



DECISION DOCUMENT FOR REGISTRATION OF GENETICALLY MODIFIED ORGANISMS (GMOs) FOR DIRECT USE AS FOOD, FEED, OR FOR PROCESSING

Regulation

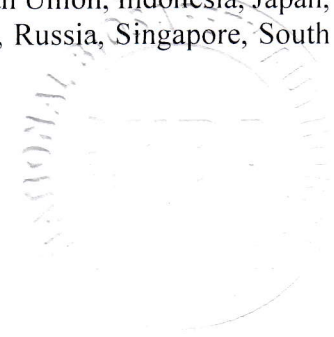
Pursuant to Sections 4, 20, 21, 22, and 23 of the Biosafety Act 2011 (Act 831), the Board of the National Biosafety Authority (NBA) has evaluated information submitted by Bayer West-Central Africa S.A. and other available safety assessment (review) reports from countries where approvals have been given for the events listed below. Based on these, the Board has determined that the events do not present any food or feed safety concerns when compared to their conventional counterparts in Ghana.

1.0 Short Description of the Genetically Modified Events

TRANSFORMATION EVENT	NBA TRACKING NUMBER	COMMON AND SCIENTIFIC NAME	OECD UNIQUE IDENTIFIER	TRAIT (S)
MON 810	2023-229-BWCA-001-F	Maize <i>Zea mays</i>	MON- 00810- 6	Resistance to Lepidoptera
MON 87411	2023-229-BWCA-002-F	Maize <i>Zea mays</i>	MON-87411-9	Resistance to Coleoptera Tolerance to Glyphosate
MON 87427	2023-229-BWCA-003-F	Maize <i>Zea mays</i>	MON-87427-7	Tolerance to Glyphosate
MON 87460	2023-229-BWCA-004-F	Maize <i>Zea mays</i>	MON-87460-4	Tolerance to drought
MON 88017	2023-229-BWCA-005-F	Maize <i>Zea mays</i>	MON-88017-3	Resistance to Coleoptera, Tolerance to Glyphosate

MON 89034	2023-229-BWCA-006-F	Maize <i>Zea mays</i>	MON-89034-3	Resistance to Lepidoptera
NK 603	2023-229-BWCA-007-F	Maize <i>Zea mays</i>	MON-00603-6	Tolerance to Glyphosate
40-3-2	2023-229-BWCA-008-F	Soybean <i>Glycine max</i>	MON-04032-6	Tolerance to Glyphosate
MON 87701	2023-229-BWCA-009-F	Soybean <i>Glycine max</i>	MON-87701-2	Resistance to Lepidoptera
MON 87705	2023-229-BWCA-010-F	Soybean <i>Glycine max</i>	MON-87705-6	Decrease saturated fatty acids; and improve the ratio of unsaturated fatty acids (oleic and linoleic levels) Tolerance to Glyphosate
MON 87708	2023-229-BWCA-011-F	Soybean <i>Glycine max</i>	MON-87708-9	Tolerance to Dicamba Herbicide
MON 87751	2023-229-BWCA-012-F	Soybean <i>Glycine max</i>	MON-87751-7	Resistance to Lepidoptera
MON 89788	2023-229-BWCA-013-F	Soybean <i>Glycine max</i>	MON-89788-1	Tolerance to Glyphosate

Bayer West-Central Africa S.A. has applied for approval of the above genetically modified events which have been modified incorporating respective genes coding for herbicide tolerance, drought tolerance, and insect resistance. The events have received approval from countries including Argentina, Australia-New Zealand, Brazil, Canada, Colombia, European Union, Indonesia, Japan, Malaysia, Mexico, Nigeria, Paraguay, Philippines, Republic of Korea, Russia, Singapore, South Africa, Thailand, Uruguay, USA, and Vietnam.



2.0 Assessment Summary

2.1 Sources of information

The Board of the NBA considered the recommendations from the Technical Advisory Committee (TAC) following the Committee's thorough evaluation of the applications 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 following considerations were evaluated:

- ✓ development of the modified events 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) on the GM products compared to their conventional counterparts;
- ✓ the potential for causing allergic reactions;
- ✓ microbiological and chemical safety of the event(s);
- ✓ the potential for production of new toxins in the event(s); and,
- ✓ the potential for any unintended or secondary effects;

2.2 Reviewers' Findings

The findings showed that safety and nutritional assessments of the events approved in countries including Argentina, Australia-New Zealand, Brazil, Canada, Colombia, European Union, Indonesia, Japan, Malaysia, Mexico, Nigeria, Paraguay, Philippines, Republic of Korea, Russia, Singapore, South Africa, Thailand, Uruguay, USA, and Vietnam, confirm the events to be as safe as their conventional counterparts. These countries have also approved the events for other purposes.

3.0 Conclusion

The Board of the NBA concludes that, based on the assessment of the events and approvals from other countries demonstrating a history of safe use, there are no biosafety concerns with the events

listed above which are intended to be imported for direct use as food, feed or for processing in Ghana.

4.0 Decision

Based on the available information, the Board of the National Biosafety Authority (NBA) grants the approval of the genetically modified events for direct use as food, feed or for processing in Ghana.

The Board of the NBA further directs that the duration for the authorisation is three years, renewable.

5.0 Terms and Conditions

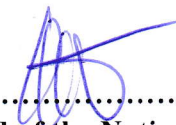
1. Bayer West-Central Africa S.A. (permit holder) shall:
 - a. note that the events shall be used for food, feed or for processing and not for cultivation purposes,
 - b. comply with all applicable statutory and regulatory requirements, and
 - c. ensure that any new scientific information obtained on the events 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 events in Ghana.
2. This authorisation remains in force until it is revoked, suspended, or when the authorisation period elapses.
3. Bayer West-Central Africa S.A. (permit holder) shall, at all times, remain the person with authorised dealings with the events and shall comply with the terms and conditions of this approval.

This approval is granted with effect from 15th February 2024 to 14th February 2027.

Signature and Date:


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Chief Executive Officer of the National Biosafety Authority

15th February 2024
Date


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Ag. Chairman, Board of the National Biosafety Authority

15th February 2024
Date

