Opinion of the Scientific Panel on Genetically Modified Organisms on a question from the Commission related to the Austrian notification of national legislation governing GMOs under Article 95(5) of the Treaty[1]

(Question N° EFSA-Q-2003-001)

Opinion adopted on 4 July 2003

Approved by
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SUMMARY

The Provincial Government of Upper Austria proposes to introduce a new law that would prohibit the cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals - in particular for hunting and fishing purposes - in Upper Austria. The proposed national legislation is based on a report entitled "GMO-free agricultural areas: design and analysis of scenarios and implementation measures". Austria then notified the European Commission of its intent in compliance with Article 95(5) of the Treaty.

In consequence, the European Commission requested a scientific opinion from the European Food Safety Authority (EFSA) to investigate whether the information in the report contains any new scientific evidence in terms of risk to human health and the environment that would justify such a prohibition of GM seeds, propagating material and transgenic animals, including those that have already been authorised under Directive 90/220/EEC or Directive 2001/18/EC. In particular, EFSA was asked to comment on whether the scientific information presented in the report provides new data that would invalidate the provisions for environmental risk assessment under the above legislation. As requested, EFSA has commented on issues within its remit relating to human health and the environment and not on other issues such as information relating to the management of co-existence.

Following investigation of the evidence presented in the Austrian submission, EFSA's Scientific Panel on Genetically Modified Organisms (GMO Panel) concludes there is no new scientific evidence, in terms of risk to human health and the environment, to justify the prohibition. Neither did it find any new data that would change the environmental risk assessment conducted on GMOs that currently hold marketing consent in the EU. No scientific evidence was presented to indicate that this area of Austria had unusual or unique ecosystems that required separate risk assessments from those carried out for Austria as a whole or for other similar areas of Europe.

Key words: GMOs, Upper Austria, Provincial Act, GM seeds, GM plants, transgenic animals, GMO-free area, human health, environment, Directive 90/220/EEC, Directive 2001/18/EC.

[1] For citation purposes: Opinion of the Scientific Panel on Genetically Modified Organisms on a question from the Commission related to the Austrian notification of national legislation governing GMOs under Article 95(5) of the Treaty, *The EFSA Journal* (2003) 1, 1-5

BACKGROUND

The Commission received, from the Permanent Representation of Austria on 13 March 2003, notification from the Provincial Government of Upper Austria of

- A draft Committee (Committee on National Economic Affairs) report concerning a Provincial Act prohibiting the cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals in particular for hunting and fishing purposes;

- A study entitled "GMO-free agricultural areas: design and analysis of scenarios and implementation steps" by Werner Müller, engineer, on which the draft is based.

Community interest

The draft Provincial Act 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 use of GM seeds, propagating material and transgenic animals equates to the prevention of their release or placing on the market as authorised for this purpose under Community legislation, notably Directive 90/220/EEC and Directive 2001/18/EC.

GMOs with Community authorisation

Eighteen authorisations for the placing on the market of GMOs were granted under the previous Directive 90/220/EEC, which was repealed by Directive 2001/18/EC on 17 October 2002. Of these products, seeds from three GM maize transformants, three GM oilseed rape transformants and a chicory transformant have been authorised for the placing on the market to include cultivation as a use (although final consent has not been granted for two of the oilseed rape lines). Approval has also been granted for cultivation of two GM carnation transformants.

The Act would, therefore, also impact on the cultivation of the above GMOs already approved under the provisions of Directive 90/220/EEC as now governed by Directive 2001/18/EC. The consents for these products will have to be renewed under Directive 2001/18/EC but not until the year 2006.

Directive 2001/18/EC also provides for the placing on the market and experimental release into the environment of transgenic animals on the basis that they are classified as GMOs. Whilst no transgenic animals (including fish) have as yet been approved for these purposes, or applications for such submitted for approval, the Directive does provide for this possibility. No approvals for release of transgenic animals were granted under Directive 90/220/EEC.

Article 95(5) of the Treaty

Article 95(5) of the Treaty requires that the introduction of national provisions, derogating from a harmonisation measure must be

- Notified to the Commission with the grounds for introducing them.
- On the grounds of a problem specific to the Member State concerned and which arises after adoption of the harmonisation measure.
- Based on *new scientific evidence* relating to the protection of the environment or the working environment.

The Office of the Provincial Government of Upper Austria has cited the scientific evidence contained in the submission as the basis for its Act. The report contains information relating to issues pertaining to the co-existence of GMOs and conventional/organic production systems and subsequent management measures.

Furthermore, the report refers to the release of GM plants and animals into the environment as a threat to the biodiversity and environment of Upper Austria. The report also makes reference to possible effects on human health in terms of allergenicity of pollen from both conventional and genetically modified plants.

TERMS OF REFERENCE

EFSA is requested, under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to provide a scientific opinion, before 15 July 2003, as to whether ;the information provided by Austria in the Report entitled 'GMO-free agricultural areas - Design and analysis of scenarios and implementational measures' provides any new scientific evidence, *in terms of risk to human health and the environment*, that would justify the prohibition of cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals, authorised for these purposes under Directive 90/220/EEC or Directive 2001/18/EC.

In particular, EFSA is requested to comment as to whether the scientific information presented in the report provides new data that would invalidate the provisions for the environmental risk assessment established under the above legislation.

EFSA is not requested to comment on information that *does not* impact on risk to human health and the environment, in particular that relating to the management of co-existence.

ASSESSMENT

Working procedure

The GMO Panel tasked a working group (WG) with examining this submission from Austria which includes the report by Werner Müller.

The Panel looked for evidence for GMO-specific risks taking into consideration the Guidance document prepared by the EC Scientific Committees [ref. 1].

Two main aspects were considered:

- whether new scientific evidence had been presented by Austria which would change the risk assessment conducted on GMOs currently given marketing consent in the EU.
- whether there was scientific evidence supplied which would indicate that the environment or ecology of Upper Austria was different from other regions of Austria or the EU and merited separate risk assessments from those conducted for other regions of Austria or neighbouring states.

Evaluation

Risk assessment and approval of GMOs according to Directive 90/220/EEC (repealed by Directive 2001/18/EC) is done on a case by case basis and provides the possibility for Member States to raise objections against marketing of specific GMOs. If necessary, this risk assessment may include features specific to certain geographical regions or subregions. Furthermore, the Directive provides safeguards in the event of new information regarding the previous risk assessment.

The provisions foreseen by Upper Austria seek to prohibit all GM plants and GM animals including those which have already been safety assessed, as well as any future GM plants and GM animals.

The evidence presented was mostly a review of current knowledge on crop to crop gene flow and crop to wild relative gene flow of a few crop types with limited references to gene flow studies in Austria. The evidence also examined issues of co-existence of GM and non-GM varieties of three main crop types and this was the main argument presented for establishing the GMO exclusion area in Upper Austria. The report concluded that gene flow *per se* was a hazard without reference to any environmental or human health impacts or consequences of gene flow. Gene flow is a basic biological function that is fundamental to the evolution and survival of all living species. No scientific evidence was presented which showed that gene flow from transgenic organisms is *per se* different to gene flow from conventional or organically grown organisms. Furthermore no reports of GM crop or animal studies in Austria were presented which indicated any adverse consequences of gene flow. The report cited only a limited number of peer reviewed references on which evidence is based. A rather high number of references were not directly related to GMOs, but reported on biological invasions, pesticide persistence and ozone depletion. Furthermore, many references were dedicated to legislation or economic affairs and therefore did not provide further scientific evidence to justify the exclusion of GMOs in Upper Austria. No references were made to GM animals.

No evidence was presented in the report to show that co-existence is an environmental or human health risk issue. EFSA was not asked by the Commission to comment on the management of co-existence of GM and non-GM crops, but the Panel recognised that it is an important agricultural issue.

The scientific evidence presented contained no new or uniquely local scientific information on the environmental or human health impacts of existing or future GM crops or animals.

No scientific evidence was presented which showed that this area of Austria had unusual or unique ecosystems that required separate risk assessments from those conducted for Austria as a whole or for other similar areas of Europe. No specific cases were presented of impacts of GMOs on biodiversity, either directly or through changes in agricultural practices.

CONCLUSION

The Scientific Panel on Genetically Modified Organisms is of the opinion that

- **the scientific information presented in the report provided no new data that would invalidate the provisions for the environmental risk assessment established under Directive 90/220/EEC or Directive 2001/18/EC.**

- **the scientific information presented in the report provided no new scientific evidence, in terms of risk to human health and the environment, that would justify a general prohibition of cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals, authorised for these purposes under Directive 90/220/EEC or Directive 2001/18/EC in this region of Austria.**

DOCUMENTATION PROVIDED TO EFSA

1. Letter, dated 17 June 2003 with ref. MW D(2003) 450012, from Mrs Jaana Husu-Kallio from the Health & Consumer Protection Directorate-General requesting a consultation of the scientific Panel on Genetically Modified Organisms.
2. Report of the Committee on National Economic Affairs concerning the Provincial Act prohibiting the cultivation of genetically modified seed and planting material and the use of transgenic animals for breeding purposes as well as the release of transgenic animals especially for the purposes of hunting and fishing (Upper Austrian Act prohibiting genetic engineering 2002).
3. Report entitled 'GMO-free agricultural areas - Design and analysis of scenarios and implementational measures' by Werner Müller (document translated by Commission services; original title: *GVO-freie Bewirtschaftungsgebiete: Konzeption und Analyse von Szenarien und Umsetzungsschritten*).

REFERENCES

1. Guidance document for the risk assessment of genetically modified plants and derived food and feed, prepared by the Joint Working Group on Novel Foods and GMOs, 6-7 March 2003. http://europa.eu.int/comm/food/fs/sc/ssc/out327_en.pdf

ACKNOWLEDGEMENTS

The Panel wishes to acknowledge the contribution of the working group that prepared the draft opinion: Detlef Bartsch, Joachim Schiemann, Willem Seinen, Angela Sessitsch and Jeremy Sweet, all members of the GMO Panel.