

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-BR-113501-1

LAST UPDATED: 27 DEC 2017

General information

Country

[Brazil](#)

PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY

ENTRY INTO FORCE: 22 FEB 2004

Title of the risk assessment

Risk assessment of maize hybrids selected by conventional crossing resulting from the combination of events technically approved by CTNBio - TC15Ø7 x MON81Ø x MIR162 x MON6Ø3 - Technical Report 4409/2015

EN

Date of the risk assessment

09 Apr 2015

Competent National Authority(ies) responsible for the risk assessment

- [COMPETENT NATIONAL AUTHORITY: BCH-CNA-BR-45556-3](#) | [BCH-CNA-BR-45556-3](#)

COMPETENT NATIONAL AUTHORITY

National Technical Biosafety Commission

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PERSON

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RELATED ORGANIZATION

Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-105689-1](#) | DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x SYN-IR162-4 x MON-ØØ6Ø3-6 - Herbicide tolerant, insect resistant corn | Pioneer Hi-Bred International Inc. | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths)), Resistance to herbicides (Glufosinate, Glyphosate)
[Show detection method\(s\)](#)

Scope of the risk assessment

LMOs for introduction into the environment
 commercial production
 field trial
LMOs for contained use
LMOs for direct use as food
LMOs for direct use as feed
LMOs for processing

Risk assessment report / summary

? [Parecer Final 4409Dupont.pdf](#) (*English*)

Methodology and points to consider

Potential adverse effects identified in the risk assessment

CTNBio reviewed the reports submitted by the applicant as well as independent scientific literature. Scientific studies conducted to evaluate biosafety, agronomic and phenotypic characteristics, as part of the risk assessment of this GMO, included representative regions for maize culture in Brazilian territory. After analyzing the data, CTNBio concluded that there are no restrictions on the use of quadruple corn and subcombinations cited, considering also their derivatives.

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Likelihood that the potential adverse effects will be realized

The double and triple combinations of the cited events have also been submitted to the CTNBio risk assessment, which concludes in their opinions that "genetic modification events are substantially equivalent to conventional corn" and "that these events are not potentially causing significant degradation of the environment".

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Possible consequences

The analysis of the risk assessment of the combined event TC1507 x MON810 x MIR162 x

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NK603 occurred on a case-by-case basis and considered, according to Art. 3 of RN 5/2008, the information previously presented for the individual events, which contain the same genetic construct, and the information of the present proposal for commercial release of the combined event, aiming to verify if the information presented and evaluated by CIBio of the applicant corroborate the hypothesis that there is no interaction between the inserts present in the combined event.

Estimation of the overall risk

All the individual events of the combined event have already been analyzed by CTNBio and released commercially and all the information on the risk assessment of these events is found in the aforementioned opinions.

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Recommendation(s) on whether the risks are acceptable/manageable and any management strategies

In addition to the literature data demonstrating the different modes of action of the Cry1Ab, Cry1F and Vip3Aa proteins that confer insect resistance, laboratory analyzes and field tests evidence the absence of unexpected effects corroborating the hypothesis that there is no interaction between proteins Cry1F, Cry1Ab, Vip3Aa, PAT, CP4 EPSPS and PMI, according to the results presented according to the tests performed

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Need(s) for further information on specific issues of concern

Considering the substantial equivalence of the TC1507 x MON810 x MIR162 x NK603 event demonstrated in the composition analysis studies and considering that there is no evidence that the combination of the four individual events resulted in a new product, according to studies, it is concluded that all the experiments that demonstrated the safety of individual events are applicable to the combined event.

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Receiving environment(s) considered

As established in art. 1 of Law No. 11,460 of March 21, 2007, "are prohibited the research and cultivation of GMOs in indigenous lands and areas of conservation units, except in the Areas of Environmental Protection"

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LMO detection and identification methods proposed

Molecular Traditional Methods

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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

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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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