



**DECISION DOCUMENT FOR REGISTRATION OF GENETICALLY
MODIFIED ORGANISM (GMO) FOR DIRECT USE AS FOOD, FEED, OR
FOR PROCESSING**

Tracking No: 2024-213-SSAL-006-F

Date: October 11, 2024

Title: Decision on an application for authorisation of genetically modified Maize (*Zea mays*) with OECD unique identifier SYN-IR604-5 for direct use as food, feed or for processing in Ghana submitted by Syngenta South Africa (Pty) Ltd., on behalf of Syngenta International AG.

Regulation

Pursuant to Sections 4, 20, 21, 22 and 23 of the Biosafety Act 2011 (Act 831), the Board of the National Biosafety Authority (NBA) has evaluated information submitted by the applicant: Syngenta South Africa (Pty) Ltd., on behalf of Syngenta International AG. This information regards the available safety assessment (review) reports from countries where approvals have been given for the Maize Event MIR604. The Board of the NBA has determined that this Maize Event MIR604 does not present any food or feed safety concern when compared to conventional maize in Ghana.

1.0 Short description of the genetically modified Maize Event MIR604

SYN-IR604-5	
Transformation Event	MIR604
Applicant	Syngenta South Africa (Pty), Limited
Organism Common Names	Maize, corn
Organism Scientific Names	<i>Zea mays</i>
Centre of Origin and Diversity	<u>Mexico - Biology Consensus Document on Maize</u>
Food and Feed Safety Issues	<u>Compositional considerations for Maize</u>
Traits	Resistance to Coleoptera
Genes	<i>mcry3Aa2</i> , <i>Phosphomannose isomerase (pmi)</i>



Syngenta South Africa (Pty) Limited, on behalf of Syngenta International AG has applied for authorization of genetically modified Maize (*Zea mays*) Event MIR604 with the OECD unique identifier SYN-IR604-5 for direct use as food, feed or for processing in Ghana.

The Maize event MIR604 OECD unique identifier SYN-IR604-5 provides control of certain coleopteran insect pests. The Maize Event MIR604 plants contain the transgene *mcry3A*, which encodes the insecticidal protein mCry3A, and the transgene *pmi*, which encodes the enzyme PMI. The native Cry3A from the soil bacterium *B. thuringensis subsp.tenebrionis* is active against certain coleopteran pests of maize. The mCry3A produced by MIR604 was modified to have enhanced activity against the Western corn rootworm (*Diabrotica virgifera*) and other related coleopteran pests. *Phosphomannose isomerase* (PMI) was used as a selectable marker in the development of MIR604 maize. PMI expressed in MIR604 maize differs from the *E. coli* PMI by two amino acids and has been designated MIR604 PMI. This Maize Event MIR604 has been reviewed and approved for diverse uses (food, feed or processing) in several countries.

2.0 Assessment Summary

2.1 Sources of information

The Board of the NBA considered the recommendations from the Technical Advisory Committee (TAC) following the Committee's thorough evaluation of the application submitted by the applicant using information available on:

- i. the Biosafety Clearing House (BCH), which is a mechanism set up by the Cartagena Protocol on Biosafety to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol and to which Ghana is a Party;
- ii. the Organisation for Economic Co-operation and Development (OECD) Biotrack Product Database;
- iii. the Food and Agriculture Organisation of the United Nations (FAO) genetically modified foods platform.

The following considerations were evaluated:

- development of the modified Maize Event MIR604, including the molecular biology data that characterize the genetic change;
- composition of, and nutritional information about the GM maize compared to its conventional counterpart;
- the potential for causing allergic reactions;
- microbiological and chemical safety of the event;
- proximate analyses; major constituents (fats, proteins, carbohydrates) and minor constituents (minerals and vitamins);

- the potential for production of new toxins in the event;
- the potential for any unintended or secondary effects.

2.2 Findings

Findings show that the Maize Event MIR604 has received authorisation for food, feed and/or processing in several countries (Argentina, Australia, Belarus, Brazil, Canada, Columbia, European Union, Indonesia, Japan, Kazakhstan, Korea Republic, Malaysia, Mexico, New Zealand, Nigeria, Philippines, Russian Federation, Singapore, South Africa, Taiwan, Thailand, United Kingdom, United States of America, Uruguay and Viet Nam) confirming the event to be as safe as its conventional counterpart. Table 1 indicates some of the countries that have approved the Maize Event MIR604 for various purposes on OECD biotrack product database.

Table 1: Approvals granted for Maize Event MIR604 (OECD biotrack product database)

Country	Date of approval	Type of use	Authority
Argentina	March 15, 2012	Cultivation	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia	August 03, 2006	Food	Food Standards Australia New Zealand
Brazil	September 04, 2014	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	July 20, 2007	Feed	Canadian Food Inspection Agency - Animal Feed Division
	July 04, 2007	Food	Health Canada - GM Foods and Other Novel Foods

Colombia	February 02, 2012	Feed	Instituto Colombiano Agropecuario
European Union	November 30, 2009	Processing	European Commission
	November 30, 2009	Food and Feed	European Commission
Japan	August 22, 2007	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
	August 17, 2007	Food	Ministry of Health, Labour and Welfare (MHLW)
Republic of Korea	November 16, 2007	Feed	Rural Development Administration (RDA)
	April 19, 2007	Food	Ministry of Food and Drug Safety
Mexico	October 08, 2007	Processing	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
	October 08, 2007	Food and Feed	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)

New Zealand	October 19, 2006	Food	Food Standards Australia New Zealand
Philippines	March 06, 2018	Food and Feed	Department of Agriculture
South Africa	September 26, 2011	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
United States of America	October 03, 2006	Biopesticide	Environmental Protection Agency (USEPA)
	January 30, 2007	Food and Feed	Food and Drug Administration (USFDA)
Viet Nam	August 12, 2016	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade

This Maize Event MIR604 has been approved for use in several countries, spanning over a decade. From the OECD biotrack product database, the first approval for direct use as food was given in August 03, 2006 by Australia, with the latest approval by Philippines on March 06, 2018. There is a more recent approval on May 20, 2022 by the United States of America on the BCH. Thus, this event has a history of safe use.

3.0 Conclusion

The Board of the NBA concludes that, based on the assessment of the Maize Event MIR604 and also approvals from other countries demonstrating a history of safe use, there are no biosafety concerns with the event intended to be imported for direct use as food, feed and for processing in Ghana.

4.0 Decision

Based on the available evidence, the Board of the National Biosafety Authority (NBA) grants the approval of genetically modified Maize (*Zea mays*) Event MIR604 with OECD unique identifier SYN-IR604-5 for direct use as food, feed or for processing in Ghana.

The Board of the NBA further directs that the duration for the authorisation be three years with subsequent renewals being administrative.

5.0 Recommended Terms and Conditions

1. The person granted this approval (permit holder) shall:
 - a. only use the event for food, feed or for processing and not for cultivation purposes;
 - b. comply with all applicable statutory and regulatory requirements;
 - c. ensure that any new scientific information obtained on the event which has potential biosafety implications be forwarded to the National Biosafety Authority (NBA) for consideration, in order to ensure the continued safe use of the event in Ghana.
2. This authorisation remains in force until it is revoked, suspended, or when the authorisation period elapses.
3. The person granted this approval (permit holder) shall, at all times, remain the person with authorised dealings with the event and shall comply with the terms and conditions of the approval.

This approval is granted with effect from 11th October, 2024 to 10th October, 2027

Signature and Date:

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Chief Executive Officer of the National Biosafety Authority

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Date

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Chairman, Board of the National Biosafety Authority

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Date

