European Food Safety Authority

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STATEMENT OF EFSA

Statement on a request from the European Commission related to the emergency measure notified by Greece on genetically modified maize MON 810 according to Article 18 of Directive 2002/53/EC[1]

European Food Safety Authority[2]

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ABSTRACT

Following a request of the European Commission, the European Food Safety Authority (EFSA) evaluated the documentation submitted by Greece in support of its request for the prohibition of the placing on the market of the genetically modified maize MON 810 for cultivation according to Article 18 of Directive 2002/53/EC. All concerns on the safety of maize MON 810 related to human and animal health or the environment raised by Greece were already addressed in previous outputs of the EFSA or its GMO Panel on maize MON 810 or related Bt maize events expressing Cry1Ab protein. The concern pertaining to co-existence was not considered as this is not in the remit of EFSA. Therefore, EFSA concludes that, based on the documentation submitted by Greece, 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 18 of Directive 2002/53/EC and that would invalidate the previous EFSA GMO Panel risk assessments of maize MON 810.

KEY WORDS

GMO, maize (*Zea mays*), MON 810, Greece, emergency measure, environment, Directive 2002/53/EC

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SUMMARY

On 11 March 2014, the European Commission requested the European Food Safety Authority (EFSA) to assess the supporting documentation submitted by Greece to introduce an emergency measure pursuant to Article 18 of Directive 2002/53/EC on genetically modified (GM) maize MON 810 cultivation in the European Union (EU).

EFSA considered the relevance of the concerns raised by Greece in the light of the most recent and relevant publications. All concerns on the safety of maize MON 810 related to human and animal health or environment raised by Greece were already addressed in previous outputs of the EFSA or its GMO Panel on maize MON 810 or related Bt maize events expressing Cry1Ab protein. The remaining concern pertaining to co-existence was not considered as this is not in the remit of EFSA.

Therefore, EFSA concludes that, based on the documentation submitted by Greece, 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 18 of Directive 2002/53/EC and that would invalidate the previous EFSA GMO Panel 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 maize MON 810 in the EU is authorised 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.

In April 2007, a notification concerning the renewed authorisation of the placing on the market of existing products of maize MON 810 was submitted to the European Commission. The notification covers the continued placing on the market of seeds and plant propagating material of varieties derived from maize MON810 for cultivation in the EU.

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 issued a Scientific Opinion[3] on the renewal under Regulation (EC) No 1829/2003 of maize MON 810 for import, processing for food & feed uses and cultivation (EFSA, 2009a). This opinion concludes that "*maize MON810 is as safe as its conventional counterpart with respect to potential effects on human and animal health, and that maize MON810 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.*"

On 30 November 2011, the EFSA GMO Panel issued a statement supplementing the evaluation of the environmental risk assessment (ERA) and risk management recommendations on maize Bt11 for cultivation (EFSA GMO Panel, 2011e). In its Statement on maize Bt11, the EFSA GMO Panel concludes 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 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: one supplementing the conclusions of the ERA and risk management recommendations for the cultivation of maize Bt11 and MON 810 (EFSA GMO Panel, 2012c); and the second one updating the risk assessment conclusions and risk management recommendations on maize MON 810 (EFSA GMO Panel, 2012d). Based on the performed literature search, 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.*"

In November 2011, Greece notified to the European Commission its scientific argumentation justifying the implementation of a national Ministerial Decision prohibiting the use and sale of maize MON 810 as seed for sowing, according to Article 23 of Directive 2001/18/EC (EC, 2001) on the deliberate release in the environment of GMOs.

In a letter received on 13 November 2013, Greece informed the European Commission of its intention to prolong the implementation of the national safeguard measure prohibiting the release in the environment for use and trade of maize MON 810, based on Article 18 of Directive 2002/53/EC (EC, 2002) and providing scientific argumentation justifying this request.

In order for the European Commission to appropriately follow-up on this announcement from Greece in accordance with Article 18 of Directive 2002/53/EC (EC, 2002a), EFSA is requested to assess if the new scientific evidence would indicate an unacceptable risk for the environment and/or human health and thereby justify this request from Greece.

[3] This Scientific Opinion was published on the EFSA webpage on 30 June 2009.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is requested in accordance with Article 31 of Regulation (EC) No 178/2002 (EC, 2002b) to provide a statement:

1) assessing if the Greek authorities have submitted new scientific evidence in support of their request for a prohibition of GM maize MON 810 cultivation according to Article 18 of Directive 2002/53/EC; 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

EFSA has scrutinized the documentation[4] provided by Greece in support of its emergency measure on maize MON 810. According to the terms of reference set by the European Commission, EFSA assessed whether the submitted documentation comprises new scientific information that would invalidate the conclusions of the previous risk assessments by the EFSA GMO Panel (EFSA GMO Panel, 2009a, 2011a,b, 2012a,b,c,d, 2013a,b,c). Moreover, EFSA considered the relevance of concerns raised by Greece in the light of the most recent and relevant scientific data published in the scientific literature.

EFSA found that all concerns on maize MON 810 related to human and animal health or the environment raised by the Greek authorities were considered previously in the EFSA GMO Panel outputs on maize MON 810 (EFSA GMO Panel, 2009a, 2011a,b, 2012a,b,c,d) or other related EFSA outputs.[5] EFSA did not consider the Greek concern pertaining to co-existence (Haefeker, 2011) as this is not in its remit.

CONCLUSIONS

In the documentation provided by Greece in support of the current measure on maize MON 810, EFSA did 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 GMO Panel, 2009a, 2011a,b, 2012a,b,c,d, 2013a,b,c). Therefore, EFSA considers that the previous EFSA GMO Panel risk assessment conclusions on maize MON 810, as well as the previous recommendations for risk mitigation measures and monitoring, remain valid and applicable.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 11 March 2014, to the EFSA Executive Director requesting the assessment by EFSA of the scientific elements supporting the request from Greece to take emergency measure on the placing on the market of GM maize MON 810 seeds for cultivation purposes in the EU.

2. Acknowledgement letter, dated 28 March 2014, from the EFSA Executive Director to the European Commission.

[4] Available at http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?unit=GMO (with Question Number EFSA-Q-2014-00180)

[5] Please consult the EFSA letter in response to a request from the European Commission to assess reports on maize 1507 from Testbiotech, available at http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?unit=GMO (with Question Number EFSA-Q-2014-00192)

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