## 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-ØØØ21-9 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

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| **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](http://www.oecd.org/dataoecd/17/40/46815758.pdf)  |
| **Food and Feed Safety Issues** | [Compositional considerations for Maize](http://www.oecd.org/dataoecd/15/63/46815196.pdf)  |
| **Traits** | Tolerance to Glyphosate |
| **Genes** | *5-enolpyruvylshikimate-3-phosphate synthase (epsps)* |

### 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-ØØØ21-9 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:

1. 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,
2. the Organisation for Economic Co-operation and Development (OECD) Biotrack Product Database,
3. 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)](https://www.argentina.gob.ar/agricultura)   |
| Australia - New Zealand | December 07, 2000 | Food | [Food Standards Australia-New Zealand](http://www.foodstandards.gov.au/)   |
| Brazil | September 18, 2008 | Commercial Release | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| Canada | July 09, 1998 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| May 13, 1999 | Food | [Health Canada - GM Foods and Other Novel Foods](https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods.html) |
| China | February 20, 2004 | Food and Feed | Biosafety Management Office of Agricultural GMOs, Ministry of Agriculture |
| Colombia | July 19, 2010 | Feed | [Instituto Colombiano Agropecuario](https://www.ica.gov.co/)   |
| 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)](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html) |
| 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)](https://nbma.gov.ng/)](https://nbma.gov.ng/)  |
| Paraguay | April 16, 2015 | Commercial Release | Ministry of Agriculture and Livestock |
| Philippines | November 20,2013 | Food and Feed | [Department of Agriculture](http://www.da.gov.ph/)  |
| November 24, 2014 | Cultivation | [Department of Agriculture](http://www.da.gov.ph/) |
| 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)](http://www.daff.gov.za/daffweb3/) |
| December 14, 2010 | Importation and exportation | [Department of Agriculture, Forestry and Fisheries (DAFF)](http://www.daff.gov.za/daffweb3/) |
| December 14, 2010 | Food and or feed | [Department of Agriculture, Forestry and Fisheries (DAFF)](http://www.daff.gov.za/daffweb3/) |
| December 14, 2010 | Food and Feed | [Department of Agriculture, Forestry and Fisheries (DAFF)](http://www.daff.gov.za/daffweb3/) |
| 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)](http://www.fda.gov/bioconinventory) |
| Uruguay | June 21, 2011 | Food and Feed | [National Biosafety Cabinet](http://www.sistemanacionaldebioseguridad.gub.uy/) |
| Vietnam | November 03, 2014 | Cultivation | [Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade](https://www.moh.gov.vn/en_US/web/ministry-of-health) |
| December 10, 2014 | Food and Feed | [Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade](https://www.moh.gov.vn/en_US/web/ministry-of-health)  |

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:

1. 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.
2. 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:
	1. only use the event for food, feed or for processing and not for cultivation purposes,
	2. comply with all applicable statutory and regulatory requirements, and
	3. 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.