Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Greek invoke of Article 23 of Directive 2001/18/EC[1] (Question N° EFSA-Q-2004-062)

Opinion adopted on 8 July 2004

SUMMARY

The Greek authorities have invoked Article 16 (safeguard clause) of Directive 90/220/EEC on the deliberate release of genetically modified organisms (GMOs) into the environment to provisionally prohibit the use and sale of an authorised genetically modified spring oilseed rape line, namely Topas 19/2. The supporting scientific evidence was evaluated by the Scientific Committee on Plants of the European Commission. In March 2004, the Commission received from Greece 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 GMO, 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 Greek 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 spring oilseed rape line Topas 19/2 established under Directive 90/220/EEC and that would justify a prohibition of this genetically modified crop authorised under Directive 90/220/EEC in Greece.

Key words: GMOs, GM spring oilseed rape (*Brassica napus* L. var *oleifera*), Topas 19/2, Greece, safeguard clause, 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 request from the Commission related to the Greek invoke of Article 23 of Directive 2001/18/EC, The EFSA Journal (2004) 78, 1-8.

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BACKGROUND

On 20 April 2004, EFSA received a request from the Commission to provide a scientific opinion on the additional information submitted by Greece 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).

Greece invoked Article 16 (safeguard clause) of Directive 90/220/EEC to provisionally prohibit the use and sale of Topas 19/2 spring oilseed rape (C/UK/95/M5/1).

Topas 19/2 spring oilseed rape, which is genetically modified for resistance to glufosinate ammonium herbicide, was authorized for import, storage and processing in the European Union by commission Decision (98/291/EC) of 22 April 1998 (EC, 1998) and final consent was granted by the competent authority of the United Kingdom on 9 June 1998.

The Scientific Committee on Plants (SCP) after examining and considering the existing information and data provided in the AgrEvo dossier, against the background of available knowledge in the areas concerned, considered that there is no evidence indicating that the seeds of AgrEvo glufosinate ammonium tolerant genetically modified oilseed rape, to be imported and processed in the manner indicated, are likely to cause adverse effects on human or animal health and the environment (SCP, 1998).

The Greek Competent Authority informed the Commission in a letter dated 3 November 1998, of its decision to invoke Article 16 of Directive 90/220/EEC. By means of a decree, which took effect on 8 September 1998, the importation of Agrevo oilseed rape seed into Greece was prohibited. The justification of the prohibition is the loss of seed during transportation, the establishment of viable modified rape plants in the environment and the potential for hybridisation with other *Brassicae*. It was argued that genetic escape will have consequences for agriculture, the natural environment and consumer health. The latter may arise from the local collection and consumption of wild *Brassicae*. The SCP's advice to the Commission on this application was to support the importation of oilseed rape seed into Europe for processing but not for cultivation and production within Member States. The potential for the loss of seed during transport and the possible establishment of feral plants in uncultivated habitats e.g. roadside verges was considered in the risk assessments carried out by the SCP when forming its opinion of February 1998. Where there is no use of glufosinate ammonium to apply selective pressure, modified rape is no more invasive than unmodified rape plants. Spring oilseed rape plants are susceptible to stress during growth. In northern Europe, they may be killed by cold weather during the winter and in southern Europe plants may be either

killed or have reduced seed set due to heat and drought stress during the summer months. Oilseed rape is not grown commercially in Greece. Spring oilseed rape exhibits a variable level of outcrossing through insect and wind pollination. Whilst there may be a low frequency of hybridisation with related wild *Brassicae*, poor vigour and high sterility of hybrids will limit spread. The risk of genetic escape was considered by the SCP to be small and the current information submitted by the Greek authorities does not change that assessment. In the absence of commercial production, the population of genetically modified rape would be restricted to that derived from seeds accidentally lost during transport and handling. The possibility of genetic escape from this extremely limited population to wild *Brassicae* spp. collected for human consumption is correspondingly very small. Should this occur, there are, in the view of the Scientific Committee on Plants, no implications for human health. PAT, the enzyme which confers resistance to glufosinate ammonium, is rapidly degraded in the digestive tract. Even when fed at high concentration in an acute toxicity study, PAT did not produce any adverse effects which would cause concern (SCP, 1999).

Confirmation of the national safeguard measure concerning spring oilseed rape Topas 19/2

In March 2004, Greece 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 Greek 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 Greek authorities 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 (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.

2. Evaluation of documents delivered by Greece

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, 2004).

Two main aspects were considered:

- whether new scientific evidence had been presented by Greece which would change the risk assessment conducted on the GMO cited by Greece (Topas 19/2 spring oilseed rape C/UK/95/M5/1) and which currently has marketing consent in the EU for import, storage and processing not including cultivation.
- whether the scientific evidence supplied indicated that the environment or ecology of Greece 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 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 sub-regions.

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

The evidence presented was based on twelve documents [docs. #2-13; see below: Documentation provided to EFSA]. The scientific content can be split into two main areas:

2.1. Documents dealing with crop management and agronomic consequences of cultivation of genetically modified herbicide-tolerant oilseed rape (supporting docs. # 2, 3, 4, 5, 9)

The ecological impact of herbicide tolerance genes in transgenic plants depends largely on the use of herbicide and not on the transgenic event. In general, herbicide tolerant oilseed rape could lead to cultivation practices that may alter in-field biodiversity as demonstrated in the UK Farm Scale study. Any sustainable cultivation of herbicide tolerant oilseed rape will depend on appropriate management measures (Beckie *et al.*, 2003; 2004; Warwick *et al.,* 2004). Since Topas 19/2 spring oilseed rape was authorized for import, storage and processing only, no cultivation is granted in the EU. Therefore, the supporting documents are not appropriate in this case.

2.2. Documents dealing with the potential of out-crossing from oilseed rape to other Brassicaceae (supporting docs. # 6, 7, 8, 10, 11, 12, 13)

The presence of hybrids between transgenic spring oilseed rape and other Brassicaceae is not a hazard in itself and does not imply inevitable ecological damage. For claims on environmental impact, hybrid fitness and other factors affecting the likelihood of environmental change should be assessed. Studies with herbicide tolerant oilseed rape have not shown any enhanced weediness or fitness, except when the complementary herbicide is applied (Crawley *et al.*, 2001). The EFSA GMO Panel concludes that the likelihood for unintended environmental effects due to the establishment and spread of herbicide tolerant oilseed rape will not be different from that of traditionally bred oilseed rape. Even if feral populations of spring oilseed rape were established and transgene flow occurred to cultivated oilseed rape and/or other Brassicae in natural habitats, a selective advantage would only occur if the complementary herbicide is applied. This will not take place in natural habitats. Without complementary herbicide application, the traits will have a neutral effect on the fitness of the potential hybrids.

Overall, the scientific evidence presented by Greece contained no new generic or uniquely local scientific information on the environmental or human health impacts of the GM oilseed rape events. No scientific evidence was presented which showed that Greece had unusual or unique ecosystems that required separate risk assessments from other similar regions of Europe. No specific data were presented that transgenic spring oilseed rape crops have an adverse effect when used for import, storage and processing.

CONCLUSIONS

The Scientific Panel on Genetically Modified Organisms, having considered the scientific information submitted by Greece, 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 Greece.

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

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 Greece, dated 3 March 2004, to Mrs. Margot Wallström, Environmental Directorate-General
    - Greece has cited the following scientific evidence contained in the submission as the basis for its action (supporting documents #2-13):
2. Champion, G.T., May, M.J., Bennett, S., Brooks, D.R., Clark, S.J., Daniels, R.E., Firbank, L.G., Haughton, A.J., Hawes, C., Heard, M.S., Perry, J.N., Randle, Z., Rossall, M.J., Rothery, P., Skellern, M.P., Scott, R.J., Squire, G.R., Thomas, M.R., 2003. Crop management and agronomic context of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops. Phil. Trans. R. Soc. Lond. B 358, http://www.pubs.royalsoc.ac.uk/phil_bio/fse_content/TB031801.pdf
3. Squire, G.R., Brooks, D.R., Bohan, D.A., Champion, G.T., Daniels, R.E., Haughton, A.J., Hawes, C., Heard, M.S., Hill, M.O., May, M.J., Osborne, J.L., Perry, J.N., Roy, D.B., Woiwod, I.P., Firbank, L.G., 2003. On the rationale and interpretation of the Farm Scale Evaluations of genetically modified herbicide-tolerant crops, Phil. Trans. R. Soc. Lond. B 358, http://www.pubs.royalsoc.ac.uk/phil_bio/fse_content/TB031779.pdf
4. Haughton, A.J., Champion, G.T., Hawes, C., Heard, M.S., Brooks, D.R., Bohan, D.A., Clark, S.J., Dewar, A.M., Firbank, L.G., Osborne, J.L., Perry, J.N., Rothery, P., Roy, D.B., Scott, R.J., Woiwod, I.P., Birchall, C., Skellern, M.P., Walker, J.H., Baker, P., Browne, E.L., Dewar, A.J.G., Garner, B.H., Haylock, L.A., Horne, S.L., Mason, N.S., Sands, R.J.N., Walker, M.J., 2003. Invertebrate responses to the management of genetically modified herbicide-tolerant and conventional spring crops. II. Within-field epigeal and aerial arthropods. Phil. Trans. R. Soc. Lond. B 358, http://www.pubs.royalsoc.ac.uk/phil_bio/fse_content/TB031863.pdf
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Responses of plants and invertebrate trophic groups to contrasting herbicide regimes in the Farm Scale Evaluations of genetically modified herbicide-tolerant crops, Phil. Trans. R. Soc. Lond. B 358; http://www.pubs.royalsoc.ac.uk/phil_bio/fse_content/TB031899.pdf

6. Wilkinson M.J., Elliott L.J., Allainguillaume J., Shaw M.W., Norris C., Welters R., Alexander M., Sweet J., Mason D.C., 2003. Hybridization between Brassica napus and B. rapa on a national scale in the United Kingdom. Science 302, 457-459.
7. The biology and ecology of Canola (*Brassica napus*), Office of the gene technology Regulator (July 2002). http://www.non-gm-farmers.com/documents/brassicaOGTR.pdf
8. Eastham K. and Sweet, J., 2002. Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer EEA Environmental issue report No 28: http://reports.eea.eu.int/environmental_issue_report_2002_28/en
9. DEFRA GMO Research Programme - Reports: Modelling the effects on farmland food webs of herbicide and insecticide management in the agricultural ecosystem Ref EPG 1/5/188: http://www.defra.gov.uk/environment/gm/research/epg-1-5-188.htm
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11. Inomata, N., 1993. Crossability and cytology of hybrid progenies in the cross between *Brassica campestris* and three wild relatives of *B. oleracea*, *B. bourgeaui*, *B. cretica* and *B. montana*. Euphytica 69, 7—17.
12. Ramsay, G., Thompson, C., Squire, G., 2003. Quantifying landscape-scale gene flow in oilseed rape. Final report of DEFRA Project RG0216: An experimental and mathematical study of the local and regional scale movement of oilseed rape transgene. http://www.defra.gov.uk/environment/gm/research/pdf/epg_rg0216.pdf
13. Squire, G.R., Beeg, G.S., Askew, M., 2003. The potential for oilseed rape feral (volunteer) weeds to cause impurities in later oilseed rape crops. Final report of the DEFRA project: Consequences for Agriculture of the Introduction of Genetically Modified Crops, RG0114. http://www.defra.gov.uk/environment/gm/research/epg-rg0114.htm

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EC, 2003. 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

EFSA, 2004. Draft guidance document for the risk assessment of genetically modified plants and derived food and feed, prepared by the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority, April 2004. http://www.efsa.eu.int/consultation/372/consultation_guidance_gmo_01_en1.pdf

SCP, 1998. Opinion of the Scientific Committee on Plants Regarding the Genetically Modified, Glufosinate-Tolerant Rape Notified by the Agrevo Company (NOTIFICATION C/UK/95/M5/1) http://europa.eu.int/comm/food/fs/sc/scp/out03_en.html

SCP, 1999. Opinion of the Scientific Committee on Plants, adopted on 18 May 1999, on the Invocation by Greece of Article 16 ('safeguard' clause) of Council Directive 90/220/EEC with respect to a genetically modified oilseed rape notification C/UK/95/M5/1 (Agrevo) - (SCP/GMO/148-final) http://europa.eu.int/comm/food/fs/sc/scp/out36_en.html

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