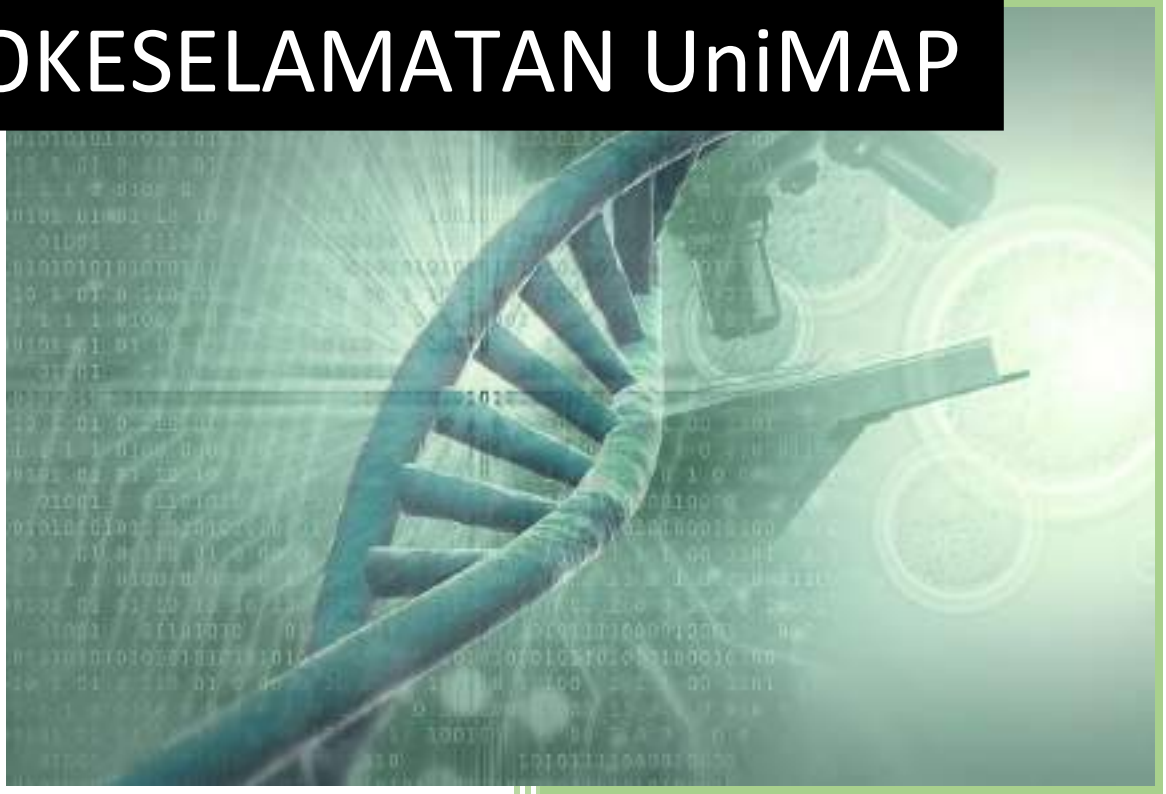
UNIVERSITI MALAYSIA PERLIS

2022

MANUAL PENGURUSAN BIOKESELAMATAN UniMAP



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Manual Pengurusan Biokeselamatan UniMAP

Dokumen ini dibangunkan oleh Universiti Malaysia Perlis *Biosafety and Biosecurity Committee* (UniMAP BBC).

Diterbitkan oleh

UniMAP BBC
Pusat Pengurusan Keselamatan, Kesihatan, dan Persekitaran Pekerjaan
Universiti Malaysia Perlis
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Kampus Alam UniMAP Pauh Putra
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Edisi Pertama, 2022

Kandungan

PRAKATA

Dengan penubuhan Akta Biokeselamatan 2007 dan Peraturan Biokeselamatan 2010, semua institusi termasuk universiti, institut penyelidikan dan syarikat swasta yang berurusan dengan Organisma Hidup Terubahsuai (LMO/rDNA) dan agen/bahan berjangkit dikehendaki mengikut Akta dan Peraturan tersebut untuk memastikan keselamatan pengguna, pelanggan dan persekitaran. Untuk mematuhi Akta dan Peraturan ini serta peraturan lain yang berkaitan bagi memantau semua aktiviti biologi tersebut yang dijalankan di Universiti Malaysia Perlis (UniMAP), *UniMAP Biosafety and Biosecurity Committee* (UniMAP BBC) telah dibentuk. Sehubungan dengan itu, UniMAP BBC membangunkan manual ini untuk membantu komuniti UniMAP yang manjalankan aktiviti melibatkan bahan biologi yang bukan sahaja mengikut Akta dan Peraturan tersebut malahan juga melakukannya dengan cara yang selamat dan teratur untuk mengurangkan risiko yang disebabkan oleh bahan.

Tanggungjawab setiap ahli komuniti UniMAP diterangkan secara terperinci dalam manual ini untuk memastikan setiap individu sedar dan mengamalkan amalan makmal yang baik. Selain daripada makmal yang baik amalan, komuniti UniMAP dikehendaki melengkapkan borang tertentu yang dihuraikan dalam perkara ini manual. Kepelbagaian jenis organisma hidup diterangkan untuk memastikan bentuk yang sepadan adalah selesai dan diserahkan kepada UniMAP BBC. Pelupusan sisa berkaitan biologi diterangkan dan langkah-langkah untuk diambil apabila insiden berlaku dihuraikan. Diharapkan masyarakat UniMAP mengamalkan apa sahaja yang telah disyorkan dalam manual ini untuk memastikan persekitaran yang selamat untuk semua individu dan persekitaran sekeliling.

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TERMA RUJUKAN

Akta	Akta Biokeselamatan 2007 (Akta 678)
Peraturan	Bahagian II Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010
UniMAP	Universiti Malaysia Perlis
COSHE	Pusat Pengurusan Keselamatan, Kesihatan dan Persekitaran Pekerjaan
UniMAP BBC	*UniMAP Biosafety and Biosecurity Committee*
JBK	Jabatan Biokeselamatan, Kementerian Alam Sekitar dan Air
LBK	Lembaga Biokeselamatan Kebangsaan
GMAC	Ahli Jawatankuasa Penasihat Pengubahsuaian Genetik
PI	Penyelidik Utama
BSO	Pegawai Biokeselamatan
HIRARC	*Hazard Identification, Risk Assessment, and Risk Control*
DNA	Asid Deoksiribonukleik
RNA	Asid Ribonukleik
rDNA	DNA Rekombinan
LMO	Organisma Hidup Terubahsuai
GMO	Organisma Terubahsuai Genetik
ERT	Pasukan Bertindak Kecemasan
SOP	Prosedur Operasi Standard
KP	Ketua Pengarah
BSC	*Biosafety Cabinet*
BSL	Tahap Biokeselamatan
BSL-1	Tahap Biokeselamatan 1
BSL-2	Tahap Biokeselamatan 2
PPE	Peralatan Pelindungan Peribadi
SWP	*Safe Work Procedure*
BMBL	*Biosafety in Microbial and Biomedical Laboratories*
WHO	Pertubuhan Kesihatan Sedunia
ERP	Pelan Tindak Balas Kecemasan
PC	Pembedungan Fizikal
PIC	*Person In Charge*
CoE	Pusat Kecemerlangan Pendidikan
HOD	Ketua Jabatan
HVAC	*Heating, ventilation, and air conditioning*
PKU	Pusat Kesihatan Universiti UniMAP
JAS	Jabatan Alam Sekitar
JKes	Jabatan Keselamatan UniMAP

Seksyen 1:
Pengenalan

1.1. Kegunaan Manual

Manual ini dibangunkan bagi menyediakan maklumat yang diperlukan untuk melindungi semua pelajar, staf, dan fakulti di Universiti Malaysia Perlis (UniMAP) berserta persekitarannya daripada kemungkinan hazad yang berkaitan dengan penggunaan agen biologi berbahaya dan rekombinan atau molekul DNA/RNA sintetik. Manual ini bertujuan untuk mengendalikan bahaya biologi di lokasi universiti yang diluluskan. Biohazad di universiti tidak dibenarkan untuk dibawa keluar dari kampus ke kediaman persendirian atau untuk tujuan lain yang tidak berkaitan atau diluluskan untuk kegunaan institusi.

1.2. Keperluan Perundangan

Manual ini dibangunkan berpandukan kepada keperluan perundangan berikut:

a. Akta Biokeselamatan 2007 (Akta 678)
b. Bahagian II Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010
c. Polisi dan Garis Panduan Biokeselamatan dan Biosekuriti Makmal Malaysia 2015
d. Dasar Keselamatan dan Kesihatan Pekerjaan UniMAP

1.3. Objektif

a. Menentukan strategi perolehan, penggunaan, penyimpanan, pemindahan atau pelupusan bahan biologi dalam aktiviti penyelidikan dan pengajaran di UniMAP.
b. Mengenalpasti agen atau vektor berbahaya/berjangkit dan cara pengendaliannya untuk pembangunan dan penyelidikan berkaitan dengan patogen.
c. Menyemak dan meluluskan sebarang permohonan untuk melaksanakan sebarang aktiviti yang melibatkan penggunaan bahan biologi dalam makmal yang ditetapkan.
d. Memastikan setiap aktiviti melibatkan penggunaan bahan biologi memenuhi keperluan yang telah ditetapkan oleh perundangan negara Malaysia.

1.4. Skop

Manual ini terpakai kepada semua individu yang terlibat dalam aktiviti pengajaran dan pembelajaran dan penyelidikan di premis UniMAP yang mengendalikan bahan biologi.

Bahan biologi tersebut melibatkan tetapi tidak terhad kepada:

a. Semua mikroorganisma berjangkit/ patogen (contoh: virus, bakteria, kulat, parasit, prion, dll.) dan toksin yang diperolehi daripada organisma sedemikian yang boleh menjangkiti manusia atau menyebabkan kemudaratan terhadap alam sekitar atau pertanian, serta LMO/ GMO dan rekombinan atau molekul asid nukleik sintetik;
b. Darah manusia atau primata bukan manusia, plasma, serum, cecair badan, organ, tisu, dan sel;
c. Haiwan ujikaji serta komponen pepejal dan cecair yang terkandung di dalamnya;
d. Tumbuhan atau haiwan yang transgenik;
e. Kajian lapangan dengan haiwan liar dan tisu haiwan yang sememangnya dijangkiti atau akan dijangkiti melalui eksperimen dengan agen Tahap Biokeselamatan 2 (BSL-2) atau agen yang lebih tinggi.

Seksyen 2:
Struktur Pengurusan dan Tanggungjawab

2.1 Dasar Keselamatan dan Kesihatan Pekerjaan Universiti Malaysia Perlis

Universiti Malaysia Perlis komited untuk mewujudkan suasana kerja yang selamat, sihat dan melindungi alam sekitar melalui budaya kerjaya yang sistematik oleh setiap pekerja, pelajar, pelawat dan kontraktor. Dasar ini dijayakan dengan UniMAP memastikan langkah-langkah pelaksanaan dalam polisi tersebut dilaksanakan setakat yang praktik.

2.2 Keinstitusian Rasmi

Keinstitusian Rasmi menyediakan kepimpinan eksekutif dalam pelaksanaan dasar biokeselamatan, piawaian dan prosedur yang terpakai kepada Akta Biokeselamatan 2007 dan peraturan lain yang berkaitan mengenai LMO/rDNA, ejen/bahan berjangkit dan berpotensi berjangkit dan penyelidikan toksin biologi. Ia mesti juga menyediakan sokongan berterusan untuk keselamatan biologi dan biosekuriti institusi. Keinstitusian Rasmi mesti menubuhkan *UniMAP Biosafety and Biosecurity Committee* (UniMAP BBC) dan melantik Pegawai Biokeselamatan untuk memastikan bahawa semua peraturan keperluan untuk keselamatan dan keselamatan biologi dipenuhi. Bagi Universiti Malaysia Perlis, peranan ini dipegang oleh Naib Canselor. Timbalan Naib Canselor Penyelidikan dan Inovasi pula bertanggungjawab kepada Naib Canselor UniMAP sebagai Pengerusi bagi UniMAP BBC untuk pelaksanaan aspek biokeselamatan dalam Dasar Keselamatan dan Kesihatan Pekerjaan UniMAP.

2.3 Sektor Biokeselamatan, Pusat Pengurusan Keselamatan, Kesihatan dan Persekitaran Pekerjaan (COSHE)

2.3.1 Merancang dan menjalankan program berkaitan biokeselamatan.
2.3.2 Bertanggungjawab untuk membangunkan dan melaksanakan polisi dan prosedur yang diperlukan seperti permohonan, aduan, dan program kesedaran yang efektif.
2.3.3 Bertanggungjawab menerima dan memproses permohonan penyelidikan berkaitan dengan penggunaan bioteknologi moden.
2.3.4 Menyelaraskan UniMAP BBC.

2.4 *UniMAP Biosafety and Biosecurity Committee*

Di bawah Sektor Biokeselamatan COSHE, semua aktiviti yang melibatkan bahan biologi mesti disemak oleh UniMAP BBC. UniMAP BBC bertanggungjawab untuk:

2.4.1 Melapor dan memberi nasihat kepada Timbalan Naib Canselor Penyelidikan dan Inovasi yang menjalankan peranan sebagai Pengerusi UniMAP BBC.

2.4.2 Menyemak Borang Pemberitahuan dan Kelulusan, penyambungan dan penamatan yang dikemukakan tentang sebarang aktiviti yang melibatkan penggunaan bahan biologi untuk pematuhan Akta Biokeselamatan 2007 (Akta 678) dan Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010, mengemaskini dasar, undang-undang, peraturan dan garis panduan yang berkaitan dengan biokeselamatan dan biosekuriti pada peringkat nasional dan antarabangsa.

2.4.3 Memaklumkan kepada Penyelidik Utama (PI) mengenai status Borang Pemberitahuan dan Kelulusan yang dikemukakan.

2.4.4 Menyemak pematuhan semua aktiviti berdaftar yang melibatkan penggunaan bahan biologi secara berkala.

2.4.5 Mewujudkan dan menilai pelaksanaan program latihan biokeselamatan dan biosekuriti.

2.4.6 Memastikan langkah-langkah biosekuriti yang relevan dan sesuai dilaksanakan. Ini termasuk keselamatan fizikal, seperti infrastruktur, zon pembendungan dan keselamatan perimeter. Maklumat keselamatan termasuk pelan perlindungan keselamatan bangunan, kata laluan, inventori, dan maklumat tapak penyimpanan bahan biologi. Keselamatan kakitangan makmal termasuk pemeriksaan latar belakang atau pelepasan keselamatan. Prosedur untuk akauntabiliti dan kebolehkesanan semua bahan perlu dilaksanakan.

2.4.7 Melaporkan semua kejadian kepada pihak berkuasa yang berkaitan.

Ahli-ahli di bawah UniMAP BBC adalah terdiri daripada;

Pengerusi - Menilai dan meluluskan setiap permohonan penyelidikan berkaitan bahan biologi. Berhubung dengan semua agensi kawal selia untuk membantu hubungan antara organisasi, komuniti dan UniMAP BBC.

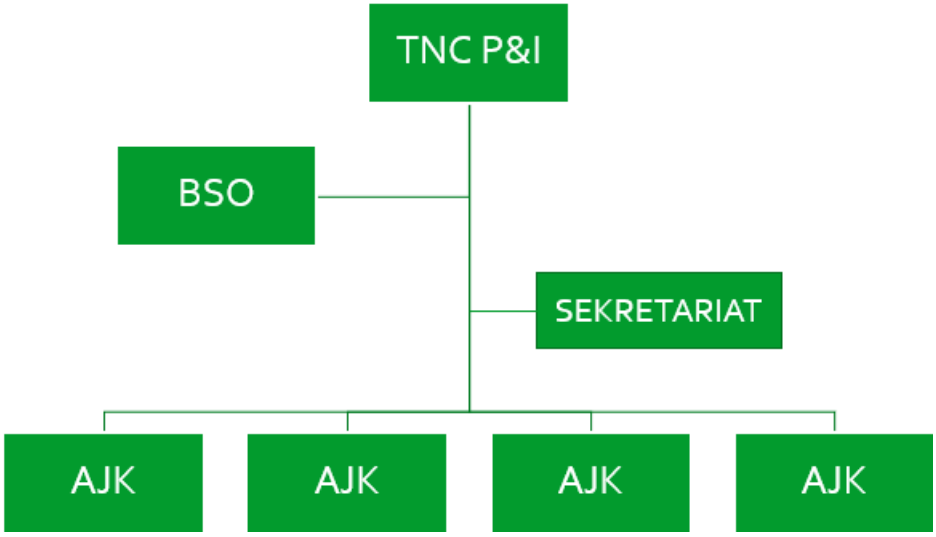
Pegawai Biokeselamatan - Memberi nasihat dan melaporkan hal-hal biokeselamatan dan biosekuriti di universiti. Mengemukakan semua permohonan untuk kelulusan dan

pemberitahuan dan laporan tahunan UniMAP BBC kepada Lembaga Biokeselamatan Kebangsaan (LBK) bagi pihak organisasi.

Sekreteriat - Merancang dan menjalankan program berkaitan biokeselamatan. Bertanggungjawab untuk membangunkan dan melaksanakan polisi dan prosedur yang diperlukan seperti permohonan, aduan, dan program kesedaran yang efektif. Menyelaraskan UniMAP Biosafety and Biosecurity Committee (UniMAP BBC).

Ahli Jawatankuasa - Bertanggungjawab untuk memastikan penyelidikan dan semua aktiviti lain yang melibatkan bahan biologi disemak dan diluluskan dengan selamat dan sesuai mengikut peraturan, dasar dan prosedur persekutuan, negeri dan institusi.

Carta organisasi UniMAP BBC:



Carta 1: Carta Organisasi UniMAP BBC

Tempoh pelantikan bagi keahlian UniMAP BBC adalah selama dua tahun.

2.5 Pegawai Biokeselamatan

Pegawai Biokeselamatan (BSO) ialah ahli UniMAP BBC yang dilantik dan diberi kuasa oleh Ketua Organisasi untuk memberi nasihat dan melaporkan aktiviti dan hal-hal berkaitan isu biokeselamatan dan biosekuriti. BSO juga membantu UniMAP BBC dalam memastikan universiti mematuhi arahan Sektor Biokeselamatan COSHE dan agensi lain yang berkaitan.

BSO harus melaksanakan fungsi berikut:

2.5.1 Menjalankan pemeriksaan secara berkala di semua makmal yang terlibat di mana penyelidikan bahan biologi dijalankan bagi memantau pematuhan standard makmal.
2.5.2 Melaporkan kepada UniMAP BBC sebarang masalah berkaitan isu biokeselamatan, ketidakpatuhan terhadap Akta Biokeselamatan 2007 (Akta 678) dan sebarang kemalangan berkaitan penyelidikan yang ketara atau penyakit yang BSO dapati, melainkan BSO menentukan bahawa laporan telah difailkan oleh Penyelidik Utama (PI).
2.5.3 Memberi panduan kepada PI dalam membangunkan pelan tindak balas kecemasan untuk mengendalikan dan menyiasat kemalangan makmal yang melibatkan bahan biologi.
2.5.4 Bekerjasama dengan Pasukan Bertindak Kecemasan (ERT) untuk memberikan nasihat teknikal tentang keselamatan penyelidikan dan prosedur keselamatan makmal kepada PI, kakitangan makmal dan UniMAP BBC.
2.5.5 Berkhidmat sebagai pegawai perhubungan antara organisasi/institusi dan agensi pengawal seliaan luar mengenai penggunaan bahan biologi. BSO bertanggungjawab mengemukakan laporan tahunan bagi UniMAP BBC kepada Jabatan Biokeselamatan (JBK) bagi pihak organisasi.
2.5.6 Berkhidmat sebagai ahli mengundi UniMAP BBC.

2.6 Dekan dan Ketua Jabatan

Dekan dan Ketua Jabatan bertanggungjawab ke atas keseluruhan pengendalian penyelidikan saintifik dan aktiviti pengajaran yang dijalankan di Fakulti masing-masing.

2.7 Pengurus Makmal dan Fasiliti

Pengurus makmal dan fasiliti bertanggungjawab untuk semua perkara berkaitan dasar, prosedur operasi standard (SOP), prosedur dan teknik yang merangkumi pembangunan, penilaian, kelulusan, pemantauan, dan semakan.

2.8 Penyelidik Utama

Penyelidik utama (penyelia akademik atau penyelia projek penyelidikan) adalah bertanggungjawab terhadap kesihatan dan keselamatan pelajar atau staf di bawah seliaan serta memastikan mereka telah menerima kursus dan latihan yang berkaitan dengan keselamatan makmal dan biokeselamatan.

Penyelidik utama juga perlu memastikan pelajar/staf di bawah seliaannya telah membuat penilaian risiko (*risk assessment*) dengan mengisi borang penilaian risiko sebelum memulakan aktiviti penyelidikan.

Penyelidik utama yang terlibat dengan pengendalian LMO/rekombinan DNA adalah tertakluk kepada Akta Biokeselamatan 2007 (Akta 678), Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010 dan peraturan lain yang berkaitan.

Penyelidik utama bertanggungjawab mendaftarkan semua aktiviti yang melibatkan penggunaan bahan biologi dan memastikan semua aktiviti tersebut mematuhi dasar, garis panduan, dan peraturan-peraturan berkaitan biosekuriti dan biokeselamatan. Penyelidik utama:

2.8.1 perlu memastikan tiada sebarang perubahan yang melibatkan pertukaran kepada aras BSL/*Risk Group* atau pertukaran premis penyelidikan yang telah dinilai oleh IBBC pada projek penyelidikan yang melibatkan LMO/rDNA.

2.8.2 melaporkan sebarang masalah yang signifikan terhadap aktiviti penyelidikan yang melibatkan perundangan, peraturan dan garis panduan biokeselamatan.

2.8.3 melaporkan sebarang kemalangan yang boleh menyebabkan sebarang penyakit/jangkitan kepada manusia, haiwan atau tumbuhan ATAU pelepasan organisma di dalam kajian secara tidak sengaja daripada makmal penyelidikan.

2.8.4 telah menamatkan latihan seperti yang dinyatakan di dalam *Guidelines for Institutional Biosafety Committees, Chapter 5.*

2.8.5 Membangunkan dan mendapatkan kelulusan UniMAP BBC bagi rancangan tindak balas kecemasan (*emergency response plans*) bagi menangani tumpahan tidak sengaja dan pencemaran kepada kakitangan, dan perlu mematuhi sepenuhnya perancangan tersebut.

2.8.6 Perlu mematuhi semua keperluan perundangan ketika melaksanakan penyelidikan melibatkan LMO/rDNA.

2.9 Kakitangan dan Pelajar

Kakitangan dan pelajar yang terlibat dalam penggunaan bahan biologi hendaklah dilatih dalam biosekuriti dan biokeselamatan makmal, termasuk *Good Microbiological Technique* (GMT), *Good Laboratory Practices* (GLP), dan amalan lain yang berkaitan.

Kakitangan dan pelajar perlu melaporkan sebarang kemalangan dan kejadian yang melibatkan bahan biologi kepada PIC makmal berkaitan dan COSHE.

2.10 Pemberitahuan dan Kelulusan Projek diproses oleh UniMAP BBC

UniMAP BBC dan penyelidik perlu mematuhi Akta Biokeselamatan 2007 (Akta 678) dan Bahagian II Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010. Tujuan akhir proses ini adalah untuk mengawal selia pelepasan, pengimportan dan penggunaan terkawal LMO, dan produk organisma tersebut.

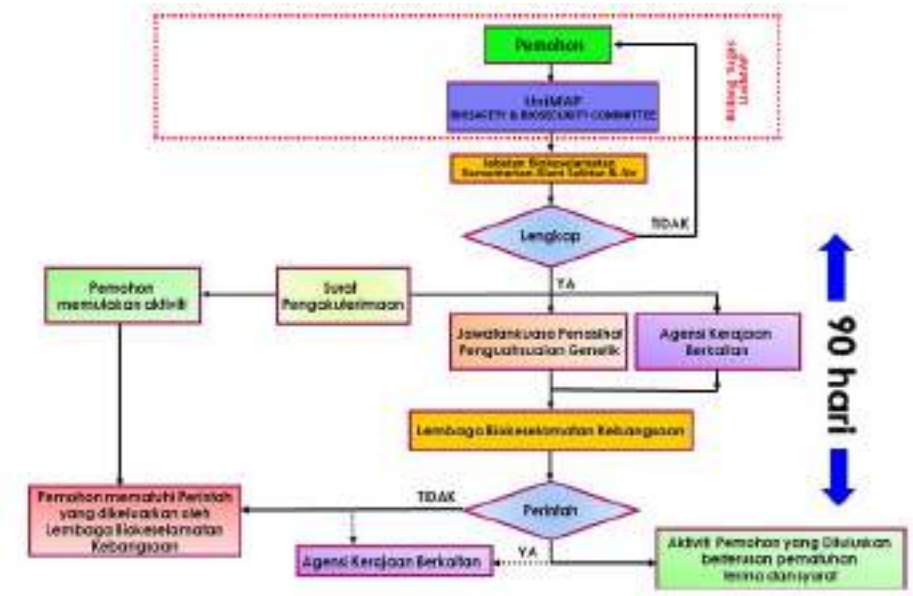
2.10.1 Pemberitahuan

Pemberitahuan perlu dihantar kepada LBK bagi semua aktiviti kegunaan terkawal yang melibatkan LMO, dan juga untuk tujuan pengeksportan LMO.

2.10.1.1 Proses Pemberitahuan

1. Bagi aktiviti penyelidikan atau eksperimen, ketua penyelidik perlu menghantar borang pemberitahuan (Borang E/Borang F) kepada UniMAP BBC.
2. Pemberitahuan disemak oleh UniMAP BBC dan diserahkan kepada Ketua Pengarah (KP) Jabatan Biokeselamatan dengan cara yang ditetapkan dan disertakan dengan:
    a. Pelan tindakan kecemasan
    b. Langkah-langkah khusus untuk aktiviti penggunaan yang terkawal
3. KP hendaklah mengeluarkan pengakuan penerimaan pemberitahuan yang dikemukakan. Apabila menerima pengakuan, yang diberitahu boleh menjalankan aktiviti yang berkaitan dengan pemberitahuan itu.
4. KP hendaklah merujuk Pemberitahuan kepada Jawatankuasa Penasihat Pengubahsuaian Genetik (GMAC) dan agensi berkaitan untuk syornya.
5. GMAC kemudiannya akan mengemukakan syornya mengenai pemberitahuan kepada Lembaga Biokeselamatan Kebangsaan (LBK).
6. Setelah mempertimbangkan syor dari GMAC, LBK boleh untuk tidak membuat perintah, mengeluarkan perintah pemberhentian, mengenakan terma dan syarat sedemikian, memerintahkan orang yang diluluskan untuk membuat pembetulan atau membuat apa-apa perintah lain yang difikirkan sesuai oleh LBK demi kepentingan biokeselamatan.

2.10.1.2 Carta Alir Proses Pemberitahuan



Carta 2: Carta alir proses Pemberitahuan bagi aktiviti kegunaan LMO terkawal.

2.10.1.3 Yuran Pemberitahuan

Tiada pembayaran yuran.

2.10.1.4 Borang Pemberitahuan

- **Borang E** (Pemberitahuan untuk aktiviti penggunaan terkawal dan aktiviti import untuk aktiviti penggunaan yang terkawal yang melibatkan LMO untuk Tahap Biokeselamatan 1, 2, 3 dan 4).

- **Annex 2** (Penilaian UniMAP BBC Terhadap Cadangan Projek Melibatkan Aktiviti Bioteknologi Moden)

- **Borang F** (Pemberitahuan untuk **eksport** LMO)

2.10.2 Kelulusan

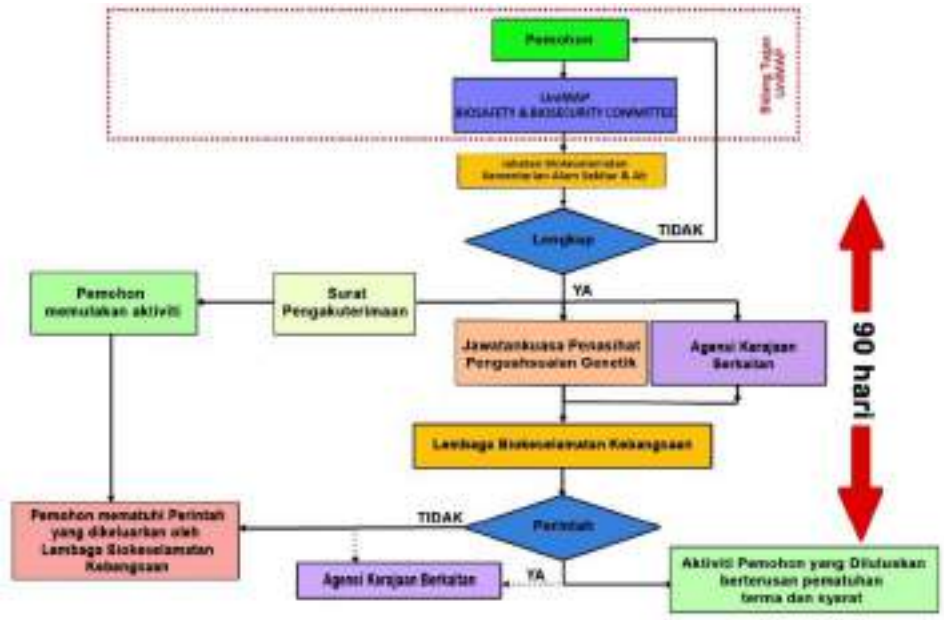
Semua keluaran dan import LMO dan produk sedemikian adalah dilarang melainkan diluluskan oleh LBK. Aktiviti pelepasan seperti yang dinyatakan dalam jadual ke-2 (Seksyen 3) dalam Akta Biokeselamatan 2007 (Akta 678) adalah:

- Untuk tujuan penyelidikan dan pembangunan dalam semua eksperimen lapangan
- Sebagai bekalan atau tawaran untuk membekalkan untuk dijual atau diletakkan di pasaran
- Tawarkan sebagai hadiah, hadiah atau item percuma
- Pelupusan
- Tujuan pemulihan
- Apa-apa aktiviti lain yang tidak termasuk penggunaan terkawal

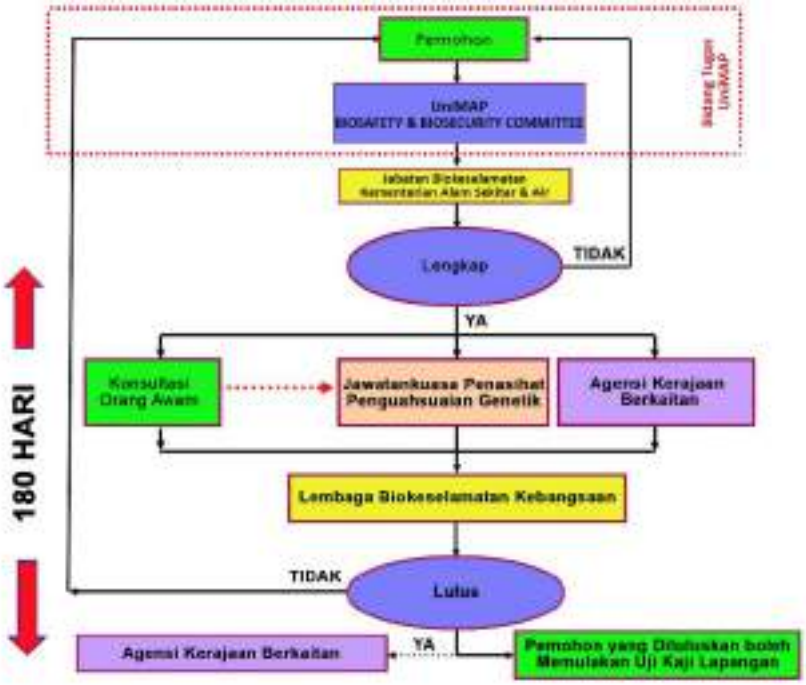
2.10.2.1 Proses Permohonan Kelulusan

1. Untuk permohonan kelulusan, PI menyerahkan Borang Kelulusan (Borang A, B, C atau D) yang lengkap kepada UniMAP BBC.
2. Borang kelulusan disemak oleh UniMAP BBC dan diserahkan kepada KP mengikut cara yang ditetapkan, bersama-sama dengan yuran yang ditetapkan, dan disertakan dengan:
    - penilaian risiko dan laporan pengurusan risiko
    - pelan respons kecemasan
    - maklumat lain seperti yang dinyatakan oleh LBK
3. Sebaik sahaja permohonan diterima, KP akan:
    - merujuk kepada GMAC untuk syornya
    - merujuk kepada agensi kerajaan yang berkaitan untuk perkara-perkara tertentu
    - menjemput penyertaan awam untuk tujuan pendedahan awam
4. GMAC hendaklah mengemukakan syornya sama ada permohonan itu perlu diluluskan serta terma dan syarat yang akan dikenakan oleh LBK, jika ada, selepas penilaian.
5. Selepas mempertimbangkan syor GMAC, ulasan jabatan atau agensi yang berkaitan, pandangan masyarakat, jika ada, dan sebarang maklumat tambahan, LBK boleh meluluskan permohonan itu dengan mengeluarkan sijil kelulusan atau menolak permohonan.

2.10.2.2 Carta Alir Proses Proses Kelulusan



Carta 3: Carta alir proses kelulusan bagi aktiviti kegunaan LMO terkawal.



Carta 4: Carta alir proses kelulusan bagi uji kaji lapangan LMO.

2.10.2.3 Yuran Kelulusan

Untuk aktiviti pelepasan, Peraturan menetapkan bayaran seperti berikut:

I. Untuk tujuan R&D dalam semua eksperimen lapangan setiap tapak keluaran:
   - kurang daripada 5 hektar – RM 100
   - 5 hektar hingga 10 hektar – RM 250
   - Lebih daripada 10 hektar – RM 500

II. Semua aktiviti pelepasan selain daripada di atas – RM 5000.

Yuran hendaklah dibayar melalui kiriman wang atau draf bank atas nama Ketua Setiausaha, Kementerian Alam Sekitar dan Air.

2.10.2.4 Borang Kelulusan Berkaitan

- **Borang A** [Kelulusan untuk **aktiviti keluaran LMO** (tujuan penyelidikan dan pembangunan dalam semua eksperimen lapangan) atau **pengimportan** LMO yang merupakan tumbuhan peringkat tinggi]

  Penerangan**:**
  Borang ini digunakan untuk menjalankan uji kaji lapangan yang melibatkan organisma hidup yang diubah suai (LMO) yang terdiri daripada tumbuhan peringkat tinggi. LMO tumbuhan tersebut boleh diimport ataupun dihasilkan di dalam negara untuk digunakan sebagai bahan uji kaji lapangan.

- **Borang B** [Kelulusan untuk **aktiviti keluaran LMO** (tujuan penyelidikan dan pembangunan dalam semua eksperimen lapangan) atau **pengimportan** LMO selain tumbuhan peringkat tinggi]

  Penerangan:
  Borang ini digunakan untuk menjalankan uji kaji lapangan yang melibatkan organisma hidup yang diubah suai (LMO) yang bukan terdiri daripada tumbuhan peringkat tinggi. LMO tersebut boleh diimport ataupun dihasilkan di dalam negara untuk digunakan sebagai bahan uji kaji lapangan.

- **Borang C** [Kelulusan untuk **aktiviti pelepasan** (jadual kedua ke-2 hingga 6 dalam Akta Biokeselamatan 2007) atau **pengimportan** LMO yang merupakan tumbuhan dan produk organisma peringkat tinggi]

  Penerangan:
  Borang ini digunakan untuk menjalankan aktiviti pelepasan yang melibatkan organisma hidup yang diubah suai (LMO) yang terdiri daripada tumbuhan peringkat tinggi serta produk tumbuhan LMO. LMO tumbuhan dan produk tumbuhan LMO tersebut boleh diimport untuk aktiviti pelepasan ataupun dihasilkan di dalam negara untuk tujuan aktiviti pelepasan.

- **Borang D** [Kelulusan untuk **aktiviti pelepasan** (jadual kedua ke-2 hingga 6 dalam Akta Biokeselamatan 2007) LMO selain daripada tumbuhan dan produk organisma peringkat tinggi]

  Penerangan:
  Borang ini digunakan untuk menjalankan aktiviti pelepasan yang melibatkan organisma hidup yang diubah suai (LMO) yang bukan terdiri daripada tumbuhan peringkat tinggi serta produk LMO tersebut boleh diimport untuk aktiviti pelepasan ataupun dihasilkan di dalam negara untuk tujuan aktiviti pelepasan.

- **Borang Annex 2** [Penilaian UniMAP BBC terhadap Cadangan Projek yang Melibatkan Aktiviti Bioteknologi Moden]

  Penerangan:
  Borang ini perlu digunakan semasa UniMAP BBC membuat penilaian aktiviti ujikaji lapangan sebelum penghantaran boring permohonan kelulusan kepada Jabatan Biokeselamatan.

Seksyen 3:
Penilaian Risiko dan Pengurusan

3.1 Penilaian Risiko

Borang *Hazard Identification, Risk Assessment and Risk Control* (HIRARC) diperlukan untuk semua kerja melibatkan bahan biologi. Maklumat yang diminta pada borang penilaian risiko adalah perlu supaya UniMAP BBC atau PI mempunyai maklumat yang mencukupi untuk memutuskan sama ada kerja-kerja biologi boleh dijalankan dengan selamat di dalam makmal dilengkapi untuk memenuhi keperluan biokeselamatan. Borang HIRARC juga meliputi pematuhan undang-undang dan kaedah terbaik pelaksanaan kerja dengan selamat. Borang HIRARC boleh dirujuk pada Lampiran C dan boleh didapati secara atas talian dari laman sesawang COSHE.

Borang Pemberitahuan atau Kelulusan diperlukan bagi semua projek yang melibatkan LMO, rDNA, dan teknik sintetik. UniMAP BBC bertanggungjawab untuk memantau kesemua projek berkaitan LMO, rekombinan, dan biologi sintetik dan kemudian melaporkan projek-projek tersebut secara tahunan kepada Jabatan Biokeselamatan. Borang Pemberitahuan atau Kelulusan untuk melakukan penyelidikan atau kerja-kerja melibatkan LMO, rDNA, dan biologi sintetik boleh dirujuk pada Lampiran B dan boleh didapati secara atas talian dari laman sesawang COSHE.

3.2 Pengurusan Risiko

3.2.1 Hierarki Kawalan

Borang penilaian risiko mengikuti proses pengurusan risiko yang diterima secara global yang dikenali sebagai hierarki kawalan. Hierarki kawalan mewujudkan pendekatan sistematik untuk mengurus risiko biologi dengan selamat dengan menyediakan struktur untuk memilih langkah kawalan yang paling berkesan untuk menghapuskan atau mengurangkan risiko bahaya yang berkaitan dengan projek penyelidikan tertentu. Hierarki kawalan mempunyai enam peringkat kawalan; ukuran yang paling berkesan adalah di bahagian atas, yang paling kurang berkesan di bahagian bawah. Sebagai amalan terbaik, disyorkan untuk cuba menggabungkan penggunaan kawalan mewah seperti penyingkiran, penggantian, pengasingan dan kawalan kejuruteraan berbanding dengan penggunaan kawalan akhir rendah seperti pentadbiran dan penggunaan alat pelindung diri. Hierarki kawalan disertakan dalam semua Borang *Hazard Identification Risk Assessment Risk Consequence* (HIRARC) untuk menyediakan pendekatan sistematik untuk menguruskan risiko yang berkaitan dengan bahaya penyelidikan biologi.

Hierarki kawalan melibatkan enam (6) langkah berikut:

1. **Penghapusan** – keluarkan punca bahaya sepenuhnya (cth. nyahaktifkan sumber berjangkit).
2. **Penggantian** – mengawal bahaya dengan menggantikannya dengan cara yang kurang berisiko untuk mencapai hasil yang sama (cth. penggunaan organisma yang kurang patogenik).
3. **Pengasingan** – memisahkan bahaya daripada orang yang berisiko dengan mengasingkannya (cth. Kabinet biokeselamatan Kelas II).
4. **Kejuruteraan/biokejuruteraan** –Tambahkan ciri keselamatan fizikal atau biologi pada loji atau peralatan (cth. Kemudahan pembendungan fizikal, vaksin).
5. **Pentadbiran** – penggunaan kawalan pentadbiran untuk mengurangkan risiko (cth. papan tanda, penilaian risiko dan prosedur kerja selamat, latihan).
6. **Peralatan Pelindungan Peribadi (PPE)** – menyediakan penghalang peribadi antara pengguna dan bahan berjangkit/toksik (cth. sarung tangan, pelindung mata dan kot makmal).

3.2.2 Tanggungjawab Penyelidik Utama

Penyelidik Utama perlu memastikan:

- Kakitangan penyelidik dan teknikal telah membaca penilaian risiko sebelum kerja bermula.
- Salinan cetak penilaian risiko tersedia di makmal untuk rujukan.
- Kakitangan penyelidik dan teknikal telah menerima latihan dan/atau penyeliaan yang mencukupi untuk dibenarkan mereka untuk bekerja dan mengendalikan agen dan bahan biologi dengan cara yang selamat.
- Peralatan yang rosak dilaporkan dan dikeluarkan daripada perkhidmatan apabila terdapat bahaya.
- Prosedur Kerja Selamat (Safe Work Procedures, SWPs) dipatuhi.
- Peraturan keselamatan dipatuhi.
- Peralatan kecemasan diservis.
- Tahap pembendungan fizikal adalah sesuai untuk kumpulan risiko.
- Insiden, kemalangan dan kejadian nyaris dilaporkan kepada COSHE.
- Pemeriksaan pematuhan tetap dan lawatan keselamatan dijalankan dan sebarang penemuan didokumenkan.

3.2.3 Tanggungjawab kakitangan penyelidikan dan teknikal

Kakitangan penyelidikan dan teknikal termasuk, tetapi tidak terhad kepada kakitangan, pelajar, kakitangan penjagaan haiwan, pembantu penyelidik dan sukarelawan. Kakitangan penyelidik mesti memastikan bahawa mereka:

- Baca penilaian risiko yang berkaitan dan bahan panduan yang berkaitan.
- Patuhi semua Prosedur dan garis panduan Kerja Selamat yang berkaitan.
- Laporkan sebarang peralatan yang rosak.
- Hadiri latihan yang diperlukan.
- Bercakap dengan penyelia atau pengurus makmal tentang sebarang kebimbangan keselamatan.
- Mematuhi peraturan dan garis panduan keselamatan yang berkaitan.

Seksyen 4:
Mikroorganisma dan Bahaya Biologi

4.1 Pengenalan

Makmal mengandungi banyak potensi bahaya biologi. Ini termasuk bekerja dengan mikroorganisma (bakteria, kulat, virus dan parasit), LMO, manusia, haiwan, dan tisu yang berkaitan dan bahan biohazardous seperti prion, darah manusia, produk darah, cecair badan dan mentah dan dirawat pembetungan. Apabila mengendalikan mikroorganisma, mereka mesti dianggap sebagai patogen yang mungkin dan diuruskan dengan prosedur mikrobiologi prinsip. Teknik sedemikian membantu meminimumkan risiko kepada kakitangan makmal persekitaran dan untuk mengekalkan ketulenan strain isolat. Semua bekerja dengan mikroorganisma dan bahan biohazardous mesti dijalankan mengikut garis panduan dalam *Biosafety in Microbiological and Biomedical Laboratories* (BMBL).

Tahap kejangkitan bagi setiap mikroorganisma berbeza. Ini boleh dikaitkan dengan pelbagai portal penyertaan (kulit, pengambilan atau melalui saluran pernafasan), fisiologi mikroorganisma, dos infektif dan keupayaan mikroorganisma untuk melepasi imuniti intrinsik dan perlindungan perumah yang berbeza.

Jangkitan yang diperolehi makmal mungkin timbul melalui:

- Penyedutan melalui penghasilan aerosol daripada proses seperti sentrifugasi, pipet, membuka kultur atau gelung tercemar yang menyala.
- Tertelan akibat terpercik secara tidak sengaja ke dalam mulut atau tangan yang tercemar.
- Kecederaan tajam melalui tusukan jarum, luka dengan kaca tercemar, dan gigitan dan calar daripada haiwan.
- Pindahkan melalui luka terbuka atau melintasi membran mukosa (mata, mulut dan hidung).

4.2 Kumpulan Risiko

Pertubuhan Kesihatan Sedunia (WHO) mengklasifikasikan mikroorganisma berjangkit ke dalam kumpulan berisiko. Amalan kerja yang selamat dan tahap pembendungan fizikal untuk setiap kumpulan diberikan secara terperinci di bawah. Senarai risiko organisma kumpulan 1, 2, 3 dan 4 boleh dirujuk pada Lampiran A.

Klasifikasi kumpulan risiko untuk mikroorganisma berjangkit manusia dan haiwan

Klasifikasi kumpulan risiko untuk manusia dan haiwan adalah berdasarkan patogenik agen, mod penghantaran, julat hos, kebolehcapaian kepada langkah pencegahan dan kebolehcapaian kepada rawatan yang berkesan.

Kumpulan risiko 1 (risiko rendah kepada individu dan komuniti) – mikroorganisma yang tidak mungkin membawa penyakit kepada manusia atau haiwan.

Kumpulan risiko 2 (risiko sederhana kepada individu, risiko terhad kepada komuniti) – mikroorganisma yang tidak mungkin risiko kritikal kepada pekerja di makmal, komuniti, ternakan atau persekitaran. Pendedahan dalam makmal mungkin membawa jangkitan, walau bagaimanapun rawatan yang berkesan dan tindakan pencegahan adalah mudah di tangan, oleh itu terdapat risiko yang terhad untuk merebak.

Kumpulan risiko 3 (berisiko tinggi kepada individu, terhad kepada risiko sederhana kepada komuniti) – mikroorganisma yang membawa penyakit yang menjejaskan manusia atau haiwan dan mungkin menjadi risiko kritikal kepada pekerja di makmal. Ia adalah juga kemungkinan terhad kepada risiko sederhana jika ia tersebar dalam komuniti atau persekitaran, walau bagaimanapun, biasanya langkah pencegahan atau rawatan yang berkesan akan sedia ada.

Kumpulan risiko 4 (berisiko tinggi kepada individu dan komuniti) – mikroorganisma yang biasanya membawa penyakit yang mengancam nyawa manusia atau haiwan, memberikan risiko kritikal kepada pekerja di makmal dan mungkin mudah berjangkit dari individu ke individu. Biasanya, rawatan dan pencegahan yang berkesan langkah-langkah tidak sedia ada.

4.3 Pembendungan Fizikal

Pembendungan mikroorganisma memerlukan gabungan bangunan, kejuruteraan, peralatan, pekerja amalan dan latihan untuk mengurus mikroorganisma dengan betul dan selamat. Istilah yang digunakan untuk menerangkan kaedah dan susunan yang digariskan untuk mengurangkan atau menyekat pelepasan organisma berdaya maju ke luar persekitaran adalah pembendungan fizikal. Tahap pembendungan fizikal yang digunakan berkaitan dengan kumpulan risiko pengelasan mikroorganisma, contohnya, Pembendungan Fizikal Tahap 2 untuk kumpulan risiko 2. Dalam sesetengah keadaan tahap pembendungan fizikal yang diperlukan untuk mikroorganisma tertentu mungkin bergantung pada kerja yang dilakukan (cth. *Human Immunodeficiency Virus* yang diklasifikasikan sebagai kedua-dua kumpulan risiko 2 dan 3 mikroorganisma). Terdapat empat klasifikasi Kemudahan Penahanan Fizikal dan dikenal pasti dengan awalan ‘PC’ (*physical containment*) diikuti dengan nombor 1 – 4. Tidak semua makmal yang beroperasi di dalam Universiti adalah kemudahan pembendungan yang diperakui.

Beberapa jenis GMO dan urusan berkaitan kuarantin diperlukan dijalankan di kemudahan yang diperakui.

Kemudahan PC1 – Makmal atau kemudahan PC 1 paling sesuai untuk mengendalikan mikroorganisma dengan bahaya yang rendah tahap yang memastikan kakitangan makmal atau kemudahan dilindungi secukupnya oleh makmal standard amalan. Makmal peringkat ini biasanya sesuai untuk makmal pengajaran sarjana muda. Spesimen yang tidak aktif atau tetap boleh diuruskan dalam kemudahan PC 1.

Kemudahan PC2 – Makmal atau Kemudahan PC2 diperlukan untuk mengendalikan mikroorganisma atau bahan yang mungkin mengandungi mikroorganisma kumpulan 2 risiko. Kabinet keselamatan biologi mesti digunakan semasa berurusan dengan spesimen yang terdiri daripada mikroorganisma yang boleh dihantar melalui laluan pernafasan atau apabila berurusan dengan kerja yang menimbulkan risiko kritikal kepada manusia atau persekitaran melalui pembuatan aerosol berjangkit.

Kemudahan PC3 – Makmal atau kemudahan PC3 diperlukan untuk mengendalikan mikroorganisma atau bahan yang berkemungkinan mengandungi mikroorganisma daripada kumpulan risiko 3. Makmal atau kemudahan PC3 membekalkan bangunan tambahan ciri dan perkhidmatan untuk mengurangkan risiko jangkitan kepada individu, komuniti dan persekitaran.

Kemudahan PC4 – Ini adalah tahap Pembendungan Fizikal tertinggi dan kerana sangat berbahaya sifat kerja yang dikendalikan di sini, terdapat keperluan ketat dalam kemudahan ini yang mesti dipatuhi dengan. Tahap makmal atau kemudahan ini diperlukan untuk mengendalikan mikroorganisma yang diklasifikasikan sebagai kumpulan risiko 4 mikroorganisma dan agen berbahaya yang lain.

Seksyen 5:
Organisma Hidup Terubahsuai (LMO)

5.1 Organism Hidup Terubahsuai

"Organisma hidup terubahsuai" (LMO) di dalam Akta Biokeselamatan ditakrifkan sebagai mana-mana organisma hidup yang mempunyai gabungan bahan genetik baharu yang diperolehi melalui penggunaan bioteknologi moden (Sub Bahagian 5.3). Gabungan bahan genetik baharu ini tidak berlaku secara semulajadi. Oleh itu, baka baharu atau strain haiwan atau tumbuhan yang dihasilkan melalui pemilihan, pembiakan kacukan atau pendebungaan kacukan tidak termasuk di bawah takrifan LMO. Sub Bahagian 5.2 dan 5.3 masing-masing menerangkan istilah "organisma hidup" dan "bioteknologi moden" bagi memahami dengan lebih mendalam takrifan LMO.

5.2 Organisma Hidup

Di dalam Akta Biokeselamatan 2007, "Organisma hidup" ditakrifkan sebagai mana-mana entiti biologi yang mampu memindahkan atau mereplikasi bahan genetik. Takrifan ini merangkumi semua prokariot dan eukariot; unisel dan multisel; mikro dan makro organisma. Semua organisma ini membawa bahan genetik mereka dalam bentuk bebenang DNA, yang seterusnya boleh disusun dengan pelbagai cara. Sebagai contoh, DNA kebanyakan bakteria boleh disusun sebagai plasmid ringkas tanpa struktur sokongan yang kompleks, manakala DNA organisma eukariot yang lebih maju disusun sebagai bebenang yang panjang dan berbilang kromosom dengan struktur yang lebih kompleks. Semua organisma ini mempunyai keupayaan untuk mereplikasi bahan genetik mereka dan memindahkannya kepada keturunan seterusnya.

Di dalam manual ini, bahan genetik bagi sesuatu organisma adalah termasuk gen, berbilang gen, bahagian daripada gen, kumpulan gen, serpihan kecil DNA, kawasan yang tidak diterjemahkan, sebahagian daripada genom atau keseluruhan genom. Dalam kes tertentu, organisma mungkin tidak dapat membiak dan memindahkan bahan genetiknya kepada progeni, i.e. menjadi steril/mandul. Walau bagaimanapun, organisma sedemikian juga termasuk di dalam takrifan "organisma hidup" menurut manual ini.

Di samping itu, takrifan "organisma hidup" mengikut konteks manual ini meliputi virus dan viroid, yang mungkin tidak mempunyai ciri-ciri konvensional organisma hidup. Oleh itu, virus dan viroid yang membawa bahan genetiknya dalam bentuk RNA dan bukan DNA juga termasuk dalam takrifan sebagai "organisma hidup" dalam manual ini.

5.3 Bioteknologi Moden

“Bioteknologi Moden” ditakrifkan sebagai aplikasi mana-mana sistem atau metodologi inventif untuk memanipulasi, mengganggu, mengubah suai atau melakukan sebarang perubahan ke dalam susunan atau gabungan sedia ada dalam bahan genetik mana-mana organisma melangkau halangan pembiakan normal organisma. Perkara 3 di dalam Protokol Cartagena mentakrifkan “Bioteknologi Moden” sebagai penggunaan teknik asid nukleik in vitro, atau gabungan sel di luar taksonomi spesis, mengatasi halangan pembiakan atau gabungan semula fisiologi semula jadi dan bukan teknik yang digunakan dalam pemilihan dan pembiakan tradisional. Bioteknologi moden yang dirangkum di dalam definisi ini termasuklah (tetapi tidak terhad kepada):

5.3.1 Teknik in vitro asid nukleik

Teknologi ini melibatkan pemindahan dan pengaturan serpihan DNA dan RNA yang baharu ke dalam perumah. Pelbagai kaedah digunapakai di dalam teknologi ini termasuklah vektor mikrob/virus, mikroprojektil pengeboman, teknik transformasi kimia, lipofeksi, peneutralan polikation dan suntikan mikro. DNA yang baharu dibentuk akan berintegrasi ke dalam perumah genom atau berada di dalam sel perumah secara berasingan. Sel perumah yang ditransformasi, dimana mengandungi serpihan DNA atau RNA yang baharu akan menunjukkan tingkah laku yang berbeza daripada sel asal, seperti penghasilan protein baharu, rintang terhadap keadaan persekitaran tertentu, pertumbuhan lebih cepat dan dapat peningkatan percambahan. Pelbagai istilah digunakan bagi merujuk kepada kemasukkan gen baharu yang disengajakan kepada sel perumah:

I. Transformasi
Istilah ini merujuk kepada pemindahan bahan genetik bukan virus dengan sengaja ke dalam bakteria atau sel perumah bukan haiwan eukariotik.

II. Transfeksi
Istilah ini merujuk kepada pemindahan bahan genetik bukan virus dengan sengaja ke dalam sel perumah haiwan.

III. Transduksi
Istilah ini merujuk kepada pemindahan bahan genetik yang dipindahkan secara sengaja oleh virus ke dalam sel perumah eukariotik.

5.3.2 Pergabungan sel somatik

Teknologi ini melibatkan gabungan dua sel di luar taksonomi sesuatu spesis samada haiwan atau pun tumbuhan secara kaedah kultur sel atau tisu. Di dalam bidang bioteknologi haiwan, pergabungan sel somatik diantara dua spesis berbeza (sel manusia dan roden) akan menghasilkan sel hibrid selepas berlakunya pergabungan DNA atau RNA. Sel hibrid yang terhasil berupaya menghasilkan produk (antibodi atau antigen) untuk proses ekspresi protein bagi gen tertentu. Manakala di dalam bioteknologi tumbuhan, pemencilan protoplas daripada dua tumbuhan yang berlainan spesis yang tidak serasi secara seksual digabungkan menggunakan agen kimia. Teknologi ini membolehkan pergabungan baharu genotip berbeza melangkau halangan ketidak serasian had seksual, dimana sukar berlaku secara semulajadi.

5.3.3 Kaedah-kaedah lain

Teknologi lain yang melibatkan manipulasi DNA atau RNA sel hidup secara langsung, yang mana akan dibawa oleh organisma sepanjang hayat dan/atau dipindahkan kepada progeni atau keturunannya.

Secara ringkasnya, manual ini mengawal selia:

Entiti biologi yang mampu memindahkan atau mereplikasikan bahan genetik yang dimiliki oleh gen mereka atau bahan genetik diubahsuai dengan mana-mana teknik selain daripada:

- Pembiakan tradisional
- Pemilihan tradisional; dan
- Teknik yang diterangkan di dalam Peraturan.

Seksyen 6:
Pelan Tindak Balas Kecemasan

Kecemasan makmal adalah termasuk: kebakaran, letupan (dengan atau tanpa kebakaran yang disertakan), kecemasan perubatan, dan tumpahan atau pelepasan bahan berbahaya / berjangkit. Apabila kecemasan berlaku, adalah penting bahawa kakitangan makmal bertindak balas dengan cepat terhadap sebarang keadaan dengan mengamankan kawasan kerja, menutup semua pintu, melaporkan kecemasan dengan segera ke talian kecemasan dan memberikan maklumat situasi untuk responden kecemasan.

Pelan Tindak Balas Kecemasan (ERP) merujuk kepada terperinci dan khusus kepada bioagen/bahan/kimia yang digunakan dalam zon pembendungan, prosedur/proses makmal yang dijalankan oleh kakitangan dan peralatan yang digunakan.

Kejadian adalah peristiwa yang berpotensi menyebabkan kecederaan, bahaya, atau kerosakan. Insiden termasuk kemalangan, serta hampir terlepas dan kejadian berbahaya yang lain. Istilah "insiden" merujuk kepada semua kejadian yang mungkin berlaku, termasuk kemalangan, pendedahan (yang boleh menyebabkan penyakit), jangkitan/intoksikasi yang diperolehi dari makmal, kegagalan pembendungan, pelepasan alam sekitar (contohnya, sisa atau tumpahan yang tidak dirawat dengan betul yang dihantar ke sistem pembetung), dan pelanggaran biosekuriti (contohnya, kecurian atau penyalahgunaan bahan berjangkit atau toksin yang disengajakan). Semua insiden yang melibatkan patogen, toksin, bahan berjangkit lain yang dikawal selia, haiwan yang dijangkiti atau melibatkan kegagalan sistem pembendungan/kawalan atau pelepasan ke alam sekitar hendaklah dilaporkan dengan segera kepada Penyelidik Utama anda dan Pegawai Biokeselamatan Kanan

Apabila kemalangan atau kejadian yang tidak dirancang berlaku di makmal, tindakan segera yang diambil pada minit awal adalah penting untuk mencegah kecederaan dan mengurangkan kesan merosakkan peristiwa tersebut. Pelan tindak balas kecemasan standard harus ada dan difahami dengan baik oleh semua pihak yang terlibat untuk mengawal dan menstabilkan keadaan kecemasan. Berikut adalah butiran tindak balas atau tindakan yang diambil untuk kejadian kecemasan biasa yang boleh berlaku di makmal:

6.1 Tumpahan Biologi

Semua tumpahan mesti dilaporkan kepada ketua penyelidik anda secepat mungkin. Mempunyai prosedur tumpahan bercetak yang tersedia (dalam lengan kalis air) di dalam atau berhampiran kit tumpahan tumpahan anda dan prosedur pasca tumpahan pada semua kabinet keselamatan biologi, *Biosafety Cabinet* (BSC). Prosedur tumpahan khusus untuk biologi anda diperlukan.

6.2 Tumpahan di Makmal:

Memberi amaran kepada rakan sekerja mengenai kejadian itu. Sekiranya aerosol, tahan/kawal pernafasan anda dan cepat meninggalkan makmal. Tutup pintu dan hantar tanda amaran. Benarkan aerosol untuk meruap sekurang-kurangnya 30 minit. Keluarkan sebarang pakaian yang tercemar dengan serta-merta. Basuh permukaan kulit yang terdedah di bawah air yang mengalir. Pakai *Protective Personal Equipment* (PPE) yang sesuai. Untuk membersihkan tumpahan biologi yang mengandungi mikroorganisma, kit tumpahan yang mengandungi disinfektan cair (seperti peluntur klorin 10%), pakej tuala kertas, sarung tangan getah, beg autoklaf, bekas untuk mengisi sisa tajam, dan forsep untuk mengambil kaca pecah mesti tersedia di setiap makmal. Tutup kawasan tumpahan dengan tuala kertas atau bahan penyerap. Tuangkan disinfektan dari luar ke arah pusat tumpahan. Benarkan disinfektan bertindak selama 20-30 minit. Sekiranya menggunakan peluntur, sediakan bancuhan untuk memberi % natrium hipoklorit yang diperlukan - biasanya 1%. Keluarkan kaca dengan forsep atau sudu. Keluarkan tuala & mop. Bersihkan lagi dengan sabun / air atau alkohol. Lap kawasan bersebelahan dengan disinfektan. Buang bahan dengan betul dalam bekas biohazard (tandakan bekas "pembersihan tumpahan - mengandungi {nama disinfektan}". Basuh tangan. Untuk tumpahan atau soalan yang lebih besar, hubungi COSHE.

6.2.1 Tumpahan di kawasan awam:

a. Selamatkan kawasan - ini bermakna mempunyai seseorang yang menjaga kawasan itu supaya tidak ada yang berjalan melalui tumpahan.
b. Ikuti prosedur untuk menangani tumpahan di makmal kecuali tumpahan mesti dibersihkan dengan segera - anda tidak boleh menunggu aerosol menetap di kawasan awam.
c. Laporkan tumpahan - jika anda memerlukan bantuan hubungi COSHE

6.2.2 Tumpahan dalam pengempar (*Centrifuge*):

a. Biarkan penutup ditutup dan biarkan aerosol untuk tidak merebak sekurang-kurangnya 1 jam (memastikan pengempar dimatikan, melekatkan tanda amaran)
b. Pindah ke BSC jika boleh
c. Membasmi kuman pengempar, pemutar dan baldi dalam disinfektan yang sesuai; benarkan sekurang-kurangnya 20 hingga 30 minit. Lap semua bahagian termasuk penutup pengempar.
d. Bilas dengan air jika peluntur digunakan

6.2.3 Tumpahan dalam BSC:

a. BSC mesti dihidupkan bagi mengelakkan aerosol merebak keluar ke persekitaran
b. Jika tumpahan berada di permukaan kerja, tutup bahan tumpah dengan lampin atau tuala yang direndam disinfektan dan biarkan duduk selama 20-30 minit, kemudian keluarkan dan buang sebagai sisa biohazad
c. Lap bahagian dalam kabinet & sebarang percikan pada radas di dalam kabinet dengan tuala yang direndam disinfektan
d. Sekiranya kabinet mempunyai lembangan tangkapan di bawah permukaan kerja dan tumpahan mengakibatkan cecair mengalir ke kawasan ini, dekontaminasi yang lebih luas diperlukan.
    - Pastikan injap longkang di bawah kabinet ditutup.
    - Tuangkan disinfektan ke permukaan kerja dan melalui gril depan dan belakang ke dalam kuali longkang. Benarkan masa hubungan 20-30 minit.
    - Menyerap cecair-disinfectant yang tumpah dari permukaan kerja dengan tuala kertas dan buang dalam beg biohazard.
    - Kosongkan kuali longkang. Buka injap longkang dan kosongkan kuali longkang ke dalam bekas pengumpulan yang mengandungi disinfektan. Siram kuali longkang dengan air dan keluarkan tiub fleksibel. Menguruskan bahan yang tercemar seolah-olah ia berjangkit.
e. Jalankan BSC sekurang-kurangnya 10 minit selepas pembersihan, sebelum meneruskan aktiviti di kabinet.

6.3 Garis Panduan Pembersihan Tumpahan Umum

Langkah pertama yang perlu diambil dalam membersihkan tumpahan umum adalah untuk mengehadkan penyebaran pencemaran dengan menutup unit pemanasan, pengudaraan, dan penyaman udara (HVAC) makmal yang dihormati. Individu yang bertanggungjawab harus memakai sarung tangan dan kot makmal sebelum bersentuhan dengan tumpahan. Cermin mata yang pecah harus dipilih menggunakan forsep dan bahan tumpah ditutup dengan tuala kertas sebelum tidak aktif tumpahan dengan disinfektan cair. Kawasan tumpahan diperlukan untuk membersihkan semula dengan mengelapnya dengan disinfektan cair. Prosedur Operasi Standard (SOP) terperinci untuk pembersihan tumpahan umum diterangkan dalam MS 1042-3:2015, Fasal 13.6 Prosedur pembersihan tumpahan.

6.4 Garis Panduan Pembersihan Tumpahan Khusus

6.4.1 Tumpahan bahan BSL-1:

Oleh kerana tumpahan biologi dari BSL-1 mengenakan risiko yang rendah kepada individu yang terlibat, tindakan yang diambil untuk membersihkan tumpahan adalah sama dengan pembersihan tumpahan umum.

6.4.2 Tumpahan Darah Manusia:

Untuk membersihkan tumpahan darah, individu yang bertanggungjawab juga perlu memakai kot makmal dan memakai sarung tangan sebelum bersentuhan dengan tumpahan darah. Darah diserap dan dibersihkan dengan tuala kertas dan kawasan yang terjejas perlu dibasahi dengan disinfektan. Sebarang kesan warna darah yang kelihatan di kawasan yang terjejas dibersihkan menggunakan larutan detergen dan seterusnya dibersihkan dengan disinfektan. SOP terperinci untuk pembersihan tumpahan darah adalah diterangkan dalam MS 1042-3:2015, Klausa 13.6 Prosedur pembersihan tumpahan.

6.4.3 Tumpahan bahan BSL-2:

Semua darah mesti dianggap sisa biologi berbahaya bukan hanya yang diketahui dijangkiti patogen.

a. Memakai PPE yang lengkap
b. Jangan sekali-kali menggunakan tangan anda untuk mengambil kaca pecah atau serpihan - gunakan forsep, sudu dll. Buang semua tajam ke dalam bekas tajam tahan tusukan.
c. Bahan organik mengurangkan keberkesanan beberapa pembasmian kuman, seperti natrium hipoklorit, jadi mungkin perlu mengeluarkan sebahagian besar tumpahan sebelum dapat menyahcemar kawasan tumpahan secara kimia. Rendam darah dengan bahan penyerap dan buang dalam bekas sisa biohazard.
d. Selepas mengeluarkan sebahagian besar tumpahan, membasmi kawasan tersebut. Benarkan masa hubungan yang cukup disinfektan untuk meneutralkan bahan biohazardous - sekurang-kurangnya 30 minit. Pastikan anda menggunakan disinfektan berkesan terhadap patogen bawaan darah.
e. Buang semua bahan pembersihan dalam bekas sisa biohazardous yang ditandakan "pembersihan tumpahan - mengandungi {nama disinfektan}"
f. Sapukan disinfektan ke tumpahan dan kawasan bersebelahan pada kali terakhir, yang membolehkan ditetapkan selama 10 minit atau udara kering.

Untuk membersihkan tumpahan bahan BSL-2, lebih banyak langkah berjaga-jaga perlu diambil memandangkan bahan tersebut lebih berbahaya daripada tumpahan umum dan tumpahan BSL-1. Tanda amaran mesti ada dan pekerja lain dijauhkan dari makmal ketika tumpahan dibersihkan. Pegawai biokeselamatan perlu dimaklumkan dengan segera dan individu yang bertanggungjawab perlu memakai pakaian pelindung (kot makmal, sarung tangan dan jika perlu, perlindungan muka dan penutup kasut). Tumpahan perlu ditutup dengan tuala kertas, rendam dengan disinfektan dan ulangi pembersihan dengan disinfektan yang sama. Semua pakaian dan bahan yang tercemar akan dimasukkan ke dalam beg biohazard untuk diautoklaf kemudian. SOP terperinci untuk pembersihan bahan BSL-2 diterangkan dalam MS 1042- 3:2015, Fasal 13.7 Tumpahan bahan yang sangat berjangkit di makmal BLS-2.

6.5 Kecederaan Teruk

Responden pertama yang menyaksikan keadaan atau individu yang terjejas harus segera menghubungi pasukan tindak balas kecemasan (ERT) institusi, yang harus segera bergerak ke tempat kejadian. Intervensi pertolongan cemas dan paramedik perlu dilakukan kepada mangsa untuk mengurangkan keterukan trauma/kecederaan. Orang pertama yang menghubungi jika ia berlaku di universiti ialah pihak keselamatan/COSHE. Pihak keselamatan hendaklah menghubungi Perkhidmatan Tindak Balas Kecemasan Malaysia (999) atau perkhidmatan kecemasan tempatan yang sesuai dengan segera dalam keadaan yang melibatkan kecederaan teruk berlaku.

Orang yang cedera harus diberi semua bantuan dan pengangkutan yang diperlukan ke bilik kecemasan terdekat untuk rawatan yang diperlukan oleh kakitangan perubatan. Orang yang cedera harus diiringi ke Pusat Kesihatan Universiti (PKU) UniMAP atau hospital terdekat sama ada oleh responden pertama, ahli fakulti atau ahli ERT untuk memberikan maklumat kepada kakitangan perkhidmatan perubatan mengenai kemalangan / pendedahan. Kemalangan hendaklah dilaporkan kepada Pengurus PI/Lab, Ketua Jabatan (HOD), UniMAP BBC, COSHE, Jabatan Keselamatan (JKes) dan pihak-pihak lain yang berkaitan untuk dokumentasi dan tindakan selanjutnya.

6.6 Percikan ke Mata

Hubungan agen mikrobiologi atau mana-mana bahan cemar biologi perlu dirawat dengan segera untuk mencegah jangkitan lanjut atau kesan merosakkan kepada individu. Mata yang terjejas harus segera dibuang menggunakan cuci mata kecemasan dengan aliran air bersih yang lembut dan sederhana selama sekurang-kurangnya 15 minit. Kelopak mata mata yang terjejas harus dipegang terbuka untuk memastikan hubungan berterusan dengan air yang mengalir. Pada masa yang sama, berhati-hati perlu diambil untuk mengelakkan pemindahan bahan cemar ke mata yang lain. Hubungi perkhidmatan kecemasan tempatan yang sesuai untuk mendapatkan rawatan lanjut. Kemalangan itu hendaklah dilaporkan kepada Pengurus PI/Lab, HOD, UniMAP BBC, COSHE dan pihak-pihak lain yang berkaitan untuk dokumentasi dan tindakan selanjutnya.

6.7 Pencemaran kepada Badan

Adalah menjadi tanggungjawab kakitangan untuk memastikan penggunaan PPE yang sesuai semasa mengendalikan agen mikrobiologi atau biohazard berbahaya yang berpotensi. Walau bagaimanapun, sekiranya berlaku sebarang pencemaran agen berlaku kepada badan, pakaian yang tercemar harus dikeluarkan dari badan dan kulit kering dengan air yang mengalir. Kawasan badan atau kulit yang terjejas hendaklah dibasuh dengan sabun dan dibilas dengan teliti dengan air yang mengalir, dan siram kawasan itu selama 15 minit. Individu yang terjejas harus mendapatkan bantuan perubatan tambahan jika perlu. Laporkan kejadian itu kepada Pengurus PI/Lab, HOD, UniMAP BBC, COSHE dan pihak lain yang berkaitan untuk dokumentasi dan tindakan selanjutnya.

6.8 Kebakaran atau Letupan yang Melibatkan Bahan Biologi

Prosedur operasi standard (SOP) bagi pelan tindak balas kebakaran/letupan yang telah digariskan oleh COSHE hendaklah dipatuhi dalam kes-kes kejadian yang berlaku di makmal atau kemudahan lain yang melibatkan bahan biologi. Sebagai tambahan kepada SOP, bahan biologi perlu diletakkan di lokasi yang selamat, seperti inkubator atau peti sejuk, jika tindakan sedemikian tidak memberi risiko tambahan kepada keselamatan kakitangan. Selepas kejadian, makmal atau kawasan yang terjejas mesti ditutup dengan segera dengan sempadan yang jelas kelihatan untuk mengelakkan sebarang akses yang tidak dibenarkan dan pencemaran selanjutnya ke dalam dan dari kawasan tersebut. Prosedur dekontaminasi yang sesuai perlu dijalankan ke kawasan yang terjejas.

6.9 Prosedur Kesiapsiagaan dan Tindak Balas Kecemasan Keselamatan, Kesihatan, dan Persekitaran Pekerjaan

Perincian Prosedur Kesiapsiagaan dan Tindak Balas Kecemasan Persekitaran Keselamatan Kesihatan untuk UniMAP adalah seperti dalam laman sesawang COSHE.

Pastikan kakitangan makmal biasa dengan sekurang-kurangnya 2 laluan keluar dari bangunan anda untuk tujuan pemindahan kecemasan. Ingatkan mereka bahawa apabila penggera kebakaran berbunyi, mereka mesti meninggalkan bangunan. Hantar arahan pemindahan kecemasan di pintu keluar dari makmal anda. Pemindahan makmal asas berikut boleh diubah suai oleh pemegang permit: Pemindahan Makmal Kecemasan Asas: Sentiasa menganggap anda mungkin tidak dapat kembali ke makmal untuk beberapa waktu. 1. Matikan sebarang sumber haba langsung (iaitu pembakar Bunsen, pinggan panas, ketuhar, air panas) 2. Tutup mana-mana bekas terbuka yang mengandungi sisa biologi dan bahan kimia. 3. Keluarkan sebarang PPE dan ambil barang peribadi anda (termasuk mana-mana pakaian luar iaitu kot musim sejuk). 4. Tinggalkan bangunan - Tutup pintu makmal di belakang anda. Pastikan pintu makmal dikunci. Haruslah mencuci tangan atau menggunakan pembersih tangan (jika berkesan terhadap biologi yang digunakan) sebelum meninggalkan makmal, tetapi ini bergantung kepada keterukan kecemasan dan apa yang mereka bekerjasama.

6.10 Kegagalan Kuasa

Patuhi sebarang arahan yang dikhususkan di makmal anda. Contohnya: jangan buka peti sejuk.

6.11 Haiwan Makmal Terlepas (jika berkenaan):

Jika bekerja dengan haiwan tertentu, dapatkan maklumat dalam manual tatacara kerja yang khusus. Jika bekerja dengan haiwan yang bukan dari haiwan kampus (contohnya invertebrata), maka anda perlu menulis arahan untuk prosedur yang diperlukan untuk memastikan tiada pelepasan yang tidak disengajakan ke alam sekitar, dan menyediakan no talian kecemasan berkaitan pengurusan haiwan tersebut.

Seksyen 7:
Pembuangan Sisi Biologi dan Selainnya

7.1 Pengenalan

Prosedur pengurusan sisa biologi dan sisa berkaitan perlu ada untuk melindungi kesihatan dan keselamatan kakitangan yang mengendalikan dan terdedah kepada sisa biologi di tempat kerja dan komuniti secara umum. Setiap Fakulti/ Jabatan/ Institut/ Pusat Kecemerlangan Penyelidikan (CoE) UniMAP bertanggungjawab untuk membangunkan, melaksana, menyelenggara dan memantau pengurusan sisa biologi dan sisa berkaitan mengikut garis panduan dan mematuhi Akta Kualiti Alam Sekeliling 1974 : Kualiti Alam Sekitar (Buangan Terjadual) Peraturan 2005, Garis Panduan Pengendalian dan Pengurusan Sisa Klinikal di Malaysia Ke-3 edisi Ogos 2010 : Jabatan Alam Sekitar, Kementerian Sumber Asli dan Alam Sekitar, Garis Panduan Biokeselamatan untuk Aktiviti Penggunaan Terkawal Organisma Diubah suai (LMO) 2010 dan lain-lain dokumen berkaitan.

Setiap Fakulti/ Jabatan/ Institut/ CoE UniMAP hendaklah melantik kakitangan yang berdedikasi yang bertanggungjawab dengan pengurusan sisa biologi dan sisa berkaitan. Mereka dikehendaki mengikuti latihan yang sesuai dan bertanggungjawab dalam mengurus:

- menyusun atau mengkategorikan bahan buangan
- kemudahan penyimpanan sisa sementara
- jadual kutipan
- aturan pelupusan akhir dengan kontraktor pelupusan sisa yang diluluskan
- merekodkan pelupusan sisa selaras dengan keperluan perundangan dan garis panduan.

7.2 Pengasingan Sisa Makmal

Makmal menghasilkan beberapa jenis sisa termasuk sisa kimia, radiologi, klinikal dan biologi serta benda tajam. Setiap kategori sisa ini memerlukan pengasingan sebelum penyimpanan dan pelupusan. Sisa makmal harus diasingkan mengikut kategori berikut untuk pengendalian, penyimpanan dan pelupusan yang sesuai:

- Kertas dan plastik tidak tercemar yang boleh dibuang sebagai sisa am
- Kaca pecah yang tidak tercemar yang diletakkan di dalam tong yang ditetapkan
- Kaca pecah tercemar yang dibuang ke dalam tong khusus
- Bahagian tajam dan runcing
- Sisa klinikal dan biologi
- Sisa sitotoksik

7.3 Sisa klinikal dan Biologi

Sisa klinikal dan biologi boleh diasingkan ke dalam kategori berikut:

- Spesimen klinikal atau sampel asal manusia yang merangkumi darah, tisu, badan dan sebarang sampel klinikal, sapuan, pembalut dan pembalut luka
- Sisa mikrobiologi yang merangkumi piring petri, kultur mikroorganisma dan bahan kultur sel
- Sisa DNA rekombinan dan LMO
- Bahan buangan tajam.
- Sisa sitotoksik dan farmaseutikal.

Sisa klinikal dan biologi berpotensi menyebabkan kecederaan, jangkitan atau kesalahan awam. Semua sisa makmal yang tercemar atau berpotensi tercemar dengan mikroorganisma mestilah dinyahcemar oleh orang yang bertanggungjawab ke atas pengurusan sisa atau setiap individu yang bekerja dengan bahan tersebut sebelum pelupusan akhir. Prosedur dekontaminasi khusus untuk setiap kategori sisa biologi diterangkan di bawah. Pertanyaan lanjut mengenai prosedur dekontaminasi boleh diperoleh daripada BSO atau UniMAP BBC.

7.3.1 Mikroorganisma, Klinikal atau Sisa Berjangkit Lain

Sisa klinikal atau sisa berjangkit boleh dirawat dengan dua kaedah bergantung kepada keperluan:

Pilihan 1

Sisa yang boleh dijadikan tidak berbahaya hendaklah dilakukan dengan cara autoklaf (pensterilan stim tekanan). Sisa hendaklah diikat dalam beg kedap legap yang menyebabkan sisa itu “tidak dapat dikenali”. Jika sisa hendak diangkut ke luar makmal ke kemudahan autoklaf, ia perlu dilakukan dalam bekas bertutup sekunder, kalis bocor, tidak boleh pecah. Walaupun dianggap tidak berbahaya selepas autoklaf, sisa dimasukkan ke dalam tong sampah tercemar khusus dan berkunci, hantar ke stor sisa jadual (jika ada) dan menunggu kutipan oleh kontraktor Jabatan Alam Sekitar (JAS) yang diluluskan. Cecair kultur yang telah didekontaminasi secara menyeluruh oleh tekanan pensterilan wap boleh dibuang ke pembetung (sinki). Pelupusan dengan kaedah ini memerlukan pemantauan ke atas kitaran pensterilan autoklaf untuk memastikan bahan buangan dinyahkontaminasi secara menyeluruh sebelum dilupuskan. Pemantauan termasuk penggunaan penunjuk wap (pita autoklaf dan jalur penunjuk) atau bahan kimia atau penunjuk biologi.

Pilihan 2

Sisa yang tidak boleh dijadikan tidak berbahaya sebelum dilupuskan mesti diikat dan dilabel dengan sewajarnya di dalam plastik "beg sisa tercemar kuning" pada pusat penghasilan sisa. Beg ini mesti diangkut dari kawasan makmal dalam bekas bertutup sekunder, kalis bocor, tidak boleh pecah (tong sampah dengan kedap tudung). Beg sampah hendaklah diletakkan di dalam tong sampah tercemar khusus, diangkut ke sisa terjadual simpan (jika ada) sehingga kutipan oleh kontraktor yang diluluskan JAS untuk dilupuskan secara insinerasi atau diautoklaf dan dihancurkan.

7.3.2 Sisa LMO

DNA rekombinan atau LMO menjadi tidak berbahaya sebelum pelupusan akhir dengan mengikut prosedur yang dihuraikan dalam Garis Panduan ‘Biosafety Contained Use Activity of Living Modified Organism (LMO) (2010)’. Walau bagaimanapun, secara amnya, sisa LMO boleh dirawat dengan dua kaedah di bawah:

Pilihan 1

Sisa yang boleh dijadikan tidak berbahaya hendaklah dilakukan dengan cara autoklaf (pensterilan stim tekanan). Sisa hendaklah dibungkus dua kali dan ditutup dalam beg kedap air yang sesuai yang menyebabkannya sisa tersebut "tidak dapat dikenali". Jika sisa hendak diangkut ke luar makmal ke kemudahan autoklaf, ia hendaklah dilakukan dalam bekas bertutup sekunder, kalis bocor, tidak boleh pecah. Walaupun dianggap tidak berbahaya selepas autoklaf, sisa dimasukkan ke dalam tong sisa yang dikhaskan dan berkunci, diangkut ke stor sisa berjadual (jika ada) dan menunggu kutipan yang diluluskan oleh kontraktor JAS. Kultur LMO cecair yang telah didekontaminasi secara menyeluruh oleh pensterilan stim tekanan boleh dibuang ke pembetung (sinki). Pelupusan dengan kaedah ini memerlukan pemantauan ke atas kitaran pensterilan autoklaf untuk memastikan bahan buangan dinyahkontaminasi secara menyeluruh sebelum dilupuskan. Pemantauan termasuk penggunaan penunjuk wap (pita autoklaf dan jalur penunjuk) atau bahan kimia atau penunjuk biologi.

Pilihan 2

Bahan buangan hendaklah dimasukkan ke dalam tong khusus untuk LMO di dalam makmal. Setelah penuh, penutup tong sisa hendaklah dikunci secara kekal. Sebelum tong sampah dimuatkan ke dalam troli pengangkut dan dikeluarkan dari makmal, permukaan luar mesti dinyahcemar. Tong sisa penuh perlu disimpan dengan menggunakan troli pengangkut di kawasan simpanan khusus dan berkunci untuk dilupuskan oleh kontraktor yang diluluskan oleh JAS.

7.3.3 Sisa Tajam

Bahagian tajam dan runcing mesti dimasukkan ke dalam tong tajam selepas digunakan. Untuk mengelakkan kecederaan tusukan jarum, jarum tidak boleh ditutup semula atau dibengkokkan dan jarum pakai buang/set picagari hendaklah dibuang sebagai satu unit. Pengurusan benda tajam disertakan dalam Garis Panduan Pengendalian dan Pengurusan Sisa Klinikal di Malaysia Edisi Ke-3 2009, Jabatan Alam Sekitar, Kementerian Alam Sekitar dan Air. Benda tajam mesti dibuang ke dalam tong benda tajam yang diluluskan. Tong tajam tidak boleh diisi melepasi garisan yang ditunjukkan dan setelah penuh, tong tajam mesti ditutup dan dimasukkan ke dalam beg sisa tercemar kuning sebelum disimpan dibuang ke dalam tong sisa. Tong tajam terpakai tidak boleh dikosongkan atau digunakan semula dalam apa jua keadaan.

7.3.4 Sisa Sitotoksik

Sisa sitotoksik termasuk sisa yang terhasil dalam pembuatan dan penyediaan dan dalam penggunaan onkologi rawatan pesakit dengan kesan sitotoksik (sifat karsinogenik mutagenik dan teratogenik). Sisa sitotoksik mesti diasingkan daripada semua aliran sisa lain di mana-mana sahaja yang mungkin dan mesti diletakkan ke dalam beg sisa sitotoksik ungu yang khusus, tong boleh dikunci atau tong sisa tajam sitotoksik ungu. Jika tong sisa hendak digunakan, setelah penuh ia perlu dikunci secara kekal dengan bahagian tepinya berkunci, dinyahkontaminasi pada semua permukaan luaran dan disimpan di kawasan khusus boleh dikunci untuk dilupuskan kontraktor. Beg sisa sitotoksik dan tong benda tajam mesti diletakkan ke dalam sisa klinikal sitotoksik berwarna ungu tong untuk kutipan kontraktor.

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LAMPIRAN A

Kategori Organisma Mengikut Kumpulan Risiko

Diadaptasi dari: Kementerian Kesihatan Malaysia, JADUAL KETUJUH [Subperaturan 6(1)], Kategori organisma mengikut kumpulan risiko.

JADUAL KETUJUH
[*Subperaturan 6(1)*]

Kategori organisma mengikut kumpulan risiko

Kumpulan risiko ditakrifkan mengikut kriteria yang dibentuk oleh Pertubuhan Kesihatan Sedunia berdasarkan kepatogenan organisma, kaedah dan kemudahan relatif penularan, tahap risiko kepada kedua-dua individu dan komuniti dan kebolehbalikan penyakit melalui langkah-langkah pencegahan dan rawatan yang diketahui dan berkesan, seperti yang berikut:

Kumpulan Risiko 1:	Organisma, yang tidak mungkin menyebabkan penyakit kepada manusia sihat, tumbuhan atau haiwan. Bagi maksud Peraturan-Peraturan ini, semua organisma yang tidak disenaraikan dalam Kumpulan Risiko 2, 3 dan 4 tergolong di bawah Kumpulan Risiko 1.
Kumpulan Risiko 2:	Organisma, yang diketahui boleh menyebabkan penyakit kepada manusia sihat. Risiko jangkitan adalah melalui sentuhan secara langsung, pengingesan atau penyedutan. Rawatan berkesan, langkah pencegahan dan pengawalan mudah didapati dan boleh dilaksanakan untuk mengawal penularan penyakit. Risiko merebak kepada komuniti adalah terhad.
Kumpulan Risiko 3:	Organisma, yang boleh merupakan agen eksotik atau asli yang berpotensi menularkan penyakit terutamanya melalui aerosol. Penyakit yang disebabkan adalah teruk dan boleh mengakibatkan kematian. Ia boleh membawa risiko jika merebak dalam komuniti, walau bagaimanapun rawatan berkesan, langkah pencegahan dan pengawalanboleh didapati.
Kumpulan Risiko 4:	Organisma, yang boleh merupakan agen eksotik atau agen baru yang biasanya boleh menyebabkan penyakit yang mengancam nyawa manusia. Penyakit berjangkit itu mudah menular daripada seorang individu kepada individu yang lain. Penyakit berjangkit ditularkan melalui aerosol atau ia mungkin tidak diketahui. Tiada rawatan berkesan atau langkah-langkah pencegahan dan kawalan. Apa-apa organisma yang baru ditemui, yang belum lagi dikategorikan di bawah Peraturan-Peraturan ini, tergolong di bawah Kumpulan Risiko 4.

***Nota:** **Ini bukan merupakan senarai yang lengkap**. Bagi maksud Peraturan-Peraturan ini, mana-mana organisma yang tidak disenaraikan dalam Kumpulan Risiko 2,3 atau 4, tidak boleh diklasifikasikan dalam Kumpulan Risiko 1 sehingga ciri-ciri dan kepatogenikannya ditentusahkan setelah berunding dengan Jawatankuasa Pakar bagi Pencegahan dan Pengawalan Penyakit Berjangkit, Kementerian Kesihatan, Malaysia.*

BAKTERIA, KLAMIDIA, MIKOPLASMA DAN RIKETSIA

Kumpulan Risiko 2

-- *Acinetobacter baumannii* (*Acinetobacter calcoaceticus*)
-- *Acinetobacter lwoffi*
-- *Actinobacillus actinomycetemcomitans*
-- *Actinomadura madurae*
-- *Actinomadura pelletieri*
-- *Actinomyces spp.* termasuk:
    -- *Actinomyces gerencseriae*
    -- *Actinomyces israelii*
    -- *Actinomyces pyogenes* (*Corynebacterium pyogenes*)
-- *Aeromonas hydrophila*
-- *Afipia spp*
-- *Agrobacterium radiobacter*
-- *Alcaligenes spp.*
-- *Amycolata autotrophica*
-- *Archanobacterium haemolyticum* (*Corynebacterium haemolyticum*)
-- *Arizona spp* - semua serotip
-- *Bacillus cereus*
-- *Bacteroides spp.* termasuk:
    -- *Bacteroides fragilis*
-- *Bartonelia bacilliformis* (*Rochalimaea bacilliformis*)
-- *Bartonella quintana* (*Rochalimaea quintana*)
-- *Bartonella henselae* (*Rochalimaea henselae*)
-- *Bartonella vinsonii* (*Rochalimaea vinsonii*)
-- *Bordetella bronchiseptica*
-- *Bordetella parapertussis*
-- *Bordetella pertussis*
-- *Borrelia spp.* termasuk:
    -- *Borrelia burgdorferi*
    -- *Borrelia duttonii*
    -- *Borrelia recurrentis*
-- *Brucella ovis*
-- *Burkholderia spp.* termasuk:
    -- *Burholderia cepacia*
    -- *Burholderia mallei* (*Pseudomonas mallei*)
    -- *Burholderia pseudomallei* (*Pseudomonas pseudomallei*)
-- *Campylobacter spp.* termasuk:
    -- *Campylobacter coli*
    -- *Campylobacter fetus*
    -- *Campylobacter jejuni*
-- *Capnocytophaga spp.*
-- *Cardiobacterium hominis*
-- *Chlamydia pneumoniae*
-- *Chlamydia psittaci* (strain bukan avian)
-- *Chlamydia trachomatis*
-- *Citrobacter spp.*
-- *Clostridium spp.* termasuk:
    -- *Clostridium botulinum*
    -- *Clostridium chauvoei*
    -- *Clostridium haemolyticum*
    -- *Clostridium histolyticum*
    -- *Clostridium novyi*
    -- *Clostridium perfringens*

-- *Clostridium septicum*
-- *Clostridium tetani*
– *Corynebacterium spp.* termasuk:
-- *Corynebacterium diphtheriae*
-- *Corynebacterium minutissimum*
-- *Corynebacterium pseudotuberculosis*
-- *Corynebacterium renale*
– *Dermatophilus congolensis*
– *Edwardsiella tarda*
– *Enterobacter spp.* termasuk:
-- *Enterobacter aerogenes / cloacae*
–.*Enterococcus spp.*
– *Erysipelothrix rhusiopathiae*
– *Escherichia coli* - semua enteropatogenik, enterotoksigenik, enteroinvasif, enterohemoragik dan strain yang membawa antigen *K1*, termasuk *E. coli 0157:H7* atau *0103*
-- *Flavobacterium meningosepticum*
– *Fluoribacter bozemanae* (dahulu dikenali sebagai *Legionella*)
– *Francisella tularensis* (Jenis *B*)
– *Fusobacterium spp.* termasuk:
-- *Fusobacterium necrophorum*
– *Gardnerella vaginalis*
– *Haemophilus spp.* termasuk:
-- *Haemophilus ducreyi*
-- *Haemophilus influenzae*
– *Helicobacter pylori*
– *Klebsiella spp.* termasuk:
-- *Klebsiella pneumonia*
-- *Klebsiella oxytoca*
– *Legionella spp.* termasuk:
-- *Legionella pneumophila*
– *Leptospira interrogans* - semua serotip
- -*Listeria ivanovii*
– *Listeria monocytogenes*
– *Moraxella catarrhalis*
– *Moraxella lacunata*
– *Morganella morganii*
–*Mycobacterium spp.* (kecuali yang disenaraikan dalam Kumpulan Risiko 3) termasuk:
-- *Mycobacterium africanum*
-- *Mycobacterium avium /intracellulare*
-- *Mycobacterium asiaticum*
-- *Mycobacterium bovis* (strain vaksin *BCG*)
-- *Mycobacterium chelonei*
-- *Mycobacterium fortuitum*
-- *Mycobacterium kansasii*
-- *Mycobacterium leprae*
-- *Mycobacterium malmoense*
-- *Mycobacterium marinum*
-- *Mycobacterium microti*
-- *Mycobacterium paratuberculosis*
-- *Mycobacterium. scrofulaceum*
-- *Mycobacterium simiae*
-- *Mycobacterium szulgai*
-- *Mycobacterium ulcerans*
-- *Mycobacterium xenopi*
– *Mycoplasma caviae*
– *Mycoplasma hominis*

- *Mycoplasma pneumoniae*
- *Neisseria elongata*
- *Neisseria gonorrhoeae*
- *Neisseria meningitis*
- *Nocardia spp.* termasuk:
    - *Nocardia asteroids*
    - *Nocardia brasiliensis*
    - *Nocardia farcinica*
    - *Nocardia nova*
    - *Nocardia otitidiscaviarum*
    - *Nocardia transvalensis*
- *Pasteurella spp.* termasuk:
    - *Pasteurella multocida* (kecuali kerintangan strain yang disenaraikan dalam Kumpulan Risiko 3)
- *Peptostreptococcus spp.* termasuk:
    - *Peptostreptococcus anaerobius*
- *Plesiomonas shigelloides*
- *Porphyromonas spp.*
- *Prevotella spp.*
- *Proteus mirabilis*
- *Proteus penneri*
- *Proteus vulgaris*
    - *Providencia spp.* termasuk:
- *Providencia alcalifaciens*
- *Providencia rettgeri*
- *Pseudomonas aeruginosa*
- *Rhodococcus equi*
- *Rochalimaea spp.* (lihat *Bartonella spp.*)
- *Salmonella spp.* termasuk:
    - *Salmonella arizonae*
    - *Salmonella cholerasuis*
    - *Salmonella enteritidis*
    - *Salmonella gallinarum-pullorum*
    - *Salmonella meleagridis*
    - *Salmonella paratyphi, A, B, C*
    - *Salmonella typhi*
    - *Salmonella typhimurium*
- *Serpulina spp.*
- *Serratia liquefaciens*
- *Serratia marcescens*
- *Shigella boydii*
- *Shigella dysenteriae* (semua serotip)
- *Shigella flexneri*
- *Shigella sonnei*
- *Sphaerophorus necrophorus*
- *Staphylococcus aureus*
- *Stenotrophomonas maltophilia*
- *Streptobacillus moniliformis*
- *Streptococcus spp.* termasuk:
    - *Streptococcus pneumoniae*
    - *Streptococcus pyvogenes*
    - *Streptococcus suis*
- *Treponema spp.* termasuk:
    - *Treponema carateum*
    - *Treponema pallidum*
    - *Treponema pertenue*

– *Ureaplasma urealyticum*
– *Vibrio spp.* termasuk:
    – *Vibrio cholerae*
    – *vibrio parahemolyticus*
    – *Vibrio vulnificus*
– *Yersinia spp* (kecuali *Yersenia pestis*, yang disenaraikan dalam Kumpulan Risiko 3)
    – *Yersinia enterocolitica*
    – *Yersenia pseudotuberculos*

Kumpulan Risiko 3

– *Bacillus anthracis*
– *Brucella spp.* (kecuali *Brucella ovis*, yang disenaraikan dalam Kumpulan Risiko 2):
    – *Brucella abortus*
    – *Brucella canis*
    – *Brucella melitensis*
    – *Brucella suis*
– *Burkholderia* (*Pseudomonas*) *mallei*
– *Burkholderia* (*Pseudomonas*) *pseudomallei*
– *Chlamydia psittaci* (strain avian)
– *Coxiella burnetii*
– *Ehrlichia spp.* termasuk:
    – *Ehrlichia sennetsu* (*Rickettsia sennetsu*)
– *Eikenella corrodens*
– *Francisella tularensis* (Jenis *A*)
– *Mycobacterium bovis* (kecuali strain *BCG*, lihat Kumpulan Risiko 2)
– *Mycobacterium tuberculosis* (strain kerintangan pelbagai dadah)
– *Pasteurella multocida* jenis *B* -*"buffalo"* dan strain virulen lain
– *Rickettsia spp.* termasuk:
    – *Rickettsia akari*
    – *Rickettsia australis*
    – *Rickettsia canada*
    – *Rickettsia conorii*
    – *Rickettsia prowazekii*
    – *Rickettsia rickettsii*
    – *Rickettsia sennetsu* (lihat *Ehrlichia sennetsu*)
    – *Rickettsia siberica*
    – *Rickettsia tsutsugamushi*
    – *Rickettsia typhi* (*Rickettsia mooseri*)
    – *Yersinia pestis*

Kumpulan Risiko 4

TIADA

VIRUS DAN PRION

Kumpulan Risiko 2

-- *Adenoviridae*
  -- *Adenoviruses*, semua serotip

-- *Arenaviridae*
  -- Kompleks virus koriomeningitis limfositik (*LCM*); strain bukan neurotropik; *Ippy*, *Mobala*
  -- Kompleks virus *Tacaribe*: *Ampari*, *Latino*, *Parana*, *Pichinde*, *Tacaribe*, *Tamiami*
  -- Virus *Hepatitis delta*

-- *Astroviridae*
  -- *Astrovirus* manusia

-- *Bunyaviridae*
  Genus: *Bunyavirus*
    -- Virus *Bunyamwera*, kumpulan virus ensefalitis *California*, termasuk virus *LaCrosse*
  Genus: *Phlebovirus*
    semua spesies, kecuali demam virus *Rift Valley*, (lihat Kumpulan Risiko 3) termasuk:
    -- strain vaksin virus demam *Rift Valley MP-12*, virus demam *Sandfly*, *Toscana*, *Uukuviru*
  Genus: *Nairovirus*
    -- Virus *Hazara*, virus *Dugbe*

-- *Caliciviridae*
  -- semua isolat termasuk virus *Norwalk*, *Sapovirus* dan virus *Hepatitis E*

-- *Coronaviridae*
  --*Coronavirus* manusia, (serotip *229E* dan *OC43*), (kecuali, *coronavirus SARS*, lihat Kumpulan Risiko 3)

-- *Flaviviridae*
  Genus: *Flavivirus* (Arbovirus Kumpulan B)
    -- Virus denggi serotip 1, 2, 3, dan 4
    -- Strain vaksin virus demam kuning *17D*
  Genus: *Hepacivirus*
    -- virus *Hepatitis C*

--*Hepadnaviridae*
  -- virus *Hepatitis B*

-- *Herpesviridae*
  semua *Herpesviruses*, kecuali *Herpesvirus simiae* (Herpes B, lihat Kumpulan Risiko 4):
    -- *Cytomegalovirus*
    -- Virus *Epstein Barr*
    --Herpes simpleks jenis 1 dan 2
    --Herpes varisela-zoster
    -- *Herpesvirus* manusia jenis 6 (*HHV 6*)
    -- *Herpesvirus* manusia jenis 7 (*HHV 7*)
    -- *Herpesvirus* manusia jenis 8 (*HHV 8*)

-- Flaviviridae - Arbovirus Kumpulan B
  Genus: *Flavivirus*
    -- virus ensefalitis *Japanese*, virus demam Kuning (jenis liar), virus demam *West Nile*, virus ensefalitis *St. Louis*, virus ensefalitis *Murray Valley*,

Kumpulan virus *Ntaya*: virus meningitis *Israel turkey*
Kumpulan virus *Modoc*: virus *Sal Vieja*, virus *San Perlita*
spesies *Tentative*: *Rocio*, *Spondweni*, *Wesselsbron*
Kumpulan virus ensefalitis bawaan *Tick*: *Absettarov*, *Hanzalova*, *Hypr*, *Kumlinge*, *Louping ill*, *Negishi*, *Powassan*

-- *Orthomyxoviridae*
-- Virus *influenza* jenis A, B, dan C kecuali Influenza A, H5N1
-- *Orthomyxovirus* bawaan *tick* seperti *Dhori* dan *Thogoto*

-- *Papillomaviridae*
Genus: *Papillomavirus*
-- semua virus *papilloma* manusia

-- *Paramyxoviridae*
Genus: *Paramyxovirus*
-- semua isolat termasuk virus *parainfluenza* manusia jenis 1, 2, 3, dan 4, dan virus penyakit *Newcastle*
Genus: *Pneumovirus*
-- semua isolat termasuk virus Pernafasan Sinsitial
Genus: *Morbillivirus*
-- semua isolat termasuk virus campak
Genus: *Rubulavirus*
-- virus Mumps
Genus: *Metapneumovirus*
-- *Metapneumovirus* manusia

-- *Parvoviridae*
Genus: *Parvovirus*
-- semua isolat termasuk *Parvovirus* (*B 19*) manusia

-- *Picornaviridae*
Genus: *Aphthovirus*
Genus: *Cardiovirus*
Genus: *Enterovirus*
-- virus Coxsackie jenis A dan B
-- *Echoviruses*
-- *Polioviruses*
-- Serotip *Enterovirus 68 – 71*
Genus: *Rhinoviruses*
Genus: *Hepatovirus*
-- *Hepatitis A*

-- *Polyomaviridae*
-- semua isolat termasuk virus *BK* dan *JC*, virus *Simian 40 (SV 40)*

-- *Poxviridae*
-- semua isolat kecuali virus *Monkeypox* dan poksvirus yang tertentu seperti *Alastrim*, *Smallpox*, dan *Whitepox* (lihat Kumpulan Risiko 3 dan 4); termasuk virus:
-- *Buffalopox*, *Cowpox*, nodule *Milker*, *Molluscum contagiosum*, *Orf*, *Vaccinia*, *Yabapox* dan *Tanapox*.

-- *Reoviridae*
Genus: *Coltivirus*
-- semua isolat termasuk virus demam kutu *Colorado*
Genus: *Rotavirus*

-- semua *Rotaviruses* manusia
Genus: semua isolat *Orthoreovirus* dan *Orbivirus*

– *Rhabdoviridae*
Genus: *Lyssavirus*
-- Virus rabies (virus "tetap" / strain vaksin)
Genus: *Vesiculovirus*
-- Virus *sfomatitis vesicular* - strain penyesuaian makmal, termasuk *VSV-Indiana, San Juan* dan *Glasgow, Piry, Chandipura*

– *Togaviridae*
Genus: *Alphavirus* - Arboviruses Kumpulan A
-- *Bebaru*, virus *Barmah forest, Chikungunya, O'nyong-nyong*, virus *Ross river*, virus *Semliki forest, Sindbis*, strain vaksin ekuin ensefalomielitis Venezuelan *TC-83* sahaja.
Genus: *Rubivirus*
-- virus Rubella

Kumpulan Risiko 3

– *Arenaviridae*
--*Flexal, Mopeia*
-- Virus limfositik koriomeningitis (*LCM*) (strain neuropatik)

– *Bunyaviridae*
Genus: *Hantavirus*
-- virus *Hantaan* (demam hemoragik *Korean*), *Seoul*, virus *Sin Nombre, Belgrade, Puumala* dan Bunyavirus yang tidak dapat diklasifikasikan
Genus: *Nairovirus*
-- *Bhanja*
Genus: *Phlebovirus*
-- virus demam *Rift Valley*

– *Coronaviridae*
Coronavirus *SARS*

– *Paramyxoviruses*
Genus: *Henipah*
-- *Hendra* (Morbillivirus ekuin), virus *Nipah*, virus *Nipah-like*

– Orthomyxoviridae

-- Influenza A, H5N1

– *Poxviridae*
-- virus *Monkeypox*

– Prion
-- Agen ensefalopati *spongioform* (TME) yang boleh berjangkit: ensefalopati *spongiform Bovine* (BSE), penyakit *Creutzfeldt-Jacob* (CJD), penyakit *Creutzfeldt-Jacob* Varian, Insomnia *familial fatal*, sindrom *Gerstmann-Straussler-Scheinker* dan *Kuru*

-- *Togaviridae - Arboviruses* Kumpulan A
Genus: *Alphavirus*
-- virus *Semliki Forest, Getah, Mayaro, Middleburg, Ndumu*
-- ensefalomielitis ekuin *Eastern*, ensefalomielitis ekuin *Western*, virus ensefalomielitis ekuin *Venezuelan* (kecuali strain vaksin *TC-83*), *Sagiyama, Tonate, Mucambo*

-- *Retroviridae*
-- virus *immunodeficiency* manusia (*HIV*) jenis 1 dan 2
-- virus *T cell lymphotropic* manusia (*HTLV* dan 2)
-- virus *Simian immunodeficiency* (*SIV*)

-- *Rhabdoviridae*
-- virus *Rabies* (virus *Street*)

Virus yang tidak terkelas
-- Agen-agen jangkitan neuropatik Kronik (CHINAs).

Kumpulan Risiko 4

-- *Arenaviridae*
Genus: *Arenaviruses*
-- *Lassa, Guanarito, Junin, Machupo*, dan *Sabia*

-- *Bunyaviruidae*
Genus: *Nairovirus*
--Virus demam hemoragik *Crimean-Congo*

-- Filoviridae
-- semua virus *Ebola* dan virus *Marburg*

-- *Flaviridae* (*Togaviruses*) - *Arboviruses* Kumpulan B
-- Virus kompleks ensefalitis *Tick-borne* termasuk ensefalitis *Central European* virus penyakit *Kyasanur Forest*, virus demam hemoragik *Omsk*, dan virus ensefalitis *Russian spring-summer*

-- *Herpesviruses* (alpha)
--*Herpesvirus simiae* (*Herpes B* atau virus *Monkey B*)

-- *Poxviridae*
--*Variola major, variola minor, whitepox, alastrim* (Pengimportan organisma-organ *alastrim, smallpox* (*variola*) dan *whitepox* dilarang sama sekali. Segala aktiviti, termasuk simpanan variola dan *whitepox*, hanya terhad diuruskan di satu makmal di dunia (*World Health Organization Collaborating Center for Smallpox Research, Center Disease Control and Prevention, Atlanta, Georgia, United States of America*).

-- Agen-agen demam hemoragik dan virus yang belum dipastikan.

PARASIT

Kumpulan Risiko 2

-- *Acanthamoeba spp*
-- *Ancylostoma* cacing kait manusia termasuk:
    -- *Ancylostoma duodenale, Ancylostoma. ceylanicum*
-- *Angiostrongylus spp.*
-- *Anisakis simplex*
-- *Ascaris spp.* termasuk:
    -- *Ascaris lumbricoides, Ascaris suum*
-- *Babesia spp.* termasuk:
    -- *Babesia divergens, Babesia microti*
-- *Balantidium coli*
-- *Blastocystis hominis*
-- *Brugia filaria* termasuk:
    -- *Brugia malayi, Brugia timori*
-- *Capillaria spp.*
-- *Coccidia*
-- *Contracaecum osculatum*
--*Cryptosporidium spp.* termasuk:
    -- *Cryptosporidium parvum*
-- *Cyclospora spp* termasuk:
    -- *Cyclospora cayetanensis*
-- *Cysticercus cellulosae* (sista hidatid, larva *Taenia solium)*
-- *Dicrocoelium dendriticum*
-- *Dientamoeba fragilis*
-- *Dracunculus medinensis*
-- *Entamoeba histolytica*
-- *Enterobius vermicularis*
-- *Enterocytozoon bieneusi*
-- *Fasciola gigantica*
-- *Fasciola hepatica,*
-- *Fasciolopsis buski*
-- *Giardia spp.* termasuk:
    -- *Giardia lamblia (Giardia intestinalis)*
-- *Heterophyes spp.*
-- *Hymenolepis diminuta*
-- *Hymenolepis nana*
-- *Isospora belli*
-- *Leishmania* spp. (mamalia) kecuali *Leishmania braziliensis* dan *Leishmania donovani* (lihat Kumpulan Risiko 3) termasuk spesies:
    -- *Leishmania ethiopia, Leishmania major, Leishmania mexicana, Leishmania peruvania, Leishmania tropica*
-- cacing filaria *Loa loa*
-- *Mansonella spp.* seperti:
    -- *Mansonella ozzardi, Mansonella perstans, Mansonella streptocerca*
-- *Metagonimus spp.*
-- *Microsporidium spp.*
-- *Naegleria spp.* kecuali *Naegleria fowleri*, (lihat Kumpulan Risiko 3)
-- Cacing kait manusia *Necator* termasuk:
    -- *Necator americanus*
-- Cacing filaria *Onchocerca* termasuk, *Onchocerca volvulus*
-- *Opisthorchis felineus*
-- *Opisthorchis sinensis (Clonorchis sinensis)*

-- *Opisthorchis viverrini (Clonorchis viverrini)*
-- *Paragonimus spp* termasuk:
    -- *Paragonimus westermani*
-- *Plasmodium spp.* (manusia dan simian) termasuk:
    -- *Plasmodium cynomologi, Plasmodium falciparum, Plasmodium malaric ovale, Plasmodium vivax*
-- *Sarcocystis suihominis* --*Schistosoma spp.* termasuk:
    -- *Schistosoma haematobium, Schistosoma intercalatum, Schistosoma japonicum Schistosoma mansoni, Schistosoma mekongi*
-- *Strongyloides spp.* termasuk:
    -- *Strongyloides stercoralis*
-- *Taenia saginata*
-- *Taenia solium*
-- *Toxocara spp.* termasuk:
    -- *Toxocara canis*
-- *Toxoplasma spp.* termasuk:
    -- *Toxoplasma gondii*
-- *Trichinella nativa*
-- *Trichinella nelsoni*
-- *Trichinella pseudospiralis*
-- *Trichinella spiralis*
-- *Trichomonas vaginalis*
-- *Trichostrongylus spp.* termasuk, *Trichostrongylus orientalis*
-- *Trichuris trichiura*
-- *Trypanosoma brucei sub-spp.* kecuali *Trypanosoma brucei rhodesiense* dan *Trypanosoma cruzi* (lihat Kumpulan Risiko 3) termasuk *Trypanosoma brucei gambiense*
-- cacing filaria *Wuchereria bancrofti*

Kumpulan Risiko 3

-- *Echinococcus spp.* seperti:
    -- *Echinococcus granulosis, Echinococcus multilocularis, Echinococcus vogeli*
-- *Leishmania braziliensis,*
-- *Leishmania donovani*
-- *Naegleria fowleri*
-- *Trypanosoma brucei rhodesiense*
-- *Trypanosoma cruzi*

Kumpulan Risiko 4

TIADA

KULAT

Kumpulan Risiko 2

-- *Asperigillus fumigatus*
-- *Asperigillus flavus*
-- *Candida albicans*
-- *Candida tropicalis*
-- *Cryptococcus neoformans var neoformans (Filobasidiella neoformans var neoformans)*
-- *Cryptococcus neoformans var gaffii (Filobasidiella bacillispora)*
-- *Dactylaria galopava (Ochroconis gallopavum)*
-- *Emmonsia parva var parva*
-- *Emmonsia parva var crescens*
-- *Epidermophyton spp.* termasuk
    -- *Epidermophyton floccosum*
-- *Exophiala (Wangiella) dermatitidis*
-- *Fonsecaea compacta*
-- *Fonsecaea pedrosoi*
-- *Madurella grisea*
-- *Madurella mycetomatis*
-- *Microsporum spp*
-- *Neotestudina rosatii*
-- *Penicillium marneffei*
-- *Scedosporium apiospermum (Pseudallescheria boydii)*
-- *Scedosporium proliferans (inflatum)*
-- *Sporothrix schenckii*
-- *Trichophyton spp.* termasuk:
    -- *Trichophyton rubrum*

Kumpulan Risiko 3

Blastomyces dermatitidis (Ajellomyces dermatitidis)
-- *Cladophialophora bantiana (Cladosporium bantianum, Xylohypha bantiana)*
-- *Cladosporium trichoides*
-- *Coccidioides immitis*
-- *Histoplasma capsulatum spp.* termasuk:
    --*Histoplasma capsulatum var capsulatum*
    -- *Histoplasma capsulatum var farcinimosum*
    -- *Histoplasma. capsulatum var. duboisii*
-- *Paracoccidioides braziliensis*

Kumpulan Risiko 4

TIADA.

LAMPIRAN B

Borang A

Diadaptasi dari: Laman Sesawang Rasmi, Jabatan Biokeselamatan, *Institutional Biosafety and Biosecurity Committee* (IBBC), Borang A

NBB REF NO: JBK (3) 602-1/1/
(For Office Use)

TITLE :

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM A

APPROVAL FOR RELEASE ACTIVITIES OF LIVING MODIFIED ORGANISM (LMO) (RESEARCH AND DEVELOPMENT PURPOSES IN ALL FIELD EXPERIMENTS) OR IMPORTATION OF LMO THAT IS HIGHER PLANT

NBB/A/ER/10/FORM A shall be submitted to the Director General as an application for certificate of approval of release of LMO [Research and development purposes in all field experiments - Second Schedule of the Act - 1] or importation of living modified organism (LMO) that is a higher plant (not for contained use activities). Any organization undertaking modern biotechnology research and development shall submit the form through its registered Institutional Biosafety Committee (IBC). The IBC should assess the information in the form prior to submission. Application must be accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

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NBB REF NO: JBK (S) 602-1/1/
(For Office Use)

Accuracy of information

The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application. Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

Confidentiality

Any information within this application which is to be treated as CBI, as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user. Please provide written proof of authorization.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

The completed forms to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia

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(For Office Use)

Please retain a copy of your completed form.

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM A is completed with relevant signatures obtained	☐
2. Application assessed and to be sent through the IBC	☐
3. A copy of clearance documents from the Department of Agriculture included (if required)	☐
4. A copy of the clearance document from the state office where the release is to take place	☐
5. Any information to be treated as confidential business information should be clearly marked "CBI" in the application	☐
6. 1 original copy and 6 copies of the completed application submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	☐
7. Fees as prescribed in the regulation: RM_____ Money order/ Bank draft No: _____Made payable to the Secretary General of the Ministry of Natural Resources and Environment	☐

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(For Office Use)

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Project Title/Unique Identification Code:	
5. IBC Project Identification No:	
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ If no, please provide information in no 7 below
7. i) Please provide the NBB reference no. for your previous notification/application. ii) How is this application different from the previous notification/application submitted for this activity? (please provide an attachment if additional space is required)	

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MBB REF NO: ...JBK (5) 602-1/1/ (For Office Use)	

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

NBR REF NO : JDK (S) 6/2-1/1/ (For Office Use)

Institutional Biosafety Committee (IBC) Assessment Report for release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities).

This must be completed by the registered IBC of the Applicant's organization

Section A – IBC Details

1	Name of organization:			
2	Name of IBC Chairperson:			
	Telephone number:		Fax:	
	Email address:			

Section B – IBC Assessment

3	Name of principal investigator:		
4	Project Title:		
5	Date of the IBC Assessment:		
6	Does the IBC consider that the principal investigator and every other person(s) authorized to be involved in the field experiment with the LMO have adequate training and experience for the task?	☐ Yes	☐ No
7	The following information related to this project has been checked and approved		
	a) The objective of the project	☐ Yes	☐ No
	b) The description and genetics of the LMO	☐ Yes	☐ No
	c) The risk assessment and risk management, taking into account the risks to the health and safety of people and the environment from the release of the LMO.	☐ Yes	☐ No

	d) The emergency response plan	☐ Yes ☐ No
8	Has the information been checked by the IBC and found to be complete?	☐ Yes ☐ No
9	Has the IBC assessed the proposed project? ☐ Yes ☐ No If yes, please append a copy of the IBC's assessment report and indicate the attachment in which details are provided.	

NBB REF NO: ...JBK (9) 602-1/1/
(For Office Use)

Signatures and Statutory Declaration

The proposed release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities) has been assessed as above and endorsed by the IBC. We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

IBC Chairperson:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

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NBR REF NO : JBK (S) 602-1/1/
(For Office Use)

Part A Risk Assessment

A1 General Information

1. Project Title.

2. Rationale of Project.

3. Project objectives:
   a) Overall Objective
   b) Specific Objective

4. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait(s)

5. Release site(s) :
   (If more than one location is involved, then the information required in numbers 5, 6, 7, 8 & 9, 10, 11) should be repeated for each location(s) of release)
   a) District(s)
   b) State(s) in which the release(s) will take place

6. Scale of release per release site.
   (Number of LMO involved, size of plot/site etc)

7. Date when the release(s) is expected to commence.

8. Frequency of releases.

9. Date when release(s) is expected to end.

10. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA).

11. Description of the proposed activities with the LMO.

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12. Name of person(s) authorized to undertake activities with the LMO.

A2 Risk Assessment Information - Parent Organism

(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)

13. Details of the parent organism

If the LMO is the result of a crossing event between more than one species/cultivar/breeding line/variety please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)

a) Family name
b) Genus
c) Species
d) Subspecies
e) Cultivar/Breeding line/Variety
f) Common name

14. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.

15. Information concerning the reproduction of the parent organism:

a) The mode or modes of reproduction
b) Any specific factors affecting reproduction
c) Generation time

16. Information regarding the sexual compatibility of the parent organism with other cultivated or wild plant species.

17. Information concerning the survivability of the parent organism:

a) Ability to form structures for survival or dormancy including seeds, spores and sclerotia
b) Any specific factors affecting survivability, for example seasonability

18. Information concerning the dissemination of the parent organism:

a) The means and extent of dissemination
b) Any specific factors affecting dissemination

19. Details of the natural habitat of the parent organism and its range.

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20. Is the parent organism exotic in Malaysia?
☐ Yes ☐ No

21. Is the parent organism naturalized in Malaysia?
☐ Yes ☐ No

22. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release(s)?
(If more than one location is involved, then the information required in numbers 22 & 23 should be repeated for each location(s) of release)

☐ Yes ☐ No

23. If yes, please provide details of the population(s) and the estimated distances between them from the proposed release(s).

24. The potentially significant interactions of the parent organism with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

25. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants or animals and, if so, the details of the possible effects.

26. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

27. Details of pathogenicity, including infectivity, toxigenicity, virulense, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

28. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

29. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

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A) Risk Assessment Information - LMO

30. Details of the modified trait(s) and how the genetic modification will change the phenotype of the LMO to be released.

31. What are the gene(s) responsible for the modified trait(s)?

32. Give details of the organism(s) from which the gene(s) of interest is derived:

(If more than one gene is involved then the information required in numbers 32, 33, 34, 35, 36 and 37 should be repeated for each gene)

a) Family name
b) Genus
c) Species
d) Subspecies
e) Cultivar/Breeding line\/variety
f) Common name

33. Indicate whether it is a:

a) viroid
b) RNA virus
c) DNA virus
d) bacterium
e) fungus
f) animal
g) plant
h) other (please specify)

34. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

35. Please provide the following information about the gene(s) of interest(s):

a) Size of sequence of the gene(s) of interest inserted
b) Sequence of the gene(s)of interest inserted
c) Intended function of the gene(s) of interest
d) Number of copies of the gene(s) of interest in the construct
e) Details of the steps involved in the construction

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f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

36. Please provide the following information about the deleted sequence(s):
   a) Size of the deleted sequence(s)
   b) Function of the deleted sequence(s)
   c) Details of the steps involved in the deletion of sequences from the parental organism
   d) Provide the map(s) of construct(s)

37. The following information is on the expression of the gene(s) of interest:
   a) Level of expression of the gene(s) of interest and methods used for its characterization
   b) The parts of the plant where the gene(s) of interest is expressed, such as roots, stem or pollen
   c) Indicate the part(s) of the vector(s) that remains in the LMO
   d) The genetic stability of the gene(s) of interest

38. A description of the methods used for the genetic modification:
   a) How gene(s) of interest was introduced into the parent organism, or
   b) How a sequence of a gene was deleted from the parent organism

39. If no vector was used for the genetic modification please provide details of how the gene(s) of interest is introduced.

40. If vector(s) was used, please provide the following information:

   (If more than one vector was used, then the information required in 40 should be repeated for each vector).

   a) Type of vector

      i. plasmid
      ii. bacteriophage
      iii. virus
      iv. cosmid
      v. phasmid
      vi. transposable element
      vii. other, please specify

b) Identity of the vector(s)

c) Information on the degree of which the vector(s) contains sequences whose product or function is not known

d) Host range of the vector(s)

e) Potential pathogenicity of the vector(s)

f) The sequence of transposons and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

41. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences of the detection of the inserted gene(s) including marker gene(s).

42. Information (biological features) on how the LMO differs from the parent organism in the following respects:

a) Mode(s) and/or the rate of reproduction

b) Dissemination

43. If there is any possibility that the inserted gene(s) in the LMO could be integrated into other species at the release site(s) and the surrounding environment and if so, please provide the following details:

a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred

b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer

c) Any possible adverse effects of the transfer including

i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)

ii. Environmental risks posed by such an advantage

44. The identification and description of the target organism(s), if any.

45. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

46. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

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47. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

48. Details of any other possible adverse consequences.

49. Details whether the LMO compared to the parent organism that will confer a selective advantage that can impact on survival in the release site(s), including a statement on how stable those features are.

50. Details of whether the modified trait(s) will confer a selective advantage on the LMO compared to the parent organism and if so, the nature of the advantages including a statement on how stable those features are and under what conditions.

51. Details of whether the gene(s) of interest or any part of the vector(s) has the ability to reproduce or transfer to other hosts and, if so, details of the host range.

52. In relation to human health:

a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
c) The capacity of the organisms for colonization
d) If the organisms are pathogenic to immunocompetent persons:

i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence,
ii. communicability,
iii. infective dose,
iv. host range and possibility of alteration,
v. possibility of survival outside of human host,
vi. presence of vectors or means of dissemination,
vii. biological stability,
viii. antibiotic-resistance patterns,
ix. allergenicity, and
x. availability of appropriate therapies.

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53. Details of unintended pleiotropic effects (if any), including undesirable effects on agronomic characteristics of the plant which may result from the expression of the gene of interest(s) in the LMO (for example, reduced fertility, increased prevalence, production losses, grain shedding), including an indication of the likelihood of these events.

54. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

55. Details of how the genetic modification will change the phenotype of the LMO to be released, including information to demonstrate the effect of the genetic modification.

56. Details of the mechanism of pollen spread (by insect vectors or by other means) in the plant population:

a) Details of pollen viability for the parent organism and of the LMO
b) Details of any potential pollinators and their range and distribution in Malaysia
c) Quantitative data on successful cross-pollination between the parent organism, the LMO and its wild relatives, if available

A4 Information about weeds

57. Details of the members of the family of parent organism that are known to be weeds in any environment.

58. Details of cross-pollination between the species to which the LMO belongs and wild relatives known to be weeds, including a copy of any literature reports that support the information.

A5 Information about the seeds of the LMO

59. A statement on whether the LMO proposed to be released will be allowed to set seed and, if not, whether setting seed is planned for a later release.

60. If the LMO is to be allowed to set seed, will the mature seed normally remain contained within an ear, capsule or pod, so that practically all of the seed can be readily harvested, or is the seed shed soon after it matures?
If the latter, provide an indication of the proportion of seed likely to remain in the release site(s) following harvest.

61. Details of the length of time that the seeds are capable of being dormant and whether it differs from the parent organism.

A6 Characteristics affecting survival of LMO

62. The predicted habitat of the LMO.

63. The biological features which affect survival, multiplication and dispersal.

64. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

65. The sensitivity to specific agents (e.g. disinfectant, pesticides, fertilizers, wind, water).

A7 Information about any secondary ecological effects that might result from the release

66 An assessment of possible effects of the proposed release on:

a) Native species
b) Resistance of insect populations to an insecticide
c) Abundance of parasites

A8 Information about resistance of the LMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

67. Details of any environmental risks related specifically to the resistance of the LMO to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the genetic modification.

A9 Information about resistance of the LMO to a biological agent

68. Details of any environmental risks related specifically to the resistance of the LMO to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A10 Information relating to the release site(s)

(If more than one release site is involved, then the information required in this part should be repeated for each release site)

69. The size of the proposed release site(s).

70. The location of the proposed release site(s). Provide site map(s) with national grid reference(s).

71. Details of the reasons for the choice of the release site(s).

72. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of the LMO and transportation of the LMO, to or from the release site(s).

73. The preparation of the release site(s) before the release(s).

74. The methods to be used for the release(s).

75. The quantity of the LMO to be released.

76. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

77. The size of local human population.

78. The local economic activities which are based on the natural resources of the area.

79. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.

80. The flora and fauna, including crops, livestock and migratory species in the release site(s).

81. The comparison of the natural habitat of the parent organism(s) with the proposed release site(s).

82. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

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Part B Risk Management

B1 Information on control, monitoring, post-release plans

83. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

84. Details of the proposed release site(s) supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the location of the applicant.

85. Details of proposed measures (if any) for monitoring any risks posed by the LMO(s), including monitoring for:

a) The survival or presence of the LMO, or transferred genetic material, beyond the proposed release site(s), including specificity, sensitivity and reliability of detection methods
b) Impacts on the characteristics, or abundance, of other species
c) Transfer of the gene(s) of interest to other species
d) Any other hazards or deleterious effect

86. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

87. Details of ongoing monitoring to be undertaken after the release(s) are completed.

88. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

89. The methods for elimination or inactivation of the organisms at the end of the experiment and the measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment plans

90. Type of waste generated.

91. Expected amount of waste.

92. Possible risks resulting from the waste.

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[For Office Use]

93. Description of waste treatment envisaged and its disposal.

Part C Emergency response plan

94. Methods and procedures for controlling/removing the LMO in case of unintentional release or any adverse effects being realized.

95. Methods for isolation of the area affected.

96. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects

Part D Data or results from any previous release(s) of the LMO

97. Give the following information from the previous applications and releases of the LMO for which the applicant is seeking an approval:
   i. Reference number of each application
   ii. Date of the certificate of approval issued
   iii. Terms and conditions (if any) attached to the approval
   iv. Data and results of post-release monitoring methods and effectiveness of any risk management procedures, terms and conditions and other relevant details
   v. Relevant data if the previous release is on a different scale or into a different ecosystem
   vi. Any other relevant details

98. Details of results of any applications made for approval of the LMO in other countries, including information about conditions (if any) attached to the approval.

99. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in this present application has been developed.

100. If the LMO has been previously released overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.

Borang B

Diadaptasi dari: Laman Sesawang Rasmi Jabatan Biokeselamatan, *Institutional Biosafety and Biosecurity Committee* (IBBC), Borang B

NBB/A/ER/10/FORM B

NBB REF NO : JBK (S) 602-1/1/
(For Office Use)

TITLE :

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM B

APPROVAL FOR RELEASE ACTIVITIES OF LIVING MODIFED ORGANISM (LMO) (S/CRESEARCH AND DEVELOPMENT PURPOSES IN ALL FIELD EXPERIMENTS) OR IMPORTATION OF LMO OTHER THAN HIGHER PLANTS

NBB/A/ER/10/FORM B shall be submitted to the Director General as an application for certificate of approval of release of LMO [Research and development purposes in all field experiments - Second Schedule of the Act - 1] or importation of living modified organism (LMO) other than a higher plant (not for contained use activities). Any organization undertaking modern biotechnology research and development shall submit the form through its registered Institutional Biosafety Committee (IBC). The IBC should assess the information in the form prior to submission. Application must be accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

1

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(For Office Use)

Accuracy of information

The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application. Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

Confidentiality

Any information within this application which is to be treated as CBI, as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user. Please provide written proof of authorization.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

The completed forms to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia

NBB/A/ER/1D/FORM B

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Please retain a copy of your completed form.

APPLICATION CHECK LIST

1. Form NBB/A/ER/1D/FORM B is completed with relevant signatures obtained	☐
2. Application assessed and to be sent through the IBC	☐
3. A copy of clearance documents from the relevant Government agencies included (if required)	☐
4. A copy of the clearance document from the state office where the release is to take place	☐
5. Any information to be treated as confidential business information should be clearly marked "CBI" in the application	☐
6. 1 original copy and 6 copies of the completed application submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	☐
7. Fees as prescribed in the regulation: RM_____ Money order/ Bank draft No: _____Made payable to the Secretary General of the Ministry of Natural Resources and Environment	☐

3

NBB/A/ER/10/FORM 5

NBB REF NO : JBK (5) 602.1/1/
(For Office Use)

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Project Title/Unique Identification Code:	
5. IBC Project Identification No:	
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ if no, please provide information in no 7 below
7. i) Please provide the NBB reference no. for your previous notification/application. ii) How is this application different from the previous notification/application submitted for this activity? (please provide an attachment if additional space is required)	

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NBSA/ENV10/FORM 8

NBS REF NO: JBK (S) 002.1/1/ (For Office Use)

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

Institutional Biosafety Committee (IBC) Assessment Report for release of LMO (Research and development purposes in all field experiments) or importation of LMO other than a higher plant (not for contained use activities).

This must be completed by the registered IBC of the Applicant's organization

Section A – IBC Details

1	Name of organization:			
2	Name of IBC Chairperson:			
	Telephone number:		Fax:	
	Email address:			

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Section B – IBC Assessment

3	Name of principal investigator:		
4	Project Title:		
5	Date of the IBC Assessment:		
6	Does the IBC consider that the principal investigator and every other person(s) authorized to be involved in the field experiment with the LMO have adequate training and experience for the task?		☐ Yes ☐ No
7	The following information related to this project has been checked and approved:		
	a) The objective of the project		☐ Yes ☐ No
	b) The description and genetics of the LMO		☐ Yes ☐ No
	c) The risk assessment and risk management, taking into account the risks to the health and safety of people and the environment from the release of the LMO.		☐ Yes ☐ No
	d) The emergency response plan		☐ Yes ☐ No
8	Has the information been checked by the IBC and found to be complete?		☐ Yes ☐ No
9	Has the IBC assessed the proposed project? ☐ Yes ☐ No If yes, please append a copy of the IBC's assessment report and indicate the attachment in which details are provided.		

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NBB/AERN10/FORM II

NBB REF NO: ...JBIK (S) 602-1/1/
(For Office Use)

Signatures and Statutory Declaration

The proposed release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities) has been assessed as above and endorsed by the IBC. We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

IBC Chairperson:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

NBS/A/ER/10/FORM B

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Part A Risk Assessment

A1 General Information

1. Project Title:

2. Rationale of Project:

3. Project objectives:
   a) Overall Objective
   b) Specific Objective

4. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait(s)

5. Release site(s):
   (If more than one site is involved, then the information required in numbers 5, 6, 7, 8 & 9 should be repeated for each site(s) of release)
   a) District(s)
   b) State(s) in which the release(s) will take place

6. Scale of release per release site.
   (number of LMO involved, size of plot/site, etc)

7. Date when the release(s) is expected to commence.

8. Frequency of releases.

9. Date when release is expected to end.

10. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia.

11. Description of the proposed activities with the LMO.

12. Name of person(s) authorized to undertake activities with the LMO.

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A2 Risk Assessment information – Parent Organism

(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each organism)

13. Details of the parent organism:
    If the LMO is the result of a crossing event between more than one species/strain, please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)
    a) Family name
    b) Genus
    c) Species
    d) Subspecies
    e) Breeding line/strain
    f) Common name

14. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.

15. Information concerning the reproduction of the organism:
    a) The mode or modes of reproduction
    b) Any specific factors affecting reproduction
    c) Generation time

16. Information regarding the sexual compatibility of the organism with other common/ domesticated or wild types.

17. Information concerning the survivability of the parent organism:
    a) Ability to form structures for survival or dormancy including spores and sclerotia
    b) Any specific factors affecting survivability, for example seasonability

18. Information concerning the dissemination of the parent organism:
    a) The means and extent of dissemination
    b) Any specific factors affecting dissemination

19. Details of the natural habitat of the parent organism and its range.

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20. Is the parent organism exotic in Malaysia?
☐ Yes ☐ No

21. Is the parent organism naturalized in Malaysia?
☐ Yes ☐ No

22. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release(s)?
(If more than one location is involved, then the information required in numbers 23 & 24 should be repeated for each site of release)
☐ Yes ☐ No

23. If yes, please provide details of the population(s) and the estimated distances between them from the proposed release(s).

24. The potentially significant interactions of the parent organism with other organisms (including plants) in the ecosystem where it is usually found, including information on toxic effects on humans, plants, animals and other organisms.

25. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants, animals and other organisms and, if so, the details of the possible effects.

26. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

27. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

28. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

29. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information - LMO

30. Details of the modified trait(s) and how the genetic modifications will change the phenotype of the LMO to be released.

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31. What are the gene(s) responsible for the modified trait(s)?

32. Give the name of the organism from which the gene(s) of insert is derived:

(If more than one source is involved then the information required in numbers 32, 33, 34, 35, 36 and 37 should be repeated for each organism)

a) Family name
b) Genus
c) Species
d) Subspecies
e) Breeding line /Strain
f) Common name

33. Indicate whether it is a:

a) viroid
b) RNA virus
c) DNA virus
d) bacterium
e) fungus
f) animal
g) plant
h) other (please specify)

34. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

35. Please provide the following information about the gene(s) of interest:

a) Size of the sequence of the gene(s) of interest inserted
b) Sequence of the gene(s) of interest inserted
c) Intended function of the gene(s) of interest
d) Number of copies of the gene(s) of interest in the construct
e) Details of the steps involved in the construction
f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

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36. Please provide the following information about the deleted sequence(s):
   a) Size of the deleted sequence(s)
   b) Function of the deleted sequence(s)
   c) Details of the steps involved in the deletion of sequences from the parental organism
   d) Provide the map(s) of construct(s)

37. The following information is on the expression of the gene(s) of interest:
   a) Level of expression of the gene(s) of interest and methods used for its characterization
   b) The parts of the organism where the gene(s) of interest is expressed
   c) Indicate the part(s) of the vector that remains in the LMO
   c) The genetic stability of the gene(s) of interest

38. A description of the methods used for the genetic modification:
   a) How the gene(s) of interest was introduced into the parent organism, or
   b) How a sequence of a gene was deleted from the parent organism

39. If no vector was used for the genetic modification please provide details of how the gene(s) of interest is introduced.

40. If vector(s) was used, please provide the following information:

(If more than one vector was used, then the information required in 40 should be repeated for each vector).

   a) Type of vector
      i. plasmid
      ii. bacteriophage
      iii. virus
      iv. cosmid
      v. phasmid
      vi. transposable element
      vii. other, please specify

   b) Identity of the vector(s)
   c) Information on the degree of which the vector(s) contains sequences whose product or function is not known
   d) Host range of the vector(s)

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e) Potential pathogenicity of the vector(s)

f) The sequence of transposons and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

41. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences for the detection of the inserted gene(s) including marker gene(s).

42. Information (biological features) on how the LMO differs from the parent organism in the following respects:

a) Mode(s) and/or the rate of reproduction

b) Dissemination

43. If there is any possibility that the inserted gene(s) in the LMO could be integrated into other species at the release site(s) and the surrounding environment and if so, please provide the following details:

a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred

b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer

c) Any possible adverse effects of the transfer including:

i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)

ii. Environmental risks posed by such an advantage

44. The identification and description of the target organism(s), if any.

45. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

46. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

47. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

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48. Details of any other possible adverse consequences.

49. Details whether the LMO compared to the parent organism that will confer a selective advantage, if any, of the LMO(s) that can impact on survival in the release site(s) and if so the nature of the advantages including a statement on how stable those feabures are.

50. Details of whether the modified trait(s) will confer a selective advantage on the LMO under certain conditions, if so the conditions, including data on the growth rate with and without the selection pressure.

51. Details of the genetic changes, if any, which will be included in the LMO(s) to limit or eliminate any capacity to reproduce or transfer genes to other organisms.

52. In relation to human health:

a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products

b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity

c) The capacity of the organisms for colonizabon,

d) If the organisms are pathogenic to immunocompetent persons:

i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence
ii. communicability
iii. infective dose
iv. host range and possibility of alteration
v. possibility of survival outside of human host
vi. presence of vectors or means of dissemination
vii. biological stability
viii. antibiotic-resistance patterns
ix. allergenicity, and
x. availability of appropriate therapies

53. Details of unintended pleiotropic effects (if any), including undesirable effects on characteristics of the organism which may result from the expression of the gene(s) of interest in the LMO(s) (for example, reduced fertility, increased prevalence, production losses), including an indication of the likelihood of these events.

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54. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

55. Details of how the genetic modification will change the phenotype of the LMO to be released, including information to demonstrate the effect of the genetic modification.

A4 Characteristics affecting survival of LMO(s)

56. The predicted habitat of the LMO.

57. The biological features which affect survival, multiplication and dispersal.

58. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

59. The sensitivity to specific agents (e.g. Disinfectant, pesticides, fertilizers, wind, water).

60 Survivability

a) Ability to form structures enhancing survival or dormancy

i. endospores
ii. cysts
iii. sclerotia
iv. asexual spores (fungi)
v. sexual spores (fungi)
vi. eggs
vii. pupae
viii. larvae
ix. other, please specify

A5 Information about any secondary ecological effects that might result from the release

61. An assessment of possible effects of the proposed release on:
a) Native species
b) Resistance of insect populations to an insecticide
c) Abundance of prey or parasites.

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A6 Information about resistance of the LMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

62. Details of any environmental risks related specifically to the resistance of the LMO to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the modification.

A7 Information about resistance of the LMO to a biological agent

63. Details of any environmental risks related specifically to the resistance of the LMO to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A 8. Information relating to the release site(s)

If more than one release site is involved, then the information required in this part should be repeated for each release site.

64. The size of the proposed release site(s).

65. The site(s) of the proposed release or releases. Provide site map(s) with national grid reference(s).

66. Details of the reasons for the choice of the release site(s).

67. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of a LMO and transportation of a LMO, to or from the release site(s).

68. The preparation of the release site(s) before the release(s).

69. The methods to be used for the release(s).

70. The quantity of LMO(s) to be released.

71. Details of features of the physical environment of the release site(s) particularly features that may minimize or exacerbate any undesirable effects of the LMO.

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72. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

73. The size of local human population.

74. The local economic activities which are based on the natural resources of the area.

75. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.

76. The flora and fauna, including crops, livestock and migratory species in the release site(s).

77. The description of target and non-target ecosystems likely to be affected.

78. The comparison of the natural habitat of the parent organisms with the proposed site or sites of release.

79. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

Part B Risk Management

B1 Information on control, monitoring, post-release plans

80. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

81. Details of proposed site supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the site(s) of the applicant.

82. A description of post-release treatment methods for the LMO.

83. Details of proposed measures (if any) for monitoring any risks posed by the LMO(s), including monitoring for:

a) The survival or presence of the LMO(s), or transferred genetic material, beyond the proposed release site or sites, including specificity, sensitivity and reliability of detection methods

b) Impacts on the characteristics, or abundance, of other species

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c) Transfer of the gene of interest to other species

d) Any other hazards or deleterious effect

84. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

85. Details of ongoing monitoring to be undertaken after the release(s) are completed.

86. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

87. The methods for elimination or inactivation of the organisms at the end of the experiment and measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment plans

88. Type of waste generated.

89. Expected amount of waste.

90 Possible risks resulting from the waste.

91. Description of waste treatment envisaged, and its disposal.

Part C Emergency Response Plan

92 Methods and procedures for controlling the LMO(s) in case of unintentional release.

93. Methods for removal of the LMO(s) in the affected areas.

94. Methods for disposal of other plants, animals and any other thing exposed during the unintentional release.

95. Methods for isolation of the area affected by the unintentional release.

96. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

97. Details of any other contingency measures that will be in place to rectify any unintended consequences if an adverse effect becomes evident during the course of the release.

Part D Data or results from any previous release(s) of the LMO

98. Give the following information from the previous applications (successful or unsuccessful) and releases of the LMO for which the applicant is seeking an approval:
   a) Reference number of each application
   b) Date of the certificate of approval issued
   c) Terms and conditions (if any) attached to the approval
   d) Data and results of post-release monitoring methods and effectiveness of any risk management procedures
   e) Relevant data if the previous release is on a different scale or into a different ecosystem
   f) Any other relevant details

99. Details of results of any applications made for approval of the LMO(s), in other countries, including information about conditions (if any) attaching to the approval.

100. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in the present application has been developed.

101. If the LMO has been previously released overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.

102. Give details of data or results from any previous releases of the LMO(s) for which the applicant is seeking an approval, especially the results of monitoring and the effectiveness of any risk management procedures, terms and conditions and any other relevant details.

PART E LMO(s) that is a Microorganism Associated with Plants

You must only respond to this Part if your application deals with a LMO(s) that is associated with plants.

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E1 Information about Modified Microorganism Associated with Plants

103. Details of the plant species, including information about the specificity of the interaction and the range of plant species with which the LMO(s) can interact.

104. An assessment of the effect of the LMO(s) on the plant species, and details of how it will be monitored.

105. An assessment of any secondary effects that the LMO(s) might have on the plant species.

106. An assessment of whether the modification is likely to cause any change to the range of host plant species susceptible to infection by the organism.

107. An assessment of the effect, if any, of the LMO(s) on the distribution and abundance of host plant species or other species with which the LMO(s) can interact.

108. An assessment of the effect the LMO(s) might have on insects, birds, animals or humans that may eat the plant.

E2 Information if the Parent Organism has an Extended History of Use in Agriculture

109. If the parent organism has an extended history of use in agriculture, a description of the use.

E3 Information if the LMO(s) is a Microorganism Associated with Plant Species that are Food Crops

110. If the LMO(s) is associated with plant species that are food crops, an assessment of whether the LMO(s) could affect the suitability of the resultant produce for consumption by animals or human beings and, if so, details of the effect.

E4 Information about the Impact of the LMO(s) on Soil and Water

111. Details of the expected effects of the LMO(s) on local soil chemistry.
(For example, pH, mineral leaching and nutrient levels)

112. Details of the possible effects of the LMO(s) on local water quality.

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113. Details of the effect the LMO(s) might have on soil organisms that are known to be beneficial to plants (for example, *Rhizobium*, *Azopirillum*, *Frankia* and mycorrhizal fungi) and that are likely to be in a release site.

E5 Information about any Interactions between LMO(s) and Closely Related Microorganisms

114. Details of any known interaction between the LMO(s) and closely related microorganisms in any partner plant (if applicable) and in the environment of the release site.

E6 Information about Known Genetic Exchange between Parent Organism and Plant Pathogens

115. Details of any known exchange of genetic material beteeen the parent organism and plant pathogens.

E7 Other Information

116. Information about the expected survival and dispersal of the LMO(s), including dispersal in natural waters, soil and on other natural surfaces.

117. A statement about whether the LMO(s) will produce spores.

118. A statement about whether the LMO(s) will be resistant to desiccation.

119. A list of sterilising and anti-microbial agents (if any) that are expected to be active against the LMO(s).

120. A statement about whether the LMO(s) will be susceptible to ultraviolet or ionizing radiation.

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PART F LMO(s) that is a Microorganism that Lives in or on Animals

You must only respond to this Part if your application deals with the release of a LMO(s) that is a microorganism that lives in or on animals, including an organism such as gut biota living in larger hosts, and a microorganism applied externally to an animal (for example, bacteria to prevent fleece rot).

F1 Information about the Impact of the LMO(s) on the Host

121. Identification of the animal host species.

122. A statement about whether the parent organism has an extended history of use in agriculture and, if so, details of the use.

123. An assessment of any new capacity the LMO(s) will provide for the host species (for example, ability to degrade plant or pasture toxins).

124. An assessment of whether the competitive advantage, ecological fitness, biology or distribution, of the host will be altered, and relevant data (if any) on the subject.

125. Details of any secondary effect expected to result from the introduction of the LMO(s) into or onto the host (for example, information about any possibility of the genetic insert being transferred to other organisms in the host, or to host cells).

F2 Information about the impact of the LMO(s) on the Environment (particularly the impact on other animals, plants, soil and water)

126. Any evidence that the LMO(s) might be capable of establishing in, or on, other animals, including feral animals.

127. Any evidence of other likely effects (including secondary effects) on other plants or animals in the agricultural and natural environments.

128. If the LMO(s) will establish in an animal, information about whether the LMO(s) will be excreted or otherwise leave the animal and, if so, the time period that is expected the LMO(s) can survive outside the animal.

129. An assessment of the possible effects of the LMO(s) on local water quality.

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F3 Other Information

130. A statement about whether the LMO(s) will produce spores.

131. A statement about whether the LMO(s) will be resistant to desiccation.

132. A list of sterilising and anti-microbial agents (if any) that are expected to be active against the LMO(s).

133. An statement about whether the LMO(s) will be susceptible to ultraviolet or ionizing radiation.

Part G LMO(s) that is a Vertebrate Animal

You must only respond to this Part if your proposal deals with a LMO(s) that is a vertebrate animal (other than aquatic organisms).

G1 Information about the effects of the LMO(s) on the environment

134. Information about the likelihood of any unintended effect on an animal resulting from the release.

135. Information about any intended gains that are directly linked to changes in other characteristics of the subject species.

G2 Information about Any Effects the Expression of the Modified Trait might have on the Animal

136. Information about the expected effects on the physiology, behaviour and reproduction of the animal or animals.

G3 Information about future LMO activities

137. A statement on whether an animal in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future.

138. A statement on whether the proposed arrangements for handling any offspring are the same as those for the experimental animal or animals, and, if not, the proposed different arrangements.

G4 Information about Feral Populations of Subject Species, if any, that Exist in Malaysia or that may be established

139. Details of any agricultural, environmental or disease-control problems caused by feral populations of the subject species.

140. Details of any experimental work that has been done on expression of the novel genetic material in feral animals (such as cross-breeding of LMO(s) with captive feral animals), and the results of such work.

141. An assessment of the likelihood of the novel genetic material entering the feral gene pool (for example, by interbreeding with modified farm animals).

142. An assessment of the effect that the entry of novel genetic material into a feral gene pool might have:
   a) On the distribution and abundance of the feral population
   b) On the ability of the feral population to cause agricultural or environmental problems
   c) In contributing to the spread of infectious disease

143. If no feral population exists in Malaysia, information about:
   a) The likelihood of the imparted characteristic enhancing the ability of the species to establish feral populations
   b) If there is a likelihood, the arrangements in place to prevent this from occurring

G5 Information about the capacity of the LMO(s) to Interbreed

144. Details of the capacity of the LMO(s) to interbreed with any species native to, or currently present in, Malaysia.

G6 Information about requirements for optimal expression of the introduced modified trait(s)

145. Details of the management procedures and environmental factors, if any, which would be required for optimal expression of the introduced trait(s).

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Part H LMO(s) that is an Aquatic Organism

You must only respond to this Part if your application deals with a LMO(s) that is an aquatic organism, for example, fish, crustaceans and molluscs not included aquatic plants.

H1 Information about Effects of the LMO(s) on the Environment

146. Information about the effect that the LMO(s) might have on the food chain.

147. A statement on whether the LMO(s) could produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators and, if so, the likely effect.

148. Details of any unintended effects that may result from the release.

149. A statement on whether the expression of the modified gene is expected to be directly linked to undesirable changes in other characteristics of the subject organisms (for example, a decrease in nutritional value).

150. Information about:
   a) Whether the modified genetic material can be transmitted to any other species
   b) If so, the expected mechanism of transfer, the likely affected species and any likely consequences

H2 Information About Any Impact On Natural Populations

151. Information about whether natural populations of parent organism, or a closely related species, exist in Malaysia (including in rivers, lakes, dams or coastal waters) and, if so, details about any problems the natural populations cause with other organisms.

152. If no natural populations of the organism to be modified exist in Malaysia, information about the potential for the modified traits to enhance the ability of the species to establish populations in aquatic habitats.

153. Information about the results of any experimental work that has been done on phenotypic expression of the modified genetic material in naturally occurring organisms (such as cross-breeding of LMO(s) with wild or farmed stocks).

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154. An assessment of the likelihood of the modified genetic material entering the gene pool of natural populations.

155. Information about any impact the entry of the modified genetic material into the gene pool of a natural organism could have on:
   a) The distribution and abundance of the organism
   b) Associated aquatic farms
   c) The environment
   d) Public health

156. Information about mechanisms intended to be used to prevent dispersal of the LMO(s) into other ecosystems.

H3 Information about Future Activities in Relation to the LMO(s)

157. A statement about whether the LMO(s) is intended to be allowed to breed or whether breeding is planned in the future.

158. A statement about whether the proposed arrangements for handling any offspring are the same as those for the experimental LMO(s) and, if not, the proposed different arrangements.

Part I LMO(s) that is an Invertebrate Animal
You must only respond to this Part if your application deals with a LMO(s) that is an invertebrate animal.

159. Information about the effect that the LMO(s) might have on the food chain.

160. Information about the potential for the LMO(s) to produce any novel metabolites, or toxins, that is likely to have deleterious effects on parasites or predators.

161. Information about other unintended effects that may result from the release.

162. A statement on whether the LMO(s) will be fertile and, if not, whether it is intended to use fertile organisms in later releases.

163. Information about whether populations of the parent organism, or a closely related species, exist in Malaysia and, if so, any environmental or public health problems, or benefits, caused by the populations.

164. Information about:
   a) Whether the modified genetic material can be transmitted by means other than by normal reproduction for the species
   b) If so, the likelihood of that genetic material entering gene pools or natural populations

165. Information about:
   a) Whether the modified genetic material can be transmitted to any other species
   b) If so, the expected mechanism of transfer and the likely affected species

166. Information about any experimental work that has been done on the phenotypic expression of the novel genetic material in other genetic backgrounds (such as cross-breeding of modified strains with wild or caught stock).

167. Information about the effect on the distribution and abundance of the natural populations of the organism, of the entry of the novel genetic material into the gene pool of those populations.

168. Details of the mechanisms proposed to be used to prevent dispersal of the LMO(s) into other ecosystems.

Part J LMO(s) that is to be used for Biological Control

You must only respond to this Part if your proposal deals with a LMO(s) that is to be used for biological control.

J1 Information about the Expected Interaction between the LMO(s) and the Species Targeted for Biological Control

169. The name of the species targeted for biological control.

170. Details of any direct effects the parent organism has on the target.

171. Details of any direct effects the LMO(s) is expected to have on the target species.

172. Details of how the LMO(s) is intended to be transferred from one target species to another and what factors affect the transferability.

173. Details of the genetic response that may be invoked in populations of the target organism as a result of the use of the LMO(s) (for example, increased resistance to the modified organism), and the expected evidence for the response.

J2 Information on the Possible Effects of the LMO(s) on Non-Target Organisms

174. Details of the host range of the LMO(s), and details of any difference between that host range and the host range of the parent organism.

175. A list of the non-target organisms that have been tested for susceptibility to the LMO(s), and the rationale for the choice of species tested.

176. If the modified traits can be transmitted to other organisms that are likely to be in the environment, details of any effects those other organisms are likely to have on non-target species.

J3 Information on Other Possible Effects of the LMO(s) on the Environment

177. A statement about the secondary effects that can be envisaged on competitors, predators, prey or parasites of the target species.

178. An assessment of the consequence of the removal, or reduction, of the target species on the management of agriculturally significant plants or farm animals.

179. Details of any predicted change in the ecosystem resulting from a reduction in the population of the target organism.

180. Information about:

a) Whether the LMO(s) produces metabolites that may have deleterious effects directly or indirectly (through concentration in the food chain) on other organisms, including human beings

b) If so, the likely effect

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PART K LMO(s) that is to be Used for Bioremediation

You must only respond to this Part if your application deals with a LMO(s) that is to be used for bioremediation

K1 Information about the Expected Interaction between the LMO(s) and the Target Substrate for Bioremediation

181. Identification of the target substrate for bioremediation.

182. Details of the effect the parent organism has on the target substrate.

183. Details of the effect the LMO(s) is expected to have on the target substrate.

184. A list of the substances other than the target substrate that can be metabolized by the LMO(s) and that cannot be metabolized by the parent organism.

K2 Information about the LMO(s) and its impact on the Environment

185. A statement about whether the LMO(s) will be self-sufficient if added to the contaminated site or whether additional measures may be required.
(For example, provision of supplementary nutrients and growth factors, or other environmental modifications)

186. A list of any metabolites produced by the LMO(s) that may have deleterious effects, either directly or indirectly (through concentration in the food chain), on other organisms.

187. Details of effects the LMO(s) might have on water, air or soil quality.

188. Details of effects the LMO(s) might have on organisms that ingest it.

189. A statement on whether the LMO(s) will be dispersed from the site of application and, if so, the proposed mechanisms involved and the likely consequences.

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PART L LMO(s) Intended to be Used as Food for Human or Vertebrate Animal Consumption

You must only respond to this Part if your application deals with a LMO(s) intended to be used as food for human or vertebrate animal consumption.

190. Details of:
   a) Whether the parent organism or the donor organism is of a kind already in use as a food for consumption by human beings or animals, or used in the production of such a food
   b) Whether any processing is needed, or is commonly applied, before consumption

191. Details of any metabolites produced by the LMO(s) that may have adverse effects on the consumer (human or animal), including available data on toxicology, allergenicity and other possible adverse effects.

192. Details of any products of the LMO(s) that are expected to concentrate in the food chain to levels which may become toxic.

193. Details of any expected changes to the nutritional quality of such food as a result of the genetic modification.

194. A statement on whether the LMO(s) is a major component of such food as consumed, or a minor component (for example, yeast cells in beer).

***Note:** For a food for human consumption that contains LMO(s) or GM products, see also the assessment requirements under the Malaysia Food Safety Act 1983*

Borang C

Diadaptasi dari: Laman Sesawang Rasmi Jabatan Biokeselamatan, *Institutional Biosafety and Biosecurity Committee* (IBBC), Borang C.

NBB/A/ER/10/FORM C

NBB REF NO : JBK (S) 602-1/1/
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TITLE :

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM C

APPROVAL FOR RELEASE ACTIVITIES (SECOND SCHEDULE 2-6) OR IMPORTATION OF LIVING MODIFIED ORGANISM (LMO) THAT IS A HIGHER PLANT AND PRODUCT OF SUCH ORGANISM

NBB/A/ER/10 FORM C shall be submitted as an application for certificate of approval for release activities (SECOND SCHEDULE 2-6) or importation for release of living modified organism (LMO) that is a higher plant and product of such organism(not for contained use activities) . Application must be accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

If the application is for release activities of an LMO or importation for release of an LMO that is a higher plant, please fill up Part A – D.
If the application is for release activities of a product of such organism or importation for release of a product of such organism, please fill up Part E.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

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Accuracy of information

The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application. Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

Confidentiality

Any information within this application which is to be treated as CBI , as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user. Please provide written proof of authorization.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

NBB/A/ER/10/FORM C

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The completed form to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia.

Please retain a copy of your completed form

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM C is completed with relevant signatures obtained	☐
2. A copy of the clearance documents from the Department of Agriculture included. (If required)	☐
3. Any information to be treated as confidential business information should be clearly marked "CBI" in the application	☐
4. 1 original and 6 copies of the completed applications submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	☐
5. Fees as prescribed in the regulation: RM_____ Money order/ Bank draft No: _____ Made payable to the Secretary General of the Ministry of Natural Resources and environment.	☐

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NBB/AER/10/FORM C

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(For office use)

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization Telephone (office) Telephone (mobile) Fax number Email Postal Address	
4. Product Name (commercial and other names)/Unique Identification Code:	
5. Type of release activity	☐ Supply or offer to supply for sale/ placing on the market ☐ Offer as gift, prize or free item ☐ Disposal ☐ Remediation purposes ☐ Commercial planting ☐ Any other activity which does not amount to contained use (please specify)
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ If no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification /application. II) How is this application different from the previous application submitted for this activity? (please provide an attachment if additional space is required)	

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Details of Agent / Importer

8. Organization:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

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Signatures and Statutory Declaration

We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

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NBS/BA/ENV/10/FORM C

(For office use)

PART A - Living Modified Organism (LMO) that is a Higher Plant

Risk Assessment

A1 General Information

1. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait (s)

2. Objective(s) of the release.

3. Release site(s):
   (If more than one site is involved, then the information required in numbers 3, 4, 5, 6, 7 & 8 should be repeated for each release site):
   a) District(s),
   b) State(s) in which the release(s) will take place.

4. Scale of release per release site.
   (Number of LMO involved, size of plot/ site etc)

5. Date when the release(s) is expected to commence.
   (Frequency of releases)

6. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia.

7. Description of the proposed activities with the LMO.

8. Name of person(s) authorized to undertake activities with the LMO.

A2 Risk Assessment Information - Parent Organism

(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)

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9. Details of the parent organism:

If the LMO is the result of a crossing event between more than one species/cultivar/ breeding line/variety, please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)

a) Family name
b) Genus
c) Species
d) Subspecies
e) Cultivar/Breeding line/Variety
f) Common name

10. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.

11. Information concerning the reproduction of the parent organism:

a) The mode or modes of reproduction
b) Any specific factors affecting reproduction
c) Generation time

12. Information regarding the sexual compatibility of the parent organism with other cultivated or wild plant species.

13. Information concerning the survivability of the parent organism:

a) Ability to form structures for survival or dormancy including seeds, spores and sclerotia,
b) Any specific factors affecting survivability (e.g. seasonability).

14. Information concerning the dissemination of the parent organism:

a) The means and extent of dissemination
b) Any specific factors affecting dissemination.

15. Details of the natural habitat of the parent organism and its range.

16. Is the parent organism exotic in Malaysia?

☐ Yes ☐ No

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17. Is the parent organism naturalized in Malaysia?
☐ Yes ☐ No

18. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release?
(If more than one location is involved, then the information required in numbers 18 & 19 should be repeated for each location(s) of release)
☐ Yes ☐ No

19. If yes, please provide details of the population or populations and the estimated distances between them from the proposed release(s).

20. The potentially significant interactions of the parent organism with organism other than plant in ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

21. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants or animals and, if so, the details of the possible effects.

22. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

23. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

24. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

25. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information - LMO

26. Details of the modified trait(s) and how the genetic modification will change the phenotype of the LMO to be released.

27. What are the gene(s) responsible for the modified trait(s)?

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28. Give details of the organism(s) from which the gene(s) of interest is derived :

(If more than one gene is involved then the information required in numbers 28, 29, 30, 31, 32 & 33 should be repeated for each gene)

a) Family name
b) Genus
c) Species
d) Subspecies
e) Cultivar/Breeding line/Variety
f) Common name

29. Indicate whether it is a:

a) viroid
b) RNA virus
c) DNA virus
d) bacterium
e) fungus
f) animal
g) plant
h) other (please specify)

30. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

31. Please provide the following information about the gene(s) of interest:

a) Size of sequence of the gene(s) of interest inserted
b) Sequence of the gene(s) of interest inserted
c) Intended function of the gene(s) of interest
d) Number of copies of the gene(s) of interest in the construct
e) Details of the steps involved in the construction
f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

32. Please provide the following information about the deleted sequence(s):
    a) Size of the deleted sequence(s)
    b) Function of the deleted sequence(s)
    c) Details of the steps involved in the deletion of sequences from the parental organism
    d) Provide the map(s) of construct

33. The following information is on the expression of the gene(s) of interest:
    a) Level of expression of the gene(s) of interest and methods used for its characterization,
    b) The parts of the LMO where the gene(s) of interest is expressed, such as roots, stem or pollen
    c) Indicate the part(s) of the vector(s) that remains in the LMO
    d) The genetic stability of the gene(s) of interest.

34. A description of the methods used for the genetic modification:
    a) How gene(s) of interest was introduced into the parent organism, or
    b) How a sequence of a gene was deleted from the parent organism

35. If no vector was used for the genetic modification, please provide the detail of how the gene(s) of interest is introduced.

36. If vector(s) was used, please provide the following information:
(If more than one vector was used, then the information required in 36 should be repeated for each vector)
    a) Type of vector:
        i. plasmid
        ii. bacteriophage
        iii. virus
        iv. cosmid
        v. phasmid
        vi. transposable element
        vii. other, please specify

    b) Identity of the vector (s)
    c) Information on the degree of which the vector (s) contains sequences whose product or function is not known
    d) Host range of the vector(s)
    e) Potential pathogenicity of the vector(s)

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f) The sequence of transposons, and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

37. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences for the detection of the inserted genes including marker genes.

38. Information (biological features) on how the LMO differs from the parent organism in the following respects.

g) Mode(s) and/or the rate of reproduction

a) Dissemination

39. If there is any possibility that the inserted genes in the LMO could be integrated into other species at the release site(s) and the surrounding environment, and if so, please provide the following details:

a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred

b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer

c) Any possible adverse effects of the transfer including

i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)

ii. Environmental risks posed by such an advantage

40. The identification and description of the target organism(s), if any.

41. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

42. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

43. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

44. Details of any other possible adverse consequences.

45. Details of whether the modified trait(s) will confer a selective advantage on the LMO compare to the parent organism and if so, the conditions including data on the growth rate with and without the selection pressure and the nature of the advantages including a statement on how stable those features are.

46. Details of the genetic changes, if any, which will be included in the LMO to limit or eliminate any capacity to reproduce or transfer genes to other organism.

47. In relation to human health:
    a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
    b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
    c) The capacity of the organisms for colonization
    d) If the organisms are pathogenic to immunocompetent persons:
        i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence
        ii. communicability
        iii. infective dose
        iv. host range and possibility of alteration
        v. possibility of survival outside of human host
        vi. presence of vectors or means of dissemination
        vii. biological stability
        viii. antibiotic-resistance patterns
        ix. allergenicity, and
        x. availability of appropriate therapies

48. Details of unintended pleiotropic effects (if any), including undesirable effects on agronomic characteristics of the plant which may result from the expression of the gene of interest(s) in the LMO (for example, reduced fertility, increased prevalence, production losses, grain shedding), including an indication of the likelihood of these events.

49. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

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50. Details of how the genetic modification will change the phenotype of the LMO to be released, including information to demonstrate the effect of the genetic modification.

51. Details of the mechanism of pollen spread (by insect vectors or by other means) in the plant population:
   a) Details of pollen viability for the parent organism and of the LMO
   b) Details of any potential pollinators and their range and distribution in Malaysia
   c) Quantitative data on successful cross-pollination between the parent organism, the LMO and its wild relatives, if available

A4 Information about weeds

52. Details of the members of the family of parent organism that are known to be weeds in any environment.

53. Details of cross-pollination between the species to which the LMO belongs and wild relatives known to be weeds, including a copy of any literature reports that support the information.

A5 Information about the seeds of the LMO

54. A statement on whether the LMO proposed to be released will be allowed to set seed and, if not, whether setting seed is planned for a later release.

55. If the LMO is to be allowed to set seed, will the mature seed normally remain contained within an ear, capsule or pod, so that practically all of the seed can be readily harvested, or is the seed shed soon after it matures?
If the latter, provide an indication of the proportion of seed likely to remain in the environment following harvest.

56. Details of the length of time that the seeds are capable of being dormant and whether it differs from the parent organism.

A6 Characteristics affecting survival of LMO

57. The predicted habitat of the LMO.

(For office use)

58. The biological features which affect survival, multiplication and dispersal.

59. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

60. The sensitivity to specific agents (e.g. disinfectant, pesticides, fertilizers, wind, water).

A7 Information about any secondary ecological effects that might result from the release

61. An assessment of possible effects of the proposed release on:
    a) Native species
    b) Resistance of insect populations to an insecticide
    c) Abundance of parasites

A8 Information about resistance of the LMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

62. Details of any environmental risks related specifically to the resistance of the LMO to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the genetic modification.

A9 Information about resistance of the LMO to a biological agent

63. Details of any environmental risks related specifically to the resistance of the LMO to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A10 Information relating to the release site(s)

(If more than one release site is involved, then the information required in this part should be repeated for each release site)

64. The size of the proposed release site(s).

65. The location of the proposed release site(s). Provide site map(s) with national grid reference(s).

66. Details of the reasons for the choice of the release site(s).

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67. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of the LMO and transportation of the LMO, to or from the release site(s).

68. The preparation of the release site(s) before the release(s).

69. The methods to be used for the release(s).

70. The quantity of LMO to be released.

71. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

72. The size of local human population.

73. The local economic activities which are based on the natural resources of the area.

74. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.

75. The flora and fauna, including crops, livestock and migratory species in the release site(s).

76. The comparison of the natural habitat of the parent organism with the proposed release site(s).

77. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

Part B Risk Management

B1 Information on control, monitoring, post-release plans

78. A description of measures (if any) to minimize the effects of any transfer of the modified trait(s) to other organisms.

79. Details of the proposed release site(s) supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the location of the applicant.

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80. Details of proposed measures (if any) for monitoring any risks posed by the LMO, including monitoring for:

a) The survival or presence of the LMO, or transferred genetic material, beyond the proposed release site(s), including specificity, sensitivity and reliability of detection methods

b) Impacts on the characteristics, or abundance, of other species

c) Transfer of the gene(s) of interest to other species.

d) Any other hazards or deleterious effect

81. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

82. Details of ongoing monitoring to be undertaken after the release(s) are completed.

83. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

84. The methods for elimination or inactivation of the organisms at the end of the release and measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment plans

85. Type of waste generated.

86. Expected amount of waste.

87. Possible risks resulting from the waste.

88. Description of waste treatment envisaged and its disposal.

Part C Emergency Response Plan

89. Methods and procedures for controlling the LMO in case of any unintentional release and adverse effects being realized.

90. Methods for isolation of affected area.

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(For office use)

91. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects during the unintentional release.

Part D Data or results from any previous release(s) of the LMO

92. Give the following information from the previous applications (successful or unsuccessful) and releases of the LMO for which the applicant is seeking an approval:
    a. Reference number of each application
    b. Date of the certificate of approval issued
    c. Terms and conditions (if any) attached to the approval
    d. Data and results of post-release monitoring methods and effectiveness of any risk management procedures, terms and conditions and other relevant details
    e. Relevant data if the previous release is on a different scale or into a different ecosystem
    f. Any other relevant details

93. Details of results of any applications made for approval of the LMO in other countries, including information about conditions (if any) attached to the approval.

94. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in this present application has been developed.

95. Give details of data or results from any previous release of the LMO(s) for which the applicant is seeking an approval, especially the results of monitoring and the effectiveness of any risk management procedures, terms and conditions and any other relevant details.

PART E - Product of Such Organism

E1 General Information

96. The name and address of the manufacturer or distributor of the product.

97. General description of the product:
    a) Type of product
    b) Composition of the product
    c) Physical state of the product

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96. For an imported product – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry Of Health, Malaysia.

99. The type of environment and/or the geographical areas within Malaysia for which the product is suited.

100. The type of expected use of the product and the description of the persons who are expected to use the product.

E2 Information regarding proposed labeling of the product (according to Malaysian regulations on the labeling of genetically modified food)

101. Is the product being simultaneously notified to another country?
☐ Yes ☐ No
If yes, please specify.

102. Is the same product marketed in a country outside Malaysia?
☐ Yes ☐ No
If yes, please supply the following information:
a) Name of country
b) Authority which granted consent (if applicable)
c) Conditions under which consent was given (if applicable)

103. Has the product ever been withdrawn from the market of a country?
☐ Yes ☐ No
If yes, please supply the following information:
a) Name of country or countries
b) Reasons for withdrawing the product, if known

104. Has the product been rejected by authorities of a country?
☐ Yes ☐ No
If yes, please supply the following information:
a) Name of country or countries
b) Authority which rejected the product
c) Reasons for rejecting the product, if known

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105. Description of identification and detection techniques for the LMO(s) in the product.

E3 Description of the LMO from which the product was derived from

(If the product is derived from more than one LMO, then the information required in numbers 106,107,108,109 & 110 should be repeated for each LMO)

106. Description of the LMO:
   a) Genus and species
   b) Common name
   c) Modified trait(s)
   d) Gene(s) responsible for the modified trait(s)

107. Details of the parent organism:
   a) Genus and species
   b) Common name

108. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

109. Give the name of the organism from which the gene(s) of interest is derived from:
   a) Genus and species
   b) Common name

110. Indicate whether the organism from which the gene(s) of interest is derived from is a:
   a) virus
   b) bacterium
   c) fungus
   d) animal
   e) plant
   f) other (please specify)

E4 Risk Management of the Product

111. Specific instructions or recommendations for storage and handling of the product.

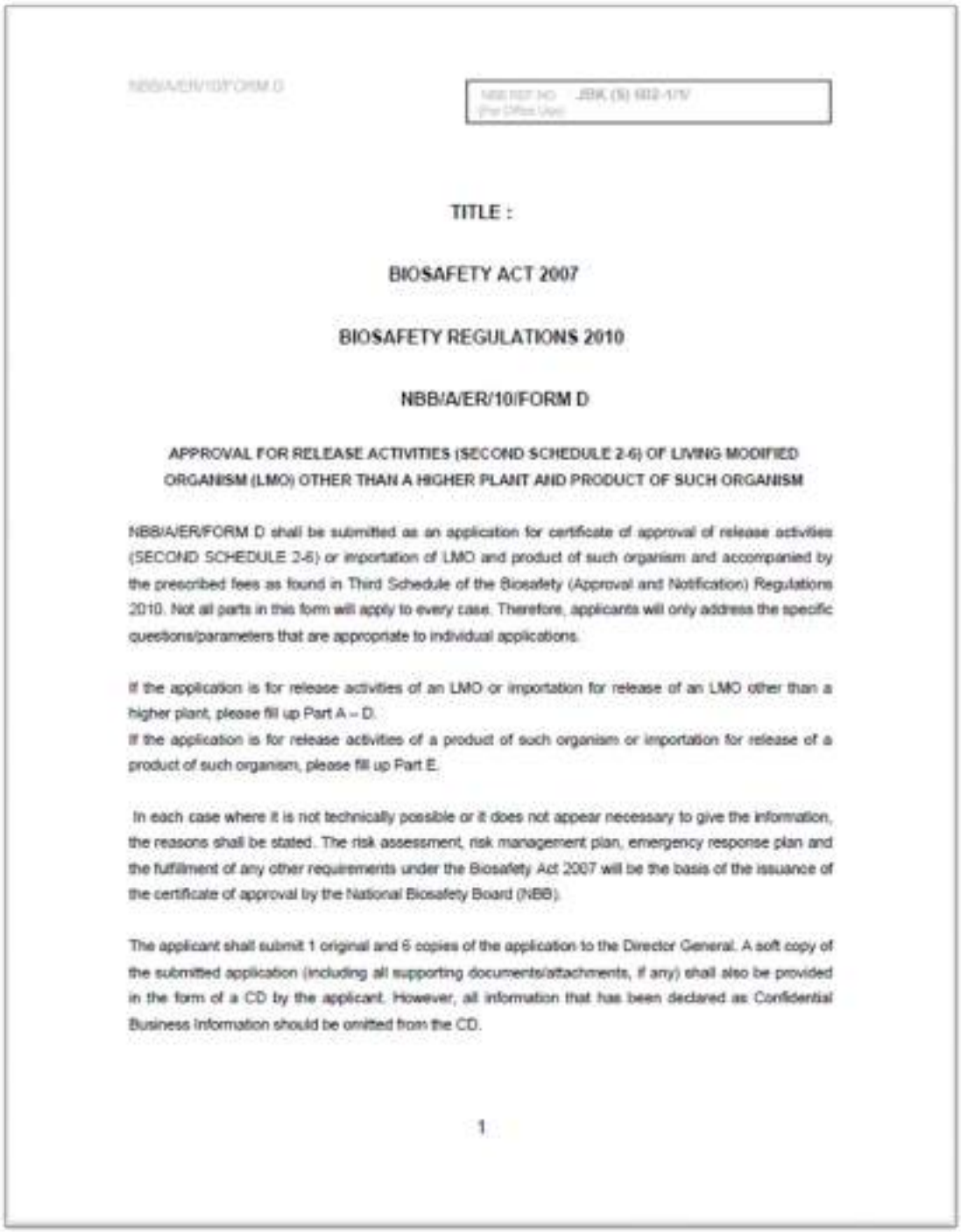
112. Measures for waste disposal and treatment of the product.

E5. Emergency Response Plan

113. Details of proposed measures to be taken in the event of adverse consequences/ misuse of the product.

Borang D

Diadaptasi dari: Laman Sesawang Rasmi Jabatan Biokeselamatan, *Institutional Biosafety and Biosecurity Committee* (IBBC), Borang D.



NBB/A/ER/10/FORM D

TITLE :

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM D

APPROVAL FOR RELEASE ACTIVITIES (SECOND SCHEDULE 2-6) OF LIVING MODIFIED ORGANISM (LMO) OTHER THAN A HIGHER PLANT AND PRODUCT OF SUCH ORGANISM

NBB/A/ER/FORM D shall be submitted as an application for certificate of approval of release activities (SECOND SCHEDULE 2-6) or importation of LMO and product of such organism and accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

If the application is for release activities of an LMO or importation for release of an LMO other than a higher plant, please fill up Part A – D.
If the application is for release activities of a product of such organism or importation for release of a product of such organism, please fill up Part E.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information should be omitted from the CD.

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NBB/AVCN/03/FORM D

For Office Use

Accuracy of information

The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application.

Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

Confidentiality

Any information within this application which is to be treated as Confidential Business Information (CBI), as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the living modified organism
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

NBB/A/ER/10/FORM D

NBB REF NO: JBK (S) 602-1/5 (For Office Use)

The completed form to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2,
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia

Please retain a copy of your completed form

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM D is completed with relevant signatures obtained	☐
2. A copy of the clearance document from the Department of Agriculture included (If required)	☐
3. Any information to be treated as confidential business information should be clearly marked "CBI" in the application	☐
4. 1 original and 6 copies of the completed applications submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	☐
5. Fees as prescribed in the regulation: RM_____ Money order/ Bank draft No: _____ Made payable to the Secretary General of the Ministry of Natural Resources and Environment	☐

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization Telephone (office) Telephone (mobile) Fax number Email Postal Address	

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4. Product Name (commercial and other names) Unique Identification Code:	
5. Type of release activity	☐ Supply or offer to supply for sale/ placing on the market ☐ Offer as gift, prize or free item ☐ Disposal ☐ Remediation purposes ☐ Commercial planting ☐ Any other activity which does not amount to contained use (please specify)
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ if no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification/application if any II) How is this application different from the previous application submitted for this activity? (please provide an attachment if additional space is required)	

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10.Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

NBB/A/05/10/FORM D

NBB REF NO: JBK (3) 662-1/1
(For Office Use)

Signatures and Statutory Declaration

We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

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NBBA/ACR/SP/FORM D

PART A Risk Assessment

A1 General Information

1. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait(s)

2. Objective(s) of the release.

3. Release site(s):
   (If more than one location is involved, then the information in numbers 3, 4, 5, 6, 7 & 8 should be repeated for each location(s) of release)
   a) District(s)
   b) State(s) in which the release(s) will take place

4. Scale of release per release site.
   (No of LMO involved, size of plot/site etc)

5. Date when the release(s) is expected to commence.
   (Frequency of releases)

6. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia.

7. Description of the proposed activities with the LMO/ product of such organism.

8. Name of person(s) authorized to undertake activities.

A2 Risk Assessment Information – The Parent Organism
(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)

NBS/ACRV/GF/FORM D

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9. Details of the parent organism:

If the LMO is the result of a crossing event between more than one species/cultivar/ breeding line/variety, please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)

a) Family name
b) Genus
c) Species
d) Subspecies
e) Breeding line/ Strains
f) Common name

10. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

11. Information concerning the reproduction of the organism:

a) The mode or modes of reproduction
b) Any specific factors affecting reproduction
c) Generation time

12. Information regarding the sexual compatibility of the organism with other common/ domesticated or wild types.

13. Information concerning the survivability of the organism:

a) Ability to form structures, including spores, sclerotia for survival or dormancy
b) Any specific factors affecting survivability like seasonability

14. Information concerning the dissemination of the organism:

a) The means and extent of dissemination
b) Any specific factors affecting dissemination

15. Details of the natural habitat of the parent organism and its range.

16. Is the parent organism exotic in Malaysia?

☐ Yes ☐ No

17. Is the parent organism naturalized in Malaysia?

☐ Yes ☐ No

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18. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release?
(If more than one location is involved, then the information required in numbers 18 & 19 should be repeated for each location(s) of release)
☐ Yes ☐ No

19. If yes, please provide details of the population(s) and the estimated distances between them from the proposed release(s).

20. The potentially significant interactions of the parent organism with organism other than plant in ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

21. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants or animals and, if so, the details of the possible effects.

22. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

23. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

24. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

25. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information – LMO

26. Details of the modified trait (s) and how the genetic modifications will change the phenotype of the LMO to be released.

27. What are the gene(s) responsible for the modified trait(s)?

28. Give details of the organism(s) from which the gene(s) of interest is derived.
(If more than one organism is involved then the information required in numbers 28, 29 & 30, should be repeated for each organism)

a) Family name
b) Genus
c) Species
d) Subspecies
e) Breeding line/ Strain
f) Common name

29. Indicate whether it is a:
a) viroid
b) RNA virus
c) DNA virus
d) bacterium
e) fungus
f) animal
g) plant
h) other (please specify)

30. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

31. Please provide the following information about the gene(s) of interest:
a) Size of sequence of the gene(s) of interest inserted
b) Sequence of the gene(s) of interest inserted
c) Intended function of the gene(s) of interest
d) Number of copies of the gene(s) of interest in the construct
e) Details of the steps involved in the construction
f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

32. Please provide the following information about the deleted sequence(s):
a) Size of the deleted sequence(s)
b) Function of the deleted sequence(s)
c) Details of the steps involved in the deletion of sequences from the parental organism
d) Provide the map(s) of construct(s)

33. The following information is on the expression of the gene(s) of interest:
a) Level of expression of the gene(s) of interest and methods used for its characterization
b) The parts of the organism where the gene(s) of interest is expressed

c) The genetic stability of the gene(s) of interest

34. A description of the methods used for the genetic modification:
   a) How gene(s) of interest was introduced into the parent organism, or
   b) How a sequence of a gene was deleted from the parent organism

35. If vector(s) was used, please provide the following information:
(If more than one vector was used, then the information required in 35 should be repeated for each vector)

   a) Type of vector
      i. plasmid
      ii. bacteriophage
      iv. virus
      v. cosmid
      vi. phasmid
      vii. transposable element
      viii. other, please specify

   b) Identity of the vector(s)
   c) Information on the degree of which the vector(s) contains sequences whose product or function is not known
   d) Host range of the vector (s)
   e) Potential pathogenecity of the vector(s)
   f) The sequence of transposons, and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

36. If no vector was used for the genetic modification please provide the detail of how the gene(s) of interest is introduced.

37. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences for the detection of the inserted gene(s) including marker gene(s).

38. Information on how the LMO(s) differs from the parent organism in the following respects:
   a) Mode(s) and/or the rate of reproduction
   b) Dissemination

39. If there is any possibility that the inserted gene(s) in the LMO(s) could be integrated into other species at the release site(s) and the surrounding environment, and if so please provide the following details:
    a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred
    b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer
    c) Any possible adverse effects of the transfer including:
        i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)
        ii. Environmental risks posed by such an advantage

40. The identification and description of the target organism(s), if any.

41. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

42. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

43. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

44. Details of any other possible adverse consequences.

45. Details of whether the modified trait(s) will confer a selective advantage on the LMO compare to the parent organism and if so, the conditions including data on the growth rate with and without the selection pressure and if so, the nature of the advantages including a statement on how stable those features are.

46. Details of the genetic changes, if any, which will be included in the LMO to limit or eliminate any capacity to reproduce or transfer genes to other organism.

47. The location of the gene(s) of interest in the cells (whether it is integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form) and the methods for its determination.

48. Details of the genetic changes, if any, which will be included in the LMO(s) to limit or eliminate any capacity to reproduce or transfer genes to other organisms.

49. In relation to human health:

a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
c) The capacity of the organisms for colonization
d) If the organisms are pathogenic to immunocompetent persons:

i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence
ii. communicability
iii. infective dose
iv. host range and possibility of alteration
v. possibility of survival outside of human host
vi. presence of vectors or means of dissemination
vii. biological stability
viii. antibiotic-resistance patterns
ix. allergenicity, and
x. availability of appropriate therapies

50. Details of unintended pleiotropic effects (if any), including undesirable effects on characteristics of the organism which may result from the expression of the gene(s) of interest in the LMO(s) (for example, reduced fertility, increased prevalence, production losses), including an indication of the likelihood of these events.

51. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

A4 Characteristics affecting survival of LMO(s)

52. The predicted habitat of the LMO(s).

53. The biological features which affect survival, multiplication and dispersal.

54. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

55. The sensitivity to specific agents (e.g. Disinfectant, pesticides, fertilizers, wind, water).

56. Survivability
    a) Ability to form structures enhancing survival or dormancy
        i. endospores
        ii. cysts
        iii. sclerotia
        iv. asexual spores (fungi)
        v. sexual spores (fungi)
        vi. eggs
        vii. pupae
        viii. larvae
        ix. other, please specify

A5 Information about any secondary ecological effects that might result from the release

57. An assessment of possible effects of the proposed release on:
    a) Native species
    b) Resistance of insect populations to an insecticide
    c) Abundance of prey or parasites

A6 Information about resistance of the LMO(s) to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

58. Details of any environmental risks related specifically to the resistance of the LMO(s) to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the modification.

A7 Information about resistance of the LMO(s) to a biological agent

59. Details of any environmental risks related specifically to the resistance of the LMO(s) to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A8 Information relating to the site of release

(If more than one release site is involved, then the information required in this part should be repeated for each release site)

60. The size of the release site(s).

61. The location of the proposed release site(s). Provide site map(s) with national grid reference.

62. Details of the reasons for the choice of release site(s).

63. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of a LMO(s) and transportation of a LMO(s), to or from the release site(s).

64. The preparation of the release site(s) before the release(s).

65. The methods to be used for the release(s).

66. The quantity of LMO to be released.

67. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

68. The size of the local human population.

69. The local economic activities which are based on the natural resources of the area.

70. The distance to the nearest drinking water supply zone areas and/or area protected for environmental purposes.

71. The flora and fauna including crops, livestock and migratory species in the release site(s).

72. The comparison of the natural habitat of the parent organism with the proposed release site(s).

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(For Office Use)

73. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

74. Details of features of the physical environment of the release site(s) particularly features that may minimize or exacerbate any undesirable effects of the LMO.

Part B Risk Management

B1 Information on control, monitoring, post-release plans and waste treatment plans

75. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

76. Details of proposed release site(s) supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the location of the applicant.

77. A description of post-release treatment methods for the LMO(s), e.g. the techniques for elimination or inactivation of the organisms at the end of the experiment.

78. Details of proposed measures (if any) for monitoring any risks posed by the LMO(s), including monitoring for:

a) The survival or presence of the LMO(s), or transferred genetic material, beyond the proposed release site or sites, including specificity, sensitivity and reliability of detection methods
b) Impacts on the characteristics, or abundance, of other species
c) Transfer of the gene(s) of interest to other species
d) Any other hazards or deleterious effect

79. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

80. Details of ongoing monitoring to be undertaken after the release is completed.

81. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

82. The methods for elimination or inactivation of the organisms at the end of the experiment and measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment

83. Type of waste generated.

84. Expected amount of waste.

85. Possible risks resulting from the waste.

86. Description of waste treatment envisaged and its disposal.

Part C Emergency Response Plan

87. Methods and procedures for controlling the LMO(s) in case of any adverse effects being realized.

88. Methods for isolation of the affected area.

89. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects.

90. Details of any other contingency measures that will be in place to rectify any unintended consequences if an adverse effect becomes evident during the course of the release.

Part D Data or results from any previous release(s) of the LMO

91. Give the following details/data/results from the previous application of releases of the LMO for which the applicant is seeking an approval:
    a. Reference number of each application
    b. Date of the certificate of approval issued
    c. Terms and conditions (if any) attached to the approval
    d. Data and results of post-release monitoring methods and effectiveness of any risk management procedures, terms and conditions and other relevant details
    e. Relevant data if the previous release is on a different scale or into a different ecosystem
    f. Any other relevant details

92. Details of results of any applications made for approval of the LMO(s), or any derived GM products in other countries, including information about conditions (if any) attaching to the approval.

93. Details of any previous notifications contained use activities according to the Biosafety Act 2007 from which the work in the present application has been developed.

94. If the LMO has been previously released in overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.

PART E Product of Such Organism

E1 General Information

95. The name and address of the manufacturer or distributor of the product.

96. General description of the product:
   a) Type of product
   b) Composition of the product
   c) Physical state of the product

97. For an imported product – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry Of Health, Malaysia.

98. The type of environment and/or the geographical areas within Malaysia for which the product is suited.

99. The type of expected use of the product and the description of the persons who are expected to use the product.

100. Information regarding proposed labeling of the product (if product is genetically modified food, then according to Malaysian regulations on the labeling)

101. Is the product being simultaneously notified to another country?
☐ Yes ☐ No
If yes, please specify.

102. Is the same product marketed in a country outside Malaysia?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country
b) Authority which granted consent (if applicable)
c) Conditions under which consent was given (if applicable)

103. Has the product ever been withdrawn from the market of a country?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country or countries
b) Reasons for withdrawing the product, if known

104. Has the product been rejected by authorities of a country?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country or countries
b) Authority which rejected the product
c) Reasons for rejecting the product, if known

105. Description of identification and detection techniques for the LMO(s) in the product.

E2 Description of the LMO from which the product was derived from

(If the product is derived from more than one LMO, then the information required in numbers 106,107, 108,109 &110 should be repeated for each LMO)

106. Description of the LMO:

a) Genus and species of the LMO
b) Common name
c) Modified trait(s)
d) Gene(s) responsible for the modified trait(s)

107. Details of the parent organism:

a) Genus and species
b) Common name

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108. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

109. Give the name of the organism from which the gene(s) of interest is derived from:
   a) Genus and species
   b) Common name

110. Indicate whether the organism from which the gene of interest is derived from is a:
   a) virus
   b) bacterium
   c) fungus
   d) animal
   e) plant
   f) other (please specify)

E3 Description of the LMO contained in the product

(If more than one LMO contained in the product, then the information required in numbers 111, 112, 113, 114, 115 & 116 should be repeated for each LMO).

111. Description of the LMO:
   a) The genus and species of the LMO
   e) Modified trait(s)
   f) Gene(s) responsible for the modified trait(s)

112. Details of the parent organism:
   a) Genus and species
   b) Common name

113. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

114. Give the name of the organism from which the gene(s) of interest is derived from:

   a) Genus and species
   b) Common name
   c) Indicate whether the organism from which the gene of interest is derived from is a:
   d)
      i. bacterium
      ii. Virus

iii. fungus
iv. animal
v. plant
vi. other (please specify)

115. Information concerning reproduction of LMO in the product.

116. Information on survival and factors affecting the LMO.

E4 Risk Management for the product

117. Specific instructions or recommendations for storage and handling of the product.

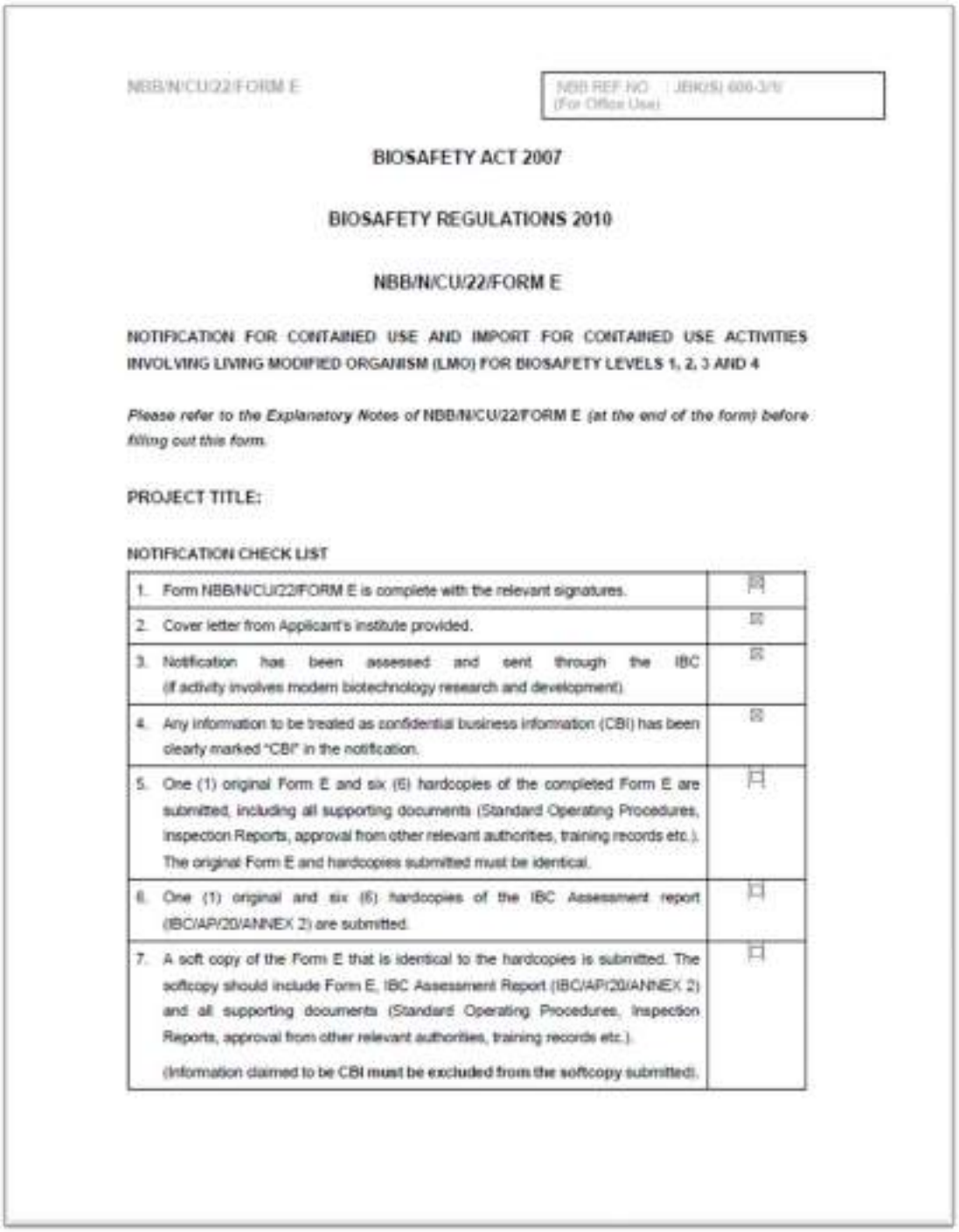
118. Measures for waste disposal and treatment of the product.

E5 Emergency Response Plan

119. Details of proposed measures to be taken in the event of adverse consequences/ misuse of the product.

Borang E

Diadaptasi dari: Laman Sesawang Rasmi Jabatan Biokeselamatan, *Institutional Biosafety and Biosecurity Committee* (IBBC), Borang E.



NBB/N/CU/22/FORM E

NBB REF NO : JBK(S) 600-3/5
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/N/CU/22/FORM E

NOTIFICATION FOR CONTAINED USE AND IMPORT FOR CONTAINED USE ACTIVITIES INVOLVING LIVING MODIFIED ORGANISM (LMO) FOR BIOSAFETY LEVELS 1, 2, 3 AND 4

Please refer to the Explanatory Notes of **NBB/N/CU/22/FORM E** *(at the end of the form) before filling out this form.*

PROJECT TITLE:

NOTIFICATION CHECK LIST

1. Form NBB/N/CU/22/FORM E is complete with the relevant signatures.	☒
2. Cover letter from Applicant's institute provided.	☒
3. Notification has been assessed and sent through the IBC (if activity involves modern biotechnology research and development).	☒
4. Any information to be treated as confidential business information (CBI) has been clearly marked "CBI" in the notification.	☒
5. One (1) original Form E and six (6) hardcopies of the completed Form E are submitted, including all supporting documents (Standard Operating Procedures, Inspection Reports, approval from other relevant authorities, training records etc.). The original Form E and hardcopies submitted must be identical.	☐
6. One (1) original and six (6) hardcopies of the IBC Assessment report (IBC/AP/20/ANNEX 2) are submitted.	☐
7. A soft copy of the Form E that is identical to the hardcopies is submitted. The softcopy should include Form E, IBC Assessment Report (IBC/AP/20/ANNEX 2) and all supporting documents (Standard Operating Procedures, Inspection Reports, approval from other relevant authorities, training records etc.). (Information claimed to be CBI must be excluded from the softcopy submitted).	☐

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8. All supporting documents/attachments required are submitted, including: i) Most recent Inspection report(s) of the premises used (inspection done not more than two years ago from date of submission) ii) SOP for LMO transportation (if activity involves movement of LMO between premises stated in Table 3) ii) SOP for LMO treatment and disposal iii) SOP for solid and liquid waste treatment and disposal iv) SOP for waste water treatment and disposal v) SOP for decontamination (All SOPs submitted must be **endorsed by the IBC prior to submission and dated not more than two years** from the date of submission).	☐
9. A copy of clearance documents (e.g. import permit, etc.) from the relevant Government agencies (if applicable).	☐
10. A letter of authorization from the IBC of the collaborating agency/institution/organization must be provided (if any premises outside the Applicant's organization is used for LMO work).	☐
11. A copy of the completed notification retained for records	☐

PRELIMINARY INFORMATION

1. Organization:	[Click here to enter text]
2. Name of Applicant (Principal Investigator):	[Click here to enter text]
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: E-mail address: Postal address:	[Click here to enter text] [Click here to enter text] [Click here to enter text] [Click here to enter text] [Click here to enter text] [Click here to enter text]
Project Title:	[Click here to enter text]
IBC Project Identification No:	[Click here to enter text]
Is this the first time the activity is being notified?	☐ Yes ☐ No

2

NBB/N/CU/22/FORM E

If this is not the first time the activity is notified, please answer the following:	
i) Please provide the NBB reference number of your previous notification.	[Click here to enter text]
ii) How is this notification different from the previous notification submitted for this activity? *(describe the differences or if this activity is using LMO produced through a previous notification)*	[Click here to enter text]

DETAILS OF IMPORTER

Importer refers to the Applicant as importer, or person or business importing/bringing the LMO on behalf of the Applicant. This section to be filled out only if the LMO is imported.

1. Importing person/ company/ organization:	[Click here to enter text]
2. Contact Person:	[Click here to enter text]
3. Designation: Telephone (office): Telephone (mobile): Fax number: E-mail address: Postal address:	[Click here to enter text] [Click here to enter text] [Click here to enter text] [Click here to enter text] [Click here to enter text] [Click here to enter text]
4. Identification of LMO to be imported (include commercial name, if any)	[Click here to enter text]
5. Describe the form in which LMO will be imported (e.g. as seeds, cuttings, live fish, etc.)	[Click here to enter text]

NBB/N/CU/22/FORM E

SUMMARY OF IBC ASSESSMENT (Refer to IBC/AP/20/ANNEX 2)

This section to be completed by the registered IBC of the Applicant's organization. Please mark [X] in the appropriate box.

1	Name of Principal Investigator:	[Click here to enter text]
2	Project Title:	[Click here to enter text]
3	Date of the IBC Assessment:	[Click here to enter text]
4	Does the IBC consider that the Principal Investigator and every other person authorized to be involved in the contained use of the LMO have adequate training and experience for the task?	☐ Yes ☐ No
5	The following information related to this project has been checked and approved	
	a) The description of project activities	☐ Yes ☐ No
	b) The description and genetics of the LMO	☐ Yes ☐ No
	c) The emergency response plan and the specific measures to be taken in relation to a contained use activity involving LMO.	☐ Yes ☐ No
	d) All persons involved are appropriately trained.	☐ Yes ☐ No
6	Has the information provided in Form NBB/N/CU/22/FORM E been checked by the IBC and found to be complete?	☐ Yes ☐ No
7	Has the IBC assessed the biosafety of the proposed project? *The risks that the IBC is required to assess are:* *a) risks to the health and safety of human (occupational exposure) from the activities associated with genetic modification* *b) risks to the health and safety of human and animals from an unintentional release of the LMO; and* *c) risks to the environment from an unintentional release of the LMO* A template of the IBC Assessment report (IBC/AP/20/ANNEX2) can be obtained at https://www.biosafety.gov.my/wp-content/uploads/2021/08/IBC-ANNEX-2_revised-9.1.2020.pdf)	☐ Yes ☐ No

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NBB/N/CU/22/FORM E

SIGNATURES AND STATUTORY DECLARATION

Please mark (X) in the appropriate box

- This application is for contained use activity involving LMO and has been assessed as above and endorsed by the IBC.
- This application is for commercial production and does not involve modern biotechnology research and development.

We declare that all information and documents herein are true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant/Principal Investigator:

Signature: _____ **Date:** [Click here to enter text]

Name as in Identity Card/Passport: Click here to enter text.

Official Stamp:

IBC Chairperson:

This section is applicable to organizations involved in modern biotechnology research and development.

Signature: _____ **Date:** [Click here to enter text]

Name as in Identity Card/Passport: Click here to enter text.

Official Stamp:

Head of Organization/Authorized representative:

Signature: _____ **Date:** [Click here to enter text]

Name as in Identity Card/Passport: [Click here to enter text]

Official Stamp:

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NBB/N/CU/22/FORM E

PART A: DETAILS OF TEAM MEMBERS

1. Project team members' details.

Note 1: Information required is for ALL persons involved in the project and IBC should have their records.
Note 2: All persons listed here should be assessed and approved by IBC.

Table 1: Description of team members' details

Name	Address, contact number & e-mail	Qualifications & Relevant Experience	Designation in Organisation
[Click here to enter text]	[Click here to enter text]	[Click here to enter text]	[Click here to enter text]
[Click here to enter text]	[Click here to enter text]	[Click here to enter text]	[Click here to enter text]
[Click here to enter text]	[Click here to enter text]	[Click here to enter text]	[Click here to enter text]
[Click here to enter text]	[Click here to enter text]	[Click here to enter text]	[Click here to enter text]
[Click here to enter text]	[Click here to enter text]	[Click here to enter text]	[Click here to enter text]

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(For Office Use)

PART B: PROJECT DESCRIPTION

Applicant is required to describe the proposed activities with the LMO within the context of the project.

2. General Objective:

[Click here to enter text]

Specific Objective(s): (If any)

[Click here to enter text]

3. Description of project activities

Note 1: Please provide a brief description that clearly shows the involvement of handling LMO materials and a flow chart of the activities that accurately reflects the narrative provided.

Note 2: In the flowchart, state all premises where each activity is conducted.

Note 3: A separate attachment may be provided for the flowchart or incorporated into the text box below.

[Click here to enter text]

4. Biosafety Level (BSL) of the proposed activity:

Note: The biosafety containment level is determined by the risk assessment of the activity.

BSL 1 ☐ BSL 2 ☐ BSL 3 ☐ BSL 4 ☐

5. Estimated duration of activity

Note 1: Please indicate the duration of this activity.

Note 2: Please provide a Gantt chart that itemizes the sequence of the activity within the time period stipulated.

Note 3: Separate attachment may be provided for the Gantt chart or incorporated into the text box below.

[Click here to enter text]

6. Intended Date of Commencement:

Note: Please provide an estimate of a feasible date that takes into account the documents processing time period of IBC (if relevant) and documents processing time period of the Department of Biosafety.

[Click here to enter text]

7. Expected Date of Completion:

Note: Please ensure that the information provided here is consistent with what is provided in the Gantt Chart.

[Click here to enter text]

8. Date of importation or expected importation of LMO (if relevant)

Note: Import of LMO is not allowed until Applicant receives the Letter of Acknowledgement from the Director General of the Department of Biosafety.

[Click here to enter text.]

9. If the experiments are successful, are there plans for an application for field experiment / large scale production /commercialization?

[○ Yes ○ No]

NBB/N/CU/22/FORM E

PART C: DESCRIPTION OF THE LMO

10. Please refer to the Explanatory Notes of NBB/N/CU/22/FORM E (at the end of the form) on part C before filling in the specific information in a tabulated form as shown below.

Table 2: Description of the LMO for contained use activities

LMO	Common and scientific name(s) of recipient organism	Common and scientific name(s) of donor organism	Vector(s) and method of genetic modification	Class of modified trait *(Refer to Box 1 of the Explanatory Notes)*	Modified trait	Number of genes involved *(Please provide the gene construct(s) map)*	Identity and function of the gene(s) involved and protein(s) expressed
1]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]
2]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]
3]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]
4]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]	Click here to enter text]

3

LMO	Common and scientific name(s) of recipient organism	Common and scientific name(s) of donor organism	Vector(s) and method of genetic modification	Class of modified trait *(Refer to Box 1 of the Explanatory Notes)*	Modified trait	Number of genes involved *(Please provide the gene construct(s) map)*	Identity and function of the gene(s) involved and protein(s) expressed
5.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

NBB/N/CUI22/FORM E

PART D: THE PREMISES

11. Please provide information for all of the premises being used for the contained use activities in the table below. This includes premises for production/ handling of LMO materials, treatment of LMO materials and storage of LMO materials.

Note 1: For notifications with more than one premises, use additional columns provided.
Note 2: For a Research and Development collaboration involving more than one organization (premises is under the oversight of a different IBC), please provide proof of collaboration (such as letter of authorization) to use the premises.

Table 3: Details of premises

Information required	Premises 1	Premises 2	Premises 3	Premises 4
1. Name of premises:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
2. Premises type: *Note 1: Example of premises type includes: animal containment premises, laboratory, insect containment premises, greenhouse, etc.)* *Note 2: Please specify if it is a large scale facility involving culture volume greater than or equal to 10L of culture of any LMO*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
3. Biosafety level (BSL):	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

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Information required	Premises 1	Premises 2'	Premises 3'	Premises 4'
4. Purpose of using the premises *Note: Please indicate which step(s) of the activity the premises is used for, e.g. genetic manipulation or the organism, feeding study on mice, treatment of LMO materials, or for storage.*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
5. Who undertook the most recent inspection of the premises? *Note: Please indicate which IBC, if more than one IBC is involved in the premises used or if it the most recent inspection was done by the Department of Biosafety enforcement.*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
6. Date of the most recent inspection : *Note: Provide the most recent inspection report which is NOT MORE than two years from the commencement date of the activity and include a record of any corrective actions as recommended by the report.*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
7. Fill the following if premises is BSL 3 or BSL 4: a) Date of certification by competent authority b) Certificate reference no:	Click here to enter text. Click here to enter text. Click here to enter text.	Click here to enter text. Click here to enter text. Click here to enter text.	Click here to enter text. Click here to enter text. Click here to enter text.	Click here to enter text. Click here to enter text. Click here to enter text.

NBB/N/CUI22/FORM E

Information required	Premises 1	Premises 2*	Premises 3*	Premises 4*
Note: Provide the latest inspection report and a record of any corrective actions as recommended by the report				
8. Full address of premises: *Note: Includes floor level, if relevant, and name of building*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
9. Name of contact person in charge of premises/ *Note: This could be the Biosafety Officer or Laboratory Manager or any other person in charge of the premises*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
10. Office/ Premises phone number: *Note: Please provide a number that the person in charge will be accessible to take the call.*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
11. Mobile phone number:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
12. Fax number:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
13. E-mail address:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

7

NBB/N/CU22/FORM E

PART E: RISK ASSESSMENT AND MANAGEMENT

E1 Risk Assessment (Basic information)

12. You are required to fill in the matrix below. Consider what are the possible hazard(s), and the likelihood and consequences of the hazard(s) occurring (i.e. the risk) from the genetic modification(s) and proposed activity to the health and safety of human, plant and animals and the environment (including unintentional release).

Please refer to Chapter 4 of Biosafety Guidelines: Contained use activity of Living Modified Organism (https://www.biosafety.gov.my/wp-content/uploads/2021/08/Garis-Panduan-Aktiviti-Kegunaan-Terkawal-LMO.pdf)

RISK ASSESSMENT MATRIX

Assessment category	Identification of Potential hazard	Comments on risk	Risk Management by Applicant
Potential risk from the science of genetic modification *Points for consideration* *a) Hazards from gene(s), protein(s), change in virulence /pathogenicity of LMO* *b) Risk from vector used (e.g. retroviral vector, etc)*	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.
Risk to human health (occupational exposure) *Points for consideration* *a) Activities with LMO (e.g. large volume, handling sharps,*	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.

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Assessment category	Identification of Potential hazard	Comments on risk	Risk Management by Applicant
competency of personnel, use of PPE, compliance to SOPs) *b) Equipment used (e.g. BSC)*	Click here to enter text.	Click here to enter text.	Click here to enter text.
Containment integrity (risk of unintentional release of the LMO to the environment) *Points for consideration* *a) Maintenance of the facility and equipment* *b) Transfer of LMO between premises* *c) Waste decontamination*	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.
Special risks unique to notification *Points for consideration* *a) Long term duration* *b) Use of animals/ arthropods/ exotic species* *c) Immunocompromised personnel* *d) Techniques used (e.g. synthetic biology, genome editing)* *e) Large scale volume of LMO*	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.

NBB/N/CU/22/FORM E

E2 Risk Management

For questions 13-17, an activity specific SOP endorsed by the IBC must be provided. The date that the SOP has been developed/approved or reviewed/revised should not exceed more than two years from the date of submission to this form.

13. Do you propose to transfer/transport the LMO between premises?

Note 1: Please ensure all the premises used are included in Part D of this form and are stated in the activity flowchart provided.
Note 2: If yes, please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text]

14. What is the treatment method and how will the LMO and related wastes be disposed of?

Note 1: If the activity involves LMO at various growth stages (seedlings, trees), the SOP should cover the disposal of LMO at each growth stage.
Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.
Note 3: Please refer to Chapter 12 and 13 of Biosafety Guidelines: Contained use activity of Living Modified Organism (https://www.biosafety.gov.my/wp-content/uploads/2021/08/Garis-Panduan-Aktiviti-Kegunaan-Terkawal-LMO.pdf)

[Click here to enter text]

15. How will the solid and liquid wastes from the activities be treated/decontaminated and disposed of?

Note 1: Examples of wastes include media, disposable gloves, planting materials, plant parts, etc.
Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text]

16. How will the wastewater from the activities be disposed of?

Note 1: Examples of wastewater include water used for cleaning equipment, watering the plants, keeping fish, etc.
Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text]

17. How will the equipment/tools/surfaces used during the activities be decontaminated?

Note 1: Examples of equipment/tools/surfaces include sharps, pipette, decontaminated glassware, etc.
Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text]

10

NBB/NI/CLI/22/FORM E

E) Emergency Response Plan

For questions 18-22, form IBC/IR/10/ANNEX3 or IBCDO/10/ANNEX4 shall to be used to report all incidents or occupational exposure to LMO materials to IBC and Department of Biosafety in addition to any internal administrative procedures in place. This requirement must be included in the SOP provided.

18. Provide plans for protecting human and animal health and the environment in case of the occurrence of an adverse effect observed during contained use activities.

Note 1: Examples include medical management which includes first aid and hospitalization, line of communication both within and outside the organization.
Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text.]

19. Provide plans for removal of the LMO in the affected areas in the case of an unintentional release

Note 1: Examples include to contain and treat spillage.
Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text.]

20. Provide plans for disposal of plants, animals and any other organisms exposed during the unintentional release.

Note: Please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text.]

21. Provide plans for isolation of the area affected by the unintentional release

Note 1: Examples include evacuation and quarantine.
Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text.]

22. Provide details of any other contingency measure that will be in place to rectify any unintended consequences if an adverse effect becomes evident during the contained use activities or when an unintentional release occurs.

Note: Please give statement(s) and identify/ state the relevant SOP provided for this.

[Click here to enter text.]

NBB/IN/CU/22/FORM E

PART F: CONFIDENTIAL BUSINESS INFORMATION

Enter in this section any information required in Parts A - E for which confidentiality is claimed together with full justification for that claim.

Criteria for confidentiality are as follows (section 59 of Biosafety Act 2007):

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
c) that reasonable steps have been taken to keep the information secret.

[Click here to enter text]

PART G: REFERENCES

Please include references mentioned in the Project Description, supporting documents for any statements in the Risk Assessment matrix or any other relevant references associated with this activity.

[Click here to enter text]

NBB/N/CU/22/FORM E

EXPLANATORY NOTES FOR FORM E

NOTIFICATION FOR CONTAINED USE AND IMPORT FOR CONTAINED USE ACTIVITIES INVOLVING LIVING MODIFIED ORGANISM (LMO) FOR BIOSAFETY LEVELS 1, 2, 3 AND 4

NBB/N/CU/20/FORM E shall be submitted to the Director General as a notification for contained use and import for contained use [not involving release into the environment of Living Modified Organism (LMO) as specified in Second Schedule of the Biosafety Act 2007]. Any organization undertaking modern biotechnology research and development shall submit the notification through its Institutional Biosafety Committee (IBC) that is registered with the National Biosafety Board (NBB). The IBC should do an assessment prior to submission and submit the result of the assessment via the IBC Assessment Form (IBC/API20/ANNEX 2). Not all parts in this form will apply to every case. Therefore, Applicants will only address the specific questions/parameters that are appropriate to individual applications.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. If there are other related documents (example If a comprehensive description of the activity is provided in the Research Project proposal, please provide a summary in in Form E but you may provide a reference to the proposal document for more details). The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the decision by the NBB.

The Applicant shall submit 1 original and 6 copies of the notification to the Director General. The six copies submitted should be identical to the original form. Please ensure that the information provided can be clearly read/seen. This submission should be accompanied by a cover letter from the Applicant's institution. A soft copy of the submitted notification **(including all supporting documents/attachments, if any)** shall also be provided by the Applicant. However, **all information that has been declared as Confidential Business Information (CBI) should be omitted from the softcopy**. You may collate documents related to one notification into one document/ softcopy (do not combine with any other notification that you may submit concurrently).

Providing information

The information provided in this notification will be used to evaluate the emergency response plan as specified in section 37 of the Biosafety Act 2007 and specific measures to be taken in relation to a contained use activity involving LMO. Therefore it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

If the LMO is imported, details of importer, date of intended importation and approval from relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia, etc. should be

provided.

If the activity involves work with animals (example of feeding studies involving LMO products), please provide the status of approval from the Institutional Animal Care and Use.

The NBB may require additional information, and the applicant will be notified should this be the case. If the applicant fails to provide the additional information requested, the notification shall be deemed to have been withdrawn but it shall not affect the right of the applicant to make a fresh notification.

Description of LMO – Table 2 (Part C)

a) 'Recipient organism' refers to the final recipient of the intended genetic modification.

b) 'Donor organism' refers to the source of the genetic sequences used for modification. If more than one gene is used and the source is different for each gene, ensure that the donor organism for each gene used is stated.

c) "Vector' should include all vectors and method (s) used.

d) 'Modified trait' can be stated as "unknown" if for example building a genomic library.

e) Identity and function of gene(s) of donor organism responsible for the modified trait can be stated as "unknown" if for example building a genomic library.

Class of modified trait, please refer box below.

If the LMO has more than one modified trait please list all. If the modified trait is not listed in the Box 1, please list it as "other" and provide details of the modified traits

Box 1: Class of modified trait

NO	Class (type) of trait
1	Abiotic stress resistance
2	Altered agronomic characteristics
3	Altered nutritional characteristics
4	Altered pharmaceutical characteristics
5	Altered physical product characteristics
6	Antibiotic resistance
7	Foreign antigen expression
8	Attenuation
9	Bacterial resistance
10	Disease resistance
11	Flower colour
12	Fungal resistance
13	Herbicide tolerance
14	Immuno-modulatory protein expression

NO	Class (type) of trait
15	Pest resistance e.g. insect resistance
16	Protein expression (please specify)
17	Reporter/marker gene expression
18	Virus resistance
19	Others (please specify)

Accuracy of information

The notification should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of notification without prejudice to the submission of a fresh notification

Confidentiality

Any information within this notification which is to be treated as Confidential Business Information (CBI), as described in section 59(3) of the Biosafety Act 2007 should be clearly marked "CBI" in the relevant parts of the notification by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this notification is being completed on behalf of the proposed user, that the person completing this notification holds proper authority to submit this notification for the proposed user. Please provide written proof of authorization.

For further information or any queries related to filling up this form, please contact jtkamp@biosafety.gov.my

NBB/NI/CU/22/FORM E

The completed form, cover letter and relevant documents shall be submitted to:
The Director General
Department of Biosafety
Ministry of Environment and Water
Level 4, Block F11, Complex F
Lebuh Perdana Timur, Precinct 1
Federal Government Administrative Centre
62000 Putrajaya, Malaysia

Acknowledgement of Receipt

Upon receipt of the notification, the Director General of the Department of Biosafety shall send to the applicant a Letter of Acknowledgement of receipt with an assigned reference number. The reference number should be used in all correspondence with respect to the notification. The activity (contained use activity and import of any LMO) can start only after the Letter of Acknowledgement is issued. The Principal Investigator is still required to be complaint to any decisions made by the NBB (as described in section 30(3) of the Biosafety Act 2007 and is required to comply with other written laws governing LMO.

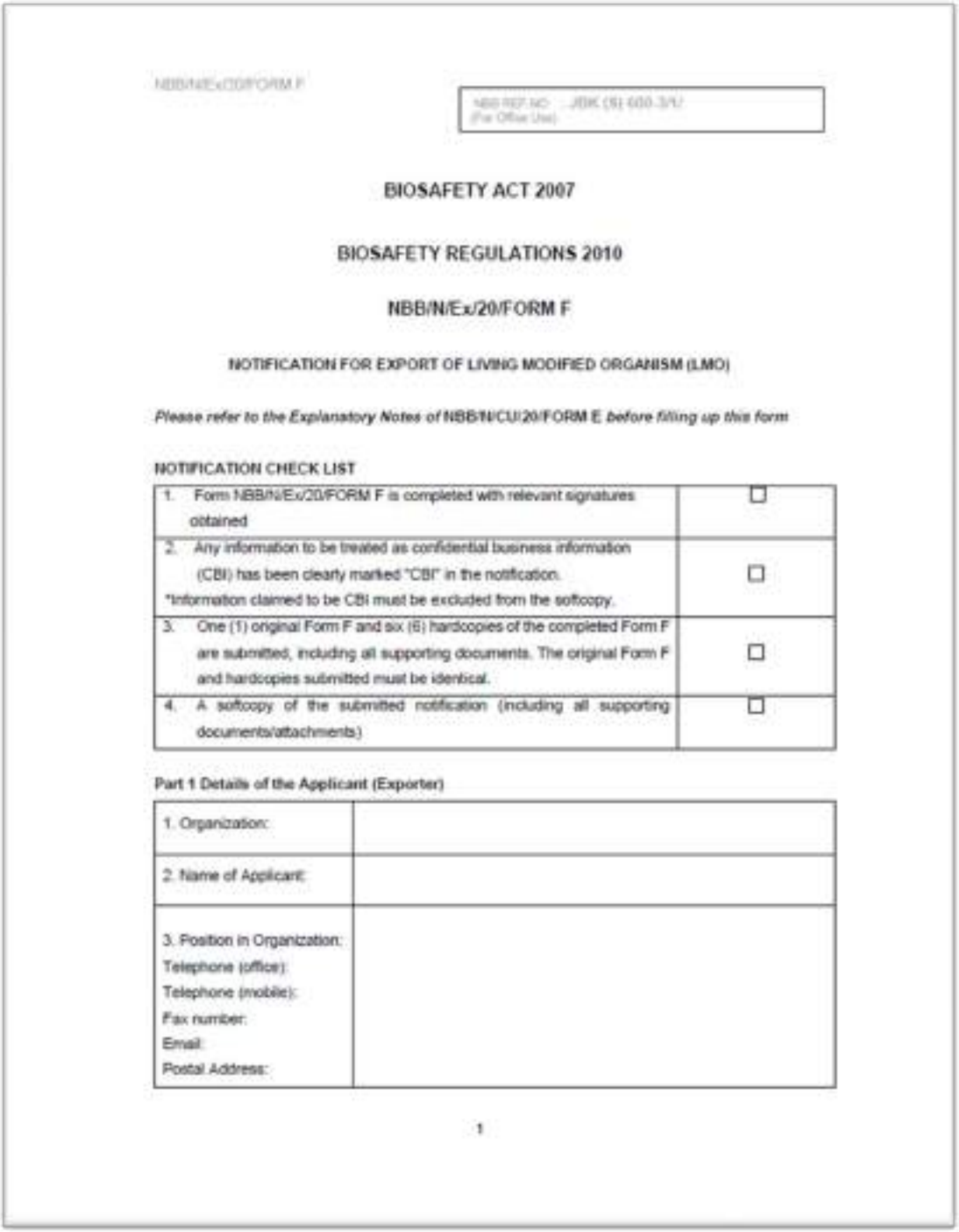
Exemption

The First Schedule of the Biosafety (Approval and Notification) Regulations 2010 allows exemptions for some types of techniques and contained use activities in relation to LMO posing a very low risk (i.e. contained research activities involving very well understood organisms and processes for creating and studying LMO). Exempted activities should be carried out under conditions of standard laboratory practice. Appropriate biosafety levels as according to Second Schedule of the Biosafety (Approval and Notification) Regulations 2010 should be used for the exempted activities and personnel should have appropriate training. Principal Investigators who believe that the work falls into any of the exemptions should nevertheless notify their IBC of the proposed project. The IBC shall review all submitted research projects to determine their exemption or non-exemption status. The IBC will provide oversight of the exempted activities and report to the Department of Biosafety through the IBC Annual Report.

Please retain a copy of your completed notification.

Borang F

Diadaptasi dari: Laman Sesawang Rasmi Jabatan Biokeselamatan, *Institutional Biosafety and Biosecurity Committee* (IBBC), Borang F.



NBB/N/Ex/20/FORM F

NBB REF NO: ...JBK (S) 600-3/U
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/N/Ex/20/FORM F

NOTIFICATION FOR EXPORT OF LIVING MODIFIED ORGANISM (LMO)

Please refer to the Explanatory Notes of NBB/N/CU/20/FORM E before filling up this form

NOTIFICATION CHECK LIST

1. Form NBB/N/Ex/20/FORM F is completed with relevant signatures obtained	☐
2. Any information to be treated as confidential business information (CBI) has been clearly marked "CBI" in the notification. *Information claimed to be CBI must be excluded from the softcopy.	☐
3. One (1) original Form F and six (6) hardcopies of the completed Form F are submitted, including all supporting documents. The original Form F and hardcopies submitted must be identical.	☐
4. A softcopy of the submitted notification (including all supporting documents/attachments)	☐

Part 1 Details of the Applicant (Exporter)

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

1

NBB/NMEx/2/FORM F

NBB REF NO : JBK (5) 600-3/1/
(For Office Use)

Part 2 Details of LMO to be exported

1.Description of LMO to be exported:	a. Plant ☐ b. Fish/shellfish ☐ c. Virus ☐ d. Animal ☐ e. Micro-organism (bacterium/fungus etc.) ☐ f. Animal cell ☐ g. Others (Please specify) ☐
2.Identification of LMO	
3.Common name(s) Scientific name	
4.Introduced Trait(s)	
5.Intended use of LMO	
6. Describe the form in which LMO will be exported e.g. as seeds, cuttings, live fish, etc.	
7.Mode of export:	a. Sea ☐ b. Rail ☐ c. Road ☐ d. Air ☐ e. Others (Please specify) ☐
8.Point of exit:	
9.Suggested methods for safe handling, storage, transport and use (if available)	

2

NBB/MEa/20/FORM F

NBB REF NO: ...JBK (S) 600-3/1/
(For Office Use)

Part 3 Importing Country

1) Name of importing country	
2) Description of evidence to show as proof of compliance with importing country's requirements (e.g. Copy of import permit, co of approval from competent authority, etc.)	

Part 4 Confidential Business Information

Enter in this section any information required in Part 1-3 for which you are claiming confidentiality, together with full justification for that claim.

Part 5 Signatures and Statutory Declaration

We declare that all information and documents provided to the importing country are accurate and true and in compliance with the requirements of the importing country.

We also understand that providing misleading information to the National Biosafety Board (NBB), deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/ Authorized Representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

3

NBB REF NO : JBK (5) 600-3/1!
(For Office Use)

EXPLANATORY NOTES FOR FORM F

NBB/N/Ex/20/FORM F shall be submitted to the Director General as a notification for export of LMO under the Biosafety Act 2007. The applicant shall submit 1 original and 6 copies of the notification to the Director General. The six copies submitted should be identical to the original form. Please ensure that the information provided can be clearly read/seen. This submission should be accompanied by a cover letter from the applicant's institution. A softcopy of the submitted notification (**including all supporting documents/attachments,** if any) shall also be provided by the applicant. However, **all information that has been declared as Confidential Business Information (CBI) should be omitted from the softcopy**. Please provide one softcopy per application (do not combine with any other application that you may submit concurrently).

Accuracy of Information

The notification should be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect or incomplete or misleading, the Director General may issue a withdrawal of the acknowledgement of submission of notification without prejudice to the submission of a fresh notification.

Compliance with Requirements of Importing Country

The applicant is required to comply with all the requirements of the importing country to export LMO. Evidence of compliance should be submitted with this notification.

Confidentiality

Any information within this application which is to be treated as Confidential Business Information (CBI), as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) Description of the LMO

NBS/NIE/LO3/FORM F

NBS Ref No: ...JBK (S) 600-3/U
(For Office Use)

For further information:
Please contact the Director General by:
Telephone: 03-8886 1580
Email: dob@biosafety.gov.my

The completed form to be submitted as follows:
Director General
Department of Biosafety
Ministry of Environment and Water
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia

Acknowledgement of Receipt
Upon receipt of the notification, the Director General shall send to the applicant an acknowledgement of receipt with an assigned reference number. The reference number should be used in all correspondence with respect to the notification.

Exemption
An applicant who has submitted a Notification for export of LMO and has received an Acknowledgement of Receipt from the Director General is exempt from making any subsequent Notifications for the same LMO, to the same country for the same purpose (as specified in the Acknowledgement of Receipt). However, there is no exemption for compliance with all the requirements of the importing country to export LMO for each subsequent export.

Please retain a copy of your completed notification.

Borang Annex 2

Diadaptasi dari: Laman Sesawang Rasmi Jabatan Biokeselamatan, *Institutional Biosafety and Biosecurity Committee* (IBBC), Borang Annex 2.

IBC/AP/20/ANNEX 2

This form is to be used for assessment of a proposal to carry out modern biotechnology activities. It serves to guide the IBC in the consideration and evaluation of the project proposal. A clear and concise explanation is required on the IBC's position on each of the experimental parameters identified in the assessment form. This form must be completed by the Biosafety Officer or a representative of the IBC. This form must be signed by the IBC Chair and submitted to National Biosafety Board with the corresponding application form. IBC must retain a copy for record and reference.

IBC ASSESSMENT OF PROJECT PROPOSAL INVOLVING MODERN BIOTECHNOLOGY ACTIVITIES

1. General Information

1.	Name of applicant	:
2.	Institutional address	:
3.	Collaborating partners *Indicate names and addresses of the institution/s (if any)*	:
4.	Project Title	:

2. Experimental Parameters
IBC assessment/recommendation on each of the following:

1.	Project objective and methodology	:
2.	Biological system i. Common name of recipient organism(s) ii. Common name of donor organism(s) iii. Name of gene(s) for the modified trait(s)	: : :

1

IBC/AP/20/ANNEX 2

3.	Premises or location(s) of contained use activity/field experiment (including any premises used outside of the organization/institution)	:
4.	Period of contained use activity/field experiment	:
5.	Risk assessment and risk management	:
6.	Emergency response plan	:
7.	SOPs	:
8.	Additional IBC recommendation (if any)	:

3. Details of Principal Investigator (PI)

1.	Experience and expertise	:
2.	Training	:
3.	Health	:
4.	Other (please specify)	:

4. List of all persons[1] involved in project

No.	Name	Designation
1.		
2.		
3.		
4.		
5.		

[1] To be assessed for suitability by PI

IBC/AP/20/ANNEX 2

Signature (of IBC Chair)

Name : _____

Date : _____

Some Specific Provisions:

Proposal for Contained Use Activity of LMO/rDNA Material

IBC may authorize or commission research work immediately, upon obtaining an acknowledgement of receipt for contained use activity from the Director General of Biosafety. The contained use activity should observe the rudimentary standards, in current or past practice, as appropriate to the particular organism under investigation.

Proposal for Field Experiment of LMO/rDNA Material

Principal Investigator (PI) must obtain endorsement from IBC and should not start a field experiment until a certificate of approval is granted by National Biosafety Board. Measures for the control and containment of field work must comply with National Biosafety Board decisions.

3

LAMPIRAN C

Borang HIRARC

Diadaptasi dari: Laman Sesawang Rasmi, Pusat Pengurusan Keselamatan, Kesihatan dan Persekitaran Pekerjaan (COSHE), Borang HIRARC

Dokumen	Kod Dokumen	Tarikh	Rev
Prosedur Pengurusan OSHMS	OSHMS-02-01	25.2.2015	5
Bab		Halaman	Dari
1.Pengenalpastian Hazard, Penilian Risiko dan Kawalan Risiko		6	8

BORANG HIRARC			
Jabatan		Dikendalikan oleh (Nama,Jawatan)	
Proses/Lokasi		Ahli (Nama,Jawatan)	
Disahkan Oleh (Nama, Jabatan)			
Tarikh		Tarikh Semak semula	

Pengenalpastian Hazard				Analisa Risiko				Kawalan Risiko	
No	Aktiviti	Hazard	Boleh Mengakibatkan	Kawalan Risiko (Jika Ada)	Kemungkinan	Keterukan	Risiko	Langkah Kawalan Yang disarankan	PBT (Tarikh ajal, Status)

Kemungkinan Boleh Berlaku

Kemungkinan	Deskripsi	Kadar
Paling Mungkin	Hazard/kejadian yang paling mungkin berlaku	5
Mungkin	Mungkin boleh berlaku dan bukannya luar biasa	4
Dapat Dijangka	Mungkin berlaku pada masa akan datang	3
Jarang	Belum diketahui berlaku selepas beberapa tahun	2
Tidak dapat dijangka	Boleh dikatakan mustahil dan tidak pernah berlaku	1

Keterukan

Kemungkinan	Deskripsi	Kadar
Malapetaka	Banyak kematian, kerosakan harta benda dan pengaluaran tidak dapat dipulihkan	5
Kematian	Kira-kira satu kematian, kerosakan besar harta benda jika hazard berlaku	4
Kecederaan Serius	Kecederaan yang tidak fatal, hilang upaya kekal	3
Kecederaan Ringan	Menyebabkan hilang upaya tetapi bukan kecederaan kekal	2
Nyaris	Sedikit lelasan, lebam, luka, kecederaan jenis rawatan kecemasan	1

Penaksiran risiko

Risiko boleh dinyatakan dalam pelbagai cara untuk menyampaikan keputusan analisis bagi membuat keputusan tentang kawalan risiko. Bagi analisis risiko yang menggunakan kemungkinan dan keterukan dalam kaedah kualitatif, menyatakan keputusan dalam matriks risiko merupakan suatu cara yang sangat berkesan untuk mengagihkan risiko di seluruh loji dan kawasan tempat kerja. Risiko boleh dihitung menggunakan formula berikut:

L x S = Risiko relatif

Di mana,

L = Kemungkinan

S = Keterukan

	Keterukan (S)				
Kemungkinan (L)	1	2	3	4	5
5	5	10	15	20	25
4	4	8	12	16	20
3	3	6	9	12	15
2	2	4	6	8	10
1	1	2	3	4	5

Tinggi Sederhana Rendah

Untuk menggunakan matriks ini, mula-mula cari lajur keterukan (S) yang paling sesuai memerihalkan hasil risiko. Kemudian ikut baris kemungkinan (L) untuk mendapatkan pemerihalan yang paling sesuai dengan kemungkinan bagi keterukan kejadian yang akan berlaku. Tahap risiko diberikan di dalam petak di mana baris dan lajur bertemu. Nilai risiko relatif boleh digunakan untuk memberikan keutamaan

kepada tindakan yang perlu di ambil untuk menguruskan hazard di tempat kerja secara efektif.

RISIKO	PERIHALAN	TINDAKAN
15-25	Tinggi	Risiko TINGGI memerlukan tindakan segera untuk mengawal hazard seperti yang diperincikan dalam hierarki kawalan. Tindakan yang diambil mestilah didokumentasikan dalam borang penaksiran risiko termasuk tarikh siap.
5-12	Sederhana	Risiko SEDERHANA memerlukan pendekatan terancang bagi mengawal hazard dan mengguna pakai langkah sementara jika perlu. Tindakan yang diambil mestilah didokumentasikan dalam borang penaksiran risiko termasuk tarikh siap.
1-4	Rendah	Risiko yang dikenal pasti sebagai RENDAH boleh dianggap sebagai boleh diterima dan pengurangan selanjutnya tidak diperlukan. Walau bagaimanapun, jika risiko tersebut boleh diselesaikan segera secara berkesan, langkah kawalan hendaklah dilaksanakan dan direkodkan.