



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

Tracking No: 2024-213-SSA -002-F

Date: October 11, 2024

Title: Decision on an application for authorization of genetically modified Maize (*Zea mays*) with OECD unique identifier SYN-BTØ11-1 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 Bt11. The Board of the NBA has determined that this Maize Event Bt11 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 Bt11

SYN-BTØ11-1	
Transformation Event	Bt11
Applicant	Syngenta South Africa (Pty), Limited
Organism Common Names	Maize
Organism Scientific Names	<i>Zea mays</i>
Centre of Origin and Diversity	<u>Mexico - Biology Consensus Document on Maize</u>
Food and Feed Safety Issues	<u>Compositional considerations for Maize</u>
Traits	Resistance to Lepidoptera, Tolerance to Glufosinate
Genes	<i>cry1Ab</i> , <i>Phosphinothricin acetyltransferase (pat)</i>

Syngenta South Africa (Pty), Limited on behalf of Syngenta International AG has applied requesting for authorization of genetically modified Maize (*Zea mays*) Event Bt11 with the OECD unique identifier SYN-BTØ11-1 for direct use as food, feed or for processing in Ghana.

The Maize Event Bt11 with OECD unique identifier SYN-BTØ11-1 contains the transgene *cryIAb* and *pat*. The transgene *cryIAb* encodes the truncated Cry1Ab protein and is active against certain susceptible lepidopteran insect pests. The transgene *pat* encodes the enzyme phosphinothricin acetyltransferase (PAT). PAT protein acetylates glufosinate-ammonium, thus inactivating it and conferring tolerance to glufosinate-ammonium in herbicide products. This Maize Event Bt11 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 Bt11, 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 Bt11 has received authorization for food, feed 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 Bt11 for various purposes on OECD biotrack product database.

Table 1: Approvals granted for Maize Event Bt11 (OECD biotrack product database)

Country	Date of approval	Type of use	Authority
Argentina	July 27, 2001	Cultivation, Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia	August 30, 2001	Food	Food Standards Australia New Zealand
Brazil	September 20, 2007	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	June 11, 1996	Feed	Canadian Food Inspection Agency - Animal Feed Division
	August 15, 1996	Food	Health Canada - GM Foods and Other Novel Foods
Colombia	February 11, 2008	Feed	Instituto Colombiano Agropecuario
	May 28, 2008	Cultivation	Instituto Colombiano Agropecuario

European Union	April 22, 1998	Feed	European Commission
	May 19, 2004	Food	
	April 22, 1998	Importing and Processing	
Japan	September 26, 1996	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
	September 03, 1996	Food	Ministry of Health, Labour and Welfare (MHLW)
Republic of Korea	August 04, 2006	Feed	Rural Development Administration (RDA)
	November 27, 2003	Food	Food and Drug Administration (KFDA)
	August 04, 2006	Processing	Rural Development Administration (RDA)
Mexico	July 16, 2007	Processing	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
	July 16, 2007	Food and Feed	
New Zealand	October 25, 2001	Food	Food Standards Australia New Zealand
Paraguay	October 24, 2012	Commercial Release	Ministry of Agriculture and Livestock

Philippines	July 19, 2013	Food and Feed	Department of Agriculture
	April 23, 2015	Cultivation	Department of Agriculture
South Africa	September 26, 2003	Commercial planting	Department of Agriculture, Forestry and Fisheries (DAFF)
	September 26, 2003	Importation exportation	Department of Agriculture, Forestry and Fisheries (DAFF)
	September 26, 2003	Food and or feed	Department of Agriculture, Forestry and Fisheries (DAFF)
	February 01, 2002	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
Switzerland	October 14, 1998	Feed	Swiss Federal Office of Agriculture
	October 14, 1998	Food	Swiss Federal Office of Public Health
United States of America	May 22, 1996	Feed	Food and Drug Administration (USFDA)
	May 22, 1996	Food	Food and Drug Administration (USFDA)
Uruguay	May 05, 2004	Food and Feed	National Biosafety Cabinet
Viet Nam	August 11, 2014	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade

	January 14, 2015	Cultivation	Ministry of Agriculture and Rural Development
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This Maize Event Bt11 has been approved for use in several countries, spanning a period of over two and a half decades. From the OECD biotrack product database, the first approval for direct use as food, feed or for processing was given in May 22, 1996 by United States of America, with the latest approval by Philippines on April 23, 2015. There is a more recent approval in 2022 by the United Kingdom 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 Bt11 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 Bt11 with OECD unique identifier SYN-BTØ11-1 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:

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Chief Executive Officer of the National Biosafety Authority

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Date

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Chairman, Board of the National Biosafety Authority

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Date