



LAWS OF MALAYSIA

Act 678

BIOSAFETY ACT 2007

Date of Royal Assent	29 August 2007
Date of publication in the <i>Gazette</i>	30 August 2007

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BIOSAFETY ACT 2007

ARRANGEMENT OF SECTIONS

PART I

PRELIMINARY

Section

1. Short title and commencement
2. Act to be read together with other laws
3. Interpretation

PART II

NATIONAL BIOSAFETY BOARD

4. Establishment of the National Biosafety Board
5. Functions of the Board
6. Establishment of the Genetic Modification Advisory Committee
7. Board and Advisory Committee may establish committees and subcommittees
8. Appointment of Director General and other officers
9. Delegation of functions of the Board
10. Power of Minister to give directions

PART III

APPROVAL FOR RELEASE AND IMPORT

11. Application of Part III
12. Requirement for approval
13. Application for approval
14. Director General to refer application to Advisory Committee, *etc.*
15. Advisory Committee to make recommendations on application for approval

Section

16. Approval for release and import
17. Approval to be valid for subsequent release and import
18. Review of approval upon obtaining new information
19. Circumstances where Board may make further order on approval
20. Appeal to Minister relating to approval

PART IV**NOTIFICATION FOR EXPORT, CONTAINED CSE AND IMPORT
FOR CONTAINED USE**

21. Application of Part IV
22. Requirement for notification
23. Compliance with requirements of importing country
24. Submission of notification
25. Acknowledgement of submission of notification by Director General
26. Specific measures to be taken in contained use
27. Director General may require additional information
28. Director General to refer notification to Advisory Committee and relevant agency
29. Advisory Committee to make recommendations on notification
30. Board to make appropriate order on notification
31. Board may require additional information
32. Review of notification upon obtaining new information
33. Circumstances where Board may make further order on notification
34. Appeal to Minister relating to notification
35. Taking of decision by the Board or Minister

PART V**RISK ASSESSMENT AND RISK MANAGEMENT REPORTS AND
EMERGENCY RESPONSE PLAN**

36. Risk assessment and risk management reports
37. Emergency response plan

Biosafety

PART VI

ENFORCEMENT

Section

38. Enforcement officers
39. Power of investigation
40. Search by warrant
41. Search without warrant
42. Access to computerized data
43. List of things seized
44. Power to seal premises
45. Forfeiture of living modified organisms or products of such organisms, *etc.*
46. Cost of holding organisms, *etc.*, seized
47. No costs or damages arising from entry, search or seizure to be recoverable
48. Obstruction of enforcement officers
49. Examination of persons acquainted with case
- 49A. Admissibility of statement of evidence
50. Power to require production of things related to offence
51. Enforcement officer may seek assistance to examine things related to offence
52. Power of Board to require information on living modified organisms or products of such organisms
53. Power to take sample
54. Procedure for taking sample
55. Appointment of analyst
56. Certificate of analysis
57. Presumption
58. Institution of prosecution

PART VII

MISCELLANEOUS

59. Confidential business information
60. Public disclosure
61. Identification and labelling
62. Assistance from multi-agencies in emergency
63. Service of notice
64. Offence by body corporate

Section

65. Offence by partner, agent or servant
66. Power to compound
67. Falsification, concealment and destruction of document
68. Power of Minister to exempt
69. Power to make regulations
70. Power to amend Schedules
71. Transitional provisions

FIRST SCHEDULE

SECOND SCHEDULE

THIRD SCHEDULE

LAWS OF MALAYSIA

Act 678

BIOSAFETY ACT 2007

An Act to establish the National Biosafety Board; to regulate the release, importation, exportation and contained use of living modified organisms, and the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity, and where there are threats of irreversible damage, lack of full scientific evidence may not be used as a reason not to take action to prevent such damage; and to provide for matters connected therewith.

[]

ENACTED by the Parliament of Malaysia as follows:

PART I

PRELIMINARY

Short title and commencement

1. (1) This Act may be cited as the Biosafety Act 2007.

(2) This Act comes into operation on a date to be appointed by the Minister by notification in the *Gazette*.

Act to be read together with other laws

2. (1) This Act shall be read together with any other written law relating to import and export, human, plant and animal health, the environment and biological diversity, and the provisions of this Act shall be in addition to, and not in derogation of, the provisions of such other written laws.

(2) In the event of any inconsistencies between the provisions of this Act and any of the other written laws referred to in subsection (1) the provisions of this Act shall prevail.

Interpretation

3. In this Act, unless the context otherwise requires—

"release activity" means any intentional introduction of living modified organisms or products of such organisms into the environment through the activities or for the purposes specified in the Second Schedule;

"modern biotechnology" means the application of—

- (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles; or
- (b) fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

"**products of such organisms**" means any product derived from a living modified organism or part of a living modified organism—

- (a) if the product contains detectable recombinant deoxyribonucleic acid (DNA); or
- (b) where the profile, characteristic or properties of the product is or are no longer equivalent to its conventional counterpart irrespective of the presence of the recombinant deoxyribonucleic acid (DNA);

"Advisory Committee" means the Genetic Modification Advisory Committee established under section 6;

"analyst" means an analyst appointed under section 55;

"contained use" means any operation including research and development, production or manufacturing operation involving living modified organisms, or storage of living modified organisms, undertaken within a facility, installation or other physical structure such that it prevents the contact and impact of the living modified organisms on the external environment;

"approval" means an approval granted under subsection 16(3);

"biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; and includes diversity within species, between species and of ecosystems;

"Director General" means the Director General appointed under subsection 8(1);

"Board" means the National Biosafety Board established under subsection 4(1);

"Minister" means the Minister charged with the responsibility for natural resources and environment:

"approved person" means —

- (a) a person to whom an approval has been granted under Part III; or
- (b) a person to whom an acknowledgement of receipt on the submission of a notification under Part IV has been issued;

"living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

"living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

"enforcement officer" means an enforcement officer appointed under subsection 8(1) and includes an officer specified in the Third Schedule and an officer authorized under paragraph 38(c);

"occupier" means a person in actual occupation or having the charge, management or control of—

- (a) any premises; or
- (b) in relation to premises where different parts of which are occupied by different persons, the respective persons in occupation or control of each part;

"Chairman" means the Chairman of the Board appointed under paragraph 4(2)(a);

"premises" includes houses, buildings, lands, tenements, easements of any tenure, whether open or enclosed, whether built on or not, whether public or private, and whether maintained or not under statutory authority and any machinery, plant, vessel, aircraft or other vehicle.

PART II

NATIONAL BIOSAFETY BOARD

Establishment of the National Biosafety Board

4. (1) A board by the name of the "National Biosafety Board" is established.

(2) The Board shall consist of the following members who shall be appointed by the Minister:

- (a) the Secretary General of the Ministry of Natural Resources and Environment who shall be the Chairman;
- (b) a representative from the Ministry of Agriculture and Agro-based Industry;
- (c) a representative from the Ministry of Health;
- (d) a representative from the Ministry of Plantation Industries and Commodities;
- (e) a representative from the Ministry of Domestic Trade and Consumer Affairs;
- (f) a representative from the Ministry of International Trade and Industry;
- (g) a representative from the Ministry of Science, Technology and Innovation; and
- (h) not more than four other persons who have the knowledge or experience or both in any of the disciplines or matters relevant to this Act.

(3) The provisions of the First Schedule shall apply to the Board.

(4) The Director General shall be the Secretary of the Board and shall carry out such duties as may be imposed by the Board.

(5) The Board shall be responsible to the Minister.

Biosafety

Functions of the Board

5. (1) The functions of the Board shall be as follows:
- (a) to decide on all applications and matters under Part III and Part IV;
 - (b) to monitor activities relating to living modified organisms and products of such organisms;
 - (c) to promote research, development, educational and training activities relating to biosafety;
 - (d) to establish mechanisms to facilitate the collection, storage and dissemination of data relating to living modified organisms and products of such organisms and biosafety; and
 - (e) where so directed by the Minister, to perform or provide for the performance of the obligations arising from agreements, conventions or treaties relating to biosafety to which Malaysia is a party where such agreements, conventions or treaties relate to the purposes of this Act.
- (2) The Board shall have power to do such things as the Board thinks fit to enable it to perform its functions effectively or which are incidental to the performance of its functions.

Establishment of the Genetic Modification Advisory Committee

6. (1) A committee by the name of the "Genetic Modification Advisory Committee" is established.
- (2) The function of the Advisory Committee is to provide scientific, technical and other relevant advice to the Minister or the Board.
- (3) The chairman of the Advisory Committee shall be appointed by the Minister.
- (4) Such number, as may be approved by the Minister, of other members of the Advisory Committee shall be appointed by the Board.

(5) Members of the Advisory Committee shall consist of experts from various science-based and other relevant disciplines.

(6) The chairman and the members of the Advisory Committee shall hold office for such term as may be specified in their respective instrument of appointment and are eligible for reappointment.

(7) The appointment of the chairman of the Advisory Committee may at any time be revoked by the Minister and the appointment of any member of the Advisory Committee may at any time be revoked by the Board, without assigning any reason for such revocation.

(8) The chairman of the Advisory Committee may at any time resign his office by a written notice addressed to the Minister and a member of the Advisory Committee may at any time resign his office by a written notice addressed to the Board.

(9) In the absence of the chairman of the Advisory Committee at a meeting of the Advisory Committee, the members present may elect one of themselves to preside over the meeting.

(10) The Advisory Committee may invite any person to attend any meeting of the committee for the purpose of advising it on any matter under discussion, but the person so invited shall not be entitled to vote at any such meeting.

(11) Subject to subsections (9) and (10), the Advisory Committee may regulate its own procedure.

(12) The chairman and members of the Advisory Committee and any person invited to attend any meeting of the Advisory Committee may be paid such allowances and other expenses in connection with the work of the committee as the Minister, with the concurrence of the Minister of Finance, thinks fit.

(13) Without prejudice to the power of the Minister to issue general directions to the Advisory Committee under section 10, the Advisory Committee shall be responsible to the Board.

Board and Advisory Committee may establish committees and subcommittees

7. (1) The Board may establish such committees, and the Advisory Committee may establish such subcommittees, as the Board and

Advisory Committee think necessary or expedient to assist them in the performance of their functions under this Act.

(2) The Board and the Advisory Committee may appoint any person to be a member of such committee or subcommittee, as the case may be, established under subsection (1).

(3) A committee or subcommittee established under this section may elect any of its members to be chairman and may regulate its own procedure.

(4) A committee or subcommittee may invite any person to attend any meeting of the committee or subcommittee for the purpose of advising it on any matter under discussion, but the person so invited shall not be entitled to vote at any such meeting.

(5) Members of a committee or subcommittee and any person invited to attend any meeting of the committee or subcommittee may be paid such allowances and other expenses in connection with the work of the committee or subcommittee as the Minister, with the concurrence of the Minister of Finance, thinks fit.

(6) A member of a committee or subcommittee shall hold office for such term as may be specified in his instrument of appointment and shall be eligible for reappointment.

(7) The appointment of any member of a committee or subcommittee may at any time be revoked by the Board or the Advisory Committee, as the case may be, without assigning any reason for such revocation.

(8) A member of a committee or subcommittee may at any time resign his office by a written notice addressed to the Chairman of the Board or the chairman of the Advisory Committee, as the case may be.

(9) A committee and subcommittee shall be subject to and act in accordance with any direction given to such committee or subcommittee by the Board or the Advisory Committee, as the case may be, in the performance of their functions.

Appointment of Director General and other officers

8. (1) There shall be appointed a Director General of Biosafety and such other officers, including enforcement officers, as may be necessary for the purposes of this Act.

(2) The Director General shall have general control of the officers appointed under subsection (1).

(3) In discharging his duties, the Director General shall act under the general authority and direction of the Board.

Delegation of functions of the Board

9. (1) The Board may, subject to such conditions, limitations or restrictions as it thinks fit to impose, delegate any of its functions, except the function under paragraph 5(1)(a), to—

- (a) any member of the Board;
- (b) the Advisory Committee or any of its members;
- (c) any committee established by the Board; or
- (d) the Director General.

(2) A delegation under this section shall not preclude the Board itself from performing or exercising at any time any of the functions so delegated.

Power of Minister to give directions

10. The Minister may give general directions to the Board and Advisory Committee consistent with this Act, and the Board and the Advisory Committee shall, as soon as possible, give effect to such directions.

PART III

APPROVAL FOR RELEASE AND IMPORT

Application of Part III

11. (1) This Part shall apply to release activities and import activities involving living modified organisms.

(2) Notwithstanding subsection (1), this Part shall not apply to the importation of living modified organisms intended for purposes of undertaking a contained use activity.

Requirement for approval

12. (1) No person shall undertake any release activity, or any importation of living modified organisms, or both without the prior approval of the Board.

(2) Any person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

(a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;

(b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Application for approval

13. (1) An application for the approval of any release activity, or any importation of living modified organisms, or both shall be submitted to the Director General in the prescribed manner, together with the prescribed fees, and shall be accompanied with—

(a) a risk assessment and a risk management report as specified in section 36;

(b) an emergency response plan as specified in section 37;
and

(c) such other information as may be specified by the Board.

(2) At any time after receiving an application made under subsection (1), the Director General may require the applicant to provide additional information, particulars or documents within such period as may be specified by the Director General.

(3) If any applicant fails to provide any additional information, particulars or documents required under subsection (2), his or its application shall be deemed to have been withdrawn without prejudice to the making of a fresh application.

Director General to refer application to Advisory Committee, etc.

14. Upon an application for approval having been submitted in accordance with section 13, the Director General—

- (a) shall refer the application to the Advisory Committee for its recommendations;
- (b) shall refer the application to any relevant Government department or agency on specific matters; and
- (c) subject to section 59, shall for purposes of public disclosure, invite public participation, in such manner as may be determined by the Director General, for their views on the application.

Advisory Committee to make recommendations on application for approval

15. (1) Upon receiving an application referred to it under paragraph 14(a), the Advisory Committee shall assess such application for the purpose of making recommendations to the Board on whether or not the application should be approved and the terms and conditions to be imposed by the Board, if any.

(2) At any time after receiving such application, the Advisory Committee may request for additional information, particulars or documents from the applicant through the Director General.

(3) If any applicant fails to provide, within such period as may be specified by the Director General, any additional information, particulars or documents required under subsection (2), his or its application shall be deemed to have been withdrawn without prejudice to the making of a fresh application.

(4) As soon as it completes its assessment on the application, the Advisory Committee shall forward its recommendations on the application to the Board.

Biosafety

Approval for release and import

16. (1) At any time after receiving the recommendations of the Advisory Committee under section 15, the Board may request the applicant to furnish additional information, particulars or documents within such period as may be specified by the Board.

(2) If any applicant fails to provide any additional information, particulars or documents required under subsection (1), his or its application shall be deemed to have been withdrawn without prejudice to the making of a fresh application.

(3) After having considered the recommendations of the Advisory Committee, the comments of the relevant department or agency referred to in paragraph 14(*b*), the views of members of the public, if any, referred to in paragraph 14(*c*), and any additional information, particulars or documents furnished pursuant to a request under subsection (1), the Board may grant the application by issuing a certificate of approval or refuse the application.

(4) Where the Board grants an approval, the Board may impose such terms and conditions as the Board thinks fit.

(5) The approved person may apply to the Board for the variation of any of the terms and conditions imposed on the approval.

(6) The Board may, at any time after approval has been granted, require the approved person to furnish such further information, particulars or documents as the Board thinks fit.

(7) Any approved person who contravenes any terms and conditions imposed on the approval or fails to furnish the information, particulars or documents required under subsection (6) commits an offence and shall, on conviction, be liable—

(*a*) where such person is an individual, to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding four years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;

- (b) where such person is a body corporate, to a fine not exceeding two hundred and fifty thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Approval to be valid for subsequent release and import

17. (1) Where an approval has been granted to an approved person for a release activity involving any living modified organisms or products of such organisms or the importation of living modified organisms, such approval shall be valid for the subsequent similar release activity involving the same living modified organisms or products of such organisms or importation involving the same living modified organisms undertaken by such approved person.

(2) The provisions of subsection (1) do not in any way absolve the approved person from complying with other written laws governing the same living modified organisms or products of such organisms.

(3) In this section, "same living modified organisms or products of such organisms" means the living modified organisms or products of such organisms as described in the approval and involving the same transformation event.

Review of approval upon obtaining new information

18. (1) The Board may, in consultation with the Advisory Committee, review any approval at any time upon obtaining new information or evidence on the living modified organisms or products of such organisms in respect of which such approval was granted.

(2) If, on review of the approval, the Board is satisfied that there is a risk posed to human, plant or animal health, the environment or biological diversity, the Board may take any of the following actions:

- (a) revoke the approval;
- (b) make a temporary cessation order;
- (c) impose additional terms and conditions;

- (d) order the approved person to make rectifications; or
- (e) make any other order as the Board thinks fit in the interest of biosafety.

(3) Where the Board revokes an approval, the approved person shall cease all activities involving the living modified organisms and products of such organisms immediately and shall, within seven days from the date of the notification of the revocation, surrender the certificate of approval to the Board.

(4) Where the Board makes a temporary cessation order, the approved person shall cease all activities involving the living modified organisms and products of such organisms immediately and shall, within seven days from the date of the notification of the cessation order, surrender the certificate of approval to the Board and the Board shall endorse the fact and duration of the temporary cessation on the certificate of approval and return the certificate to the approved person.

(5) Where the Board imposes any additional terms and conditions the approved person shall, within seven days of the notification of the imposition of the additional terms and conditions, surrender the certificate of approval to the Board and the Board shall endorse such additional terms and conditions on the certificate of approval and return the certificate to the approved person.

(6) Any approved person who contravenes any order made by the Board under subsection (2) or contravenes subsection (3), (4) or (5) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Circumstances where Board may make further order on approval

19. (1) Notwithstanding the power of the Board to take any action under subsection 18(2), the Board may revoke the approval, make a temporary cessation order, impose any additional terms and conditions, order the approved person to make rectifications, or make any other order as the Board thinks fit in the interest of biosafety in the following circumstances:

- (a) where there is a risk posed to human, plant or animal health, the environment or biological diversity;
- (b) where the approved person fails to comply with any terms and conditions imposed on the approval;
- (c) where the approved person fails to comply with any order made by the Board;
- (d) where the approved person has contravened any of the provisions of this Act or any regulations made under this Act, whether or not prosecution has been instituted against him; or
- (e) where the approved person has been convicted of an offence under this Act or any regulations made under this Act.

(2) Where the Board revokes an approval, the approved person shall cease all activities involving the living modified organisms and products of such organisms immediately and shall, within seven days from the date of the notification of the revocation, surrender the certificate of approval to the Board.

(3) Where the Board makes a temporary cessation order, the approved person shall cease all activities involving the living modified organisms and products of such organisms immediately and shall, within seven days from the date of the notification of the cessation order, surrender the certificate of approval to the Board and the Board shall endorse the fact and duration of the temporary cessation on the certificate of approval and return the certificate to the approved person.

(4) Where the Board imposes any additional terms and conditions the approved person shall, within seven days of the notification of the imposition of the additional terms and conditions, surrender the certificate of approval to the Board and the Board shall endorse such additional terms and conditions on the certificate of approval and return the certificate to the approved person.

(5) Any approved person who contravenes any order made by

the Board under subsection (1) or contravenes subsection (2), (3) or (4) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Appeal to Minister relating to approval

20. (1) Any person or approved person aggrieved with any decision or action of the Board under section 16, 18 or 19 may appeal against such decision to the Minister.

(2) The Minister shall have the power to confirm, reverse or vary the decision or action of the Board.

PART IV

NOTIFICATION FOR EXPORT, CONTAINED USE AND IMPORT FOR CONTAINED USE

Application of Part IV

21. Part IV shall apply to the exportation and contained use activities involving living modified organisms and importation of living modified organisms for purposes of undertaking a contained use activity.

Requirement for notification

22. (1) No person shall undertake any of the following activities without giving prior notification to the Board:

- (a) exportation of living modified organisms;

- (b) contained use involving living modified organisms;
- (c) importation of living modified organisms for purposes of undertaking a contained use activity.

(2) Any person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Compliance with requirements of importing country

23. (1) Any person who intends to export living modified organisms shall comply with the requirements of the importing country on the importation of living modified organisms and shall inform the Board of such requirement, if any, and of his or its compliance with that requirement in the prescribed manner and accompanied by the prescribed fees.

(2) The information given under subsection (1) shall be sufficient notification for the purposes of paragraph 22(1)(a).

(3) The compliance with subsection (1) shall in no way absolve the person from complying with other written laws governing export and foreign trade.

Submission of notification

24. The notification required under paragraphs 22(1)(b) and (c) shall be submitted to the Director General in the prescribed form and manner together with the prescribed fees and accompanied by the following documents:

- (a) an emergency response plan as specified in section 37;

- (b) in relation to a contained use activity involving living modified organisms, the specific measures to be taken; and
- (c) such other information as may be specified by the Board.

Acknowledgement of submission of notification by Director General

25. (1) The Director General shall issue an acknowledgement of receipt of a notification submitted under subsection 23(1) and section 24 and the person to whom such acknowledgement is issued may undertake the activities relating to the notification and may continue to undertake such activities subject to any order made by the Board under subsection 30(3).

(2) The acknowledgement issued under subsection (1) shall in no way absolve the person from complying with other written laws governing such living modified organism and its importation.

Specific measures to be taken in contained use

26. (1) Any approved person who undertakes a contained use activity shall take such specific measures referred to in paragraph 24(b) and as approved by the Board.

(2) Any approved person who contravenes subsection (1) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Director General may require additional information

27. (1) At any time after receiving the notification made under subsection 23(1) and section 24, the Director General may require the approved person to provide additional information, particulars or documents.

(2) Where any approved person fails to provide the information, particulars or documents required under subsection (1), the acknowledgement issued to him or it under section 25 shall be deemed to have been withdrawn without prejudice to the submission of a fresh notification.

Director General to refer notification to Advisory Committee and relevant agency

28. Upon having been duly acknowledged a notification in accordance with section 25, the Director General shall refer such notification to the Advisory Committee and any relevant Government agency on specific matters.

Advisory Committee to make recommendations on notification

29. (1) Upon receiving the notification under section 28, the Advisory Committee shall assess such notification for the purpose of making recommendations to the Board on whether or not the activity relating to the notification should continue, and the terms and conditions to be imposed by the Board, if any.

(2) At any time after receiving such notification, the Advisory Committee may request for additional information, particulars or documents through the Director General.

(3) Where any approved person fails to provide the information, particulars or documents required under subsection (2), the acknowledgement issued to him or it under section 25 shall be deemed to have been withdrawn without prejudice to the submission of a fresh notification.

(4) Upon making an assessment on the notification, the Advisory Committee shall forward its recommendations on the notification to the Board.

Board to make appropriate order on notification

30. (1) At any time after receiving the recommendations of the Advisory Committee and the comments of the relevant agency referred to in section 28, the Board may request for additional information, particulars or documents through the Director General.

(2) Where any approved person fails to provide any additional information, particulars or documents required under subsection (1), the acknowledgement issued to him or it under section 25 shall be deemed to have been withdrawn without prejudice to the submission of a fresh notification.

(3) Upon having considered the recommendations of the Advisory Committee under subsection 29(4), the Board may make no order, issue a cessation order, impose such terms and conditions, order the approved person to make rectifications or make any other order as the Board thinks fit in the interest of biosafety.

(4) The Board shall make its decision under subsection 30(3) within ninety days from the date of receipt of the notification and communicate its decision in writing to the approved person.

(5) Where the Board issues a cessation order, the approved person shall cease all activities involving living modified organisms immediately and shall, within seven days from the date of the notification of the cessation order, surrender the acknowledgement of receipt of a notification issued to him or it under section 25 to the Board.

(6) Any approved person who contravenes any order made by the Board under subsection (3) or contravenes subsection (5) commits an offence and shall, on conviction, be liable—

(a) where such person is an individual, to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding four years or to both, and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;

(b) where such person is a body corporate, to a fine not exceeding two hundred and fifty thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Board may require additional information

31. (1) The Board may, at any time, after exercising its powers under subsection 30(1), require the approved person to furnish any additional information, particulars or document as the Board thinks fit.

(2) Any approved person who fails to furnish any information, particulars or documents required under subsection (1) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding four years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding two hundred and fifty thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Review of notification upon obtaining new information

32. (1) The Board may, in consultation with the Advisory Committee, review any notification at any time upon obtaining new information or evidence on the living modified organisms relating to such notification.

(2) Upon review, where there is a risk posed to human, plant or animal health, the environment or biological diversity, the Board may take any of the following actions:

- (a) make a cessation order;
- (b) impose additional terms and conditions;
- (c) order the approved person to make rectifications; or
- (d) make any other order as the Board thinks fit in the interest of biosafety.

(3) Where the Board makes a cessation order, the approved person shall cease all activities involving living modified organisms immediately and shall, within seven days from the date of the

Biosafety

notification of the cessation order, surrender the acknowledgement of submission of notification issued under section 25 to the Board.

(4) Any approved person who contravenes any order made by the Board under subsection (2) or contravenes subsection (3) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding four years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding two hundred and fifty thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Circumstances where Board may make further order on notification

33. (1) Notwithstanding the power of the Board to take any action under subsection 32(2), the Board may make a cessation order, impose any additional terms and conditions, order the approved person to make rectifications, or make any other order as the Board thinks fit in the interest of biosafety in the following circumstances:

- (a) where there is a risk posed to human, plant or animal health, the environment or biological diversity;
- (b) where the approved person fails to comply with any terms and conditions imposed on the notification;
- (c) where the approved person fails to comply with any order made by the Board;
- (d) where the approved person has contravened any of the provisions of this Act or any regulations made under this Act whether or not any prosecution has been instituted against him; or
- (e) where the approved person has been convicted for an offence under this Act or any regulations made under this Act.

(2) Where the Board makes a cessation order, the approved person shall cease all activities involving living modified organisms immediately and shall, within seven days from the date of the notification of the cessation, surrender the acknowledgement of the submission of notification issued under section 25 to the Board.

(3) Any approved person who contravenes any order made by the Board under subsection (1) or contravenes subsection (2) commits an offence and shall, on conviction, be liable—

(a) where such person is an individual, to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding four years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;

(b) where such person is a body corporate, to a fine not exceeding two hundred and fifty thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Appeal to Minister relating to notification

34. (1) Any person or approved person aggrieved with any decision of the Board relating to the notification may appeal against such decision to the Minister.

(2) The Minister shall have the power to confirm, reverse or vary the decision of the Board.

Taking of decision by the Board or Minister

35. The Board or Minister shall not be prevented from taking a decision, as appropriate, under Part III or Part IV, where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of living modified organisms or products of such organisms on human, plant and animal health, the environment and biological diversity and may also take into account socio-economic considerations.

Biosafety

PART V

RISK ASSESSMENT AND RISK MANAGEMENT REPORTS AND
EMERGENCY RESPONSE PLAN

Risk assessment and risk management reports

36. (1) The risk assessment and risk management reports shall be in a form prescribed by the Minister and shall contain—

- (a) an assessment of the risk and adverse effect that such living modified organisms and products of such organisms will have or are likely to have on the human, plant and animal health, the environment and biological diversity; and
- (b) the proposed measures that shall be undertaken to prevent, reduce or control the risks and adverse effect that such living modified organisms and products of such organisms will have or are likely to have on human, plant and animal health, the environment and biological diversity.

(2) Notwithstanding any risk assessment and risk management reports submitted by an approved person, the approved person shall comply with the minimum risk management measures as may be determined by the Board, after consultation with the Advisory Committee.

(3) Upon obtaining an approval or an acknowledgement from the Board, the approved person shall, in the course of undertaking the release, import or contained use activity relating to the approval or acknowledgement, as the case may be,—

- (a) incorporate into the design, construction and operation, whichever is applicable, of the release, import or contained use activity the proposed measures in the risk management reports of the approved person; and
- (b) carry out and comply with, to the satisfaction of the Board, the minimum risk management measures referred to in subsection (2).

(4) Any approved person who contravenes subsection (3) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Emergency response plan

37. (1) An emergency response plan shall provide—

- (a) safety measures and procedures for the protection of human, plant and animal health, the environment and biological diversity against harm or damage caused directly or indirectly by living modified organisms or products of such organisms; and
- (h) all necessary measures to be taken in the event of an emergency.

(2) Any approved person who fails to take the necessary measures in an emergency according to the emergency response plan commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Biosafety

PART VI

ENFORCEMENT

Enforcement officers

38. The following officers may exercise the powers under this Part:

- (a) an enforcement officer of the Board;
- (b) officers specified in the Third Schedule; and
- (c) any other officer of the Board or any other public officer authorized in writing by the Board.

Power of investigation

39. (1) An enforcement officer shall have all the powers necessary to carry out an investigation under this Act or any regulations made under this Act.

(2) An enforcement officer shall, on demand, declare his office, and produce to the person against whom he is acting or from whom he seeks any information, such authority card as the Board may direct to be carried by such officer.

(3) In any case relating to the commission of an offence under this Act or any regulations made under this Act, any enforcement officer carrying out an investigation may exercise all or any of the special powers in relation to police investigation in seizable cases given by the Criminal Procedure Code [*Act 593*].

(4) This section shall not be construed as limiting or affecting any similar powers conferred on any person under any other written law.

Search by warrant

40. (1) If it appears to a Magistrate, upon written information on oath and after such enquiry as he considers necessary, that there is reasonable cause to believe that in any premises there is or has been any contravention of this Act or any regulations made

under this Act, the Magistrate may issue a warrant authorizing any enforcement officer named therein, at any reasonable time by day or by night and with or without assistance, to enter the premises, if need be by force, and there to—

- (a) search for and seize any organism or product that is suspected of being a living modified organism or a product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter, or thing including in digital form, that is reasonably believed to furnish evidence of the contravention of this Act or any regulations made under this Act;
- (b) take samples of any organism or product that is suspected of being a living modified organism or product of such organism or thing found in the premises for the purpose of ascertaining, by testing or otherwise, whether any offence under this Act or any regulations made under this Act has been committed; and
- (c) make copies of or take extracts from any book, document, computerized data or thing including in digital form, or make back-up copies of computerized data or thing including in digital form, for purposes of investigations.

(2) Where by reason of its nature, size or amount, it is not practicable to remove any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized under subsection (1), the enforcement officer shall, by any reasonable means, seal such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form in the premises or container in which such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, is found.

(3) It shall be an offence for any person without lawful authority to break, tamper with or damage the seal referred to in subsection (2) or to remove any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter, or thing including in digital form under seal or to attempt to do so.

(4) Any person who contravenes subsection (3) commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding one year or to both.

(5) Any enforcement officer entering any premises under this section may take with him such other persons and equipment as may appear to him to be necessary.

(6) Any enforcement officer may in the exercise of his powers under this section, if it is necessary to do so—

- (a) break open any outer or inner door of the premises and enter the premises;
- (b) forcibly enter the premises and every part of the premises;
- (c) remove by force any obstruction to entry, search, seizure and removal as he is empowered to effect; and
- (d) detain every person found in the premises until the premises has been searched.

(7) Subject to any other written law, in carrying out the powers under this section, an enforcement officer shall also have the power to stop, board or detain any vessel, aircraft or other vehicle.

Search without warrant

41. If any enforcement officer in any of the circumstances referred to in subsection 40(1) has reasonable cause to believe that by reason of a delay in obtaining a search warrant under that section the investigation would be adversely affected or evidence of the commission of an offence is likely to be tampered with, removed, damaged or destroyed, the enforcement officer may enter the premises and exercise in, upon and in respect of the premises all the powers provided in section 40 in as full and ample a manner as if he were authorized to do so by a warrant issued under that section.

Access to computerized data

42. Any enforcement officer conducting a search under section 40 or 41 shall be given access to computerized data whether stored in a computer or otherwise, and for such purpose, shall be provided

with the necessary password, encryption code, decryption code, software or hardware and any other means required to enable comprehension of computerized data.

List of things seized

43. (1) Where any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form is seized under this Part, the seizing officer shall prepare a list of the organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, seized.

(2) The occupier of the premises searched, or some person on his behalf, shall in every instance be permitted to attend during the search, and a copy of the list prepared and signed under this section shall be delivered to that occupier or person at his request.

(3) Where the premises are unoccupied, the seizing officer shall whenever possible post a list of the organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, seized conspicuously on the premises.

Power to seal premises

44. In exercise of the powers under section 40 or 41, an enforcement officer may seal temporarily any premises.

Forfeiture of living modified organisms or products of such organisms, etc.

45. (1) Any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized in exercise of any power conferred under this Act shall be liable to forfeiture.

(2) An order for the forfeiture of any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form referred to in subsection (1) shall be made by the court before which the prosecution with regard thereto has been held if it is proved to the satisfaction of the court that an offence under this Act or any regulations made under this Act has been committed and that the said organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, was the subject matter of or was used in the commission of the offence, notwithstanding that no person may have been convicted of such offence.

(3) Where there is no prosecution with regard to any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, seized in exercise of any power conferred under this Act, a notice shall be served to the last-known address of the person from whom the said organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form was seized.

(4) The notice referred to in subsection (3) shall indicate that—

- (a) there is no prosecution in respect of such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form; and
- (b) such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, shall be taken and deemed to be forfeited at the expiration of one calendar month from the date of service of such notice unless before that date a claim thereto is made in the manner set out in subsections (5), (6) and (7).

(5) Any person asserting that he is the owner of the organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form referred to in subsection (3) and that such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, is not liable to forfeiture may personally or by his agent authorized in writing give written notice to the enforcement officer in whose possession such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form is held that he claims such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form.

(6) On receipt of the notice under subsection (5), the enforcement officer shall refer the claim to a Magistrate of the First Class for his decision.

(7) The Magistrate to whom a matter is referred under subsection (6) shall issue a summons requiring the person asserting that he is the owner of the organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form and the person from whom it was seized to appear before him, and upon their appearance or default to appear, due service of the summons being proved, the Magistrate shall proceed to the examination of the matter, and on proof that the offence under this Act or any regulations made under this Act has been committed and that such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, was the subject matter of or was used in the commission of such offence, shall order the organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment,

device, machinery, vehicle, matter or thing including in digital form to be forfeited or may, in the absence of such proof, order the release of such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form to the person entitled to it.

(8) Where an order for forfeiture is made by the court under subsection (2) or (7) or where no claim is made under subsection (5), the enforcement officer shall dispose of the organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, in accordance with any direction issued by the Director General and any costs incurred for such disposal shall be borne by the owner of such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form.

(9) Where any organism or product that is suspected of being a living modified organism or product of such organism that is seized in exercise of the powers conferred under this Act is of a perishable nature or is subject to speedy and natural decay or where the custody of such organism or product that is suspected of being a living modified organism or product of such organism involves unreasonable expense or hazard to the public, the enforcement officer may dispose of such organism or product that is suspected of being a living modified organism or product of such organism in accordance with the direction issued by the Director General and any costs incurred for such disposal shall be borne by the owner.

(10) Any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, forfeited or deemed to be forfeited under this Part shall be the property of the Federal Government.

(11) The Director General or an enforcement officer acting in good faith in exercising the powers under this section shall not be liable to any person for any deterioration, depreciation

or damage, however caused, in the quality of any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery or vehicle, matter or thing including those in digital form seized under this Act.

Cost of holding organisms, etc., seized

46. Where any organism or product that is suspected of being a living modified organism or product of such organism, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, seized under this Act is held in the custody of the Federal Government pending completion of any proceedings in respect of an offence under this Act or any regulations made under this Act, the cost of holding such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including those in digital form, in custody shall be recoverable as a civil debt due to the Federal Government from the owner.

No costs or damages arising from entry, search or seizure to be recoverable

47. No person shall, in respect of any entry or search, or seizure of any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, seized in the exercise of any power conferred by this Act, be entitled to the costs of such entry, search, or seizure or to any damages or other relief unless such entry, search or seizure was made without reasonable cause.

Obstruction of enforcement officers

48. Any person who assaults, impedes, obstructs or interferes with, or refuses access to any premises to, an enforcement officer in the performance of his duties under this Act commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding one year or to both.

Examination of persons acquainted with case

49. (1) An enforcement officer making an investigation under this Act or any regulations made under this Act may examine orally any person supposed to be acquainted with the facts and circumstances of the case.

(2) Such person shall be bound to answer all questions relating to such case put to him by the enforcement officer, but he may refuse to answer any question the answer to which would have a tendency to expose him to a criminal charge or penalty or forfeiture.

(3) A person making a statement under this section shall be legally bound to state the truth, whether or not such statement is made wholly or partly in answer to questions.

(4) The enforcement officer examining a person under subsection (1) shall first inform that person of the provisions of subsections (2) and (3).

(5) A statement made by any person under this section shall, wherever possible, be reduced into writing and signed by the person making it or affixed with his thumb print, as the case may be, after—

- (a) it has been read to him in the language in which he made it; and
- (b) he has been given an opportunity to make any correction he may wish.

Admissibility of statement in evidence

49A. (1) Except as provided in this section, no statement made by any person to an enforcement officer in the course of an investigation made under this Act or any regulations made under this Act shall be used in evidence.

(2) When any witness is called for the prosecution or for the defence, other than the accused, the court shall, on the request of the accused or the prosecutor, refer to any statement made

by that witness to an enforcement officer in the course of an investigation under this Act or any regulations made under this Act and may then, if the court thinks fit in the interest of justice, direct the accused to be furnished with a copy of it and the statement may be used to impeach the credit of the witness in the manner provided by the Evidence Act 1950 [Act 56].

(3) Where the accused had made a statement during the course of investigation such statement may be admitted in evidence in support of his defence during the course of the trial.

(4) Nothing in this section shall be deemed to apply to any statement made in the course of an identification parade or falling within section 27 or paragraphs 32(1)(a), (i) and (j) of the Evidence Act 1950.

(5) When any person is charged with any offence in relation to the making or the contents of any statement made by him to an enforcement officer in the course of an investigation made under this Act or any regulations made under this Act, that statement may be used as evidence in the prosecution's case.

Power to require production of things related to offence

50. (1) Any enforcement officer may, by notice in writing, require any person to produce to him such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, that the enforcement officer reasonably believes to have been used in the commission of an offence under this Act or any regulations made under this Act, as are in the possession, or custody or under the control of that person or within the power of that person to produce.

(2) All enforcement officer shall have the power to detain such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, produced to him under subsection (1) for purposes of investigations.

(3) The provision on forfeiture in section 45 shall apply, *mutatis mutandis*, to any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form detained under subsection (2).

(4) Any person who fails to produce any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including those in digital form, as is required by an enforcement officer under subsection (1) commits an offence and shall, on conviction, be liable—

(a) where such person is an individual, to a fine not exceeding one hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;

(b) where such person is a body corporate, to a fine not exceeding two hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Enforcement officer may seek assistance to examine things related to offence

51. An enforcement officer may seek the assistance of any person to examine any organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, seized or detained under this Act if such person has the necessary qualification to examine such organism or product that is suspected of being a living modified organism or product of such organism, or book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form, for the purposes of an investigation under this Act or any regulations made under this Act.

Power of Board to require information on living modified organisms or products of such organisms

52. (1) The Board may require any person undertaking any activity involving living modified organisms or products of such organisms to furnish to the Board information relating to the composition and use of such living modified organisms or products of such organisms.

(2) Any person who fails to furnish any information relating to the composition and use of any living modified organism or product of such organism as may be required under subsection (1) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding one hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding two hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Power to take sample

53. (1) An enforcement officer may demand, select, take or obtain samples of any organism or product suspected of being or containing living modified organisms or products of such organisms for the purposes of analysis—

- (a) upon payment, from any person selling such organism or product, or his or its agent or servant; or
- (b) without payment, from any manufacturer or importer of such organism or product or his or its agent or servant.

(2) The samples demanded, selected, taken or obtained under subsection (1) shall be accepted in any court.

(3) Any person who refuses to comply with any demand made by an enforcement officer under subsection (1) commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding one hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding two hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Procedure for taking sample

54. (1) Where it is intended to submit any sample of any organism or product that is suspected of being or containing living modified organism or product of such organism for analysis the enforcement officer purchasing or otherwise procuring the sample shall inform the seller, manufacturer or importer or his or its agent or servant from whom the said organism or product is purchased or otherwise procured that he intends to have the sample analysed by an analyst.

(2) The procedure for taking and dealing with the samples shall be as prescribed by regulations.

Appointment of analyst

55. The Board may appoint any qualified person to be an analyst for the purposes of carrying out an analysis under this Act.

Certificate of analysis

56. (1) A certificate of analysis signed by an analyst shall, on production by the Public Prosecutor in any trial under this Act or any regulations made under this Act, be sufficient evidence of the facts stated in the certificate unless the accused requires that the analyst be called as a witness, in which case he shall give a written notice to the Public Prosecutor not less than three clear days before the commencement of the trial.

(2) Where the Public Prosecutor intends to give in evidence any certificate referred to in subsection (1) he shall deliver a copy of such certificate to the accused not less than ten clear days before the commencement of the trial.

Presumption

57. Where evidence or a certificate of analysis is given by an analyst stating that an organism or product in whatever form produced before the court is a living modified organism or product of such organism, the court shall presume that such organism or product is a living modified organism or product of such organism unless the contrary is proved.

Institution of prosecution

58. No prosecution in respect of any offence under this Act or any regulations made under this Act shall be instituted except by or with the written consent of the Public Prosecutor.

PART VII

MISCELLANEOUS

Confidential business information

59. (1) Any person making an application under section 13 or submitting a notification under subsection 22(1) may apply to the Director General for confidentiality of any commercial and industrial information relating to the application or notification, as the case may be.

(2) The Director General may grant confidentiality based on the criteria in subsection (3) and where confidentiality is granted such information shall not be made public.

(3) The Director General shall consider the claim for confidentiality according to the following criteria:

- (a) that the information is not known generally among, or readily accessible to, any person within the circle that normally deals with the kind of information sought to be made confidential;

- (b) that the information has commercial value because it is secret; and
- (c) that reasonable steps have been taken to keep the information secret.

(4) Except for the purposes of this Act or for the purposes of any civil or criminal proceedings under any written law or where otherwise authorized by the Director General, as the case may be—

- (a) no member of the Board or Advisory Committee, or any of its committees or subcommittees, as the case may be;
- (b) no person attending any meeting of the Board or Advisory Committee, or any of its committees or subcommittees, as the case may be; or
- (c) the Director General and any officer appointed under subsection 8(1),

whether during his tenure of office or during his employment or thereafter, shall disclose any information obtained by him in the course of his duties for which confidentiality has been granted under subsection (3).

(5) Any person who contravenes subsection (4) commits an offence and shall, on conviction, be liable to a fine not exceeding ten thousand ringgit to or imprisonment for a term not exceeding one month or to both."

Public disclosure

60. (1) Subject to the discretion of the Board, the public may have access to such information relating to any application for approval, approval granted or notification, which has not been granted confidentiality under subsection 59(2) in such manner as the Board thinks fit.

(2) Any decision made under Part III and Part IV shall be made available to the public in such manner as the Board thinks fit.

Identification and labelling

61. All living modified organisms, items containing living modified organisms and products of such organisms shall be clearly identified and labelled in a manner to be prescribed and the requirements for such identification and labelling shall be in addition to any other written law.

Assistance from multi-agencies in emergency

62. (1) The Director General shall forward the emergency response plan submitted under paragraphs 13(1)(b) and 24(a) to all relevant agencies for their necessary action.

(2) In the event of any emergency involving any living modified organism or product of such organism, the Director General may seek the assistance and co-operation of the relevant agencies in implementing any emergency measure including those measures provided in the emergency response plan.

(3) Any costs incurred by any agency in implementing any emergency measure shall be borne by the approved person.

(4) Nothing in this section shall absolve or be deemed to absolve the approved person from any of his or its obligation to take all necessary measures in the event of any emergency.

Service of notice

63. (1) Any notice required to be given or served under this Act shall be sent personally or by A.R. registered post, unless some other form of service is prescribed—

(a) in the case of a company incorporated in Malaysia, to the address of the registered office of the company;

(b) in the case of a company incorporated outside Malaysia, either to the individual authorized to accept service of process under the Companies Act 1965 [Act 125], or to the address filed with the Registrar of Companies or to the registered office of the company, wherever it may be situated: or

- (c) in the case of an individual or a body of persons, to the last-known business or private address of such individual or body of persons.

(2) Where the person to whom there has been addressed an A.R. registered letter containing any notice which may be given under this Act is informed of the fact that there is an A.R. registered letter awaiting him at a post office, and such person refuses or neglects to take delivery of such registered letter, such notice shall be deemed to have been served upon him on the date on which he was so informed.

Offence by body corporate

64. Where a body corporate commits an offence under this Act or any regulations made under this Act, any person who at the time of the commission of the offence was a director, manager, secretary or other similar officer of the body corporate or was purporting to act in any such capacity or was in any manner or to any extent responsible for the management of any of the affairs of the body corporate or was assisting in such management—

- (a) may be charged severally or jointly in the same proceedings with the body corporate; and
- (b) where the body corporate is found guilty of the offence, shall be deemed to be guilty of that offence unless, having regard to the nature of his functions in that capacity and to all circumstances, he proves—
 - (i) that the offence was committed without his knowledge, consent or connivance; and
 - (ii) that he took all reasonable precautions and had exercised due diligence to prevent the commission of the offence; and
- (c) shall, on conviction, be liable to the penalty applicable to an individual.

Offence by partner, agent or servant

65. Any person who would have been liable to any penalty under this Act or any regulations made under this Act for any

act, omission, neglect or default if the act, omission, neglect or default is committed by him personally shall be liable to the same penalty if the act, omission, neglect or default is committed by his partner, agent or servant unless he proves—

- (a) that the act, omission, neglect or default was committed without his knowledge, consent or connivance; and
- (b) that he took all reasonable precautions and had exercised due diligence to prevent the act, omission, neglect or default.

Power to compound

66. (1) The Board may, with the consent of the Public Prosecutor, offer in writing to compound any offence under this Act or any regulations made under this Act, and determined by the Minister to be a compoundable offence by regulations made under this Act, by accepting from the person reasonably suspected of having committed the offence such amount, not exceeding fifty per centum of the amount of the maximum fine for that offence to which that person would have been liable if he or it had been convicted of the offence, within such time as may be specified in the offer.

(2) An offer under subsection (1) may be made at any time after the offence has been committed, but before any prosecution for it has been instituted, and if the amount specified in the offer is not paid within the time specified in the offer or within such extended period as the Board may grant, prosecution for the offence may be instituted at any time after that against the person to whom the offer was made.

(3) Where an offence has been compounded under subsection (1), no prosecution shall be instituted in respect of the offence against the person to whom the offer to compound was made.

(4) Any money received by the Board under this section shall be paid into and form part of the Federal Consolidated Fund.

Falsification, concealment and destruction of document

67. Any person, with intent to deceive, in respect of a document to be produced or submitted under any provision of this Act or any regulations made under this Act, who makes or causes to

be made a false entry, omits to make, or causes to be omitted, any entry, or alters, abstracts, conceals or destroys, or causes to be altered, abstracted, concealed or destroyed, any entry, forges a document, or makes use of or hold in his possession a false document, purporting to be a valid document, alters any entry made in any document, or issues or uses a document which is false or incorrect, wholly or partially, or misleading, commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding two hundred and fifty thousand ringgit or to imprisonment for a term not exceeding five years or to both: or
- (b) where such person is a body corporate, to a fine not exceeding five hundred thousand ringgit.

Power of Minister to exempt

68. The Minister may, upon recommendation of the Board, exempt from the application of any or all of the provisions of this Act any person, class of persons, activity, category of activities, living modified organism or products of such organism.

Power to make regulations

69. (1) The Minister may, upon consultation with the Board, make such regulations as may be expedient or necessary for the better carrying out of the provisions of this Act.

(2) Without prejudice to the generality of subsection (1), regulations may be made for the following:

- (a) the manner to be followed, and the information, including detection methods and sample to be furnished in an application for an approval under section 13;
- (b) the certificate of approval granted under subsection 16(3);
- (c) the manner to be followed, information and reports to be furnished in submitting a notification under subsection 22(1);
- (d) the form of the acknowledgement of receipt issued under section 25:

- (e) risk assessment and risk management reports including periodic reports by the approved person on monitoring and evaluation of risk;
- (f) emergency response plan;
- (g) the procedures to be followed in appeals made to the Minister;
- (h) the contained use activity for any research and development carried out by teaching and public research institutes;
- (i) the procedure with taking and dealing with samples;
- (j) the identification and labelling of living modified organisms, items containing living modified organisms and products of such organisms;
- (k) the compounding of offences;
- (l) the fees payable under this Act;
- (m) any other matter as the Minister thinks expedient or necessary for the purposes of this Act.

(3) Regulations made under this section may provide that any person who contravenes any of the provisions of these regulations commits an offence and shall, on conviction, be liable—

- (a) where such person is an individual, to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding six months or to both and, in the case of a continuing offence, to a further fine not exceeding ten thousand ringgit for each day during which the offence continues after conviction;
- (b) where such person is a body corporate, to a fine not exceeding two hundred thousand ringgit and, in the case of a continuing offence, to a further fine not exceeding twenty thousand ringgit for each day during which the offence continues after conviction.

Power to amend Schedules

70. The Minister may, after consultation with the Board, by order published in the *Gazette* amend the Schedules to this Act.

Transitional provisions

71. (1) Any person who, on the date of the coming into operation of this Act, is undertaking an activity to which this Act applies shall, within three months from the date of the coming into operation of this Act, make an application for approval under section 13 or submit a notification under subsection 22(1), as the case may be.

(2) Upon receipt of an application for approval or submission of notification under subsection (1), the Director General shall issue an acknowledgement of receipt to such person.

(3) Pending the determination of such application or notification in accordance with Part III or Part IV, as the case may be, such person may continue to undertake such activity.

FIRST SCHEDULE

[Subsection 4(3)]

PROVISIONS RELATING TO BOARD

Alternate member

1. (1) The Minister may, in respect of each member of the Board other than the Chairman and the members appointed under paragraph 4(2)(h), appoint an alternate member to attend, in place of that member, meetings of the Board that that member is for any reason unable to attend.

(2) When attending meetings of the Board, an alternate member shall for all purposes be deemed to be a member of the Board.

Tenure of office

2. (1) Subject to such terms and conditions as may be specified in his instrument of appointment, a member of the Board other than the Chairman shall, unless he sooner resigns or vacates his office or his appointment is sooner revoked, hold office for a term not exceeding three years and is eligible for reappointment.

(2) An alternate member shall, unless he sooner resigns or vacates his office or his appointment is sooner revoked, cease to be an alternate member when the member in respect of whom he is an alternate ceases to be a member of the Board.

Revocation and resignation

3. (1) The appointment of any member of the Board other than the Chairman may at any time be revoked by the Minister without assigning any reason therefor.

(2) A member of the Board other than the Chairman may at any time resign his office by a written notice addressed to the Minister.

Vacation of office

4. (1) The office of a member of the Board shall be vacated—

- (a) if he dies;
- (b) if there has been proven against him, or he has been convicted on, a charge in respect of—
 - (i) an offence involving fraud, dishonesty or moral turpitude;
 - (ii) an offence under any law relating to corruption; or
 - (iii) any other offence punishable with imprisonment (in itself only or in addition to or in lieu of a fine) for more than two years;
- (c) if he becomes a bankrupt;
- (d) if he is of unsound mind or is otherwise incapable of discharging his duties;
- (e) if he absents himself from three consecutive meetings of the Board without leave of the Chairman or in the case of the Chairman, without leave of the Minister;
- (f) in the event of his resignation being accepted by the Minister; or
- (g) if his appointment is revoked by the Minister.

(2) Where any person ceases to be a member of the Board by reason of any of the provisions of subparagraph (1), another person shall be appointed in his place.

Temporary exercise of functions of Chairman

5. (1) Where the Chairman is for any reason unable to perform the functions of the Chairman or during any period of vacancy in the office of the Chairman, the Minister may appoint any member of the Board to perform the functions of the Chairman.

(2) Until an appointment under subparagraph (1) is made or in default of such appointment or in the absence of the Chairman from any meeting of the Board, the members present shall appoint one of them to be the Chairman for the purposes of that meeting.

(3) A member appointed under subparagraph (1) or (2), as the case may be, shall, during the period in which he is performing the functions of the Chairman under this section, be deemed to be the Chairman.

Meetings

6. (1) The Board shall meet at least once in every six months at a time and place as may be appointed by the Chairman.

(2) At least fourteen days notice in writing of a meeting shall be given to the members of the Board.

(3) Every member of the Board present shall be entitled to one vote.

(4) If on a question to be determined by the Board there is an equality of votes, the Chairman shall have a casting vote.

(5) The Chairman and four other members present at a meeting of the Board shall constitute a quorum.

Chairman of Advisory Committee to be present at meeting of the Board

7. (1) The chairman of the Advisory Committee or his representative shall be present at every meeting of the Board, but his presence shall not constitute a quorum for the meeting and he shall not be entitled to vote at the meeting.

(2) Where the chairman of the Advisory Committee or his representative attends a meeting of the Board he shall be paid such fees as the Board may determine.

Board may invite others to meetings

8. (1) The Board may invite any person to attend a meeting or deliberation of the Board for the purposes of advising it on any matter under discussion but that person shall not be entitled to vote at the meeting or deliberation.

(2) A person invited under subparagraph (1) may be paid such fees as the Board may determine.

Disclosure of interest

9. A member of the Board having, directly or indirectly, by himself or his partner, any interest in any matter under discussion by the Board shall disclose to the Board the fact of his interest and the nature thereof, and such disclosure shall be recorded in the minutes of the Board and such member shall not be present in any deliberation or decision of the Board relating to the matter.

Minutes

10. (1) The Secretary of the Board shall maintain minutes of all meetings of the Board in a proper form.

(2) Minutes made of meetings of the Board shall, if duly signed, be admissible in evidence in all legal proceedings without further proof.

(3) Every meeting of the Board in respect of the proceedings of which minutes have been so made shall be deemed to have been duly convened and held and all members thereat to have been duly qualified to act.

Allowance

11. The Chairman and members of the Board shall be paid such allowances as the Minister may, with the concurrence of the Minister of Finance, determine.

Procedure

12. Subject to this Act, the Board shall regulate its own procedure.

Common seal

13. (1) The Board shall have a common seal which shall bear such device as the Board shall approve and such seal may be broken, changed, altered or made anew as the Board thinks fit.

(2) Until a seal is provided by the Board, a stamp bearing the words "National Biosafety Board" or "*Lembaga Biokeselamatan Negaru*" may be used and shall be deemed to be the common seal of the Board.

(3) The common seal shall be kept in the custody of the Director General or such other person as may be authorized by the Board, and shall be authenticated by the Director General or such authorized person or by any officer authorized by either of them in writing; and all deeds, documents and other instruments purporting to be sealed with the said seal, authenticated as aforesaid, shall, until the contrary is proved, be deemed to have been validly executed.

(4) Any document or instrument which, if executed by a person not being a body corporate would not be required to be under seal, may in like manner be executed by the Board; and any such document or instrument may be executed on behalf of the Board by any officer or servant of the Board generally or specially authorized by the Board in that behalf.

(5) The common seal of the Board shall be officially and judicially noticed.

Validity of acts and proceedings

14. No act done or proceeding taken under this Act shall be questioned on the ground of—

- (a) a vacancy in the membership of, or a defect in the constitution of, the Board;

- (b) the contravention by any member of the Board of the provisions of paragraph 9; or
- (c) an omission, a defect or an irregularity not affecting the merit of the case.

Members of Board to devote time to business of Board

15. Every member of the Board shall devote such time to the business of the Board as may be necessary to discharge his duties effectively.

SECOND SCHEDULE

[Section 3]

RELEASE ACTIVITIES

1. Research and development purposes in all field experiments
2. Supply or offer to supply for sale or placing on the market
3. Offer as gift, prize or free item
4. Disposal
5. Remediation purposes
6. Any other activity which does not amount to contained use

THIRD SCHEDULE

[Section 38]

ENFORCEMENT OFFICERS

1. Any police officer not below the rank of Inspector as provided for in the Police Act 1967 [**Act 344**]
2. Any Inspecting Officer of the Department of Agriculture as defined in section 2 of the Plant Quarantine Act 1976 [**Act 167**]
3. Any authorized officer as defined in section 2 of the Food Act 1983 [**Act 281**]
4. Any Officer of customs as defined in section 2 of the Customs Act 1967 [**Act 235**]
5. Any port officer as defined in section 2 of the Merchant Shipping Ordinance 1952 [**Ord. 70/1952**]

- i. Any fisheries officer as defined in section 2 of the Fisheries Act 1985 [Act 317]
7. Any authorized officer as defined in section 2 and appointed under section 53 of the Protection of New Plant Varieties Act 2004 [Act 634]
8. Any veterinary authority as defined in section 2 of the Animals Act 1953 [Act 647]