SCIENTIFIC OPINION

Statement on the safety of MON810 maize pollen occurring in or as food[1]

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

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ABSTRACT

In this statement the EFSA GMO Panel responds to a request from the European Commission on whether data provided within application RX-MON810 on maize MON810 are sufficient to conclude on the safety of MON810 pollen as or in food and, if it is the case, to confirm MON810 pollen safety. Data on molecular characterisation did not identify features of maize MON810 pollen with a potential to raise any safety concerns. The EFSA GMO Panel has previously assessed the safety of the Cry1Ab protein in MON810 and the assessment and conclusions of the GMO Panel on safety of the protein Cry1Ab (including toxicity and allergenicity) reached for food/feed aspects also apply to 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 MON810 maize does not constitute an additional health risk if MON810 maize pollen were to replace maize pollen from non-GM maize in or as food.

KEY WORDS

GMO, maize, MON810 pollen, food, Cry1Ab, honey

[1] On request from the European Commission, Question No EFSA-Q-2011-01092, adopted on 20 October 2011.

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SUMMARY

Following the submission of a request from the European Commission received on 4 October 2011 the EFSA GMO Panel was asked to verify whether data provided within application RX-MON810 where sufficient to positively conclude on the safety of MON810 pollen as or in food and if this is the case to confirm its safety.

In delivering its scientific statement, the GMO Panel considered the data available on the safety of MON810 maize in application RX-MON810, as well as data available on maize pollen in general, and MON810 maize pollen in particular.

The molecular characterisation data established that maize MON810 expresses the Cry1Ab insecticidal protein under the control of enhanced 35S promoter from *Cauliflower mosaic virus* and incorporates the maize *Hsp*70 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 ranged from undetectable to 0.097 μg/g fw, which is lower than levels observed in MON810 maize 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 of the GMO Panel on safety of the protein Cry1Ab (including toxicity and allergenicity) reached for food/feed aspects also apply to pollen.

For maize MON810 grain and forage, the GMO Panel previously concluded, based on data from field trials as presented in application RX-MON810, that maize MON810 is compositionally, phenotypically and agronomically not different from the non-GM counterparts and conventional maize varieties, except for the new trait.

While limited data are available on the compositional and safety characteristics of maize pollen in general and in particular on those of MON810 maize pollen in comparison to non-GM maize pollen, the EFSA GMO Panel considered a range of additional data constituting a weight of evidence approach for the safety of MON810 maize pollen. These data consist of 1) the abovementioned molecular characterization of MON810 maize; 2) its extensive comparative data of agronomic, phenotypic and compositional characteristics, including reproductive traits related to pollen production and viability; and 3) the food and feed safety of MON810 maize and the newly expressed Cry1Ab protein. These data neither indicate potential concerns over the safety of the newly expressed Cry1Ab protein nor the occurrence of unintended effects that could raise safety concerns.

Maize MON810 is intended to be cultivated and used like any conventional maize which was the basis for a theoretical estimate of exposure of consumers to MON810 maize pollen through consumption of honey containing this pollen instead of pollen from non-GM maize. Since the level of exposure was found low, any unexpected, unintended effect of the genetic modification, if it occurred, would not be likely to result in an adverse health effect from honey consumption.

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 MON810 maize does not constitute an additional health risk if MON810 maize pollen were to replace maize pollen from non-GM maize in or as food.

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EVALUATION

1. Introduction

The EFSA GMO Panel has received a request from the European Commission (4 October 2011, Ref. SANCO/E1/SP/mb Ares (2011) 1144054) to verify whether data provided within application RX-MON810

- Are sufficient to positively conclude on the safety of MON810 pollen as or in food
- If it is the case, to confirm safety

Below, the EFSA GMO Panel summarizes the findings of its review of data available on the safety of MON810 maize and maize pollen in general, and MON810 maize pollen in particular. In short, it concludes that the genetic modification in MON810 maize does not constitute an additional health risk if MON810 maize pollen were to replace maize pollen from non-GM maize in or as food.

2. Molecular characterization aspects

Maize MON810 expresses the Cry1Ab insecticidal protein under the control of enhanced 35S promoter from *Cauliflower mosaic virus* and incorporates the maize *Hsp*70 intron. Stability of the MON810 insert over three generations was established by Southern analyses, implying that the integrity of the insert was maintained throughout microsporogenesis and pollen production (EFSA, 2009). Bioinformatic analyses of the putative translation products of open reading frames spanning the 5' and 3' junction regions of the insert did not reveal significant similarity to known allergens or toxins (EFSA, 2009).

In field trials conducted in 1994 and 1995 in the USA, France and Italy, the levels of Cry1Ab protein in young leaf tissue ranged from 7.59 to 10.34 μg/g fresh weight (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, 2009). Levels of Cry1Ab in pollen ranged from undetectable to 0.097 μg/g fw (EPA, 2000; Nguyen and Jehle, 2007).

Molecular characterisation did not identify features of maize MON810 pollen with a potential to raise any safety concerns.

3. Food Feed aspects

The safety of the newly expressed protein in maize MON810, as well as the safety of pollen from maize MON810 as compared to those from non-GM maize, has been considered by the EFSA GMO Panel.

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 of the GMO Panel on safety of the protein Cry1Ab (including toxicity and allergenicity) reached for food/feed aspects (EFSA, 2009) also apply to pollen. The EFSA GMO Panel has previously assessed the safety of the Cry1Ab protein in MON810 and did not identify concerns regarding potential toxicity and allergenicity. In addition, as mentioned above, the levels of Cry1Ab in pollen were lower than in grains and the other tissues analysed.

With regard to the safety of pollen from maize MON810 as compared to those from non-GM maize, the EFSA GMO Panel considered the possibility that unintended effects of the genetic modification might have occurred in maize MON810 pollen. Unintended effects are identified by the molecular characterisation and the comparative analysis of compositional, agronomic and phenotypic characteristics of the GM crop versus its non-GM comparator, including characteristics related to pollen production and viability. For maize MON810 grain and forage, the GMO Panel previously concluded, based on data from field trials as presented in application RX-MON810, that maize

MON810 is compositionally, phenotypically and agronomically not different from the non-GM counterparts and conventional maize varieties, except for the new trait (EFSA, 2009). No information is available on the composition of pollen of maize MON810 or its conventional counterpart.

The analysis of, and interpretation of data, on pollen composition is constrained by the limited data in the scientific literature on the composition of pollen collected by bees [e.g., reviewed by Campos *et al*. (2008) and Roulston and Cane (2000)] and on that of maize pollen specifically (e.g. Anaya *et al*., 1992; Bianchi *et al*., 1990; Ceska and Styles, 1984; Pfahler and Linskens, 1970, 1971, 1973), and also by the lack of consensus documents (e.g OECD).

Maize MON810 is intended to be cultivated and used like any conventional maize which will be the basis for a theoretical estimate of exposure of consumers to MON810 maize pollen through consumption of honey containing this pollen instead of pollen from non-GM maize.

For the estimated "worst-case" exposure through consumption of honey, it is assumed that honey contains a high level of pollen, *i.e.* 1,000,000 pollen per 10 g of pressed honey (Von der Ohe *et al*., 2004). Of this pollen population, 15% is estimated to be maize pollen, which corresponds to the upper boundary observed in the few samples that tested positive for presence of maize pollen in a semi-quantitative study on honey from the German region of Brandenburg (Hedtke and Etzold, 1996). The weight of a maize pollen grain is set at 250 ng (Fonseca *et al*., 2003). It can be estimated that 15,000 pollen grains, or 3.8 milligrams of maize pollen are contained in a gram of honey. A high intake of honey of 50 grams per person per day (JECFA, 2008; EFSA, 2011) would then correspond to 190 mg of maize pollen per individual or 3.2 mg pollen per kilogram bodyweight for a 60-kg individual. Considering this low level of exposure, any unexpected, unintended effect of the genetic modification, if it occurred, would not be likely to result in an adverse health effect from honey consumption.

There are limited data on the safety of maize pollen consumed as food. As no concerns have been identified over the safety of MON810 maize relative to that of non-GM maize (EFSA, 2009), the EFSA GMO Panel considers it unlikely that the replacement of non-GM maize pollen with MON810 maize pollen would raise additional safety issues.

CONCLUSION

The molecular characteristics, comparative assessment, and the food and feed safety of maize MON810 have been the subject of previous evaluations including the opinion published by the EFSA GMO Panel in 2009 on the request for renewal of the authorized uses of this maize in the European Union (EFSA, 2009). The molecular characterization of the inserted genetic material in MON810 maize expressing the insecticidal Cry1Ab protein, such as the stability of the trait transferred through the reproductive tissues of MON810 maize provides evidence of the intactness of the inserted genetic material within MON810 maize pollen. While limited data are available on the compositional and safety characteristics of maize pollen in general and in particular on those of MON810 maize pollen in comparison to non-GM maize pollen, the EFSA GMO Panel considered a range of additional data constituting a weight of evidence approach for the safety of MON810 maize pollen. These data consist of 1) the abovementioned molecular characterization of MON810 maize; 2) its extensive comparative data of agronomic, phenotypic and compositional characteristics, including reproductive traits related to pollen production and viability; and 3) the food and feed safety of MON810 maize and the newly expressed Cry1Ab protein. These data neither indicate potential concerns over the safety of the newly expressed Cry1Ab protein nor 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 in or as food in general, it concludes that the genetic modification in MON810 maize does not constitute an additional health risk if MON810 maize pollen were to replace maize pollen from non-GM maize in or as food.

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