



## DECISION DOCUMENT FOR REGISTRATION OF GENETICALLY MODIFIED ORGANISM (GMO) FOR DIRECT USE AS FOOD, FEED, OR FOR PROCESSING

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Tracking No: 2022-040-ASST-002-F

Date: 30<sup>th</sup> JUNE 2022

**Decision on an application for approval of genetically modified soybean (*Glycine max*) with OECD unique identifier ACS-GM006-4 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**

### Legislation

Pursuant to Sections 4, 20, 21, 22 and 23 of the Biosafety Act 2011 (Act 831), and the relevant procedures under the Biosafety (Management of Biotechnology) Regulations, 2019 (L.I. 2383), the Board of the National Biosafety Authority (NBA) evaluated information submitted by the applicant: BASF South Africa on behalf of BASF Agricultural Solutions Seed US LLC. This information addresses the safety of the genetically modified soybean event A5547-127. The Board of the NBA has determined that this soybean event A5547-127 does not present any food or feed safety concern when compared to conventional soybean in Ghana.

### Short description of the genetically modified soybean event A5547-127

ACS-GM006-4	
<b>Transformation Event</b>	A5547-127
<b>Applicant<sup>1</sup></b>	<a href="#">Bayer CropScience</a>
<b>Organism Common Names</b>	Soyabean, Soybean
<b>Organism Scientific Names</b>	<i>Glycine max</i>
<b>Centre of Origin and Diversity</b>	<a href="#">Biology Consensus Document on Soybean</a>
<b>Food and Feed Safety Issues</b>	<a href="#">Compositional considerations for Soybean</a>
<b>Traits</b>	Tolerance to Glufosinate
<b>Genes</b>	phosphinothricin acetyltransferase (pat)

BASF South Africa on behalf of BASF Agricultural Solutions Seed US LLC has applied requesting for approval of genetically modified soybean (*Glycine max*) for direct use as food, feed or for processing in Ghana. The event is A5547-127 with an OECD unique identifier ACS-GM006-4.

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<sup>1</sup> The Applicant that registered the Soybean event A2704-12 on the OECD Biotrack Product Database with the unique identifier ACS-GM005-3 and not necessarily the Applicant whose application is being reviewed.

The soybean event A5547-127 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 the glufosinate and detoxifies it. 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), Brazil (cultivation), Nigeria (food, feed and processing), the United States of America (cultivation, food and feed), Australia (food), and European Union (food, feed and processing) among others.

### **Assessment Summary**

**Sources of information:** The Board of the NBA considered the recommendations from the Technical Advisory Committee (TAC) following the Committee's thorough evaluation of 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 to assist the Parties to better comply with their obligations under the Protocol and to which Ghana is a Party; information available on the Organisation for Economic Co-operation and Development (OECD) Biotrack Product Database; and information available on the Food and Agriculture Organisation of the United Nations (FAO) genetically modified foods platform.

The following considerations were evaluated:

- ✓ 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;

### **Findings**

Findings showed that safety and nutritional assessments of the soybean event A5547-127 approved in Argentina, Brazil, Nigeria, South Africa, USA, Australia, and European Union confirm the event is as safe as its conventional counterpart.

Moreover, there are other countries where similar approvals had been granted on the soybean event A5547-127 including Canada, Japan, Mexico, New Zealand, Republic of Korea, Viet Nam, Philippines, Costa Rica, Uruguay, and Colombia. These countries have also approved the soybean event A5547-127 for various purposes, including for cultivation, and for direct use as food, feed or for processing (FFP) (see Table below).

<b>Country</b>	<b>Date of approval</b>	<b>Type of use</b>	<b>Authority</b>
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	February 10, 2012	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
Mexico	August 13, 2003	Food	Sanitary Services and Regulations Directorate (Secretary of Health)
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	September 1, 2011	Feed	Rural Development Administration (RDA)
	October 06, 2011	Food	Ministry of Food and Drug Safety
Brazil	February 11, 2010	Commercial Release	The National Technical Biosafety Committee (CTNBio)
South Africa	December 08, 2016	Import as food and feed	Department of Agriculture, Forestry and Fisheries (DAFF)
Viet Nam	September 09, 2015	Food and Feed	Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade
Philippines	February 01, 2017	Food and Feed	Department of Agriculture

Costa Rica	October 05, 2011	Seed production for export	Ministry of Agriculture and Livestock State Phytosanitary Service
Uruguay	September 19, 2012	Food and Feed	National Biosafety Cabinet
Colombia	September 28, 2012	Feed	Instituto Colombiano Agropecuario
Argentina	August 23, 2011	Cultivation and Food and Feed	Ministry of Agriculture, Livestock and Fisheries (MAGyP)
Nigeria	February 15, 2021	Food, Feed and Processing	National Biosafety Management Agency (NBMA)

The soybean event A5547-127 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 approval in 2021 by Nigeria. Thus, the soybean event A5547-127 has a history of safe use.

#### **Conclusion**

The Board of the NBA concludes that, based on the assessment of the soybean event A5547-127 approved for direct use as food, feed or for processing in the country of origin (South Africa) and 16 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.

#### **Decision**

In light of the foregoing, the Board of the National Biosafety Authority (NBA) grants approval of genetically modified soybean (*Glycine max*) event A5547-127 with OECD unique identifier ACS-GM006-4 for direct use as food, feed or for processing in Ghana.

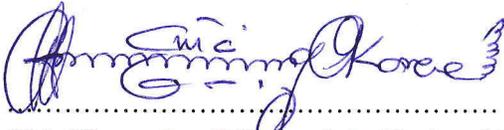
The Board further directs that the duration for this approval shall be three (3) years with subsequent renewals being administrative-based.

**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 other applicable statutory and regulatory requirements; and
  - c. ensure that any new information obtained which has potential biosafety implications is 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 approval shall remain in force until it is revoked, suspended, or when the approval 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.

**This approval is granted with effect from 30<sup>TH</sup> JUNE 2022 to 29<sup>TH</sup> JUNE 2025**

**Signature and Date:**



**Chief Executive Officer of the National Biosafety Authority**

30<sup>TH</sup> JUNE 2022

**Date**



**Chairman, Board of the National Biosafety Authority**

30<sup>TH</sup> JUNE 2022

**Date**

