BIOSAFETY (MANAGEMENT OF BIOTECHNOLOGY) REGULATIONS, 2018

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BIOSAFETY (MANAGEMENT OF BIOTECHNOLOGY) REGULATIONS, 2018

IN exercise of the powers conferred on the Authority with the prior approval in writing of the Minister by subsection (1) of Section 40 of the Biosafety Act, 2011 (Act 831), and in consultation with the Ministers responsible for Health and Food and Agriculture, these Regulations are made this ……day of…… 2018.

Institutional Arrangements

The national focal point

1. (1)The Authority as the national focal point in accordance with paragraph (c) of section 4 of the Act is responsible for the following:

(a) liaising with the Secretariat of the United Nations Convention on Biological Diversity for the performance of the administrative functions required under the Cartagena Protocol on Biosafety;

(b) informing other Parties to the Cartagena Protocol on Biosafety of any bilateral, regional or multilateral agreements and arrangements that Ghana has entered into before and after the date of entry into force of the Protocol;

(c) the exchange of information and provision of information to other Parties to the Cartagena Protocol and other countries in relation to

(i) biosafety and biotechnology;

(ii) decisions and other administrative arrangements under the Act;

(iii) development, transfer, handling, use and other activities in respect of genetically modified organisms within Ghana that may have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health; or activities that have or are likely to have significant adverse effects on the conservation and sustainable use of biological diversity or to human health;

(d) notification and receipt of notification in relation to unintentional transboundary movements and emergency measures;

(e) notification and receipt of notification under the Cartagena Protocol in relation to transboundary movements of genetically modified organisms and other related activities.

(2) In furtherance of the functions conferred on the Authority in Section 4 of the Act, the Authority may

(a) facilitate training of scientists and other persons in biosafety;
(b) suggest practical alternatives to high-risk laboratory procedures;
(c) inform the various institutions engaged in biotechnological work about new developments in biosafety in order to avoid exposure of laboratory personnel, the community or the environment to undue risks;
(d) co-ordinate efforts between the relevant government agencies and private organizations to maintain safety levels in biotechnological work and to prepare them for emergencies;
(e) certify laboratories, greenhouses and animal facilities intended for high-risk work, and recommend additional measures where necessary;
(f) inspect high-risk laboratories and containment facilities on a regular basis in collaboration with the designated regulatory agencies,
(g) inspect laboratories and facilities of physical containment levels at any time after certification without prior notice; and
(h) inspect systems, equipment, vessels and instruments governing ambient biosafety levels in genetic modification laboratories.

Implementation roles

2. (1) The Authority shall supervise the implementation of biosafety practices in biotechnological work, in collaboration with

(a) the regulatory agencies specified in the Fifth Schedule to the Act,
(b) the relevant institutional biosafety committees certified by the Board, and
(c) the Principal Investigator.

(2) The organizations and persons specified in sub-regulation (1) shall, in addition to their functions

(a) pursue the common objective of supporting and preserving the integrity and the intent of these Regulations and any guidelines that may be issued under the Act; and

(b) promote and facilitate adherence to these Regulations and any guidelines that may be issued under the Act for the safety of personnel, the community and the environment.

(3) Where a person fails to comply with biosafety measures prescribed by the Authority, whether deliberate or unintentional the Authority may

(a) stop the work on issuing a notice to show cause and request proper investigation through the relevant Institutional Biosafety Committee, or

(b) prescribe additional safety measures or conditions, or

(c) intervene in any other manner appropriate under the Act.

Memorandum of Understanding with regulatory agencies

3. (1) In the performance of its functions, the Authority may enter into an agreement through a Memorandum of Understanding with

(a) regulatory agencies specified in the Fifth Schedule to the Act, and

(b) other persons, agencies or organizations not listed in the Act.

(2) The Memorandum of Understanding shall spell out clearly the areas of operation, roles to be performed and the financial arrangements related to the execution of the specified roles.

Institutional biosafety committee

4. (1) A public or private institution or organization, engaged in, or with the intent to engage in the acquisition, development, propagation or field release of genetically modified organisms or products of genetically modified organisms for purposes of research shall

(a) each establish an institutional biosafety committee; and

(b) support the needs and demands of the committee for the effective performance of its functions.

(2) Despite sub-regulation (1), an institution which is unable to constitute its own institutional biosafety committee may request any other institutional biosafety committee to help monitor and supervise the biosafety aspects of its work.

(3) A request under sub regulation (2) shall be in the form of a written Agreement entered into between the parties involved and the Authority shall be notified of the Agreement.

(4) A representative of the institution requesting assistance shall maintain close ties with the respective institutional biosafety committee or serve as a member on the supporting institutional biosafety committee.

Certification of the institutional biosafety committee

5. (1) The Authority shall

(a) prepare and provide to the institutional biosafety committees, the various notification and assessment forms, appropriate guidelines and any other relevant documents;

(b) provide assistance to the institutional biosafety committees and advise them on the various notification and assessment forms, biosafety guidelines and any other relevant documents;

(c) certify each institutional biosafety committee to undertake monitoring functions for contained use and confined use activities for certain levels of classified risks to be issued periodically through guidelines;

(2) For the purposes of certification, the completed notification forms of an institutional biosafety committee, detailing the academic and professional history of each member appointed to the Committee shall contain information relating to

(a) members of the institutional biosafety committee,

(b) the designated biosafety officer where applicable,

(c) a list of the current projects indicating the risk assessment category,

(d) a list of the laboratories approved for biotechnological work indicating the category of containment, and

(e) a list of the institution's greenhouses and animal facilities, certified and intended for work with genetically modified organisms indicating category of containment.

Relationship between the institutional biosafety committee and the Authority

6. (1) Work classified as "minimal risk" and "low risk" shall be assessed, and approved by the institutional biosafety committee, with written notice to the Authority.

(2) Work involving higher level of risk shall be assessed and approved by the Authority.

Composition of the institutional biosafety committee

7. An Institutional Biosafety Committee shall include

(a) four members of the institution with expertise in biosafety regulation and the environmental effects of biotechnological work;

(b) the biosafety officer of the institution

(c) representatives from cognate organizations or institutions;

(d) two members who are not affiliated with the institution and representing the interest of the community such as

(i) members of government, public health or environmental agencies.
(ii) persons active in human, plant or animal health concerns, and
(iii) persons active in environmental concerns, and who do not require a previous affiliation with the institution.

(e) The head of the institution shall appoint members of the institutional biosafety committee and shall designate a chairperson and a secretary for the effective performance of the functions of the committee.

Functions of an institutional biosafety committee

8. (1) In order to enforce the appropriate guidelines issued by the Authority, an institutional biosafety committee shall

(a) monitor the regulated work under progress within the institution and counsel the proponents on issues of biosafety and on compliance with the Act and the appropriate guidelines on a regular basis, or as requested;

(b) report infractions to the institutional head or to the Authority and recommend to the institutional head or the Authority to stop a biosafety activity if its continuation under the existing circumstances, is a threat to the public, the environment or laboratory personnel;

(c) determine additional biosafety measures and draft supplementary terms and conditions for work at the institution, in line with and addressing the specific risks and concerns identified;

(d) assist researchers in undertaking risk analysis;

(e) organize training programmes for staff of the institute and other stakeholders;

(f) set apart time for researchers and for laboratory and field personnel to approach the committee with questions, disputes or concerns;

(g) maintain and update a directory of the personnel engaged in activities at every biosafety level, and instruct new personnel on the correct laboratory or field practices, emergency procedures and equipment operation at the relevant levels; and

(h) where appropriate, serve as a gateway for the flow of information, ideas and opinions among the Authority, the research teams and all stakeholders.

(2) To ensure that biotechnological work within the institution conforms to these Regulations and the appropriate guidelines issued by the Authority, the institutional biosafety committee shall

(a) assess biosafety applications referred to the committee, and on the basis of the information provided determine under which category of work the applications fall and whether to endorse the work for approval;

(b) maintain records of approved biosafety applications for laboratory biotechnological work, including notification for exemption and the assessment of the committee;

(c) forward the biosafety applications submitted for notification and the committee's assessments to the Authority for records and information or for review and recommendation in the case of applications classified as higher risks, for risk assessment as specified in the National Biosafety Guidelines ;

(d) undertake risk assessment and risk management, in co-operation with the research teams as necessary to determine the appropriate containment and biosafety terms and conditions, standard operating procedures and emergency safeguards as specified in the appropriate guidelines;

(e) in collaboration with the research teams, specify contingency plans after undertaking risk assessments and reviewing biosafety applications;

(f) ensure compliance with the terms and conditions stipulated by the Authority on approval of an application;

(g) facilitate inspection and certification of the appropriate level of laboratories, greenhouses and animal facilities, before use in biotechnological work;

(h) monitor and assess the integrity of containment facilities, and the working conditions

within the laboratories, greenhouses and animal facilities supporting the institution's work to ensure that the various facilities are maintained at the standards and requirements outlined in the appropriate guidelines for laboratory and field work;

(i) facilitate preparation of dossiers for submission to the Authority for the conduct of laboratory and field work; and

(j) as required by the Authority, report on work being undertaken in the institution.

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Biosafety Officer

9. (1) An institution or organization involved in biotechnological work shall appoint a Biosafety Officer to serve on the institutional biosafety committee.

(2) In addition to the function specified in sub-regulation (1) of Regulation 8, the Biosafety Officer, in conjunction with the institutional biosafety committee, shall

(a) review the standard operating procedures and biosafety records;
(b) assess the integrity of containment facilities and safety equipment or utilities; and
(c) investigate and report incidents and infractions to the Authority in a timely manner.

Principal Investigator

10. (1) A Principal Investigator is responsible for submitting an application to the institutional biosafety committee for approval.

(2) The Principal Investigator shall use the appropriate guidelines to

(a) submit a completed biosafety applications to the supervising institutional biosafety committee for consideration and recommendations; and
(b) inform the committee of any notable intent such as plans to import regulated material.

(3) Biotechnological work may begin after authorisation from the institutional biosafety committee as directed by the Authority, and the Principal Investigator may be required to provide additional details of the research for assessment and monitoring activities of the institutional biosafety committee.

(4) The Principal Investigator shall comply with the provisions of the appropriate guidelines and the terms and conditions of approval throughout the duration of the research in addition to,

(a) ensuring that persons entering controlled areas have been properly instructed on applicable codes of conduct;

(b) co-operating closely with the institutional biosafety committee and the Biosafety Officer in carrying out various safety tests and, monitoring of containment facilities;

(c) informing the institutional biosafety committee of details of the contingencies and the emergency measures put in place to deal with incidents

Procedures

Processing of applications

11. (1) Where a person formally submits an application to the Authority, it shall be recorded and a tracking number assigned to the dossier in order to systematically keep track of the application.

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(2) Where an application is recorded, it shall be screened for completeness, to check whether the application complies with information required.

(3) Where it is concluded that the request is in compliance with the information required under sub-regulation (2) the risk assessment included in the dossier shall be

reviewed by the technical advisory committee, as a scientific process, based on the best available and up to date, scientific knowledge and data.

(4) The Authority shall consider the application and communicate its decision as set out in Sections 21 and 22 of the Act.

Confidential information

12. (1) Where an applicant satisfies the Authority that the information specified in the application

(a) is a trade secret, or

(b) has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information was disclosed, or

(c) has other information that

(i) concerns the lawful commercial or financial affairs of a person, organization or undertaking, and

(ii) if it were disclosed, could unreasonably affect the person, organization or undertaking,

the Authority shall declare that the information is confidential information for the purposes of the Act.

(2) Subject to Section 16(1)(d) of the Act, the Authority may refuse to declare that the information is confidential if the Authority is satisfied that the public interest in disclosure outweighs prejudice that the disclosure would cause to a person.

(3) Subject to Section 16(1)(d) of the Act, the Authority may, by written notice given to the applicant, revoke a declaration under sub regulation (1), if the Authority is satisfied that the

(a) information concerned no longer satisfies sub-regulation 1, or

(b) public interest in disclosure outweighs prejudice that the disclosure would cause to any person.

(4) For the purposes of sub-regulation (1), the Authority shall not consider as confidential,

(a) the name and address of the applicant,

(b) a general description of the genetically modified organism,

(c) a summary of the risk assessments performed on the genetically modified organism, and

(d) any methods and plans for emergency response.

Contained Use or Confined Use

13. (1) A person submitting an application under Section 11 of the Act for a permit for contained use activities shall, in addition to submitting the information set out in the Second Schedule to the Act, identify the risk classification of the proposed genetically modified organisms in accordance with the guidelines provided by the Authority.

(2) The Authority may extend an approval granted in sub regulation (1) to a person to continue work with genetically modified organisms in the same risk classification without further applications for a specified period.

(3) A contained use activity of a higher risk classification other than already authorised is subject to approval under Section 11 of the Act

(4) A person submitting an application under Section 11 of the Act for a permit for a confined use activity shall, in addition to submitting the information set out in the Second Schedule to the Act, submit a risk assessment as set out in the Fourth Schedule to the Act.

Introduction into the environment, placing on the market and import

14. (1) An application under Section 12 of the Act, may be submitted together with an application under Section 13 to import the specified genetically modified organism for purposes of the proposed introduction into the environment.

(2) An approval issued for applications under Section 12 and 13 of the Act shall set out clearly the terms and conditions that may be prescribed or imposed including 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) handling and transport;
(g) storage;
(h) measures to manage risks posed to human health or the environment;
(i) data collection, including studies to be conducted;
(j) auditing and reporting; and

(k) controls to limit the spread and persistence of the genetically modified organism; and

(l) contingency plans.

(3) The holder of an approval may

(a) with the consent of the Authority, surrender the approval, or
(b) jointly apply with another person to the Authority to transfer the approval from the approval holder to that other person.

(4) An application under sub regulation 3 (b) shall be in writing.

(5) Where the Authority decides to transfer the approval, the same terms and conditions shall apply as those in force immediately before the transfer.

Authorisation for placing on the market

15. (1) A written approval granted by the Authority to an application for the placing on the market of a genetically modified organism shall be in the form of an authorisation for a specified period of up to ten years and is renewable.

(2) An authorisation under sub regulation (1) includes the possibility to import the authorised genetically modified organism.

Export

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

Transit

17. (1) An application to transport genetically modified organism through the Republic shall contain

(a) the authorisation by the recipient country for the importation;

(b) a contingency plan in case of an unintentional or accidental release; and

(c) the anticipated date of the movement across the borders of Ghana and the respective entry or exit locations.

(2) The application shall be submitted to the Authority not less than fifteen working days prior to the departure of the cargo from the exporting country.

(3) An applicant handling genetically modified organism in transit shall inform the Authority prior to the transboundary movement of the genetically modified organism across the borders of Ghana.

(4) The genetically modified organism shall be transported on agreed terms and conditions specified by the Authority, and the instrument of agreement shall designate a specific entry or exit point manned by a certified regulatory officer.

(5) The genetically modified organism shall be accompanied by a customs officer in collaboration with officials of the designated regulatory agency specified in the Fifth Schedule to the Act to ensure safe transport across the border.

Monitoring and enforcement

18. (1) The Authority is responsible for the overall monitoring, risk management and environmental release of genetically modified organisms.

(2) The Principal Investigator shall conduct the first tier of monitoring.

(3) The institutional biosafety committee shall conduct the second tier of monitoring

(4) The third tier of monitoring, inspection and enforcement shall be performed by the Authority through

(a) the regulatory agencies specified in the Fifth Schedule to the Act; and

(b) biosafety inspectors provided for in Sections 33 and 34 of the Act.

Public awareness, participation and education

19. (1) The Authority shall publish on regular basis, exemptions granted under Section 20 of the Act in the *Gazette* and the electronic and print media.

(2) In furtherance of section 18(1) of the Act, a person may submit a written comment on an application for release of a genetically modified organism within sixty days from the date of the publication of the notice in the *Gazette*.

(3) A comment received by the Authority and any response by the Authority to the comment shall be made available to the public on request.

Register

20. The Authority shall include in the register established under Section 23 of the Act, a list of

(a) a genetically modified organism for which authorisation is granted by the Authority including whether the genetically modified organism has been authorised for placing on the market;

(b) a genetically modified organism and activities that are exempted or subject to simplified procedures as determined by the Board; and

(c) a genetically modified organism that is deregulated as determined by the Board.

Biosafety Clearing House and information

21. (1) The Authority is responsible for the management of the National Biosafety Clearing House established under the Cartagena Protocol and shall fulfil its obligations under the Protocol.

(2) The Authority shall provide the Biosafety Clearing House with

(a) a copy of these Regulations, including the amendments to the Regulations and any other legislation and national guidelines of relevance to the implementation of the Act or the management of genetically modified organisms;

(b) the summaries of risk assessments generated pursuant to these Regulations;

(c) the final decision regarding the importation or intentional introduction in the environment or placing on the market of genetically modified organisms and any changes to a previous decision and the reasons for the changes within thirty days.

(d) the reports concerning national implementation of the Cartagena Protocol in accordance with the Protocol; and

(e) any other information required under the Cartagena Protocol.

(3) Where the Authority makes a final decision regarding domestic use, including placing on the market, of a genetically modified organism that may be subject to export for direct use as food or feed product or for processing, it shall ensure that information concerning the authorisation of that organism, as specified in the appropriate guidelines for the release, importation and placing on the market, is provided to the National Biosafety Clearing House within fifteen days of making the decision.

Appeals Tribunal

22. The Appeals Tribunal, established under Section 26 of the Act, shall consider an appeal within sixty days on receipt of the appeal and shall communicate its decision and the reasons for the decision in writing to the Authority and to the applicant.

Food safety

23. (1) The Authority shall liaise with the relevant regulatory agencies with mandate to regulate food to ensure safety of food derived from genetically modified organisms.

(2) Where an application for placing on the market concerns a food or feed product, the applicant shall include information concerning food and feed safety in its application to the Authority for consideration.

(3) Where the Authority is satisfied with the information provided by the applicant under sub-regulation (2), the Authority shall approve the application and inform the applicant of its decision

(4) Any genetically modified organism that has been approved by the Authority shall be published in the register and may be imported into the country for use as food, feed or for processing.

Cessation orders

24. (1) The Authority may, in writing, issue a cessation order, for an activity covered by an authorisation or which has been the subject of a notification, to stop if the Board determines that

(a) there is a significant risk to human health and the environment; or

(b) the holder of the approval has not, or is not in a position to implement, adequate risk management measures to deal with that risk.

(2) For the purposes of sub regulation (1) the Authority shall take into account any

(a) breaches of the terms and conditions prescribed or imposed in the

approval;

(b) tests conducted and evaluated in a manner consistent with accepted scientific procedures; or

(c) other validated scientific evidence.

(3) The Authority may issue a cessation order on the failure of a holder of an approval to demonstrate substantial compliance, after a reasonable period of time of an order issued under these Regulations, or with respect to an authorisation granted or a notification submitted under these Regulations where there exists a material infringement of a provision of these Regulations.

(4) The Board shall withdraw a cessation order where the Board determines that sufficient information exists to permit the activity to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, taking into account the risk to human health and the environment.

Deregulation

25. (1) The Authority may, deregulate the handling and use of a genetically modified organism approved for introduction into the environment or placement on the market

(a) where the holder of an approval to introduce into the environment or place on the market a genetically modified organism submits a petition to the Board; or

(b) on the a determination by the Board.

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(2) The Authority shall deregulate the handling and use of a genetically modified organism where the Authority is satisfied that

(a) the risks to human health or the environment posed by the genetically modified organism are minimal, and

(b) it is not necessary for persons handling and using the genetically modified organism to be covered by an approval, in order to protect human health and the environment.

(3) For the purposes of making a decision, the Authority shall have regard to the following:

(a) any data available to the Board about adverse effects posed by the genetically modified organism,

(b) any advice given by the technical advisory committee,

(c) any other information as to risks identified in previous approvals, and

(d) any other matters that the Board considers relevant.

(4) The decision shall be in writing and shall come into effect on the date specified in the decision.

(5) A copy of the decision to deregulate a genetically modified organism shall be placed on the register in accordance with sub-section 23(e) of the Act.

Miscellaneous Provisions

Fees

26. (1) An applicant shall pay the applicable fee for applications submitted to the Authority.

(2) In determining the fees payable for applications required under the Act, for inclusion in the Fees and Charges (Miscellaneous Provisions) Act,.. the Board shall consider

(a) the cost of processing by the Authority;

(b) the cost of inspection;

(c) the cost of the services from any of the regulatory agencies; and

(d) any other cost relevant matters.

Interpretation

27. In these Regulations, unless the context otherwise requires,

"Cartagena Protocol" means the Cartagena Protocol on Biosafety of the United Nations Convention on Biological Diversity;

"Principal Investigator" means a trained scientist with thorough knowledge in the codes, regulations and laws applicable to biotechnological work and exhibits an appreciation for the biosafety concerns and is recognized by the institution or organization as the Principal Investigator;

"products of genetically modified organisms" means processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of biotechnology; and

"food or feed product" means a genetically modified organism or its product that is used for food, feed or processing and is primarily intended for consumption by humans or animals or for the consumption of both humans and animals;

Transitional provisions

28. (1) An application pending on the date of the coming into force of these Regulations is subject to these Regulations.

(2) An application for approval shall be made in accordance with these Regulations for contained or confined use, introduction into the environment, to import or to place on the market of a genetically modified organism that has already been carried out prior to the coming into force of these Regulations.

(3) An application under sub regulation (2) shall be submitted to the Authority within a time limit to be determined by the Authority.

(4) Where the application has been made within the prescribed time limit the activity in respect of which the application is made may continue until a decision is made by the Authority.

Revocation

29. The Biosafety (Management of Biotechnology) Regulations, 2007 (L.I. 1887) and any previous guidance issued prior to the adoption of the Biosafety Act, 2011(Act 831) are hereby revoked.

Annex 1: Fee Schedule for Biosafety Applications in Ghana

	ITEM	COST	
		GHS	USD
1	Institutional Accreditation and Certification of Institutional Biosafety Committee (IBC)	16,810.79	3,909.49
	Renewal of Institutional Biosafety Committee (IBC) Certificate	9,680.67	1,623.41
2	Facility Certification	6,100.00	1,418.60
3	Renewal of Facility Certificate	3,600.00	837.20
4	Confined Field Trial (CFT)	27,845.34	6,475.60
5	Renewal of CFT Permit	5,587.09	1,299.32
6	Environmental Release/placing on the market	54,940.93	12,776.96
7	Renewal of Environmental/Commercial Release Permit	15,351.60	3,570.14
8	Appeals	7,612.84	1,770.43
9	Transit	4,335.45	1,008.25
10	Multi-Location Trials	42,866.88	9,969.04
11	Renewal of Multi-Location Trial Permit	28,180.50	6,553.61
12	Export / Import	15,370.90	3,574.63
13	Contained Use	27,845.04	6,475.60
14	Renewal of Contained Use permit	11,470.00	2,667.67
15	Genetically Modified Free Status Certificate	2,000.00	465.12