



THE REPUBLIC OF KENYA

LAWS OF KENYA

BIOSAFETY ACT

NO. 2 OF 2009

Revised Edition 2018 [2009]

Published by the National Council for Law Reporting
with the Authority of the Attorney-General

www.kenyalaw.org

NO. 2 OF 2009

BIOSAFETY ACT

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NO. 2 OF 2009

BIOSAFETY ACT

[*Date of assent: 12th February, 2009.*]

[*Date of commencement: 1st July, 2011.*]

An Act of Parliament to regulate activities in genetically modified organisms, to establish the National Biosafety Authority, and for connected purposes

[Act No. 2 of 2009, L.N. 71/2011, Act No. 18 of 2018.]

PART I – PRELIMINARY

1. Short title

This Act may be cited as the Biosafety Act, 2009.

2. Interpretation

In this Act, 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, and the conservation of the environment, as a result of the use of genetically modified organisms;

“**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;

“**environment**” includes the physical factors of the surroundings of human beings, including land, water, atmosphere, soil, vegetation, climate, sound, odour, aesthetics, fish and wildlife;

“**financial year**” means the period of twelve months ending on the thirtieth June in each year;

“**genetically modified organism**” means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

“**intentional introduction into the environment**” means any deliberate use of genetically modified organisms other than not contained use;

“**Minister**” means the Minister for the time being responsible for matters relating to science and technology.

“**modern biotechnology**” includes 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, or such other agency as the Minister may, by Order in the *Gazette*, determine.

3. Scope of the Act

(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.

4. Objects of the Act

The objects of this Act are—

- (a) to facilitate responsible research into, and minimize the risks 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, science-based 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

5. Establishment of the Authority

(1) There is established an Authority to be known as the National Biosafety 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;
- (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.

6. Board of the Authority

(1) The Authority shall be managed by a Board comprising of nine members as follows—

- (a) a Chairperson who shall be an eminent scientist, appointed by the Cabinet Secretary;
- (b) the Principal Secretary in the Ministry for the time being responsible for Science and Technology or a representative;
- (c) the Principal Secretary in the Ministry for the time being responsible for finance or a representative;

- (d) the Principal Secretary in the Ministry for the time being responsible for agriculture or a representative;
- (e) the Principal Secretary in the Ministry for the time being responsible for health or a representative;
- (f) two experts in the biological, environmental and social sciences respectively, appointed by the Cabinet Secretary;
- (g) one member with financial expertise, appointed by the Cabinet Secretary; and
- (h) the Chief Executive Officer who shall be an ex-officio member.

(1A) Any person who, immediately before the commencement of this section was a member of the Board shall be deemed to be a member of the reconstituted Board for the unexpired period of his or her term of service.

(2) The members of the Board appointed under paragraphs (b) to (j) of subsection (1) may attend in person or designate a representative to attend on their behalf.

(3) The appointment of the chairperson and the members under paragraphs (k) and (l) of subsection (1) shall be by name and by notice in the *Gazette*.

(4) The chairman and members of the Board, other than the *ex officio* members, shall hold office for a period of three years but shall be eligible for reappointment for a further term of three years.

[Act No. 18 of 2018, Sch.]

7. Objects and functions of the Authority

(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 and animal health;
- (b) provision of an adequate level of protection of the environment.

(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 and the environment;
- (c) co-ordinate research and surveys in matters relating to the safe development, 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) establish and maintain a biosafety clearing house to serve as a means through which information is made available facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms;
- (h) perform any other function which is incidental to the performance of any of the foregoing functions.

8. Powers of the Board

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 Kenya 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.

9. Conduct of business and affairs of the Board

The business and affairs of the Board shall be conducted in accordance with the Second Schedule.

10. Delegation by the Board

The Board may, by resolution either generally or in any particular case, delegate to a committee or any officer, member of staff or agent of the Board, the exercise of any of the powers or the performance of any of the functions or duties of the Board under this Act.

11. Remuneration of members of the Board

The members of the Board shall be paid such remuneration, fees, allowances and disbursements for expenses as may be approved by the Minister.

12. The Chief Executive Officer

(1) There shall be a Chief Executive Officer of the Board who shall be appointed by the Board.

(2) The Chief Executive Officer shall hold office for a period of four years, which period may be renewed once subject to satisfactory performance, as evaluated by the Board of the Authority.

(3) The Chief Executive Officer shall be an *ex officio* member of the Board but shall have no right to vote at any meeting of the Board.

(4) The Chief Executive Officer shall, subject to the direction of the Board, be responsible for the day to day management of the Authority.

[Act No. 18 of 2018, Sch.]

13. Functions of the Chief Executive Officer

(1) The Chief Executive Officer shall, subject to the directions of the Board, be responsible for the management of the affairs and transactions of the Authority, the exercise, discharge and performance of its objectives, functions and duties.

(2) The Chief Executive Officer shall—

- (a) ensure the maintenance of efficiency and discipline by all staff of the Authority;
- (b) manage the budget of the Authority to ensure that its funds are properly expended and accounted for;
- (c) perform such other duties as the Authority may, from time to time, assign.

14. Staff of the Authority

The Authority may employ a Corporation Secretary and such other officers, agents and staff as may be necessary for the performance of the functions of the Authority under this Act.

[Act No. 18 of 2018, Sch.]

15. The common seal of the Authority

(1) The common seal of the Authority shall be kept in the custody of the Chief Executive Officer or of such other person as the Board may direct, and shall not be used except upon the order of the Board.

(2) The common seal of the Authority, when affixed to a document and duly authenticated, shall be judicially and officially noticed, and unless the contrary is proved, any necessary order or authorisation by the Board under this section shall be presumed to have been duly given.

(3) The common seal of the Authority shall be authenticated by the signature of the chairperson of the Board and the Chief Executive Officer:

Provided that the Board shall, in the absence of either the chairperson or the Chief Executive Officer, in any particular matter, nominate one member of the Board to authenticate the seal of the Authority on behalf of either the chairperson or the Chief Executive Officer.

16. Protection from personal liability

No matter or thing done by a member of the Board or by any officer, member of staff, or agent of the Authority shall, if the matter or thing is done *bona fide* for executing the functions, powers or duties of the Authority under this Act, render the member, officer, employee or agent or any person acting on their directions personally liable to any action, claim or demand whatsoever.

17. Liability for damages

The provisions of section 16 shall not relieve the Authority of the liability to pay compensation or damages to any person for any injury to him, his property or any of his interests caused by the exercise of any power conferred by this Act or any other written law or by the failure, wholly or partially, of any works.

PART III – APPLICATIONS FOR APPROVAL AND RISK ASSESSMENT

18. Application for contained use activity

(1) A person shall not conduct any 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 manner; 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.

19. Application to introduce into the environment

(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 in 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*, at least two newspapers with nationwide circulation, and in an appropriate electronic media, 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.

20. Application for importation

(1) A person shall not import into Kenya 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.

21. Application for placing on the market

(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 in 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.

22. Genetically modified organisms in transit

(1) A person transporting through Kenya genetically modified organisms, which are not destined for use in Kenya 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 Kenya shall be in the prescribed manner.

23. Application to export

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

24. Withdrawal of application

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

25. Confidential information

- (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 24, 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.

26. Acknowledgement of application

(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.

27. Risk assessment and risk management

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

- (a) subject to section 28, 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.

28. Non-assessment of risks

The Authority may opt not to undertake a risk assessment for purposes of sections 18, 19 and 20, 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.

29. Determination of an application

(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, where the decision relates to an application under section 19 of this Act.

(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.

30. Communication of decision

(1) The Authority shall communicate its final decision of approval or rejection of the application to the applicant, within one hundred and fifty days of the receipt of the application but not earlier than ninety days of such receipt.

(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.

31. Suspension or revocation of an approval

(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 conditions 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*, at least two newspapers with nationwide circulation, and in an appropriate electronic media.

32. Register

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.

PART IV – REVIEW AND APPEALS

33. Review of decision

(1) The Authority may review a decision made under section 29 of this Act 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 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 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.

34. Offence of withholding information

Where a person upon whom approval has been granted withholds information that becomes available to him before and after the approval of his application, and the information could reasonably be expected to change the evaluation of the risk posed by the person'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.

35. Establishment of the Appeals Board

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

- (a) a chairperson who shall be an advocate of the High Court qualified for appointment as a judge of the High Court of Kenya, appointed by the Minister;
- (b) four other persons, each of whom shall be an expert in either biological, environmental or social sciences, appointed by the Minister.

(2) Appointments to the Appeals Board shall be by notice in the *Gazette*.

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

(4) 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;
- (e) a decision of a biosafety inspector;
- (f) any other decision of the Authority under this Act,

may, within thirty days of being notified of the relevant decision of the Authority, appeal to the Appeals Board in the prescribed manner.

(5) 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.

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

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

(8) 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.

(9) The Appeals Board shall communicate its final decision to the appellant within ninety days from the date the appeal was made.

36. Powers of the Appeals Board

(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.

37. Provisions as to the Appeals Board

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

PART V – REGULATORY AGENCIES

38. Consultation with regulatory agencies

(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 granted 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.

39. Unintentional release into the environment

(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 mitigate any adverse effects to both human beings and the environment.

(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

40. Environmental restoration order

(1) 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 be 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 person or organization to restore the environment to the state in which it was before the release of a genetically modified organism.

41. Contents of restoration order

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.

42. Cessation orders

(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 presence of additional risk management measures, without posing a significant risk to human health and the environment.

PART VII – INSPECTION AND MONITORING

43. Appointment of biosafety inspectors

The Minister may, on the recommendation of the Authority, and 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.

44. Functions of biosafety inspectors

A biosafety inspector shall—

- (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.

45. Powers of biosafety inspectors

(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

46. Funds of the Authority

The funds and assets of the Authority shall consist of—

- (a) such moneys as may be appropriated by Parliament 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 or any other written law;
- (d) such gifts as may be given to the Authority; and
- (e) all moneys from any other source provided, donated or lent to the Authority.

47. Annual estimates

(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, and the Permanent Secretary to the Treasury.

48. Accounts and audit

(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.

(3) The accounts of the Authority shall be examined, audited and reported upon annually by the Controller and Auditor-General in accordance with the provisions of the Public Audit Act (No. 12 of 2003).

49. Investment of funds

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 which the Treasury may, from time to time, approve;
- (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

50. Handling, packaging, etc., of genetically modified organisms

Any person manufacturing or importing any genetically modified organisms shall ensure that the handling, packaging, identification and transportation of genetically modified organisms is done in the prescribed manner.

51. Regulations

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 organisms;
- (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 handling, packaging, transporting and labelling 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.

52. Offences and penalties

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 twenty million shillings, or to imprisonment for a term not exceeding ten years, or both.

53. Restriction on institution of proceedings

No proceedings for an offence under this Act shall be instituted without a prior written consent of the Attorney-General.

54. Public awareness and participation

(1) The Authority shall promote public awareness and education of the public and those conducting the activities subject to the Act, concerning biosafety matters, through the publication of guidance documents and other materials aimed at improving the understanding of biosafety.

(2) The Authority shall give notice in the *Gazette* of all decisions made regarding applications for approval.

(3) Upon request, the Authority shall, upon payment of the prescribed fee, avail to any person copies of records kept under section 32, including details of any application that do not qualify as confidential information.

(4) Any person may submit written comments on a proposed decision for any application for placing a genetically modified organism on the market, within thirty days from the date the notice is posted.

55. Transitional provisions

(1) Any application for approval to undertake an activity involving genetically modified organisms, which had been made to the National Council for Science and

Technology in accordance with the Science and Technology Act (Cap. 250), and which had not been finally determined on the date on which this Act came into force, shall be deemed to be an application for approval made under this Act and shall be dealt with accordingly.

(2) Any approval to undertake an activity involving genetically modified organisms which had been granted by the National Council for Science and Technology in accordance with the Science and Technology Act (Cap. 250), and which was in force on the date on which this Act came into force, shall be deemed to be an approval of the Authority under this Act.

FIRST SCHEDULE

[Section 2.]

REGULATORY AGENCIES

1. Department of Public Health.
2. Department of Veterinary Services.
3. Kenya Bureau of Standards.
4. Kenya Plant Health Inspectorate Services.
5. Kenya Industrial Property Institute.
6. Kenya Wildlife Service.
7. Pest Control Products Board.
8. National Environment Management Authority.

SECOND SCHEDULE

[Section 9.]

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

1. Committees and co-opted advisors

(1) The Board may establish such committees as it may consider appropriate to perform such functions and responsibilities as it shall determine, but all findings of such committees shall be presented to the Board for its consideration and determination.

(2) The Board may, at any time and for any length of time, invite any person to attend any of its deliberations but such person shall not be entitled to vote on any matter at any meeting of the Board.

2. Meetings of the Board

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

(2) The chairperson shall preside at every meeting of the Board at which he is present, but in his absence, the members shall elect one of their number who shall, with respect to that meeting and the business transacted thereat, have all the powers of a chairperson.

(3) Unless a unanimous decision is reached, a decision on any matter before the Board shall be by a majority of votes of the members present and in the case of

an equality of votes, the chairperson shall have a casting as well as a deliberative vote.

3. Vacation of office

(1) A member of the Board, other than an *ex officio* member, shall 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 Board, from three successive meetings of the Board of which he has received notice;
- (g) upon notice in writing of his intention to resign his office;
- (h) if in the opinion of the Board, he becomes by reason of mental or physical infirmity incapable of performing his duties as a member of the Board; or
- (i) upon the commission of an offence under this Act.

4. Disclosure of interest

If a member of the Board has any interest direct or indirect in any application or other matter which is the subject of consideration at a meeting of the Board, the member shall, at the meeting, disclose the fact to the 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.

THIRD SCHEDULE

[Section 18.]

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 19, 20 and 21.]

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 applicant.
2. 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.
3. Intended dates of the trans-boundary movement.
4. Taxonomic status, common name, point of collection or acquisition and characteristics of the recipient organism or parental organism related to Biosafety.
5. Centre of origin and centre of genetic diversity if known, of the recipient organism and the parental organism and the description of the habitat where the organism may persist.
6. 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.
7. Intended use of the genetically modified organism.
8. Quantity or volume of the genetically modified organism to be transferred.
9. Suggested methods for the safe handling, storage, transport and use.
10. A sworn declaration of the applicant that the above mentioned information is factually correct.

FIFTH SCHEDULE

[Section 27.]

PROVISIONS ON RISK ASSESSMENT

1. Objective of risk assessment

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.

2. Use of risk assessment

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

3. General principles

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 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.

4. Methodology

To fulfil 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.

5. Points to consider

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, centres of origin and centres 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 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 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 centres of origin of the likely potential receiving environment.

SIXTH SCHEDULE

[Section 37.]

PROVISIONS AS TO THE APPEALS BOARD

1. Vacation of office

(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.

2. Disclosure of interest

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.

3. Vacancy

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.

4. Majority decisions

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

5. Venue

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

6. Proof of documents

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