Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC[1] (Question No EFSA-Q-2004-062)

Opinion adopted on 8 July 2004

SUMMARY

The Austrian authorities have invoked Article 16 (safeguard clause) of Directive 90/220/EEC on the deliberate release of genetically modified organisms (GMOs) into the environment on three separate occasions to provisionally prohibit the use and sale of three authorised genetically modified maize lines, namely Bt176, MON 810 and T25. The supporting scientific evidence was evaluated by the Scientific Committees of the European Commission. In February 2004, the Commission received from Austria an additional submission to support the proposed measures, now under Article 23 of Directive 2001/18/EC which has replaced Directive 90/220/EEC.

In consequence, the European Commission requested a scientific opinion from the European Food Safety Authority (EFSA) to investigate whether the submission contains any new or additional information affecting the environmental risk assessment or re-assessment of existing information on the basis of new or additional scientific knowledge such that detailed grounds exist to consider that the above authorized GMOs, for the uses laid down in the corresponding consents, constitute a risk to human health or the environment.

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, that would invalidate the risk assessments of genetically modified maize lines Bt176, MON 810 and T25 established under Directive 90/220/EEC or Directive 2001/18/EC and that would justify a prohibition of these genetically modified crops authorised under Directive 90/220/EEC or Directive 2001/18/EC in Austria.

Key words: GMOs, maize (*Zea mays*), Bt176, MON 810, T25, Austria, safeguard clause, human health, environment, Directive 90/220/EEC, Directive 2001/18/EC.

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BACKGROUND

On 20 April 2004, EFSA has received a request from the Commission to provide a scientific opinion on the additional information submitted by Austria in the context of the safeguard clauses invoked under Article 16 of Directive 90/220/EC (EC, 1990), as replaced by Article 23 of Directive 2001/18/EC (EC, 2001). On 7 May EFSA received from the Commission the additional information submitted by Austria. The mandate for the request was adopted at the plenary meeting of the GMO Panel on 26 May 2004.

Austria invoked Article 16 (safeguard clause) of Directive 90/220/EEC (EC, 1990) on three separate occasions to provisionally prohibit the use and sale of three authorised genetically modified maize varieties, namely Bt176 (Reference C/F/94/11-03), MON 810 (Reference C/F/95/12-02) and T25 (Reference C/F/95/12-07).

Bt176 maize

Bt176 maize (C/F/94/11-03) was authorised for all uses in the European Union by Commission Decision 97/98/EC of 23 January 1997 (EC, 1997) and final consent was granted by the French competent authority on 4 February 1997.

On 14 February 1997 Austria invoked Article 16 of Directive 90/220/EEC.

The Scientific Committee on Food (on 21 March 1997), the Scientific Committee for Animal Nutrition (on 10 April 1997) and the Scientific Committee on Pesticides (on 12 May 1997) delivered opinions providing that the justification and information submitted by the Austrian authorities did not impact on the original assessment in terms of risks to human health or the environment (SCF, 1997; SCAN, 1997; SCP; 1997).

MON 810 maize

MON 810 maize (C/F/95/12-02) was authorised in the European Union for all uses with the exception of food by Commission Decision 98/294/EC on 22 April 1998 (EC, 1998a) and final consent was granted by the French competent authority on 3 August 1998. Food use of maize derivatives was approved under Regulation (EC) 258/97 – Art. 5 on 6 February 1998 (EC, 2004).

On 1 June 1999 Austria invoked Article 16 of Directive 90/220/EEC.

The Scientific Committee on Plants (on 24 September 1999) delivered an opinion providing that the justification and information submitted by the Austrian authorities did not impact on the original assessment in terms of risks to human health or the environment (SCP, 1999a).

T25 maize

T25 maize (C/F/95/12-07) was authorised in the European Union for all uses with the exception of food by Commission Decision 98/293/EC on 22 April 1998 (EC, 1998b) and final consent was granted by the French competent authority on 3 August 1998. Food use of maize derivatives was approved under Regulation (EC) 258/97 – Art. 5 on 6 February 1998 (EC, 2004).

On 8 May 2000 Austria invoked Article 16 of Directive 90/220/EEC.

The Scientific Committee on Plants (on 20 July 2001) delivered an opinion providing that the justification and information submitted by the Austrian authorities did not impact on the original assessment in terms of risks to human health or the environment (SCP, 2001a).

Confirmation of the national safeguard measure concerning the Bt176, MON 810 and T25 maize varieties

In February 2004, Austria provided additional information to support the national safeguard measures. This information should be considered under Article 23 of Directive 2001/18/EC.

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, within 60 days, as to whether, in accordance with Article 23 of Directive 2001/18/EC, the statements and documents submitted by the Austrian authorities comprise new or additional information affecting the environmental risk assessment or re-assessment of existing information on the basis of new or additional scientific knowledge such that detailed grounds exist to consider that the above authorized GMOs, for the uses laid down in the corresponding consents, constitute a risk to human health or the environment.

EFSA is not requested to give an opinion on political and legal arguments put forward by the Austrian in the context of the application of legislation or requests for further legislative/implementing measures.

ASSESSMENT

1. Introduction

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 consents for these products will have to be renewed under Directive 2001/18/EC but not until the year 2006.

Article 23 of the Directive states that

- Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory. The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public. The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

- A decision shall be taken on the matter within 60 days in accordance with the procedure laid down in Article 30(2). For the purpose of calculating the 60 day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee(s) which has/have been consulted shall not be taken into account. The period of time during which the Commission is awaiting the opinion of the Scientific Committee(s) consulted shall not exceed 60 days. Likewise, the period of time the Council takes to act in accordance with the procedure laid down in Article 30(2) shall not be taken into account.

The three genetically modified maize lines under consideration, namely Bt176 (Reference C/F/94/11-03), MON 810 (Reference C/F/95/12-02) and T25 (Reference C/F/95/12-07) have been evaluated at the national and EU level prior to their market approval and thereafter.

Bt176 has been the subject of opinions of the Scientific Committees for Pesticides (SCP, 1996; 1997), Animal Nutrition (SCAN, 1996; 1997), Food (SCF, 1996; 1997) and Plants (SCP, 1999b; 2000).

MON 810 maize was assessed by the Scientific Committee for Plants (SCP, 1998; 1999b).

T25 maize was considered in evaluations by the Scientific Committee for Plants (SCP, 2001a; 2001b; 2001c).

2. Evaluation of documents delivered by Austria

The GMO Panel has examined the submission and supporting documents [docs. #3-16; see below: Documentation provided to EFSA] from Austria. The Panel looked for evidence for GMO-specific risks taking into consideration the Guidance document prepared by the EC Scientific Committees (EC, 2003) and the EFSA draft guidance document for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2004a).

Two main aspects were considered:

- whether new scientific evidence had been presented by Austria which would change the risk assessment conducted on the GMOs cited by Austria (Bt176, MON 810, T25) which are currently given marketing consent in the EU.
- whether there was scientific evidence supplied which would indicate that the environment or ecology of Austria was different from other regions of the EU and merited separate risk assessments from those conducted for other regions of neighbouring states.

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. The Directive provides the possibility for Member States to raise objections against marketing of specific GMOs. If necessary, the risk assessment may include features specific to certain geographical regions or sub-regions.

Furthermore, the Directive provides safeguards in the event of new information regarding the previous risk assessment. The provisions foreseen by Austria seek to prohibit certain GM plants of which the safety has been established.

Three reports from Austria (supporting docs. #3-5) investigated the requirements for toxicology and allergenicity related safety evaluations of genetically modified plants and derived products destined for human and/or animal consumption. The results and recommendations of these two studies are intended to contribute to national and international discussion on the improvement of safety evaluation of GM products. According to internationally established principles, endorsed by EFSA, the risk assessment strategy for GMOs seeks to deploy appropriate methodologies and approaches to compare the GMO and derived products with their non-GM counterparts. The underlying assumption of this comparative assessment approach for GMOs is that traditionally-cultivated crops have a history of generally accepted safe use with regard to human and animal consumption and the environment. These crops therefore serve as baseline comparators for the risk assessment of GMOs. This comparison is the starting point for the safety assessment which then focuses on the impact of any intended or unintended differences identified. The three reports do not provide any new scientific data to indicate adverse affects on human and animal health or the environment of the maize events Bt176, MON 810 and T25.

Other scientific evidence presented within the four peer-reviewed papers (Zwahlen *et al.* 2003a,b; Morin *et al.* 2003, Saxena *et al.* 2002; supporting docs. #6-9) do not contain scientific information that would alter the risk assessment of the three maize events.

- The Morin *et al.* (2003) manuscript reports that field populations of pink bollworm *(Pectinophora gossypiella*), a major cotton pest, harbours three mutant alleles of a gene encoding cadherin which are linked with resistance to Bt toxin Cry1Ac and

survival on transgenic Bt cotton. However, this manuscript has no relevance to transgenic maize lines MON 810 and Bt176 expressing Bt toxin Cry1Ab and providing resistance to the target European pest species *Ostrinia nubilalis* and *Sesamia nonagrioides* as the crop, Cry protein, target insects and conditions in this study are not relevant for these GMOs.

- Zwahlen et al. (2003a) report a 200-day study investigating the impact of transgenic Bt maize event Bt11 (expressing Cry1Ab Bt toxin) on immature and adult Lumbricus terrestris in a single worst-case laboratory study and in a single small scale field test. At the end of the laboratory test the earthworms showed a significant weight loss of 18% (compared with of their initial weight) when fed (Bt+) maize litter whereas a weight gain of 4% occurred with non GM control maize. No difference was found in the higher tier small scale field test. Due to the experimental design, the authors were unable to exclude that possibility that the weight loss of earthworms fed with Bt maize in the laboratory test was due to other factors. Consequently, the authors themselves conclude: "Further studies are necessary to see whether or not this difference in relative weight was due to the Bt toxin or other factors discussed in the study".

- Zwahlen *et al.* (2003b) published the results of two field studies in the temperate maize-growing region of Switzerland with regard to the degradation of Cry1Ab toxin in transgenic Bt maize leaves during autumn, winter and spring periods. Each of the two field trials (in 1999/2000 and 2000/2001) covered a period of 200 days. The results suggest that Bt toxin is not completely degraded within the period tested. The authors discuss their findings in the light of potential differences in lignification (Saxena and Stotzky, 2001a), although lignin content was not determined. New more comprehensive data suggest that the extent of lignification of Bt transgene maize (several lines derived from MON 810 and Bt11) does not differ from the non-transgenic controls (Jung and Sheaffer, 2004). Furthermore, the degradation study of Zwahlen *et al.* (2003b) did not investigate the possibility of adverse environmental effects e.g. on non-target soil organisms. At the same time, a four year study on the decay of transgenic maize Bt toxin was published (Hopkins and Gregorich, 2003). This followed the rate at which the toxin in Bt-maize leaves decomposed in soil from a field in which Bt-maize had been cultivated for four years. The results suggested that much of the Bt toxin in crop residues is highly labile and quickly decomposes in soil, but that a small fraction may be protected from decay in relatively recalcitrant residues. It is known from experience with conventional Bt sprays, that Bt toxins (including Cry1Ab) can persist in soils, e.g. for at least 28 months as reported by Vettori *et al.* (2003). In conclusion, there is no sustainable reason why the previous environmental safety assessment of Bt maize by the Scientific Committee on Plants should be modified.

- Saxena *et al.* (2002) found that the release of Cry1Ab proteins by roots is a common phenomenon with transgenic maize. Although the release of Bt toxin from roots and decaying plant material has theoretical implications for the activity and survival of root-feeding invertebrates and organisms involved in decomposition processes, there is currently little evidence for any significant adverse effects of the Bt toxin on non-target soil organisms, either from transgenic plant material expressing the toxin or from extensive studies with *B. thuringiensis* preparations used historically as a control agent. Saxena and Stotzky (2001b) did not report any deleterious effects on soil microorganisms, earthworms or nematodes with Bt-maize. In addition, tests with *B. thuringiensis* preparations showed no deleterious effects on a variety of invertebrates (Glare and O'Callaghan, 2000). Thus there are no data in the Saxena

et al. (2002) study which should modify the environmental risk assessment for Bt maize.

The seven conference abstracts (supporting docs. #10-16) provided by Austria do not contain any data that can be evaluated on a scientific basis. The GMO Panel strongly recommends that Member States should support any claims to invoke the safeguard clause using the best possible, consistent factual evidence which hold up to detailed scientific scrutiny, preferably published in full scientific papers which have been peer reviewed.

3. Evaluation of other relevant documents

As stated in a letter sent from Austria to DG Environment on February 2004, Austria invoked Article 16 of Directive 90/220/EEC on February 1997 with health concerns on

- the use of ampicillin resistance marker genes (Bt176),
- ecological impact of herbicide tolerance genes (T25 and Bt176),
- impact of Bt toxin on non-target organisms (Bt176 and MON 810),
- and resistance development of target pest species (Bt176 and MON 810).

The GMO Panel has considered the relevance of these concerns again in the light of other scientific data.

- The Panel has evaluated the potential risks associated with the use of specific antibiotic resistance genes as marker genes (ARMGs) taking into account their current usage in clinical and veterinary medicine, the likely occurrence of horizontal gene transfer from genetically modified (GM) plants to microbes and the potential impact of horizontal gene transfer where naturally occurring resistance to the relevant antibiotics exists in the microbial gene pool. These factors will impact on the likelihood of any adverse effects on humans or the environment of ARMGs used in GM plants (EFSA, 2004b). The GMO Panel considers the frequency of horizontal gene transfer from GM plants to other organisms as very low for all ARMGs considered. This, in itself, is an important consideration with regard to any risk posed by the use of ARMGs. With respect to clinical importance the Panel has categorised ARMGs into three groups with different potentials for compromising human health and the environment. The ARMG gene inserted in Bt176 (amp) falls in the second group of ARMGs. The GMO Panel is of the opinion that the use of these genes should be avoided in future GM plants to be placed on the market, on the basis of the revised legal framework (Art. 17 and recital 51 of Directive 2001/18/EC). However, no new evidence is presented indicating that the previous safety assessment on Bt176, stating that the likelihood of adverse effects due to the use of Bt176 is extremely low, needs to be revised. This is further supported by the fact that no gene transfer from Bt176 transgenic maize to culturable bacteria has been detected under field conditions (Badosa *et al.*, 2004).

- The ecological impact of herbicide tolerance genes depends largely on the use of herbicide and not on the transgenic event. Herbicide tolerant maize may also enable cultivation practices that increase in-field biodiversity (Champion *et al.*, 2003; Perry *et al.*, 2004).

- Previous worst-case scenario tests on Bt maize reporting potential adverse effect on non-target organisms have been proven irrelevant in laboratory and environmental field tests. Bt toxin (Cry1Ab) has no direct effect on larvae of the green lacewing (Romeis *et al.*, 2004). A substantial number of other entomophagous arthropods are not sensitive to Cry1Ab (Dutton *et al.*, 2003). Ecological field tests in France (Bourguet *et al.*, 2002) have also shown no effects on non-lepidopteran species. A study by Sears *et al.* (2001) suggests that the impact of Bt corn pollen from current commercial hybrids on monarch butterfly populations is negligible.

- With regard to the development of resistance to Bt data are available from Spain which are relevant to European agricultural systems. Approximately 22000 hectares (5% of the total maize growing area) of transgenic maize expressing the Cry1Ab toxin have been planted annually since 1998. Changes in the susceptibility of Spanish populations of the Mediterranean corn borer (MCB), *Sesamia nonagrioides*, and the European corn borer (ECB), *Ostrinia nubilalis* to Cry1Ab, were assessed by annual monitoring of Bt maize fields. No consistent shifts in susceptibility were found after 5 years of Bt maize cultivation (Farinos *et al.*, 2004).

Finally, in 2001, the US Environmental Protection Agency assessed data collected during the process of renewing the registration of Bt crop whose registration expired. These crops had been cultivated in the US since 1996. The study concluded that Bt crops, including Bt maize, posed no significant risk to the environment or to human health (Mendelson *et al.*, 2003).

Overall, the evidence presented by Austria contains no new generic, or uniquely local, scientific information on the environmental or human health impacts of the specified GM maize events. No new scientific evidence is presented which shows that Austria has unusual or unique ecosystems that require separate risk assessments compared with other similar regions of Europe. No specific data were presented to show that transgenic Bt maize crops have an adverse effect on biodiversity, either directly or indirectly through changes in agricultural practices.

CONCLUSIONS

The Scientific Panel on Genetically Modified Organisms, having considered the scientific information submitted by Austria, is of the opinion that

- there is no new data that would invalidate the provisions for the environmental risk assessment established under Directive 90/220/EEC or Directive 2001/18/EC.

- there is no specific scientific evidence, in terms of risk to human health and the environment, that would justify a prohibition of the genetically modified crops authorised under Directive 90/220/EEC or Directive 2001/18/EC in Austria.

In conclusion, the Panel finds that the scientific evidence available does not sustain the arguments provided by Austria.

DOCUMENTATION PROVIDED TO EFSA

1. Letter to Mr. Herman Koëter, dated 15 April 2004 with ref. SANCO.D5 MW/mhr D(2004) 450095, from Mrs. Jaana Husu-Kallio from the Health & Consumer Protection Directorate-General requesting a consultation of the Scientific Panel on Genetically Modified Organisms with supporting document:
   - Letter from Austria, dated 9 February 2004, to Mrs. Margot Wallström, Environment Directorate-General
2. Letter to Mrs. Ellen Van Haver, dated 7 May 2004 with ref. ENV.B.4 BW:sf D(2004) MW/mhr D(2004) 450095, from Mrs. Barbara Weber from the Environment Directorate-General comprising the supporting documentation submitted by Austria.
   - Letter from Austria to Goetz-Eike zur Hausen, Legal Service of the Commission, dated 9 January 2004
   - Austria has cited the following scientific evidence contained in the submission as the basis for its action (supporting documents #3-16):
3. Spök, A., Hofer, H., Valenta, R., Kienzl-Plochberger, K., Lehner, P., Gaugitsch, H., 2003. Toxikologie und Allergologie von GVO-Produkten – Teil 1: Empfehlungen zur Standardisierung der Sicherheitsbewertung von gentechnisch veränderten Pflanzen auf Basis der Richtlinie 90/220/EWG (2001/18/EG). Umweltbundesamt Wien, Monographien Band 109: 214 pages.
4. Spök, A., Hofer, H., Valenta, R., Kienzl-Plochberger, K., Lehner, P., Stirn, S., Gaugitsch, H., 2003. Toxikologie und Allergologie von GVO-Produkten – Teil 2a: Untersuchung zur Praxis und Empfehlungen zur Standardisierung der Sicherheitsbewertung von gentechnisch veränderten Lebensmitteln. Umweltbundesamt Wien, Monographien Band 164A: 359 pages.
5. Spök, A., Karner, S., Stirn, S., Gaugitsch, H., 2003. Toxikologie und Allergologie von GVO-Produkten – Teil 2b: Untersuchung zur Sicherheitsbewertung von gentechnisch veränderten Lebensmitteln in der EU und den USA. Umweltbundesamt Wien Monographien Band 164B: 163 pages.
6. Zwahlen, C., Hilbeck, A., Howald, R., Nentwig, W., 2003a. Effects of transgenic Bt corn litter on the earthworm Lumbricus terrestris. Molecular Ecology 12, 1077–1086.
7. Zwahlen, C., Hilbeck, A., Gugerli, P., Nentwig, W., 2003b. Degradation of the Cry1Ab protein within transgenic Bacillus thuringiensis corn tissue in the field. Molecular Ecology 12, 765-775.
8. Morin, S., Biggs, R.W., Sisterson, M.S., Shriver, L., Ellers-Kirk, C., Higginson, D. Holley, D, Gahan, L.J., Heckel, D.G., Carrie, Y., Dennehy, T.J., Brown, J.K., Tabashnik, B.E., 2003. Three cadherin alleles associated with resistance to Bacillus thuringiensis in pink bollworm. PNAS 100, 5004–5009
9. Saxena, D., Flores, S., Stotzky, G., 2002. Bt toxin is released in root exudates from 12 transgenic corn hybrids representing three transformation events. Soil Biology and Biochemistry, 34, 133–137.
10. Szekacs, A., Abstract in: Darvas and Szekacs, December (2003).
11. Darvas, B., Abstract in: Darvas and Szekacs, December (2003).
12. Darvas, B. and Szekacs, A., Abstract in: Darvas and Szekacs, December (2003).
13. Zwahlen *et al.*, Abstract in: Hilbeck, A. and de Maagd, R. Biodiversity Implications of Genetically Modified Plants (2003), p. 59.

14. Bakker *et al.*, Abstract in: Hilbeck, A. and de Maagd, R. Biodiversity Implications of Genetically Modified Plants (2003), p.12.
15. Vojtech *et al.*, Abstract in: Hilbeck, A. and de Maagd, R. Biodiversity Implications of Genetically Modified Plants (2003), p. 53.
16. Birch *et al.*, Abstract in: Hilbeck, A. and de Maagd, R. Biodiversity Implications of Genetically Modified Plants (2003), p. 10.

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