BIOSAFETY ACT 2007

BIOSAFETY (APPROVAL AND NOTIFICATION) REGULATIONS 2010

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BIOSAFETY ACT 2007

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IN exercise of the powers conferred by paragraphs 69*(a)*, *(b)*, *(c)*, *(g)*, *(h)* and *(l)* of the Biosafety Act 2007 [*Act 678*], the Minister, upon consultation with the Board, makes the following regulations:

PART I
PRELIMINARY

Citation and commencement

1. (1) These regulations may be cited as the **Biosafety (Approval and Notifcation) Regulations 2010**.

(2) These Regulations come into operation on 1 November 2010.

Non-application

2. These Regulations shall not apply to —

(a) products of such organisms which are pharmaceuticals and addressed by relevant international treaties or organizations, or regulated under any other written laws relating to pharmaceuticals; and

(b) techniques and contained use activities in relation to living modified organisms as specified in the First Schedule.

Interpretation

3. In these Regulations –

"certificate" means the certificate of approval issued by the Board under subsection 16(3) of the Act;

"classes" in relation to an activity involving modern biotechnology means four classes of Biosafety Levels as specified in the Second Schedule.

Fees

4. (1) The fees to be paid under these Regulations shall be as specified in the Third Schedule.

(2) The fees shall be paid to the Secretary General of the Ministry charged with the responsibility for natural resources and environment in a manner as the Director General may direct.

PART II

INSTITUTIONAL BIOSAFETY COMMITTEE

Establishment of an institutional biosafety committee

5. (1) The Board may, in exercising its function under paragraph 5(1)*(b)* and subsection 5(2) of the Act, direct any organization that undertakes modern biotechnology research and development to establish an institutional biosafety committee for the purpose of –

(a) to provide guidance for safe use of modern biotechnology;

(b) to monitor activities dealing with modern biotechnology;

(c) establishing and monitoring the implementation of policies and procedures for the purpose of handling living modified organisms; and

(d) determining the classes of Biosafety Levels for contained use activity for the purpose of modern biotechnology research and development undertaken within a facility where the institutional biosafety committee is established.

(2) The institutional biosafety committee which has been established upon the direction of the Board under subregulation (1) shall be registered with the Board in a manner as the Board may determine.

(3) Any organization who fails to comply with the direction made under subregulations (1) and (2) commits an offence.

PART III

APPROVAL FOR ANY RELEASE ACTIVITY AND IMPORTATION OF LIVING MODIFIED ORGANISMS

Application for approval

6. (1) Every application for approval of —

(a) any release activity, or any importation of living modified organism shall be submitted to the Director General;

(b) any release activity for the purpose as specified under item 1 of the Second Schedule of the Act shall be submitted to the Director General through the institutional biosafety committee,

and shall be accompanied by the prescribed fee.

(2) An applicant shall have a place of residence, business premises or in the case of an agent, with an address for service in Malaysia.

(3) The applicant shall ensure that the application –

(a) is complete; and

(b) does not contain any error or contain any unauthorized alteration.

(4) If the application is being made not in accordance with the requirements specified under subregulation (1), the Director General may refuse to process the application and –

(a) shall require that it is amended or to be completed and to be resubmitted; or

(b) shall require that a fresh application be submitted.

(5) If the applicant fails to comply the subregulation (4), the application shall be treated as withdrawn but it shall not affect the right of the applicant to make a fresh application in accordance with this regulation.

Application fee not refundable

7. Where an application is treated as withdrawn under subregulation 6(5) or an applicant withdraws his application, the fee paid for the application shall not be refunded.

Acknowledgement of receipt of application

8. (1) Upon receipt of the application under regulation 6 and after considering that the applicant complies with subregulation 6(3), the Director General shall send to the applicant an acknowledgement of receipt in a manner as the Director General may determine.

(2) The Director General shall inform the applicant of the decision made by the Board, whether to approve or refuse the application, within one hundred and eighty working days from the date of the issuance of the acknowledgement of receipt under subregulation (1).

(3) If the Board is unable to decide whether to approve or refuse the application within the time as specified in subregulation (2), the Board may extend the time but the extension shall not exceed sixty working days.

PART IV

CERTIFICATE OF APPROVAL

Issuance of certificate

9. (1) Where the application for approval under regulation 6 is granted, the Board may issue a certificate and may impose such terms and conditions as the Board thinks fit.

(2) The Board in imposing such terms and conditions pursuant to subsections 16(4) and 30(3) of the Act may consider the following factors:

(a) authorized scope of the activity;

(b) purposes for which the activity may be undertaken;

(c) variations to the scope or purposes of the activity;

(d) documentations and record-keeping requirements;

(e) required level of containment in respect of the activity;

(f) waste disposal requirements;

(g) measures to manage risks posed to the health and safety of human or the environment;

(h) data collection, including studies to be conducted;

(i) auditing and reporting including, where appropriate, condition for entry into premises where the activity is being undertaken;

(j) actions to be taken in the case of release of living modified organisms from a contained environment;

(k) geographical area in which the authorized activity may occur;

(l) compliance with any code of practice or technical or procedural guideline that may be issued;

(m) supervision and monitoring by the institutional biosafety committee;

(n) contingency plan relating to unintended effects of the authorized activity;

(o) limiting the dissemination or persistence of the living modified organisms or its genetic material in the environment;

(p) conditions requiring the approved person to be adequately insured against any loss, damage, or injury that may be caused to human health, property or the environment by the approved person, his servants or agents.

(3) Notwithstanding subregulation (1), the Board may consider any other in imposing terms and conditions relating to approval or notification as the Board thinks fit.

Variation of the terms and conditions of certificate

10. (1) Notwithstanding regulation 9, an approved person may propose any variation of any of the terms and conditions imposed on the approval referred to in regulation 9.

(2) Any proposal shall be submitted to the Board through Director General in writing and shall include —

(a) the proposed dates for the proposal to become valid;

(b) the details of the proposal; and

(c) the reasons for such variation.

(3) After receiving the proposal, the Board may require the approved person to submit any additional information or document within thirty days from the date the Board notifies the approved person of such requirement.

(4) If the additional information or document required to be submitted is not provided by the approved person within the time as specified under subregulation (3) or

any extension of time granted by the Board, the application shall be treated as withdrawn but it shall not affect the right of the approved person to make a fresh proposal in accordance with subregulation (1).

(5) The extension of time referred to in subregulation (4) may be applied by the approved person in writing to the Board and the Board may grant the extension of time as it deems fit.

Approval of variation

11. (1) The Director General shall refer the proposal and the additional information or documents submitted under regulation 10 to the Advisory Committee or relevant Government department or agencies for a recommendation or comment.

(2) The Board after having considered the recommendation or comment, if any, may approve or refuse the proposal and the decision shall be communicated to the approved person in writing.

Replacement of certificate

12. (1) Where a certificate is lost or destroyed, an approved person shall immediately inform the Board and lodge a police report in respect of the loss or destruction.

(2) The approved person may make an application to the Board in writing for a replacement of the certificate and shall be accompanied by a police report made under subregulation (1).

(3) The Board may, after having considered the application and is satisfied that the loss or destruction of the certificate did not involve any fraud, replace the

certificate by issuing the same certificate as the original certificate with the word “DUPLICATE” endorsed on the certificate bearing a different serial number.

(4) The duplicate certificate issued under subregulation (3) shall have the same effect as the original certificate.

Assignment or transfer of certificate

13. (1) An approved person shall apply to the Board through the Director General in writing to assign or transfer his certificate and shall be accompanied by the relevant particulars of the proposed assignment or transfer, and including the particulars of the proposed assignee or transferee.

(2) The Director General may, at any time after the receipt of an application under subregulation (1), require the approved person to provide him any further information or other document relating to the application within ten working days from the date the Director General notifies the approved person of the requirement to submit such additional information or other document relating to the application.

(3) If such additional information or other document required is not provided by the approved person within the time as specified in subregulation (2) or any extension of time granted by the Board, the application shall be treated as withdrawn but it shall not affect the right of the approved person to make a fresh application.

(4) The extension of time referred to in subregulation (3) may be applied by the approved person in writing to the Board and the Board may grant the extension of time as it deems fit.

Approval to assign or transfer certificate

14. (1) The Board shall process the application made under regulation 13 and may approve or refuse the application with reasons to it.

(2) The decision of the Board made under subregulation (1) shall be informed to the approved person in writing.

(3) An approved person who assigns or transfers his certificate without the approval of the Board commits an offence and shall, on conviction, be liable —

(a) where the 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; or

(b) where the 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.

Activities other than for which the certificate is issued

15. (1) An approved person shall not undertake any release activity or any importation of living modified organisms other than for which the certificate has been issued.

(2) An approved person who contravenes this regulation commits an offence and shall, on conviction, be liable —

(a) where the 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; or

(b) where the 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.

PART V

NOTIFICATION

Notification of activities

16. (1) A person undertaking any activity as specified in paragraphs 22(1)*(a) to (c)* of the Act shall give prior notification to the Board.

(2) The notification required under paragraphs 22(1)*(b)* and *(c)* of the Act shall be submitted —

(a) to the Director General; or

(b) for the purpose in accordance with the establishment of the institutional biosafety committee under subregulation 5(1), to the Director General through the Institutional Biosafety Committee,

and shall be accompanied by a prescribed fee.

Withdrawal of notification

17. (1) The person who submits the notification under subregulation 16(2) shall ensure that the notification –

(c) is complete; and

(d) does not contain any error or contain any unauthorized alteration.

(2) If the submission of the notification is being made not in accordance with the requirements specified under subregulation (1), the Director General may refuse to process the notification and –

(c) shall require that it is to be amended or to be completed and to be resubmitted; or

(d) shall require that a fresh notification be submitted.

(3) If any person fails to comply with subregulation (2), the notification shall be treated as withdrawn but it shall not affect the right of the person to submit or make a fresh notification in accordance with regulation 16.

Acknowledgement of receipt of notification

18. Upon receipt of the notification under regulation 16 and after considering that the person complies with regulation 17, the Director General shall send to the person an acknowledgement of receipt in a manner as the Director General may determine.

Rectification to notification

19. (1) An approved person shall, upon being ordered by the Board pursuant to subsection 30(3) of the Act, notify the Board through the Director General in writing of any rectification to the notification.

(2) Upon receipt of the rectification under subregulation (1), the Board may require the approved person to provide any additional information or other document as the Board may determine within fifteen working days from the date the Board notifies the approved person of the requirement to submit such additional information or other documents.

(3) If such additional information or other documents required is not provided by the approved person within the time as specified in subregulation (2) or any extension of time granted by the Board, the rectification shall be treated as withdrawn but it shall not affect the right of the approved person to make a fresh rectification.

(4) The extension of time referred to in subregulation (3) may be applied by the approved person in writing to the Board and the Board may grant the extension of time as it deems fit.

(5) The Board may approve the rectification and upon such approval, rectify the particulars of the original notification or direct a fresh notification to be submitted in accordance with regulation 16.

(6) Notwithstanding subregulation (5), the approved person may undertake and continue the activities as specified in the notification pending decision from the Board.

PART VI

APPEAL

Notice of appeal

20. (1) Any person or approved person who is aggrieved by any decision or action of the Board under section 16, 18, 19, 30, 31, 32 or 33 of the Act may, within

thirty working days from the date the decision was communicated to the person or approved person, give notice to the Minister in writing that he intends to appeal against the decision.

(2) The appellant may, not later than thirty working days after giving the notice under subregulation (1), submit the grounds of appeal and other documents as may be necessary for the purpose of the appeal.

PART VII

MISCELLANEOUS

Directives

21. (1) The Director General, in exercising the functions delegated by the Board pursuant to section 9 of the Act and with the approval of the Board, may issue directives to any organization as may be necessary to give effect to these Regulations.

Maintenance of register

22. The Board shall maintain a register of any application, notification, information, particulars, document and any other matters in relation to these Regulations in the manner as the Board may determine.

Cessation of calculation of period of time

23. Where an applicant or an approved person is given a period of time as specified in the Act or these Regulations to submit any information required for the purpose of the Act or these Regulations, the calculation of the period of time as specified in subsection 30(4) of the Act and subregulation 9(2) of these Regulations shall cease, pending the submission of the information required.

Change of address in the certificate issued

24. An approved person shall inform the Board in writing of any change of address in the certificate.

Socio-economic considerations

25. The Board or the Minister, in taking into account socio-economic considerations pursuant to section 35 of the Act, may consider –

(a) the changes in the existing social and economic patterns and means of livelihood of the communities that are likely to be affected by the introduction of the living modified organisms or products of such organisms;

(b) the effects to the religion, social, cultural and ethical values of communities arising from the use or release of the living modified organisms or products of such organisms.

FIRST SCHEDULE

(regulation 2)

TECHNIQUES IN RELATION TO LIVING MODIFIED ORGANISMS TO WHICH THESE REGULATIONS ARE NOT APPLICABLE

(a) *in vitro* fertilization*;

(b) natural processes including conjugation, transduction or transformation*;

(c) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination**;

(d) cell fusion (including protoplast fusion) of cells of any eukaryotic species within its taxonomic family, including production of hybridomas and plant cell fusions**;

(e) self-cloning, where the resulting organism is unlikely to cause disease or harm to humans, animals or plants**;

(f) mutagenesis****.

Notes:

(i) *Provided that the techniques do not involve the use of living modified organisms made by techniques other than those listed in paragraphs (c) and (e) or the use of recombinant nucleic acid molecules.

(ii) **Provided that the techniques do not involve the use of recombinant nucleic acid molecules or of living modified organisms other than those recombinant nucleic acid molecules or living modified organisms produced by one or more of the techniques under paragraphs (c) and (e).

(iii) ***Applicable for both items (i) and (ii).

(iv) "Self-cloning" –

(A) means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into cells of the same species or into cells of phylogenetically closely related species (able to hybridize naturally) which can exchange genetic material by homologous recombination; and

(B) may include the use of recombinant vectors, with an extended history of safe use in a particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

CONTAINED USE ACTIVITIES WHICH ARE EXEMPTED FROM NOTIFICATION

Item	*Activity*
1	An activity with genetically modified *Caenorhabditis elegans* and *Arabidopsis,* unless – *(a)* an advantage is conferred on the organism by the genetic modification; or *(b)* as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent, toxins or other products that can potentially cause adverse effects on living organisms

Item	*Activity*
2	An activity with an organism into which genetically modified somatic cells have been introduced, if – *(a)* the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and *(b)* the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.
3	An activity involving a host/vector system mentioned in the Host/Vector Systems Not Regulated For Contained Use where the donor nucleic acid – *(a)* must be characterized and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector; *(b)* must not code for a toxin; and *(c)* must not include a viral sequence unless the donor nucleic acid – (i) is missing at least 1 gene essential for viral multiplication that – (A) is not available in the cell into which the nucleic acid is introduced; and (B) will not become available during the activity; and

Item	*Activity*
	(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions; and *(d)* must not confer an oncogenic modification.
4	An activity involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of the Host/Vector Systems Not Regulated For Contained Use, if the donor nucleic acid is not derived from either – *(a)* a pathogen; or *(b)* a toxin-producing organism.

HOST/VECTOR SYSTEMS NOT REGULATED FOR CONTAINED USE ACTIVITIES

Item	*Class*	*Host*	*Vector*
1	Bacteria	*Escherichia coli* K12, *E. coli* B or *E. coli* C – any derivative that does not contain – *(a)* generalized transducing phages; or *(b)* genes able to complement the conjugation defect in a	1. Non-conjugative plasmids 2. Bacteriophage – (a) lambda; (b) lambdoid; (c) Fd or F1 (eg M13). 3. Non-vector systems*

Item	*Class*	*Host*	*Vector*
		non-conjugative plasmid	
		Bacillus – specified species – asporogenic strains with a reversion frequency of less than 10^{-7} – *(a) B. amyloliquefaciens;* *(b) B. licheniformis;* *(c) B. punilus;* *(d) B. subtilis;* *(e) B. thuringiensis.*	1. Non-conjugative plasmids 2. Plasmids and phages whose host range does not include *B. cereus, B. anthracts* or any other pathogenic strain of *Bacillus* 3. Non-vector systems*
		Pseudomonas putida – strain KT 2440	
		Pseudomonas putida – strain KT 2440	1. Non-conjugative plasmids including certified plasmids; pKT 262, pKT 263, pKT 264 2. Non-vector systems*
		Streptomyces – specified species – *(a) S. aureofaciens;* *(b) S. coelicolor;*	1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2,

Item	*Class*	*Host*	*Vector*
		(c) S. cyaneus; *(d) S. griseus;* *(e) S. lividans;* *(f) S. parvulus;* *(g) S. rimosus;* *(h) S. venezuelae.*	PIJ101 and derivatives 3. Actinophage phi C31 and derivatives 4. Non-vector systems*
		Agrobacterium radiobacter *Agrobacterium rhizogenes* – disarmed strains *Agrobacterium tumefaciens* – disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. Non-vector systems*
		Lactobacillus *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium*)	1. Non-conjugative plasmids 2. Non-vector systems*
2	Fungi	*Neurospora crassa* – laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Trichoderma reesei*	1. All vectors 2. Non-vector systems*

Item	*Class*	*Host*	*Vector*
3	Slime moulds	*Dictyostelium* species	1. *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. Non-vector systems*
4	Tissue culture	Animal or human cell cultures (including packaging cell lines)	1. Non-conjugative plasmids 2. Non-viral vectors, or defective viral vectors unable to transducer human cells 3. Avipox vectors (attenuated vaccine strains) 4. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedron minus 5. Non-vector systems*
		Plant cell cultures	1. Non-tumorigenic disarmed Ti

Item	*Class*	*Host*	*Vector*
			plasmid vectors, or Ri plasmid vectors in *Agrobacterium tumefaciens, Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2. Non-pathogenic viral vectors 3. Non-vector systems*

Note:

1. *In relation to non-vector systems , the approved hosts may also be used in experiments where DNA is inserted into the host cell without the use of a biological vector (non-vector system) (for example, by mechanical, electrical or other means), provided that the DNA –

(a) is not derived from microorganisms able to cause disease in humans, animals or plants, unless the DNA to be introduced is fully characterised and will not increase the virulence of the host or vector;

(b) does not code for a toxin for vertebrates and is not an oncogene;

(c) must not include a viral sequence unless the donor nucleic acid –

(i) is missing at least 1 gene essential for viral multiplication that -

(A) is not available in the cell into which the nucleic acid is introduced; and

(B) will not become available during the activity; and

(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent.

2. The exemption list for Notification includes any commercially available Host-Vector System fulfilling the criteria as specified under item 1.

SECOND SCHEDULE

(regulation 2)

CLASSES OF ACTIVITIES INVOLVING MODERN BIOTECHNOLOGY

Class	*Description*
BSL1	Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
BSL2	Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.
BSL3	Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
BSL4	Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.

Note:

"BSL" means biosafety level as recognized by international standards.

THIRD SCHEDULE

(regulation 4)

FEES

Provisions	Release Activity	Fees (RM)
Paragraph 6(1)*(a)*	*(a)* supply or offer to supply for sale or placing on the market;	5000
	(b) offer as gift, prize or free item;	5000
	(c) disposal;	5000
	(d) remediation purposes;	5000
	(e) any other activity which does not amount to contained use except for commercial field release.	5000
Paragraph 6(1)*(b)*	Research and development purposes in all field experiments per release site -	
	Less than 5 ha	100
	5 ha – 10 ha	250
	More than 10 ha	500

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Minister of Natural Resources and Environment