

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2016/87

of 22 January 2016

on the withdrawal from the market of existing products derived from MON 863 (MON-ØØ863-5) and repealing Decisions 2010/139/EU, 2010/140/EU, 2010/141/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863×MON810×NK603 (MON-ØØ863-5×MON-ØØ810-6×MON-ØØ603-6), MON863×MON810 (MON-ØØ863-5×MON-ØØ810-6) and MON863×NK603 (MON-ØØ863-5×MON-ØØ603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2016) 204)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

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 its Articles 8(6) and 20(6), as well as its Articles 9(2) and 21(2) thereof,

Whereas:

- (1) By Commission Decision 2005/608/EC ⁽²⁾, the placing on the market of feed containing or consisting of MON 863 maize and MON 863 maize in products consisting of it or containing it for any other uses than food and feed, with the exception of cultivation, is authorised in accordance with Directive 2001/18/EC of the European Parliament and of the Council ⁽³⁾, until 12 January 2016.
- (2) By Commission Decision 2006/68/EC ⁽⁴⁾, the placing on the market of food containing, consisting of, or produced from MON 863 maize is authorised in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁵⁾, until 12 January 2016.
- (3) Food additives, feed materials and feed additives produced from genetically modified maize MON 863 were placed on the market before the entry into force of Regulation (EC) No 1829/2003 and were notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation when it came into force.
- (4) On 13 April 2007, Monsanto Europe S.A. submitted to the Commission an application in accordance with Articles 8(4), 11, 20(4) and 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation for continued marketing of existing food additives, feed materials and feed additives produced from MON 863 maize which were previously notified in accordance with Article 8(1)(b) and Article 20(1)(b) of that Regulation ('the application'). On 30 March 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 and concluded that the new information provided in the renewal application and the review of the scientific literature that has been published since the previous scientific opinions on MON 863 maize by EFSA do not require changes of the opinions.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2005/608/EC of 8 August 2005 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 MON 863) genetically modified for resistance to corn rootworm (OJ L 207, 10.8.2005, p. 17).

⁽³⁾ 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 (OJ L 106, 17.4.2001, p. 1).

⁽⁴⁾ Commission Decision 2006/68/EC of 13 January 2006 authorising the placing on the market of foods and food ingredients derived from genetically modified maize line MON 863 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 34, 7.2.2006, p. 26).

⁽⁵⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

Therefore it reiterated its previous conclusions that MON 863 maize is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses. 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 Regulation (EC) No 1829/2003.

- (5) By Commission Decisions 2010/139/EU ⁽¹⁾, 2010/140/EU ⁽²⁾ and 2010/141/EU ⁽³⁾, the placing on the market of food and feed containing, consisting of, or produced from MON863×MON810×NK603 maize, MON863×MON810 maize and MON863×NK603 maize is authorised in accordance with Regulation (EC) No 1829/2003, until 1 March 2020.
- (6) On 29 June 2015, Monsanto Europe S.A. asked the Commission to put an end to all the authorisations granted by the Commission to products containing, consisting or produced from genetically modified maize MON 863, as single event and in stacked events, following a commercial decision of the company not to market these products anymore in the EU.
- (7) As a consequence, Monsanto Europe S.A. withdrew the application for the renewal of the authorisation for continued marketing of existing food additives, feed materials and feed additives produced from MON 863 maize submitted on 13 April 2007 for which EFSA published an opinion on 30 March 2010 and asked the European Commission to repeal Decisions 2005/608/EC, 2006/68/EC, 2010/139/EU, 2010/140/EU and 2010/141/EU.
- (8) As MON 863, as single event or in stacked events, has not been commercially cultivated since 2011 in third countries and the commercial phase out is completed, it is not necessary to provide for a limited period of time within which existing stocks of the product may be used up.
- (9) Decisions 2005/608/EC and 2006/68/EC expire on 12 January 2016. Since no applications for the renewal of the authorisation granted in these decisions have been lodged by Monsanto Europe S.A, the products covered in these decisions should not be placed on the market after this date.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

1. Food additives produced from MON-ØØ863-5 maize notified as existing products under Article 8(1)(b) of Regulation (EC) No 1829/2003 as well as feed materials and feed additives produced from MON-ØØ863-5 maize notified as existing products under Article 20(1)(b) shall be withdrawn from the market no later than the date of the publication of this Decision in the *Official Journal of the European Union*.
2. Decisions 2010/139/EU, 2010/140/EU and 2010/141/EU shall be repealed on the date of the publication of this Decision in the *Official Journal of the European Union*.

Article 2

The entries in the Community Register of genetically modified food and feed, referred to in Article 28 of Regulation (EC) No 1829/2003, regarding MON-ØØ863-5 maize, MON-ØØ863-5×MON-ØØ81Ø-6×MON-ØØ6Ø3-6, MON-ØØ863-5×MON-ØØ81Ø-6 and MON-ØØ863-5×MON-ØØ6Ø3-6 shall be adapted in order to take account of this Decision.

⁽¹⁾ Commission Decision 2010/139/EU of 2 March 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863×MON810×NK603 (MON-ØØ863-5×MON-ØØ81Ø-6×MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 55, 5.3.2010, p. 68).

⁽²⁾ Commission Decision of 2010/140/EU of 2 March 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863×MON810 (MON-ØØ863-5×MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 55, 5.3.2010, p. 73).

⁽³⁾ Commission Decision 2010/141/EU of 2 March 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863×NK603 (MON-ØØ863-5×MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 55, 5.3.2010, p. 78).

Article 3

This Decision is addressed to Monsanto Europe S.A., Scheldelaan 460, Haven 627, 2040 Antwerp, Belgium.

Done at Brussels, 22 January 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission
