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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

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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/EC 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/EEC[1], and in particular the first subparagraph of Article 18(1) thereof,

After consulting the European Food Safety Authority (hereinafter, EFSA),

Whereas:

(1) Pursuant to Directive 2001/18/EC[2], the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms 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 maize product (*Zea mays* L., line Bt11, hereinafter: "Bt11 maize") was submitted by Syngenta Seeds SAS to the competent authority of France.

(3) The notification covers the placing on the market of seeds of varieties derived from the Bt11 maize 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 the placing on the market of these products is currently authorised and is subject to the procedures set out in Article 20 of Regulation (EC) No 1829/2003, therefore they will not be addressed by this Decision. The scope of the notification does not cover the commercial use of the product as a plant tolerant to

[1] 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)

[2] OJ L 106, 17.4.2001, p. 1

glufosinate in the EU, since the *pat gene* for glufosinate tolerance was only to be used as a marker gene. Therefore, without prejudice to Directive 91/414/EEC, the product should not be used with glufosinate herbicides in any manner differing from conventional practice with maize not tolerant to such herbicides.

(4) 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 Bt11 maize poses any risk to human and animal health or the environment for the requested uses.

(5) The assessment report was submitted in August 2003 to the Commission and the competent authorities of the other Member States, some of which raised and maintained objections to the placing on the market of the product.

(6) The opinion of EFSA, adopted on 20 April 2005[3], concluded that there is no evidence to indicate that placing Bt11 maize on the market is likely to cause adverse effects on human and animal health or the environment in the context of its proposed use.

(7) 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; certain Member States raised their concerns relating to the risk assessment of the product and requested a better explanation of the potential effects of the Bt toxin on non-target organisms and their monitoring.

(8) The Commission subsequently requested EFSA to complement its opinion on Bt11 maize by providing more specific information concerning the lepidopteran species referred to in the EFSA opinion of 20 April 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). After the publication of the above annex, eleven scientific studies, published after the adoption of the EFSA opinion of 20 April 2005, came to the attention of the Commission. Therefore the Commission requested EFSA on 24 July 2008 to review these studies, as well as any other relevant study, and confirm its risk assessment of Bt11 maize or comment on whether these studies would lead EFSA to alter its conclusions or refine them.

(9) On 29 October 2008 EFSA adopted its opinion which concluded that these publications do not provide new information that would change previous risk assessments conducted on Bt11 maize. Having also considered other recent scientific publications, EFSA reaffirmed its previous conclusions on the environmental safety of Bt11 maize.

(10) An examination of each of the Member State objections in the light of (i) Directive 2001/18/EC, (ii) the information submitted in the notification and (iii) the opinion of EFSA, discloses no evidence to indicate that the placing on the market of Bt11 maize is likely to cause adverse effects on human and animal health or the environment in the context of its proposed use.

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[3] The EFSA Journal (2005) 213, 1-33

(11) In view of the opinion of the EFSA, it is not necessary to establish specific conditions for the intended uses with regard to the handling or packaging of the product and the protection of particular ecosystems, environments or geographical areas.

(12) Bt11 maize is authorised for food, feed and other uses except cultivation under Regulation (EC) No 1829/2003.

(13) A unique identifier has been assigned to the Bt11 maize for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[4] and Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms[5].

(14) Prior to the placing on the market of Bt11 maize, the necessary measures to ensure its labelling and traceability at all stages of its placing on the market, including verification by appropriate validated detection methodology, should be applied. A detection method for Bt11 maize has been validated by the Community Reference Laboratory as referred to in the Annex of Regulation (EC) No 1829/2003, in accordance with Commission Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 [6]. For the purpose of appropriate information for operators and consumers, and to facilitate better management practices, the label, or an accompanying document, should also indicate that the product protects itself against the European Corn Borer (*Ostrinia nubilalis*) and the Mediterranean Corn Borer (*Sesamia nonagrioides*). The consent holder should be required to include labelling to inform potential users of Bt11 maize seeds that they should not use glufosinate ammonium for weed control in any manner differing from conventional practice with maize not tolerant to glufosinate ammonium and that, under Directive 91/414/EEC, glufosinate herbicides must be used in accordance with the provisions of the relevant national authorisation.

(15) As EFSA indicated in its opinion of 20 April 2005, "the only adverse effect identified was the possibility that resistance to Cry1Ab toxin might evolve in corn borers exposed to Bt11 maize following cultivation for some years. The Panel accepts the monitoring plan developed by the applicant to monitor specifically for resistance in corn borers and recommends that cultivation should be accompanied by appropriate risk management strategies to minimise exposure of non-target insects and to delay the development of resistance to the Cry1Ab protein in target insects". Therefore the consent holder should carry out monitoring and provide instruction to farmers in order to ensure the implementation by them of required measures, such as the planting of refuge maize and monitoring, to minimise development of resistance in target pests and to assist farmers in cultivating Bt11 maize. These measures should be listed in a leaflet distributed with each bag of seeds to the operators.

(16) In accordance with the EFSA opinion of 20 April 2005, "(..)management recommendations for the cultivation of Bt11 maize, as given by the applicant to users

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4 OJ L 268, 18.10.2003, p.24
5 OJ L 10, 16.01.2004, p. 5-10
6 OJ L 102, 07.04.2004, p.14.

of Bt11 maize, considers measures to reduce exposure of non-target lepidoptera (as well as the target pests), such as the use of non-transgenic border rows as refugia for the targets that would also reduce exposure of field margin weeds (and hence non-target lepidoptera) to pollen from Bt maize".

(17) For the purpose of best possible handling and use of the product, the consent holder should distribute with each bag of seeds to the operators a leaflet detailing information about the product and practices for its use.

(18) Monitoring should be conducted in accordance with Article 20(1) of Directive 2001/18/EC, the monitoring plan and revisions submitted by the notifier, and the opinions of EFSA.

(19) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 30(1) of Directive 2001/18/EC.

HAS ADOPTED THIS DECISION:

Article 1
Consent

1. Without prejudice to other Community legislation, in particular Directive 2002/53/EC, written consent shall be granted by the competent authority of France to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified by Syngenta Seeds SAS (Reference C/FR/96/05.01).

2. The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, including any specific condition of use, handling and packaging of the GMO(s) as or in products, and conditions for the protection of particular ecosystems/environments and/or geographical areas, which are set out in Articles 3 (conditions for placing on the market) and 4 (monitoring).

Article 2
Product

1. The genetically modified organisms to be placed on the market as or in products, hereinafter 'the product', are seeds of maize (*Zea mays* L., line Bt11), with resistance to the European Corn Borer (*Ostrinia nubilalis*) and the Mediterrranean Corn Borer (*Sesamia nonagrioides*) and with tolerance to the herbicide glufosinate ammonium, derived from *Zea mays* line Bt11, which has been transformed using biolistics with the larger DNA fragment obtained by a restriction digest of the plasmid pZO1502 derived from the plasmid pUC 18 and containing:

   (a) A truncated version of the *cry*1Ab gene derived from *Bacillus thuringiensis* ssp *kurstaki* HDI (*Btk*), protecting the plant against damage by the larvae of stem-boring lepidoptera (European Corn Borer (*Ostrinia nubilalis*) and Mediterranean Corn Borer (*Sesamia nonagrioides*)), under the control of the CaMV 35S promoter and *nos* 3' termination sequences. The IV6 intron from

1S maize alcohol dehydrogenase has been incorporated to enhance gene expression in monocotyledons;

(b) The *pat* gene, isolated from the Tü494 strain of the soil micro-organism *Streptomyces viridochromogenes*, placed under the control of the CaMV 35S promoter and *nos* 3' termination sequences. The IV2 intron from 1S maize alcohol dehydrogenase has been incorporated to enhance gene expression in monocotyledons.

2. The consent shall cover seeds from genetically modified progeny derived from crosses of *Zea mays* L., line Bt11 with any traditionally bred maize as or in products.

Article 3
Conditions for placing on the market

The product may be placed on the market and cultivated as any other maize that is not tolerant to glufosinate, subject to the following conditions:

(a) In accordance with Article 15(4) of Directive 2001/18/EC, the period of validity of the consent shall be 10 years starting from the date at which the consent for *Zea mays* L., line Bt11 is issued;

(b) the unique identifier of the product shall be SYN-BTØ11-1;

(c) without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall make available positive and negative control samples of the product and its genetic materials to the competent authorities of Member States as well as to the Community control laboratories on request; the consent holder shall announce where the reference material[7] can be accessed;

(d) the detection method specific to *Zea mays* L., line Bt11, as validated by the Community reference laboratory as referred to in the Annex of Regulation (EC) No 1829/2003 shall be used for the purpose of inspection and control;

(e) the words 'This product contains genetically modified organisms' or 'This product contains genetically modified Bt11 maize' shall appear either on a label or in a document accompanying the product, except where other Community legislation sets a threshold below which such information is not required;

(f) it shall also be indicated on the label, or in an accompanying document for non-pre-packaged products, that:

– the product protects itself against the European Corn Borer and the Mediterranean Corn Borers;

[7] Reference Material: ERM®-BF412 accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm.

– without prejudice to Directive 91/414/EEC the product shall not be used with glufosinate herbicides in any manner differing from conventional practice with maize not tolerant to glufosinate;

(g) the practices of the insect resistance management plan as contained in the notification shall be applied;

(h) the consent holder shall provide instruction to farmers in order to ensure the implementation by them of required measures, such as the planting of refuge maize in border rows and monitoring, to minimise development of resistance in target pests and exposure of non-target insects to Bt-toxins, and to assist farmers in cultivating Zea mays L., line Bt11;

(i) for the purpose of best possible handling and use of the product, the consent holder shall distribute with each bag of seeds to the operators a leaflet detailing information about the product and practices for its use, including the requirements indicated in para (h). The content of this leaflet is listed in Annex II.

Article 4
Monitoring by the consent holder

1. Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan contained in the notification and modified in accordance with this Article, is put in place and implemented. The resulting consolidated monitoring plan is available on the website of the European Commission (*web link to the consolidated monitoring plan to be added).*

2. The consent holder shall directly inform the operators and users of the introduction of *Zea mays* L., line Bt11 into the Community as well as of the safety and general characteristics of the product and of the conditions as to monitoring.

3. The following obligations are laid down for the consent holder:

(a) The consent-holder shall monitor the development of resistance in target species through exposure to the Cry1Ab protein in accordance with the insect resistance management plan appended to the monitoring plan contained in the notification to:

(i) Measure the baseline susceptibility of target pests to Cry1Ab protein;

(ii) Detect changes relative to baseline susceptibility that cause inadequate field protection against target pests.

(b) The consent holder shall increase the frequency of monitoring activities, as appropriate, taking account of the rate at which potential resistance to the Cry1Ab protein is likely to evolve, the resistance management strategy as well as the scale and the geographical dispersal of *Zea mays* L., line Bt11.

(c) Without prejudice to Article 20 of Directive 2001/18/EC, the monitoring plan shall, where appropriate and subject to the agreement of the Commission and

the competent authority of the Member State which received the original notification, be revised in line with the results of the monitoring activities by the consent holder, and/or by the competent authority of the Member State which received the original notification. Revised monitoring plans shall be submitted by the competent authority to the Commission and the competent authorities of the other Member States.

(d) The consent holder shall establish a general surveillance network as described in the general surveillance part of its monitoring plan, including through use of the farmer questionnaire detailed in the notification and taking account of the additional measures referred to in Annex I. The consent holder shall continue to develop the content and format of the questionnaire.

4. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

(a) that the networks for monitoring of resistance and general surveillance will gather the information necessary for the monitoring and surveillance of the products, and

(b) on the time schedule for receipt of the above information by the consent holder and its transmission to the Commission and the competent authorities of the Member States.

5. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of all monitoring activities, including general surveillance. The presentation of these reports shall be made in accordance with the Cultivation Monitoring Format to be established by the Commission.

Article 5
Addressee

This Decision is addressed to the Republic of France.

Done at Brussels,

For the Commission
Stavros Dimas
Member of the Commission

ANNEX I

Monitoring by the consent holder

1. The consent holder shall undertake case-specific monitoring of the possible development of resistance in target species as indicated in the monitoring plan submitted with the notification.

2. The consent holder shall carry out general surveillance of potential effects on non-target insects in particular (including parasitoids), taking into account the possibility of both direct and indirect effects on those and other non-target organisms including arthropods.

3. The consent holder shall establish a general surveillance network, as referred to in Article 4, paragraph 3(d) and paragraph 4(a), including through use of the farmer questionnaire in the notification. In accordance with EFSA's comments, the consent-holder shall amend the questionnaire to ensure that:

   (a) the design of the questionnaire allows for the input of general farm information (data on fertilizer usage, soil fertility, crop rotations, crop performance, crop yields, pests and diseases, pesticide use and weed abundance) as well as field-specific information for several fields when more than one field of a specific farmer is included in the monitoring;

   (b) the questionnaire includes an advisory note explaining that separate data sets are required for each Bt11 maize field to be monitored on a single farm;

   (c) the questionnaire to farmers for the year(s) after the Bt maize cultivation is adapted for the monitoring of the specific crops (maize or different) that follow the Bt11 maize cultivation; it should be in a format that is statistically compatible with the questionnaires supplied for the Bt11 maize growing season.

4. The consent holder shall ensure that the general surveillance network involves all necessary existing surveillance systems and any new surveillance systems required in addition to that established through the farmer questionnaire. The consent holder shall consult networks involved in relevant biodiversity surveys at local, national and Community level.

5. The monitoring plan shall include: observation parameters; survey methods, location and frequency; timetable for inspections; description and details of representativeness of the receiving environment; reference areas; agreements with third parties; adaptation of the plan to regional conditions.

ANNEX II

Content of the leaflet for operators

Throughout the period of validity of the consent, the consent holder, when placing seeds from varieties derived from the *Zea mays* L., line Bt11 on the market in a Member State, shall distribute a leaflet with each bag of seeds of the *Zea mays* L., line Bt11 indicating the following:

(a) General description of the product, including general characteristics of and safety requirements for varieties derived from the *Zea mays* L., line Bt11, and the unique identifier assigned to the GMO;

(b) Mention of the requirement that the transmission of seed from varieties derived from the *Zea mays* L., line Bt11 between operators be recorded by the operators, and that written information regarding the product must be provided as established by Article 4 of Regulation(EC) No 1830/2003;

(c) Design and management of the planting, including guidance to the operators to design refuges around the fields according to the Insect Resistance Management Plan proposed by the notifier, with the purpose of minimising development of resistance while, at the same time, reducing the potential exposure of both target and non-target insects to Bt-toxins, including non-target aquatic insects in neighbouring water courses;

(d) Guidance about the use of the product with herbicides, including a reminder that the product shall not be used with glufosinate herbicides in any manner differing from conventional practice with maize not tolerant to glufosinate, ;; and that, under Directive 91/414/EEC, glufosinate herbicides must be used in accordance with the provisions of the relevant national authorisation;

(e) An indication of the applicable national legislation on the cultivation of GMOs, including legislation on co-existence between GM maize crops and non-GM maize crops where applicable, and its detailed provisions as regards treatment of equipment and product material, notification requirements if applicable, and distances of buffer zones where relevant, among others, and reminder of the basic obligations for the cultivation and use of the product at national and Community level.

(f) Monitoring requirements according to the Insect Resistance Management Plan, and reference to the farmer questionnaire.