

# **Opinion on the invocation by Austria of Article 16 of Council Directive 90/220/EEC regarding a genetically modified maize line T25 notified by AGREVO FRANCE (now AVENTIS CROPSCIENCE, REF. C/F/95/12-07) (Opinion adopted by the Scientific Committee on Plants on 30 November 2000)**

## **1. TITLE**

**Opinion of the Scientific Committee on Plants on the invocation by Austria of Article 16 ('Safeguard' clause) of Council Directive 90/220/EEC regarding the genetically modified maize Line T25 notified by AgrEvo (now Aventis CropScience, ref. C/F/95/12-07).**

(Opinion adopted by the Scientific Committee on Plants on 30 November 2000)

## **2. TERMS OF REFERENCE**

The Scientific Committee on Plants (SCP) is requested to express its opinion on the following question:

"Does the information submitted by Austria constitute relevant scientific evidence, which would cause the Committee to consider that this product constitutes a risk to human health and the environment?"

## **3. BACKGROUND**

The Scientific Committee on Plants (SCP) was consulted by the Commission on the dossier for a genetically modified maize line T25 transformed to express the *pat* gene from *Streptomyces viridochromogenes* which encodes phosphinothricin acetyltransferase - PAT: this enzyme inactivates glufosinate ammonium, thereby conferring an increased tolerance of the post-emergence herbicide to the maize plants. The SCP published its favourable opinion on 10 February 1998. A Commission Decision to place this maize on the market was adopted on 22 April (Decision n° 98/293/EC <sup>1</sup>) and the French authorities issued the corresponding consent on 3 August 1998.

The Commission received notification from the Austrian authorities of their decision to invoke Article 16 of Directive 90/220/EEC on 8 May 2000. This informed the Commission that the marketing of genetically modified maize Line T25 notified by Aventis CropScience had been prohibited by means of a decree, which entered force on 29 April 2000. The Austrian Competent Authority took the decision to invoke Article 16 on the grounds that the maize line T25 had not been examined under realistic conditions of use of glufosinate and that neither the notification seeking approval nor the Commission decision foresaw a monitoring programme. The lack of a monitoring programme is seen by the Austrian authorities as important in regard to the protection of sensitive areas and furthermore regional ecological aspects were not differentiated.

## **4. OPINION**

## 4.1 Question 1

The Commission has asked the Scientific Committee on Plants to consider the following:

**"Does the information submitted by Austria constitute relevant scientific evidence, which would cause the Committee to consider that this product constitutes a risk to human health and the environment?"**

### *Opinion of the Committee*

**The Scientific Committee on Plants has examined the information submitted by the Austrian authorities and concludes that it does not provide new scientific information to change the original risk assessment carried out on the AgrEvo (now Aventis CropScience) maize line T25.**

### *Scientific background on which the opinion is based*

The SCP was provided with a translated document from the Federal Institute for Less-favoured and Mountainous Areas, Vienna (Hoppichler J., 1998, 1999), which summarised a two-part study conducted on behalf of the Austrian Federal Ministry of Women's Affairs and Consumer Protection. This deals with concepts of GMO-free environmentally sensitive areas. The first part summarises the arguments for such areas and the second part summarises a survey of Austrian experts' opinions about GMO-free areas relating to the deliberate release of GMOs and the natural or/and agricultural environment (including organic farming). The Committee considered this document as the basis for its opinion to the Commission.

At the outset the SCP advises the Commission that this Austrian document does not contain any new scientific information which is relevant to the original scientific risk assessment that it published in 1998<sup>2</sup>. Rather the document contains arguments for the establishment of GMO-free environmentally-sensitive areas and summarises surveyed opinions of people who may be confronted professionally with any environmental effects of the release of GMOs.

### *Genetic transfer*

Maize, which belongs to the grass family, has no closely related species in Europe and therefore the probability of genetic transfer of the herbicide tolerance trait to other wild species is remote. The Committee is of the opinion that there is no biodiversity issue and herbicide tolerance is extremely unlikely to transfer from cultivated maize into the environment.

The original dossier showed that the *pat* gene is not expressed in pollen and there is no detectable PAT activity in the pollen of this modified maize. Therefore in the transgenic form of this anemophilous species, i.e. largely pollinated by wind and gravity, pollen dispersal and outcropping frequency should be no different from that of other maize varieties and the herbicide tolerance trait should not transfer to any other varieties of cultivated maize.

There are many reported studies of pollen dispersal, some of which show that maize pollen may travel long distance. However, most of the released pollen is deposited close to the crop plant and there is a very steep deposition gradient away from the source plant. In low to moderate winds it has been estimated that, compared with pollen concentrations only 1 m

from the source, approximately 2 % of the pollen is recorded at 60 m, 1.1% at 200 m and 0.75-0.5% at 500 m distant (Emberlin *et al.* 1999).

At 10 m from the field on average the number of pollen grains per unit area is ten times less than that observed 1 m from the edge. If the established separation distances developed for seed production are observed, pollen transfer to adjacent varieties should be minimised and in any case will not contain genetic material to transfer herbicide tolerance.

Since there is minimal chance of tolerance to glufosinate ammonium being transferred out of maize, the potential development of resistance in other species does not arise. Any volunteer maize plants surviving to the next crop, in areas free from winter frosts which will kill residual plants, may be controlled by other agronomic practices including cultivation and the application of alternative non-selective herbicides.

In view of the remote chance of the transfer into the environment of genetic tolerance to the herbicide glufosinate ammonium from cultivated maize, there is no evidence that this transgenic maize will pose any problem to the ecology of the alpine grassland and meadow systems as suggested in the Austrian document (see Pascher K. and Gollman G. 1998 and 1999).

## **5. REFERENCES**

Emberlin, J., B. Adams-Groom and J. Tidmarsh (1999). A report on the dispersal of maize pollen. National Pollen Research Unit for the Soil Association.

Hoppichler J. 1998: Konzepte und Kriterien zur Definition von "sensiblen Gebieten", in denen aufgrund der ökologischen Bedingungen nachteilige Umweltauswirkungen durch die Freisetzung von GVOs möglich sind. Studie in Auftrag des Bundesministerium für Frauenangelegenheiten und Konsumentenschutz Sektion VI, Bundesanstalt für Bergbauernfragen, Wien 1998.

Hoppichler J. 1999: ExpertInnenbefragung zur Bewertung und Evaluation "GVO-frier ökologisch sensibler Gebiete". Forschungsberichte 10/99 - Bundeskanzleramt (Sektion VI), Wien 1999.

Pascher K. and Gollmann G., 1998: Biologische Grundlagen und Möglichkeiten der Auskreuzung von gentechnisch veränderten Pflanzen - Grenzen der Prognostizierbarkeit des ökologischen Verhaltens. Gutachten im Auftrag der BA für Bergbauernfragen, Wien 1998.

Pascher K. and Gollman G., 1999: Ecological risk assessment of transgenic plant release: an Austrian perspective. *Biodiversity and Conservation* 8/ 1139-1158, Kluwer Acad. Publ. 1999.

## **6. DOCUMENTATION MADE AVAILABLE TO THE COMMITTEE**

Invocation by Austria of Article 16 of Council Directive 90/220/EEC regarding a genetically modified maize line T25 notified by AgrEvo (now Aventis CropScience) - notification C/F/95/12-0, [Doc. SCP/GMO/256] comprising the following papers:

- A letter from the Bundesministerium für Soziale Sicherheit und Generationen to the European Commission (DG Environment).

- A document titled "Reason for the decision of the Republic of Austria to prohibit the placing on the market of genetically modified maize line T25, notified by AgrEvo France (now Aventis Science) following Directive 90/220/EEC, consent given by the European Commission on 22 April 1988 and by the French Republic on 3 August 1998." (English translation provided by the Commission services).

- A copy of the "Summary notification information format for products containing genetically modified organisms (GMOs)".

## **7. ACKNOWLEDGEMENTS**

The Committee wishes to acknowledge the contributions of the working group that prepared the initial draft opinion:

*GMO Working group:* Prof. O'Gara (Chairman) and Committee members: Prof. Davies, Dr. Delcour-Firquet, Prof. Hardy, Prof. Karenlampi, Mr. Koepp, Dr Kuiper, Prof. Silva-Fernandes, Dr. Speijers and invited experts: Dr. Aumaitre, Dr. Chesson, Prof. Moseley, Prof. Vighi and Prof. von Wright.

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<sup>1</sup> OJ No L131, 22.4.98 p30

<sup>2</sup> Opinion of the Scientific Committee on Plants Regarding "Submission for Placing on the market of Glufosinate Tolerant Corns (*Zea mays*) Transformation event T25" by the Agrevo Company, [http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com\\_scp\\_out04\\_en.pdf](http://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out04_en.pdf)