EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on an application (EFSAGMO-NL-2012-107) for the placing on the market of maize MON 810 pollen under Regulation (EC) No 1829/2003 from Monsanto

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SCIENTIFIC OPINION

Scientific Opinion on an application (EFSA-GMO-NL-2012-107) for the placing on the market of maize MON 810 pollen under Regulation (EC) No 1829/2003 from Monsanto[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3]

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ABSTRACT

In this opinion, the EFSA GMO Panel addresses the safety of maize MON 810 pollen to complete the scope of an application (RX-MON 810) for the marketing of genetically modified maize MON 810 with the use of MON 810 pollen as or in food. Data on molecular characterisation of maize MON 810 did not raise any safety concerns with respect to its pollen. The EFSA GMO Panel has previously assessed the safety of the newly expressed Cry1Ab protein in maize MON 810. The assessment and conclusions of the GMO Panel on the safety of this protein, including its potential toxicity and allergenicity, also apply to the Cry1Ab protein expressed in MON 810 pollen. While the EFSA GMO Panel is not in a position to conclude on the safety of maize pollen in or as food in general, it concludes that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen is to replace maize pollen from non-GM maize in or as food.

KEY WORDS

GMO, maize, MON 810 pollen, food, Cry1Ab, honey.

[1] On request from the Competent Authority of the Netherlands for an application (EFSA-GMO-NL-2012-107) submitted by Monsanto, Question No EFSA-Q-2012-00408, adopted on 6 December 2012.

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SUMMARY

Following the submission of an application (EFSA-GMO-NL-2012-107) under Regulation (EC) No 1829/2003 from Monsanto, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the safety of the genetically modified (GM) maize MON 810 pollen as or in food.

In delivering its scientific opinion, the EFSA GMO Panel considered the application EFSA-GMO-NL-2012-107, other applications related to maize MON 810 submitted in the European Union (EU), scientific comments submitted by the Member States and relevant scientific publications.

The molecular characterisation data established that maize MON 810 expresses the Cry1Ab insecticidal protein under the control of enhanced 35S promoter from *Cauliflower* mosaic virus and incorporates the maize Hsp70 intron. Bioinformatic analysis of the open reading frames spanning the junctions between the inserted DNA and maize genomic DNA did not raise safety concerns. The stability of the inserted DNA was confirmed over several generations, implying that the integrity of the insert was maintained throughout microsporogenesis and pollen production. Analyses of the levels of newly expressed proteins in various plant tissues did not raise safety concerns. Levels of Cry1Ab in pollen were undetectable or lower than levels observed in maize MON 810 grain and forage.

With regards to the newly expressed Cry1Ab protein, the results of the molecular characterisation indicate that the same Cry1Ab protein is expressed in pollen as in other parts of the plant. Therefore, the assessment and conclusions reached by the GMO Panel on the safety of the protein Cry1Ab, including its potential toxicity and allergenicity, for food/feed aspects also apply to pollen.

While limited data are available on the compositional and safety characteristics of maize pollen in general and pollen of maize MON 810 in particular, the EFSA GMO Panel considered a range of additional data constituting a weight of evidence approach for the safety of maize MON 810 pollen compared with other maize pollen. These data consist of (1) the above-mentioned molecular characterisation of maize MON 810; (2) extensive data on composition and agronomic/phenotypic characteristics in maize MON810, including reproductive traits related to pollen production and viability; and (3) the food and feed safety of maize MON 810 and the newly expressed Cry1Ab protein. These data do not indicate potential concerns over the safety of the newly expressed Cry1Ab protein or the occurrence of unintended effects that could raise safety concerns.

While the EFSA GMO Panel is not in a position to conclude on the safety of maize pollen occurring in or as food in general, it concludes that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen were to replace maize pollen from non-GM maize in or as food.

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BACKGROUND

On 12 March 2012, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application (Reference EFSA-GMO-NL-2012-107), for authorisation of maize MON 810 (Unique Identifier MON-ØØ81Ø-6) pollen, submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on GM food and feed.[4] After having received the application EFSA-GMO-NL-2012-107 and in accordance with Article 5(2)(b) of Regulation (EC) No 1829/2003, EFSA informed Member States and the European Commission, and made the summary of the application available to the public on the EFSA website. EFSA initiated a formal review of the application to check compliance with the requirements laid down in Articles 5(3) of Regulation (EC) No 1829/2003. On 29 May 2012, EFSA declared the application as formally valid in accordance with Articles 6(1) of Regulation (EC) No 1829/2003.

EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC[5] following the requirements of Article 6(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. Member State bodies had three months after the date of receipt of the valid application (until 28 August 2012) within which to make their opinion known.

The EFSA Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) carried out an evaluation of the scientific risk assessment of the maize MON 810 pollen as or in food, in accordance with Article 6(6) of Regulation (EC) No 1829/2003. When carrying out the safety evaluation, the EFSA GMO Panel took into account the principles described in its risk assessment and monitoring guidelines (EFSA, 2006, 2011a), other applications related to maize MON 810 submitted in the European Union (EU) and the scientific comments of the Member States.

In giving its Scientific Opinion on maize MON 810 pollen to the European Commission, the Member States and the applicant in accordance with Article 6(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of six months from the acknowledgement of the valid application.

According to Regulation (EC) No 1829/2003, this Scientific Opinion is to be seen as the report requested under Article 6(6) of that Regulation and thus will be part of the EFSA overall opinion in accordance with Article 6(5).

TERMS OF REFERENCE

The EFSA GMO Panel was requested to carry out a scientific risk assessment of maize MON 810 pollen as or in food in accordance with Article 6(6) of Regulation (EC) No 1829/2003. Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas should be indicated in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003.

The EFSA GMO Panel was not requested to give a Scientific Opinion on information required under Annex II to the Cartagena Protocol, nor on the proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

[4] 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, pp. 1–2).

[5] Directive 20010/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17/04/2001, pp. 1–38).

1. Introduction

Maize MON 810 is intended to be cultivated and used like any conventional maize in the EU. This opinion covers the possible consequences of the substitution of pollen of maize origin with pollen of maize MON 810 and does not consider the safety of pollen per se.

Most consumers are known to be exposed to pollen via consumption of honey containing pollen collected by bees. A high intake of honey, corresponding to 50 g per person per day (JECFA, 2008; EFSA, 2011b) corresponds to an intake of 190 mg of maize pollen per individual, or 3.2 mg pollen per kilogram body weight for an individual weighing 60 kg (EFSA, 2011c).

A higher intake may result from the use of pollen pellets as food supplements which may lead to exposures as high as 36 g per person per day for adults.

The evaluation of the risk assessment presented here is based on the information provided in the application relating to maize MON 810 pollen, including issues raised by the Member States (see Annex G), other applications related to maize MON 810 submitted in the European Union (EU) and other relevant scientific publications.

ASSESSMENT

Maize MON 810 has been developed to provide protection against certain lepidopteran target pests, such as the European corn borer (*Ostrinia nubilalis*), and species belonging to the genus *Sesamia* (in particular the Mediterranean corn borer (*Sesamia nonagrioides*)), by the introduction of a truncated *Bacillus thuringiensis* (Bt) gene encoding the insecticidal Cry1Ab protein.

2. Expression of Cry1Ab in pollen

Maize MON 810 expresses the insecticidal protein Cry1Ab under the control of enhanced 35S promoter from *Cauliflower mosaic virus*. Stability of the single MON 810 insert over three generations was established by Southern analyses, implying that the integrity of the insert was maintained throughout microsporogenesis and pollen production (EFSA, 2009a).

In field trials carried out in 1994 and 1995 in the USA, France and Italy, the levels of Cry1Ab in pollen ranged from undetectable to 0.097 µg/g fresh weight (fw) in trials carried out in the USA and in Germany (EPA, 2000; Nguyen and Jehle, 2007). In comparison, the levels of Cry1Ab protein ranged in young leaf tissue from 7.59 to 10.34 µg/g fw, in forage from 3.65 to 9.23 µg/g fw and in grain from 0.19 to 0.69 µg/g fw (EFSA, 2009a). Székács *et al.* (2010) reported similar Cry1Ab levels [after allowance for the dry weight (dw) basis of analysis] in pollen to be 0.47 µg/g dw: levels in other tissues were approximately 17 µg/g dw in leaves, 5 µg/g dw in roots and 0.8 µg/g dw in grain.

3. Comparative analysis of MON 810

Pollen analysis forms part of the comparative assessment of a crop's agronomic and phenotypic characteristics.

With regard to the comparative compositional analysis, no guidance exists for the compositional analysis of pollen (*e.g.*, OECD consensus documents detailing recommendations for key compositional parameters for new plant varieties). Moreover, only a limited number of data are available with regard to the composition of maize pollen collected from the plant as such (Pfahler and Linskens, 1970, 1971, 1973; Ceska and Styles, 1984; Bianchi *et al*., 1990; Anaya *et al*., 1992) and pollen collected by bees [reviewed by Roulston and Cane (2000) and Campos *et al*. (2008)].

To date, the Panel has not seen the need for specific data on pollen composition and has presumed compositional similarity provided that experimental data confirm similarity in other maize tissues (*i.e.* grains and forage).

3.1. Agronomic and phenotypic characteristics

The agronomic and phenotypic characteristics of maize MON 810 in relation to appropriate non-GM maize control materials having a comparable genetic background have been assessed by the EFSA GMO Panel in connection with the renewal applications for food and feed use and cultivation of maize MON 810 (EFSA, 2009a), as well as in connection with the assessment of several stacked GM maize events (EFSA, 2005a,b,c,d,e, 2009b). It was concluded that maize MON 810 is agronomically and phenotypically equivalent to currently grown non-GM maize varieties, with the exception of the insect resistance conferred by the Cry1Ab protein (EFSA, 2009a). In particular, pollen production and viability remained unchanged in maize MON 810 relative to its comparator (EFSA, 2009a).

3.2. Composition

The previous safety assessment of maize MON 810 included an extensive comparative compositional assessment of forage and grains from MON 810 and from its conventional counterpart, showing that there were no biologically relevant compositional differences between maize MON 810 and its comparator, except for the introduced traits (EFSA, 2009a).

4. Safety of Cry1Ab protein for human health

The EFSA GMO Panel has previously assessed the safety of the Cry1Ab protein in MON 810 and did not identify concerns regarding potential toxicity and allergenicity. The results of the molecular characterisation indicate that the same Cry1Ab protein is expressed in pollen as in other parts of the plant (EFSA, 2009a). Therefore the assessment and conclusions of the GMO Panel on safety of the protein Cry1Ab, including toxicity and allergenicity, reached for food/feed aspects (EFSA, 2009a) also apply to pollen. In addition, as mentioned above, the levels of Cry1Ab in pollen were lower than in grains and the other tissues analysed.

5. Safety of MON 810 pollen for human health

As only limited data are available on the compositional and safety characteristics of maize pollen in general, and of pollen of maize MON 810 in particular, the EFSA GMO Panel considered a range of data constituting a weight-of-evidence approach for the safety of maize MON 810 pollen compared with other maize pollen. These data consisted of:

1. The above-mentioned molecular characterisation of maize MON 810;

2. The extensive data on composition and agronomic/phenotypic characteristics of maize MON810, including reproductive traits related to pollen production and viability;

3. The safety of the Cry1Ab protein, as expressed in maize MON 810.

As no concerns have thus been identified over the safety of maize MON 810 relative to that of non-GM maize, the EFSA GMO Panel considers it unlikely that the replacement of non-GM maize pollen with maize MON 810 pollen would raise additional safety issues.

6. Conclusion

While the EFSA GMO Panel is not in a position to conclude on the safety of maize pollen in or as food in general, it concludes that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen were to replace maize pollen from non-GM maize in or as food.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the Competent Authority of the Netherlands, received on 15 March 2012, concerning a request for placing on the market of pollen MON 810 in the European Union in accordance with Regulation (EC) No 1829/2003.

2. Acknowledgement letter, dated 3 April 2012, from EFSA to the Competent Authority of The Netherlands (Ref. PB/KL/EW/sm (2012) out-6472368).

3. Letter from EFSA to the applicant, dated 25 April 2012, requesting additional information under completeness check (Ref. KL/EW/CE/sm (2012) out-6513991).

4. Letter from the applicant, received on 14 May 2012, providing additional information under completeness check.

5. Letter from EFSA to the applicant, dated 29 May 2012, delivering the "Statement of Validity" for application EFSA-GMO-NL-2012-107, pollen MON 810 submitted by Monsanto Europe S.A./N.V. under Regulation (EC) No 1829/2003 (Ref. KL/EW/sm (2012) out-6602627).

6. Letter from the applicant, received on 4 June 2012, providing EFSA with an updated version of the application EFSA-GMO-NL-2012-107 submitted by Monsanto Europe S.A./N.V. under Regulation (EC) No 1829/2003.

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