FEDERAL REPUBLIC OF NIGERIA

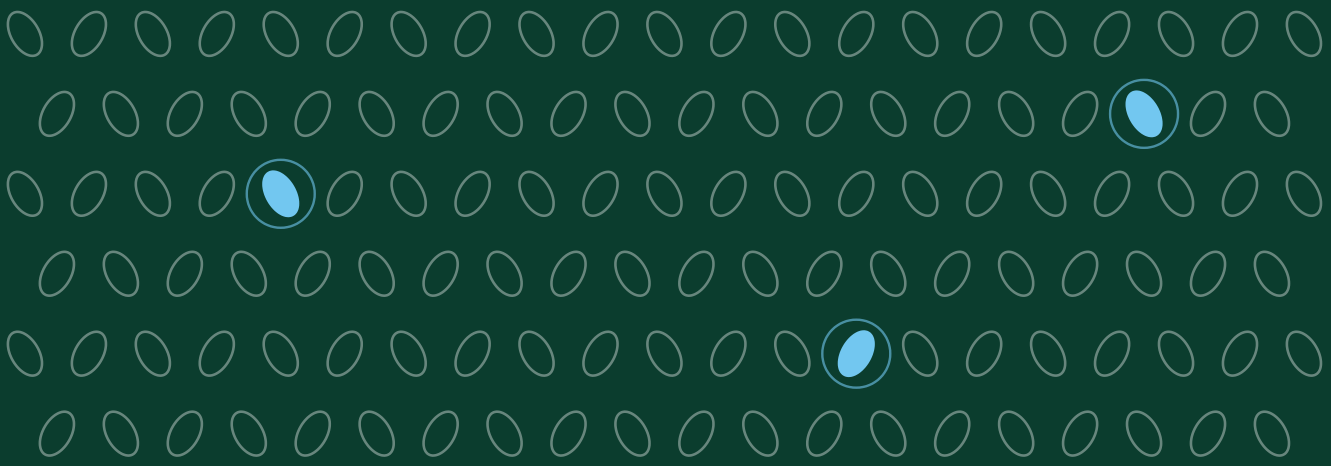
National Biosafety Management Agency

Federal Ministry of Environment

NATIONAL BIOSAFETY GUIDELINES ON

Low-Level Presence (LLP) of Genetically Modified Organisms

Thresholds and procedures for unintended low-level presence of GM events in imported seeds and grains



GM EVENT APPROVED ABROAD, NOT YET IN NIGERIA

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Abbreviations

AP:	Adventitious Presence
BCH:	Biosafety Clearing-House
CAC:	Codex Alimentarius Commission
CPB:	Cartagena Protocol on Biosafety
DNA:	Deoxyribonucleic Acid
FAO:	Food and Agriculture Organization of the United Nations
GM:	Genetically Modified/Genetic Modification
GMO:	Genetically Modified Organism
LLP:	Low-Level Presence
NAFDAC:	National Agency for Food and Drug Administration and Control
NASC:	National Agricultural Seeds Council
NBMA:	National Biosafety Management Agency
OECD:	Organisation for Economic Co-operation and Development

FOREWORD

The transboundary movement of agricultural products is crucial for ensuring global food security and promoting socio-economic development in an increasingly interconnected world. Genetically Modified Organisms (GMOs) account for a significant share of commodities traded on the global market. However, asynchronous approvals (that is, GMO approvals granted outside Nigeria but not yet in Nigeria) may result in the unintended presence, at low levels, of unapproved GMOs in commodities imported into the country. This presents unique challenges for regulators, traders and consumers in an importing country. There is, therefore, an urgent need to adopt a harmonised approach to addressing Low-Level Presence (LLP) situations in Nigeria, in order to uphold safety standards while minimising trade disruptions.

The National Biosafety Guidelines on LLP of GMOs provide direction on the regulatory requirements to be considered in managing LLP of GMOs in grains and seeds to be imported into Nigeria. The Guidelines are based on legally mandated biosafety laws and globally recognised safety evaluations, ensuring that decisions prioritise the health of people, animals and the environment. Furthermore, the Guidelines provide trade-facilitative solutions without compromising safety standards, while acknowledging the pragmatic realities of commerce and logistics.

Developed through collaboration among experts and stakeholders, these Guidelines align with global best practices while tailoring their approach to Nigeria's local context. By upholding transparency, efficiency and safety in LLP decision-making, the Guidelines will contribute to fostering international trade relations and enhance public trust in the national biosafety system.

Bello Bawa Bwari
Director-General/Chief Executive Officer
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1.0 INTRODUCTION

Authorisation for the commercialisation of Genetically Modified Organisms (GMOs) is rising rapidly worldwide, resulting in increased importation of GMOs and products thereof. In the context of plant biotechnology, "Low-Level Presence (LLP)" refers to the unintentional presence of GMOs in food, feed, grain or seed at levels consistent with widely accepted agricultural and manufacturing practices. This occurrence is an inherent aspect of plant biology, seed production and the distribution of commodity crops, driven by factors such as pollen dispersal, volunteer plants, mixing during harvesting, transportation, storage and processing, as well as human error and accidents. LLP therefore relates to seeds or grains containing small amounts of GM events authorised in a country of export but not yet authorised in Nigeria. It covers agricultural seed used for planting, and commodities (e.g. grains and oilseeds) that can grow into plants when unintentionally released into the environment or used for planting.

It is important to reiterate that LLP is a trade issue and not a safety issue. This is because the events involved would have been approved for human consumption and introduction into the environment in the exporting country, meaning that the exporting country would have conducted all relevant safety assessments of the event in question. Any LLP situation in Nigeria shall nonetheless be handled in accordance with the National Biosafety Management Agency Act, 2015 (as Amended).

In 2013, the OECD[1] provided guidance on how regulatory authorities may evaluate the environmental risk/safety of LLP of GM plants in seed and grain commodities. The guidance was not intended for the purpose of authorisation; rather, the assessment can provide a basis for, and may be used by, the importing country to inform decisions to mitigate and/or manage the LLP situation. This guidance is based on **familiarity**. The concept of familiarity described in the guidance document is not synonymous with safety. Instead, it indicates that there is enough information to judge the safety of the introduction of a GM event that is not yet approved in Nigeria, in this instance, or to indicate ways of handling the risks. These principles apply to an LLP situation in the following ways:

1. available knowledge and experience can guide the risk assessment;
2. an environmental risk/safety assessment can be used to evaluate potential risks to the environment in a particular LLP situation; and
3. information and understanding from previous assessments of the same or similar plant, both domestically and in other countries, may inform the assessment.

It is important to re-emphasise that, in an LLP situation, the environmental risk/safety assessment is not intended to lead to an authorisation. However, the results of the assessment can be useful in supporting environmental risk management decisions by scientifically evaluating potential options for managing any risk identified.

A key consideration in determining any potential environmental risk that an unauthorised GM plant may pose is the potential exposure, which, in the case of LLP, is on a limited scale. The amount and depth of information required may therefore differ for an LLP situation because of the reduced scale and the purpose of the assessment.

Most LLP situations to date have involved "common" crop species and trait combinations that have been widely adopted and are under large-scale cultivation in the exporting country. There is substantial knowledge of, and experience with, these crop species, as they are grown regularly, as non-GM or GM crops, within the countries in which LLP situations have occurred.

[1] https://www.oecd-ilibrary.org/low-level-presence-of-transgenic-plants-in-seed-and-grain-commodities_5jm22qcs2xd0.pdf?itemId=%2Fcontent%2Fcomponent%2F9789264253421-4-en&mimeType=pdf

The *Codex Alimentarius* Commission (CAC) LLP Annex[2] calls for the establishment of a publicly accessible online platform hosted by the Food and Agriculture Organization of the United Nations (FAO) to share information on the safety assessment of foods derived from recombinant-DNA plants approved in accordance with the *Codex* Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants[3]. This database, the FAO GM Foods Platform, summarises the information on which authorising countries base their decisions for full food safety assessments, consistent with the *Codex* Plant Guideline. Through this database, Nigeria can access relevant information to support prompt decisions during an LLP situation.

Furthermore, Nigeria, as a Party to the Cartagena Protocol on Biosafety (CPB), may leverage the simplified procedure provided for in Article 13 of the Protocol in an LLP situation where it determines that sufficient information exists to make a decision on the limited introduction of the LLP event.

In conclusion, these Guidelines align with other national policies and international best practices to support informed decision-making on LLP scenarios in Nigeria.

1.1 Objectives

These Guidelines seek to provide information to persons wishing to trade in seeds and grains which may contain small amounts of GM events authorised in a country of export but not yet authorised in Nigeria.

The objectives of these Guidelines are to:

1. uphold safety for humans, animals and the environment;
2. prevent unnecessary trade disruptions;
3. support an innovative and competitive agricultural sector; and
4. develop a risk-based approach within the current legislative framework in Nigeria.

1.2 Scope

These Guidelines shall apply to:

a. agricultural seeds for planting (these may be GM seeds of an approved event that may contain an unapproved event, or conventional seeds that may contain GM seeds of an approved and/or unapproved event); and
b. imported whole grains for both food and feed purposes.

These Guidelines do not cover:

a. GM seeds intended for environmental propagation;
b. GM fruits and vegetables;
c. the unintended introduction of GM crops that have not been approved for use in any country, which is known as adventitious presence;
d. GM animals or microorganisms; and
e. imported food and feed products derived from grains that are highly processed.

The implementation of these Guidelines shall not override or conflict with existing standards relating to varietal purity, organic certification or other relevant agricultural standards, including those established under the following:

[2] https://www.fao.org/fileadmin/user_upload/agns/topics/LLP/Presentations/04_Codex_Final.pdf
[3] https://www.fao.org/fileadmin/user_upload/gmfp/docs/CAC.GL_45_2003.pdf

- **National Biosafety Management Agency Act, 2015 (as Amended):** This Act provides the regulatory framework and the institutional and administrative mechanisms for safety measures in the application of modern biotechnology in Nigeria, with a view to preventing any adverse effect on human health, animals, plants and the environment.
- **Nigeria Agricultural Quarantine Service Act, 2017:** This Act regulates the importation and exportation of plants and plant products and establishes control of plant pests.
- **Nigeria Customs Service Act, 2023 (as Amended):** This Act regulates the management and collection of customs and excise duties and provides for purposes ancillary thereto.
- **National Agency for Food and Drug Administration and Control (NAFDAC) Act, Cap N1, Laws of the Federation of Nigeria, 2004:** This Act mandates NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water (known as regulated products).
- **National Agricultural Seeds Council Act, 2019:** This Act charges the National Agricultural Seeds Council (NASC) with the overall development and regulation of the national seed industry.

2.0 PRINCIPLES

These Guidelines are based on key principles that ensure the safety of genetically modified (GM) events in accordance with national standards and international best practices. Any GM event must undergo a thorough safety assessment, following established national standards, before it can be considered for trade or use in Nigeria. Threshold levels for the presence, in seeds and grains, of a GM event approved in the exporting country but not yet approved in Nigeria are set and applied, taking into account the practical challenges and realities of grain-handling logistics. Additionally, marketing thresholds commonly used in international seed and grain handling and trade were considered in setting these thresholds, to ensure that the Guidelines align with global trade practices and do not constitute an undue barrier to trade. These principles work together to balance safety, pragmatism and trade facilitation.

3.0 THRESHOLD VALUES

Threshold values refer to the maximum allowable levels of genetically modified (GM) material that may be present in shipments without triggering regulatory action. In determining threshold levels for LLP of GMOs in Nigeria, the practical challenges of seed and grain handling, the realities of international trade, and the complexities of detecting and identifying GMOs are critical considerations. These thresholds also align with established international guidelines to promote consistency in global trade practices.

In view of the above, the threshold values applicable in Nigeria are as follows:

a. Agricultural seeds for planting:
    i. Breeder seeds – **0% (zero tolerance)**
    ii. Foundation seeds – **less than or equal to 0.3%**
    iii. Certified seeds – **less than or equal to 1%**
b. Imported whole grains for both food and feed purposes – **less than or equal to 4%**

4.0 REQUEST FOR GUIDANCE ON LLP ISSUES

A person who wishes to import seeds and/or whole grains shall seek guidance on the LLP situation of the shipment to be imported into Nigeria by submitting a written request to the National Biosafety Management Agency (NBMA) at least ninety (90) days before the shipment leaves the exporting country.

The request shall include:

1. relevant information such as the country of origin, description and intended use of the commodity;
2. a laboratory test result (original or certified) from an accredited laboratory in the exporting country, stating the percentage levels of detectable novel combinations of replicable genetic material of the GM event(s) involved, that is, the approved GM event(s) of the seed or grain concerned;
3. relevant information on the current regulatory status of the GM event(s);
4. risk assessment review reports and country decisions on the GM event(s), sourced from the BCH, the OECD BioTrack Product Database and/or the FAO GM Foods Platform; and
5. evidence of compliance with other extant laws and regulations in Nigeria.

5.0 HANDLING OF REQUESTS FOR GUIDANCE ON LLP ISSUES

Upon receipt of a request for guidance on LLP issues, NBMA shall check the request for completeness of the required documents and information. Where the request is incomplete, NBMA shall notify the person in writing, and the process shall be suspended until the missing document(s) or information is provided to NBMA. Where the request is complete, NBMA shall assess the submission using a simplified procedure based on data obtained from the following sources:

- the risk assessment review reports and country decisions sourced from the BCH, the OECD BioTrack Product Database and/or the FAO GM Foods Platform;
- the developer; and/or
- the regulatory authority of the exporting country.

6.0 DECISION MAKING

Upon reviewing the potential risks presented by the LLP situation, NBMA shall make a decision within ninety (90) days of receipt of the request, excluding any period during which the process is suspended owing to an incomplete submission. NBMA shall communicate the decision to the person concerned in writing.

Any decision to permit a shipment with unavoidable LLP of a GM event that is not yet approved in Nigeria shall not be construed as an approval for the environmental release or placing on the market of such an event. In addition, all applicable extant laws and regulations governing such a shipment, including a simplified procedure confirming the risk assessment of the event that creates the LLP scenario, shall apply. However, where the LLP is below the threshold value, a conventional shipment shall not be subject to GM labelling requirements.

Where the level of detectable novel combinations of replicable genetic material of the GM event that creates the LLP scenario is above the threshold value set out in Section 3.0 of these Guidelines, the applicable GM approval procedure and GM labelling requirements in Nigeria shall apply, as appropriate.

7.0 NON-COMPLIANCE

Where a person does not comply with the requirements provided in Section 4.0 of these Guidelines, the shipment shall be placed on hold.

While the shipment is on hold, NBMA shall obtain the required samples and carry out the necessary laboratory analysis to determine the levels of detectable novel combinations of replicable genetic material of the GM event(s) involved, that is, the GM event(s) of the seeds or grains concerned that are approved in the country of export. The cost of such analysis shall be borne by the person concerned.

NBMA shall thereafter assess the LLP situation based on the laboratory results and the risk assessment review reports and country decisions sourced from the BCH, the OECD BioTrack Product Database and/or the FAO GM Foods Platform.

The outcome of the review shall be subject to the provisions of Section 6.0 of these Guidelines.

Definition of terms

In these Guidelines,

Act means the National Biosafety Management Agency Act, 2015 (as Amended);

Adventitious Presence (AP) means the unintentional presence, in seed, food or feed, of GMOs that have not been approved for cultivation, food and/or feed use in any country;

Agency means the National Biosafety Management Agency (NBMA);

Breeder seed means the initial generation of seed produced and maintained by a plant breeder or institution responsible for the maintenance of the cultivar. It is the progeny of the parental stock and is a genetically pure and accurate representative of the variety's characteristics identified by the breeder during variety selection;

Certified seed means a class of seed that has been produced, inspected and tested according to specific standards set by a certification institution to ensure its genetic purity, varietal identity and quality;

Feed means any substance, mixture of substances or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes water and other drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of food, but does not include cosmetics, tobacco or substances used only as drugs;

Foundation seed means a class of seed produced from breeder seed under controlled conditions to maintain genetic purity and quality. It serves as the source for producing certified seed;

Genetically Modified Organism (GMO) means any organism, living or non-living, that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

Grain means a small, hard, edible seed of a cereal crop, such as wheat, rice, barley or maize, cultivated specifically for human or animal consumption, and which is a key source of carbohydrates, fibre and other nutrients. Grains are typically harvested from cereal crops and include both the seed and its protective outer layers (husk or bran);

Low-Level Presence (LLP) means the unintended presence, at low levels, of an unapproved GMO in imported seed, grain, food or feed, where the genetically modified crop is approved for cultivation, food and/or feed use in one or more countries but is not yet approved in Nigeria;

Person means an entity that has legal rights and obligations and can participate in legal relationships;

Products thereof means processed materials of living modified organism origin containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

Seed means the reproductive unit of a flowering plant that can grow into a new plant. All grains are seeds, but not all seeds are grains: seeds may come from a wide variety of plants, not only cereals, and may be used for purposes other than consumption, such as planting or oil extraction (e.g. sunflower and chia seeds).

FEDERAL REPUBLIC OF NIGERIA

National Biosafety Management Agency

Federal Ministry of Environment

Established under the National Biosafety Management Agency Act, 2015 (as Amended) to provide the regulatory framework and institutional mechanisms for the safe application of modern biotechnology in Nigeria, protecting human health, animals, plants and the environment.

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