RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-115892-1

LAST UPDATED: 18 FEB 2021

General information

Country

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

Title of the risk assessment

Determination for the Safety Assessment of Corn DAS 40278-9 for Direct Use as Food, Feed and for Processing EN

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
Elliptical Road, Diliman
Quezon City
1100, Philippines
Phone: +632 920-3986, +632 924-1278 local 2802
Fax: +632 920-3986
Email: osec.da@gmail.com
Website: http://www.da.gov.ph

Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-104814-1 | DAS-4Ø278-9 - Enlist™ Maize | Dow AgroSciences GmbH Resistance to herbicides Tolerance to 2,4-Dichlorophenoxyacetic acid Tolerance to aryloxyphenoxypropionate
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

http://biotech.da.gov.ph/Decision_docs_jdc_direct.php?fbclid=IwAR1DfDu4QHnejzgzo7mOdByQboQaHxxmQzFUMcRI6EoKw492 *(English)*

Methodology and points to consider

Potential adverse effects identified in the risk assessment

Corn is not known to be a toxicant, except for improperly stored grain that can be infested by insects and toxin-producing molds. Corn grain is not a source of allergen. However, the pollen of the corn plant is known to be allergenic to hypersensitive individuals. The potential pollen allergens known are Zea m1 and Clone C13. The pollen specific cDNAs of these are similar to those found in rye (Lol P1 sequence) and olives (ole e1). Pollen is shed at specific time points in the growing season. Since the subject of this application is corn grain, then pollen is not expected to be included in the importation.	EN

Likelihood that the potential adverse effects will be realized

The transgene insert in DAS-40278-9 corn occurred as a single integration of a single intact copy of aad-1 expression cassette from plasmid pDAS 1740. The insert is stably integrated and inherited across and within the breeding generations. No plasmid backbone sequences are present in DAS-40278-9 corn. here was no indication of truncations in the Southern blots. The number and expected sizes of the specific hybridizing bands were consistently observed were consistently observed. There was also no indication of deletions in the Southern blots.	EN

Possible consequences

Southern blot analyses were conducted with five (5) distinct generations (T3, T4, BC3S3, and BC3S2) of DAS-40278-9 corn. Results across all DAS-40278-9 corn samples indicated stable inheritance of the intact single copy insert across multiple generations of DAS040278-9 corn. Segregation in T1, T2, BC1, BC2 BC3 and BC3S1 of DAS-40278- 9 corn were performed on leaf tissues through Southern blotting and immunoassay for the expressed AAD-1. The typical Mendelian inheritance ratio of 3:1 was observed. From the BC3S1 line for example, 65 tested positive for AAD-1 protein expression and 20 were null segregants. The aad-1 probe hybridized to each of the 65 plants that tested positive for AAD-1. The 20 null segregants did not show this hybridization band, indicating the absence or non-inheritance of the inserted aad-1.	EN

Estimation of the overall risk

Corn DAS 40278-9 applied for Direct Use for food, feed and/or for processing will not cause any significant adverse effect on both humans and animals and the environment, including non-target organisms.	EN

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

For the transgenic DAS-40278-9 corn, enough evidence is provided to support the equivalence of the genetically modified crop, in terms of the nutritional composition and food safety, with the conventional corn other than tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitors (“fop” herbicides. A biosafety permit for direct use can be issued for the said event.	EN

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

The digestibility of AAD-1 protein was tested in vitro using simulated gastric fluid (SGF). Samples were analyzed via SDS-PAGE and Western blot. The results demonstrated that AAD-1 protein was readily digested or inactivated (not detected at 30 seconds in SGF). Heat inactivation tests were also done, the lowest temperature used was 50oC for 30 min. These conditions already inactivated 97 % of the enzyme activity. The common cooking conditions applied to corn processing covers this and with the average field expression level of the AAD-1 present at 4.81 ng/mg tissue, processed products from DAS-40278-9 corn can be expected to be inactivated. Human consumption of raw corn is not the norm.	EN

Receiving environment(s) considered

The application of corn DAS40278-9 is not for propagation. This LMO will be directly used for food, feed and for processing.	EN

LMO detection and identification methods proposed

Diagnostic lateral flow strips, ELISA and PCR for routine qualitative and semi-quantitative detection of transgenes. For higher sensitivity, real-time PCR methods may be used.	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

Corn DAS40278-9 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 during the evaluation of this combined trait product.	EN

Other relevant website addresses and/or attached documents

http://biotech.da.gov.ph/

Decision_docs_jdc_direct.php?fbclid=IwAR1DfDu4QHnejzgzo7mOdByQboQaHxxmQzFUMcRI6EoKw492
(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