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STATEMENT OF EFSA

Statement on a request from the European Commission related to the emergency measure notified by Bulgaria on genetically modified maize MON 810 according to Article 34 of Regulation (EC) 1829/2003[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request of the European Commission, the European Food Safety Authority (EFSA) evaluated the concerns raised by Bulgaria and the accompanying documentation submitted under Article 34 of Regulation (EC) 1829/2003 in support of its request to prohibit the cultivation of the genetically modified maize MON 810 in the European Union. EFSA concludes that neither the arguments put forward by Bulgaria nor the documentation reveal new scientific evidence, in terms of risk to human and animal health or the environment, that would support the adoption of an emergency measure on the cultivation of maize MON 810 under Article 34 of Regulation (EC) 1829/2003. In the absence of new relevant scientific evidence, EFSA concludes that its previous risk assessment conclusions and risk management recommendations on maize MON 810 and those of its GMO Panel remain valid and applicable.

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KEY WORDS

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

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SUMMARY

Upon request of the European Commission, the European Food Safety Authority (EFSA) evaluated the concerns raised by Bulgaria and the accompanying documentation submitted under Article 34 of Regulation (EC) 1829/2003[3] in support of its request to prohibit the cultivation of the genetically modified (GM) maize MON 810 in the European Union.

EFSA did not identify new arguments related to maize MON 810 or the Cry1Ab protein that reveal new scientific evidence in terms of risk to human and animal health or the environment. In addition, EFSA did not further consider the peer-reviewed publications, referred to by Bulgaria, that were previously addressed in its scientific outputs on maize MON 810 or related *Bt* maize events expressing Cry1Ab protein, or those of its GMO Panel.

For completeness of the evaluation, EFSA considered the proceedings abstract by Büchs et al. (2004) referred to in the report submitted by Bulgaria. However, due to limitations of the publication format and in the absence of sufficient information on the experimental design of the study and data generation and analysis, EFSA could not draw any conclusions on the reliability and relevance of this abstract for the present evaluation nor for the risk assessment of maize MON 810 in general. Therefore EFSA strongly recommends Member States who invoke safeguard clauses under Directive 2001/18/EC[4] or emergency measures under Regulation (EC) No 1829/2003 to supply relevant new scientific data of a quality which can be subjected to detailed scientific scrutiny.

EFSA therefore concludes that neither the arguments put forward by Bulgaria nor the supporting documentation reveal new scientific evidence, in terms of risk to human and animal health or the environment, that would support the adoption of an emergency measure on the cultivation of maize MON 810 under Article 34 of Regulation (EC) 1829/2003. In the absence of new relevant scientific evidence, EFSA concludes that its previous risk assessment conclusions and risk management recommendations on maize MON 810 and those of its GMO Panel remain valid and applicable.

[3] Regulation 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.

[4] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 17.04.2001, p. 1-39.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

The marketing of maize MON 810 (notification C/F/95/12-02) was authorised under Directive 90/220/EEC[5] in the European Union (EU) for all, other than food, uses by the Commission Decision 98/294/EC[6] of 22 April 1998. Consent was granted to the applicant (Monsanto Europe S.A.) by France on 3 August 1998. Food uses of maize derivatives were notified according to Article 5 of the Novel Food Regulation (EC) No 258/97[7] on 6 February 1998.

On 15 June 2009, the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (hereafter referred to as EFSA GMO Panel) issued a scientific opinion on the renewal of the authorisation for the continued marketing of: (1) existing food and food ingredients produced from maize MON 810; (2) feed consisting of and/or containing maize MON 810, including the use of seed for cultivation; and (3) food and feed additives, and feed materials produced from maize MON 810. The EFSA GMO Panel concluded that "*maize MON 810 is as safe as its conventional counterpart with respect to potential effects on human and animal health", and 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*". In addition, 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*" (EFSA, 2009).

On 30 November 2011, the EFSA GMO Panel adopted a statement supplementing the environmental risk assessment conclusions and risk management recommendations on maize Bt11 cultivation (EFSA Panel on Genetically Modified Organisms, 2011b). In its statement, the EFSA GMO Panel concluded that "*subject to appropriate management measures, maize Bt11 cultivation is unlikely to raise additional safety concerns for the environment compared to conventional maize*" (EFSA Panel on Genetically Modified Organisms, 2011b). The EFSA GMO Panel considered that the environmental risk assessment conclusions and risk management recommendations on non-target Lepidoptera for maize Bt11 apply equally to maize MON 810 due to the similarities between both *Bt* maize events (i.e., identity of amino acid sequence of the core of the Cry1Ab protein, similar biological activity against susceptible Lepidoptera, similar Cry1Ab protein expression level in pollen).

The EFSA GMO Panel further supplemented its previous risk management recommendations on maize Bt11 and MON 810 cultivation by reapplying the mathematical model developed by Perry et al. (2010, 2011, 2012), in order to consider additional hypothetical agricultural conditions, and to provide additional information on the factors affecting the insect resistance management (IRM) strategy (EFSA Panel on Genetically Modified Organisms, 2012d).

On 6 December 2012, following a request from the European Commission, the EFSA GMO Panel compiled its previous risk assessment conclusions and risk management recommendations on maize MON 810, and considered their validity in the light of new relevant scientific publications published from 2009 onwards (EFSA Panel on Genetically Modified Organisms, 2012e). 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.*"

[5] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. OJ L 117, 8.5.1990, p. 15-27.
[6] Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON810), pursuant to Council Directive 90/220/EEC (98/294/EC). OJ L 131, 5.5.1998, p. 32-33.
[7] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1-9.

Following requests of the European Commission to assess the annual post-market environmental monitoring (PMEM) reports on maize MON 810 cultivation submitted by the applicant, the EFSA GMO Panel issued scientific opinions on the 2009, 2010, 2011 and 2012 PMEM reports on maize MON 810 (EFSA Panel on Genetically Modified Organisms, 2011a, 2012a, 2013c, 2014). The EFSA GMO Panel noted shortcomings in the methodology for case-specific monitoring and general surveillance, and made recommendations to strengthen the annual PMEM activities on the GM maize. So far, the data submitted by the applicant in its PMEM reports did not indicate any adverse effects on human and animal health or the environment arising from the cultivation of maize MON 810.

Several EU Member States invoked safeguard clauses or emergency measures to provisionally restrict or prohibit the marketing of maize MON 810 on their territory. EFSA or its GMO Panel has been asked by the European Commission to evaluate whether the invocation was justifiable on the basis of the scientific information submitted in support of a safeguard clause or emergency measure. For all cases, EFSA or its GMO Panel concluded that, in terms of risk to human and animal health and the environment, no new scientific evidence had been presented that would invalidate its previous risk assessment conclusions on maize MON 810 (EFSA, 2004, 2005, 2006a, b, 2008a, b, c, d, 2014a, b; EFSA Panel on Genetically Modified Organisms, 2012b, c, 2013a, b, 2014).

In April 2014, Bulgaria notified to the European Commission the need to take emergency measures under Article 34 of Regulation (EC) 1829/2003[8] but at that time did not provide any scientific evidence to support the proposed measures prohibiting the cultivation of maize MON 810.

In July 2014, Bulgaria notified to the European Commission its analytical report justifying the implementation Decision No 431/26.06.2014 of the Council of Ministers of Republic of Bulgaria prohibiting the cultivation of maize MON 810 on the territory of Bulgaria.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is requested, in accordance with Article 31 of Regulation (EC) 178/2002,[9] to provide a statement:

1. assessing if the Bulgarian authorities have submitted new scientific evidence in support of their 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 GMO Panel to reconsider its previous safety assessments of GM maize MON 810.

CONTEXT OF THE SCIENTIFIC OUTPUT

The legislative framework regulating GMOs in the EU gives Member States the possibility to temporarily restrict the placing on the market of a GMO or its derived food and feed products on their territory or in the EU subject to indications of a clear and serious risk to the human and animal health or the environment. Member States invoking the so called 'safeguard clauses' under Article 23 of Directive 2001/18/EC or 'emergency measures' under Article 34 of Regulation (EC) 1829/2003 must justify their claims with new or additional scientific evidence that was made available after the consent for placing on the market of the GMO or its derived food and feed products was granted.

In this statement, EFSA evaluates, upon request of the European Commission, whether the documentation (a report and its complete list of references) submitted by Bulgaria justifies or invalidates its request to prohibit the cultivation of maize MON 810.

[8] Regulation 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.

[9] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1-24.

EFSA considers the concerns put forward by Bulgaria in the light of recent and relevant scientific publications. Concerns of Bulgaria related to co-existence and socio-economic aspects as well as regulatory- and policy-related documents listed in the report provided by Bulgaria are not considered in this statement as they fall outside the remit of EFSA and its GMO Panel.

EVALUATION

At the request of the European Commission, EFSA evaluated the concerns raised by Bulgaria and the accompanying documentation (a report and its complete list of references).

EFSA points out that the arguments put forward by Bulgaria in the aforementioned report do not reveal new scientific evidence in terms of risk to human and animal health or the environment. EFSA also notes that the peer-reviewed publications, referred to in the report, were addressed previously by EFSA or its GMO Panel in various scientific outputs on maize MON 810 or related *Bt* maize events expressing Cry1Ab protein (EFSA, 2004, 2005, 2006a, b, 2008a, b, c, d, 2014a, b; EFSA Panel on Genetically Modified Organisms, 2012b, c, 2013a, b, 2014). These publications are therefore not considered further in this statement.

The list of references cited by Bulgaria also contains a workshop proceedings abstract by Büchs et al. (2004). Even though not recently published, the latter was considered by EFSA for completeness of the evaluation. However, owing to limitations of the publication format (an abstract) and in the absence of sufficient information on the experimental design of the study and data generation and analysis, EFSA could not draw any conclusions on the reliability and relevance of this abstract for the present evaluation nor for the risk assessment of maize MON 810 in general. In order to facilitate a thorough assessment of potential risks and quality appraisal of supplied studies, EFSA strongly recommends Member States who invoke safeguard clauses under Directive 2001/18/EC or emergency measures under Regulation (EC) No 1829/2003 to provide relevant new scientific data of a quality which can be subjected to detailed scientific scrutiny.

In addition, EFSA is not aware of any literature including recent peer-reviewed publication(s) with new relevant and detailed scientific data that would invalidate previous risk assessment conclusions and risk management recommendations on maize MON 810 (e.g., EFSA Panel on Genetically Modified Organisms, 2011 b, 2012 d, e, 2013 c; EFSA, 2009).

CONCLUSIONS

EFSA concludes that neither the arguments put forward by Bulgaria nor the supporting documentation reveal new scientific evidence, in terms of risk to human and animal health or the environment, that would support the adoption of an emergency measure on the cultivation of maize MON 810 under Article 34 of Regulation (EC) 1829/2003. In the absence of new relevant scientific evidence, EFSA concludes that its previous risk assessment conclusions and risk management recommendations on maize MON 810 and those of its GMO Panel remain valid and applicable.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 19 November 2014, to the EFSA Executive Director requesting the assessment by EFSA of the scientific elements supporting the request from Bulgaria to take emergency measure on the placing on the market of maize MON 810 seeds for cultivation purposes in the EU.

2. Acknowledgement letter, dated 8 December 2014, from the EFSA Executive Director to the European Commission.

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