

SCIENTIFIC OPINION

Scientific Opinion on a question from the European Commission related to the notification by Portugal, pursuant to Article 95 (5) of the EC Treaty, for the prohibition of cultivation of Genetically Modified Plants in the Autonomous Region of Madeira¹

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

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SUMMARY

According to Article 95(5) of the EC Treaty, Portugal notified to the European Commission its intention to declare the Autonomous Region of Madeira as a region free from the cultivation of GM plants. Portugal therefore proposed to introduce a regional decree to prohibit the cultivation of GM seeds and propagating plant material in the Autonomous Region of Madeira. Two reports were provided in support of the national measure.

Following the notification of Portugal, the European Commission requested a scientific opinion from the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) to investigate whether the information mentioned in the supporting documents contains any new scientific evidence in terms of protection of the environment in the Autonomous Region of Madeira, that would justify such a prohibition of the use of GMOs, including those that have already been authorised under Directive 90/220/EEC or Directive 2001/18/EC.

In its evaluation, the EFSA GMO Panel only investigated and commented on aspects that relate to the protection of human and animal health and the environment. Socio-economic aspects related to the cultivation of GM plants and the coexistence between cropping systems fall outside the remit of EFSA, and are not addressed in this scientific opinion.

1 On request from the European Commission, Question No EFSA-Q-2009-00851, adopted on 27 January 2010.

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3 Acknowledgement: The Panel wishes to thank the members of the Environmental Working Group for the preparation of this opinion: Salvatore Arpaia, Detlef Bartsch, Rosie Hails, Niels Hendriksen, Jozsef Kiss, Antoine Messéan, Gerd Neemann, Marco Nuti, Joe Perry, Angela Sessitsch, Jeremy Sweet, Christoph Tebbe and EFSA's staff member(s) Yann Devos and Sylvie Mestdagh for the support provided to this EFSA scientific output.

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Following investigation of the evidence presented in the Portuguese submission, the EFSA GMO Panel did not identify new scientific information on the environmental or human and animal health impacts of EU approved GM plants.

The EFSA GMO Panel therefore concludes that, based on the supporting documents submitted by Portugal, no new scientific evidence, in terms of risk to human and animal health and the environment, was provided that would justify a prohibition of the cultivation of GM plants in the Autonomous Region of Madeira.

KEY WORDS

GM plants, Madeira, risk assessment, coexistence, food and feed safety, environmental safety, cultivation, Directive 2001/18/EC.

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BACKGROUND

On 5 May 2009, the Republic of Portugal notified to the European Commission its intention to declare the Autonomous Region of Madeira as a region free from the cultivation of GM plants. Portugal therefore proposed to introduce a regional decree to prohibit the cultivation of GM seeds and propagating plant material in the Autonomous Region of Madeira. The draft regional decree implies a general ban on the cultivation of all EU approved GM plant events⁴ in the Autonomous Region of Madeira, as these plants could have adverse effects on the specific biodiversity of the Autonomous Region of Madeira.

The draft regional decree was submitted under Article 95(5) of the Treaty and is currently being examined in terms of admissibility in the context of Community legislation. The proposed prohibition of the cultivation of EU approved GM plants equates to the prevention of their placing on the market as authorised for this purpose under Community legislation, notably Directive 90/220/EEC and Directive 2001/18/EC or Regulation (EC) No 1829/2003, and might deviate from legal EU provisions. In accordance with Article 95 of the EC Treaty, *“a Member State shall, in the case a problem specific to that Member State arises, be entitled to introduce national provisions on the protection of the environment deviating from EU law, if such provisions are based on relevant new scientific evidence. The Member State shall notify the Commission of such provisions, and the Commission shall, within six months of the notification, approve or reject the national provisions.”* Article 95(5) of the EC Treaty requires that the introduction of national provisions, as the ones notified by Portugal, are based on *new scientific evidence* on the protection of the environment or the working environment. On 31 July 2009, upon request of the European Commission, the Permanent Representation of Portugal forwarded additional evidence to support its position on the safety of EU approved GM plant events.

On 23 September 2009, the European Food Safety Authority (EFSA) received a request from the European Commission to provide a scientific opinion from its Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) on the two supporting documents submitted by Portugal in the context of its notification according to Article 95(5) of the EC Treaty.

TERMS OF REFERENCE

The EFSA GMO Panel has been requested, under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to provide a scientific opinion on the evidence submitted by Portugal at the latest on 31 January 2010. The opinion must assess, in light of the requirements of Article 95(5) of the EC Treaty, whether the particular scientific evidence relates to the protection of the environment in the concerned area.

⁴ Community Register of GM food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

ASSESSMENT

1. Introduction

Article 95(5) of the EC Treaty gives the possibility for a Member State to derogate from harmonised measures, including provisions for protection of the environment, on the grounds of a problem specific to the Member State concerned and which arises after adoption of the harmonisation measure. According to the European Commission, such national measures are only allowed if these measures are justified without endangering the unity of the market based on new scientific evidence relating to the protection of the environment or the working environment. Against this background, provisions foreseen by Portugal seek to prohibit the cultivation of GM plants in the Autonomous Region of Madeira.

The EFSA GMO Panel examined the set of supporting documents submitted by Portugal, and assessed whether the submitted documents comprise new scientific information that would affect the protection of the environment of the Autonomous Region of Madeira.

The EFSA GMO Panel looked for evidence for GMO-specific risks taking into consideration the EFSA GMO Panel guidance document for the risk assessment of GM plants and derived food and feed (EFSA, 2006). In addition, the EFSA GMO Panel considered the relevance of the issues and concerns raised by Portugal in the light of the most recent scientific data and relevant peer-reviewed publications.

2. Assessment of documents provided by Portugal

A set of supporting documents, accompanying the mandate of the European Commission (see chapter *Terms of Reference*), was forwarded to EFSA on 23 September 2009.

Portugal provided the following documents in support of its notification for prohibiting the cultivation of EU approved GM plants in the Autonomous Region of Madeira according to Article 95(5) and (6) of the EC Treaty:

- (1) Report entitled 'Establishment of the autonomous region of Madeira (RAM) as an Area Free of Genetically Modified Organisms (GMOs) – Arguments';
- (2) Additional information attached to the letter, dated 31 July 2009, from the Permanent Representation of Portugal to the European Commission/DG Environment.

It is noted that the reports contain a large set of information relating to management measures needed to ensure coexistence between cropping systems. Aspects related to the coexistence of cropping systems (including the implementation of agricultural management measures) and the adventitious presence of authorised GM material in non-GM products fall outside the remit of the EFSA GMO Panel.

From the supporting documents, the EFSA GMO Panel considered the following five points of concern related to the protection of the environment in the Autonomous Region of Madeira:

- (1) Large-scale field studies not being appropriate to assess possible adverse effects of GMOs to the particular biodiversity of Madeira ;
- (2) Cross-pollination and invasiveness in local flora and its consequences (e.g., development of herbicide resistance);
- (3) Fate of the Bt toxin in soil;
- (4) Possible effects of Bt toxin on non-target organisms;
- (5) Horizontal gene transfer.

The relevance of the aforementioned concerns was considered in light of the most recent scientific data and relevant peer-reviewed papers.

3. Environmental risk assessment

The EFSA GMO Panel assessed whether scientific evidence was supplied by Portugal which would indicate that the environment, ecology or biodiversity of the Autonomous Region of Madeira was different from other regions of Portugal or the EU, and merit separate risk assessment evaluations from those conducted for other regions of Portugal or neighbouring states.

The EFSA GMO Panel notes that for the five identified points of environmental concern (see Chapter 2) little or no information is provided that enables a thorough risk assessment evaluation. Both reports submitted in support of the Portuguese notification provide no references to peer-reviewed or other scientific literature to support their submission. Furthermore, no report of environmental risk assessment studies conducted with GM plants in Portugal and in particular, the Autonomous Region of Madeira, was presented indicating adverse environmental consequences on non-target organisms, other biota or biodiversity associated with GM plants cultivation. Hence, no evidence was presented in the reports to show that the introduction of GM plants would produce a specific environmental or human and animal health risk in the Autonomous Region of Madeira.

Since the supporting documents submitted by Portugal refer to GM maize MON810 varieties registered in the common catalogue of varieties of agricultural plant species, the EFSA GMO Panel invites Portugal to consult its recently adopted scientific opinion on the renewal of the market consent of GM maize MON810 for further details about the environmental safety of maize MON810 in the EU (EFSA, 2009).

The main arguments presented by Portugal for establishing the prohibition of GM plants in the Autonomous Region of Madeira focus on the coexistence between cropping systems and the adventitious presence of authorised GM material in non-GM products. Although the EFSA GMO Panel recognised that ensuring the coexistence between cropping systems is an important agricultural issue, the EFSA GMO Panel did not comment on this issue, as it falls outside its remit.

CONCLUSIONS

The EFSA GMO Panel has investigated the claims and documents provided by Portugal. The scientific evidence presented in the two supporting reports contains no new scientific information on the environmental or human and animal health impacts of EU approved GM plants. The Portuguese submission did not supply scientific evidence that the environment or ecology of the Autonomous Region of Madeira was different from other regions of Portugal or the EU sufficient to merit separate risk assessments from those conducted for other regions in the EU. No particular cases were presented of impacts of GM plants on biodiversity, either directly or through changes in agricultural practices.

The EFSA GMO Panel therefore concludes that, based on the supporting documents submitted by Portugal, no new scientific evidence, relating to risks to human and animal health and the environment, were provided that would justify a prohibition of cultivation of GM plants in the Autonomous Region of Madeira.

DOCUMENTATION PROVIDED TO EFSA

1. Letter, dated 23 September 2009, with supporting documents from Mr. Karl Falkenberg, Director-General Environment EC, to Catherine Geslain-Lanéelle, Executive Director EFSA (ref ENV/B3/YK/lh ARES(2009) 248376) requesting for a scientific opinion on the notification from by Portugal, pursuant to Article 95(5) of the EC Treaty, for the prohibition of cultivation of GMOs in the Autonomous Region of Madeira, and comprising the following supporting documents:
 - Report entitled ‘Establishment of the autonomous region of Madeira (RAM) as an Area Free of Genetically Modified Organisms (GMOs) – Arguments’;
 - Additional information attached to the letter, dated 31 July 2009, from the Permanent Representation of Portugal to the European Commission/DG Environment.
2. Acknowledgement letter, dated 7 October 2009, from EFSA to Mr. Karl Falkenberg, Director-General Environment EC.

REFERENCES

- EFSA, 2006. Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal, 99: 1-100,
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm
- EFSA, 2009. Scientific opinion on applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal, 1149, 1-85.
[http://www.efsa.europa.eu/cs/BlobServer/Scientific Opinion/gmo_op_ej1149_maizeMON810_finalopinion_en_rev.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific%20Opinion/gmo_op_ej1149_maizeMON810_finalopinion_en_rev.pdf?ssbinary=true)