## 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

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| **MON-ØØ81Ø-6** | |
| **Transformation Event** | MON 810 |
| **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 Lepidoptera |
| **Genes** | *Cry1Ab* |

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:

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 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)](https://www.argentina.gob.ar/agricultura) |
| Australia - New Zealand | December 07, 2000 | Food | [Food Standards Australia-New Zealand](http://www.foodstandards.gov.au/) |
| Brazil | August 16, 2007 | Commercial Release | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| Canada | January 22, 1997 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| February 17, 1997 | 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) |
| Colombia | December 15, 2006 | Feed | [Instituto Colombiano Agropecuario](https://www.ica.gov.co/) |
| 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)](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html) |
| 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)](https://nbma.gov.ng/)](https://nbma.gov.ng/) |
| Paraguay | October 24, 2012 | Commercial Release | Ministry of Agriculture and Livestock |
| Philippines | February 23, 2018 | Food and Feed | [Department of Agriculture](http://www.da.gov.ph/) |
| February 23, 2018 | Cultivation | [Department of Agriculture](http://www.da.gov.ph/) |
| 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)](http://www.daff.gov.za/daffweb3/) |
| Switzerland | July 27, 2000 | Feed | Swiss Federal Office of Agriculture |
| United States of America | September 18, 1996 | Feed | [Food and Drug Administration (USFDA)](http://www.fda.gov/bioconinventory) |
| September 18, 1996 | Food | [Food and Drug Administration (USFDA)](http://www.fda.gov/bioconinventory) |
| Uruguay | June 20, 2003 | Food and Feed | [National Biosafety Cabinet](http://www.sistemanacionaldebioseguridad.gub.uy/) |
| 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 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:

1. 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.
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.