

Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-EUR-116347-1

LAST UPDATED: 12 OCT 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

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

Title / Reference number of the decision or communication

Commission Implementing Decision (EU) 2021/1391 of 17 August 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rapes Ms8 × Rf3 × GT73, Ms8 × GT73 and Rf3 × GT73 pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council

EN

Date of the decision

17 Aug 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-104829-2](#) LIVING MODIFIED ORGANISM | ACS-BN005-8 X ACS-BN003-6 X MON-00073-7 - MALE STERILE/ FERTILITY RESTORED HERBICIDE TOLERANT CANOLA |
Bayer CropScience LP | Changes in physiology and/or production (Reproduction, Male sterility), Resistance to herbicides (Glufosinate, Glyphosate)

[BCH-LMO-SCBD-116284-2](#) LIVING MODIFIED ORGANISM | ACS-BN005-8 × MON-00073-7 - MALE-

STERILE, HERBICIDE-TOLERANT CANOLA

Bayer CropScience Changes in physiology and/or production - Reproduction - Male sterility Resistance to herbicides - Glufosinate, Glyphosate

BCH-LMO-SCBD-116285-1 LIVING MODIFIED ORGANISM | ACS-BN003-6 x MON-00073-7 - HERBICIDE TOLERANT, MALE FERTILITY RESTORING CANOLA

Bayer CropScience Changes in physiology and/or production - Fertility restoration Resistance to herbicides - Glufosinate, Glyphosate

Risk assessment

BCH-RA-EUR-116346-1 RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | SCIENTIFIC OPINION ON AN APPLICATION BY BAYER CROPSCIENCE AND MONSANTO (EFSA-GMO-NL-2009-75) FOR PLACING ON THE MARKET OF GENETICALLY MODIFIED GLUFOSINATE-AMMONIUM- AND GLYPHOSATE-TOLERANT OILSEED RAPE MS8 x RF3 x GT73 AND SUBCOMBINATIONS, WHICH HAVE NOT BEEN AUTHORISED PREVIOUSLY (I.E. MS8 x GT73 AND RF3 x GT73) INDEPENDENTLY OF THEIR ORIGIN, FOR FOOD AND FEED USES, IMPORT AND PROCESSING, WITH THE EXCEPTION OF ISOLATED SEED PROTEIN FOR FOOD, UNDER REGULATION (EC) NO 1829/2003

ACS-BN005-8 x ACS-BN003-6 x MON-00073-7 - Male Sterile/ Fertility Restored Herbicide Tolerant Canola Changes in physiology and/or production - Reproduction - Male sterility Resistance to herbicides - Glufosinate, Glyphosate ACS-BN005-8 x MON-00073-7 - Male-sterile, Herbicide-tolerant canola Bayer CropScience Changes in physiology and/or production - Reproduction - Male sterility Resistance to herbicides - Glufosinate, Glyphosate ACS-BN003-6 x MON-00073-7 - Herbicide tolerant, male fertility restoring canola Bayer CropScience Changes in physiology and/or production - Fertility restoration Resistance to herbicides - Glufosinate, Glyphosate

Document on the decision, communication, notification or declaration

? [EUR-Lex \(English \)](#)

? [EU Decision 2021/1391.pdf \(English \)](#)

? [EU register of GM Food and Feed \(English \)](#)

Additional Information

Detection methods for the oilseed rape Ms8xRf3xGT73 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 European Union database of reference methods for GMO analysis \(English \)](#)

? [EU Detection Method Ms8.pdf \(English \)](#)

? [EU Detection Method Rf3.pdf \(English \)](#)

? [EU Detection Method RT73.pdf \(English \)](#)

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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