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Statement complementing the EFSA Scientific Opinion on the assessment of genetically modified oilseed rape MS11 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2016-138)

EFSA Panel on Genetically Modified Organisms (GMO),
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Abstract

In a previous scientific opinion on application EFSA-GMO-BE-2016-138, the EFSA Panel on Genetically Modified Organisms (GMO Panel) could not conclude on the comparative analysis and on the food/feed safety assessment of genetically modified (GM) oilseed rape (OSR) MS11 because of the lack of an appropriate compositional data set. Following a request from the European Commission, the GMO Panel assessed additional information related to OSR MS11 to complement the original scientific opinion. The GMO Panel concluded that the information submitted (on the composition of the two-event stack MS11 × RF3) could not be used for the assessment of the composition of OSR MS11 and requested the applicant to perform a complementary set of field trials to generate additional data. The applicant did not perform the requested field trials and did not provide any new experimental data on the composition of OSR MS11. Hence, the GMO Panel is still not in the position to conclude on either the compositional analysis or the toxicological, allergenicity or nutritional assessment of OSR MS11. Therefore, the previous conclusions of the GMO Panel still hold.

Keywords: GMO, oilseed rape (*Brassica napus*), MS11, Regulation (EC) No 1829/2003, Barnase, Barstar, PAT/bar

Requestor: European Commission

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Summary

On 2 April 2020, the GMO Panel adopted a scientific opinion on application EFSA-GMO-BE-2016-138 for the placing on the market of oilseed rape (OSR) MS11 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. In its scientific opinion, the GMO Panel noted that OSR MS11 is not expected to be commercialised as a stand-alone product for food/feed uses, and that the characteristics of the intended traits of OSR MS11 challenge the design of the field trials for comparative analysis in Regulation (EU) No 503/2013. In the case of application EFSA-GMO-BE-2016-138, part of the compositional data generated in the field trials (those for seeds from MS11 plants treated with the intended herbicide) could not be considered of adequate quality because of a heterogeneous genetic background. The compositional data set was considered incomplete and no conclusions could be drawn for the compositional analysis. Owing to the incompleteness of the compositional analysis, the toxicological, allergenicity and nutritional assessment of OSR MS11 could not be completed.

On 5 January 2021, the European Commission mandated EFSA to assess additional information received from the applicant on the comparative analysis of OSR MS11. The GMO Panel considered the information submitted (on the composition of the two-event stack MS11 $\times$ RF3) and concluded that it could not be used for a risk assessment of MS11 in line with the intended scope and with Regulation (EU) No 503/2013. Following this assessment, the GMO Panel requested the applicant to perform a complementary set of stand-alone field trials, designed to address the issues related to the materials in the original application. The applicant did not perform the requested field trials and did not provide any new experimental data on the composition of OSR MS11. Hence, the GMO Panel is still not in the position to conclude on either the compositional analysis or the toxicological, allergenicity or nutritional assessment of OSR MS11 in line with the intended scope. Therefore, the previous conclusions of the GMO Panel still hold.

Table of contents

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-BE-2016-138 for the placing on the market of oilseed rape (OSR) MS11 for food and feed uses, import and processing under Regulation (EC) No 1829/2003.

In its scientific opinion (EFSA GMO Panel, 2020), the GMO Panel noted that OSR MS11 is not expected to be commercialised as a stand-alone product for food/feed uses. MS11 is designed to be used only as part of a dedicated breeding system intended to produce: (1) MS11 × RF3 hybrid seed to produce male fertile OSR plants; and (2) new OSR MS11 seed to maintain the male sterile (MS) line. Therefore, seeds harvested from OSR MS11 are not expected to enter the food/feed chain, except in the case of accidental presence in products coming from non-EU countries. The risk assessment of application EFSA-GMO-BE-2016-138, however, was conducted according to the scope defined by the applicant (food and feed uses, import and processing) and following the requirements of Regulation (EU) No 503/2013[1].

The GMO Panel noted that the characteristics of the intended traits of OSR MS11 challenge the comparative analysis to the extent that it is not possible to produce the materials and collect the data for the comparative analysis without deviating from the requirements. The MS11 event, in fact, expresses both MS and herbicide tolerant traits and, in accordance with Regulation (EU) No 503/2013, the field trials submitted by the applicant included (among other materials) plots with MS11 plants treated with the intended herbicide; as required, such plants were genetically very close to the conventional counterpart grown in the same field trials. However, as MS11 plants treated with the intended herbicides were male sterile, they did not produce viable pollen; in order to produce seeds, they had to be pollinated by the male fertile plants in the nearby plots, which included several commercial reference varieties and not only the conventional counterpart. As a result, the seeds produced from plots with MS11 plants treated with the intended herbicide had a heterogeneous genetic background, influenced by the different genotypes of the pollen donor plots. For this reason, the compositional data of MS11 seeds collected from plants treated with the intended herbicide could not be considered of adequate quality for the comparative analysis. Consequently, the compositional data set was considered incomplete and no conclusions could be drawn for the compositional analysis. Owing to the incompleteness of the compositional analysis, the toxicological, allergenicity and nutritional assessment of OSR MS11 could not be completed. In conclusion, in the absence of an appropriate comparative assessment and considering the scope of application EFSA-GMO-BE-2016-138 as defined by the applicant (food and feed uses, import and processing), the food/feed assessment of OSR MS11 could not be completed (EFSA GMO Panel, 2020).

On 5 January 2021, the European Commission (EC) mandated EFSA to assess additional information received from the applicant on the comparative analysis of OSR MS11. EFSA was asked to complement its original scientific opinion on OSR MS11 taking into consideration this additional information. EFSA acknowledged receipt of the mandate on 5 February 2021. To finalise the assessment, the GMO Panel asked for further information on 28 May 2021; the information was provided on 24 September 2021. EFSA requested the EC to extend the deadline for the finalisation of the mandate on 28 October 2021; the EC accepted EFSA's request on 11 November 2021.

According to the mandate received from the EC, this statement complements the EFSA scientific opinion on OSR MS11 (EFSA GMO Panel, 2020), which is the report requested under Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003[2] and is part of the EFSA Overall Opinion in accordance with Articles 6(5) and 18(5) of that Regulation.

2. Data and methodologies

2.1. Data

In the preparation of this statement, the GMO Panel took into account the additional information provided by the applicant, the additional information requested during the risk assessment, relevant

[1] 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

[2] 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.

peer-reviewed scientific publications and the EFSA scientific opinion on application EFSA-GMO-BE-2016-138 (EFSA GMO Panel, 2020).

2.2. Methodologies

The GMO Panel carried out a scientific risk assessment of the additional information in line with the principles described in Regulation (EU) No 1829/2003, Regulation (EU) No 503/2013 and the applicable guidelines (i.e. EFSA GMO Panel, 2011, 2015) for the risk assessment of GM plants.

3. Assessment

The additional information provided by the applicant consisted of the comparative compositional analysis of the two-event stack OSR MS11 × RF3. In the accompanying letter, the applicant remarked that MS11 is not expected to be commercialised as a stand-alone product for food/feed uses; hence, seeds harvested from OSR MS11 are not expected to enter the food/feed chain except in the case of accidental presence (see Introduction). According to the applicant, as OSR is a segregating crop, MS11 would instead be expected to enter (non-accidentally) the food/feed chain as part of the progeny of harvested F2 seeds of MS11 × RF3 or derived products. The applicant concluded that the compositional analysis of MS11 × RF3 seeds would cover the risk assessment of the expected food/feed uses of MS11. The GMO Panel considered the arguments of the applicant and concluded that the information provided was not adequate for the assessment. While MS11 is not expected to be commercialised as a stand-alone food/feed product, application EFSA-GMO-BE-2016-138 is for food and feed uses, import and processing of MS11 in the EU, and a complete risk assessment of MS11 is required in accordance with Regulation (EU) No 503/2013. Such assessment includes the identification of compositional changes in seeds of the single event MS11. By conducting the assessment of the MS11 × RF3 mixture as suggested by the applicant, it would not be possible to isolate changes linked only to MS11 from changes linked to the interaction between MS11 and RF3. Therefore, the GMO Panel concluded that the information submitted on MS11 × RF3 was inadequate for the assessment of the composition of MS11.

Following this assessment, the GMO Panel requested the applicant to perform a complementary set of stand-alone field trials to generate appropriate materials to conclude on the comparative analysis of MS11. For these field trials, the GMO Panel suggested alterations to the recommended experimental design (Regulation (EU) No 503/2013 and EFSA GMO Panel (2015)) to address the issues related to the materials in application EFSA-GMO-BE-2016-138 (see Introduction). The alterations aimed to produce materials with a suitable, non-heterogeneous genetic background by preventing plots with MS11 plants from being pollinated by the reference varieties. This required splitting the materials at each site in two groups such that plots with the conventional counterpart and MS11 (both treated and not treated with the intended herbicide) had to be separated from the reference variety plots (to avoid accidental pollen flow) and kept under an insect-proof net (to prevent cross-fertilisation via pollinators). Hence, the design included altered management practices (EFSA GMO Panel, 2015) and deviations from the criteria for randomisation and blocking (Regulation (EU) No 503/2013). Because of such deviations, the materials produced with the modified experimental design would not be optimal; however, the GMO Panel noted that it is not possible to produce materials for MS11 in full compliance with the current regulations and guidance documents (see Introduction) and considered that the information generated in the new field trials would be adequate to complement the original data set for compositional analysis.

In their reply, the applicant did not provide the requested field trials, mentioning both logistic and scientific concerns related to the request. According to the applicant, the deviations in the design would introduce a strong bias in the materials, alter the representativeness of receiving environments and ultimately compromise the possibility of producing adequate material. The GMO Panel acknowledges the objections of the applicant and notes, however – as explained above – that the design had been identified specifically to complement the comparative analysis data for application EFSA-GMO-BE-2016-138 and that the limitations and potential issues of the design had been carefully evaluated prior to the request and considered acceptable. In the same reply, the applicant proposed, as an alternative, to reconsider the field trials originally submitted for application EFSA-GMO-BE-2016-138 (and evaluated in EFSA GMO Panel (2020)) with the argument that the quality of the materials, including MS11 treated with the intended herbicide, was acceptable. However, the applicant did not supply any new experimental data to change the conclusions of EFSA GMO Panel (2020) on the suitability of the materials.

As the information submitted for this Mandate was not considered adequate and the applicant did not perform the additional field trials requested by the GMO Panel, there are no new data available to the GMO Panel on the composition of MS11. Hence, the GMO Panel is still not in the position to conclude on either the compositional analysis or the toxicological, allergenicity or nutritional assessment of OSR MS11.

4. Conclusions

The GMO Panel was mandated to assess additional information on the comparative analysis of the composition of OSR MS11 to complement its original scientific opinion on application EFSA-GMO-BE-2016-138. The GMO Panel concluded that the additional information was inadequate to support the continued assessment of MS11 and requested the applicant to perform new field trials to generate compositional data that could adequately complement the original data set. The applicant did not perform the requested field trials and did not provide any new experimental data on the composition of MS11. Hence, the GMO Panel is still not in the position to conclude on either the compositional analysis or the toxicological, allergenicity or nutritional assessment of OSR MS11. Therefore, the conclusions of EFSA GMO Panel (2020) still hold.

5. Documentation as provided to EFSA

1) Mandate from European Commission (EC) for the assessment of additional information related to the application for authorisation of food and feed containing, consisting of and produced from genetically modified oilseed rape MS11 (EFSA-GMO-BE-2016-138), letter received on 18 January 2021.
2) Mandate accepted by EFSA on 5 February 2021.
3) Request for supplementary information to the applicant, 28 May 2021.
4) Receipt of supplementary information from the applicant, 20 September 2021.
5) Request to EC to extend the deadline of the mandate, from 27 October 2021 to 27 January 2022, 28 October 2021.
6) Acceptance of the deadline extension requested to EC, 11 November 2021.

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Abbreviations

GM	genetically modified
GMO	genetically modified organism
GMO Panel	EFSA Panel on Genetically Modified Organisms