

RISK ASSESSMENT RECOMMENDATION DOCUMENT

Tracking No: 2023-229-BWCA-008-F

Date: January 26, 2024

Title: Review of an application for authorisation of genetically modified soybean (*Glycine max*) with OECD unique identifier MON-Ø4Ø32-6 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 Soybean Event 40-3-2

MON-Ø4Ø32-6	
Transformation Event	40-3-2
Applicant	Bayer West-Central Africa S.A.
Organism Common Names	Soyabean, Soybean
Organism Scientific Names	<i>Glycine max</i>
Centre of Origin and Diversity	<u>Biology Consensus Document on Soybean</u>
Food and Feed Safety Issues	<u>Compositional considerations for Soybean</u>
Traits	Tolerance to Glyphosate
Genes	<i>5-enolpyruvylshikimate-3-phosphate synthase (epsps)</i>

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified Soybean (*Glycine max*) Event 40-3-2 with the OECD unique identifier MON-Ø4Ø32-6 for direct use as food, feed or for processing in Ghana.

The Roundup Ready Soybean Event 40-3-2 expresses *cp4 epsps* gene which encodes CP4 EPSPS protein that confers tolerance to glyphosate, the active ingredient in Roundup¹ agricultural herbicides. This Soybean Event 40-3-2 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 40-3-2, 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 40-3-2 approved in countries including Argentina, Australia-New Zealand, Brazil, Canada, Colombia, Costa Rica, European Union, Japan, Mexico, Nigeria, Republic of Korea, South Africa, Switzerland, Paraguay, Philippines, USA, Uruguay, and Vietnam confirm the event to be as safe as its conventional counterpart. These countries have approved the Soybean Event 40-3-2 for various purposes (Table 1).

Table 1: Approvals Granted for Soybean Event 40-3-2

Country/Economic Bloc	Date of approval	Type of use	Authority
Argentina	March 25, 1996	Cultivation and Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Australia	December 07, 2000	Food	Food Standards Australia-New Zealand
Brazil	September 24, 1998	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Canada	June 13, 1995	Feed	Canadian Food Inspection Agency - Animal Feed Division
	April 09, 1996	Food	Health Canada - GM Foods and Other Novel Foods
Colombia	November 06, 2007	Feed	Instituto Colombiano Agropecuario
	July 19, 2010	Cultivation	Instituto Colombiano Agropecuario

Costa Rica	November 14, 2001	Seed production for export	Ministry of Agriculture and Livestock State Phytosanitary Service
European Union	April 03, 1996	Food, Feed, Importation and Processing	European Commission
Japan	September 03, 1996	Food	Ministry of Health, Labour and Welfare (MHLW)
	September 26, 1996	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)
Mexico	September 18, 1996	Food	Sanitary Services and Regulations Directorate (Secretary of Health)
New Zealand	December 07, 2001	Food	Food Standards Australia-New Zealand
Nigeria	March 25, 2019	Food, Feed and Processing	National Biosafety Management Agency (NBMA)
Republic of Korea	June 24, 2000	Food	Food and Drug Administration (KFDA)
	May 18, 2004	Feed	Rural Development Administration (RDA)
	May 18, 2004	Processing	Rural Development Administration (RDA)
South Africa	August 01, 2001	Commercial planting, Importation exportation, Food and or feed	Department of Agriculture, Forestry and Fisheries (DAFF)
Switzerland	August 15, 2000	Feed	Swiss Federal Office of Agriculture
	October 31, 2002	Food	Swiss Federal Office of Public Health
Paraguay	December 28, 2004	Commercial Release	Ministry of Agriculture and Livestock

Philippines	July 19, 2013	Food and Feed	Department of Agriculture
	October 22, 2018	Food, Feed and Processing	Department of Agriculture
United States of America	September 19, 1994	Feed	Food and Drug Administration (USFDA)
	September 19, 1994	Food	Food and Drug Administration (USFDA)
Uruguay	October 02, 1996	Food and Feed	National Biosafety Cabinet
Vietnam	April 20, 2015	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade

TAC notes that the Soybean Event 40-3-2 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 1994 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 Soybean Event 40-3-2 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Soybean Event 40-3-2 is safe for use as food, feed or for processing. TAC therefore recommends:

- i. the authorisation of the genetically modified Soybean (*Glycine max*) Event 40-3-2 with the OECD unique identifier MON-Ø4Ø32-6 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.