

RISK ASSESSMENT RECOMMENDATION DOCUMENT

Tracking No: 2023-229-BWCA-005-F

Date: January 26, 2024

Title: Review of an application for authorisation of genetically modified maize (*Zea mays*) with OECD unique identifier MON-88Ø17-3 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 88017

MON-88Ø17-3	
Transformation Event	MON 88017
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	Resistance to Coleoptera, Tolerance to Glyphosate
Genes	<i>cp4 epsps</i> , <i>cry3Bb1</i>

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified Maize (*Zea mays*) Event MON 88017 with the OECD unique identifier MON-88Ø17-3 for direct use as food, feed or for processing in Ghana.

The Maize Event MON 88017 expresses *cry3Bb1* gene which encodes Cry3Bb1 protein that confers protection to corn rootworm. It also expresses *cp4 epsps* gene which encodes CP4 EPSPS protein that confers tolerance to glyphosate, the active ingredient in Roundup1 agricultural herbicides. This Maize Event MON 88017 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 88017, 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;
- ✓ proximate analyses; major constituents (fats, proteins, carbohydrates) and minor constituents (minerals and vitamins);
- ✓ 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 88017 approved in countries including Argentina, Australia-New Zealand, Brazil, Canada, Colombia, Costa Rica, European Union, Japan, Mexico, Nigeria, Philippines, Republic of Korea, South Africa, and Vietnam confirm the event to be as safe as its conventional counterpart. These countries have approved the Maize Event MON 88017 for various purposes (Table 1).

Table 1: Approvals Granted for Maize Event MON 88017

Country/Economic Bloc	Date of approval	Type of use	Authority
Argentina	October 07, 2010	Cultivation and Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia	August 03, 2006	Food	Food Standards Australia-New Zealand
Brazil	December 16, 2010	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	February 17, 2006	Food	Health Canada - GM Foods and Other Novel Foods
	February 20, 2006	Feed	Canadian Food Inspection Agency - Animal Feed Division

Colombia	April 09, 2010	Feed	Instituto Colombiano Agropecuario
Costa Rica	January 17, 2017	Seed production for export	Ministry of Agriculture and Livestock State Phytosanitary Service
European Union	October 30, 2009	Food, Feed and Processing	European Commission
Japan	October 25, 2005	Food	Ministry of Health, Labour, and Welfare (MHLW)
	August 31, 2006	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
Mexico	March 28, 2006	Food, Feed and Processing	The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health)
New Zealand	October 19, 2006	Food	Food Standards Australia-New Zealand
Nigeria	March 25, 2019	Food, Feed and Processing	National Biosafety Management Agency (NBMA)
Philippines	January 04, 2018	Food and Feed	Department of Agriculture
Republic of Korea	April 07, 2006	Food	Food and Drug Administration (KFDA)
	October 26, 2006	Feed	Rural Development Administration (RDA)
	October 26, 2006	Processing	Rural Development Administration (RDA)
South Africa	September 26, 2011	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
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 88017 has been approved for use in several countries, spanning a period of over one and a half decades. The first approval for direct use as food was given in 2005 by Japan, 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 88017 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Maize Event MON 88017 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 88017 with the OECD unique identifier MON-88Ø17-3 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.