ARRANGEMENT OF SECTIONS

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ENTITLED

BIOSAFETY ACT, 2010

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

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, in accordance with the precautionary principle, an adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms resulting from modern biotechnology that may have an adverse effect on 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, 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,

(c) to act as the national focal point responsible for liaison with any other agency or internatural organisations concerned with 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 chairman,
(b) the chairman of the technical advisory committee established under section 27,
(c) the Chief Director, Ministry responsible for Science or the representative of the Chief Director, 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 organizations,
(g) the chief executive officer of the Authority, and
(h) two other members who are persons with a sufficient background knowledge relevant to the subject matter of this Act one of whom is a woman.

(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.

Administration

Conduct of business and affairs of the Authority

6. (1) The provisions relating to the conduct and regulation of the business and affairs of the Authority 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 a member of the Board the remuneration, fees or allowances for expenses determined by the Board with the approval of the Minister, acting 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.

The 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 five years and is eligible for re-appointment.

(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 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 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 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 of, 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.

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 ninety days of the receipt, and

(b) shall screen the application for completeness.

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

Gazette publication

18. (1) The Board shall 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 Board may avail to a person portions of an application which does 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 two hundred and seventy days of the receipt of the 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.

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. An applicant who withholds information

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

(b) which could change the evaluation of risk posed by the applicant's intended activity.

commits an offence and is liable on conviction to a fine not exceeding two thousand penalty units or to a term of imprisonment not exceeding ten years.

Appeals board

26. (1) There is hereby established an appeals board consisting of

(a) an eminent biological scientist as the chairman,

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

(c) the chief executive officer of the Authority, and

(d) two other members, who have qualifications in biotechnology and biosafety management.

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

(3) With the exception of the chief executive officer of the Authority, a member of the Board shall not be appointed a member of the appeals board

(4) The members of the appeals board 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 appeal board in the prescribed manner.

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

Technical advisory committee

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 Minister on the recommendations of the Board for a period not exceeding five years as follows:

(a) one representative each from
  (i) the Council for Scientific and Industrial Research, and
  (ii) the Atomic Energy Commission,

(b) not more than two members who are persons knowledgeable in the fields of science applicable to ecology and the development and release of genetically modified organisms,

(c) two persons who are knowledgeable in socio-economic matters and genetically modified organisms, and

(d) one representative each from
  (i) the Customs Excise and Preventive Service,
  (ii) the Environmental Protection Agency,
  (iii) the Food and Drugs Board,
  (iv) the Veterinary Services Directorate, and
  (v) the Plant Protection and Regulatory Services Directorate.

(2) The Board shall, in recommending members for appointment to the committee, endeavour to achieve representation from a range of the sciences relevant to genetically modified organisms and ecology.

(3 The Minister shall, on the recommendation of the Board, designate a member of the committee as the chairman of the committee.

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

(5 The acting chairman shall perform the functions of the chairman where the chairman 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, audit of applications at the request of the Board, and

(b) advise, on request or of its own accord, the Minister, the Board, the Ministries and appropriate bodies, on matters concerning the genetic modification of organisms including
  (i) aspects relating to the introduction 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.

Remuneration

29. (1) The members of the technical advisory committee and of a subcommittee shall be paid the remuneration determined by the Minister, with the concurrence of 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.

Duties 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 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 authorized by the Authority;

(b) take possession of the equipment or material required for the purpose for which the power to entry 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.

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 government 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 Board 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 Minister responsible for 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 board;

(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).

Offence and penalties

41. A person commits an offence and is liable on conviction to a fine not exceeding seven hundred and fifty penalty units or to a term of imprisonment not exceeding three years, if that person

(a) makes contained use of, 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 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,

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 board" means the appeals board 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 exployed 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;

"functions" includes powers and duties;

"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 Environment and 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;

"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 AUTHORITY

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 Minister.

(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 chairman shall preside at the meetings of the Board, and in the absence of the chairman, 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 chairman or the member presiding shall have a casting vote.

(4) The quorum for the transaction of the business of the Board is half of the membership of the Board.

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 chairman of the Board and the chief executive officer of the Authority.

(2) In the absence of the chairman, a member of the Board designated by the chairman 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 acitivity.

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 the environment.

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;

(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 mange the risk; and

(f) where there is uncertainty regarding the level of risk, the Board may request further information onthe 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.

MEMORANDUM

This Bill seeks to establish a framework that provides the machinery for regulating biotechnology and biosafety and to provide for related matters.

Biotechnology, as an application that uses biological systems, living organisms or derivatives, to make or modify products or processes for specific use, has been in existence and has been used in Ghana for a very long time. The fermentation processes used in the

local preparation of certain foods and beverages are biotechnological applications. Kenkey production and pito brewing are typical examples of indigenous industries that employ biotechnology. Modern biotechnology, however, is the " application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injections into cells or organelles, or fusion of cells beyond the taxonomic family".

This implies the artificial movement of genes from one living organism to a similar or widely unrelated organism such as a plant, an animal, bacteria, fungi or any other micro-organism to form new products or develop new processes. The movement of genes does not involve natural reproduction. It is artificial and is some times referred to as genetic engineering. The individual formed as a result of the process is a genetically modified organism or living modified organism.

In that sense, modern biotechnology may be said to be relatively young in Ghana and its application is rather limited.

Traditional biotechnology, that is, first and second generations, is actively employed in the micropropagation of forest, horticulture and medicinal plants. Tissue Culture, for example, is used extensively in the production of improved varieties of root tubers, especially cassava, plantains and pineapples. Other on-going applications of first and second generation biotechnology include enzyme-based activities, such as the development of starter cultures, biofertilizer and non-recombinant vaccines.

Although modern, that is, third generation biotechnology has been recognized as an important tool for seeking solutions to some of the country's agricultural and health-related problems, only a few research institutes and universities, including the Biotechnology and Nuclear Agriculture Research Institute, the Council for Scientific and Industrial Research, the Cocoa Research Institute and the Noguchi Memorial Institute for Medical Research are in a position to employ modern biotechnology techniques. Currently, there is no evidence that any of these institutes or the universities has developed genetically modified organisms or living modified organisms. These terms are used interchangeably in our context, although they have the capacity and the capability to do so.

Recognizing its potential and taking cognizance of the inherent danger its application may have on the environment and on human health, the Government inaugurated a National Biosafety Committee in 2000 with the mandate to develop guidelines for the safe application of modern biotechnology in the country. Clearly, the national focus has been on the precautionary approach and the environmentally sound management of biotechnology in the country. Thus, although there is no record of a field trial or cultivation of genetically modified crops in Ghana, the Government, in pursuance of the precautionary approach, established negotiations on the Cartagena Protocol on Biosafety . On May 30, 2003 Ghana ratified the Cartagena Protocol and by so doing joined other countries to receive assistance from United Nations Environmental Programme/Global Environment Facility UNEP/GEF Project on Biosafety to develop its own National Biosafety Framework.

The development of the National Biosafety Framework is a country and multistakeholder driven process to evolve a management system for the sound and environmentally safe management of biotechnology practices in Ghana The framework itself comprises legal, technical, administrative and information systems put in place to address safety in the field of modern biotechnology. Hence *clauses 1 to 5* of the Bill address

the scope, objectives and the establishment of the National Biosafety Authority. *Clauses 6 to 10* deal with the administrative matters concerning the National Biosafety Authority.

The UNEP/GEF Project on the "Development of a National Biosafety Framework for Ghana" started in November 2002, and was supposed to end in April 2004 but an extension to end of July 2004 was granted. The project was divided into three phases, namely, information gathering and inventories, information analysis and consultations, and development of draft, that is the present Bill and its ancillary activities.

In the information gathering and inventories phase there has been completed, the following surveys:

(a) Programme for Safe Use and Existing Capacity for Modern Biotechnology in Ghana,
(b) Existing Legislation and Legal Instruments Related to Modern Biotechnology in Ghana,
(c) Regional Mechanisms for Harmonization of Biosafety Activities,
(d) Development of a Roster of Experts Biotechnology/Biosafety, and
(e) Public Perception of Biotechnology/Biosafety Activities in Ghana.

Information gathered through the survey reports is being organized into a national database on biosafety and will eventually be part of the National Biosafety Clearing House to assist with information dissemination and capacity building activities in modern biotechnology in the country. The database has the following fields: Experts directory, Institutional directory, Equipment database, Laws and Regulations. Other relevant information will be added at a later date as it becomes available.

The second phase of the project involved public awareness fora and stakeholder and technical consultations. Public awareness seminars were held in five of the ten regions of the country covering both the southern and northern regions of the country. The topics discussed in the seminars included

(a) "Genetically Modified Crops – How safe are they?"
(b) "Enhanced Animal Industry – The Role of Biotechnology and Biosafety".
(c) "Developing a National Biotechnology Framework for Ghana"

Participants included media personnel, non-governmental organizations, teachers, environmentalists, farmers' representatives, students and researchers.

The consultations were in the form of national workshops and specific stakeholders were invited. Five such workshops have been held :

(a) National Review Workshop on "Surveys on Biotechnology, Biosafety and Related Legislation in Ghana",
(b) Legal and Technical Consultations Workshop on the NBF Development Process 1,
(c) Workshop on the Cartagena Protocol on Biosafety,
(d) Legal and Technical Consultations Workshop on the NBF Development Process II, and
(e) a national stakeholder workshop to discuss the final draft of the framework has also been organized.

For uniformity the UNEP/GEF blueprint for the development of national biosafety frameworks has been adopted for the country's framework, comprising the key elements of

government policy on biosafety, a regulatory system, an administrative system, a decision-making system, mechanisms for public participation and information sharing.

The Bill is the first attempt to have a clear-cut policy on regulation of biotechnology, although in the National Science and Technology Policy (2000), the use of modern biotechnology as a tool for enhanced agricultural, health, environmental and industrial productivity has been recognized. With regard to a regulatory system, an existing document on "Biosafety Guidelines in Genetic Engineering and Biotechnology" (2000) has been reviewed as part of the NBF development process. It includes directions, regulations and laws to guide practice in modern biotechnology.

An administrative system, *clauses 11 to 23,* deals with requests for permits for certain activities such as contained use and release of living modified organisms. *Clauses 31 to 34* deal with the regulatory agencies and inspection and *Clauses 35 to 39* deal with the financial aspect of the activities of the National Biosafety Authority the set up of which is provided for by *clause 3,* and its functions and governing body are provided for under *clauses 4 and 5* .

In fulfilling the obligations of the National Competent Authority, the National Biosafety Authority in decision-making on living modified organisms, there is the need for the country to develop a genetically modified organisms detection laboratory or referral laboratory to support national capacity and assist in issues of validation and development of standard methodologies for monitoring enforcement and settling of disputes. Assistance will also be needed to equip the existing regulatory agencies, such as the Environmental Protection Agency, Food and Drugs Board, the Customs, Excise and Preventive Service, to meet the challenges in the handling of genetically modified organisms.

It is hoped that when in place this piece of legislation will give Ghana the requisite environment for achieving an adequate level of protection in the safe transfer, handling and use of genetically modified organisms resulting from modern biotechnology and the establishment of a transparent and predicable process to review and make decision on genetically modified organisms.

MS. SHERRY AYITTEY
Minister of the Environment, Science and Technology

Date: *27th May, 2010.*