

## Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-EUR-102062-6

LAST UPDATED: 21 JAN 2021

## General information

Country

[European Union](#)**PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY****ENTRY INTO FORCE: 11 SEP 2003**

Title of the risk assessment

Opinion of the Scientific Panel on GMOs on the placing on the market for import and processing of insect-protected genetically modified maize MON863 and MON863 x MON810

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Date of the risk assessment

02 Apr 2004

Competent National Authority(ies) responsible for the risk assessment

- [COMPETENT NATIONAL AUTHORITY: BCH-CNA-EUR-100918-4](#) | [BCH-CNA-EUR-100918-4](#)**COMPETENT NATIONAL AUTHORITY**

European Food Safety Authority (EFSA) GMO Panel  
Via Carlo Magno 1A  
Parma  
43126, Italy  
Phone: +39 0521 036 666  
Email: [GMO\\_secretariat\\_applications@efsa.europa.eu](mailto:GMO_secretariat_applications@efsa.europa.eu),  
[international.cooperation@efsa.europa.eu](mailto:international.cooperation@efsa.europa.eu)  
Website: <http://www.efsa.europa.eu/>

Contact details of the main responsible risk assessor

- [PERSON: DR. ANA AFONSO](#) | [BCH-CON-EU-107908-6](#)**PERSON**

Dr. Ana Afonso  
Head of Unit, GMO Unit  
Via Carlo Magno 1A  
Parma, PR  
43126, Italy  
Phone: +39 0521 036 666

Email: [GMO\\_secretariat\\_applications@efsa.europa.eu](mailto:GMO_secretariat_applications@efsa.europa.eu),  
[international.cooperation@efsa.europa.eu](mailto:international.cooperation@efsa.europa.eu)  
Website: <https://www.efsa.europa.eu/>

#### RELATED ORGANIZATION

## Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-14778-15](#) | MON-ØØ863-5 - YieldGard™ Rootworm™ maize | Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Insects - Coleoptera (beetles)

[Show detection method\(s\)](#)

[BCH-LMO-SCBD-14890-7](#) | MON-ØØ863-5 x MON-ØØ81Ø-6 - YieldGard™ Rootworm™ maize | Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Insects - Coleoptera (beetles), Lepidoptera (butterflies and moths)

[Show detection method\(s\)](#)

Scope of the risk assessment

LMOs for direct use as food  
LMOs for direct use as feed  
LMOs for processing

Risk assessment report / summary

? [European Food Safety Authority \(EFSA\)](#) ( *English* )

? [EU Risk Assessment Maize MON863 EFSA Opinion.pdf](#) ( *English* )

## Methodology and points to consider

LMO detection and identification methods proposed

Detection methods for the single events maize MON863 and maize MON810 and method for the stack (MON863 x MON810) 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>

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## Information sharing with other databases

Is this risk assessment related to an LMO for commercial use?

No

Should this risk assessment be forwarded to the OECD Secretariat for possible inclusion in the [BioTrack Product Database](#)?

No

Is this risk assessment 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

## Additional Information

Additional opinion from the European Food Safety Authority (EFSA) available on the renewal of food feed authorisation of maize MON863 and on the safety of foods and food ingredients derived from maize MON863 and MON863xMON810

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Other relevant website addresses and/or attached documents

- ? [European Food Safety Authority \(EFSA\) Renewal Opinion](#) ( *English* )
- ? [Renewal Maize MON863 EFSA Opinion.pdf](#) ( *English* )
- ? [European Food Safety Authority \(EFSA\) Safety Opinion](#) ( *English* )
- ? [Safety Foods and Food Ingredients from Maize MON863 and MON863xMON810 EFSA Opinion.pdf](#) ( *English* )
- ? [EURL GMFF](#) ( *English* )
- ? [EU Detection Method Maize MON863.pdf](#) ( *English* )
- ? [EU Detection Method Maize MON810.pdf](#) ( *English* )
- ? [EU Detection Method Maize \(MON863 x MON810\) Verified.pdf](#) ( *English* )
- ? [Assessment report of German National Competent Authorities](#) ( *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](mailto:secretariat@cbd.int)