

RISK ASSESSMENT RECOMMENDATION DOCUMENT

Tracking No: 2023-229-BWCA-004-F

Date: January 26, 2024

Title: Review of an application for authorisation of genetically modified maize (*Zea mays*) with OECD unique identifier MON-87460-4 for direct use as food, feed or for processing in Ghana submitted by Bayer West-Central Africa S.A.

1.0 Short description of the genetically modified Maize Event MON 87460

MON-87460-4	
Transformation Event	MON 87460
Applicant	Bayer West-Central Africa S.A.
Organism Common Names	Maize
Organism Scientific Names	<i>Zea mays</i>
Centre of Origin and Diversity	<u>Biology Consensus Document on Maize</u>
Food and Feed Safety Issues	<u>Compositional considerations for Maize</u>
Traits	Tolerance to drought
Genes	<i>cspB</i> , <i>neomycin phosphotransferase II (npt II)</i>

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified Maize (*Zea mays*) Event MON 87460 with the OECD unique identifier MON-87460-4 for direct use as food, feed or for processing in Ghana.

The Maize Event MON 87460 expresses *cspB* gene which encodes a cold shock protein B (CSPB) that confers reduction of yield loss under water-limited condition, and *nptII* gene which encodes NPTII protein, a selectable marker that confers tolerance to neomycin and related antibiotics. This Maize Event MON 87460 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 MON 87460, 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 MON 87460 approved in countries including Australia-New Zealand, Brazil, Canada, Colombia, European Union, Japan, Mexico, Nigeria, Republic of Korea, South Africa, USA, and Vietnam confirm the event to be as safe as its conventional counterpart. These countries have approved the Maize Event MON 87460 for various purposes (Table 1).

Table 1: Approvals Granted for Maize Event MON 87460

Country/Economic Bloc	Date of approval	Type of use	Authority
Australia	September 02, 2010	Food	Food Standards Australia-New Zealand
Brazil	October 06, 2016	Food and Feed	The National Technical Biosafety Committee (CTNBio)
Canada	December 17, 2010	Feed	Canadian Food Inspection Agency - Animal Feed Division
	January 20, 2011	Food	Health Canada - GM Foods and Other Novel Foods
Colombia	February 02, 2012	Feed	Instituto Colombiano Agropecuario
European Union	April 24, 2015	Food and Feed	European Commission
Japan	June 13, 2011	Food	Ministry of Health, Labour and Welfare (MHLW)

	September 07, 2011	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
Mexico	February 28, 2011	Food, Feed, and Processing	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
New Zealand	November 04, 2010	Food	Food Standards Australia-New Zealand
Nigeria	March 25, 2019	Food, Feed and Processing	National Biosafety Management Agency (NBMA)
Republic of Korea	November 09, 2011	Feed	Rural Development Administration (RDA)
	August 29, 2012	Food	Ministry of Food and Drug Safety
South Africa	June 12, 2015	Food and Feed Importation and exportation Commercial planting	Department of Agriculture, Forestry and Fisheries (DAFF)
United States of America	December 10, 2010	Food and Feed	Food and Drug Administration (USFDA)
Vietnam	September 09, 2015	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade

TAC notes that the Maize Event MON 87460 has been approved for use in several countries, spanning a period of over a decade. The first approval for direct use as food was given in 2010 by Australia, with a more recent approval by Nigeria in 2019. Thus, this event has a history of safe use.

3.0 Recommendations

TAC reviewed various safety records on the Maize Event MON 87460 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the

Maize Event MON 87460 is safe for use as food, feed or for processing. TAC therefore recommends:

- i. the authorisation of the genetically modified Maize (*Zea mays*) Event MON 87460 with the OECD unique identifier MON-87460-4 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.