

# RISK ASSESSMENT RECOMMENDATION DOCUMENT

Tracking No: 2023-229-BWCA-007-F

Date: January 26, 2024

**Title: Review of an application for authorisation of genetically modified maize (*Zea mays*) with OECD unique identifier MON-ØØ6Ø3-6 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 NK 603**

<b>MON-ØØ6Ø3-6</b>	
<b>Transformation Event</b>	NK 603
<b>Applicant</b>	Bayer West-Central Africa S.A.
<b>Organism Common Names</b>	Maize
<b>Organism Scientific Names</b>	<i>Zea mays</i>
<b>Centre of Origin and Diversity</b>	<u>Biology Consensus Document on Maize</u>
<b>Food and Feed Safety Issues</b>	<u>Compositional considerations for Maize</u>
<b>Traits</b>	Tolerance to Glyphosate
<b>Genes</b>	<i>5-enolpyruvylshikimate-3-phosphate synthase (epsps)</i>

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified Maize (*Zea mays*) Event NK 603 with the OECD unique identifier MON-ØØ6Ø3-6 for direct use as food, feed or for processing in Ghana.

The Maize Event NK 603 expresses *cp4 epsps* gene which encodes CP4 EPSPS protein that confers tolerance to glyphosate, the active ingredient in Roundup®1 agricultural herbicides. 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 NK 603, 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 NK 603 approved in countries including Argentina, Australia-New Zealand, Brazil, Canada, Colombia, Costa Rica, European Union, Japan, Mexico, Nigeria, Paraguay, Philippines, Republic of Korea, South Africa, USA, Uruguay, and Vietnam confirm the event to be as safe as its conventional counterpart. These countries have approved the Maize Event NK 603 for various purposes (Table 1).

**Table 1: Approvals Granted for Maize Event NK 603**

<b>Country/Economic Bloc</b>	<b>Date of approval</b>	<b>Type of use</b>	<b>Authority</b>
Argentina	July 13, 2004	Cultivation and Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia	June 20, 2002	Food	Food Standards Australia New-Zealand
Brazil	September 18, 2008	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	February 19, 2001	Food	Health Canada - GM Foods and Other Novel Foods
	March 07, 2001	Feed	Canadian Food Inspection Agency - Animal Feed Division
Colombia	December 15, 2006	Feed	Instituto Colombiano Agropecuario
	May 29, 2008	Cultivation	Instituto Colombiano Agropecuario

Costa Rica	January 17, 2017	Seed production for export	Ministry of Agriculture and Livestock State Phytosanitary Service
European Union	April 24, 2015	Food and Feed	European Commission
Japan	March 27, 2001	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
	March 30, 2001	Food	Ministry of Health, Labour, and Welfare (MHLW)
Mexico	July 07, 2002	Food	Sanitary Services and Regulations Directorate (Secretary of Health)
New Zealand	November 14, 2002	Food	Food Standards Australia New-Zealand
Nigeria	March 25, 2019	Food, Feed and Processing	National Biosafety Management Agency (NBMA)
Paraguay	January 08, 2014	Commercial Release	Ministry of Agriculture and Livestock
Philippines	September 10, 2013	Food and Feed	Department of Agriculture
	March 16, 2015	Cultivation	Department of Agriculture
Republic of Korea	December 24, 2002	Food	Food and Drug Administration (KFDA)
	June 04, 2004	Feed	Rural Development Administration (RDA)
	June 04, 2004	Processing	Rural Development Administration (RDA)
South Africa	August 02, 2002	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
	September 20, 2002	Commercial planting, Importation exportation,	Department of Agriculture, Forestry and Fisheries (DAFF)

		Food and or feed	
United States of America	October 09, 2000	Food and Feed	Food and Drug Administration (USFDA)
Uruguay	June 21, 2011	Food and Feed	National Biosafety Cabinet
Vietnam	August 11, 2014	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade
	November 03, 2014	Cultivation	Ministry of Agriculture and Rural Development

TAC notes that the Maize Event NK 603 has been approved for use in several countries, spanning a period of over two decades. The first approval for direct use as food and feed was given in 2000 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 NK 603 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Maize Event NK 603 is safe for use as food, feed or for processing. TAC therefore recommends:

- i. the authorisation of the genetically modified Maize (*Zea mays*) Event NK 603 with the OECD unique identifier MON-ØØ6Ø3-6 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.