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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 (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89034-3 × DAS-01507-1 × MON-88017-3), MON89034 × 1507 × 59122 (MON-89034-3 × DAS-01507-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89034-3 × MON-88017-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-01507-1 × MON-88017-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON89017 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON 88017 × 59122

(a) Applicant and A 1745-5912273) musuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2013) 4755) (Only the Dutch, English and French texts are authentic)

Name (Text with EEA relevance) 6013/650/EUs App. 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

Address [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 : [F1Bayer Agriculture BVBA]

Address : [F1Scheldelaan 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 genetically modified maizes (*Zea mays* L.) as specified in (e);
- (2) feed containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (3) the genetically modified maizes (*Zea mays* L.) as specified in (e) in products containing it or consisting of it for any other uses than (1) and (2), with the exception of cultivation.

MON-89Ø34-3 maize expresses the Cry1A.105 and Cry2Ab2 proteins which confer protection against certain lepidopteran pests.

DAS-Ø15Ø7-1 maize, expresses the Cry1F protein which confers protection against certain lepidopteran pests and the PAT protein, which confers tolerance to the herbicide glufosinate-ammonium.

MON-88Ø17-3 maize expresses a modified Cry3Bb1 protein which provides protection to certain coleopteran pests and the CP4 EPSPS protein which confers tolerance to the herbicide glyphosate.

DAS-59122-7 maize expresses Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests and the PAT protein, which confers tolerance to the herbicide glufonisate-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';

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DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017
(MON-89Ø34-3 × DAS-015Ø7-1 × MON-88Ø17-3), MON89034 × 1507 × 59122 (MON-89Ø34-3 × DAS-015Ø7-1 ×
DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7), 1507 ×
MON 88017 × 59122 (DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)) and four related GM maizes combining

- (2) two larger enough that the first of the Council (notified under document C(2013) 4755) (Only the Dutch, English and French texts are authentic)
- (d) (Text with FEA relevance) (2013/650/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 PCR based methods for quantitative detection of genetically modified maize MON-89Ø34-3, DAS-Ø15Ø7-1, MON-88Ø17-3 and DAS-59122-7 maize; the detection methods validated on the single-trait events and verified on MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 would function with a comparable efficacy for the individual GMOs as specified in (e);
- 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®-BF424 (for DAS-59122-7) and ERM®-BF418 (for DAS-Ø15Ø7-1) 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) and AOCS 0406-D and AOCS 0406-A (for MON-88Ø17-3) accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm
- (e) Unique identifiers

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MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7;

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3;

MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7;

MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7;

DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7;

MON-89Ø34-3 × DAS-Ø15Ø7-1;

MON-89Ø34-3 × DAS-59122-7;

DAS-Ø15Ø7-1 × MON-88Ø17-3;

MON-88Ø17-3 × DAS-59122-7.
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(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 of 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.

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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 (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 $(MON-89Ø34-3 \times DAS-Ø15Ø7-1 \times MON-88Ø17-3), MON89034 \times 1507 \times 59122$ $(MON-89Ø34-3 \times DAS-Ø15Ø7-1 \times DAS-59122-7), MON89034 \times MON88017 \times 59122$ Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 \times 1507 (MON-89Ø34-3 \times DAS-Ø15Ø7-1), MON89034 × 59122 (MON-89Ø34-3 × DAS-59122-7), 1507 × MON88017 (DAS-Ø15Ø7-1 × MON-88Ø17-3), MON 88017 × 59122 (MON-88Ø17-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2013) 4755) (Only the Dutch, English and French texts are authentic) (Text with EEA relevance) (2013/650/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. 7(4)
- Annex point (a) substituted by S.I. 2023/235 reg. 7(4)
- Annex point (a) substituted by S.I. 2023/379 reg. 7(4)
- Annex Note word omitted by S.I. 2019/705 reg. 205