National Biosafety Authority

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

Tracking No: 2024-219-SSAL-003-F **Date: October 11, 2024**

Title: Decision on an application for authorisation of genetically modified Maize (*Zea mays*) with OECD unique identifier SYN- Ø53Ø7-1 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 5307. The Board of the NBA has determined that this Maize Event 5307 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 5307

SYN- Ø53Ø7-1	
Transformation Event	5307
Applicant	Syngenta South Africa (Pty), Limited
Organism Common Names	Maize
Organism Scientific Names	*Zea mays*
Centre of Origin and Diversity	Mexico-Biology Consensus Document on Maize
Food and Feed Safety Issues	Compositional considerations for Maize
Traits	Resistance to Coleoptera
Genes	*Phosphomanose isomerase (pmi)*

Syngenta South Africa (Pty), Limited on behalf of Syngenta International AG has applied for authorisation of genetically modified Maize (*Zea mays*) Event 5307 with the OECD unique identifier SYN- Ø53Ø7-1 for direct use as food, feed or for processing in Ghana.

The maize plants derived from the transformation of Event 5307 provide control of corn rootworm (*Diabrotica* spp.). The Maize Event 5307 plants contain the gene *ecry3.1Ab*, which encodes the insecticidal protein eCry3.1Ab, and gene *pmi*. The engineered protein eCry3.1Ab is a chimera of mCry3A and Cry1Ab. The portion of Cry1Ab included in eCry3.1Ab has not preserved the activity of Cry1Ab against lepidopterans. The mCry3A protein provides enhanced activity against Western corn root worm (*D. virgifera virgifera*) and other related coleopteran pests. Phosphomannose isomerase (PMI) was used as a selectable marker in the development of Maize Event 5307. This Maize Event 5307 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 5307, 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

The findings show that Event 5307 maize has received authorization for food, feed and/or processing in several countries (Argentina, Australia, Belarus, Canada, China, Columbia,

European Union, Indonesia, Japan, Kazakhstan, Korea Republic, Malaysia, Mexico, New-Zealand, Nigeria, Paraguay, Philippines, Russian Federation, Singapore, South Africa, Taiwan, 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 5307 for various purposes on OECD biotrack product database.

Table 1: Approvals granted for Maize Event 5307 (OECD biotrack product database)

Country	**Date of approval**	**Type of use**	**Authority**
Argentina	March 02, 2018	Cultivation	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia	April 26, 2012	Food	Food Standards Australia New Zealand
Brazil	October 08, 2015	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	February 21, 2013	Feed	Canadian Food Inspection Agency - Animal Feed Division
	February 22, 2013	Food	Health Canada - GM Foods and Other Novel Foods
Colombia	July 05, 2013	Feed	Instituto Colombiano Agropecuario

European Union	July 26, 2019	Food and Feed	European Commission
Japan	February 26, 2013	Food	Ministry of Health, Labour and Welfare (MHLW)
	May 02, 2013	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
Mexico	August 26, 2013	Processing	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
	August 26, 2013	Food and Feed	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
New Zealand	August 02, 2012	Food	Food Standards Australia New Zealand
Philippines	November 06, 2015	Food and Feed	Department of Agriculture
Republic of Korea	April 05, 2013	Feed	Rural Development Administration (RDA)

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:

..... 11/10/2024.....

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

..... 15/10/2024.....

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