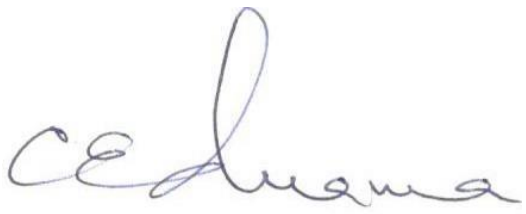
Biosafety Guidelines for Handling Requests for Use of Genetically Modified Organisms (GMO) in Ghana

UNDER THE BIOSAFETY ACT, 2011 (ACT 831)

I, Christina Amoako-Nuama, the Chairman of the National Biosafety Authority, acting under Section 40(3) of the Biosafety Act, 2011 (Act 831), hereby issue these guidelines.

Dated this 30th day of November, 2016



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1. Purpose

The Guidelines for Handling Requests to Approve GMO Use (hereafter referred to as the Guidelines) are issued for the purposes of Sections 11, 12, 13, 14 and 15 of the Biosafety Act, 2011 (Act 831), namely:

- Section 11 – Application for contained or confined use
- Section 12 – Application for introduction into the environment
- Section 13 – Application to import or place on the market
- Section 14 – Application to export
- Section 15 – Genetically modified organisms in transit

2. Scope

The Guidelines cover procedures for submitting applications, procedures for administrative handling and decision making, and the terms and conditions that may be imposed on an approval, **as well as** the responsibility of the applicant, and confidentiality.

3. Introduction

The use of genetically modified organism (GMO) in Ghana is governed by the Biosafety Act, 2011 (Act 831) (hereafter referred to as the Act) to ensure adequate protection of the environment and biological diversity taking also into consideration risk to human and animal health. The Act establishes the National Biosafety Authority (NBA) to administer the legislation.

Prior to the Act, GMO use was regulated by the Biosafety (Management of Biotechnology) Regulations, 2007 (LI 1887), which covers the conduct of research on GMO use in containment (laboratory enclosure or greenhouse) and confinement (in the field and under limited environmental exposure). **Act 831 stipulates that LI1887 shall continue to be enforced until regulations to the Act are made.**

In addition, Ghana is a signatory to the Cartagena Protocol on Biosafety under the Convention on Biological Diversity (ratified in 2003) that regulates the transboundary movement of GMOs.

These Guidelines are issued by the NBA in accordance with Section 40(3) of the Act. "Despite subsections (1) and (2), the Authority may issue guidelines in respect of the matters referred to in subsections (1) and (2)".

Section 40(1) deals with putting in place the Legislative Instrument (Regulations) for performance of the NBA's actions whilst Section 40(2) allows the use of a transitional legislative instrument (LI 1887) in the conduct of its business pending the passage by parliament of the legislative instrument to Act 831.

The Guidelines provide greater detail on the requirements for the submission of an application and its review for a decision by the NBA to issue or refuse the permit under stated reasons.

The Guidelines are intended to assist the following categories of applicants seeking approval of GMO use:

- Importers and exporters of GMOs
- Researchers and biotechnology companies working with GMOs
- Farmers who grow GMOs
- Extension or Technology Transfer agencies that handle GMOs
- Persons associated with the **development,** production, processing, distribution or transit of GMOs
- Any other individual, organisation or company whose activities fall within the scope of the Act.

4. Procedures for submitting an application

The written application requesting approval for the use of GMO must be addressed to:

National Biosafety Authority
P. O. Box WY2287
Kwabenya, Accra

The applicant should first contact the NBA for the appropriate form with the following information: the cover page with the title of the project, the address of the Principal Investigator and collaborators, the address of the institution/organisation/registered company, name and telephone number of a contact person, and the Abstract of the project.

The NBA may request further information/clarification from the applicant in accordance with Section 17(2) of the Act.

4.1 Application for contained or confined use

4.1.1 An application for contained use of a GMO includes activities in a facility such as a laboratory, glasshouse, screen house, animal house, insectary or aquarium. The facility should be certified by the NBA, including the level of containment.

4.1.2 An application for confined use of a GMO includes activities in an open system where there are control measures specified in the terms and conditions of the approval to restrict the spread and persistence of the GMO, or its exposure to people and the environment, thereby effectively limiting the impact on humans and the environment.

4.1.3 Applications for contained or confined use of a GMO shall be submitted to the Institutional Biosafety Committee (IBC) for onward submission to the NBA.

4.2 Application for introduction into the environment

4.2.1 An application under Section 12 of the Act may be joined together with an application under Section 13 to import the specified genetically modified organism for purposes of a proposed introduction into the environment.

4.2.2 Proposed introduction into the environment covers applications for intentional release of GMOs into the environment not intended for commercial trade.

4.3 Application to import or place on the market

An application to place a GMO on the market refers to intended commercial trade of a GMO, including activities for the purposes of, or in the course of: growing or manufacturing a GMO; processing a GMO; or possession, supply or use of a GMO.

An application to place a GMO on the market includes the possibility to import the authorised GMO.

4.4 Application to export

For purposes of Section 14 of the Act, written documentation demonstrating that a genetically modified organism has been approved, permitted or otherwise authorised by the country of import shall be considered as written advance informed agreement of the competent authority of the importing country.

4.5 Genetically modified organisms in transit

An applicant handling **GMO** in transit shall inform the NBA prior (not less than fifteen working days) to the transboundary movement **of the product** across the borders of Ghana.

The application for the transit authorisation shall contain the authorisation by the recipient country for the importation, contingency plan in case of an accident, and the anticipated date of the movement across the borders of Ghana and the respective entry or exit locations.

The products shall be transported on terms and conditions specified by the NBA, and the **permit** shall designate a specific entry or exit point manned by a certified regulatory officer.

The products shall be accompanied by a **certified** Customs official in collaboration with the designated regulatory agency official(s) to ensure safe transport across the border.

5. Procedures for handling applications

5.1 Administrative handling

Application for GMO use under Sections 11, 12 and 13 of the Act submitted to the NBA shall be verified for completeness and acknowledged by the NBA.

The NBA shall forward the verified completed application for GMO use under Sections 11, 12 and 13 of the Act to the Technical Advisory Committee (TAC) for review / risk assessment and recommendation**.**

The NBA shall within fourteen days publish in the *Gazette*, for the general information of the public a notice concerning an application for release into the environment / placement on the market.

5.2 Technical review / Risk Assessment

Risk assessment will be conducted in accordance with the appropriate Schedule of the Act commensurate with the purpose of the application.

For applications for contained or confined use of a GMO (Section 11 of the Act), Risk assessment will be conducted in accordance with Schedule Four (4) of the Act.

For applications for introduction into the environment and import or placement on the market (Sections 12 and 13 of the Act), Risk assessment shall be conducted in accordance with Schedule Four (4) of the Act and in accordance with the Cartagena Protocol on Biosafety.

5.3 Food/Feed Safety Assessment

Food safety assessment for applications to place a GMO on the market **or introduced into the environment** shall be conducted in accordance with the current CODEX guidelines for safety assessment of food derived from recombinant DNA organisms.

5.4 Decision making and communication

The Board shall take a decision based on Section 21 of the Act on a case-by-case basis and under specific terms and conditions. The decision of the Board shall be communicated to the applicant within the time frame stipulated in Section 22 of the Act.

Decision making by the board shall be based on simple majority.

After decision, the public shall be notified in accordance with Section 42 (2) of the Act.

After approval, the GMO shall be listed on the register according to Section 23(d) of the Act.

6. Conditions imposed on an approval

An approval issued for applications under Section 11, 12, 13**, 14 and 15** of the Act shall set out clearly the specific conditions that may be prescribed or imposed that relate to, but are not limited to, the following:

a) the scope of the activities authorized by the approval,
b) the purposes for which the activities may be undertaken,
c) variations to the scope and purposes of the activities,
d) documentation and record-keeping requirements,
e) waste disposal requirements,
f) measures to manage risks posed to health or the environment,
g) data collection, including studies to be conducted,
h) auditing and reporting,
i) controls to limit the spread and persistence of the genetically modified organism
j) contingency plans

The holder of a permit with the consent of the NBA, may surrender the permit.

The permit holder and another person may jointly apply to the NBA to transfer the approval from the permit holder to the transferee.

The application for transferring an approval shall be in writing, and must contain such information as is required by the NBA.

If the NBA decides to transfer the approval, the same conditions apply as those enforced before the transfer.

The written approval of an application for contained or confined use of a GMO shall be in the form of an authorisation for a specified period of time up to five years, which shall be renewable.

The approval of an application for the placing on the market **and introduction into the environment** of a GMO shall be **for a** specified period, not exceeding ten years, which shall be renewable.

7. Responsibility of the applicant

The Applicant is responsible for ensuring that the terms and conditions associated with the approval for GMO use are complied with. The Applicant shall ensure compliance with the terms and conditions by all persons or agents involved in the release of the GMO.

The Applicant is required to disclose all relevant information to the NBA, including all previous approvals or refusals for release in other countries.

The Applicant shall proceed with the release of the GMO only when the Applicant has received official approval in writing from the NBA and **shall** comply with all relevant existing legislation in Ghana with regards to the application.

The Applicant shall continually collect information, conduct monitoring and report as specified in the terms and conditions.

8. Confidentiality

The NBA shall take steps to protect any confidential information so designated as required by Section 16 of the Act.

9. Review and update of the Guidelines

The Guidelines shall be reviewed and updated as and when deemed necessary.

Definitions and acronyms

"Act" refers to the Biosafety Act, 2011 (Act 831)

"Authority" refers to the National Biosafety Authority

"Board" refers to the governing body of the NBA

"GMO" refers to Genetically Modified Organism

"GMO in transit" means transboundary movement of GMO across the borders of Ghana

"GMO use" means activities with a GMO, including possession, supply or use of a GMO for the purposes of, or in the course of, containment, confinement, introduction into the environment, import or **placement** on the market, export, or in transit.

"IBC" refers to Institutional Biosafety Committee

"Introduction into the environment" means release of a GMO into the environment with no confined conditions.

"NBA" refers to the National Biosafety Authority

"TAC" refers to the Technical Advisory Committee