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

Tracking No: 2024-219-SSAL-005-F **Date: October 11, 2024**

Title: Decision on an application for authorisation of genetically modified Maize (*Zea mays*) with OECD unique identifier SYN-IR162-4 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 MIR162.The Board of the NBA has determined that this Maize Event MIR162 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 MIR162

SYN-IR162-4	
Transformation Event	MIR162
Applicant	Syngenta South Africa (Pty), Limited
Organism Common Names	Maize, corn
Organism Scientific Names	*Zea mays*
Centre of Origin and Diversity	Biology Consensus Document on Maize
Food and Feed Safety Issues	Compositional considerations for Maize
Traits	Promoting of mannose metabolism, Resistance to Lepidoptera
Genes	Modified *vip3A,* *Phosphomannose isomerase (pmi)*

Syngenta South Africa (Pty), Limited. on behalf of Syngenta International AG has applied requesting for authorization of genetically modified Maize (*Zea mays*) Event MIR162 with the OECD unique identifier SYN-IR162-4 for direct use as food, feed or for processing in Ghana.

The Maize Event MIR162 unique identifier SYN-IR162-4 contains the transgene *vip3Aa20* and *pmi*. The transgene *vip3Aa20* encodes the vip3Aa20 protein and is active against certain lepidopteran pests. The transgene *pmi* encodes the enzyme phosphomannose isomer (PMI) enabling transformed plant cells to utilize mannose as a primary carbon source; it was used as a selectable marker in the development of Maize MIR162. This Maize Event MIR162 has been reviewed and approved for diverse uses (food, feed or for 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 MIR162, 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 MIR162 has received authorization for food, feed and/or processing in several countries (Argentina, Australia, Brazil, Canada, China, European Union, Indonesia, Japan, Korea Republic, Malaysia, Mexico, New Zealand, Nigeria, Paraguay, Philippines, Russian Federation, Singapore, South Africa, Switzerland, Taiwan, Thailand, United Kingdom, United States of America, 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 MIR162 for various purposes on OECD biotrack product database.

Table 1: Approvals granted for Maize Event MIR162 (OECD biotrack product database)

Country	Date of approval	Type of use	Authority
Argentina	May 19, 2011	Cultivation, Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia	February 12, 2009	Food	Food Standards Australia New Zealand
Brazil	September 07, 2009	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	February 11, 2010	Feed	Canadian Food Inspection Agency - Animal Feed Division
	March 24, 2010	Food	Health Canada - GM Foods and Other Novel Foods
Colombia	December 27, 2010	Feed	Instituto Colombiano Agropecuario
	September 28, 2012	Cultivation	Instituto Colombiano Agropecuario

European Union	October 18, 2012	Food and Feed	European Commission
Japan	June 01, 2010	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
	January 21, 2010	Food	Ministry of Health, Labour and Welfare (MHLW)
Mexico	January 20, 2010	Processing	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
	January 20, 2010	Food and Feed Authority	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
New Zealand	April 16, 2009	Food	Food Standards Australia New Zealand
Paraguay	February 20, 2014	Commercial Release	Ministry of Agriculture and Livestock
Philippines	February 11, 2015	Food and Feed	Department of Agriculture
Republic of Korea	June 03, 2010	Feed	Rural Development Administration (RDA)
	October 25, 2010	Food	Ministry of Food and Drug Safety

South Africa	March 11, 2014	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
Viet Nam	August 11, 2014	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade

The Maize Event MIR162 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 February 12, 2009 by Australia, with a latest approval by Philippines on February 11, 2015. There is a more recent approval in 2023 by European Union 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 MIR162 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 MIR162 with OECD unique identifier SYN-IR162-4 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:

…… ……...

Chief Executive Officer of the National Biosafety Authority **Date**

…… ……...

Chairman, Board of the National Biosafety Authority **Date**