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

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
Food and Feed Safety Issues	Compositional considerations for Soybean
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:

i. 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,
ii. the Organisation for Economic Co-operation and Development (OECD) Biotrack Product Database,
iii. 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)
Australia	July 10, 2008	Food	Food Standards Australia New Zealand
Brazil	August 03, 2018	Food and Feed	The National Technical Biosafety Committee (CTNBio)
Canada	July 03, 2007	Feed	Canadian Food Inspection Agency - Animal Feed Division
	June 27, 2007	Food	Health Canada - GM Foods and Other Novel Foods
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)
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
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
	June 22, 2018	Food, Feed and Processing	Department of Agriculture
Republic of Korea	January 19, 2009	Feed	Rural Development Administration (RDA)
	February 27, 2009	Food	Ministry of Food and Drug Safety
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)
Vietnam	December 24, 2014	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade

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:

i. 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.
ii. 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:
    a. only use the event for food, feed or for processing and not for cultivation purposes,
    b. comply with all applicable statutory and regulatory requirements, and
    c. 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.