National Biosafety Authority

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

Tracking No: 2023-294-SSAL-001-F **Date: February 15, 2024**

Title: Decision on an application for authorisation of genetically modified maize (*Zea mays*) with OECD unique identifier MON-ØØØ21-9 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) Limited 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 GA21. The Board of the NBA has determined that the Maize Event (GA21) does not present any food or feed safety concerns when compared to its conventional counterpart in Ghana.

1.0 Short description of the genetically modified Maize Event GA21

MON-ØØØ21-9	
Transformation Event	GA21
Applicant	Syngenta South Africa (Pty) Limited
Organism Common Names	Maize
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	Tolerance to Glyphosate
Genes	*5-enolpyruvylshikimate-3-phosphate synthase (epsps)*

Syngenta South Africa (Pty) Limited, on behalf of Syngenta International AG has applied for authorisation of genetically modified Maize (*Zea mays*) Event GA21 with the OECD unique identifier MON-ØØØ21-9 for direct use as food, feed or for processing in Ghana.

The maize plant derived from the transformation of event GA21 contain the transgene *mepsps*, which encodes the enzyme mEPSPS (double-mutated *5-enolpyruvylshikimate-3-phosphate synthase*). The native 5-enol pyruvylshikimate-3-phosphate synthase (EPSPS) from *Z. mays* is involved in the synthesis of aromatic amino acids and is inhibited by glyphosate. The mEPSPS produced by GA21 maize has a low affinity for glyphosate compared to the native EPSPS, thus conferring tolerance to glyphosate in herbicide products. This Maize Event GA21 has been reviewed and approved for diverse uses (food, feed or for processing and/or cultivation) 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 GA21, including the molecular biology data that characterizes the genetic change;
- ✓ proximate analyses; major constituents (fats, proteins, carbohydrates) and minor constituents (minerals and vitamins);
- ✓ composition of, and nutritional information (including anti-nutrients) on the GM maize compared to its conventional counterpart;
- ✓ the potential for causing allergic reactions;
- ✓ microbiological and chemical safety of the event;
- ✓ the potential for production of new toxins in the event; and,
- ✓ the potential for any unintended or secondary effects;

2.2 Findings

The findings showed that safety and nutritional assessments of the Maize Event GA21 have been approved in several countries and confirmed to be as safe as its conventional counterpart. (Table 1).

Table 1: Approvals Granted for Maize Event GA21

Country/Economic Bloc	Date of approval	Type of use	Authority
Argentina	August 22, 2005	Cultivation, Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia - New Zealand	December 07, 2000	Food	Food Standards Australia-New Zealand
Brazil	September 18, 2008	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	July 09, 1998	Feed	Canadian Food Inspection Agency - Animal Feed Division
	May 13, 1999	Food	Health Canada - GM Foods and Other Novel Foods
China	February 20, 2004	Food and Feed	Biosafety Management Office of Agricultural GMOs, Ministry of Agriculture
Colombia	July 19, 2010	Feed	Instituto Colombiano Agropecuario
	September 06, 2010	Cultivation	Instituto Colombiano Agropecuario
European Union	January 13, 2006	Food	European Commission
Indonesia	October 29, 2018	Food, Feed and Cultivation	Indonesian Agency for Agricultural Research and Development
Japan	November 29, 1999	Food	Ministry of Health, Labour and Welfare (MHLW)
	December 14, 1999	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
Malaysia	March 10, 2016	Food and Feed	Department of Biosafety Malaysia
Mexico	May 24, 2002	Food	Sanitary Services and Regulations Directorate (Secretary of Health)

Nigeria	March 25, 2019	Food, Feed and Processing	National Biosafety Management Agency (NBMA)
Paraguay	April 16, 2015	Commercial Release	Ministry of Agriculture and Livestock
Philippines	November 20,2013	Food and Feed	Department of Agriculture
	November 24, 2014	Cultivation	Department of Agriculture
Republic of Korea	June 29, 2002	Food	Food and Drug Administration (KFDA)
	March 05, 2005	Feed	Rural Development Administration (RDA)
	March 05, 2005	Processing	Rural Development Administration (RDA)
Russia	July 12, 2000	Food	FSBI Institute of Nutrition RAMS
Singapore	July 10, 2017	Import as food and feed	Singapore Food Agency (SFA)
South Africa	October 18, 2002	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
	December 14, 2010	Importation and exportation	Department of Agriculture, Forestry and Fisheries (DAFF)
	December 14, 2010	Food and or feed	Department of Agriculture, Forestry and Fisheries (DAFF)
	December 14, 2010	Commercial planting	Department of Agriculture, Forestry and Fisheries (DAFF)
Thailand	December 04, 2022	Food	National Bureau of Agricultural Commodity and Food

United States of America	February 10, 1998	Food and Feed	Food and Drug Administration (USFDA)
Uruguay	June 21, 2011	Food and Feed	National Biosafety Cabinet
Vietnam	November 03, 2014	Cultivation	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade
	December 10, 2014	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade

This Maize Event GA21 has been approved for use in several countries, spanning a period of over two and a half decades. The first approval for direct use as food, feed or for processing was given in 1998 by the United States of America, with a more recent approval by Thailand in 2022. Thus, the 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 GA21 and 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 or for processing in Ghana.

4.0 Decision

Based on the available information, the Board of the National Biosafety Authority (NBA) grants the approval of the genetically modified Maize (*Zea mays*) Event GA21 with OECD unique identifier MON-ØØØ21-9 for direct use as food, feed or for processing in Ghana.

The Board of the NBA further directs that the duration for the authorisation is three years, renewable.

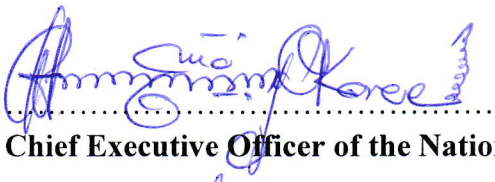
5.0 Terms and Conditions

1. Syngenta South Africa (Pty), Limited (permit holder) shall:
    a. note that the event shall be used for food, feed or for processing and not for cultivation purposes,
    b. comply with all applicable statutory and regulatory requirements, and
    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, 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. Syngenta South Africa (Pty), Limited (permit holder) shall, at all times, remain the entity with authorised dealings with the event and shall comply with the terms and conditions of this approval.

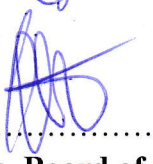
This approval is granted with effect from 15th February 2024 to 14th February 2027.

Signature and Date:



..... **15th February 2024**

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



..... **15th February 2024**

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