Tracking No: 2022-040-ASST-001-F **Date: June 09, 2022**

Title: Review of an application for authorisation of genetically modified soybean (*Glycine max*) with OECD unique identifier ACS-GMØØ5-3 for direct use as food, feed or for processing in Ghana submitted by BASF South Africa on behalf of BASF Agricultural Solutions Seed US LLC

Short description of the genetically modified soybean event A2704-12

ACS-GMØØ5-3	
Transformation Event	A2704-12
Applicant[1]	Bayer CropScience
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 Glufosinate
Genes	phosphinothricin acetyltransferase (pat)

BASF South Africa on behalf of BASF Agricultural Solutions Seed US LLC has applied requesting for authorisation of genetically modified soybean (*Glycine max*) for direct use as food, feed or for processing in Ghana. The event is A2704-12 with an OECD unique identifier ACS-GMØØ5-3.

The A2704-12 soybean event is modified by incorporating the *pat* gene into its genome. The modified plants produce the enzyme phosphinothricin acetyl-transferase (PAT), which confers tolerance to herbicides with glufosinate ammonium as an active ingredient. PAT acetylates and thereby detoxifies glufosinate. Other countries, in addition to South Africa, where this event has been authorised for direct use as food, feed, or for processing include Argentina (cultivation, food and feed), Brazil (cultivation, food and feed), Nigeria (food, feed and processing), and the United States of America (cultivation, food and feed) among others.

Assessment Summary

Sources of information: The Technical Advisory Committee (TAC) evaluated information submitted by the applicant, information available on 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, information available

[1] The Applicant that registered the Soybean event A2704-12 on the OECD Biotrack Product Database with the unique identifier ACS-GMØØ5-3 and not necessarily the Applicant whose application is being reviewed.

on the Organisation for Economic Co-operation and Development (OECD) Biotrack Product Database, as well as information available on the Food and Agriculture Organisation of the United Nations (FAO) genetically modified foods platform.

The Technical Advisory Committee (TAC) with individual and varied expertise, assessed the genetically modified event on the following:

- ✓ development of the modified organism, including the molecular biological data that characterizes the genetic change;
- ✓ composition of, and nutritional information about the GM food compared to a non-modified counterpart food;
- ✓ the potential for causing allergic reactions;
- ✓ microbiological and chemical safety of the food;
- ✓ major constituents (for example, fats, proteins, carbohydrates) and minor constituents (for example, minerals and vitamins).
- ✓ key nutrients and toxicants; and,
- ✓ the potential for production of new toxins in the food;
- ✓ the potential for any unintended or secondary effects;

Reviewers' Findings

Findings showed that safety and nutritional assessments of the soybean event A2704-12 approved in Argentina, Brazil, Nigeria, South Africa, and USA confirm that the event is as safe as its conventional counterpart.

The TAC also noted that there are other countries where similar approvals had been granted on the soybean event A2704-12 including Australia, Canada, European Union, Japan, New Zealand, Republic of Korea, Viet Nam, Uruguay, and Colombia. These countries have also approved the soybean event A2704-12 for various purposes, including for cultivation, and for direct use as food, feed or for processing (FFP) (see Table below).

Country	**Date of approval**	**Type of use**	**Authority**
Australia	April 29, 2004	Food	Food Standards Australia New Zealand
Canada	December 18, 2000	Feed	Canadian Food Inspection Agency - Animal Feed Division
	November 20, 2000	Food	Health Canada - GM Foods and Other Novel Foods
European Union	November 28, 2019	Food and Feed	European Commission
Japan	March 27, 2003	Feed	Ministry of Agriculture, Forestry and Fisheries (MAFF)

	July 08, 2002	Food	Ministry of Health, Labour and Welfare (MHLW)
	November 24, 2006	Importing and Processing	Ministry of Agriculture Forestry and Fisheries and Ministry of the Environment
New Zealand	July 22, 2004	Food	Food Standards Australia New Zealand
United States of America	May 15, 1998	Feed	Food and Drug Administration (USFDA)
	May 15, 1998	Food	Food and Drug Administration (USFDA)
Republic of Korea	March 02, 2009	Feed	Rural Development Administration (RDA)
	April 02, 2009	Food	Ministry of Food and Drug Safety
Brazil	February 11, 2010	Commercial Release	The National Technical Biosafety Committee (CTNBio)
Viet Nam	September 09, 2015	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade
Uruguay	September 19, 2012	Food and Feed	National Biosafety Cabinet
Colombia	September 28, 2012	Feed	Instituto Colombiano Agropecuario
Argentina	August 23, 2011	Cultivation, Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Nigeria	August 5, 2021	Food, Feed and Processing	National Biosafety Management Agency (NBMA)
South Africa	December 12, 2001	Food, Feed and Processing	Department of Agriculture, Forestry and Fisheries (DAFF)

TAC notes that the soybean event A2704-12 has been used in several countries, spanning a period of over two decades, as it was first approved for cultivation and for direct use as food, feed and for processing in 1998 by the United States of America, and with more recent approvals in 2019 and 2021 by the European Union and Nigeria respectively. Thus, this event has a history of safe use.

Recommendations

The TAC concludes that, based on the assessment of the soybean event A2704-12 approved for direct use as food, feed or for processing in the country of origin (South Africa) and 13 other countries, there are no biosafety concerns with the event intended to be imported for direct use as food, feed and for processing in Ghana.

Taking these evaluations into account, TAC has no objection to the authorisation of genetically modified soybean (*Glycine max*) event A2704-12 with OECD unique identifier ACS-GMØØ5-3 for direct use as food, feed or for processing in Ghana.

TAC also recommends that the duration for this authorisation should be three years with subsequent renewals being administrative-based. The proposed three-year duration also aligns with the food product registration validity period stipulated by the Ghana Food and Drugs Authority (FDA).

Recommended Terms and Conditions

1. The person granted this approval (permit holder) shall
    a. only use the event for food, feed and for processing and not for cultivation purposes,
    b. comply with all applicable statutory and regulatory requirements, and
    c. ensure that any new information obtained which has potential biosafety implications must be forwarded to the National Biosafety Authority (NBA) for consideration, in order to ensure the continued safety and integrity 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.