## RISK ASSESSMENT RECOMMENDATION DOCUMENT

### Tracking No: 2023-229-BWCA-013-F Date: January 26, 2024

### Title: Review of an application for authorisation of genetically modified soybean (*Glycine max*) with OECD unique identifier MON-89788-1 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 Soybean Event MON 89788

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| **MON-89788-1** | |
| **Transformation Event** | MON 89788 |
| **Applicant** | Bayer West-Central Africa S.A. |
| **Organism Common Names** | Soyabean, Soybean |
| **Organism Scientific Names** | *Glycine max* |
| **Centre of Origin and Diversity** | [Biology Consensus Document on Soybean](http://www.oecd.org/dataoecd/16/56/46815668.pdf) |
| **Food and Feed Safety Issues** | [Compositional considerations for Soybean](http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2012)24&doclanguage=en) |
| **Traits** | Tolerance to Glyphosate |
| **Genes** | *cp4 epsps* |

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified Soybean (*Glycine max*) Event MON 89788 with an OECD unique identifier MON-89788-1 for direct use as food, feed or for processing in Ghana.

The Soybean Event MON 89788 expresses *cp4 epsps* gene which encodes CP4 EPSPS protein that confers tolerance to glyphosate, the active ingredient in Roundup®1 agricultural herbicides. Roundup Ready 2 Yield Soybean Event MON 89788 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 Soybean Event MON 89788, 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 soybean 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 Soybean Event MON 89788 approved countries including Argentina, Australia-New Zealand, Brazil, Canada, Colombia, Costa Rica, European Union, Japan, Mexico, Nigeria, Paraguay, Philippines, Republic of Korea, South Africa, USA, and Vietnam confirm the event to be as safe as its conventional counterpart. These countries have approved the Soybean Event MON 89788 for various purposes (Table 1).

**Table 1: Approvals Granted for Soybean Event MON 89788**

|  |  |  |  |
| --- | --- | --- | --- |
| **Country/Economic Bloc** | **Date of approval** | **Type of use** | **Authority** |
| Argentina | July 27, 2016 | Cultivation, Food and Feed | [Ministry of Agriculture, Livestock and Fisheries (MAGyP)](https://www.argentina.gob.ar/agricultura) |
| Australia | July 10, 2008 | Food | [Food Standards Australia New Zealand](http://www.foodstandards.gov.au/) |
| Brazil | August 03, 2018 | Food and Feed | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| Canada | July 03, 2007 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| June 27, 2007 | 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 | April 09, 2010 | Feed | Instituto Colombiano Agropecuario |
| Costa Rica | December 02, 2005 | Seed Production for export | Ministry of Agriculture and Livestock State Phytosanitary Service |
| European Union | November 28, 2019 | Food and Feed | European Commission |
| Japan | October 25, 2007 | Feed | Ministry of Agriculture, Forestry and Fisheries (MAFF) |
| November 12, 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) |
| New Zealand | October 10, 2008 | Food | [Food Standards Australia New Zealand](http://www.foodstandards.gov.au/) |
| Nigeria | March 25, 2019 | Food, Feed and Processing | National Biosafety Management Agency (NBMA) |
| Paraguay | December 05, 2018 | Commercial Release | Ministry of Agriculture and Livestock |
| Philippines | November 16, 2012 | Food and Feed | [Department of Agriculture](http://www.da.gov.ph/) |
| June 22, 2018 | Food, Feed and Processing | [Department of Agriculture](http://www.da.gov.ph/) |
| Republic of Korea | January 19, 2009 | Feed | Rural Development Administration (RDA) |
| February 27, 2009 | Food | [Ministry of Food and Drug Safety](http://www.mfds.go.kr/eng/index.do) |
| South Africa | December 05, 2013 | Food and Feed | Department of Agriculture, Forestry and Fisheries (DAFF) |
| United States of America | January 19, 2007 | Food and Feed | [Food and Drug Administration (USFDA)](http://www.fda.gov/bioconinventory) |
| Vietnam | December 24, 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) |

TAC notes that the Soybean Event MON 89788 has been approved for use in several countries, spanning a period of over one and half decades. The first approval for seed production for export was given in 2005 by Costa Rica, 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 Soybean Event MON 89788 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Soybean Event MON 89788 is safe for use as food, feed or for processing. TAC therefore recommends:

1. the authorisation of the genetically modified Soybean (*Glycine max*) Event MON 89788 with the OECD unique identifier MON-89788-1 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.