

Biosafety Clearing-House (BCH)

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-ZA-113684-1

LAST UPDATED: 20 AUG 2018

Amendment

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

No

General information

Country

South Africa

PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY

ENTRY INTO FORCE: 12 NOV 2003

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

- **COMPETENT NATIONAL AUTHORITY:** BCH-CNA-ZA-254-4 | [BCH-CNA-ZA-254-4](#)

COMPETENT NATIONAL AUTHORITY

National Department of Agriculture, Land Reform and Rural Development
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Title / Reference number of the decision or communication

Commodity Clearance of Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21

EN

Date of the decision

08 Jun 2018

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) with conditions

Conditions

Import permit is still required for transboundary movement of this event.
The procedure to follow is to complete the application form for importation of a GMO that has obtained general release or commodity clearance under the GMO Act.

The applicant still needs to comply with any other relevant legislation in South Africa, with particular reference to phytosanitary requirements.

The application form for importation of a GMO that has general release or commodity clearance status in SA is available on the website of the Department of Agriculture at <http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Genetic-Resources/Biosafety/Services/Word-Application-Forms>

EN

Reasons

Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21 obtained commodity clearance under the Genetically Modified Organisms (GMO) Act, 1997 (Act No. 15 of 1997).

EN

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-112993-1 LIVING MODIFIED ORGANISM | SYN-BTØ11-1 X SYN-IR162-4 X SYN-IR6Ø4-5 X MON-89Ø34-3 X SYN-Ø53Ø7-1 X MON-ØØØ21-9 - INSECT RESISTANT, HERBICIDE TOLERANT MAIZE | Syngenta Crop Protection AG | Resistance to diseases and pests (Insects, Coleoptera (beetles), Lepidoptera (butterflies and moths)), Resistance to herbicides (Glufosinate, Glyphosate), Selectable marker genes and reporter genes

Risk assessment

BCH-RA-ZA-113683-1 RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | RISK ASSESSMENT OF BT11 X MIR162 X MIR604 X MON89034 X 5307 X GA21 | SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-89Ø34-3 x SYN-Ø53Ø7-1 x MON-ØØØ21-9 - Insect resistant, herbicide tolerant maize | Resistance to diseases and pests, Resistance to herbicides, Selectable marker genes and reporter genes

Document on the decision, communication, notification or declaration

? www.daff.gov.za (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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