





Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-EUR-115314-1

LAST UPDATED: 16 DEC 2019

Amendment

Is this an amendment to a decision or communication already published on the BCH?

No

General information

Country

European Union

PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY

ENTRY INTO FORCE: 11 SEP 2003

Competent National Authority(ies) responsible for the decision or communication

- COMPETENT NATIONAL AUTHORITY: BCH-CNA-EUR-49387-10 | BCH-CNA-EUR-49387-10

COMPETENT NATIONAL AUTHORITY

European Commission - Health and Food Safety Directorate General SANTE

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Brussels

1040, Belgium

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Email: anastasia.pagida@ec.europa.eu

Website: http://ec.europa.eu/dgs/health_food-safety/index_en.htm

Title / Reference number of the decision or communication

Commission Implementing Decision (EU) 2019/1303 of 26 July 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 5307 (SYN-Ø53Ø7-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

ΕN

Date of the decision

26 Jul 2019

Is the decision taken prior to entry into force of the Protocol?

No

Subject of the decision, notification, communication or declaration

Decision on LMOs for direct use as food or feed, or for processing (Article 11, LMOs-FFP)

LMOs for direct use as food or feed, or for processing (LMOs-FFP)

Use(s) of LMO

LMOs for direct use as food

LMOs for direct use as feed

LMOs for processing

Has the decision been taken in the absence of a domestic regulatory framework and in accordance with Article 11.6?

No

Result of the decision

Result of the decision

Approval of the import and/or use of the LMO(s) without conditions

Information sharing with other databases

Is this decision related to an LMO for commercial use?

No

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

No

Is this decision 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

LMO identification & risk assessment

LMO identification

BCH-LMO-SCBD-104791-4 LIVING MODIFIED ORGANISM | SYN-Ø53Ø7-1 - AGRISURE® DURACADE™ MAIZE |

Syngenta Crop Protection AG | Resistance to diseases and pests (Insects, Coleoptera (beetles), Western corn rootworm (Diabrotica virgifera), Northern corn rootworm (Diabrotica barberi))

Risk assessment

BCH-RA-EUR-115313-1 RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | SCIENTIFIC OPINION ON APPLICATION (EFSA-GMO-DE-2011-95) FOR THE PLACING ON THE MARKET OF GENETICALLY MODIFIED MAIZE 5307 FOR FOOD AND FEED USES, IMPORT AND PROCESSING UNDER REGULATION (EC) NO 1829/2003 FROM SYNGENTA CROP PROTECTION AG

SYN-Ø53Ø7-1 - Agrisure® Duracade™ Maize Mannose tolerance Resistance to diseases and pests - Insects - Coleoptera (beetles) - Western corn rootworm (Diabrotica virgifera), Northern corn rootworm (Diabrotica barberi) Selectable marker genes and reporter genes

Document on the decision, communication, notification or declaration

? EUR-Lex (English)

? EU register of GM Food and Feed (<code>English</code>)

? EU Decision 2019-1303.pdf (English)

Additional Information

Event specific real-time quantitative PCR based method for detection of the genetically modified maize SYN- Ø53Ø7-1; validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx

Other relevant website addresses and/or attached documents

? EURL GMFF (English)

? GMOMETHODS (English)

? EU Detection Method maize 5307.pdf (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.

Secretariat of the Convention on Biological Diversity

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