



Brussels,
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Draft

COMMISSION DECISION

of [...]

concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line Bt11) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium

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**(Only the French text is authentic)
(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC¹ of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC², and in particular the first subparagraph of Article 18(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms (GMO) is subject to written consent being granted by the competent authority of the Member State that received the notification for the placing on the market of that product, in accordance with the procedure laid down in that Directive.
- (2) A notification (Reference C/F/96/05.10) concerning the placing on the market of a genetically modified (GM) maize product (*Zea mays* L., line Bt11) was submitted by Syngenta Seeds SAS to the competent authority of France.
- (3) *Zea mays* L., line Bt11, is a "Bt maize", i. e. a genetically modified maize expressing an insecticidal toxin, the "Bt toxin" (CryIAb), tolerant to the herbicide glufosinate-ammonium.

¹ OJ L 106, 17.4.2001, p. 1

² OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p.24)

- (4) The notification covers the placing on the market of seeds of varieties derived from the *Zea mays* L., line Bt11 for cultivation in the Community. The notification initially covered also import of grain and grain products for storage and processing into animal feed and industrial uses; however an application for these uses was later submitted under Article 20 of Regulation (EC) No 1829/2003, therefore they will not be addressed by this Decision.
- (5) In accordance with the procedure under Article 14 of Directive 2001/18/EC, the competent authority of France prepared an assessment report, which concluded that there is no scientific evidence to indicate that the placing on the market of the *Zea mays* L. line Bt11 poses any risk to human and animal health or the environment for the requested uses.
- (6) The assessment report was submitted in August 2003 to the Commission and the competent authorities of the other Member States, which raised and maintained objections to the placing on the market of the product. The objections concerned notably the adverse effects on soil organisms as well as on arthropods and the long-term effects of the Bt-toxin, which is contained by the product, on the environment.
- (7) The opinion of the European Food Safety Authority (EFSA), adopted on 20 April 2005³, concluded that *Zea mays* L. line Bt11 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed use.
- (8) The Commission convened a technical meeting with national competent authorities on 19 June 2006, to address the remaining objections of Member States in view of the EFSA opinion; Member States raised their concerns relating to the risk assessment of the product and requested a better explanation of the potential effects of Bt-toxin on non-target organisms and their monitoring.
- (9) The Commission subsequently requested EFSA to complement its opinions on *Zea mays* L. line Bt11 by providing more specific information concerning the lepidoptera species referred to in the EFSA opinion of 19 January 2005; EFSA was also asked to recommend whether more precise risk management measures, notably monitoring plans, including specific scientific research studies on non-target organisms and taking account of geographical regions, should be implemented. EFSA adopted the annex complementing its opinion on non-target organisms on 7 November 2006 (published 21 November 2006).
- (10) Directive 2001/18/EC, and in particular its Annex II supplemented by guidance notes on environmental risk assessment established in Commission Decision 2002/623/EC of 24 July 2002⁴ require consideration of potential effects on non-target organisms as well as potential delayed effects as well cumulative long term effects; these effects must be fully assessed as part of the environmental risk assessment prior to any authorisation.

³ The EFSA Journal (2005) 181, 1-33.

⁴ OJ L 200, 30.7.2002, p. 22–33

- (11) In line with the Action Plan presented by the Commission at the Environment Council of 26 June 2006 and supported by all delegations⁵, EFSA organised on 20 and 21 June 2007 a scientific colloquium with a view to considering the approaches to environmental risk assessment, addressing environmental issues and monitoring progress in science in order to further develop scientific approaches in risk assessment of GMOs. Preliminary conclusions⁶ indicate that experts from 19 EU Member States, Australia, Brazil, Croatia, Iran, Norway, Switzerland, Turkey and USA agreed that more specific guidance may be needed for the assessment of the potential impact on non-target organisms in terms of design and statistical power of testing. They also agreed that tests aiming at assessing long term effects need to be improved (e.g. need to have a sampling strategy adapted to long-term effects). The methodology to assess the effects on non-target organisms also has to be clarified, e. g. list of relevant indicator species. These conclusions concern GMOs containing the Bt-toxin and intended for cultivation as well, like *Zea mays* L. line Bt11.
- (12) In line with the outcome of the above-mentioned colloquium, EFSA launched in August 2007 a call for proposals entitled "*Cry proteins and their expression in micro-organisms and genetically modified plants*"⁷. The purpose of the assignment is to provide EFSA with a review of all appropriate scientific data on Bt proteins that are relevant for the risk assessment of GM plants expressing such proteins. The report will present a review of relevant scientific data on Bt proteins and their use in GM plants. The focus of the report will be on the safety issues on humans and animals (including target and non target organisms and soil organisms) and the environment possibly associated with the use of Bt proteins in GM plants. A section will be included identifying areas where there is a lack of scientific knowledge and including recommendations on areas and topics where more research would be of value. This report is intended to be used as background document by EFSA GMO Panel during the environmental risk assessment of GM herbicide tolerant plants and may form a basis for a review of the current "*Guidance document for the risk assessment of genetically modified plants and derived food and feed by the Scientific Panel on Genetically Modified Organisms (GMO)*"⁸.
- (13) In view of the above, EFSA is in the process of implementing the measures agreed in the Action Plan presented to the Council as referred to in recital 11.
- (14) Since the publication of the annex of EFSA's opinion, several scientific studies have been published confirming that the issue of adverse effects of maize expressing the Bt toxin on non-target organisms is still debated within the scientific community.
- (15) Although some authors indicate that non-target populations are not affected by Bt maize, others indicate that some insects exposed to Bt maize can be adversely affected. Prasifka *et al.* indicate that larvae of the monarch butterfly exposed to Bt maize behave

⁵ IP/06/498;
<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/498&format=HTML&aged=1&language=EN&guiLanguage=en>

⁶ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178621166773.htm

⁷ Call CFP/EFSA/GMO/2007/01

⁷ http://www.efsa.europa.eu/EFSA/Non_Scientific_Document/CFP_EFSA_GMO_2007_01_Call_for_proposals_and_Guidance,0.pdf

⁸ 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 (2006) 99, 1-100.

differently that other larvae and that ingestion may not be the only way Bt toxin can affect non-target insects like the monarch butterfly^{9,10}. Moreover, Rosi-Marshall *et al.* showed that consumption of Bt corn by-products reduced growth and increased mortality of non-target stream insects¹¹.

- (16) Some authors also indicate that Bt maize can modify multitrophic interactions between plants, herbivores and pests. Faria *et al.* indicate that a parasitoid of Lepidoptera lives longer and parasitizes more caterpillars in the presence of aphid-infested Bt maize than in the presence of aphid-infested isogenic maize, which could have an effect on the food chain¹². Rosi-Marshall *et al.* also indicated that stream insects are important prey for aquatic and riparian predators, and widespread planting of Bt crops has unexpected ecosystem-scale consequences¹¹.
- (17) The potential adverse effects of *Zea mays* L. line Bt11 are assessed on the basis of studies provided by the notifier conducted on whole plants, as referred to in EFSA opinions; the concentration of the toxin in these plants has not been determined in the field trials. Recent studies¹³ indicate that there is both a high variation of toxin concentration between plants on a field as well as statistically significant differences between different locations in Germany, where the studies have been conducted. The reasons for such differences in the plants and in the locations as well as the range of variation are not yet identified and may lead to unpredicted interactions with the environment that could cause adverse effects.
- (18) The possible existence of delayed or long term effects on the environment and biodiversity which may not be observed during the period of the release of the GMO but become apparent at a later stage are still unknown, and some aspects have not been thoroughly studied by the scientific community. Some issues remain disputed, such as the persistence of the toxin in waters or sediments¹⁴ (DNA from Bt maize and Bt toxin are persistent in aquatic environments and are detected in rivers draining farming areas) or the consequences on microbial communities of cropland's soils¹⁵ (the Bt toxin appears to influence the composition of the microbial community).
- (19) All the above mentioned studies have been conducted on maize expressing the CryIAb toxin.

⁹ Prasifka PL, Hellmich RL, Prasifka JR & Lewis LC (2007). Effects of Cry1Ab-expressing corn anthers on the movement of monarch butterfly larvae. *Environ Entomol* 36(1):228-33

¹⁰ Hilbeck, A. & J. E. U. Schmidt (2006) Another view on Bt proteins - How specific are they and what else might they do? *Biopesticides International* 2(1): 1-50

¹¹ Rosi-Marshall E. J., Tank J. L., Royer T. V., Whiles M. R., Evans-White M., Chambers C., Griffiths N. A., Pokelsek J., M. L. Stephen (published online before print October 8, 2007) Toxins in transgenic crop byproducts may affect headwater stream ecosystems, *PNAS*

¹² Faria CA, Wäckers FL, Pritchard J, Barrett DA, Turlings TC (2007) High susceptibility of bt maize to aphids enhances the performance of parasitoids of lepidopteran pests. *PLoS ONE* 2(7)

¹³ Nguyen, H. T. & J. A. Jehle (2007). Quantitative analysis of the seasonal and tissue-specific expression of Cry1Ab in transgenic maize MON810. *Journal of Plant Diseases and Protection* 114(2): 820-87

¹⁴ Douville M, Gagne F, Blaise C, Andre C. (2007) Occurrence and persistence of *Bacillus thuringiensis* (Bt) and transgenic Bt corn cry1Ab gene from an aquatic environment. *Ecotoxicol Environ Saf.* 66(2):195-203

¹⁵ Mulder C, Wouterse M, Raubuch M, Roelofs W, Rutgers M. (2006) Can transgenic maize affect soil microbial communities? *PLoS Comput Biol.* 2006 Sep 29;2(9)

- (20) The necessity to develop a more specific guidance as regards the methodology to assess the effects of GM plants on non-target organisms as well as their potential long-term effects is confirmed by a number of scientific studies published since the publication of the annex of EFSA's opinion^{16,17,18,19,20}.
- (21) In view of the above there are still serious indications that the cultivation of *Zea mays* L. line Bt11 could (i) adversely affect non-target organisms, such as particular species of butterflies, (ii) increase the presence of parasitoids in caterpillars and thus modify the food chains, (iii) generate an uneven concentration of the Bt-toxin on plants of the same locations, (iv) influence the composition of the microbial community and (v) lead to the persistence of Bt-toxin in aquatic environments. As the studies indicate that the spread of these potential effects in the environment would be wide, the concentration of Bt-toxin uneven, the affected organisms and eco-systems considerably diverse and their potential damage on the environment irreversible, it is not possible to establish appropriate management measures which would effectively mitigate the potential damage on the environment..
- (22) In accordance with Article 174(2) of the EC Treaty, Community policy on the environment shall aim at a high level of protection and shall be based on the precautionary principle. Recital 8 of Directive 2001/18/EC requires that "*the precautionary principle [...] must be taken into account when implementing [this Directive]*". Furthermore, Article 1 of the Directive ("Objective") indicates that "*in accordance with the precautionary principle, the objective of this Directive is [...] to protect human health and the environment when [...] placing on the market genetically modified organisms as or in products within the Community*".
- (23) It follows from the precautionary principle that where there is uncertainty as to the existence or extent of risk to human health and the environment, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent²¹.
- (24) Taking into account (i) EFSA's opinions on *Zea mays* L. line Bt11 and (ii) the on-going scientific debate on key issues regarding effects on non-target organisms, long term effects as well as the methodology to assess these effects, the degree of uncertainty attached to the results of the evaluation of the available scientific information as regards cultivation is considerably high. This uncertainty is such that it could compromise the high level of protection of the environment as foreseen by Article 174(2) of the EC Treaty and Directive 2001/18/EC.

¹⁶ Rose, R.I., G. P. Dively, and J. Pettis. (2007). Effects of Bt corn pollen on honey bees: emphasis on protocol development. *Apidologie*

¹⁷ Johnson, K.L. et al. (2007). How does scientific risk assessment of GM crops fit within the wider risk analysis? *Trends in Plant Science*, 12 (1).

¹⁸ Andow, D.A & Zwahlen, C. (2006). Assessing environmental risks of transgenic plants. *Ecology Letters*, 9: pp. 196-214

¹⁹ Butler, S.J., Vickery, J.A. & Norris, K. (2007). Farmland biodiversity and the footprint of agriculture. *Science*, 315, 381-384.

²⁰ Widmer F. (2007) Assessing effects of transgenic crops on soil microbial communities. *Adv Biochem Eng Biotechnol.* 2007;107:207-34.

²¹ ECJ, Case C-157/96 National Farmers' Union and Others (1998) ECR I-2211, para. 63 and Case C-180/96 United Kingdom v Commission (1998) ECR I-2265, para. 99.

(25) In the light of the above, *Zea mays* L. line Bt11 should not be approved for placing on the market for cultivation in the Community. This Decision is provisional and subject to review, depending on the development of scientific knowledge. The relevant scientific evidence may be made available to the Commission by any source, including the notifier.

HAS ADOPTED THIS DECISION:

Article 1

Zea mays L. line Bt11 is not approved for placing on the market for cultivation in the Community.

Article 2 Addressee

This Decision is addressed to the Republic of France.

Done at Brussels, [...] 2007.

For the Commission
Stavros Dimas
Member of the Commission