NBA
National Biosafety Authority

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

Tracking No: 2022-040-ASST-003-F **Date: 30TH JUNE 2022**

Decision on an application for approval of genetically modified maize (*Zea mays*) with OECD unique identifier ACS-ZMØØ3-2 for direct use as food, feed or for processing in Ghana submitted by BASF South Africa on behalf of BASF Agricultural Solutions Seed US LLC

Legislation

Pursuant to Sections 4 and 20 of the Biosafety Act 2011 (Act 831), and the relevant procedures under the Biosafety (Management of Biotechnology) Regulations, 2019 (L.I. 2383), the Board of the National Biosafety Authority (NBA) evaluated information submitted by the applicant: BASF South Africa on behalf of BASF Agricultural Solutions Seed US LLC. The information addressed the safety of the genetically modified maize event T25. The Board of the NBA has determined that this maize event T25 does not present any food or feed safety concern when compared to conventional maize in Ghana. The Board has therefore approved the soybean event T25 for direct use as food, feed or for processing in Ghana. The validity period is three (3) years and is renewable.

Short description of the genetically modified maize event T25

ACS-ZMØØ3-2	
Transformation Event	T25
Applicant[1]	Bayer CropScience
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 Glufosinate
Genes	bla, phosphinothricin acetyltransferase (pat)

BASF South Africa on behalf of BASF Agricultural Solutions Seed US LLC has applied requesting for approval of genetically modified maize (*Zea mays*) for direct use as food, feed or for processing in Ghana. The event is T25 with an OECD unique identifier ACS-ZMØØ3-2.

[1] The Applicant that registered the Maize event T25 on the OECD Biotrack Product Database with the unique identifier ACS-ZMØØ3-2 and not necessarily the Applicant whose application is being reviewed.

The maize event T25 is modified by incorporating the *pat* gene into its genome. The modified plants produce the enzyme phosphinothricin acetyl-transferase (PAT), which confers tolerance to herbicides with glufosinate ammonium as an active ingredient. PAT acetylates the glufosinate and detoxifies it. Other countries, in addition to South Africa, where this event has been authorised for direct use as food, feed, or for processing include Argentina (food and feed), Canada (food and feed), the United States of America (cultivation, food and feed), Republic of Korea (food, feed and processing), and European Union (food, feed and processing) among others.

Assessment Summary

Sources of information: The Board of the NBA considered the recommendations from the Technical Advisory Committee (TAC) following the Committee's thorough evaluation of information submitted by the applicant, information available on 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, information available on the Organisation for Economic Co-operation and Development (OECD) Biotrack Product Database, as well as information available on the Food and Agriculture Organisation of the United Nations (FAO) genetically modified foods platform.

The following considerations were evaluated:

- ✓ development of the modified organism, including the molecular biological data that characterizes the genetic change;
- ✓ composition of, and nutritional information about the GM food compared to a non-modified counterpart food;
- ✓ the potential for causing allergic reactions;
- ✓ microbiological and chemical safety of the food;
- ✓ major constituents (for example, fats, proteins, carbohydrates) and minor constituents (for example, minerals and vitamins).
- ✓ key nutrients and toxicants; and,
- ✓ the potential for production of new toxins in the food;
- ✓ the potential for any unintended or secondary effects;

Findings

Findings showed that safety and nutritional assessments of the maize event T25 approved in Argentina, Canada, European Union, South Africa, Republic of Korea, and USA confirm the event is as safe as its conventional counterpart.

Moreover, there are other countries where similar approvals had been granted on the maize event T25 including Australia, Japan, Mexico, New Zealand, Brazil, Viet Nam, Philippines, Nigeria, and Colombia. These countries have also approved the maize event T25 for various purposes, including for cultivation, and for direct use as food, feed or for processing (FFP) (see Table below).

Country	Date of approval	Type of use	Authority
Australia	May 09, 2002	Food	Food Standards Australia New Zealand
Canada	March 27, 1997	Feed	Canadian Food Inspection Agency - Animal Feed Division
	April 03, 1997	Food	Health Canada - GM Foods and Other Novel Foods
European Union	April 24, 2015	Food and Feed	European Commission
Japan	March 07, 1997	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
	May 26, 1997	Food	Ministry of Health, Labour and Welfare (MHLW)
Mexico	April 27, 2007	Processing	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
	April 27, 2007	Food and Feed	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
New Zealand	November 14, 2002	Food	Food Standards Australia New Zealand
United States of America	December 14, 1995	Feed	Food and Drug Administration (USFDA)
	December 14, 1995	Food	Food and Drug Administration (USFDA)
Republic of Korea	November 5, 2004	Feed	Rural Development Administration (RDA)
	December 30, 2003	Food	Food and Drug Administration (KFDA)
Brazil	May 16, 2007	Commercial Release	The National Technical Biosafety Committee (CTNBio)
South Africa	September 25, 2001	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
Viet Nam	September 09, 2015	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade
Philippines	December 05, 2013	Food and Feed	Department of Agriculture

Colombia	September 16, 2011	Feed	Instituto Colombiano Agropecuario
Argentina	June 29, 1998	Cultiv and Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Nigeria	June 22, 2018	Food, Feed and Processing	National Biosafety Management Agency (NBMA)

This maize event T25 has been used in several countries, spanning a period of over two and a half decades, as it was first approved for cultivation and for direct use as food, feed and for processing in 1995 by the United States of America, and with more recent approval in 2018 by Nigeria. Thus, the maize event T25 has a history of safe use.

Conclusion

The Board of the NBA concludes that, based on the assessment of the maize event T25 approved for direct use as food, feed or for processing in the country of origin (South Africa) and 14 other countries, there are no biosafety concerns with the event intended to be imported for direct use as food, feed and for processing in Ghana.

Decision

In light of the foregoing, the Board of the National Biosafety Authority (NBA) grants the approval of genetically modified maize (*Zea mays*) event T25 with OECD unique identifier ACS-ZMØØ3-2 for direct use as food, feed or for processing in Ghana.

The Board of the NBA further directs that the duration for this approval shall be three years with subsequent renewals being administrative-based.

Recommended Terms and Conditions

1. The person granted this approval (permit holder) shall
    a. only use the event for food, feed and for processing and not for cultivation purposes;
    b. comply with all applicable statutory and regulatory requirements; and
    c. ensure that any new information obtained which has potential biosafety implications must be forwarded to the National Biosafety Authority (NBA) for consideration, in order to ensure the continued safety and integrity of the event in Ghana.
2. This approval shall remain in force until it is revoked, suspended, or when the approval 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.

This approval is granted with effect from 30th JUNE 2022 to 29TH JUNE 2025

Signature and Date:

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Chief Executive Officer of the National Biosafety Authority

30TH JUNE 2022

Date

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Chairman, Board of the National Biosafety Authority

30TH JUNE 2022

Date

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National Biosafety Authority