Commission Decision of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604xGA21 (SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2011) 9536) (Only the French text is authentic) (Text with EEA relevance) (2011/894/EU)

COMMISSION DECISION

of 22 December 2011

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(1)], and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 31 March 2008, Syngenta Seeds SAS submitted to the competent authority of the United Kingdom an application, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from Bt11xMIR604xGA21 maize ('the application').

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of Bt11xMIR604xGA21 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, it includes the data and information required by Annexes III and IV 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[(2)] and information and conclusions about the risk assessment carried out in accordance with

the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(3) On 15 June 2010, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003. It considered that maize Bt11xMIR604xGA21 is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore it concluded that it is unlikely that the placing on the market of the products containing, consisting of, or produced from Bt11xMIR604xGA21 maize as described in the application ('the products') will have any adverse effects on human or animal health or the environment in the context of their intended uses[(3)]. In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of that Regulation.

(4) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended use of the products.

(5) Taking into account those considerations, authorisation should be granted for the products.

(6) A unique identifier should be assigned to each GMO as provided for in 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[(4)].

(7) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from Bt11xMIR604xGA21 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of feed containing or consisting of the GMO and products other than food and feed containing or consisting of the GMO for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(8) 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[(5)], lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(9) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring

results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council[6]. The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(10) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(11) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms[7].

(12) The applicant has been consulted on the measures provided for in this Decision.

(13) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chair and the Commission therefore submitted to the Council a proposal relating to these measures.

(14) Since, at its meeting on 15 December 2011, the Council was unable to reach a decision by qualified majority either for or against the proposal and the Council indicated that its proceedings on this file were concluded, these measures are to be adopted by the Commission,

HAS ADOPTED THIS DECISION:

(**1**) OJ L 268, 18.10.2003, p. 1.

(**2**) OJ L 106, 17.4.2001, p. 1.

(**3**) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00834

(**4**) OJ L 10, 16.1.2004, p. 5.

(**5**) OJ L 268, 18.10.2003, p. 24.

(**6**) OJ L 275, 21.10.2009, p. 9.

(**7**) OJ L 287, 5.11.2003, p. 1.