ARRANGEMENT OF SECTIONS

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THE EIGHT HUNDRED AND THIRTY-FIRST

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: *31st December, 2011.*

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,

(c) 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,

(c) 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.

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.