## RISK ASSESSMENT RECOMMENDATION DOCUMENT

### Tracking No: 2023-229-BWCA-006-F Date: ……………….

### Title: Review of an application for authorisation of genetically modified maize (*Zea mays*) with OECD unique identifier MON-89Ø34-3 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 89034

|  |  |
| --- | --- |
| **MON-89Ø34-3** | |
| **Transformation Event** | MON 89034 |
| **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** | *cry1A.105,*  *cry2Ab2* |

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified maize (*Zea mays*) event MON 89034 with the OECD unique identifier MON-89Ø34-3 for direct use as food, feed or for processing in Ghana.

The Maize Event MON89034 expresses the genes *Cry1A.105* and *Cry2Ab2* which encodes Cry1A.105 and Cry2Ab2 proteins that confer protection against certain lepidopteran pests such as European corn borer, fall armyworm, black cutworm, and the corn earworm. This Maize Event has been reviewed and approved for diverse uses (e.g., 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 89034, including the molecular biology data that characterizes the genetic change;
* composition of, and nutritional information 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 89034 approved in countries including Australia-New Zealand, Brazil, Canada, USA, Nigeria, Japan, Mexico, Republic of Korea, Paraguay, Vietnam, South Africa, Philippines, Costa Rica, Columbia, Argentina, and European Union confirm the event to be as safe as its conventional counterpart. These countries have approved the Maize Event MON 89034 for various purposes (Table 1).

**Table 1: Approvals Granted for Maize Event MON 89034**

|  |  |  |  |
| --- | --- | --- | --- |
| **Country/Economic Bloc** | **Date of approval** | **Type of use** | **Authority** |
| Australia | December 04, 2008 | Food | [Food Standards Australia-New Zealand](http://www.foodstandards.gov.au/) |
| New Zealand | March 05, 2009 | Food | [Food Standards Australia-New Zealand](http://www.foodstandards.gov.au/) |
| Canada | May 18, 2008 | 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) |
| June 19, 2008 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| European Union | October 30, 2009 | Food, Feed and Processing | European Commission |
| Japan | October 02, 2007 | Feed | Ministry of Agriculture, Forestry and Fisheries (MAFF) |
| November 06, 2007 | 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 22, 2008 | Food, Feed and Processing | The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health) |
| Republic of Korea | March 02, 2009 | Feed | Rural Development Administration (RDA) |
| April 02, 2009 | Food | Ministry of Food and Drug Safety |
| Paraguay | December 04, 2013 | Commercial Release | Ministry of Agriculture and Livestock |
| Brazil | October 15, 2009 | Commercial Release | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| South Africa | December 14, 2010 | Commercial planting, Importation and exportation, Food and or feed | [Department of Agriculture, Forestry and Fisheries (DAFF)](http://www.daff.gov.za/daffweb3/) |
| Vietnam | August 27, 2014 | Cultivation | Ministry of Agriculture and Rural Development |
| November 08, 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) |
| Philippines | April 29, 2014 | Food and Feed | [Department of Agriculture](http://www.da.gov.ph/) |
| November 19, 2015 | Cultivation | [Department of Agriculture](http://www.da.gov.ph/) |
| Costa Rica | January 17, 2017 | Seed production for export | Ministry of Agriculture and Livestock State Phytosanitary Service |
| Colombia | August 28, 2007 | Feed | [Instituto Colombiano Agropecuario](https://www.ica.gov.co/) |
| Argentina | October 07, 2010 | Cultivation and Food and Feed | [Ministry of Agriculture, Livestock and Fisheries (MAGyP)](https://www.argentina.gob.ar/agricultura) |
| Nigeria | March 25, 2019 | Food, Feed and Processing | [[National Biosafety Management Agency (NBMA)](https://nbma.gov.ng/)](https://nbma.gov.ng/) |

TAC notes that the Maize Event MON 89034 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 feed was given in 2007 by Columbia, 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 89034 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Maize Event MON 89034 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 89034 with the OECD unique identifier MON-89Ø34-3 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.