## RISK ASSESSMENT RECOMMENDATION DOCUMENT

### Tracking No: 2023-229-BWCA-012-F Date: January 26, 2024

### Title: Review of an application for authorisation of genetically modified soybean (*Glycine max*) with OECD unique identifier MON-87751-7 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 87751

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| **MON-87751-7** |
| **Transformation Event** | MON 87751 |
| **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** | Resistance to Lepidoptera |
| **Genes** | *cry1A.105,**cry2Ab2* |

Bayer West-Central Africa S.A. has applied requesting for authorisation of genetically modified Soybean (*Glycine max*) Event MON 87751 with an OECD unique identifier MON-87751-7 for direct use as food, feed or for processing in Ghana.

The Soybean Event MON 87751 expresses *cry1A.105* and *cry2Ab2* genes which encode Cry1A.105 and Cry2Ab2 proteins conferring protection against certain lepidopteran insect pests. Soybean Event MON 87751 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 87751, 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 87751 approved in countries including Argentina, Australia-New Zealand, Brazil, Canada, European Union, 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 Soybean Event MON 87751 for various purposes (Table 1).

**Table 1:** **Approvals Granted for Soybean Event MON 87751**

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| --- | --- | --- | --- |
| **Country/Economic Bloc** | **Date of approval** | **Type of use** | **Authority**  |
| Argentina | May 12, 2022 | Processing | [Ministry of Agriculture, Livestock and Fisheries (MAGyP)](https://www.argentina.gob.ar/agricultura) |
| Australia-New Zealand  | January 14, 2016 | Food | [Food Standards Australia-New Zealand](http://www.foodstandards.gov.au/)   |
| Brazil | March 09, 2017 | Commercial Release | [The National Technical Biosafety Committee (CTNBio)](http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo) |
| Canada | October 31, 2014 | Feed | [Canadian Food Inspection Agency - Animal Feed Division](http://www.inspection.gc.ca/animals/feeds/novel-feeds/eng/1370227088259/1370227136675) |
| October 31, 2014 | 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) |
| October 31, 2014 | Unconfined Release | [Canadian Food Inspection Agency - Plant Biosafety Office](http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml) |
| European Union | July 26, 2019 | Food and Feed | European Commission |
| Mexico | May 12, 2016 | 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 | September 05, 2018 | Food, Feed and Processing | [Department of Agriculture](http://www.da.gov.ph/)  |
| Republic of Korea | May 31, 2016 | Feed | Rural Development Administration (RDA) |
| July 05, 2016 | Food | [Ministry of Food and Drug Safety](http://www.mfds.go.kr/eng/index.do) |
| United States of America | October 16, 2014 | Food, Feed and Environment | Animal and Plant Health Inspection Service (USDA-APHIS) |
| Vietnam | March 15, 2020  | Food and Feed | [Ministry of Agriculture and Rural Development](https://www.mard.gov.vn/en/Pages/default.aspx) |

TAC notes that the Soybean Event MON 87751 has been approved for use in several countries, spanning a period of over eight (8) years. The first approval for direct use as food, feed, and environmental release was given in 2014 by Canada, with a more recent approval by Argentina in 2022. Thus, this event has a history of safe use.

**3.0 Recommendations**

TAC reviewed various safety records on the Soybean Event MON 87751 and also approvals from other countries demonstrating a history of safe use. Based on these, TAC concludes that the Soybean Event MON 87751 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 87751 with the OECD unique identifier MON-87751-7 for direct use as food, feed or for processing in Ghana.
2. TAC also recommends 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.