## RISK ASSESSMENT RECOMMENDATION DOCUMENT

### Tracking No: 2023-229-BWCA-002-F Date: January 26, 2024

### Title: Review of an application for authorisation of genetically modified maize (*Zea mays*) with OECD unique identifier MON-87411-9 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 87411

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| **MON-87411-9** | |
| **Transformation Event** | MON 87411 |
| **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,*  *DvSnf7* |

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified Maize (*Zea mays*) Event MON 87411 with the OECD unique identifier MON-87411-9 for direct use as food, feed or for processing in Ghana.

The Maize Event MON 87411 expresses *cry3Bb1* and *cp4 epsps* genes which encode Cry3Bb1 and CP4 EPSPS proteins, respectively conferring protection against corn rootworm (*Diabrotica* spp.) and tolerance to glyphosate, respectively. It also contains DvSnf7 suppression cassette that expresses an inverted repeat sequence designed to match the sequence in western corn rootworm (WCR) and thereby utilizes the RNA interference (RNAi) pathway to control corn rootworm (*Diabrotica* spp.). This Maize Event MON 87411 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 87411, 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 87411 approved in countries including Argentina, Australia-New Zealand, Brazil, Canada, Colombia, European Union, Japan, Mexico, Paraguay, Philippines, Republic of Korea, USA, and Vietnam confirm the event to be as safe as its conventional counterpart. These countries have approved the Maize Event MON 87411 for various purposes (Table 1).

**Table 1: Approvals Granted for Maize Event MON 87411**

|  |  |  |  |
| --- | --- | --- | --- |
| **Country/Economic Bloc** | **Date of approval** | **Type of use** | **Authority** |
| Argentina | May 03, 2018 | Cultivation | [Ministry of Agriculture, Livestock and Fisheries (MAGyP)](https://www.argentina.gob.ar/agricultura) |
| Australia- New Zealand | August 06, 2015 | Food | [Food Standards Australia New Zealand](http://www.foodstandards.gov.au/) |
| Brazil | September 01, 2016 | Commercial Release | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| Canada | October 21, 2015 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| October 21, 2015 | Unconfined release | [Canadian Food Inspection Agency - Plant Biosafety Office](http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml) |
| October 23, 2015 | 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 12, 2016 | Feed | Instituto Colombiano Agropecuario |
| European Union | July 26, 2019 | Food and Feed | European Commission |
| Japan | July 04, 2016 | Feed | Ministry of Agriculture, Forestry and Fisheries (MAFF) |
| July 11, 2016 | Food | [Ministry of Health, Labour and Welfare (MHLW)](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html) |
| August 26, 2016 | Unconfined release | [Ministry of Agriculture Forestry and Fisheries and Ministry of the Environment](https://www.biodic.go.jp/bch/) |
| Mexico | August 17, 2015 | Food, Feed and Processing | The Federal Commission for the Protection against Sanitary Risk - COFEPRIS (Secretary of Health) |
| Paraguay | November 08, 2019 | Commercial Release | Ministry of Agriculture and Livestock |
| Philippines | November 19, 2018 | Food, feed, and processing | [Department of Agriculture](http://www.sistemanacionaldebioseguridad.gub.uy/) |
| Republic of Korea | May 12, 2016 | Feed | Rural Development Administration (RDA) |
| September 28, 2016 | Food | Ministry of Food and Drug Safety |
| United States of America | October 10, 2015 | Food, Feed and Environment | Environmental Protection Agency (USEPA) |
| Vietnam | September 14, 2020 | Food and Feed | Ministry of Agriculture and Rural Development |

TAC notes that the Maize Event MON 87411 has been approved for use in several countries, spanning a period of eight (8) years. The first approval for direct use as food was given by Australia-New Zealand in 2015. Thus, this event has a history of safe use.

**3.0 Recommendations**

TAC reviewed various safety records on the Maize Event MON 87411 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Maize Event MON 87411 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 87411 with the OECD unique identifier MON-87411-9 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.