RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA) BCH-RA-PH-105878-1

LAST UPDATED: 12 SEP 2014

General information

Country

Philippines **PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY** **ENTRY INTO FORCE: 03 JAN 2007**

Title of the risk assessment

Decision for the Safety Assessment of Monsanto and Dow AgroSciences' corn MON 89034 x TC 1507 x NK603, for Direct Use as food and feed or for processing EN

Date of the risk assessment

10 Dec 2010

Competent National Authority(ies) responsible for the risk assessment

- COMPETENT NATIONAL AUTHORITY: BCH-CNA-PH-46524-5 | BCH-CNA-PH-46524-5

COMPETENT NATIONAL AUTHORITY

Department of Agriculture
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Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-101288-8 | MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 - Power Core™ Maize | 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 direct use as food
LMOs for direct use as feed

LMOs for processing

Risk assessment report / summary

? DA-BPI Biotech Website *(English)*

Methodology and points to consider

Potential adverse effects identified in the risk assessment

Based on the modes of action of the Cry1A.105, Cry2Ab2, Cry1F, PAT and CP4 EPSPS proteins expressed in MON89034 x TC1507 x NK603, there is no known mechanism of interaction among/between the gene products that could lead to adverse effects in human and animals.	EN

Likelihood that the potential adverse effects will be realized

Each protein is not designed to alter the corn plant's metabolism and has been shown in the evaluation of each single event (MON89034, TC1507, NK603) to be equivalent to conventional corn. Having different modes and/or mechanisms of action and binding sites involved for each protein, production of the Cry1A.105, Cry2Ab2, Cry1F, PAT and CP4 EPSPS proteins in the combined trait product does not produce any adverse effects (interactive or synergistic) on plant metabolism. .	EN

Possible consequences

There were no synergistic or antagonistic interactions identified in the combined trait product corn, MON89034 x TC1507 x NK603, it is anticipated that there will be no biologically significant interactions in the dual event combinations that could occur in the grain derived from this combined trait product.	EN

Estimation of the overall risk

After reviewing the scientific data and information relevant to the combined trait product corn MON89034 x TC1507 x NK603 application of Monsanto Philippines and Dow AgroSciences, it is concluded that no interaction found between/among the combined traits. Hence, this plant product was found to be as safe as its conventional corn and can substitute for its traditional counterpart for direct use as food, feed and for processing. .	EN

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

A biosafety notification for combined trait product : corn MON89034 x TC1507 x NK603 and all progenies derived from crosses of the product with any conventionally bred corn and corn containing approved biotech events for direct use as food, feed or for processing was issued to Monsanto and Dow AgroSciences.	EN

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

MON89034 x TC1507 x NK603 is found to be as safe as its conventional counterpart and does	EN

not pose any significant risk to human and animal health.

Receiving environment(s) considered

This LMO will be directly used for food, feed and processing. EN

LMO detection and identification methods proposed

Quantitative diagnostic lateral flow strips, ELISA and PCR for routine quantitative and semi-quantitative detection of transgenes. For higher sensitivity, real-time PCR.Methods and protocols for safe handling, storage, transport and use are all indicated in the implementing rules and regulations (IRRs), memo circulars supplementing Administrative Order No. 8 of the Department of Agriculture; also the general guidelines of the National Committee on Biosafety of the Philippines. EN

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

The combined trait product MON89034 X TC1507 X NK603 is intended for direct use as food, feed and for processing.

All relevant references submitted by the technology developer in their application; other references requested by the Scientific and Technical Review Panel (STRP) members and DA Regulatory Agencies during the evaluation of MON89034 X TC1507 X NK603. EN

Other relevant website addresses and/or attached documents

? OECD Consensus Document on Corn *(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.

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