

## **Biosafety Act, 2011 Act 831**

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**ACT**

**OF THE PARLIAMENT OF THE REPUBLIC OF GHANA**

**ENTITLED**

## **BIOSAFETY ACT, 2011**

AN ACT to regulate biotechnology and to provide for related matters.

DATE OF ASSENT:

PASSED by Parliament and assented to by the President:

### *Scope, objectives and establishment*

#### Scope of the Act

1. (1) The requirements of this Act are in addition to, and not in derogation of, the requirements imposed by any other enactment.

(2) This Act does not apply to genetically modified organisms that are pharmaceuticals for human use, and which are the subject of any other enactment.

#### Objectives of the Act

2. The objectives of the Act are,

(a) to ensure an adequate level of protection in the field of safe development transfer, handling and use of genetically modified organisms resulting from biotechnology that may have an adverse effect on health and the environment, and

(b) to establish a transparent and predictable process to review and make decisions on genetically modified organisms specified in paragraph (a) and related activities.

#### **Establishment of the National Biosafety Authority**

3. (1) There is established by this Act a body corporate to be known as the National Biosafety Authority.

(2) Where there is a hindrance to the acquisition of property by the Authority, the property may be acquired for the Authority under the State Property and Contracts Act, 1960 (C.A. 6) or the State Lands Act, 1962 (Act 125) and the cost shall be borne by the Authority.

#### Functions of the Authority

4. The functions of the Authority are

(a) to receive, process, respond to and to make decisions on applications under and in conformity with this Act,

(b) to establish administrative mechanisms to ensure the appropriate handling and storage of documents and data in connection with the processing of applications and any other matters covered by this Act,

(e) to act as the national focal point responsible for liaising with any other agency or international organisations concerned with biotechnology and biosafety, and

(d) to promote public awareness, participation and education concerning the activities of the Authority under this Act.

### **The governing body**

5. (1) The governing body of the Authority is a Board consisting of (a) an expert in biotechnology and related biological sciences including biosafety, as the chairperson,

(b) the chairperson of the technical advisory committee established under section 27,

(e) one representative of the Ministry responsible for Science not below the rank of Director,

(d) one representative of the Association of Ghana Industries, (e) one legal practitioner of not less than ten years standing, who has a sufficient background knowledge relevant to the subject matter of this Act,

(f) one representative of non-governmental organisations, (g) the chief executive officer of the Authority,

(h) two members from the academia who are persons with a sufficient background knowledge relevant to the subject matter of this Act at least one of whom is a woman,

(i) one representative of the Council for Scientific and Industrial Research not below the rank of a Director,

(j) one representative of the Ministry of Food and Agriculture not below the rank of a Director,

(k) one representative of the Ministry of Health not below the rank of a Director, and

(l) one representative from the Customs Division of the Ghana Revenue Authority,

(2) The members of the Board shall be appointed by the President in accordance with article 70 of the Constitution and shall hold office for three years.

(3) A member of the Board is eligible for reappointment for a further term not exceeding three years.

(4) Subsections (2) and (3) do not apply to the *ex officio* members. (5) The names of the members of the Board shall be published as a notice in the *Gazette*.

(6) The Board is responsible for the proper and efficient performance of the functions of the Authority.

(7) The Minister responsible for Science may give policy directives to the Board.

### *Administration*

#### **Conduct of business and affairs of the Board**

6. (1) The provisions relating to the conduct and regulation of the business and affairs of the Board are set out in the First Schedule

(2) Except as provided in the First Schedule, the Board shall regulate its own procedure and the procedure of any of its committees.

(3) The Authority shall pay to members of the Board allowances approved by the Minister in consultation with the Minister responsible for Finance.

#### **Delegation of powers of the Authority**

7. Subject to this Act, the Board may, generally or in a particular case, delegate to a committee of the Board or to a member of the Board, or to an officer, employee or agent of the Authority, the performance of a function of the Authority under this Act.

#### **Chief executive officer**

8.(1) There shall be a chief executive officer of the Authority.

(2) The President shall appoint, in accordance with article 195 of the Constitution, the chief executive officer of the Authority, on the terms and conditions of service stated in the instrument of appointment.

(3) The chief executive officer shall hold office for a period not exceeding five years and is eligible for re-appointment for another term only.

(4) The chief executive officer is responsible, subject to the direction of the Board, for the day to day management of the affairs of the Authority.

#### **Staff of the Authority**

9. The President shall appoint for the Authority, in accordance with article 195 of the Constitution, the officers and any other staff necessary for the proper performance of its functions under this Act, on the terms and conditions of service determined by the Board.

#### **Protection from personal liability**

10. A matter or thing done by a member of the Board or by an officer, employee or agent of the Authority, shall not, if the matter or thing is done bona fide in the performance of a function of the Authority, render the member, officer, employee or agent personally liable to an action, a claim or demand.

#### *Handling requests for approval*

##### Application for contained or confined use

11. (1) A person shall not conduct a contained or confined use activity involving genetically modified organisms or their development without the written approval of the Authority.

(2) The application shall include

(a) the details that are set out in the Second Schedule, and

(b) any other additional information that the applicant may consider necessary for an assessment of the potential risk and benefits of the requested activity.

##### Application for introduction into the environment

12. (1) A person shall not introduce into the environment a genetically modified organism without the prior written approval of the Authority.

(2) A person wishing to introduce a genetically modified organism into the environment shall submit to the Authority an application describing the activity for which the approval is sought.

(3) An application under subsection (2) shall include (a) the information set out in the Third Schedule,

(b) a risk assessment as set out in the Fourth Schedule,

(c) a sworn declaration that the information contained in the application is factually correct, and

(d) any other additional information that the applicant may consider necessary for an assessment of the potential risks and benefits of the requested activity.

(4) An applicant may withdraw the application at any time prior to the issuance of a final decision by the Authority.

##### **Application to import or place on the market**

13. (1) A person shall not, without the prior written approval of the Authority, import or place on the market a genetically modified organism.

(2) An application under subsection (1) shall include (a) the information set out in the Third Schedule,

(b) a risk assessment as set out in the Fourth Schedule, and

(c) any other information that the applicant may consider necessary for an assessment of the potential risks and benefits of the requested activity.

### **Application to export**

**14.** A person intending to export a genetically modified organism shall provide the Authority with a written advance informed agreement or the appropriate certification from the competent authority of the importing country.

### **Genetically modified organisms in transit**

**15. (1)** A person intending to transport a genetically modified organism through the Republic which is not destined for use in the Republic

(a) shall apply to the Authority for a written approval for the transportation, and

(b) shall ensure that the genetically modified organism is properly packaged and transported in accordance with the Regulations and international standards.

(2) An application to transport genetically modified organisms through the Republic shall be in the form prescribed by the Regulations.

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### **Confidential information 16.** (1) The Authority

(a) shall allow an applicant to designate information provided to the Authority in accordance with the requirements of this Act and the Regulations as confidential information, and the applicant shall supply the justification for the claims of confidentiality;

(b) shall decide whether it accepts as confidential the information designated as confidential by the applicant;

(c) shall inform the applicant of its rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation; and

(d) shall, where an applicant withdraws an application, respect the applicant's claims of confidentiality.

(2) The Authority shall not use confidential information for a purpose not authorised under this Act and shall ensure that the information is protected by the person involved in handling applications under this Act.

### **Acknowledgement of application**

**17.** (1) On receipt of the application, the Authority

(a) shall acknowledge in writing, the receipt of the application within seven days of the receipt, and

(b) shall screen the application for completeness within sixty days.

(2) Where an application is not complete, the Authority shall request the applicant to submit additional information.

### **Gazette publication**

**18.** (1) The Authority shall within fourteen days publish in the *Gazette*, a notice concerning an application for release into the environment, for the general information of the public.

(2) On request, the Authority may avail to a person portions of an application which do not qualify as confidential information.

### **Risk assessment and risk management**

**19.** (1) Where an application is screened and found to be complete, the Board shall act in accordance with the advice of the technical advisory committee in respect of the risk assessment conducted as set out in the Fourth Schedule.

(2) Risk assessment shall be carried out taking into account available information concerning a potential exposure to the genetically modified organism.

(3) The Board may request an additional risk assessment. (4) On completion of the risk assessment, the Board shall

(a) make a report giving its decision and the justification on the disposition of the application, and

(b) indicate the measures to be taken to ensure the safe use of the genetically modified organism.

(5) The Board shall liaise with the appropriate regulatory agency to ensure that measures are in place to manage and control risks identified during the risk assessment process.

### **Exemption**

20. The Board may exempt a genetically modified organism from certain requirements of section 11, 12, or 13, where it is satisfied that sufficient experience or information exists to conclude that the genetically modified organism or activity does not pose a significant risk to the environment.

#### Determination of the application

21. In reaching a final decision on an application, the Board shall

take into account

(a) information submitted by the applicant, (b) the risk assessment report,

(c) relevant comments submitted by the public, and

(d) socio-economic considerations arising from the impact of a proposed activity and of the genetically modified organisms on the environment.

#### Communication of decision

22. (1) The Board shall communicate its final decision to the applicant (a) as soon as possible, but in any case not later than one hundred and eighty days after the receipt of the complete application, or

(b) within the time that the Board may in special circumstances determine.

(2) The approval shall set out clearly the specific conditions related to the approval.

(3) The approval shall be specific and limited to the activity authorised as set out in the decision document.

#### Register

23. The Authority shall maintain a register, which shall contain a copy of

(a) the application,

(b) the risk assessment report, (c) the decision document, (d) the approval, and

(e) any other information the Board may consider necessary.

#### *Reviews and approvals*

##### Review of approval

24. (1) The Board may review a decision made under section 21 at any time on obtaining significant new scientific information indicating that the genetically modified organism or the approved activity may adversely affect human health, plant health, animal health or the environment.

(2) A regulatory agency or an applicant may request the Board to review the Board's decision under section 21 with respect to an activity conducted by the applicant on the ground

(a) that a change in the circumstances has occurred that may have a material effect on the outcome of the risk assessment on which the decision was based; or

(b) that additional scientific or technical information is available which may have a material effect on the decision including the conditions, limitations or requirements imposed under an approval.

(3) Where on a review the Board is satisfied that a change is warranted, the Board shall issue a revised approval.

(4) The Board shall take a decision on a review within one hundred and fifty days from the date of notification of the review and shall set out the reasons for the decision.

(5) Where the Board has knowledge that an activity possesses potential risk to the environment, the Board shall take immediate action to put the necessary measures in place.

(6) The Board shall give special consideration for review requests from a regulatory agency.

#### Withholding information

25. (1) A person who withholds information

(a) which becomes available to the applicant after the approval of the application, and

(b) which could change the evaluation of risk posed by the

intended activity of the person

commits an offence and is liable on summary conviction to a fine of not less than two thousand five hundred penalty units and not more than five thousand penalty units or to a term of imprisonment of not less than five years and not more than ten years or to both the fine and the term of imprisonment.

(2) Where an applicant has information which the applicant ought to have disclosed with the application, but does not do so, the applicant commits an offence and is liable on summary conviction to a fine of not less than two thousand five hundred penalty units and not more than five thousand penalty units or to a term of imprisonment of not less than five years and not more than ten years or to both the fine and the term of imprisonment.

#### Appeals Tribunal

26. (1) There is hereby established an Appeals Tribunal consisting of (a) an eminent biological scientist as the chairperson,

(b) one legal practitioner of not less than ten years standing with professional qualifications in biotechnology or biosafety matters; and

(c) three other members, who have qualifications in biotechnology and biosafety management at least one of whom is a woman.

(2) The members of the Appeals Tribunal shall be appointed by the Minister and the appointments shall be published in the *Gazette*.

(3) A member of the Board shall not be appointed a member of the Appeals Tribunal.

(4) The members of the Appeals Tribunal shall hold office for three years.

(5) A person who is aggrieved by

(a) a refusal to grant an approval under this Act, or (b) the conditions of approval under this Act, or

(c) the revocation, suspension or revision of an approval under this Act, or

(d) a refusal to treat an application as confidential

may appeal, within thirty days of the decision of the Board, to the Appeals Tribunal in the prescribed manner.

(6) A person aggrieved by a decision of the Appeals Tribunal may, within thirty days of the decision, appeal against the decision to the High Court.

*Technical advisory committee*

27. (1) In addition to any other committees that the Board may establish under the First Schedule, there is hereby established a technical advisory committee consisting of not more than eleven persons appointed by the Board for a period not exceeding three years as follows:

(a) one representative each from

(i) the Council for Scientific and Industrial Research, and

(ii) the Atomic Energy Commission,

(b) two persons one of whom is a woman, who are persons knowledgeable in the fields of science applicable to ecology and the development and release of genetically modified organisms,

(c) two persons one of whom is a woman who are knowledgeable in socio-economic matters and genetically modified organisms, and

(d) one representative each from the

(i) Ghana Revenue Authority,

(ii) Environmental Protection Agency,

(iii) Food and Drugs Board,

(iv) Veterinary Services Directorate, and

(v) Plant Protection and Regulatory Services Directorate.

(2) The Board in consultation with the Minister responsible for Science shall in appointing members to the committee, endeavour to achieve representation from a range of the sciences relevant to genetically modified organisms and ecology.

(3) The Board shall designate a member of the committee as the chairperson of the committee.

(4) In the absence of the chairperson, the members of the committee shall elect one of their number to act as chairperson.

(5) The acting chairperson shall perform the functions of the chairperson where the chairperson is unable to do so.

(6) A member of the committee whose period of office has expired is eligible for reappointment.

### **Functions of the committee**

**28.** (1) The technical advisory committee shall

(a) act as the national advisory body on matters concerning or related to genetic modification of organisms, and carry out risk assessment and audit of applications at the request of the Board, and

(b) advise, on request or of its own accord, the Minister and through the Board and the Minister advise the Ministries and appropriate bodies, on matters concerning the genetic modification of organisms including

(i) aspects relating to the introduction and development of genetically modified organisms into the environment,

- (ii) proposals for specific activities or projects concerning genetic modification of organisms,
- (iii) aspects concerning the contained use of genetically modified organisms,
- (iv) the importation and exportation of genetically modified organisms, and
- (v) proposed Regulations and written guidelines.

(2) The committee shall annually submit a budget to the Board. (3) The committee may appoint subcommittees to deal with specific matters as required.

### **Allowances**

**29.** The members of the technical advisory committee and of a subcommittee shall be paid the allowances determined by the Minister, in consultation with the Minister responsible for Finance.

### **Conflict of interest**

**30.** (1) A member of the technical advisory committee who has an interest, directly or indirectly in a matter which is the subject of consideration by the committee shall disclose that fact to the committee and the nature of the interest and shall not take part in the consideration, discussion of or vote on a question in respect of that matter.

(2) A member who fails to comply with subsection (1) ceases to be a member of the committee.

### *Regulatory agencies* Functions of regulatory agencies

**31.** (1) A regulatory agency shall, where appropriate, monitor an applicant's activities to ensure that those activities comply with the requirements of this Act, the Regulations and the conditions imposed in connection with the approval under this Act.

(2) Where a regulatory agency becomes aware of significant new scientific information indicating that approved activities with genetically modified organisms may adversely affect the environment or pose potential risks not previously known, the regulatory agency shall immediately inform the Authority of the new information and of the measures put in place to ensure the continued safe use of the genetically modified organism.

### Unintentional release into the environment

**32.** (1) A regulatory agency with knowledge of an unintentional or unapproved introduction into the environment of a genetically modified organism that is likely to have an adverse effect on the environment, shall, within twenty four hours of having that knowledge, notify the Authority of the occurrence.

(2) A notification under subsection (1) shall include adequate information for the Board to undertake a risk assessment.

(3) The Board, in consultation with the regulatory agency, shall determine whether an action is necessary to minimize an adverse effect on the environment.

### *Inspections*

#### Appointment of inspectors

33. (1) Subject to subsection (5) of section 19, the Board may appoint a duly qualified person as a biosafety inspector of the Authority, for the area of authority specified in the letter of appointment.

(2) The appointment of an inspector under subsection (1) shall be published in the *Gazette*.

(3) An individual or a company incorporated in the Republic may be appointed as an inspector.

#### Functions of inspectors

34. (1) A biosafety inspector may, in the performance of a function under this Act, at a reasonable time and without a warrant,

(a) enter any premises, vessel or property, which the inspector has reason to believe it is necessary to enter, in order to ascertain whether the requirements of this Act or of the Regulations are, or an approval under this Act is, being complied with, and may be accompanied by a person duly authorised by the Authority;

(b) take possession of the equipment or material required for the purpose for which the power to enter is being exercised; (c) carry out the tests and inspection and make the recordings that are necessary in the circumstances;

(d) direct that a part of the premises, or anything in the premises, shall be left undisturbed for so long as it is reasonably necessary for the purposes of the test or inspection;

(e) take appropriate samples of the organisms, articles or substances found in the premises, an analysis or any other thing relevant for the purposes of this Act;

(f) in the case of anything found in the premises which appears to contain genetically modified organism which has adversely affected or is likely to adversely affect the environment, the biosafety inspector may cause it to be dismantled or subjected to a process or test but not so as to damage or destroy it, unless it is necessary; or

(g) require the production of the records which are required to be kept under this Act.

(2) In the performance of a function under this Act, a biosafety inspector shall supply the appropriate identification.

(3) An inspector who without reasonable cause acts in contravention of a provision of subsections (1) and (2) commits an offence and is liable on summary conviction to a fine of not less than two



thousand five hundred penalty units and not more than five thousand penalty units or to a term of imprisonment of not less than five years and not more than ten years or to both the fine and the term of imprisonment.

### *Finance*

#### Funds of the Authority

35. The funds of the Authority include

- (a) the moneys appropriated by Parliament for the purposes of the Authority,
- (b) the moneys that accrue to or vest in the Authority in the performance of its functions under this Act, and
- (c) the moneys from any other source provided for, donated or lent to the Authority,

#### Investment of funds

36. The Authority may

- (a) invest any of its surplus funds in securities, and
- (b) place on deposit with a bank approved by the Minister responsible for Finance the moneys not immediately required for the purposes of the Authority.

#### Financial year

37. The financial year of the Authority shall be the same as the financial year of the Government.

#### Annual estimates

38. (1) Before the commencement of each financial year, the Board shall prepare the annual estimates of revenue and expenditure of the Authority for the financial year.

(2) The annual estimates shall make provision for the estimated expenditure of the Authority for the financial year concerned and in particular, shall provide for

- (a) the acquisition, maintenance, repair and replacement of the equipment and any other property of the Authority, (b) the payment of salaries, allowances and any other charges in respect of the staff of the Authority, and

(c) the payment of pensions, gratuities and any other charges in respect of retirement benefits which are payable out of the funds of the Authority.

#### Accounts and audit

39. (1) The sums of money provided in the estimates shall not be increased without the prior consent of the Board.

(2) The Authority shall keep proper books and records of account of the income, expenditure, assets and liabilities of the Authority in the form approved by the Auditor-General.

(3) Within three months from the end of the financial year, the Board shall submit for audit to the Auditor-General the books and accounts of the Authority together with

(a) a statement of the income and expenditure of the Authority on the last day of that year, and

(b) a statement of the assets and liabilities of the Authority on the last day of that year.

(4) The accounts of the Authority shall be audited and reported on in accordance with article 187 of the Constitution.

(5) The activities and operations of the Authority shall be accessible to the public unless there are reasons of commercial confidentiality or security, justifying exclusion.

#### *Miscellaneous*

#### **Regulations**

40. (1) The Authority may, with the prior approval in writing of the Minister, and in consultation with the Ministers responsible for Health and Food and Agriculture and any other relevant sector Minister make Regulations, by legislative instrument, for the better performance of its functions under this Act and in particular for prescribing

(a) anything required by this Act to be prescribed;

(b) the procedures for conducting contained and confined use activities involving genetically modified organisms;

(c) the procedures for

(i) the release of genetically modified organisms into

the environment,

(ii) the importation of genetically modified organisms, (iii) the exportation of genetically modified organisms, (iv) genetically modified organisms in transit;

(d) the procedures for appeals to the Appeals Tribunal; (e) the forms to be used for applications for approvals;

(f) the schedules of fees to cover administrative costs of processing applications and notices; and

(g) the procedures for deregulation.

(2) Until Regulations are made under subsection (1), the Biosafety (Management of Biotechnology) Regulations, 2007 (L.I. 1887) shall continue in force as if made under this Act.

(3) Despite subsections (1) and (2), the Authority may issue guidelines in respect of the matters referred to in subsections (1) and (2).

### **Offences and penalties**

**41. (1)** A person commits an offence and is liable on conviction to a fine of not less than two thousand five hundred penalty units and not more than five thousand penalty units or to a term of imprisonment of not less than five years and not more than ten years or to both the fine and the term of imprisonment if that person

(a) makes contained or confined use, releases into the environment, places on the market, imports or exports, a genetically modified organism without the approval of the Authority, or

(b) contravenes a condition attached to an approval under this Act, or

(c) fails to furnish an information as required by or under this Act, or

(d) uses or releases confidential information for a purpose not authorised by or under this Act, or

(e) uses a genetically modified organism for mischievous or unethical purposes, or

(f) obstructs or fails to assist the Authority or officers of the Authority in the performance of a function under this Act, or

(g) contravenes any other provision of this Act.

(2) Where a body corporate is convicted of an offence specified in subsection (1) a Director and any other officer of that body corporate shall be deemed to have committed the offence for which the body corporate is convicted.

(3) A person shall not be convicted of an offence pursuant to subsection (2) where it is proved to the satisfaction of the Court that, having regard to the nature of the offence,

(a) that person did not consent to, or did not connive at, the commission of the offence, or

(b) that person did exercise the degree of reasonable diligence as ought in the circumstances to have been exercised to prevent the commission of the offence.

(4) For the purposes of subsections (2) and (3), a body corporate includes a firm or partnership and those subsections shall be construed accordingly in the case of a firm or partnership.

#### Public awareness and participation

42. (1) The Authority shall promote public awareness participation and education concerning biosafety matters for the benefit of the people of the Republic through

(a) the publication of this Act and of the Regulations in as many languages as possible, and

(b) public lectures, seminars and workshops.

(2) The Authority shall publish notices of final decisions concerning applications made under this Act in the *Gazette* and the electronic and print media.

#### Civil liability and redress

43. Liability or redress for a damage that occurs as a result of an activity under this Act is subject to the applicable laws.

#### Interpretation

44. In this Act, unless the context otherwise requires,

"Appeals Tribunal" means the Appeals Tribunal established under section 26;

"applicant" means a person who submits an application pursuant to a provision of this Act;

"Authority" means the National Biosafety Authority established under section 3;

"biotechnology" means a technological application that uses biological systems, living organisms or derivatives of those systems and organisms to make or modify products or processes for a specific use;

"biosafety" is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products;

"confined use" means a field trial of a genetically modified organism in an open system in which physical barriers are employed to effectively limit their impact with, and their impact on, human and external environment;

"contained use" means an activity undertaken within a facility, an installation or any other physical structure which involves genetically modified organisms that are controlled by specific measures;

"genetically modified organism" includes an organism that has been transformed by the insertion of one or more genes, or regulatory elements, or an organism that has had its own genes modified without the insertion of any new genes and their products;

"genetically modified organisms register" means the register maintained under section 23;

"Minister" means the Minister responsible for Science; "placing on the market" means making a genetically modified organism available on a commercial basis;

"precautionary approach" means that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation;

"Regulations" means the Regulations made under this Act; and "regulatory agency" means a regulatory agency specified in the Fifth Schedule.

## *SCHEDULES*

### **FIRST SCHEDULE**

*(Section 6)*

#### PROVISIONS AS TO THE CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD

##### **Committees and co-opted advisers**

1. (1) The Board shall establish the committees it considers appropriate to perform the functions and exercise the responsibilities determined by the Board.

(2) The findings of a committee shall be presented to the Board for its consideration and determination.

(3) The Board may at any time co-opt a person to attend any of its meetings, but a co-opted person is not entitled to vote on a matter for decision by the Board.

##### **Vacation of office**

2. (1) The appointment of a member of the Board, other than an *ex-*

*officio* member, shall be terminated by the President (a) on the expiry of the appointment, or (b) on the death of the member, or

(c) if the member

(i) is adjudged bankrupt, or is sentenced for an offence to a term of imprisonment of not less than six months, or

(ii) is convicted of an offence involving fraud, dishonesty or moral turpitude, or

(iii) is absent, without the permission of the Board, from three successive meetings of the Board for which the member has received notice;

(d) on notice in writing of the intention to resign from office; or (e) if in the opinion of the Board, the member becomes by reason of mental or physical infirmity, incapable of performing the functions of office as a member of the Board; or

(f) on the commission of an offence under this Act.

(2) A member of the Board may resign at any time from office in writing addressed to the President through the Minister.

(3) The President may by letter addressed to a member revoke the appointment of that member.

(4) Where a member of the Board is, for a sufficient reason, unable to act as a member, the Minister shall determine whether the inability would result in the declaration of a vacancy.

(5) Where there is vacancy, the Minister shall notify the President of the vacancy and the President shall appoint a person to fill the vacancy.

### **Meetings of board**

3.(1) The Board shall meet at least four times in every financial year.

(2) The chairperson shall preside at the meetings of the Board, and in the absence of the chairperson, the members present shall elect one of their number to preside at the meeting.

(3) Unless a unanimous decision is reached, a decision on a matter before the Board shall be determined by a majority of the votes of the members present and voting, and in the case of an equality of votes, the chairperson or the member presiding shall have a casting vote.

(4) The quorum for the transaction of the business of the Board is seven members of the Board but in respect of financial matters or any other matter of importance as determined by the Board, the quorum shall be nine members.

### **Disclosure of interest**

4. A member of the Board who has an interest, directly or indirectly, in an application or any other matter which is the subject of consideration by the Board shall disclose the fact to the Board and

shall not take part in the consideration or discussion of or vote on, a question in respect of the application or that other matter.

### **Seal of the board**

5. (1) The seal of the Authority shall be authenticated by the signatures of the chairperson of the Board and the chief executive officer of the Authority.

(2) In the absence of the chairperson, a member of the Board designated by the chairperson for the purpose may authenticate the seal.

## **SECOND SCHEDULE**

*(Section 11)*

### **INFORMATION REQUIRED IN APPLICATIONS FOR CONTAINED OR CONFINED USE**

1. An application to conduct activities under contained or confined use with genetically modified organisms under contained use shall be submitted to the Authority at least sixty days before the activities are due to begin.

2. The application shall include

(a) the name and contact address of the applicant,

(b) the location where the contained use activities are to be undertaken,

(c) the nature and identity of the genetically modified organisms to be involved,

(d) the nature and purpose of the activities including storing, transporting, producing, processing, disposing or use of the genetically modified organisms in any other way,

(e) a description of the potential risks associated with the genetically modified organism activities to be undertaken, (f) a description of the potential risk associated with genetically modified organism activities to be undertaken, and

(g) a description of the remedial measures to be undertaken for unintentional release at the end of the activity.

## **THIRD SCHEDULE**

*(Sections 12, 13)*

### **INFORMATION REQUIRED IN APPLICATIONS FOR RELEASE, IMPORTATION AND PLACING ON THE MARKET**

1. Name, address and contact details of the exporter.
2. Name, address and contact details of the importer.
3. Name and identity of the genetically modified organism as well as the domestic classification of the biosafety level of the genetically modified organism in the country of export.
4. Intended date of the transboundary movement.
5. Taxonomic status, scientific and technical names, common name, unique identifier, transformation code or event point collection or acquisition and characteristics of the recipient organism or parental organism related to biosafety.
6. Center of origin and center of genetic diversity, of the recipient organism and the parental organism and the description of the habitat where the organism is related to biosafety.
7. Taxonomic status, common name, point of collection or acquisition and characteristics of the modification introduced, the technique used and the resulting characteristics of the genetically modified organism.
8. Intended use of the genetically modified organism and the products of the genetically modified organism.
9. Quantity or volume of the genetically modified organism to be transferred and released.
10. The appropriate risk assessment report.
11. Suggested methods for the safe handling, storage, transport and use, including procedures for unintentional or accidental release.
12. A sworn declaration of the applicant that the above mentioned information is factually correct.

## **FOURTH SCHEDULE**

*(Section 12, 13, 19)*

### **RISK ASSESSMENT**

#### **Objective of risk assessment**

1. The objective of the risk assessment is to identify and evaluate the potential adverse effects of genetically modified organisms on health and the environment.



### **13. Use of risk assessment**

2. The risk assessment shall be used by the Board to make informed decisions regarding genetically modified organism.

3. The general principles guiding risk assessment are,

(a) risk assessment shall be carried out in a scientifically sound and transparent manner and may take into account expert advice and guiding principles developed by relevant organisations;

(b) lack of scientific knowledge or scientific consensus shall not necessarily be interpreted to indicate a particular level of risk, an absence of risk or an acceptable risk; and

(c) risk associated with genetically modified organisms or products of these organisms shall be considered in the context of the risk posed by the genetically modified organism's recipient or the parental organisms in the likely potential receiving environment.

### **Methodology**

4. To fulfill its objective, risk assessment shall entail

(a) an identification of any of the genotypic and phenotypic characteristics associated with genetically modified organisms that may have an adverse effect on the environment;

(b) an evaluation of the likelihood of these adverse effects being realised, taking into account the level and the kind of exposure of the likely potential receiving environment of the genetically modified organism;

(c) an evaluation of the consequences should these effects be realised;

(d) an estimation of the overall risk posed by the genetically modified organisms based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) a recommendation as to whether or not the risks are acceptable or manageable, including identification of strategies to manage the risk; and

(f) where there is uncertainty regarding the level of risk, the Board may request further information on the specific issues of concern or may recommend appropriate risk management strategies and monitoring of the genetically modified organisms in the receiving environment.

Points to consider

5. Risk assessment shall take into account the relevant technical and scientific details regarding the characteristics of,

(a) *recipient organisms or parental organisms*: the biological characteristics of the recipient organism or parental organism including taxonomic status, common name, origin, centers of origin and centers of genetic diversity and a description of the habitat where the organism persists;

(b) *donor organism*: taxonomic status and common name, source and the relevant biological characteristics of the donor organisms;

(c) *vector*: characteristics of the vector including its identity of origin and host range;

(d) *insert and characteristics of modification*: genetic characteristics of the inserted nucleic acid and the function it specifies and characteristics of the modification introduced;

(e) *genetically modified organisms*: identity of the genetically modified organisms and the differences between the biological characteristics of the genetically modified organisms and those of the recipient organism or parental organisms;

(f) *detection and identification of genetically modified organisms*: suggested detection identification methods and the specificity, sensitivity and reliability;

(g) *information relating to the intended use*: information related to the intended use of the genetically modified organisms including new or changed use compared to the recipient organism or parental organism;

(h) *receiving environment*: information, the location, geographical climatic and ecological characteristics including relevant information on biological diversity and centers of origin of the likely potential receiving environment.

## **FIFTH SCHEDULE**

*(Section 31)*

### **REGULATORY AGENCIES**

1. The Food and Drugs Board
2. The Veterinary Services Directorate
3. The Plant Protection and Regulatory Services Directorate
4. The Environmental Protection Agency
5. The Customs Division of the Ghana Revenue Authority

6. District Assemblies, Metropolitan Assemblies, Municipal Assemblies and any other local government authority

7. The Standards Authority.

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