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STATEMENT

Statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-NL-2015-126) for authorisation of food and feed containing, consisting of and produced from genetically modified soybean MON 87705 × MON 87708 × MON 89788

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Abstract

Following a request from the European Commission, the GMO Panel assessed additional information related to the application for authorisation of food and feed containing, consisting of and produced from genetically modified soybean MON × MON 87708 × MON 89788 (EFSA-GMO-NL-2015-126). The applicant conducted a 90-day feeding study on GM soybean MON 87705 and provided a proposal for post-market monitoring considering the altered fatty acid profile of GM soybean MON 87705 × MON 87708 × MON 89788, to fulfil the deficiencies identified by EFSA GMO Panel, addressing elements that remained inconclusive from a previous EFSA scientific opinion issued in 2020. The GMO Panel concludes 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 GMO Panel reiterates the recommendation for a PMM for food in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013 and concludes that the proposal provided by the applicant is in line with the recommendations described for the PMM plan of soybean MON 87705 × MON 87708 × MON 89788 in the adopted scientific opinion. Taking into account the previous assessment and the new information, the GMO Panel concludes that soybean MON 87705 × MON 87708 × MON 89788, 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.

KEYWORDS

90-day feeding study, GMO, MON 87705, MON 87705 × MON 87708 × MON 89788, post-market monitoring (PMM), soybean (Glycine max)

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SUMMARY

On 2 April 2020, the GMO Panel adopted a scientific opinion on application EFSA-GMO-NL-2015-126 for the placing on the market of soybean MON 87705 × MON 87708 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003.[1] In the context of this application, the applicant did not provide a 90-day feeding study on soybean MON 87705 in line with the applicable legal requirements (i.e. no treatment with the intended herbicide was applied to MON 87705 soybean used to produce the test material). Furthermore, considering the altered fatty acid profile of soybean MON 87705 × MON 87708 × MON 89788, the applicant did not provide a proposal for a post-market monitoring (PMM) in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013.[2] Therefore, the GMO Panel was not in the position to finalise the risk assessment of soybean MON 87705 × MON 87708 × MON 89788 under the current regulatory frame.

On 10 April 2024, the European Commission requested the GMO Panel to complement its original scientific opinion on application EFSA-GMO-NL-2015-126 for placing on the market soybean MON 87705 × MON 87708 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/20031, taking into consideration new additional information provided by the applicant. This new information consisted of a 90-day feeding study on soybean MON 87705 and a proposal for a post-market monitoring (PMM).

The GMO Panel assessed the supplementary 90-day feeding study in rats on soybean MON 87705. The study was conducted in accordance with OECD TG 407 and with the principles of Good Laboratory Practice. No adverse effects were observed in this study. Taking into account the previous assessment and the new information, the GMO Panel concludes that soybean MON 87705 × MON 87708 × MON 89788, as assessed in the scientific opinion on application EFSA-GMO-NL-2015-126 (EFSA GMO Panel, 2020) 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 the application.

The GMO Panel reiterates the recommendation for a PMM for food in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013 and concludes that the proposal provided by the applicant is in line with the recommendations described for the PMM plan of soybean MON 87705 × MON 87708 × MON 89788 in the adopted scientific opinion.

[1]Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

[2]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. OJ L157, 8.6.2013, p. 1–48.

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1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

On 2 April 2020, the GMO Panel adopted a scientific opinion on application EFSA-GMO-NL-2015-126 for the placing on the market of soybean MON 87705 × MON 87708 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. In the context of this application, the applicant did not provide a 90-day feeding study on soybean MON 87705 in line with the applicable legal requirements (i.e. no treatment with the intended herbicide was applied to MON 87705 soybean used to produce the test material). Furthermore, considering the altered fatty acid profile of soybean MON 87705 × MON 87708 × MON 89788, the applicant did not provide a proposal for a post-market monitoring (PMM) in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013. Therefore, the GMO Panel was not in the position to finalise the risk assessment soybean MON 87705 × MON 87708 × MON 89788 under the current regulatory frame.

On 10 April 2024, the European Commission asked EFSA to complement the inconclusive scientific opinion (EFSA GMO Panel, 2020) on application EFSA-GMO-NL-2015-126 for placing on the market soybean MON 87705 × MON 87708 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/20031, taking into consideration new additional information provided by the applicant, consisting of a 90-day feeding study in rodents with whole GM food and feed from GM soybean MON 87705, and a proposal for a post-market monitoring (PMM), provided by the applicant to EC on 20 March 2024.

On 31 May 2024, EFSA asked the applicant clarifications on the confidentiality requests and to provide additional data on the 90-day feeding study. The applicant delivered to EFSA the requested Additional Information on 12 July 2024.

In the frame of contract EOI/EFSA/2022/01 - CT NIF 2023 02, the contractor performed preparatory work and delivered a report on the statistical analysis of the 90-day feeding study in rodents on soybean MON 87705.

This statement reports the GMO Panel assessment of the 90-day feeding study in rodents with whole GM food and feed from GM soybean MON 87705 and a proposal for a post-market monitoring (PMM).

2 | DATA AND METHODOLOGIES

2.1 | Data

In delivering this statement, the GMO Panel took into account the supplementary 90-day feeding study in rodents on soybean MON 87705 provided by the applicant in the context of this mandate, the proposal for a post-market monitoring (PMM) plan and the EFSA scientific opinion on application EFSA-GMO-NL-2015-126 (EFSA GMO Panel, 2020).

2.2 | Methodologies

The GMO Panel carried out a scientific risk assessment of this supplementary toxicity study taking into account the principles described in Regulation (EU) No 503/2013 and its guideline for the risk assessment of genetically modified (GM) plants and derived food and feed (EFSA GMO Panel, 2011).

3 | ASSESSMENT

3.1 | 90-day feeding study

In this study, provided in the context of the current mandate, pair-housed Sprague Dawley Crl:CD(SD) rats (16 per sex per group; 2 rats per cage) were allocated to three groups using a randomised complete block design with 8 replications per sex.

Groups were fed diets containing soybean MON 87705 meal from plants treated with the intended herbicide (glyphosate) at 30% and 15% of inclusion level (the latter supplemented with 15% of the non-GM comparator) and the non-GM comparator (inclusion level 30%).

The study was adapted from OECD test guideline 408 (2018), aligned with EFSA Scientific Committee guidance (EFSA Scientific Committee, 2011) and EFSA Explanatory statement (EFSA, 2014) and complied with the principles of good laboratory practice (GLP) with some minor deviations described in the study report, not impacting the study results and interpretation.

The stability of the test and control materials was not verified; however, in accordance to product expiration declared by the diet manufacturer, the constituents of the diets are considered stable for the duration of the treatment. The GMO Panel considered this justification acceptable. Diet preparation procedures and regular evaluations of the mixing methods guaranteed the homogeneity and the proper concentration of the test or control substances in them.

Event-specific PCR analysis confirmed the presence of the MON 87705 in both the GM grains and diets and excluded the presence of the event in the respective controls. Both the GM and control meals and diets were analysed for nutrients, antinutrients and potential contaminants. Balanced diets were formulated based on the specifications for LabDiet® Certified Rodent Diet 5002. Feed and water were provided ad libitum. In-life procedures and observations and terminal procedures were conducted in accordance to OECD test guideline 408 (2018).

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An appropriate range of statistical tests were performed on the results of the study. Detailed description of the methodology and of statistically significant findings identified in rats given diets containing meals derived from soybean MON 87705 is reported in Appendix A.

There were no test diet-related incidents of mortality or clinical signs. No test diet-related adverse findings were identified in any of the investigated parameters. A small number of statistically significant findings were noted but these were not considered adverse effects of treatment for one or more of the following reasons:

- were within the normal variation[3] for the parameter in rats of this age;
- were of small magnitude;
- were identified at only a small number of time intervals with no impact on the overall value;
- exhibited no consistent pattern with related parameters or endpoints.
- exhibited no consistency with increasing incorporation levels.

No gross pathology findings related to the administration of the test diet were observed at necropsy, and the microscopic examinations of a wide range of organs and tissues did not identify relevant differences in the incidence or severity of the histopathological findings related to the administration of the test diet compared to the control group.

The GMO Panel concludes that this study 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.

3.2 | Post-market monitoring on the genetically modified food or feed

The three-event stack soybean MON 87705 × MON 87708 × MON 89788 was produced by conventional crossing to combine three single soybean events: MON 87705 (producing dsRNAs downregulating endogenous FAD2 and FATB enzymes, and expressing the CP4 EPSPS protein), MON 87708 (expressing the DMO protein) and MON 89788 (expressing the CP4 EPSPS protein). This combination is intended to confer an altered fatty acid profile (increased oleic acid content), and tolerance to dicamba and to glyphosate containing herbicides. During the pre-market risk assessment of soybean MON 87705 × MON 87708 × MON 89788, the compositional analysis in seeds showed that 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) and total fat were significantly different as compared to the non-GM comparator, and showed a lack of equivalence with the set of non-GM reference varieties (EFSA GMO Panel, 2020).

Post-market monitoring for food

The nutritional assessment in humans was focused on the refined bleached deodorised oil (RBD oil) as this is the main fat-containing processed product from soybean for human consumption, and also the most relevant considering the outcome of the compositional analysis. As previously identified during the nutritional assessment of the corresponding single event MON 87705 and the two-event stack MON 87705 × MON 89788, the main nutritionally aspect linked to the consumption of the RBD oil produced from soybean MON 87705 × MON 87708 × MON 89788 (GM oil) refers to its linoleic acid content. The concentration of linoleic acid is more than three-fold lower in the three-event stack soybean seeds as compared to the non-GM comparator (EFSA GMO Panel, 2020). At the time of the pre-market risk assessment, dietary intake estimations were considered to assess the nutritional relevance of the low levels of linoleic acid in the GM oil. In the absence of real consumption data on the GM oil, different assumptions of consumption were made as part of replacement scenarios of conventional foods. Based on these assumptions, the GMO Panel concluded that the consumption of soybean MON 87705 × MON 87708 × MON 89788 does not represent a nutritional concern in humans (EFSA GMO Panel, 2020).

Notwithstanding the safety of the three-event stack soybean, the GMO Panel also recommended that the applicant should provide a proposal for post-market monitoring (PMM) with the aim to confirm the expected consumption, the application of conditions of use or identified effects, in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013 (EFSA GMO Panel, 2020). This post-market monitoring should be initially focused on the collection of import data to Europe of the three-event stack soybean and/or its products, in particular RBD oil. Following the identification of imports, an updated nutritional assessment should be conducted in the case the available information on consumption (e.g. new dietary surveys, data from FAOSTAT database on amounts and type of vegetable oils consumed) differs from that used during the risk assessment of the EFSA GMO Panel in 2020. Likewise, the applicant should collect and provide any scientific information that might change the conclusions of the pre-market nutritional assessment (EFSA GMO Panel, 2020).

[3]Although animals used in a toxicology study are of the same strain, from the same supplier and are closely matched for age and body weight at the start of the study, they exhibit a degree of variability in the parameters investigated during the study. This variability is evident even within control groups. To help reach a conclusion on whether a statistically significant finding in a test group is treatment-related, account is taken of whether the result in the test group is outside the normal range for untreated animals of the same strain and age. To do this, a number of sources of information are considered, including the standardised effect size, the standard deviations and range of values within test and control groups in the study and, if applicable, data from other studies performed in the same test facility within a small timeframe and under almost identical conditions (Historic Control Data).

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In the additional information provided, the applicant communicated that as authorisation holder they will collaborate with third parties, such as farmers, crushers and all exporters involved in the production and trade of GM soybean products for crushing into oil, to collect information on the quantities of soybean oil and soybean for oil extraction from these GM soybean products, imported in the EU for the placing on the market as or in products for food. The applicant also mentioned that they will monitor significant changes in EU imports of relevant oils considered during the assessment, and based on the information collected and reported, review the nutritional assessment conducted as part of the pre-market risk assessment. The applicant provided information to further confirm the conclusions reported at the time of the adoption that soybean MON 87705 × MON 87708 × MON 89788 does not represent a nutritional concern in humans.

The GMO Panel reiterates the recommendation for a PMM in food in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013 and concludes that the proposal provided by the applicant is in line with the recommendations described for the PMM plan of soybean MON 87705 × MON 87708 × MON 89788 in the adopted scientific opinion (EFSA GMO Panel, 2020).

Post-market monitoring for feed

The nutritional assessment in animals considered both the primary soybean products entering the feed supply chain, such as meal and oil, as well as other soybean products that might be included in animal diets, such as soybean forage, hulls and protein concentrates.

In the absence of compositional differences between the three-event stack soybean and its non-GM comparator and the non-GM reference varieties tested, other than those regarding fatty acids levels in seeds as reported in the EFSA GMO Panel opinion (2020), the GMO Panel considered that the consumption of defatted soybean products from this soybean MON 87705 × MON 87708 × MON 89788 does not represent a nutritional concern for animals.

For full-fat soybean and oil of the three-event stack soybean, a nutritional assessment was conducted considering the altered fatty acid profile. The GMO Panel concluded that consumption of the three-event stack soybean products does not represent a nutritional concern for animals, in the context of the scope of the application (EFSA GMO Panel, 2020).

The GMO Panel notes that fatty acid composition is properly balanced in rations to satisfy nutrient requirements of animals (EFSA GMO Panel, 2020).

In conclusion, the GMO Panel reiterates that, based on the information considered in its safety assessment, a post- market monitoring plan for feed is not necessary.

4 | CONCLUSIONS

The 90-day feeding study in rodents on soybean MON 87705 provided by the applicant in the context of this mandate was assessed by the GMO Panel and did not show adverse effects.

Taking into account the previous assessment and the new information, the GMO Panel concludes that soybean MON 87705 × MON 87708 × MON 89788, as assessed in the scientific opinion on application EFSA-GMO-NL-2015-126 (EFSA GMO Panel, 2020) 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.

The GMO Panel reiterates the recommendation for a PMM for food in accordance with Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013 and concludes that the proposal provided by the applicant is in line with the recommendations described for the PMM plan of soybean MON 87705 × MON 87708 × MON 89788 in the adopted scientific opinion.

5 | DOCUMENTATION AS PROVIDED TO EFSA

- Mandate from the European Commission (EC) received on 10 April 2024 requesting EFSA to assess the additional information related to the application for authorisation of food and feed containing, consisting of and produced from GM soybean MON 87705 × MON 87708 × MON89877 (EFSA-GMO-NL-2015-126) submitted under Regulation (EC) NO 1829/2003 by Bayer Agriculture BV.
- The mandate was accepted on 30 April 20204.
- Additional information (Clock 1) was requested on 31 May 2024.
- Additional information (Clock 1) was received on 12 July 2024.

ABBREVIATIONS

ALP	alkaline phosphatase
ALT	alanine transaminase
BUN	blood urea nitrogen
bw	body weight
CI	confidence interval
DMO	dicamba mono-oxygenase
EPSPS	5-enolpyruvulshikimate-3-phosphate synthase

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FAOSTAT	Food and Agriculture Organization Corporate Statistical Database
GLP	good laboratory practice
GM	genetically modified
GMO	Genetically Modified Organism
GMO	Panel EFSA Panel on Genetically Modified Organisms
HDL	high-density lipoproteins
LDL	low-density lipoproteins
LMMs	linear mixed models
LS	least-square
OECD	Organisation for Economic Co-operation and Development
PCR	polymerase chain reaction
PMM	post-market monitoring
RBD	refined bleached deodorised
SD	Sprague Dawley
SE	standard error
SES	standardised effect sizes
TSH	thyroid stimulating hormone

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REQUESTOR

European Commission

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APPENDIX A

Statistical analysis and statistically significant findings in the 90-day feeding study on soybean MON 87705 in rats

The following endpoints were statistically analysed: food consumption, body weights, cumulative body weight changes, clinical pathology values (haematology, coagulation, clinical chemistry and urinalysis), absolute and relative organ weights, functional observational battery, locomotor activity and histopathological data. Summary statistics, including sample mean, standard deviation, median, minimum and maximum, difference, standardised difference, 95% confidence intervals (CI) and standardised 95% CI were provided for each dose group, sex, variable and period. Data were also presented in terms of the standardised effect sizes (SES). The main statistical analysis compared rats across the experimental groups, distinguishing between those on the test diets (low and high test substance MON 87705, respectively) and those on the control diet. Linear mixed models (LMMs) were employed to analyse continuous data for each variable and period, followed by pairwise comparisons between each test and control diet group (separately for each sex and period, if necessary) using a t-test (at the 5% level of significance). Note that only when the interaction of the 'dose group per sex' (*F*-test) was significant (at the 5% level of significance), the comparison of the treated (low and high diets) versus the control group was conducted separately for the two sexes. For those where no significant interaction existed, pairwise comparisons between each test and control dose groups across sexes were tested using t-tests. For each LMM, the full output, including the visual examination of residual plots and histograms, the estimated means and standard errors for each fixed effect (i.e. Least-squares (LS) means and standard errors (SE) and degrees of freedom of each fixed effect), and the variance components for the random terms in each mixed model is provided. Concerning missing data, a summary was provided for each endpoint and no systematic trends were observed that might bias the results (Table A.1).

TABLE A.1 Statistically significant findings in the 90- day toxicity study on soybean MON 87705 in rats.

Statistically significant parameter/endpoint	Finding (versus control)	GMO panel interpretation
Food consumption (week 6–7)	Increased (25%) in low dose animals (sexes combined)	Transient with no impact on overall body weight. Not seen at the high dose. Not an adverse effect of treatment
Basophil count	Reduced (20%) in low dose animals (sexes combined)	Not seen at the high dose. All values within control range. Not an adverse effect of treatment
Eosinophil count	Reduced (25%) in low and high dose animals (sexes combined)	No dose response. All high dose values within control range. Not an adverse effect of treatment
Neutrophil count	Reduced (15%) in high dose animals (sexes combined)	Low magnitude. All values within control range. Not an adverse effect of treatment
Erythrocyte count, haematocrit and haemoglobin	Increased 2%–5% in low dose animals (sexes combined)	Low magnitude. Not seen at the high dose. Not an adverse effect of treatment
Potassium	Reduced (5%) in high dose animals (sexes combined). Increased (4%) in low dose females	Low magnitude, no pattern across dose groups. Within normal variation. Not an adverse effect of treatment
Calcium	Reduced (4%) in low dose females	Low magnitude. Not seen at the high dose. Not an adverse effect of treatment
ALT	Reduced (50%) in females of both dose groups	No dose response. Control values showed a high level of variability. No associated liver pathology findings. Not an adverse effect of treatment
HDL	Reduced (25%) in low dose females	Not seen at the high dose. Within normal variation. Not an adverse effect of treatment
ALP	Reduced (15%) in high dose animals (sexes combined)	Low magnitude. All values within control range. Not an adverse effect of treatment
Cholesterol and LDL	Reduced (18%) in low dose animals (sexes combined)	Low magnitude. Not seen at the high dose. Not an adverse effect of treatment
Chloride	Increased (1%) in low dose animals (sexes combined)	Low magnitude. Not seen at the high dose. Not an adverse effect of treatment
Creatinine	Increased (8%) in high dose animals (sexes combined)	Low magnitude. Only 3/32 animals outside control range (p822/828). No associated kidney pathology. Not an adverse effect of treatment
Glucose	Reduced (5%) in low dose animals (sexes combined)	Low magnitude. Not seen at the high dose. Not an adverse effect of treatment
BUN	Increased (12%) in low and high dose animals (sexes combined)	Low magnitude. No clear dose response. Within normal variation. No associated kidney pathology. Not an adverse effect of treatment

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TABLA.1 (Continued)

Statistically significant parameter/endpoint	Finding (versus control)	GMO panel interpretation
Urinary specific gravity	Increased (1%) in low dose males	Low magnitude. Not seen at the high dose. Not an adverse effect of treatment
Urinary creatinine	Increased (50%) in low and high dose animals (sexes combined)	No clear dose response. Within normal variation. No associated kidney pathology. Not an adverse effect of treatment
T4	Increased (20%) in high dose males and (35%) in low and high dose females	Within normal variation. No changes in T3. No associated Pathology changes
TSH	Reduced (40%) in low dose males	Not seen at high dose. All values are within control range. No impact on T4/T3 Not an adverse effect of treatment
Adrenal weights (relative to bw)	Increased (10%) in low dose animals (sexes combined)	Low magnitude. No dose response. Within normal variation. No associated pathology. Not an adverse effect of treatment

Notes: Where changes are given as percentages (e.g. reduced (30%)) this indicates the magnitude of the change relative to the control value (e.g. 30% decrease in mean body weights means a value of 70 grams in test group animals vs. 100 grams in controls).

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