RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-EUR-115433-1

LAST UPDATED: 16 MAR 2020

General information

Country

European Union **PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY** **ENTRY INTO FORCE: 11 SEP 2003**

Title of the risk assessment

Assessment of genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing, under Regulation (EC) No 1829-2003 (application EFSA-GMO-NL-2013-112) EN

Date of the risk assessment

28 Nov 2018

Competent National Authority(ies) responsible for the risk assessment

- COMPETENT NATIONAL AUTHORITY: BCH-CNA-EUR-100918-4 | BCH-CNA-EUR-100918-4

COMPETENT NATIONAL AUTHORITY

European Food Safety Authority (EFSA) GMO Panel
Via Carlo Magno 1A
Parma
43126, Italy
Phone: +39 0521 036 666
Email: GMO_secretariat_applications@efsa.europa.eu, international.cooperation@efsa.europa.eu
Website: http://www.efsa.europa.eu/

Contact details of the main responsible risk assessor

- PERSON: DR. ANA AFONSO | BCH-CON-EU-107908-6

PERSON

Dr. Ana Afonso
Head of Unit, GMO Unit
Via Carlo Magno 1A
Parma, PR
43126, Italy

Phone: +39 0521 036 666
Email: GMO_secretariat_applications@efsa.europa.eu, international.cooperation@efsa.europa.eu
Website: https://www.efsa.europa.eu/

RELATED ORGANIZATION

Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-105851-1 | MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x DAS-4Ø278-9 - Insect resistant, herbicide tolerant maize | Dow AgroScience | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths)), Resistance to herbicides (Glufosinate, Glyphosate), Tolerance to 2,4-Dichlorophenoxyacetic acid, Tolerance to aryloxyphenoxypropionate
Show detection method(s)

BCH-LMO-SCBD-105850-1 | DAS-4Ø278-9 x MON-ØØ6Ø3-6 - Herbicide tolerant maize | Dow AgroScience | Resistance to herbicides (Glyphosate), Tolerance to 2,4-Dichlorophenoxyacetic acid, Tolerance to aryloxyphenoxypropionate
Show detection method(s)

BCH-LMO-SCBD-112463-1 | DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x DAS-4Ø278-9 - Insect resistant, herbicide tolerant maize | Dow AgroSciences | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths)), Resistance to herbicides (Glufosinate, Glyphosate), Tolerance to 2,4-Dichlorophenoxyacetic acid, Tolerance to aryloxyphenoxypropionate
Show detection method(s)

Scope of the risk assessment

LMOs for direct use as food
LMOs for direct use as feed
LMOs for processing

Risk assessment report / summary

? European Food Safety Authority (EFSA) *(English)*

? EU Risk Assessment maize MON 89034 × 1507 × NK603 × DAS-40278-9 EFSA Opinion.pdf *(English)*

Methodology and points to consider

LMO detection and identification methods proposed

The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events MON-89Ø34-3, DAS-Ø15Ø7-1, MON-ØØ6Ø3-6 and DAS-4Ø278-9 and further verified on maize stack MON 89034 × 1507 × NK603 × DAS-40278-9 Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx	EN

Information sharing with other databases

Is this risk assessment related to an LMO for commercial use?

No

Should this risk assessment be forwarded to the OECD Secretariat for possible inclusion in the BioTrack Product Database?

No

Is this risk assessment related to food safety?

No

Was it conducted in accordance with the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*?

No

Should this information be forwarded to the Secretariat of the FAO GM Foods Platform?

No

Additional Information

Other relevant website addresses and/or attached documents

? EURL GMFF *(English)*

? GMOMETHODS *(English)*

? EU Detection Method maize MON 89034.pdf *(English)*

? EU Detection Method maize 1507.pdf *(English)*

? EU Detection Method maize NK603.pdf *(English)*

? EU Detection Method maize DAS 40278-9.pdf *(English)*

BCH-RA-EUR-115433-1

Further Information

Questions about the Cartagena Protocol on Biosafety or the operation of the Biosafety Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

Secretariat of the Convention on Biological Diversity
413 rue Saint-Jacques, suite 800
Montreal, Québec, H2Y 1N9
Canada
Fax: +1 514 288-6588
Email: secretariat@cbd.int