## 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

|  |  |
| --- | --- |
| **MON-ØØ6Ø3-6** | |
| **Transformation Event** | NK 603 |
| **Applicant** | Bayer West-Central Africa S.A. |
| **Organism Common Names** | Maize |
| **Organism Scientific Names** | *Zea mays* |
| **Centre of Origin and Diversity** | [Biology Consensus Document on Maize](http://www.oecd.org/dataoecd/17/40/46815758.pdf) |
| **Food and Feed Safety Issues** | [Compositional considerations for Maize](http://www.oecd.org/dataoecd/15/63/46815196.pdf) |
| **Traits** | Tolerance to Glyphosate |
| **Genes** | *5-enolpyruvylshikimaete-3-phosphate synthase (epsps)* |

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-ØØ6Ø3-6for 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:

1. 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,
2. the Organisation for Economic Co-operation and Development (OECD) Biotrack Product Database,
3. 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**

|  |  |  |  |
| --- | --- | --- | --- |
| **Country/Economic Bloc** | **Date of approval** | **Type of use** | **Authority** |
| Argentina | July 13, 2004 | Cultivation and Food and Feed | [Ministry of Agriculture, Livestock and Fisheries (MAGyP)](https://www.argentina.gob.ar/agricultura) |
| Australia | June 20, 2002 | Food | [Food Standards Australia New-Zealand](http://www.foodstandards.gov.au/) |
| Brazil | September 18, 2008 | Commercial Release | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| Canada | February 19, 2001 | Food | [Health Canada - GM Foods and Other Novel Foods](https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods.html) |
| March 07, 2001 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| Colombia | December 15, 2006 | Feed | [Instituto Colombiano Agropecuario](https://www.ica.gov.co/) |
| 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)](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html) |
| 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)](https://nbma.gov.ng/)](https://nbma.gov.ng/) |
| Paraguay | January 08, 2014 | Commercial Release | Ministry of Agriculture and Livestock |
| Philippines | September 10, 2013 | Food and Feed | [Department of Agriculture](http://www.da.gov.ph/) |
| March 16, 2015 | Cultivation | [Department of Agriculture](http://www.da.gov.ph/) |
| 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)](http://www.daff.gov.za/daffweb3/) |
| September 20, 2002 | Commercial planting, Importation exportation, Food and or feed | [Department of Agriculture, Forestry and Fisheries (DAFF)](http://www.daff.gov.za/daffweb3/) |
| United States of America | October 09, 2000 | Food and Feed | [Food and Drug Administration (USFDA)](http://www.fda.gov/bioconinventory) |
| Uruguay | June 21, 2011 | Food and Feed | [National Biosafety Cabinet](http://www.sistemanacionaldebioseguridad.gub.uy/) |
| Vietnam | August 11, 2014 | Food and Feed | [Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade](https://www.moh.gov.vn/en_US/web/ministry-of-health) |
| 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:

1. 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.
2. 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:
   1. only use the event for food, feed or for processing and not for cultivation purposes,
   2. comply with all applicable statutory and regulatory requirements, and
   3. 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.