





Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-EUR-102074-4

LAST UPDATED: 21 JAN 2021

General information

Country

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

Title of the risk assessment

European Food Safety Authority (EFSA) Opinion on the safeguard clause related to genetically modified crops (BT176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1oilseed rape)

ΕN

Date of the risk assessment

29 Mar 2006

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-14757-7 ACS-BNØØ4-7 x ACS-BNØØ1-4 - InVigor™ canola | Changes in physiology and/or production - Reproduction - Male sterility Resistance to antibiotics - Kanamycin Resistance to herbicides - Glufosinate

Show detection method(s)

BCH-LMO-SCBD-14751-10 SYN-EV176-9 - NaturGard KnockOut™ maize | Resistance to antibiotics -

Ampicillin Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths)

Resistance to herbicides - Glufosinate

Show detection method(s)

BCH-LMO-SCBD-14750-19 MON-ØØ81Ø-6 - YieldGard™ maize | Resistance to diseases and pests -

Insects - Lepidoptera (butterflies and moths)

Show detection method(s)

BCH-LMO-SCBD-14761-7 | ACS-BNØØ7-1 - Liberty-Link™ Innovator Canola | Resistance to antibiotics -

Kanamycin Resistance to herbicides - Glufosinate

Show detection method(s)

BCH-LMO-SCBD-14767-14 | ACS-ZMØØ3-2 - Liberty Link™ maize | Resistance to antibiotics -

Ampicillin Resistance to herbicides - Glufosinate

Show detection method(s)

Scope of the risk assessment

LMOs for introduction into the environment

commercial production

LMOs for direct use as food

LMOs for direct use as feed

LMOs for processing

Risk assessment report / summary

? EFSA opinion safeguard clause oilseed rape Ms1xRf1 and Topas 19/2, maize MON810, Bt176 and T25.pdf (English)

? European Food Safety Authority (EFSA) panel on GMOs (English)

Methodology and points to consider

LMO detection and identification methods proposed

EU Detection Method validated by the European Union Reference Laboratory for GM Food

Feed (EURL GMFF)

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

EU Detection Method validated by the European Union Reference Laboratory for GM Food Feed (EURL GMFF)

ΕN

Other relevant website addresses and/or attached documents

- ? European Union Reference Laboratory for GM Food Feed (EURL GMFF) (<code>English</code>)
- ? EU Detection Method Oilseed Rape Ms1.pdf (English)
- ? EU Detection Method Oilseed Rape Rf1.pdf (English)
- $\ref{MOMETHODS}$: European Union database of reference methods for GMO analysis (<code>English</code>)

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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