

Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-EUR-115401-1

LAST UPDATED: 26 FEB 2020

Amendment

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

Yes

Decision(s) or communication(s) amended

BCH-DEC-EUR-110593-1 COUNTRY'S DECISION OR ANY OTHER COMMUNICATION | COMMISSION IMPLEMENTING DECISION 2013/327/EU OF 25 JUNE 2013 AUTHORISING THE PLACING ON THE MARKET OF FOOD CONTAINING OR CONSISTING OF GENETICALLY MODIFIED OILSEED RAPE MS8, RF3 AND MS8 × RF3, OR FOOD AND FEED PRODUCED FROM THOSE GENETICALLY MODIFIED ORGANISMS PURSUANT TO REGULATION (EC) NO 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL | ACS-BNØØ5-8 - InVigor™ canola | Rapeseed, Canola plant, Canola | ACS-BNØØ3-6 - InVigor™ canola | Rapeseed, Canola plant, Canola | ACS-BNØØ5-8 x ACS-BNØØ3-6 - InVigor™ canola | Canola plant

Brief summary of the amendment(s)

The applicant asked the Commission to merge into a single authorisation the uses of oilseed rapes Ms8, Rf3 and Ms8 × Rf3 covered by the renewal application and the uses of those oilseed rapes covered by Implementing Decision 2013/327/EU. The Commission considers that the request of the applicant is justified, in the interest of simplification.

EN

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) 2019/1301 of 26 July 2019 amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

EN

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 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-14759-8 LIVING MODIFIED ORGANISM | ACS-BNØØ5-8 - INVIGOR™ CANOLA |
Changes in physiology and/or production - Reproduction - Male sterility Resistance to herbicides - Glufosinate

BCH-LMO-SCBD-14755-7 LIVING MODIFIED ORGANISM | ACS-BNØØ3-6 - INVIGOR™ CANOLA |
Changes in physiology and/or production - Fertility restoration Resistance to herbicides - Glufosinate

BCH-LMO-SCBD-14760-9 LIVING MODIFIED ORGANISM | ACS-BNØØ5-8 X ACS-BNØØ3-6 - INVIGOR™ CANOLA |
Changes in physiology and/or production - Reproduction - Male sterility Resistance to herbicides - Glufosinate

Risk assessment

BCH-RA-EUR-115400-1 RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | ASSESSMENT OF GENETICALLY MODIFIED OILSEED RAPE MS8, RF3 AND MS8×RF3 FOR RENEWAL OF AUTHORISATION UNDER REGULATION (EC) NO 1829/2003 (APPLICATION EFSA-GMO-RX-004) |
ACS-BNØØ5-8 - InVigor™ canola Changes in physiology and/or production - Reproduction - Male sterility Resistance to herbicides - Glufosinate ACS-BNØØ3-6 - InVigor™ canola Changes in physiology and/or production - Fertility restoration Resistance to herbicides - Glufosinate ACS-BNØØ5-8 x ACS-BNØØ3-6 - InVigor™ canola Changes in physiology and/or production - Reproduction - Male sterility Resistance to herbicides - Glufosinate

Document on the decision, communication, notification or declaration

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

? [EU Decision 2019/1301.pdf \(English \)](#)

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

Additional Information

Event specific real-time PCR detection method for Ms8, Rf3, Ms8xRf3 oilseed rapes. Validated on seeds 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 Oilseed rape Ms8.pdf](#) (*English*)

? [EU Detection Method Maize Oilseed rape Rf3.pdf](#) (*English*)

[BCH-DEC-EUR-115401-1](#)

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