the body. EFSA concluded that the contribution of other soybean processed products to the total intake of fatty acids is considered minor as compared to that of RBD oil and is not expected to affect the outcome of the nutritional assessment. In addition, EFSA concluded that the consumption of the three-event stack soybean does not represent a nutritional concern in humans, in the context of the scope of this application.

The main soybean products entering the feed supply chain are seeds, meal and oil; the use of unprocessed soybean seeds for animal feed is limited due to the presence of antinutritional factors, inactivated by adequate heat processing. EFSA considers that the consumption of defatted soybean products from the three-event stack soybean does not represent a nutritional concern for animals.

The FSA and FSS agreed with the EFSA Scientific Opinion, confirming the three-event stack soybean is not nutritionally disadvantageous for animal and human health.

2.3.5. Conclusions on the food/feed assessment

EFSA concluded that the newly expressed proteins CP4 EPSPS and DMO and the dsRNAs and their deriving siRNAs present in soybean MON 87705 x MON 87708 x MON 89788 do not raise safety concerns for human and animal health.

Bioinformatics analyses of the sequences of newly expressed proteins found no evidence of potential toxicity or allergenicity concerns, and the stability of the proteins to temperature, pH, and *in vitro* digestion did not raise safety concerns.

EFSA evaluated the human and animal dietary exposure to the three-event stack soybean, and found no safety concerns. The comparative assessment confirmed that the only difference between the three-event stack soybean

and the conventional counterpart was Gly m 3 and total fat, which do not represent a safety, or nutritional, concern. The change in the fatty acid profile is consistent with the intended trait.

EFSA concluded that the three-event stack soybean does not show any toxicological concern for animal and human health.

The FSA/FSS agree with all the conclusions of EFSA which are applicable to GB, and confirm that soybean MON 87705 x MON 87708 x MON 89788 does not raise any safety concerns in terms of human and animal health.

2.4. Environmental risk assessment

As the application does not cover cultivation, EFSA's environmental risk assessment focussed on the accidental release of the three-event stack soybean into the environment, and exposure of micro-organisms to recombinant DNA from the three-event stack soybean. The establishment and survival of volunteer soybean plants in the EU is limited and transient, and it is unlikely that the traits inserted into the three-event stack soybean will affect the ability of the soybean plants to survive. In addition, there is no evidence that the genetic modifications made to the three-event stack soybean increase the likelihood of horizontal gene transfer to micro-organisms in the environment. Therefore, EFSA concluded that it is unlikely that the three-event stack soybean would differ from conventional soybean in its ability to persist under European conditions.

Following a request from EFSA, the applicant provided a proposal for post-market monitoring (PMM) to address the deficiencies identified as inconclusive in the EFSA scientific opinion issued in 2020. The FSA and FSS agree with the EFSA Scientific Opinion, concluding that the proposal provided by the applicant is in line with the recommendations described for the PMM plan of three-event stack soybean in the adopted scientific opinion.

3. Other regulator's opinion and conclusions

The EFSA GMO Panel concluded that taking into account the previous assessment and the new information, the three-event stack soybean, as assessed in the scientific opinion on application EFSA-GMO- NL-2015-126 and in the supplementary toxicity study, is as safe as its non-GM comparator and the non-GM reference varieties tested and does not represent a nutritional concern in humans and animals, within the scope of this application.

4. Uncertainties and limitations

No specific uncertainties or limitations were flagged in the assessment by EFSA. The FSA and FSS did not identify further uncertainties or limitations to be considered for this assessment.

5. FSA & FSS conclusions for GB assessment

The FSA and FSS assessed the EFSA opinion (EFSA, 2020) and the Statement complementing the EFSA Opinion (EFSA, 2024) for soybean MON 87705 x MON 87708 x MON 89788 and confirmed that this is adequate and relevant for GB risk analysis. The conclusions of the EFSA opinion, and the Statement complementing the EFSA Opinion, have been reviewed in detail by the FSA and FSS and, are considered appropriate and consistent, including the uncertainties and limitations identified in the opinion which are applicable to GB. Sufficient evidence has been demonstrated to conclude without further questions or risk assessment.

The FSA and FSS, after reviewing the proposal provided by the applicant for post-market monitoring (PMM) in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013, agree with EFSA that this is in line with the recommendations described for the PMM plan of soybean MON 87705 x MON 87708 x MON 89788 in the adopted scientific opinion.

The environmental risk assessment of soybean MON 87705 x MON 87708 x MON 89788 is within the remit of Advisory Committee on Releases to the Environment (ACRE), and their assessment will form part of the final scientific assessment published by the FSA/FSS.

ACRE concluded that soybean MON 87705 x MON 87708 x MON 89788 would not raise safety concerns in the event of accidental release of viable seeds or propagating material into the environment.

ACRE's advice is available at the following link:

ACRE advice: applications to market GM soybeans and maize - GOV.UK (www.gov.uk)

6. Outcome of the assessment

The FSA and FSS have reviewed the applicant's dossier, supporting documentation, and most notably the EFSA Opinion (EFSA-GMO-NL-2015-126) and the Statement complementing the EFSA Opinion (EFSA, 2024), and consider that there is sufficient evidence to conclude the assessment of soybean MON 87705 x MON 87708 x MON 89788 without obtaining further information or conducting a further risk assessment.

The FSA and FSS conclude that genetically modified soybean MON 87705 x MON 87708 x MON 89788 is as safe as its non-GM conventional comparator with respect to its potential effects on human and animal health, and the environment.

In making this assessment, the FSA and FSS were able to rely on sufficient scientific evidence provided by the EFSA Opinion and by the applicant, to make a conclusion on safety with no further questions to the applicant, and therefore no further risk assessment activities are necessary.

The applicant provided sufficient relevant information as requested by the FSA and FSS.

The FSA and FSS review did not find any issues of divergence from the EFSA guidance (EFSA NDA Panel, 2016), or mutual approaches or new scientific issues for consideration.

The FSA and FSS, after reviewing the proposal provided by the applicant for post-market monitoring (PMM) in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013, agree with EFSA that this is in line with the recommendations described for the PMM plan of soybean MON 87705 x MON 87708 x MON 89788 in the adopted scientific opinion.

There were no other specific issues that would require an assessment for the UK or the nations of the UK.

Abbreviations

Abbreviation	Definition
DMO	dicamba mono-oxygenase
ELISA	enzyme-linked immunosorbent assay
EPSPS	E 5-enolpyruvylshikimate-3-phosphate synthase
ERA	environmental risk assessment
GM	genetically modified
GMO	genetically modified organism
ORF	open reading frame
PAT	phosphinothricin acetyltransferase
PCR	polymerase chain reaction
PMM	Post-market monitoring

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