TECHNICAL REPORT

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Scientific advice on the Testbiotech's requests for internal review of Commission Implementing Decisions (EU) No 2019/2083 and 2019/2084 on soybean MON 89788 and soybean A2704-12 (applications EFSA-GMO-RX-011 and EFSA-GMO-RX-009)

European Food Safety Authority (EFSA)

Abstract

Following a request of the European Commission, the European Food Safety Authority (EFSA) reviewed the scientific arguments raised by the non-governmental organisation Testbiotech against the Commission Implementing Decisions (EU) 2019/2083 and 2019/2084 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified (GM) soybean MON 89788 (application EFSA-GMO-RX-011) and soybean A2704-12 (application EFSA-GMO-RX-009). Testbiotech claims that EFSA should have requested from the applicants new field trials reflecting the different management practices and meteorological and agronomic conditions under which soybean A2704-12 and soybean MON 89788 are expected to be grown, as well as new feeding studies with whole feed and food from these GM soybeans. EFSA analysed each of the scientific arguments put forward in the technical background of Testbiotech's complaint on soybean MON 89788 and soybean A2704-12 and concludes that none reveals new information that would invalidate the previous risk assessment conclusions and risk management recommendations made by the EFSA scientific Panel on Genetically Modified organisms (GMO Panel). Therefore, EFSA considers that the previous GMO Panel risk assessment conclusions and risk management recommendations on soybean MON 89788 and soybean A2704-12 remain valid and applicable.

Key words: agronomic and phenotypic characterisation, compositional analysis, comparative analysis, food-feed safety

Requestor: European Commission

Question number: EFSA-Q-2020-00104

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Summary

Following a request of the European Commission (EC), the European Food Safety Authority (EFSA) assessed the scientific content of the technical background of Testbiotech's requests for an internal review of the Commission Implementing Decisions (EU) No 2019/2083 and 2019/2084 under Regulation (EC) No 1367/2006, authorising the placing on the market of genetically modified soybean MON 89788 (application EFSA-GMO-RX-011) and soybean A27014-12 (application EFSA-GMO-RX-009).

In this request for internal review, the Testbiotech claims that, in accordance with Regulation (EU) No 503/2013, EFSA should have requested from the applicants new field trials reflecting the different management practices and meteorological and agronomic conditions under which soybean A2704-12 and soybean MON 89788 are expected to be grown, as well as new feeding studies with whole feed and food from these GM soybeans. To justify these claims, Testbiotech refers to two recent scientific publications, i.e. Fang et al. (2018) and Miyazaki et al. (2019).

EFSA analysed each of the scientific arguments put forward in the technical background of Testbiotech's requests, including an assessment of the two scientific publications. EFSA concludes that the arguments raised by Testbiotech and the findings reported by Fang et al. (2018) and Miyazaki et al. (2019) do not reveal new information that would invalidate the previous risk assessment conclusions and risk management recommendations on soybean MON 89788 and soybean A2704-12 made by the GMO Panel. Therefore, EFSA considers that the previous GMO Panel risk assessment conclusions and risk management recommendations on these two soybean events remain valid and applicable.

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1. Introduction

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

The European Food Safety Authority scientific Panel on Genetically Modified organisms (hereafter referred to as 'GMO Panel') performed a pre-market risk assessment of soybean MON 89788[1] and soybean A2704-12,[2] in the context of applications EFSA-GMO-RX-011 and EFSA-GMO-RX-009; the scientific opinions of the GMO Panel were published on 17 October 2018 (EFSA GMO Panel, 2018) and on 29 November 2019 (EFSA GMO Panel, 2019). On 28 November 2019, the European Commission (EC) issued the Commission Implementing Decisions (EU) 2019/2083[3] and 2019/2084,[4] renewing the authorisation for the placing on the market of products containing, consisting of or produced from soybean MON 89788 and A2704-12. On 23 December 2019, the EC received from a non-governmental organisation, Testbiotech,[5] a request for internal review of these Commission Implementing Decisions, under Article 10 of Regulation (EC) No. 1367/2006.

On 15 January 2020, EFSA received a request from EC for an in-depth analysis of all scientific elements present in the technical background of the request by Testbiotech for internal review.[6]

2. Data and Methodologies

2.1. Data

In delivering this report, EFSA considered the scientific arguments put forward in the technical backgrounds of Testbiotech's request for internal review, as well as relevant data supplied in the context of applications EFSA-GMO-NL-2005-18, EFSA-GMO-NL-2006-36, EFSA-GMO-RX-009 and EFSA-GMO-RX-011 or published in the scientific literature.

2.2. Methodologies

EFSA applied the appropriate principles described in the applicable guidelines for risk assessment of genetically modified (GM) plants and derived food and feed products and other relevant documents (EFSA GMO Panel, 2015a).

3. Assessment

The EFSA assessment below focuses on the scientific elements raised by Testbiotech, while EFSA has not considered in this assessment those grounds referring to the legal framework, as they are outside EFSA's remit.

3.1. Request for new field data or new feeding studies

Testbiotech claims that, in accordance with Regulation (EU) No 503/2013,[7] EFSA should have requested from the applicants new field trials reflecting the different management practices and meteorological and agronomic conditions under which soybean A2704-12 and soybean MON 89788 are expected to be grown, as well as new feeding studies with whole feed and food from these GM soybeans. To justify these claims, Testbiotech refers to two recent scientific publications, i.e. Fang et al. (2018) and Miyazaki et al. (2019).

EFSA's clarifications and replies to the points raised in the technical background of Testbiotech's complaints are given below, including an assessment of the publications by Fang et al. (2018) and Miyazaki et al. (2019).

[1] Soybean MON 89788 is tolerant to glyphosate-containing herbicides by the expression of the CP4 EPSPS protein.
[2] Soybean A2704-12 is tolerant to glufosinate-containing herbicides by the expression of the phosphinothricin N-acetyltransferase (PAT) protein.
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2083&from=EN
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2084&from=EN
[5] Registered under identification number 151554816791-61 in the Transparency Register http://ec.europa.eu/transparencyregister/public/homePage.do
[6] EFSA question number EFSA-Q-2020-00104 on the EFSA Register of Questions.
[7] 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.

3.1.1. Applications for renewal of authorisation of soybean A2704-12 and soybean MON 89788

EFSA notes that the dataset submitted for renewal of authorisation of soybean A2704-12 (EFSA-GMO-RX-009) and soybean MON 89788 (EFSA-GMO-RX-011) was in accordance with the data requirements outlined in the GMO Panel guidance for renewal of applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015a).[8] This guidance requires information on the additional studies produced, controlled or sponsored by the applicant and not previously submitted to the EU, and the assessment of their relevance for molecular characterisation, human and animal safety and the environment rather than the production of new studies.

- For renewal application EFSA-GMO-RX-009, the dataset included the summary of an additional field study evaluating the agronomic characteristics of soybean A2704-12.[9]
- For renewal application EFSA-GMO-RX-011, the dataset included nine additional studies evaluating the agronomic and phenotypic or compositional characteristics of soybean MON 89788.[10]

The GMO Panel evaluated the summary and/or the full study reports of these additional studies and concluded that this new information did not raise any concern for human and animal health and the environment which would change the original risk assessment conclusions on soybean A2704-12 (EFSA GMO Panel, 2019) or soybean MON 89788 (EFSA GMO Panel, 2018a).

3.1.2. Applications for placing on the market soybean A2704-12 and soybean MON 89788: Comparative analysis and toxicological assessment of the whole GM food and feed

EFSA would like to underline that the agronomic, phenotypic and compositional characteristics as well as the safety of soybean A2704-12 and soybean MON 89788 were already assessed by the GMO Panel in the context of applications EFSA-GMO-NL-2005-18 and EFSA-GMO-NL-2006-36 (EFSA GMO Panel, 2007, 2008), respectively, in compliance with the principles described in its applicable guidance document for the risk assessment of GM plants and derived food and feed (EFSA, 2006).

Comparative analysis of soybean A2704-12 and soybean MON 89788

- For application EFSA-GMO-NL-2005-18, the applicant submitted different sets of field trials to evaluate the agronomic, phenotypic and compositional characteristics of soybean A2704-12. These studies included data from GM soybean plants treated and untreated with the

[8] The data received in the context of EFSA-GMO-RX-009 and EFSA-GMO-RX-011 contained a copy of the authorisation, annual post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses and additional documents or studies performed by or on behalf of the applicant.

[9] Study M–413199-01-1: Agronomic characteristics of glufosinate-tolerant soybean A2704-12, USA, 2006. Based on the content of the summary of the study and on the outcome of the comparative analysis of soybean A2704-12 in application EFSA-GMO-NL-2006-36 (EFSA GMO Panel, 2007), the GMO Panel considered there was no need for requesting the full report.

[10] Study MSL0020867: Phenotypic evaluation and ecological interactions of MON 89788 glyphosate tolerant soybean in U.S. field trials during 2006.
Study MSL #21149: Composition analyses of MON 89788 soybean untreated and treated with Roundup® herbicide grown in the United States in 2007.
Study MSL #21238: Compositional analyses of MON 89788 soybean seed and forage untreated and treated with Roundup herbicide grown in Puerto Rico in 2007.
Study MSL0022100: Compositional analyses of soybean forage and Harvested Seed Collected from MON 89788 grown in Brazil field trials during 2007/2008.
Study MSL0022336: Compositional analyses of soybean seed collected from MON 89788 untreated with glyphosate grown in Brazil during 2007/2008.
Study MSL0023111: Compositional analyses of soybean forage and seed collected from MON 89788 (glyphosate-treated) grown in Brazil during 2008/2009.
Study MSL0023114: Compositional analyses of soybean forage and seed collected from MON 89788 (untreated) grown in Brazil during 2008/2009.
Study MSL0023106: Compositional analyses of soybean forage and seed collected from MON 89788 grown in the United States during the 2009 growing season.
Study MSL0023945: Phenotypic evaluation and environmental interactions of glyphosate-tolerant soybean MON 89788 when sprayed with glyphosate in U.S. field trials during 2009.

complementary glufosinate-containing herbicide. EFSA considers that the complementary herbicide was applied according to good agricultural practices (GAP).

- For application EFSA-GMO-NL-2006-36, the applicant submitted different sets of field trials to evaluate the agronomic, phenotypic and compositional characteristics of soybean MON 89788. These studies included data from GM plants treated and untreated with the complementary glyphosate-containing herbicide. EFSA considers that the time and application rate of the complementary herbicide is in the range of the current GAP. Further details on the field trials, including information on the application of the complementary herbicide, are given below when assessing the publication by Miyazaki et al. (2019).

The GMO Panel concluded that soybean A2704-12 and soybean MON 89788 are agronomically and compositionally equivalent to conventional soybean lines, except for the introduced transgenic traits (EFSA GMO Panel, 2007, 2008).

Toxicological assessment of the whole GM food and feed from soybean A2704-12 and soybean MON 89788

In its applicable guidance document for the risk assessment of GM plants and derived food and feed (EFSA, 2006) the GMO Panel clarified that a toxicological assessment of the whole food and feed with a 90-day toxicity study is only required if the composition of the GM plant is modified substantially, or if there are any indications for the potential occurrence of unintended effects, based on the preceding molecular, compositional or phenotypic analysis. Since no substantial compositional modifications or indications of potential unintended effects from preceding analyses were identified for soybean A2704-12 and soybean MON 89788 in the context of the respective applications, the GMO Panel did not request such studies to complete the assessment of these GM soybeans.

- For application EFSA-GMO-NL-2005-18, the applicant did not provide a 90-day toxicity study with the whole food and feed. However, based on the outcome of the molecular characterization assessment and comparative analysis, the GMO Panel concluded that soybean A2704-12 is equivalent to its non GM comparator, and considered that animal safety studies on food and feed from that GM soybean were not necessary (EFSA GMO Panel, 2007).
- For application EFSA-GMO-NL-2006-36, the applicant voluntarily conducted a 90-day oral toxicity study in rats with up to 15% processed soybean meal from soybean MON 89788 even though it was not requested by the GMO Panel. The GMO Panel assessed the provided 90-day study and concluded that it indicated no toxicity of soybean MON 89788 (EFSA GMO Panel, 2008).

3.1.3. Findings reported by Fang et al. (2018)

The publication by Fang et al. (2018) is cited by Testbiotech in its technical background for soybean MON 89788 to support the claim that new field trials should have been requested for application EFSA-GMO-RX-009.

In its publication, Fang et al. (2018) report on increased fitness of *Arabidopsis* plants expressing EPSPS genes conferring tolerance to glyphosate. This increase in fitness is observed in the absence of glyphosate treatment. Thus, the authors conclude that it is the surplus of EPSPS that may affect plant growth and confer the increase in fitness.

EFSA's assessment

EFSA notes that the findings reported by Fang et al. (2018) have already been assessed by EFSA and/or its GMO Panel in the context of application EFSA-GMO-DE-2016-133 (EFSA GMO Panel, 2018b)[11] and in previous requests of the European Commission to review the scientific arguments raised by Testbiotech on application EFSA-GMO-BE-2013-118 (EFSA, 2019) and to assess public comments received on several GMO applications.[12]

[11] The publication by Fang et al. (2018) was identified in the systematic literature search submitted by the applicant.

[12] Application EFSA-GMO-NL-2016-128 (EFSA-Q-2020-00072); application EFSA-GMO-NL-2016-131 (EFSA-Q-2019-00597); application EFSA-GMO-NL-2016-134 (EFSA-Q-2019-00689); application EFSA-GMO-NL-2016-135 (EFSA-Q-2019-00598) and application EFSA-GMO-NL-2017-144 (EFSA-Q-2020-00028). Available at EFSA Register of Questions.

EFSA concluded that the findings reported by Fang et al. (2018) observed in *Arabidopsis* cannot be generalised and that further research on a broader range of species expressing EPSPS genes and in different environmental conditions is required (EFSA, 2019).

Moreover, for soybean MON 89788, which expresses the EPSPS protein, event-specific data were provided to assess its agronomic and phenotypic characteristics in the context of application EFSA-GMO-NL-2006-36. These included, among others, seedling vigour, seed weight and yield. An increase in fitness was not observed in the absence of glyphosate treatment. The GMO Panel concluded that the GM soybean MON 89788 is agronomically equivalent to the non-GM comparator, except for the newly introduced trait (EFSA GMO Panel, 2008).

EFSA's conclusions

In conclusion the findings reported by Fang et al. (2018) do not reveal new information that would invalidate the previous risk assessment conclusions made by the GMO Panel on soybean MON 89788.

3.1.4. Findings reported by Miyazaki et al. (2019)

One of the scientific arguments put forward in the technical background of the Testbiotech complaints is based on the recent publication by Miyazaki et al. (2019) concerning the exposure levels of glyphosate-tolerant GM soybean plants to the complementary herbicide. Among other aspects,[13] Miyazaki et al. (2019) consider the conditions under which the field trials in support of the authorisation of GM plants were conducted and conclude that they were not representative of the current farming practices.

To support their conclusions, Miyazaki et al. (2019) focus on three aspects: (i) the changed farming practices in respect to the use of glyphosate in North and South America over the last decades; (ii) the application rates of glyphosate in several field trials conducted by the applicants in support of the request of authorisation for import and processing of GM glyphosate tolerant soybean plants;[14] and (iii) the phenotypic and compositional changes in herbicide tolerant GM soybean plants exposed to different dosage of glyphosate as reported in several peer reviewed publications.

On the basis of the information reported by Miyazaki et al. (2019), Testbiotech states in its technical background that the currently higher dosage of glyphosate application "*may also influence the expression of the transgenes or other genome activities in the plants*" and that "*the material used in the feeding study was not representative of the product for consumption, since application of the complementary herbicide was not in accordance with current agricultural practices*".

EFSA's assessment

In the context of this request, EFSA considers that the publication by Miyazaki et al. (2019) is relevant for soybean MON 89788 because (i) it is tolerant to glyphosate-containing herbicides; and (ii) it was specifically addressed in the publication. EFSA considers that the publication by Miyazaki et al. (2019) is not relevant for soybean A2704-12 since this soybean is tolerant to glufosinate-containing herbicides but not to glyphosate.

As indicated above, EFSA reminds that in the context of applications for renewal authorisations of GM plants, applicants are not requested to produce new scientific data (EFSA GMO Panel, 2015b).

For the specific case of soybean MON 89788, the GMO Panel, following the submission of application EFSA-GMO-NL-2006-36, issued a scientific opinion for the placing on the market of that GM soybean (EFSA GMO Panel, 2008). Soybean MON 89788 was assessed with reference to its intended uses, which excluded cultivation in the EU, taking into account the appropriate principles described in the applicable EFSA guidance (EFSA, 2006). With respect to the field trials for the comparative analysis of soybean MON 89788, the GMO panel requested further data in addition to the dataset originally submitted by the applicant. Overall, the field trial design to produce the agronomic, phenotypic and compositional characteristics were considered in line with EFSA (2006). The GMO Panel also considered that the timing and rate of the applied complementary herbicide were in line with the recommendations of the

[13] The publication by Miyazaki et al. (2019) also discusses the assessment of herbicide residues and metabolites, but this is not in the remit of the GMO Panel and it will be not discussed in the current document.

[14] The soybean events addressed in the Miyazaki et al. (2019) publication are the single events FG72, MON 87705 MON 89788 and RR 40-3-2, and the double-stacked events FG72 × A5547-127 MON 87701 × MON 89788; MON 87705 × MON 89788 and MON 87708 × MON 89788.

manufacturer. EFSA considers that the time and application rate of the target herbicide in the submitted studies is in the range of the current GAP.

The strategy applied at the selected sites corresponds in most of the cases to a preemergence application of herbicides, and this might include glyphosate, followed by an in crop application of glyphosate only on the soybean MON 89788 plots. EFSA recognises that different weed control strategies might be selected by farmers in different countries following specific local management practices, the weed population, crop rotation, and profitability linked to the herbicide selection. However, it is considered neither feasible nor necessary to assess herbicide tolerant GM plants under all possible scenarios. The different strategies selected in application EFSA-GMO-NL-2006-36 were considered suitable to assess whether the agricultural practices, representative of the regions where the plant can be grown, influence the expression of compositional endpoints soybean MON 89788.

The event specific data produced in support of application for authorisation of soybean MON 89788 identified significant compositional changes in soybean seeds exposed to the complementary herbicide for tryptophan, 17:0 heptadecanoic acid, stachyose, carbohydrates and trypsin inhibitor. These observed compositional changes fell within the normal variation of soybean constituents, therefore soybean MON 89788 was considered compositionally equivalent to the non-GM counterpart soybean and other conventional soybean varieties, except for the introduced trait (EFSA GMO Panel, 2008). The GMO Panel was able to conclude the risk assessment based on the information provided by the applicant.

EFSA would like to remind that the application of the complementary herbicide in the field trials for the comparative assessment of herbicide tolerant GM plants is a mandatory requirement of the EFSA guidance for risk assessment of food and feed (EFSA GMO Panel, 2011), which was adopted before Regulation (EU) No 503/2013. Later on, in the EFSA guidance on the agronomic and phenotypic characterisation of GM plants (EFSA GMO Panel, 2015b), the GMO Panel provided further clarifications on the type of information that applicants should report with regards to the application of the complementary herbicides (e.g. timing, dose, volumes, coadjuvants) to ensure a proper evaluation of its correct application.

With regards to animal feeding studies, EFSA reminds that the Miyazaki et al. (2019) publication does not specifically analyse and comment on the study spontaneously provided in support of application EFSA-GMO-NL-2006-36 for soybean MON 89788. EFSA confirms that the considerations reported in Section 3.1.2 on the toxicological assessment of the whole GM food and feed from soybean MON 89788 are still valid.

EFSA's conclusions

In conclusion, the findings reported by Miyazaki et al. (2019) do not reveal new information that would invalidate the previous risk assessment conclusions made by the GMO Panel on soybean MON 89788

4. Conclusions

The GMO Panel conducted the assessment of GM soybean A2704-12 and soybean MON 89788 for renewal authorisation in line with its guidance document (EFSA GMO Panel, 2015a). During the assessment of both GM soybeans, EFSA and its GMO Panel requested additional information from the applicants. Based on the information provided in the valid applications EFSA-GMO-RX-009 and EFSA-GMO-RX-011, the additional information submitted during the risk assessments, and the available scientific literature relevant for these applications, the GMO Panel concluded that that there was no evidence in renewal applications EFSA-GMO-RX-009 and EFSA-GMO-RX-011 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean A2704-12 and soybean MON 89788, respectively.

The arguments raised by Testbiotech did not put forward new information that would invalidate the previous risk assessment conclusions and risk management recommendations made by the GMO Panel for GM soybean A2704-12 and soybean MON 89788. Therefore, EFSA considers that the previous risk assessment conclusions on these soybean events remain valid.

Documentation provided to EFSA

1. Letter from the European Commission to the EFSA Executive Director, dated 15 January 2020, requesting technical and scientific assistance on the internal review under Regulation (EC) No 1367/2006 of the Commission's decisions renewing the authorisation for the placing on the market of genetically modified soybean MON 89788 and soybean A2704-12.

2. Testbiotech's technical background for a request for internal review of administrative acts under Article 10 of Regulation (EC) No. 1367/2006 against the decision of the EU Commission to renew the market authorisation for genetically engineered soybean A2704-12 under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-009) from company Bayer.

3. Testbiotech's technical background for a request for internal review of administrative acts under Article 10 of Regulation (EC) No. 1367/2006 against the decision of the EU Commission to renew the market authorisation for genetically engineered soybean MON 89788 (application EFSA-GMO-RX-011) under Regulation (EC) No 1829/2003 from company Monsanto (Bayer).

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