





Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-EUR-109585-1

LAST UPDATED: 21 JAN 2016

General information

Country

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

Title of the risk assessment

Scientific Opinion on an application (EFSA-GMO-NL-2010-80) for the placing on the market of herbicide-tolerant genetically modified maize NK603 \times T25 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto

ΕN

Date of the risk assessment

24 Jun 2015

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/

Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-100975-11 | MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 - Roundup Ready™ Liberty Link™ maize | Resistance to antibiotics - Ampicillin Resistance to herbicides - Glufosinate, Glyphosate 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 NK603 x T25 EFSA Opinion.pdf (English)

Methodology and points to consider

LMO detection and identification methods proposed

Detection method for the single events maize NK603 and T25 and methods for the stack (NK603 x T25) respectively validated and verified by the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) available at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx

ΕN

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)

? EU Detection Method Maize T25.pdf (English)

? EU Detection Method Maize NK603.pdf (<code>English</code>)

? EU Detection Method (NK603 x T25) Verified.pdf (English)

? GMOMETHODS: European Union Database of Reference Methods for GMO Analysis (<code>English</code>)

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

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