

SCIENTIFIC OPINION

Scientific Opinion on a request from the European Commission related to the emergency measure notified by Italy on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003¹

EFSA Panel on Genetically Modified Organisms (GMO)^{2,3}

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ABSTRACT

Following a request of the European Commission, the European Food Safety Authority's Panel on Genetically Modified Organisms (EFSA GMO Panel) evaluated the documentation submitted by Italy in support of its request for the prohibition of the placing on the market of the genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003. All concerns related to human and animal health or the environment raised by Italy were already addressed in previous scientific opinions of the EFSA GMO Panel on maize MON 810 while other concerns relate to co-existence and thus fall outside the remit of EFSA. Therefore, the EFSA GMO Panel concludes that, based on the documentation submitted by Italy, there is no specific scientific evidence, in terms of risk to human and animal health or the environment, that would support the notification of an emergency measure under Article 34 of Regulation (EC) No 1829/2003 and that would invalidate its previous risk assessments of maize MON 810.

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KEY WORDS

GMO, maize (*Zea mays*), MON 810, Italy, emergency measure, environment, Regulation (EC) No 1829/2003

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SUMMARY

On 29 May 2013, the European Commission requested the European Food Safety Authority's Panel on Genetically Modified Organisms (EFSA GMO Panel) to assess the supporting documentation submitted by Italy to introduce an emergency measure pursuant to Article 34 of Regulation (EC) No 1829/2003 on maize MON 810 cultivation in the European Union (EU).

The EFSA GMO Panel considered the relevance of concerns raised by Italy in the light of the most recent and relevant scientific data published in the scientific literature. All concerns related to human and animal health or environment raised by Italy were already addressed in previous scientific opinions of the EFSA GMO Panel on maize MON 810. The remaining concern relates to co-existence and thus falls outside the remit of EFSA and its GMO Panel.

Therefore, the EFSA GMO Panel concludes that, based on the documentation submitted by Italy, there is no specific scientific evidence, in terms of risk to human and animal health or the environment, that would support the notification of an emergency measure under Article 34 of Regulation (EC) No 1829/2003 and that would invalidate its previous risk assessments of maize MON 810.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

The placing on the market for cultivation of the genetically modified (GM) maize MON 810 in the European Union (EU) is authorized since 1998 through Commission Decision 98/294/EC of 22 April 1998 (EC, 1998) and the consent granted on 3 August 1998 by the Competent Authority of France.

On 15 June 2009, following the request by the applicant for the renewal of the authorisation for placing maize MON 810 on the market, the EFSA GMO Panel adopted a Scientific Opinion⁴ on the renewal under Regulation (EC) No 1829/2003 (EC, 2003) of maize MON 810 for import, processing for food and feed uses and cultivation (EFSA, 2009). The EFSA GMO Panel concluded that “*maize MON 810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target (NT) Lepidoptera*”. The EFSA GMO Panel recommended that, “*especially in areas of abundance of non-target Lepidoptera populations, the adoption of the cultivation of maize MON 810 be accompanied by management measures in order to mitigate the possible exposure of these species to maize MON 810 pollen*”. Further, the EFSA GMO Panel advised that “*resistance management strategies continue to be employed and that the evolution of resistance in lepidopteran target pests continues to be monitored in order to detect potential changes in resistance levels in pest populations*”.

On 30 November 2011, the EFSA GMO Panel adopted a Statement supplementing the evaluation of the environmental risk assessment (ERA) and risk management recommendations on the GM insect resistant maize Bt11 for cultivation (EFSA, 2011b). In its Statement on maize Bt11, the EFSA GMO Panel made recommendations for management measures and concluded that, “*subject to appropriate management measures, maize Bt11 cultivation is unlikely to raise additional safety concerns for the environment compared to conventional maize*”. In light of the similarities between both GM Cry1Ab-expressing maize Bt11 and MON 810 (e.g., identity of amino acid sequence in core protein, similar biological activity against sensitive Lepidoptera, similar Cry1Ab protein expression level in pollen), the EFSA GMO Panel considered that the conclusions on the risk to non-target Lepidoptera from maize Bt11 apply equally to maize MON 810.

On 6 December 2012, in response to two requests of the European Commission to provide additional evidence and to further clarify certain aspects of the above statement, the EFSA GMO Panel adopted two scientific opinions supplementing and updating the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of maize Bt11 and MON 810 (EFSA, 2012c,d). The EFSA GMO Panel concluded that its previous risk assessment conclusions on maize MON 810 as well as its recommendations on risk management measures and monitoring remain valid and applicable.

Furthermore, the EFSA GMO Panel was requested by the European Commission to assess the post-market environmental monitoring (PMEM) reports submitted by the applicant on the cultivation of maize MON 810 in 2009 and 2010. The EFSA GMO Panel therefore adopted a scientific opinion on the 2009 and 2010 PMEM reports on maize MON 810, on 7 September 2011 (EFSA, 2011a) and 7 March 2012 (EFSA, 2012b) respectively. The EFSA GMO Panel did not identify adverse effects on the environment, human and animal health due to maize MON 810 cultivation during the 2009 and 2010 growing seasons.

On 29 March 2013, Italy requested the European Commission to introduce an emergency measure pursuant to Article 34 of Regulation (EC) No 1829/2003 on maize MON 810.

⁴ This Scientific Opinion was published on the [EFSA webpage](#) on 30 June 2009.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The EFSA GMO Panel is requested in accordance with Article 29 of Regulation (EC) No 178/2002 to provide a scientific opinion:

- (1) assessing if the Italian authorities submitted new scientific evidence in support of its request for a prohibition of GM maize MON 810 cultivation according to Article 34 of Regulation (EC) 1829/2003; and, where appropriate,
- (2) indicating whether this new scientific evidence might lead the EFSA GMO Panel to reconsider its previous safety assessments of GM maize MON 810.

ASSESSMENT

The EFSA GMO Panel has scrutinized the documentation provided by Italy in support of its emergency measure on maize MON 810. According to the terms of reference set by the European Commission, the EFSA GMO Panel assessed whether the submitted documentation comprises new scientific information that would invalidate the conclusions of its previous risk assessments of maize MON 810 (EFSA, 2009, 2011a,b, 2012a,b,c,d). Moreover, the EFSA GMO Panel considered the relevance of concerns raised by Italy in the light of the most recent and relevant scientific data published in the scientific literature.

The EFSA GMO Panel found that all concerns related to human and animal health or the environment raised by the Italian authorities on maize MON 810 (e.g. gene flow between GM and non GM plants, impacts of maize MON 810 on non-target organisms) were considered previously in its scientific opinions on maize MON 810 (EFSA, 2009, 2011a,b, 2012a,b,c,d).

The EFSA GMO Panel has noted that, in its supporting documentation, the Italian authorities refer to the same concerns previously raised by France in its notification to the European Commission of an emergency measure on maize MON 810. These concerns were already addressed by the EFSA GMO Panel in its scientific opinion, adopted on 7 May 2012 (EFSA, 2012a), and concluding that no new science-based evidence was provided by France that would support the notification of an emergency measure under Article 34 of Regulation (EC) No 1829/2003 and that would invalidate its previous risk assessments of maize MON 810.

Moreover, the Italian authorities refer to two reports (i.e. Franke et al. (2011), Sweet and Bartsch (2012)) and claim that these reports provide further elements as regards the impact of the GM cultivation on the environment. The Dutch report by Franke et al. (2011) addresses the question of sustainability of GM crops to be imported to The Netherlands in comparison with the cropping of conventional crops. The authors consider the sustainability and benefits of a GM-based cropping system from an environmental (e.g. soil and water conservation, biodiversity), economic (e.g. farmer income) and human (e.g. health of workers) viewpoints. The report by Sweet and Bartsch (2012) provides a synthesis and overview of the worldwide scientific information on GMOs of relevance to Swiss environments. The EFSA GMO Panel did not find any new scientific and specific information related to the safety of maize MON 810 in either report referred to by the Italian authorities.

An additional concern of the Italian authorities relates to co-existence and thus falls outside the remit of EFSA and its GMO Panel.

CONCLUSIONS

In the documentation provided by Italy in support of the current emergency measure on maize MON 810, the EFSA GMO Panel could not identify any new science-based evidence to support the notified emergency measure and to invalidate its previous conclusions on the safety of maize MON 810 (EFSA, 2009, 2011a,b, 2012a,b,c,d). Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize MON 810, as well as its previous recommendations for risk mitigation measures and monitoring, remain valid and applicable.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 29 May 2013, to the EFSA Executive Director requesting the assessment by EFSA of the scientific elements supporting the request from Italy to take emergency measure on the placing on the market of GM maize MON 810 for cultivation purposes in the EU.
2. Acknowledgement letter, dated 28 June 2013, from the EFSA Executive Director to the European Commission.

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