



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.1.2004
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Proposal for a

COUNCIL DECISION

authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council

(presented by the Commission)

EXPLANATORY MEMORANDUM

On 11 February 1999, Novartis (in the meantime Syngenta) submitted a request under Article 4 of the Novel Food Regulation (EC) N° 258/97 to the competent authorities of the Netherlands for placing sweet maize from genetically modified maize line Bt11 on the market as a novel food or as a novel food ingredient.

Following the transmission of the Dutch initial assessment report, which concluded that Bt11 sweet maize is as safe as conventional sweet maize, to all Member States, reasoned objections to the marketing of the product were raised.

Therefore, a Community Decision was required under Article 7, paragraph 1 of Regulation (EC) No 258/97 and the Commission requested an opinion of the Scientific Committee on Food as there might be an effect on public health. On 17 April 2002, the Scientific Committee on Food delivered its opinion that Bt11 sweet maize is as safe for human food use as its conventional counterparts.

In order to grant a Community authorisation, a draft Commission Decision was submitted to the Standing Committee on Food Chain and Animal Health on 8 December 2003. This Committee did not deliver its opinion on the draft submitted by the Commission, since no qualified majority was reached.

The results of the vote were:

In favour: 33 (Spain, Ireland, The Netherlands, Finland, Sweden, United Kingdom)

Against: 29 (Denmark, Greece, France, Luxembourg, Austria, Portugal)

Abstention: 25 (Belgium, Germany, Italy)

Some Member States, in particular France, claimed that scientific questions had not been addressed adequately in the assessment. However, the data provided by the applicant and the safety assessment of the product followed the criteria and requirements laid down in the Commission Recommendation 618/97/EC¹. The methodology used for the safety assessment of Bt11 was also in line with the recent guidelines prepared by the Scientific Steering Committee concerning the assessment of GMOs, GM food and GM feed² and with the Codex Principles and Guidelines on Foods Derived from Biotechnology³.

The concerns raised in the opinion of the “Agence française de sécurité sanitaire des aliments” (AFSSA) of 26 November 2003 do not bring any new scientific elements in addition to the initial assessment of sweet maize Bt11 carried out by the competent authorities of the Netherlands. In fact these concerns were also expressed in two AFSSA opinions of 21

¹ “Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation EC No 258/97 of the European Parliament and of the Council (OJ L 253 of 16.09.97).

² “Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed” Joint Working Group on Novel foods and GMOS, 6-7 March 2003.
http://europa.eu.int/comm/food/fs/sc/ssc/out327_en.pdf

³ Codex Alimentarius Commission, 2003. Codex Principles and Guidelines on Foods Derived from Biotechnology. Joint FAO/WHO Food Standards Programme, Food and Agriculture Organisation: Rome. <ftp://ftp.fao.org/codex/standard/en/CodexTextsBiotechFoods.pdf>

July 2000 and 20 March 2001 and were duly considered by the Scientific Committee on Food (SCF) in its opinion of 17 April 2002, which confirmed the findings of the initial assessment that Bt11 sweet maize is as safe for human food use as conventional maize.

Pursuant to Article 13, paragraph 4 b) of Regulation (EC) No 258/97 and in accordance with the Regulatory Committee procedure of Article 5, and in particular paragraph 4, of the Council Decision 1999/468/EC, the Commission must now submit a proposal to the Council.

In accordance with Article 46 of Regulation (EC) No 1829/2003 on genetically modified food and feed, the authorisation in case must be granted under the provisions of Regulation (EC) No 258/97. However, in order take into account the new legislative framework for the authorisation of genetically modified food and feed and as requested by the Member States at the meeting of the Standing Committee on Food Chain and Animal Health of 10 November 2003, the Commission proposal includes also the particulars required by Article 6, paragraph 5 and Article 7, paragraph 2 of Regulation (EC) No 1829/2003.

The proposed authorisation is to take effect from 18 April 2004, date of application of Regulation (EC) No 1829/2003, and to be valid for a period of 10 years.

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authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) N° 258/97 of the European Parliament and of the Council

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients⁴, (hereinafter referred to as the Regulation), and in particular Article 7 thereof,

Having regard the proposal of the Commission,

Whereas:

- (1) Consent has been granted on 22 April 1998 for the placing on the market of grains of genetically modified maize line Bt11 to be used for feed, processing and importing⁵, in accordance with Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.⁶
- (2) Food and food ingredients derived from the original transformant Bt11 and any inbred and hybrid lines derived from it and containing the introduced genes may be placed on the market in the Community following a notification⁷ pursuant to Article 5 of Regulation (EC) N° 258/97.
- (3) On 11 February 1999, Novartis (in the meantime: Syngenta), submitted a request to the competent authorities of the Netherlands for placing sweet maize from genetically modified maize line Bt11 on the market as a novel food or as a novel food ingredient.
- (4) In their initial assessment report of 12 May 2000, the Netherlands' competent food assessment body came to the conclusion that Bt11 sweet maize is as safe as conventional sweet maize.
- (5) The Commission forwarded the initial assessment report to all Member States on 15 June 2000. Within the 60 days period laid down in Article 6 (4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.

⁴ OJ L43, 14.02.1997, p.1

⁵ Commission Decision 98/292/EC, OJ L131/28, 05.05.1998, p.28

⁶ OJ L 117, 08.05.1990, p.15

⁷ OJ C 181, 26.06.1999, p.22

- (6) On 13 December 2000, the Commission requested an opinion from the Scientific Committee on Food, in accordance with Article 11 of the Regulation. On 17 April 2002, the Scientific Committee on Food delivered its opinion that Bt11 sweet maize is as safe for human food use as its conventional counterparts. This opinion focused, as requested by the Commission, on the issues raised in the comments made by Member States' authorities, including molecular characterisation and toxicity studies. The concerns raised in the opinion of the "Agence française de sécurité sanitaire des aliments" (AFSSA) of 26 November 2003 do not bring any new scientific elements in addition to the initial assessment of sweet maize Bt11.
- (7) The data provided by the applicant and the safety assessment of the product carried out followed the criteria and requirements laid down in the Commission Recommendation 618/97/EC⁸ concerning the scientific aspects and the presentation of applications under the Novel Food Regulation. The methodology used for the safety assessment of Bt11 was also in line with the recent guidelines prepared by the Scientific Steering Committee concerning the assessment of GMOs, GM food and GM feed and with the Codex Principles and Guidelines on Foods Derived from Biotechnology.
- (8) Article 46(1) of Regulation (EC) No 1829/2003 on genetically modified food and feed⁹ provides that requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of Regulation (EC) No 1829/2003, in cases where the additional assessment report required in accordance with Article 6(3) of Regulation (EC) No 258/97 has been transmitted to the Commission before the date of application of Regulation (EC) No 1829/2003.
- (9) The Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), has carried out a full validation study (ring-trial) following internationally accepted guidelines to test the performance of a quantitative event-specific method to detect and quantify the Bt11 transformation event in sweet maize. The method validated had been developed by the National Veterinary Institute of Norway and INRA, France. The materials needed in the study (GM and non-GM DNA as well as the method-specific reagents) had been provided by Syngenta. The JRC has considered that the method performance was appropriate for its aimed purpose, taken into account the performance criteria proposed by the ENGL for methods submitted for regulatory compliance as well as the current scientific understanding about satisfactory method performance. Both the method and the results of the validation have been made publicly available.
- (10) Reference material for sweet maize from genetically modified maize line Bt11 has been produced by the Joint Research Centre (JRC) of the European Commission.
- (11) Sweet maize from genetically modified maize line Bt11 and food containing sweet maize from genetically modified maize line Bt11 as ingredient shall be labelled in accordance with the provisions of Regulation (EC) No 1829/2003 and shall be subject to the traceability requirements laid down in Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the

⁸ OJ L 253 of 16.09.97

⁹ OJ L 268, 18.10.2003, p.1

traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC¹⁰.

- (12) Information on the identification of sweet maize from genetically modified maize line Bt11, including the validated detection method and the reference material, contained in the annex, shall be retrievable from the Register to be established by the Commission in accordance with Article 28 of Regulation (EC) No 1829/2003.
- (13) Genetically modified maize Bt11 has been notified to the Biosafety Clearing-House, pursuant to Articles 11(1) and 20(3)(c) of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
- (14) The Standing Committee on the Food Chain and Animal Health has not given a favourable opinion.

HAS ADOPTED THIS DECISION:

Article 1

Sweet maize from genetically modified maize line Bt11 (hereinafter referred to as “the product”), as designated and specified in the Annex, may be placed on the Community market as a novel food or novel food ingredient.

Article 2

The product shall be labelled as “genetically modified sweet maize”, in accordance with the labelling requirements laid down in Article 13 of Regulation (EC) N° 1829/2003.

Article 3

The product and the information included in the Annex shall be entered in the Community register of genetically modified food and feed.

Article 4

This Decision is addressed to Syngenta Seeds BV, The Netherlands, representing Syngenta Seeds AG, Switzerland. It shall take effect from 18 April 2004. It shall be valid for a period of 10 years.

Done at Brussels,

*For the Council
The President*

¹⁰ OJ L268, 18.10.2003, p.24

ANNEX

INFORMATION TO BE ENTERED IN THE COMMUNITY REGISTER OF GENETICALLY MODIFIED FOOD AND FEED

(a) Authorisation holder:

Name: Syngenta Seeds BV

Address: Westeinde 62, Enkhuizen, The Netherlands

On behalf of: Syngenta Seeds AG, Schwarzwaldallee 215, CH-4058 Basel, Switzerland

(b) Designation and specification of the product:

Sweet maize, fresh or canned, that is progeny from traditionally crosses of traditionally bred maize with genetically modified maize line Bt11 that contains:

- a synthetic version of the *cryIA* (b) gene derived from *Bacillus thuringiensis kurstaki* strain HD1 under the control of a 35S promoter from Cauliflower Mosaic Virus, and IVS 6 intron from the maize alcohol dehydrogenase gene and the nopaline synthase terminator sequence of *Agrobacterium tumefaciens*, and
- a synthetic version of the *pat* gene derived from *Streptomyces viridochromogenes* under the control of a 35S promoter from Cauliflower Mosaic Virus, an IVS intron from the maize alcohol dehydrogenase gene and the nopaline synthase terminator sequence of *Agrobacterium tumefaciens*.

(c) Labelling: “Genetically modified sweet maize”

(d) Method for detection:

- Event specific real-time quantitative PCR based method for genetically modified Bt11 sweet maize, published in *European Food Research and Technology*, Vol. 216/2003, pages 347-354.
- Validated by the Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), published at <http://engl.jrc.it/crl/oj/bt11sm.pdf>.
- Reference Material: IRMM-412R, produced by the Joint Research Centre (JRC) of the European Commission.

(e) Unique identifier: SYN-BT Ø11-1

(f) Information required under Annex II to the Cartagena Protocol:

Biosafety Clearing House, Record ID 1240

(see: <http://bch.biodiv.org/Pilot/Record.aspx?RecordID=1240>)

(g) Conditions or restrictions on the placing on the market of the product:

Not applicable

(h) Monitoring plan for environmental effects:

Not appropriate