RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-EUR-110990-3

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

Scientific Opinion on an application by Syngenta (EFSA-GMO-DE-2009-66) for placing on the market of herbicide tolerant and insect resistant maize Bt11 × MIR162 × MIR604 × GA21 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/20031

EN

Date of the risk assessment

29 Oct 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
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Contact details of the main responsible risk assessor

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RELATED ORGANIZATION

Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-101252-11 | SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9 - Agrisure Viptera® 4 Maize | Mannose tolerance Resistance to diseases and pests - Insects - Coleoptera (beetles) - Western corn rootworm (Diabrotica virgifera), Lepidoptera (butterflies and moths) Resistance to herbicides - Glufosinate, Glyphosate Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-101251-11 | SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9 - Agrisure® Viptera™ 3110 Maize | Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glufosinate, Glyphosate Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-43635-9 | SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9 - Agrisure™ 3000GT Maize | Syngenta Crop Protection AG | Mannose tolerance, Resistance to diseases and pests (Insects, Coleoptera (beetles), Lepidoptera (butterflies and moths), European corn borer (Ostrinia nubilalis)), Resistance to herbicides (Glufosinate, Glyphosate), Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-104749-3 | SYN-BTØ11-1 x SYN-IR162-4 - Insect Resistant Maize | Syngenta Crop Protection AG | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths)), Resistance to herbicides (Glufosinate), Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-43624-10 | SYN-BTØ11-1 x SYN-IR6Ø4-5 - Agrisure™ CB/LL/RW maize | Resistance to diseases and pests (Insects, Coleoptera (beetles), Western corn rootworm (Diabrotica virgifera), Lepidoptera (butterflies and moths), European corn borer (Ostrinia nubilalis)), Resistance to herbicides (Glufosinate), Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-16121-8 | SYN-BTØ11-1 x MON-ØØØ21-9 - YieldGard™ Roundup Ready™ maize | Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glufosinate, Glyphosate
Show detection method(s)

BCH-LMO-SCBD-43630-9 | SYN-IR6Ø4-5 x MON-ØØØ21-9 - Agrisure™ RW Rootworm-Protected Roundup Ready™ maize | Syngenta Crop Protection AG | Mannose tolerance, Resistance to diseases and pests (Insects, Coleoptera (beetles)), Resistance to herbicides (Glyphosate), Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-110983-1 | SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 - Insect resistant, herbicide

tolerant maize | Syngenta France SAS | Resistance to diseases and pests (Insects, Coleoptera (beetles), Lepidoptera (butterflies and moths)), Resistance to herbicides (Glufosinate), Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-110984-2 | SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9 - Insect resistant, herbicide tolerant maize | Syngenta France SAS | Resistance to diseases and pests (Insects, Coleoptera (beetles), Lepidoptera (butterflies and moths)), Resistance to herbicides (Glyphosate), Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-110985-1 | SYN-IR162-4 x SYN-IR6Ø4-5 - Insect resistant maize | Syngenta France SAS | Resistance to diseases and pests (Insects, Coleoptera (beetles), Lepidoptera (butterflies and moths)), Selectable marker genes and reporter genes
Show detection method(s)

BCH-LMO-SCBD-110986-3 | SYN-IR162-4 x MON-ØØØ21-9 - Insect resistant, herbicide tolerant maize | Syngenta France SAS | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths)), Resistance to herbicides (Glyphosate), Selectable marker genes and reporter genes
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 Bt11xMIR162xMIR604xGA21 EFSA Opinion.pdf *(English)*

Methodology and points to consider

LMO detection and identification methods proposed

Detection methods for the single events maize Bt11, MIR162, MIR604 and GA21 and methods for the stack (Bt11xMIR162xMIR604xGA21) respectively validated and verified by the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) are available 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)*

? EU Detection Method Maize (Bt11xMIR162xMIR604xGA21) Verified.pdf *(English)*

? EU Detection Method Maize Bt11.pdf *(English)*

? EU Detection Method Maize MIR162.pdf *(English)*

? EU Detection Method Maize MIR604.pdf *(English)*

? EU Detection Method Maize GA21.pdf *(English)*

? GMOMETHODS: European Union database of reference methods for GMO analysis *(English)*

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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.

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