

RISK ASSESSMENT RECOMMENDATION DOCUMENT

Tracking No: 2023-229-BWCA-001-F

Date: January 26, 2024

Title: Review of an application for authorisation of genetically modified maize (*Zea mays*) with OECD unique identifier MON-ØØ81Ø-6 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 810

MON-ØØ81Ø-6	
Transformation Event	MON 810
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 Lepidoptera
Genes	<i>Cry1Ab</i>

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified Maize (*Zea mays*) Event MON 810 with the OECD unique identifier MON-ØØ81Ø-6 for direct use as food, feed or for processing in Ghana.

The Maize Event MON 810 expresses *cry1Ab* gene which encodes Cry1Ab protein that confers protection against certain Lepidopteran pests including the European corn borer, the Southwestern corn borer, and the pink borer. This Maize Event 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 810, 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 810 approved in countries including Argentina, Australia-New Zealand, Brazil, Canada, Colombia, European Union, Japan, Mexico, Nigeria, Paraguay, Philippines, Republic of Korea, South Africa, Switzerland, USA, Uruguay, and Vietnam confirm the event to be as safe as its conventional counterpart. These countries have also approved the Maize Event MON 810 for various purposes (Table 1).

Table 1: Approvals Granted for Maize Event MON 810

Country/Economic Bloc	Date of approval	Type of use	Authority
Argentina	July 16, 1998	Cultivation, Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia - New Zealand	December 07, 2000	Food	Food Standards Australia-New Zealand
Brazil	August 16, 2007	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	January 22, 1997	Feed	Canadian Food Inspection Agency - Animal Feed Division
	February 17, 1997	Food	Health Canada - GM Foods and Other Novel Foods
Colombia	December 15, 2006	Feed	Instituto Colombiano Agropecuario
	February 27, 2007	Cultivation	Instituto Colombiano Agropecuario

European Union	July 04, 2017	Food and Feed	European Commission
Japan	May 26, 1997	Food	Ministry of Health, Labour, and Welfare (MHLW)
	June 13, 1997	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
Mexico	November 06, 2002	Food	Sanitary Services and Regulations Directorate (Secretary of Health)
Nigeria	March 25, 2019	Food, Feed and Processing	National Biosafety Management Agency (NBMA)
Paraguay	October 24, 2012	Commercial Release	Ministry of Agriculture and Livestock
Philippines	February 23, 2018	Food and Feed	Department of Agriculture
	February 23, 2018	Cultivation	Department of Agriculture
Republic of Korea	June 29, 2002	Food	Food and Drug Administration (KFDA)
	December 06, 2004	Feed	Rural Development Administration (RDA)
	December 06, 2004	Processing	Rural Development Administration (RDA)
South Africa	August 20, 1997	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
Switzerland	July 27, 2000	Feed	Swiss Federal Office of Agriculture
United States of America	September 18, 1996	Feed	Food and Drug Administration (USFDA)
	September 18, 1996	Food	Food and Drug Administration (USFDA)
Uruguay	June 20, 2003	Food and Feed	National Biosafety Cabinet
Vietnam	September 09, 2015	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural

			Development and Ministry of Industry and Trade
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TAC notes that the Maize Event MON 810 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 and feed was given in 1996 by the United States of America, 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 810 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Maize Event MON 810 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 810 with the OECD unique identifier MON-ØØ81Ø-6 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.