Commission Implementing Decision of 6 November 2013 authorising the placing on the market... ANNEX Document Generated: 2023-11-16

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89034-3 × DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2013) 4719) (Only the Dutch, English and French texts are authentic) (Text with EEA relevance) (2013/648/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX

(a)Applicants and Authorisation holders

Name	:	[^{F1} Dow AgroSciences Distribution S.A.S.]
Address	:	[^{F1} 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France]

Textual Amendments

F1 Substituted by Commission Implementing Decision (EU) 2019/240 of 6 February 2019 amending Implementing Decisions 2013/648/EU and 2013/650/EU as regards the representative of the authorisation holders (notified under document C(2019) 747) (Only the Dutch, French and English texts are authentic) (Text with EEA relevance).

on behalf of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States;

and

Name	:	[^{F1} Bayer Agriculture BVBA]
Address	:	[^{F1} Scheldelaan 460, 2040 Antwerp, Belgium]

on behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.

(b) **Designation and specification of the products**

- (1) foods and food ingredients containing, consisting of, or produced from MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;
- (2) feed containing, consisting of, or produced from MON-89Ø34-3 \times DAS-Ø15Ø7-1 \times MON-ØØ6Ø3-6 maize;
- (3) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize in products containing it or consisting of it for any other use than (1) and (2), with the exception of cultivation.

The genetically modified MON-89Ø34-3 × DAS- \emptyset 15Ø7-1 × MON- $\emptyset\emptyset$ 6Ø3-6 maize, as described in the application, is produced by crosses between maize containing MON-89Ø34-3, DAS- \emptyset 15Ø7-1 and MON- $\emptyset\emptyset$ 6Ø3-6 events and expresses the Cry1A.105, Cry2Ab2, Cry1F proteins which confer protection against certain lepidopteran pests, the CP4 EPSPS protein which confers tolerance to herbicide glyphosate and the PAT protein which confers tolerance to the herbicide glufosinate-ammonium.

(c) Labelling

- (1) For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';
- (2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-89Ø34-3 \times DAS-Ø15Ø7-1 \times MON-ØØ6Ø3-6 maize, with the exception of products referred to in point (a) of Article 2.

(d) Method for detection

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Decision of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2013) 4719) (Only the Dutch, English and French texts are authentic) (Text with EEA relevance) (2013/648/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- Event specific real-time quantitative PCR based methods for quantitative detection of genetically modified MON-89Ø34-3, DAS-Ø15Ø7-1 and MON-ØØ6Ø3-6 maize validated on the single-trait events and verified on MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;
- DNA extraction method validated on ground maize seeds by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx
- Reference Material: ERM®-BF418 (for DAS-Ø15Ø7-1) and ERM®-BF415 (for MON-ØØ6Ø3-6) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at https://irmm.jrc.ec.europa.eu/rmcatalogue and AOCS 0906-E and AOCS 0406-A (for MON-89Ø34-3) accessible via the American Oil Chemists Society at http:// www.aocs.org/tech/crm

(e) Unique identifier

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6.

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Biosafety Clearing-House, Record ID: see [to be completed when notified].

(g) Conditions or restrictions on the placing on the market, use or handling of the products

Not required.

(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/ EC.

[Link: *plan published on the internet*]

(i) Post market monitoring requirements for the use of the food for human consumption

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

Changes to legislation:

There are outstanding changes not yet made to Commission Implementing Decision of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89Ø34-3 × DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2013) 4719) (Only the Dutch, English and French texts are authentic) (Text with EEA relevance) (2013/648/EU). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

View outstanding changes

Changes and effects yet to be applied to :

- Annex point (a) substituted by S.S.I. 2023/59 reg. 6(4)
- Annex point (a) substituted by S.I. 2023/235 reg. 6(4)
- Annex point (a) substituted by S.I. 2023/379 reg. 6(4)
- Annex Note word omitted by S.I. 2019/705 reg. 196