

# RISK ASSESSMENT RECOMMENDATION DOCUMENT

Tracking No: 2023-294-SSAL-001-F

Date: January 26, 2024

**Title: Review of an application for authorisation of genetically modified maize (*Zea mays*) with OECD unique identifier MON-00021-9 for direct use as food, feed or for processing in Ghana submitted by Syngenta South Africa (Pty), Limited. on behalf of Syngenta International AG.**

## **1.0 Short description of the genetically modified Maize Event GA21**

<b>MON-00021-9</b>	
<b>Transformation Event</b>	GA21
<b>Applicant</b>	Syngenta South Africa (Pty), Limited
<b>Organism Common Names</b>	Maize
<b>Organism Scientific Names</b>	<i>Zea mays</i>
<b>Centre of Origin and Diversity</b>	<u>Biology Consensus Document on Maize</u>
<b>Food and Feed Safety Issues</b>	<u>Compositional considerations for Maize</u>
<b>Traits</b>	Tolerance to Glyphosate
<b>Genes</b>	<i>5-enolpyruvylshikimate-3-phosphate synthase (epsps)</i>

Syngenta South Africa (Pty), Limited. on behalf of Syngenta International AG has applied requesting for authorisation of genetically modified Maize (*Zea mays*) Event GA21 with the OECD unique identifier MON-00021-9 for direct use as food, feed or for processing in Ghana.

The maize plants 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 synthesis of aromatic amino acids and is inhibited by glyphosate. The mEPSPS produced by GA21 maize has 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 Technical Advisory Committee (TAC) evaluated 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 Technical Advisory Committee (TAC) reviewed the genetically modified event based on the following existing information:

- ✓ 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) about 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 Reviewers' Findings

Findings showed that safety and nutritional assessments of the Maize Event GA21 approved in countries including Argentina, Australia-New Zealand, Brazil, Canada, China, Colombia, European Union, Indonesia, Japan, USA, Malaysia, Mexico, Nigeria, Paraguay, Philippines, Republic of Korea, Russia, Singapore, South Africa, Thailand, Uruguay, and Viet Nam confirm the event to be as safe as its conventional counterpart. These countries have approved the Maize Event GA21 for various purposes (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	Commercial planting	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	Food and Feed	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

TAC notes that the 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, this event has a history of safe use.

### **3.0 Recommendations**

TAC reviewed various safety records on the Maize Event GA21 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Maize Event GA21 is safe for use as food, feed or for processing. TAC therefore recommends:

- i. the authorisation of the 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.
- ii. that the duration for the authorisation be three years with subsequent renewals being administrative.

### **3.1 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, 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, 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 a person with authorised dealings with the event and shall comply with the terms and conditions of the approval.