## 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

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| **MON-88Ø17-3** | |
| **Transformation Event** | MON 88017 |
| **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** | Resistance to Coleoptera,  Tolerance to Glyphosate |
| **Genes** | *cp4 epsps,*  *cry3Bb1* |

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:

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 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)](https://www.argentina.gob.ar/agricultura) |
| Australia | August 03, 2006 | Food | [Food Standards Australia-New Zealand](http://www.foodstandards.gov.au/) |
| Brazil | December 16, 2010 | Commercial Release | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| Canada | February 17, 2006 | 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) |
| February 20, 2006 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| 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)](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html) |
| 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](http://www.foodstandards.gov.au/) |
| Nigeria | March 25, 2019 | Food, Feed and Processing | [[National Biosafety Management Agency (NBMA)](https://nbma.gov.ng/)](https://nbma.gov.ng/) |
| Philippines | January 04, 2018 | Food and Feed | [Department of Agriculture](http://www.da.gov.ph/) |
| 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)](http://www.daff.gov.za/daffweb3/) |
| Vietnam | September 09, 2015 | 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) |

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:

1. 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.
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.