





Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC) BCH-DE

BCH-DEC-EUR-116069-1

LAST UPDATED: 01 JUN 2021

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 Rue Belliard, B232 Brussels 1040, Belgium Phone: +32 2 29 20485 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) 2021/60 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/ 2003 of the European Parliament and of the Council

Date of the decision

22 Jan 2021

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-110488-1 LIVING MODIFIED ORGANISM MON-87427-7 X MON-89Ø34-3 X SYN-IR162-4 X MON-ØØ6Ø3-6 - INSECT RESISTANT HERBICIDE TOLERANT CORN

Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes

BCH-LMO-SCBD-115665-5 LIVING MODIFIED ORGANISM | MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 - HERBICIDE TOLERANT, INSECT RESISTANT MAIZE |

Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes

BCH-LMO-SCBD-114160-3 LIVING MODIFIED ORGANISM MON-87427-7 × MON-ØØ6Ø3-6 -

GLYPHOSATE TOLERANT MAIZE

Resistance to herbicides - Glyphosate

BCH-LMO-SCBD-105692-1 LIVING MODIFIED ORGANISM MON-87427-7 X MON-89Ø34-3 X MON-ØØ6Ø3-6 - INSECT RESISTANT HERBICIDE TOLERANT CORN

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

BCH-LMO-SCBD-112647-1 LIVING MODIFIED ORGANISM MON-87427-7 X MON-89Ø34-3 - INSECT RESISTANT HERBICIDE TOLERANT MAIZE

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

BCH-LMO-SCBD-115666-2 LIVING MODIFIED ORGANISM | MON-87427-7 × SYN-IR162-4 × MON-ØØ6Ø3-6 - GLYPHOSATE TOLERANT, LEPIDOPTERA RESISTANT MAIZE

Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes

BCH-LMO-SCBD-115663-4 LIVING MODIFIED ORGANISM | MON-87427-7 × SYN-IR162-4 - HERBICIDE TOLERANT, INSECT RESISTANT MAIZE

Bayer CropScience Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes

BCH-LMO-SCBD-115664-1 LIVING MODIFIED ORGANISM | MON-89Ø34-3 X SYN-IR162-4 - INSECT RESISTANT MAIZE |

Bayer CropScience Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Selectable marker genes and reporter genes

BCH-LMO-SCBD-46305-16 LIVING MODIFIED ORGANISM | MON-89Ø34-3 X MON-ØØ6Ø3-6 - GENUITY® VT DOUBLE PRO™ MAIZE

Monsanto Europe S.A. | Resistance to antibiotics (Kanamycin), Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths)), Resistance to herbicides (Glyphosate)

BCH-LMO-SCBD-115667-1 LIVING MODIFIED ORGANISM MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 - HERBICIDE TOLERANT, INSECT RESISTANT MAIZE

Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes

BCH-LMO-SCBD-112129-1 LIVING MODIFIED ORGANISM SYN-IR162-4 X MON-ØØ6Ø3-6 - INSECT RESISTANT, HERBICIDE TOLERANT MAIZE

Dr. Wendelyn Jones | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths)), Resistance to herbicides (Glyphosate), Selectable marker genes and reporter genes

Risk assessment

BCH-RA-EUR-116068-1 RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS ASSESSMENT OF GENETICALLY MODIFIED MAIZE MON 87427 × MON 89034 × MIR162 × NK603 AND SUBCOMBINATIONS, FOR FOOD AND FEED USES, UNDER REGULATION (EC) NO 1829/2003 (APPLICATION EFSA-GMO-NL-2016-131)

MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ6Ø3-6 - Insect resistant Herbicide tolerant Corn Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides -Glyphosate Selectable marker genes and reporter genes MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 - Herbicide tolerant, insect resistant maize Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes MON-87427-7 \times MON-ØØ6Ø3-6 - Glyphosate tolerant maize Resistance to herbicides - Glyphosate MON-87427-7 \times MON-89Ø34-3 x MON-ØØ6Ø3-6 - Insect resistant Herbicide tolerant Corn Resistance to diseases and pests - Insects -Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate MON-87427-7 x MON-89Ø34-3 - Insect resistant Herbicide tolerant Maize Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate MON-87427-7 × SYN-IR162-4 × MON-ØØ6Ø3-6 - Glyphosate tolerant, Lepidoptera resistant maize Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes MON-87427-7 × SYN-IR162-4 - Herbicide tolerant, Insect resistant maize Bayer CropScience Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 - Herbicide tolerant, insect resistant maize Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes MON-89Ø34-3 x MON-ØØ6Ø3-6 - Genuity® VT Double Pro™ Maize Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate MON-89Ø34-3 x SYN-IR162-4 - Insect resistant maize Bayer CropScience Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Selectable marker genes and reporter genes SYN-IR162-4 x MON-ØØ6Ø3-6 - Insect resistant, herbicide tolerant maize Mannose tolerance Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate Selectable marker genes and reporter genes

Document on the decision, communication, notification or declaration

- ? EUR-Lex (English)
- ? EU Decision 2021/60 (English)
- ? EU register of GM Food and Feed (English)

Additional Information

Detection methods for the maize MON 87427 × MON 89034 × MIR162 × NK603 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

Other relevant website addresses and/or attached documents

- ? EURL GMFF (English)
- **?** GMOMETHODS (*English*)
- ? EU Register of GM Food and Feed (*English*)
- ? EU Detection Method maize MIR162.pdf (English)
- ? EU Detection Method maize MON 87427.pdf (*English*)
- PEU Detection Method maize MON 89034.pdf (English)

? EU Detection Method maize NK603.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 413 rue Saint-Jacques, suite 800 Montreal, Québec, H2Y 1N9 Canada Fax: +1 514 288-6588 Email: secretariat@cbd.int