[SB. 412]

A BILL

FOR

AN ACT TO REGULATE ACTIVITIES IN GENETICALLY MODIFIED ORGANISMS, TO ESTABLISH THE NATIONAL BIOSAFETY AUTHORITY, AND FOR CONNECTED PURPOSES

Sponsored by SENATOR GRACE FOLASHADE BENT
(*Adamawa South*)

[ ] Commencement.

BE IT ENACTED BY THE National Assembly of the Federal Republic of Nigeria—

Short Title.

1. This Bill may be cited as the Biosafety Bill, 2010.

Interpretation.

2. In this Bill, unless the context otherwise requires—

"applicant" means a person submitting an application pursuant to the provisions of this Act;

"Authority" means the National Biosafety Authority established under section 5;

"biosafety" means the avoidance of risk to human health and safety to the conservation of the environment, as a result of the use for research and commerce of genetically modified organisms;

"biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

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

"financial year" means the period of twelve months ending on the thirtieth June in each year;

"genetically modified organism" means any living or non-living organism that possesses a novel ,combination of genetic material obtained through the use of modem biotechnology techniques;

"Minister" means the Minister for the time being responsible for matters

relating to the Environment;

"modern biotechnology" include the application of—

(*a*) in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

(*b*) fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive and recombination barriers and which are not techniques used in traditional breeding and selection;

"placing on the market" means making a genetically modified organism available for sale; and

"regulatory agency" means a regulatory agency as set out in the First Schedule to the Act.

Scope of Act.

3.—(1) The requirements of this Act are in addition to the requirements imposed by any other Act.

(2) This Act shall not apply to genetically modified organisms that are pharmaceuticals for human use.

Objects of the Act.

4. The objects of this Act are—

(*a*) to facilitate responsible research into, and minimize the risks of harm that may be posed by, genetically modified organisms;

(*b*) to ensure an adequate level of protection for the safe transfer, handling and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment; and

(*c*) to establish a transparent and predictable process for reviewing and making decisions on the transfer, handling and use of genetically modified organisms and related activities;

PART II — ESTABLISHMENT, POWERS AND FUNCTIONS OF THE AUTHORITY

Establishment of the Authority.

5.—(1) There is hereby established an Authority to be known as the National Biosafety Authority (in this Bill referred to as the authority).

(2) The Authority is a body corporate with perpetual succession and a common seal and shall in its corporate name, be capable of —

(*a*) suing and being sued in its corporate name;

(*b*) taking, purchasing or otherwise acquiring, holding, charging or disposing of moveable and immovable property;

(*c*) entering into contracts; and

(*d*) doing or performing all other things or acts necessary for the proper performance of its functions under this Act, which may lawfully be done or performed by a body corporate.

Establishment of the Governing Board of the Authority.

6.—(1) There is hereby established for the management of the affairs of the Authority a governing Board (in this Act referred to as "the Board") which shall, subject to this Act, have general control and management of the Authority

(2) The Board shall consist of—

(*a*) a chairman;

(*b*) One representative each of the following Federal Ministries and bodies (not below the rank of a director) that is —

(*i*) Ministry of Environment

(*ii*) Ministry of Science and Technology

(*iii*) Ministry of Health

(*iv*) Ministry of Finance;

(*v*) Director General National Environment Standard Enforcement and Regulatory Agency

(*vi*) Director General Nigeria Standards Organization

(*vii*) Director General Nigeria Agricultural Quarantine Services.

(*viii*) Director Nigeria Veterinary Council

(*ix*) Six other persons of whom—

(*i*) three shall be expert in the following respective sciences namely biological Environmental and social sciences

(*ii*) one shall represent the interest of consumers

(c) The Executive Secretary

(3) The Chairman and other members of the Board shall—

(*a*) be appointed by the President subject to the confirmation of the Senate; and

(*b*) be persons with proven integrity.

(4) The supplementary provisions contained in the Schedule to this Act shall have effect with respect to the proceedings of the Board and other matters mentioned therein.

Tenure of office.

7.—(1) The members of the Board appointed under section 6 (2) (*a*) and (*b*) of this Act shall hold office for a period of 4 years in the first instance and may be eligible for re appointment for a further period of 4 years and no more.

(2) The members of the Board shall be paid such remuneration and allowances as the Revenue Mobilization Allocation and Fiscal Commission may, from time to time, determine.

(3) A member of the Board other than an *ex-officio* member may resign his appointment by a notice in writing under his hand, addressed to the Minister and which resignation shall take effect only upon acknowledgment by the Minister.

Cessation of Membership.

8.—(1) A member of the Board shall cease to hold office if —

(*a*) he becomes of unsound mind; or

(*b*) he becomes bankrupt or makes a compromise with his creditors; or

(*c*) he is convicted of a felony or of any offence involving dishonesty; or

(*d*) he is guilty of serious misconduct in relation to his duties.

(2) A member of the Board may be removed from office by the President, if, he is satisfied that it is not in the interest of the Board or the interest of the public that the member should continue in office.

(3) Where a vacancy occurs in the membership of the Board, it shall be filled by the appointment of a successor to hold office for the remainder of the term of office of his predecessor, so however that the successor shall represent the same interest and shall he appointed by the President.

Objects and functions of the Authority.

9.—(1) The object and purpose for which the Authority is established is to exercise general supervision and control over the transfer, handling and use of genetically modified organisms with a view to ensuring—

(*a*) safety of human health;

(*b*) provision of an adequate level of protection of the environment,

(*c*) to be the principal adviser of the Government on all matters related

thereto.

(2) Without prejudice to the generality of subsection (1), the Authority shall—

(*a*) consider and determine applications for approval for the transfer, handling and use of genetically modified organisms, and related activities in accordance with the provisions of this Act;

(*b*) co-ordinate, monitor and assess activities relating to the safe transfer, handling and use of genetically modified organisms in order to ensure that such activities do not have adverse effect on human health or the environment;

(*c*) undertake and co-ordinate research, investigation and surveys in matters relating to the safe transfer, handling and use of genetically modified organisms, and to collect. collate and disseminate information about the findings of such research, investigation or survey:

(*d*) identify national requirements for manpower development and capacity building In biosafety;

(*e*) advise the Government on legislative and other measures relating to the safe transfer handling and use of genetically modified organisms;

(*f*) promote awareness and education among the general public in matters relating to biosafety: and

(g) perform any other function which is incidental to the performance of any of the foregoing functions.

Powers of the Board.

10. The Board shall have all the powers necessary for the proper performance of the functions of the Authority under this Act and, in particular but without prejudice to the generality of the foregoing, the Board shall have power to—

(*a*) enter into contracts;

(*b*) manage, control and administer the assets of the Authority in such manner and for such purposes as best promote the purpose for which the Authority is established;

(*c*) receive any gifts, grants, donations or endowments made to the Authority or any other moneys in respect of the Authority and make disbursements

therefrom in accordance with the provisions of this Act;

(*d*) enter into association with such other bodies or organizations within or outside Nigeria as it may consider desirable or appropriate and in furtherance of the purposes for which the Authority is established;

(*e*) open a banking account or banking accounts for the funds of the Authority; and

(*f*) offer services to any person upon such terms as the Board may from time to time determine.

PART III — STAFF OF THE AUTHORITY

Appointment of Executive Secretary. etc.

11.—(1) There shall be appointed for the Commission an Executive Secretary who shall be appointed by the President on the recommendation of the Minister.

(2) The Executive Secretary shall subject to the general control of the Board —

(*a*) be responsible for the implementation of the decisions of the Board and the day to day administration of the affairs of the Authority;

(*b*) be responsible for keeping proper records of the proceedings of the Board; and

(*c*) be the head of the Board's secretariat and be responsible for the administration thereof and the direction and control of all other employees of the Authority with the approval of the Board.

(3) The Executive Secretary shall hold office for four years and may be eligible for the appointment for a further period of four years.

Other Staff of the Authority.

12.—(1) The Board shall have power to appoint either on transfer or on secondment from and public service in the Federation, such number of employees as may, in the opinion of the Board, be required to assist the Authority in the discharge of any of its functions under this Act; and shall have power to pay to persons so employed such remuneration (including allowances) as the Board may, from time to time, determine.

(2) The terms and conditions of service (including terms and conditions as to remuneration, allowance, pensions, gratuities and other benefits) of the

person employed by the Authority shall be as determined by the Board from time to time.

Staff regulations.

13.—(1) The Board may, subject to the provisions of this Act, make staff regulations relating generally to the conditions of service of the employees of the Authority and without prejudice to the generality of the foregoing, such regulations may provide for—

(*a*) the appointment, promotion and disciplinary control (including dismissal) of employees of the Authority; and

(*b*) appeals by such employees against dismissal or other disciplinary measures and until such regulations are made, any instrument relating to the conditions of service of officers in the Civil Service of the Federation shall be applicable, with such modifications as may be necessary, to the employees of the Authority.

(2) Staff regulations made under subsection (1) of this section shall not have effect until approved by the President.

Pensions.

14. It is hereby declared that service in the Authority shall be public service for the purposes of the Pensions Reform Act 2004 and, accordingly, officers and other persons employed in the Commission shall, in respect of their service in the Authority be entitle to pension, gratuities and other retirement benefits as are prescribed there under, so however that nothing in this Act shall prevent the appointment of a person to any office on terms which preclude the grant of a pension or gratuity in respect of that office

PART III — APPLICATIONS FOR APPROVAL AND RISK ASSESSMENT

Application for contained use activity.

15.—(1) A person shall not conduct any contained use activity involving genetically modified organisms without the written approval of the Authority.

(2) An application for approval to conduct a contained use activity shall—

(*a*) be in the prescribed form; and

(*b*) contain—

(*i*) the information set out in the Third Schedule to this Act; and

(*ii*) such other information that the applicant or the Authority may consider necessary for the assessment of the potential risk or benefits of

the particular contained use activity.

Application to introduce into the environment.

16.—(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 to introduce a genetically modified organism into the environment shall—

(*a*) be in the prescribed manner;

(*b*) contain —

(*i*) the information set out m the Fourth Schedule; and

(*ii*) such other information that the applicant or the Authority may consider necessary for the assessment of the potential risk or benefits of the introduction of the particular genetically modified organism into the environment.

(4) The Authority shall publish in the Gazette and in at least two newspapers with nationwide circulation, notice concerning any application for release into the environment of a genetically modified organism, for the general information of the public.

(5) Any person may, within thirty days from the date of publication of the notice, make representations to the Authority regarding such an application, and the Authority shall address appropriately any relevant concerns raised by such a person.

Application for importation.

17.—(1) A person shall not import into Nigeria a genetically modified organism without the written approval of the Authority.

(2) An application for importation of a genetically modified organism shall—

(*a*) be in the prescribed manner;

(*b*) contain—

(*i*) the information set out in the Fourth Schedule;

(*ii*) such other information that the applicant or the Authority may

consider necessary for the assessment of the potential risk or benefits of importation of the particular genetically modified organism.

Application for placing on the market.

18.—(1) A person shall not place on the market a genetically modified organism without the written approval of the Authority.

(2) An application to place on the market a genetically modified organism shall—

(*a*) be in the prescribed manner;

(*b*) contain—

(*i*) the information set out m the Fourth Schedule; and

(*ii*) such other information that the applicant or the Authority may consider necessary for the assessment of the potential risk or benefits of the placement of the particular genetically modified organism on the market.

Genetically modified organisms in transit.

19.—(1) A person transporting through Nigeria genetically modified organisms, which are not destined for use in Nigeria shall—

(*a*) apply for a written approval of such transportation from the Authority; and

(*b*) ensure that the genetically modified organisms being transported are properly packaged and transported in accordance with such regulations as may be prescribed and any applicable international standards.

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

Application to export.

20. A person intending to export a genetically modified organism from Nigeria shall provide the Authority with an advance written consent granted by a relevant authority of the country (I) which the genetically modified organism is destined, to the effect that such relevant authority has no objection to the intended exportation.

Withdrawal of application.

21. A person applying for any approval may withdraw his application at any time prior to the issuance of a final decision by the Authority.

Confidential information.

22.—(1) The Authority shall—

(*a*) allow an applicant to identify information provided to the Authority in

accordance with the requirements of this Act and any regulations made hereunder, that is to be treated as confidential, with justification for claims of confidentiality to be provided upon request;

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

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

(*d*) in the event that an applicant withdraws an application in accordance with section 28, respect the applicant's claims of confidentiality.

(2) The Authority shall not use confidential information for any purpose not authorized under this Act, and shall ensure that such information is protected by any person involved in handling applications under this Act.

Acknowledgment of application.

23.—(1) Upon receipt of an application, the Authority shall screen the application for completeness and shall, within thirty days from the date of receipt, acknowledge receipt of the application in writing.

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

(3) Where the Authority requests for additional information from the applicant, the time taken before getting the information shall not be reckoned by the Authority in calculating the time taken prior to making a final decision on the application.

Risk assessment and risk management.

24.—(1) Where the application for approval under this Act has been screened and found to be complete, the Authority shall—

(*a*) subject to section 25, undertake a risk assessment in terms of the provisions of the fifth Schedule; and

(*b*) audit risk assessment information submitted by the applicant, if any.

(2) Risk assessment under this section shall be carried out taking into account available information concerning any known risk posed by potential exposure to a genetically modified organism.

(3) Upon completion of the risk assessment, the Authority shall make a report of its findings and shall indicate any measures to be taken to ensure the

safe use of a genetically modified organism.

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

Non-assessment of risks.

25. The Authority may opt not to undertake a risk assessment for purposes of sections 16, 17 and 18, where it determines that sufficient experience or information exists to conclude that the genetically modified organism or contained use activity concerned do not pose a significant risk.

Determination of an application.

26.—(1) In determining an application, the Authority shall take into account—

(*a*) the information submitted by the applicant;

(*b*) such information and conditions as may be submitted by the relevant regulatory agency;

(*c*) the risk assessment report;

(*d*) any relevant representations submitted by members of the public; and

(*e*) socio-economic considerations arising from the impact of the genetically modified organism on the environment.

(2) The Authority shall, prior to determining an application, liaise with the relevant regulatory agency, and such regulatory agency shall submit to the Authority any conditions that the regulatory agency considers appropriate to be attached to the approval.

Communication of decision.

27.—(1) The Authority shall communicate its final decision of approval or rejection of the application to the applicant, within two hundred and seventy days of the receipt of the application.

(2) An approval—

(*a*) shall be specific to the activity authorized; and

(*b*) if granted subject to some conditions, including such conditions as may be given by an appropriate regulatory agency, shall clearly state such conditions.

(3) Where an application for approval is rejected, the reasons for such rejection shall be clearly stated.

Suspension or revocation of an approval.

28.—(1) The Authority may suspend or revoke any approval given under this Act where the person who has been granted such approval is in contravention of any of the condition imposed on the grant of the approval, or the provisions of this Act.

(2) The Authority shall, before suspending or revoking an approval, give a written notice of its intention to suspend or revoke the approval to the person upon whom it is given, and shall accordingly invite such person to make representations within thirty days from the date of such notice.

(3) Where the Authority suspends or revokes an approval, it shall publish the order suspending or revoking the approval in the Gazette and in at least two newspapers with nationwide circulation.

Register.

29. The Authority shall maintain a register, which shall contain—

(*a*) a copy of —

(*i*) every application received;

(*ii*) the risk assessment report;

(*iii*) the decision document;

(*iv*) the approval; and

(*b*) any other information the Authority may consider necessary.

Review of decision.

30.—(1) The Authority may review an earlier decision not to undertake a risk assessment, at any time upon obtaining significant new scientific information relating to biosafety of the genetically modified organism or contained use activity involved.

(2) A regulatory agency or an applicant may request the Authority to review its decision with respect to an activity conducted by the applicant where the regulatory agency or the applicant considers that—

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

(*b*) additional scientific or technical information has become available that may have a material effect on the decision or any conditions, limitations or requirements imposed under a decision.

(3) If upon review the Authority is satisfied that a change is warranted, the Authority shall issue substitute its earlier approval with another approval which shall take into account the changed circumstances.

(4) The Authority shall make a decision on a review within one hundred and fifty days from the date of request for the review and shall state clearly the reasons for its decision.

(5) Where the Authority has knowledge that an activity poses a threat to biosafety, the Authority shall take immediate action to put necessary safety measures in place.

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

Offence of withholding information.

31. Where a person upon whom approval has been granted withholds information that has become available to him after the approval of his application, and the information could reasonably be expected to change the evaluation of the risk posed by the person I s intended activity, such person commits an offence and is liable on conviction to a fine not exceeding two million shillings, or imprisonment for a term not exceeding ten years, or both.

Establishment of the Appeals Board.

32.—(1) There is hereby established an Appeals Board which shall consist of—

(*a*) a chairperson who shall be a Judge of a High Court qualified appointed by the Minister;

(*b*) three other persons, each of whom shall be a holder of at least a Master's degree in biological, environmental or social sciences from a recognized institution, appointed hy tl11' Minister.

(2) A member of the Appeals Board shall hold office for three years.

(3) Any person who is aggrieved by—

(*a*) a refusal to grant an approval;

(*b*) the imposition of any conditions on an approval;

(*c*) the revocation, suspension or variation of an approval;

(*d*) a refusal to treat an application as confidential may, within thirty days of being notified of the relevant decision of the Authority, appeal to the

Appeals Board in the prescribed manner.

(4) Any person aggrieved by a decision of the Appeals Board may, within thirty days of the making of the decision, appeal against the decision to the High Court.

(5) The decision of the High Court on any appeal under this section shall be final.

(6) Subject to subsection (8), the Appeals Board shall regulate its own procedure.

(7) The Minister may make rules —

(*a*) prescribing the manner in which an appeal shall be made to the Appeals Board and the fees to be paid in respect of an appeal;

(*b*) prescribing a scale of costs which may be awarded by the Appeals Board; and

(*c*) generally for the better carrying out of the provisions of this Act relating to the Appeals Board and appeals thereto.

Powers of the Appeals Board.

33.—(1) On hearing an appeal, the Appeals Board shall have the powers of a court to summon witnesses, take evidence upon oath or affirmation, and to call for the production of books and other documents.

(2) Where the Appeals Board considers it desirable for the purpose of avoiding expense or delay or any other special reason so to do, it may receive evidence by affidavit and administer interrogatories and require the person to whom interrogatories are administered to make a full and true reply to the interrogatories within the time specified by the Appeals Board.

(3) In the determination of any matter, the Appeals Board may take into consideration any evidence which it considers relevant to the subject of an appeal before it, notwithstanding that such evidence would not otherwise be admissible under the law relating to evidence.

(4) The Appeals Board shall have the power to award the costs of any proceedings before it and to direct that costs shall be taxed in accordance with any scale prescribed.

(5) All summonses, notices or other documents issued under the hand of

the chairperson of the Appeals Board shall be deemed to be issued by the Appeals Board.

(6) Any interested party may be represented before the Appeals Board by an advocate or by any other person whom the Appeals Board may admit to be heard on behalf of the party.

Provisions as to the Appeals Board.

34. The provisions of the Sixth Schedule shall apply to the Appeals Board.

PART V — REGULATORY AGENCIES

Consultation with regulatory agencies.

35.—(1) The Authority shall coordinate all activities involving genetically modified organisms and in carrying out its role of coordination, the Authority may consult with the relevant regulatory agency.

(2) Regulatory agencies shall, where appropriate, monitor any activity for which approval has been by the Authority to ensure that such an activity complies with conditions imposed, if any. on the grant of an approval.

(3) Where a regulatory agency, in carrying out its mandate, becomes aware of any significant new scientific information indicating that approved activities with genetically modified organisms may pose potential biosafety risks not previously known, the regulatory agency shall immediately inform the Authority of the new information and of the measures proposed to be put in place to ensure the continued safe use of the genetically modified organism.

Unintentional release into the environment.

36.—(1) A regulatory agency with knowledge of an unintentional or unapproved introduction into the environment of a genetically modified organism that is likely to pose biosafety risks shall, within twenty- four hours of knowledge of the introduction, notify the Authority of the occurrence.

(2) A notification under this section shall include such adequate information as would enable the Authority to undertake a risk assessment.

(3) The Authority shall, in consultation with the regulatory agency concerned, determine whether any action is necessary to minimize any biosafety risks.

PART VI — RESTORATION AND CESSATION ORDERS

Environmental restoration order.

37. The Authority may issue and serve on any person a restoration order in respect of any matter relating to release of a genetically modified organism

into the environment.

(2) An environmental restoration order issued under subsection (1) shall be issued to —

(*a*) require the person on whom it is served to restore the environment as near as it may he to the state in which it was before the release of a genetically modified organism;

(*b*) levy a charge on the person on whom it is served which, in the opinion of the Authority, represents a reasonable estimate of the costs of any action taken by an authorized persoll or organization to restore the environment to the state in which it was before the release or d genetically modified organism.

Contents of restoration order.

38. An environmental restoration order shall specify clearly and in a manner which may be easily understood—

(*a*) the activity to which it relates;

(*b*) the person to whom it is addressed;

(*c*) the time at which it comes into effect;

(*d*) the action which should be taken to remedy the harm to the environment and the time, being not more than thirty days or such further period as may be prescribed in the order. within which the action should be taken; and

(*e*) the penalty which may be imposed if the action specified is not undertaken.

Cessation orders.

39.—(1) The Authority, in consultation with the relevant regulatory agency, may Issue an order for the immediate cessation of an approved activity, or for the immediate imposition of additional risk management measures with respect to such activity, if the Authority, in consultation with the relevant regulatory agency, determines that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account risks to the human health on the basis of —

(*a*) one or more tests conducted and evaluated in a manner consistent with acceptable scientific procedures;

(*b*) other validated scientific evidence.

(2) The Authority may issue a cessation order—

(*a*) upon the failure of any person issued with an approval to demonstrate compliance with such approval after a reasonable period of time; or

(*b*) in the event of non-compliance with the provisions of this Act or regulations made thereunder.

(3) A cessation order issued under this Act may be withdrawn once the Authority determines that sufficient information exists to permit the activity concerned to resume, or to resume in the absence of additional risk management measures, without posing a significant risk to human health and the environment.

PART VII — INSPECTION AND MONITORING

Appointment of biosafety inspectors.

40. The Minister may, by notice in the Gazette, appoint duly qualified persons whether by name or by title of office, to be biosafety inspectors of the Authority, for such jurisdictional units as may be specified in the notice of appointment—

(*a*) monitor compliance with this Act and regulations made thereunder;

(*b*) undertake inspections and submit reports thereof to the Authority;

(*c*) perform such other functions as the Authority may deem necessary.

Functions of biosafety inspectors.

41.—(1) A biosafety inspector may, in the performance of his duties under this Act, at all reasonable times and without a warrant—

(*a*) enter any premises, facility, vessel or property which the inspector has reason to believe it is necessary for him to enter in order to ascertain whether the requirements of this Act or any approval under this Act are being complied with, and may take with him any person duly authorized by the Authority;

(*b*) take with him any equipment or material required for any purpose for which the power of entry is being exercised;

(*c*) carry out such tests and inspections, and make such recordings as may be necessary in the circumstances;

(*d*) direct that any part of premises which he has power to enter, or anything in such premises, shall be left undisturbed for so long as is reasonably necessary for the purpose of any test or inspection;

(*e*) take appropriate samples of any organisms, articles or substances

found in any premises which he has power to enter for analysis or any other relevant purpose under this Act;

(*f*) in the case of anything found in the premises which he has power to enter, which appears to him to contain genetically modified organisms which pose biosafety risk, cause it to be dismantled or subjected to any process or test but not so as to damage or destroy it, unless it is necessary;

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

(2) When exercising his powers under this Act, a biosafety inspector shall suitably identify himself.

PART VIII — FINANCIAL PROVISIONS

Funds of the Authority.

42. The funds and assets of the Authority shall consist of—

(*a*) such moneys as may be appropriated by National Assembly for the purposes of the Authority;

(*b*) such moneys or assets as may accrue to or vest in the Authority in the course of the exercise of its powers or the performance of its functions under this Act;

(*c*) such moneys as may be payable to the Authority pursuant to this Act;

(*d*) such gifts as may be given to the Authority; and

(*e*) all moneys from any other source provided, or lent to the donated Authority.

Annual estimates.

43.—(1) At least three months before the commencement of each financial year, the Board shall cause to be prepared estimates of the revenue and expenditure of the Authority for that financial year.

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

(*a*) the payment of the salaries, allowances and other charges in respect of the officers, members of staff, or agents of the Authority;

(*b*) the payment of the pensions, gratuities and other charges in respect of retirement benefits payable to the members of staff of the Authority.

(*c*) the proper maintenance of the buildings and grounds of the Authority;

(*d*) the proper maintenance, repair and replacement of the equipment and other movable property of the Authority; and

(*e*) the creation of such reserve funds to meet future or contingent liabilities in respect of retirement benefits, insurance, replacement of buildings or equipment, or in respect of such other matters as the Board may deem fit.

(3) The annual estimates shall be approved by the Board before the commencement of the financial year to which they relate and, once approved, the sum provided in the estimates shall be submitted to the Minister for approval.

(4) No expenditure shall be incurred for the purposes of the Authority except in accordance with the annual estimates approved under subsection (3), or in pursuance of an authorisation of the Board given with prior written approval of the Minister.

Accounts and audit.

44.—(1) The Board shall cause to be kept proper books and other records of accounts of the income, expenditure, assets and liabilities of the Authority.

(2) Within a period of three months after the end of each financial year, the Board shall submit to the Controller and Auditor-General the accounts of the Authority, in respect of that year, together with—

(*a*) a statement of income and expenditure during that financial year; and

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

Audit.

(3) The accounts of the Authority shall be examined, audited and reported upon annually by the Auditor-General.

Investment of funds.

45. The Board may—

(*a*) invest any of the funds of the Authority in securities in which the Board may by law invest trust funds, or in any other securities;

(*b*) place on deposit, with such bank or banks as it may determine, any moneys not immediately required for the purposes of the Authority.

PART IX — MISCELLANEOUS

Packaging and labelling of genetically modified organisms.

46. Any person manufacturing or importing any genetically modified organisms shall package and label such genetically modified organisms in the prescribed manner.

Regulations.

48. The Minister may, in consultation with the Authority, make regulations for the better carrying into effect the provisions of this Act, and in particular for prescribing—

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

(*b*) procedures for conducting contained use activities involving genetically modified orgamsms;

(*c*) procedures for release of genetically modified organisms into the environment:

(*d*) procedures for importation and exportation of genetically modified organisms:

(*e*) procedures for genetically modified organisms in transit;

(*f*) procedure for packaging and labeling of genetically modified organisms;

(*g*) forms to be used for applications for approvals;

(*h*) schedules of fees to cover administrative costs of processing applications and notices.

Offences and penalties.

49. Any person who—

(*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:

(*b*) contravenes any conditions attached to an approval under this Act;

(*c*) fails to furnish any information as required by this Act;

(*d*) uses any confidential information for any purpose not authorized under this Act;

(*e*) uses a genetically modified organism in a manner inconsistent with the approval granted by the Authority or for unethical purposes;

(*f*) obstructs or fails to assist the Authority or officers of the Authority in the performance of their duties under this Act;

(*g*) contravenes any of the provisions of this Act, commits an offence and is liable on conviction to a fine not exceeding one million shillings, or to imprisonment for a term not exceeding three years, or both.

SECOND SCHEDULE

Section 6 (4)

SUPPLEMENTARY PROVISIONS RELATING TO THE BOARD

Proceedings of the Board

1.—(1) Subject to this Act and Section 27 of the Interpretation Act, the Board may make standing orders regulating its proceedings or those of any of its committees.

(2) The quorum of the Board shall be the chairman and seven other members and the quorum of any committee shall be determined by the Board.

2.—(1) The Board shall meet not less than two times in each year and subject thereto, the Board shall meet whenever it is summoned by the Chairman; and if the Chairman is required to do so by notice given to him by not less than four other members, he shall summon a meeting of the Board, to be held within fourteen days from the date on which the notice is given.

(2) At any meeting of the Board, the Chairman shall preside but if he is absent, the members present at the meeting shall appoint one of their members to preside at that meeting.

(3) Where the Board desires to obtain the advice of any person on a particular matter the Board may co opt him to the Board for such period as it thinks fit; but a person who is in attendance by virtue of this subparagraph shall not be entitled to vote at any meeting of the Board and shall not count towards a quorum.

Committees

3.—(1) The Board may appoint one or more committees to carry out, on behalf of the Board some of its functions as the Board may determine.

(2) A committee appointed under this paragraph shall consist of such number of persons (not necessarily members of the Board) as may be determined by the Board; and a person other than a member of the Board shall hold office on the committee in accordance with the terms of his appointment.

(3) A decision of a committee of the Board shall be of no effect until it is ratified by the Board.

Miscellaneous

4.—(1) The fixing of the seal of the Authority shall be authenticated by the signature of the chairman or of any other person authorized generally or specially to act for that purpose hy the Board.

(2) Any contract or instrument which, if made or executed by a person not being a body corporate, would not be required to be under seal may be made or executed on behalf of the Authority by the chairman or any person generally or specially authorized to act for that purpose by the Board.

(3) Any document purporting to be a document duly executed under the seal of

the Authority shall be received in evidence and shall, unless and until the contrary is proved, be presumed to be so executed.

5. The validity of any proceeding of the Board or of a Committee thereof shall not be adversely affected by any vacancy in the membership of the Board or Committee or by any defect in the appointment of a member of the Board or of a Committee, or by reason that a person not entitled to do so took part in the proceedings of the Board or Committees.

THIRD SCHEDULE

INFORMATION REQUIRED IN APPLICATIONS FOR APPROVAL OF CONTAINED USE ACTIVITY

1. The name and contact address of the applicant.

2. The location where contained use activities are to be undertaken.

3. The nature and identity of genetically modified organisms to be involved.

4. The nature and purpose of the activities including such activities as storing, transporting, producing, processing, disposing or using the genetically modified organisms in any other way.

5. A description of the containment measures to be provided and the suitability of those measures for the genetically modified organisms and activities to be undertaken.

6. A description of any potential risks associated with the genetically modified organisms or the activities to be undertaken, and

7. A description of remedial measures to be undertaken in the event of any accident.

8. A sworn declaration by the applicant that the above information is factually correct.

FOURTH SCHEDULE

Sections 16, 17, 18

INFORMATION REQUIRED IN APPLICATIONS FOR APPROVAL OF RELEASE INTO THE ENVIRONMENT, IMPORTATION AND PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISMS

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, if any, of the Biosafety level of the genetically modified organism in the country of export.

4. Intended dates of the trans-boundary movement.

5. Taxonomic status, common name, point of collection or acquisition and characteristics of the recipient organism or parental organism related to Biosafety.

6. Center of origin and center of genetic diversity if known, of the recipient organism and the parental organism and the description of the habitat where the organism may persist.

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.

9. Quantity or volume of the genetically modified organism to be transferred.

10. Suggested methods for the safe handling, storage, transport and use.

11. A sworn declaration of the applicant that the above mentioned information is factually correct.

12. The objective of the risk assessment is to identify and evaluate the potential adverse effects of genetically

FIFTH SCHEDULE

Section 24

PROVISIONS ON 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 human health and the environment.

Use of risk assessment.

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

General principles

3. The general principles guiding risk assessment are—

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

(*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 shall be considered in the context of the risks posed by the genetically modified organisms recipient or the parental organisms in the likely potential receiving environment.

Methodology

4. To fulfill its objective, a risk assessment shall entail the following steps—

(*a*) an identification of any genotype and phenotypic characteristics associated with the genetically modified organisms that may have adverse effects on the environment and on human health,

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

(*c*) an evaluation of the consequences should these effects be realized,

(*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 these risks, and

(*f*) where there is uncertainty regarding the level of risk, the Authority may request for further information on the specific issues of concern or may recommend implementing appropriate risk management strategies and monitoring 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 the following subjects—

(*a*) **Recipient organism or parental organism:** 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 and the sources of origin and host range.

(*d*) **Insert and characteristics of modification:** Genetic characteristics of the inselied 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 organism.

(*f*) **Detection and identification of genetically modified organisms:** Suggested detection and 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 on the location, geographical, climatic and ecological characteristics including relevant information on biological diversity and centers of origin of the likely potential receiving environment.

SIXTH SCHEDULE

Section 32

PROVISIONS AS TO THE APPEALS BOARD

Vacation of office

1.—(1) A member of the Appeals Board may vacate office on any of the following grounds—

(*a*) upon the expiry of his appointment;

(*b*) upon his death;

(*c*) if he is adjudged bankrupt;

(*d*) if he is sentenced for any offence against any written law to a term of imprisonment of six months or more;

(*e*) if he is convicted of an offence involving fraud, dishonesty or moral turpitude;

(*f*) if he is absent, without permission of the chairperson of the Appeals Board from three successive sittings of the Appeals Board of which he has received notice;

(*g*) upon giving notice in writing of his intention to resign his office,

(*h*) if he becomes, by reason of mental or physical infirmity, incapable of performing his duties as a member of the Appeals Board; or

(*i*) upon the commission of an offence under this Act.

Disclosure of interest

2. If a member of the Appeals Board has any interest direct or indirect in any application or other matter which is the subject of consideration at a sitting of the Appeals Board, the member shall at the sitting, disclose the fact to the Appeals Board and shall take no part in the consideration or discussion of or vote on any question with respect to the application or the other matter.

Vacancy

3. Where the office of any member becomes vacant, whether by death or otherwise, the Minister may appoint another person to be a member of the Appeals Board for the remainder of the term of the member whose vacancy caused the appointment.

Majority decisions

4. The decision of the Appeals Board shall be that of the majority and shall be signed by the members thereof agreeing thereto.

Venue

5. The Appeals Board shall sit at such place as it may consider most convenient having regard to all the circumstances of the particular proceedings.

Proof of documents

6. A document purporting to be a copy of any order of the Appeals Board, and certified by tile chairperson to be a true copy thereof, shall in any legal proceedings be prima facie evidence of the order.

EXPLANATORY MEMORANDUM

This Bill seeks to facilitate responsible research into, and minimize the risks of harm that may be posed by genetically modified organisms and to ensure an adequate level of protection for the safe transfer, handling and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment and also to establish a transparent and predictable process for reviewing and making decisions on the transfer, handling and use of genetically modified organisms and related activities.