200413 **L.I**

BIOSAFETY (MANAGEMENT OF BIOTECHNOLOGY)

REGULATIONS 2017

ARRANGEMENT OF REGULATIONS

Regulation

BIOSAFETY (MANAGEMENT OF BIOTECHNOLOGY) REGULATIONS, 2017

IN EXERCISE of the powers conferred on the Authority by subsection (1) of Section 40 of the Biosafety Act, 2011 (Act 831) these Regulations are made the ……..day of …… 2017 with the prior approval in writing of the Ministers and in consultation with Ministers responsible for Health and Food and Agriculture.

Institutional arrangements

The National Focal Point

1. (1) The National Biosafety Authority as the National Focal Point for the purposes of Section 4(c) of the Act is responsible for the following:
   (a) liaison with the Secretariat of the United Nations Convention on Biological Diversity for the administrative functions required under the Cartagena Protocol on Biosafety;
   (b) informing other Parties to the Cartagena Protocol on Biosafety of any bilateral, regional and multilateral agreements and arrangements that Ghana has entered into before and after the date of entry into force of that Protocol;
   (c) exchange of information and provision of information to other Parties to the Protocol and other countries in relation to
      (i) biosafety and biotechnology;
      (ii) decisions and other administrative arrangements under the Act;
      (iii) transport, use, handling and other activities in relation to genetically modified organisms within Ghana that had significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; or where such activities have or are likely to significant adverse effects on the conservation and sustainable use biological diversity, taking also into account risks 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 Protocol in relation to transboundary movements of genetically modified organisms and other related activities.

(2) The National Biosafety Authority

Consistent with the functions conferred by the Act under Section 4(a) to (b), the National Biosafety Authority

   (a) may certify the institutional biosafety committees to undertake contained and confined field trials and monitoring functions for certain levels of classified risks to be issued periodically through guidelines;
   (b) may provide assistance to the institutional biosafety committees and advise on the various notification and assessment forms, biosafety guidelines and any other relevant documents;
   (c) may prepare and provide to the institutional biosafety committees, the various notification and assessment forms, appropriate Guidelines and any other relevant documents;
   (d) may facilitate training of scientists and other persons in biosafety
   (e) may suggest practical alternatives to high-risk laboratory procedures;
   (f) may inform the various institutions engaged in genetic modification work about

new developments in biosafety so as to avoid exposure of laboratory personnel, the community or the environment to undue risks;

(g) may co-ordinate efforts between the relevant Government agencies and private organizations to maintain safety levels in biotechnological work and to prepare them for biological emergencies;

(h) may certify high-level laboratories, greenhouses and animal facilities intended for high-risk work, for which purpose the Authority, on request by the institution, and at the earliest convenience, and with assistance from the technical advisory subcommittee, will inspect the facility, issue certification or recommend additional precautions where necessary;

(i) may inspect high-level laboratories and containment facilities on a regular basis through the designated regulatory agencies, for which purpose an inspectorate established pursuant to the Act–may inspect laboratories and facilities of physical containment levels at any time subsequent to certification without prior notice;

(j) may inspect systems, equipment, vessels and instruments governing ambient biosafety levels in genetic modification laboratories;

Implementation Roles

2. (1) The implementation of biosafety practices in genetic modification and biotechnological work shall be supervised by the Authority in collaboration with:

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

(b) the relevant institutional biosafety committees certified by the Authority, and

(c) the Principal Investigator.

(2) The organizations and persons specified in sub-regulation (1) though retaining their different functions

(a) shall 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) shall promote and facilitate adherence to this Regulation and any guidelines that may be issued under the Act for the safety of personnel, the community and the environment.

(3) Where there is a non-compliance with the prescribed biosafety measures, whether deliberate or unintentional, the Authority

(a) may stop the work on issuing a notice to show cause and requesting proper investigation through the relevant institutional biosafety committee, or

(b) may prescribe additional safety measures or conditions or may intervene in any other manner appropriate under the Act.

Subcommittees of the Technical Advisory Committee

3. (1) Subcommittees of the Technical Advisory Committee shall have functions determined by the Committee.

(2) In appointing a subcommittee, the Technical Advisory Committee, shall consider its mandate and endeavor to draw on the various disciplines.

(3) A member of the Technical Advisory Committee shall be the chairperson of any technical

advisory subcommittee.

Institutional Biosafety Committee

4. (1) Institutions and organizations, public or private, engaged in, or with the intent to engage in, the purchase, construction, propagation or field release of genetically modified organisms or their products shall each establish an institutional biosafety committee and support the needs and demands of the committee to enable it perform its functions efficiently.

(2) An institutional biosafety committee shall include representatives from cognate organizations or institutions in its membership.

(3) Institutions and organizations, particularly those engaged in industrial grade or other large-scale work may recruit a biosafety officer to work in conjunction with the various institutional biosafety committees.

(4) Small research institutions which may encounter difficulties in constituting an independent institutional biosafety committee may request any other institutional biosafety committee to help monitor and supervise the biosafety aspects of their work.

(5) Agreements under sub regulation (4) shall be entered into between the parties involved and the Authority shall be notified of the proceedings.

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

Relationship between the Various Committees and the Authority

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

(2) Work involving higher level of risk shall be evaluated, and granted permission by the Authority.

Memorandum of Understanding with Regulatory Agencies

6. (1) In the performance of its functions, the Authority may enter into an agreement through a memorandum of understanding with the regulatory agencies specified in the Fifth Schedule to the Act. The memorandum shall spell out clearly the areas of operation and roles expected and the financial arrangements related to the execution of the specified roles.

(2) The Authority may enter into agreement with other persons, agencies or organizations not listed under the act through a Memorandum of Understanding.

Procedures

Processing of Applications

7. (1) Where an application is formally submitted to the Authority, it shall be recorded and a tracking number assigned to the dossier so as to systematically keep track of the application.

(2) The tracking numbers shall be kept in the Authority's register to make the information readily available to all stakeholders.

(3) Where an application is recorded, the request itself shall be handled in a number of steps:
   (a) the first step, which is an administrative step is screening for completeness, that is checking whether the request complies with legally required information;
   (b) where it is concluded that the request is in compliance with the information requirements, the risk assessment included in the dossier shall be reviewed as a scientific process, based on the best available and up to date, scientific knowledge and data;
   (c) the review of the risk assessment shall be carried out by the Technical Advisory Committee;
   (d) the key elements for determination and communication of the decision are set out in Sections 21 and 22 of the Act.

Confidential Information

8. (1) Where an applicant satisfies the Authority that the information specified in the application is;
   (a) a trade secret, or
   (b) any information that 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) other information that;
      (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking, and
      (ii) if it were disclosed, could unreasonably affect the person, organisation or undertaking,

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

(2) Subject to Section 16(1)(d) [of the Act, the Authority may refuse to declare that the information is confidential information if the Authority is satisfied that the public interest in disclosure outweighs prejudice that the disclosure would cause to any 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-section 1 if the Authority is satisfied that;
   (a) the information concerned no longer satisfies sub-regulation [1], or
   (b) the 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.

Fees

9. (1) In determining the fees payable for applications required by the 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
   (d) any other cost relevant factors .

   (2) Fees specified in Annex I shall apply. Annex I shall be updated from time to time as deemed necessary by the Authority.

Contained Use and Confined Use

10. (1) Laboratories and other contained facilities submitting an application under Section 11 of the Act for a permit for Contained Use activities shall, in addition to submitting the information set forth in the Second Schedule of the Act, identify the risk classification of the proposed genetically modified organisms and information on risk classification shall be provided by the Authority in the appropriate Guidelines.

   (2) In deciding on the initial application, the Authority may authorize laboratories and other facilities to continue work with genetically modified organisms in the same risk classification without further applications for a specified period of time.

   (3) Contained use activities with genetically modified organisms subject to higher risk classification than already authorized, shall be subject to approval under Section 11 of the Act.

   (4) Persons submitting an application under Section 11 of the Act for a permit for Confined Use activities shall, in addition to submitting the information set forth in the Second Schedule of the Act, submit a risk assessment as set out in the Fourth Schedule of the Act.

Certification of the Institutional Biosafety Committee

11. (1) The Authority shall formally endorse each institutional biosafety committee.

   (2) For the purposes of sub regulation (1), the completed notification forms of the 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 genetic modification work indicating the category of containment, and
      (e) a list of the institution's greenhouses and animal facilities, certified and intended for work with transgenic species indicating category of containment

Composition of the Institutional Biosafety Committee

12. An institutional biosafety committee shall include

   (a) the biosafety officer and four other members selected because of their experience and expertise for the evaluation of the biosafety and environmental effects of

biotechnology research including genetic modification;

(b) two members who are not affiliated with the institution but are knowledgeable in biotechnology 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

Functions of the Institutional Biosafety Committee

13. (1) In order to enforce the appropriate Guidelines issued by the Authority, an institutional biosafety committee shall report infractions to the institutional head or to the Authority and recommend to the relevant authority to stop a project if its continuation under the existing circumstances, is a threat to the public, the environment or to laboratory personnel.

(2) An institutional biosafety committee

(a) shall 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) shall determine additional biosafety mechanisms and draft supplementary operating instructions for work at the institution, in line with and addressing the specific risks and concerns uncovered;

(c) shall evaluate the qualification of researchers involved in biotechnological projects and assess whether each retains a thorough understanding of good laboratory practices necessary for the supervision of students, assistants, technicians and junior personnel.

(d) shall assist researchers in undertaking risk assessment and organize training programmes.

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

(f) shall 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;

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

(3) To ensure that laboratory genetic modification work within the institution conforms to these Regulations and the appropriate Guidelines, the institutional biosafety committee

(a) shall assess the projects referred to the committee, and on the basis of the information provided and the risks forecast determine under which category of work the proposals fall and whether to endorse the work proposed;

(b) shall maintain records of approved project proposals for laboratory genetic modification work, including notification for project exemption and the committee's assessment;

(c) shall forward summaries of the project proposals submitted for notification and the committee's assessments to the Authority for records and information or for review and recommendation in the case of proposals for risk assessment as specified in the National Biosafety Guidelines;

(d) shall undertake risk assessment, in co-operation with the research teams as necessary to determine the appropriate containment and biosafety conditions, standard operating procedures and emergency safeguards for risk assessment as specified in the appropriate Guidelines and for the housing, storage or movement

of regulated material and also for waste management;

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

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

(g) shall facilitate inspection and certification of the appropriate level of laboratories, conventional animal houses, and greenhouses, before use in genetic modification work;

(h) shall monitor and assess the containment features, 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) shall facilitate preparation of dossiers for submission to the Authority for the conduct of laboratory work, and

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

The Biosafety Officer

14. (1) An institution or organization involved in genetic modification work shall appoint a Biosafety Officer to the institutional biosafety committee.

(2) The Biosafety Officer in conjunction with the institutional biosafety committee shall review the standard operating procedures and biosafety records, and assess the integrity of containment facilities and safety equipment or utilities.

Principal Investigator

15. (1) The Principal Investigator is responsible for the initial stages of originating proposals and obtaining approval of the institutional biosafety committee.

(2) For laboratory genetic modification work, the Principal Investigator shall assess the nature of the research and determine whether the work proposed falls with the scope of the appropriate guidelines.

(3) Where there is an uncertainty or doubt, the matter shall be addressed by submitting a detailed proposal of the work to the institutional biosafety committee for endorsement or clearance before work is carried out.

(4) Where the work is regulated under the appropriate Guidelines, the Principal Investigator shall submit a completed project proposal, including requests for exemption to the supervising institutional biosafety committee for consideration and recommendations, and inform the committee of any notable intent such as plans to import regulated material.

(5) Laboratory work may begin after authorization 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 evaluation and monitoring activities of the institutional biosafety committee.

(6) The Principal Investigator shall comply with the provisions of the appropriate Guidelines

throughout the duration of the research, with special emphasis on

(a) avoidance of the adoption of radical operating procedures or substantially changing the parameters of the work, especially approaches to physical and biological containment, which may introduce novel risk, delimit new biosafety levels or warrant change of classification;

(b) establishing and maintaining working conditions appropriate to the level of biosafety as approved and advised by the institutional biosafety committee and/or, in accordance with the requirements of the Authority;

(c) ensuring that students, junior personnel, technicians, co-investigators and any other person entering controlled areas realize the nature and degree of the risks involved and that those persons have been properly instructed on applicable codes of conduct;

(d) co-operating closely with the institutional biosafety committee and the biosafety officer in carrying out various safety tests and, inspection of containment facilities;

(e) reporting to the institutional biosafety committee on the medical and other conditions of the personnel including unusual illnesses;

(f) relaying to the institutional biosafety committee details of the contingencies and the emergency procedures instigated to deal with incidents.

Introduction into the Environment, Placing on the Market and Import

16.(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 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 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

(5) The holder of an approval may, with consent of the Authority, surrender the approval.

(6) The approval holder and another person may jointly apply to the Authority to transfer the approval from the approval holder to the transferee.

(7) The application shall be in writing, and must contain such information as is specified in writing by the Authority.

(8) If the Authority decides to transfer the approval the same conditions apply as those in force immediately before the transfer.

Authorisation for Placing on the Market

17. (1) The written approval of an application for the Placing on the Market of a genetically modified organism shall be in the form of an authorization for a specified period of time up to ten years, which shall be renewable.

(2) An authorisation for Placing on the Market of a genetically modified organism includes the possibility to import the authorised genetically modified organism.

Export

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

Transit

19. (1) An applicant handling products in transit shall inform the Authority prior to the transshipment across the borders of Ghana.

(2) The products 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.

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

(4) The application for the transit authorization shall contain

(a) the authorization by the recipient country for the importation,

(b) contingency plan in case of an accident,

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

(5) The documents referred in sub-regulation (4) shall be submitted to the Authority not less than fifteen working days prior to the cargo's departure from the exporting country.

Monitoring and enforcement

20. (1) The Authority shall be responsible for the overall monitoring, risk management and commercial release of the regulated materials.

(2) The Principal Investigator shall conduct the first tier of monitoring as provided for in Regulation 10.

(3) The institutional biosafety committee

(a) shall conduct the second tier of monitoring;

(b) shall serve, in part, as a channel for the flow of information between the researchers and the Authority, forwarding proposals, assessments and recommendations to the Authority;

(c) shall receive applications, propose measures for improvement and for laboratory set-up as well as planned release and effectively monitor any of those matters.

(4) Information or any other data that needs to be submitted to the Authority shall be sent through the institutional biosafety committee

(5) The third tier of monitoring, inspection and enforcement shall be performed by the Authority through the regulatory agencies specified in the Fifth Schedule to the Act and biosafety inspectors as provided for in sections 33 and 34 of the Act.

Public awareness, participation and education

21. (1) The Authority shall develop procedures to engage the public through education and awareness, through the issuance of public participation and regulatory guidelines and strategies on public engagement.

(2) The Authority shall publish on a regular basis, in the appropriate medium as determined by the Board

(a) notices concerning proposals or petitions for exemptions and simplified procedures, and

(b) proposed decisions on applications for intentional introduction into the environment or placing on the market.

(3) A person may submit a written comment on a proposed decision for an application for release of a genetically modified organisms within sixty days from the date the notice is posted.

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

(5) The Authority shall include in the register established under Section 23 of the Act a list of:

(a) genetically modified organisms for which authorization is granted by the Authority including whether the genetically modified organism has been authorized for placing on the market,

(b) genetically modified organisms and activities that are exempted or subject to simplified procedures as determined by the Board, and genetically modified organisms that are deregulated as determined by the Board.

The Biosafety Clearing House and information

22. (1) The Authority is responsible for the management of the National Biosafety Clearing House and for that purpose the Authority may request any other agency to manage that obligation on its behalf.

(2) The applicant or the Authority shall inform the National Biosafety Clearing House of a notification, decision or an activity that is required to be made or conducted under these Regulations.

(3) In addition to sub regulations (I) and (2),

(a) the Authority shall notify the National Biosafety Clearing House that the Authority's domestic regulation shall apply to the importation of genetically modified organisms to the area of national jurisdiction of Ghana:

(b) the Authority shall provide the National Biosafety Clearing House with

(i) a copy of these Regulations, including the amendments to the Regulations decisions made pursuant to the Regulations and any other legislation and national guidelines of relevance to the implementation of the Cartagena Protocol or the management of genetically modified organisms;

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

(iii) the final decision regarding the importation or intentional introduction in the environment or placing on the market of genetically modified organisms:

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

(v) a copy of the decision describing the changes to the previous decision and the reasons for the decision within thirty days; and

(vi) any other information required under the Cartagena Protocol or any other international agreement concerning the subject matter dealt with under these Regulations;

(c) where the Authority takes 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 or for processing, it shall ensure that information concerning the authorization 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 established under the Cartagena Protocol within fifteen days of taking the decision.

Appeals Tribunal

23. Consistent with Section 26 (5) of the Act, the Appeals Tribunal shall decide an appeal within a reasonable time, not exceeding sixty days and shall communicate its decision and the reasons for the decision in writing to the Authority and to the applicant.

Food Safety

24. (1) Consistent with Sections 19 (5), 31 and 40 (1) of the Act, the Authority shall laise with the relevant Regulatory Agencies with mandate to regulate and also ensure food safety.

20.

(2) Where an application for Placing on the Market concerns a food , feed product, the applicant shall include information concerning food and feed safety in its application and the Authority shall forward such information to the Food and Drugs Authority for food/feed safety assessment.

(3) Where a genetically modified organism has been determined to be substantially equivalent to non-modified counterparts and assessed as safe for food and/or feed use by at least one country in accordance with the Codex Principles and Guidelines enumerated above, the Food and Drugs Authority may certify the genetically modified organism for purposes of making a food and/or feed product available for consumption based on recognition of the assessment of such country(ies).

(4) The Food and Drugs Authority shall forward its decision concerning the food and feed safety assessment of an application to the Authority within 90 days. Days waiting for relevant additional information requested by the Food and Drugs Authority shall not be counted.

(5) Any genetically modified organism that has been approved shall be published in the register and thereafter may be imported into Ghana for direct use for food, feed or for processing.

Cessation orders

25. (1) The Authority may issue an order, in writing, for the cessation of an activity covered by an authorization or which has been the subject of a notification, if the Board determines that there is a significant risk to human health, plant health, animal health or the environment or that 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

(a) any breaches of conditions prescribed or imposed in the approval,

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

(c) any other validated scientific evidence.

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

(4) An order issued under this regulation shall be withdrawn 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 risks to human and animal health and the environment.

Deregulation

26. (1) The Authority may deregulate the handling and use of a genetically modified organism under Section 40(1)(g) of the Act if the genetically modified organism is approved for introduction into the environment or to place on the market.

(2) The Authority must not deregulate the handling and use of a genetically modified organism unless the Authority is satisfied that;

(a) any risks to 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 health and the environment.

(3) For the purposes of sub regulation (1), 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) other information as to risks identified in previous approvals, and

(d) other matters that the Board considers relevant.

(4) A determination, in writing, under sub regulation (1) may be made:

(a) on petition by the holder of an approval to introduce into the environment or place on the market a genetically modified organism, or

(b) on the initiative of the Board.

(5) A determination under sub regulation (1) comes into effect on the day specified in the determination.

(6) A copy of the determination to deregulate a genetically modified organism will be placed on the register according to subsection 23(e) of the Act.

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 a copy of which is set out as the First Schedule.

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

"food and/or feed product" shall mean 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 in terms of 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.

Repeals

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 +are hereby repealed.

Annex 1: Fee Schedule for Biosafety Applications in Ghana

ITEM		COST	
		GHS	USD
1	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/Commercial Release	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