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STATEMENT

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Risk assessment of additional information on maize MIR162

EFSA Panel on Genetically Modified Organisms (GMO),
Ewen Mullins, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst,
Michelle M Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko,
Francisco Javier Moreno, Hanspeter Naegeli, Fabien Nogué, Nils Rostoks,
Jose Juan Sánchez Serrano, Giovanni Savoini, Eve Veromann, Fabio Veronesi,
Andrea Gennaro, Franco Maria Neri and Nikoletta Papadopoulou

Abstract

The European Commission requested the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) to assess new scientific information on maize MIR162, and to indicate whether the previous conclusions on the safety of maize MIR162 as a single event and as a part of stacked events remain valid. The new information is included in a European patent that reports a decrease in male fertility in some MIR162 inbred lines, pointing to a potential link between such decrease and the Vip3 protein expressed by maize MIR162. The EFSA GMO Panel evaluated the data provided by the patent owner and found scarce support for a causal link between Vip3 and decreased fertility. The general hypothesis of an association between event MIR162 and altered fertility could not be confirmed. The EFSA GMO Panel conducted the safety assessment based on the conservative assumption that such an association exists. The EFSA GMO Panel concluded that a decrease in male fertility would have no impact on the previous conclusions on maize MIR162 and stacked events containing MIR162.

Keywords: GMO, maize (*Zea mays*), MIR162, Regulation (EC) No 1829/2003

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Correspondence: nif@efsa.europa.eu

Panel members: Ewen Mullins, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Hanspeter Naegeli, Fabien Nogué, Nils Rostoks, Jose Juan Sánchez Serrano, Giovanni Savoini, Eve Veromann, and Fabio Veronesi.

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1. Introduction

Maize event MIR162 expresses the Vip3Aa20 protein to confer resistance against certain lepidopteran pests and the phosphomannose isomerase (PMI) protein used as a selectable marker. The Panel on Genetically Modified Organisms of the European Food Safety Authority (hereafter, 'GMO Panel') has adopted several scientific opinions on the assessment of MIR162 and stacked events including MIR162 (Table 1).

Table 1: EFSA GMO Panel scientific opinions on maize MIR162

#	Event	Owner	Application or mandate	EFSA Scientific Opinion
1	MIR162	Syngenta	EFSA-GMO-DE-2010-82	EFSA GMO Panel (2012)
			EFSA-GMO-RX-025	EFSA GMO Panel (2022a)
2	MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and subcombinations	Corteva	EFSA-GMO-NL-2018-151	EFSA GMO Panel (2022b)
3	Bt11 × MIR162 × MIR604 × GA21 and subcombinations	Syngenta	EFSA-GMO-DE-2009-66	EFSA GMO Panel (2015)
4	Bt11 × MIR162	Syngenta	M-2016-0248	EFSA GMO Panel (2017)
5	Bt11 × MIR162 × 1507 × GA21 and subcombinations	Syngenta	EFSA-GMO-DE-2010-86	EFSA GMO Panel (2018)
6	Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and subcombinations	Syngenta	EFSA-GMO-DE-2011-103	EFSA GMO Panel (2019a)
7	1507 × MIR162 × MON810 × NK603 and subcombinations	Corteva	EFSA-GMO-NL-2015-127	EFSA GMO Panel (2021)
8	MON 87427 × MON 89034 × MIR162 × NK603 and subcombinations	Bayer	EFSA-GMO-NL-2016-131	EFSA GMO Panel (2019b)
9	MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and subcombinations	Bayer	EFSA-GMO-NL-2016-134	EFSA GMO Panel (2019c)
10	MON 87427 × MON 89034 × MIR162 × MON 87411 and subcombinations	Bayer	EFSA-GMO-2017-144	EFSA GMO Panel (2019d)

The owners of the events in Table 1 are designated either as 'applicants' (they own events that have not yet been authorised) or 'authorisation holders' (they own authorised events) or both (they own authorised and unauthorised events). The expression 'applicants and authorisation holders' will be used in the rest of this statement to refer to all the owners in Table 1.

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

Two of the scientific opinions in Table 1 were adopted recently. The opinion on application EFSA-GMO-NL-2018-151 for the five-event stack maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and subcombinations was adopted on 4 July 2022 (EFSA GMO Panel, 2022a). The opinion on application EFSA-RX-GMO-RX025 for the renewal of maize MIR162 was adopted on 1 September 2022 (EFSA GMO Panel, 2022b).

Following the provisions of Regulation (EC) No 1829/2003,[1] the public was requested to comment on the scientific opinions after they were published. On 21 September 2022, the European Commission (EC) asked EFSA to assess whether the scientific comments received for the five-event stack maize contain new information that might change the conclusions of EFSA GMO Panel (2022a) ('**request 1**').[2] On 10 November 2022, the EC asked EFSA to assess whether the scientific comments received

[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] Public comments on an application submitted under Regulation (EC) No 1829/2003 on GM Food and Feed – Application EFSA-GMO-NL-2018-151 - Ares(2022)6510903. The public comments are accessible on the European Commission website at https://food.ec.europa.eu/system/files/2022-09/gmo_pub-cons_comments_2022-7451.pdf

for the renewal application contain new information that might change the conclusions of EFSA GMO Panel (2022b) ('**request 2**').[3]

Comments received for both request 1 and request 2 refer to a European patent by Syngenta on genetic loci associated with altered fertility in maize ('the patent').[4] The text of the patent points to a potential link between Vip3 proteins and altered male fertility. This is novel information, previously not considered by the GMO Panel.

As maize MIR162 expresses a Vip3 protein (Vip3Aa20), the information may be directly relevant for the safety of maize MIR162 and all stacked events that include MIR162. Thus, a potential impact on the conclusion of all the GMO Panel opinions listed in Table 1 should be assessed. Requests 1 and 2 ask for such an assessment for the first two events in Table 1. On 28 November 2022, the EC requested EFSA to extend the assessment to the remaining stacked events (#3–10) in Table 1 ('**request 3**').[5]

The present statement reports the assessment of the additional information on MIR162 within the scope of requests 1, 2 and 3, which altogether cover all the applications for which the GMO Panel has issued a scientific opinion (Table 1). The statement does not consider the maize stacked events that include MIR162 and for which the GMO Panel has not yet completed the assessment. For those events, the impact of the additional information will be assessed within the respective applications. The statement also does not consider the parts of the public comments in requests 1 and 2 that are not related to the patent.

2. Data and Methodologies

2.1. Data

In the preparation of this statement, the GMO Panel took into account the public comments, the description of the patent, the additional information provided by the applicants/authorisation holders during the risk assessment, relevant peer-reviewed scientific publications and the relevant GMO Panel scientific opinions (Table 1).

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[6] and the applicable guidelines (EFSA GMO Panel, 2011) for the risk assessment of GM plants.

3. Assessment

The European patent EP 3632202 B1 property of Syngenta states that 'Vip3 has been observed to cause decreased male fertility in certain inbred maize plants under normal growing conditions'.[7] The patent also states that reduced male fertility was observed in several maize inbred lines homozygous for event MIR162.

In conducting the assessment, the GMO Panel requested additional information from the three applicants and authorisation holders (Bayer, Corteva and Syngenta, see Table 1). In summary: (a) Syngenta, as the owner of both the patent and maize MIR162, was requested to clarify why the information about the patent had not been disclosed in the frame of recent applications (#1 and #2 in Table 1); (b) Syngenta was requested to clarify if the effect (reduced male fertility) is associated with event MIR162; (c) Syngenta, Bayer and Corteva were requested to assess the impact of the effect on the safety of each of the respective events (Table 1). The replies to the three requests are summarised below.

a) *Syngenta was requested to clarify why the information about the patent was not disclosed*.

Syngenta replied that the claims in the patent that Vip3 can 'cause decreased male fertility' are not corroborated by scientific data, and that there is no evidence of a direct causal link between Vip3A or

[3] Public comments on a renewal application submitted under Regulation (EC) No 1829/2003 on GM Food and Feed (RX-025) - Ares(2022)7751206. The public comments are accessible on the European Commission website at https://food.ec.europa.eu/system/files/2022-12/gmo_pub-cons_comments_2022-7562.pdf

[4] https://data.epo.org/publication-server/pdf-document?pn=3632202&ki=B1&cc=EP&pd=20220720

[5] Available online https://open.efsa.europa.eu/questions/EFSA-Q-2022-00853

[6] 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.

[7] Available online https://data.epo.org/publication-server/pdf-document?pn=3632202&ki=B1&cc=EP&pd=20220720

event MIR162 and male fertility. The effect was reported to be present in some MIR162-expressing inbred lines, and not in the hybrid lines intended for commercialisation. Hence, the information had not been provided to EFSA because 'it lacks any safety implications that could impact the risk assessment'.

b) *Syngenta was requested to clarify if the reduced male fertility is associated with event MIR162*.

Syngenta replied that the claim of the patent ('Vip3 has been observed to cause decreased male fertility in certain inbred maize plants under normal growing conditions') cannot be validated by the data. To determine whether the reduced male fertility observed in certain MIR162 inbred lines is due to a plant genomic region genetically linked to the inserted T-DNA, Syngenta identified genes (and quantitative trait loci) related to male fertility and present in some inbred lines. However, the specific combination of the genetic regions leading to this effect has not been adequately identified and characterised. Syngenta also pointed out that as part of the sequencing and bioinformatics analysis assessed by the GMO panel, the molecular characterisation of the MIR162 insertion was not shown to interrupt any known endogenous gene (EFSA GMO Panel, 2022a,b).

The GMO Panel considers that based on the available information and on the known functions of the proteins (EFSA GMO Panel, 2012), it is unlikely that Vip3Aa20 and/or PMI expressed by the maize event MIR162 may cause reduced male fertility in the maize inbred lines. Furthermore, the GMO Panel confirms that the information available does not show disruption of any endogenous gene. Therefore, based on the data available, it is not possible to confirm that the decreased male fertility observed in some MIR162 inbred lines is associated with the genetic modification.

In response to requests 1, 2 and 3 from the EC, the GMO Panel conducted a re-evaluation of the conclusions of the scientific opinions in Table 1. In the re-evaluation, the GMO Panel assumed as a conservative scenario that the effect is associated with maize MIR162. The GMO Panel also assumed that the effect is present in all the lines and hybrids harbouring maize MIR162 and in all maize stacked events that include MIR162.

c) *Syngenta, Bayer and Corteva were requested to assess the safety impact on maize event MIR162 and maize stacked events*.

The three applicants/authorisation holders each provided an assessment under a conservative scenario similar to the one defined by the GMO Panel. Hence, they assessed the impact of a decrease in male fertility associated with event MIR162 and present in all the stacks in Table 1.

In summary, their assessment stated as follows. MIR162 inbred lines from hybrid seed production and GM hybrids containing event MIR162 are not cultivated in Europe. Reduced male fertility has no implications for the risk assessment of hybrid maize for food and feed. As for environmental impact, reduced male fertility would not increase the likelihood of persistence or invasiveness of the crop in the case of accidental release of viable seeds into the environment. Therefore, there are no environmental safety concerns related to reduced male fertility.

In case this effect is present in MIR162 and all stacked maize events, the GMO Panel does not identify any implications to the safety of MIR162 for food and feed or the environment. The GMO Panel therefore confirms that the conclusions for maize MIR162 and the maize stacked events in Table 1 remain valid.

4. Conclusions

Following the provision of additional information on maize MIR162 and stacked events including MIR162:

- The GMO Panel based the safety assessment on the conservative scenario that the effect is associated with the genetic modification and that it is present in MIR162 and all maize stacked events including MIR162. The GMO Panel did not identify any implications of the decreased male fertility on the safety of all these events for food and feed or the environment.
- The GMO Panel confirms that the conclusions of the past scientific opinions on maize MIR162 and maize stacked events including MIR162 remain valid.

The public comments identified a potentially valid point that deserved further investigation. This underlines the importance of the consultation process (as in Regulation (EC) No 1829/2003 on GM food and feed) as the public directly contributed to improving the work of EFSA for a more comprehensive risk assessment.

Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013 require that authorisation holders and applicants provide new information which might 'influence the evaluation of the safety in use of the food [and feed]' (authorisation holders) or 'influence the risk assessment' (applicants) as soon as such information arises. This is fundamental to the risk assessments completed by EFSA. In this case, potentially relevant information known to Syngenta was not disclosed. Going forward, it is incumbent on all applicants to complete a comprehensive search of all relevant published literature and patents and guarantee the delivery of potentially relevant scientific information to EFSA to assist in the processing of applications.

Documentation as provided to EFSA

- Request to assess the public comments on application EFSA-GMO-NL-2018-151 (request 1). Letter from the European Commission (EC) to EFSA received on 21 September 2022.
- Request for an extension of the deadline for request 1 (from 21 October 2022 to 10 December 2022). Letter from EFSA to the EC sent on 21 October 2022.
- Request for deadline extension accepted. Letter from the EC to EFSA received on 10 November 2022.
- Request to assess the public comments on application EFSA-GMO-RX-025 (request 2). Letter from the EC to EFSA received on 10 November 2022.
- Mandate from the EC to EFSA concerning new information on maize MIR162, with the request to assess the validity of the conclusions of the opinions on all authorised GM stacked maize events where event MIR162 is present (request 3). Letter from the EC to EFSA received on 28 November 2022.
- Acceptance of the mandate (request 3) and request to align the timeline of requests 1, 2 and 3. Letter from EFSA to the EC sent on 13 December 2022.
- Acceptance of the request to align the timeline of requests 1, 2 and 3. Letter from the EC to EFSA received on 25 January 2022.
- Request for supplementary information to Syngenta, 19 December 2022.
- Request for supplementary information to Bayer, 19 December 2022.
- Request for supplementary information to Corteva, 19 December 2022.
- Receipt of supplementary information from Syngenta, 16 February 2023.
- Receipt of supplementary information from Bayer, 16 February 2023.
- Receipt of supplementary information from Corteva, 17 February 2023.

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Abbreviations

GM	genetically modified
GMO Panel	EFSA Panel on Genetically Modified Organisms
PMI	phosphomannose isomerase