## 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

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| --- | --- |
| **MON-Ø4Ø32-6** | |
| **Transformation Event** | 40-3-2 |
| **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** | *5-enolpyruvylshikimate-3-phosphate synthase (epsps)* |

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:

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 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)](https://www.argentina.gob.ar/agricultura) |
| Australia | December 07, 2000 | Food | [Food Standards Australia-New Zealand](http://www.foodstandards.gov.au/) |
| Brazil | September 24, 1998 | Commercial Release | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| Canada | June 13, 1995 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| April 09, 1996 | 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 | November 06, 2007 | Feed | [Instituto Colombiano Agropecuario](https://www.ica.gov.co/) |
| 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)](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html) |
| 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)](https://nbma.gov.ng/)](https://nbma.gov.ng/) |
| 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)](http://www.daff.gov.za/daffweb3/) |
| 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](http://www.da.gov.ph/) |
| October 22, 2018 | Food, Feed and Processing | [Department of Agriculture](http://www.da.gov.ph/) |
| United States of America | September 19, 1994 | Feed | [Food and Drug Administration (USFDA)](http://www.fda.gov/bioconinventory) |
| September 19, 1994 | Food | [Food and Drug Administration (USFDA)](http://www.fda.gov/bioconinventory) |
| Uruguay | October 02, 1996 | Food and Feed | [National Biosafety Cabinet](http://www.sistemanacionaldebioseguridad.gub.uy/) |
| Vietnam | April 20, 2015 | 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 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:

1. 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.
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.