



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

Tracking No: 2024-213-SSAL-004-F

Date: October 11, 2024

Title: Decision on an application for authorisation of genetically modified Maize (*Zea mays*) with OECD unique identifier SYN- 00098-3 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 MZIR098. The Board of the NBA has determined that this Maize Event MZIR098 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 MZIR098

SYN- 00098-3	
Transformation Event	MZIR098
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, Tolerance to Glufosinate
Genes	<i>cry3Aa2</i> , <i>pat</i>

Syngenta South Africa (Pty), Limited on behalf of Syngenta International AG has applied for authorization of genetically modified Maize (*Zea mays*) Event MZIR098 with the OECD unique identifier SYN- 00098-3 for direct use as food, feed or for processing in Ghana.

Maize event MZIR098 OECD unique identifier SYN- 00098-3 contains the transgene *mcry3A*, which encodes the mCry3A protein, and the transgene *ecry3.1Ab*, which encodes the ECry3.1Ab protein; and the transgene *pat*, which encodes the PAT protein. The modified Cry3A (mCry3A) protein contained in MZIR098 has enhanced activity against certain coleopteran pests of maize. The engineered protein eCry3.1Ab confers insecticidal activity against certain coleopteran pests. PAT protein acetylates glufosinate-ammonium, thus inactivating it and conferring tolerance to glufosinate-ammonium in herbicide products. This Maize Event MZIR098 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 MZIR098, 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 Maize Event MZIR098 has received authorisation for food, feed, or processing in several countries (Argentina, Australia, Belarus, Brazil, Canada, China, 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 MZIR098 for various purposes on OECD biotrack product database.

Table 1: Approvals granted for Maize Event MZIR098 (OECD biotrack product database)

Country	Date of approval	Type of use	Authority
Australia	July 21, 2016	Food	Food Standards Australia New Zealand
Brazil	October 4, 2018	Food and Feed	The National Technical Biosafety Committee (CTNBio)
Canada	August 09, 2016	Feed	Canadian Food Inspection Agency - Animal Feed Division
	August 09, 2016	Food	Health Canada - GM Foods and Other Novel Foods
	August 09, 2016	Unconfined Release	Canadian Food Inspection Agency - Plant Biosafety Office

Japan	February 20, 2019	unconfined use	Ministry of Agriculture Forestry and Fisheries and Ministry of the Environment
Republic of Korea	August 06, 2019	Feed, Food	Rural Development Administration (RDA)
	November 20, 2019	Food	Ministry of Food and Drug Safety

This Maize Event MZIR098 has been approved for use in several countries. From the OECD biotrack product database, the first approval for direct use as food was given in July 21, 2016 by Australia, with the latest approval by Republic of Korea on November 20, 2019. There is a more recent approval on May 20, 2022 by United Kingdom 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 MZIR098 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 MZIR098 with OECD unique identifier SYN- ØØØ98-3 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 _____ to _____

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