

## LEĠISLAZZJONI SUSSIDJARJA 549.49

### REGOLAMENTI DWAR UŻU KONTENUT TA' MIKRO-ORGANIŻMI MODIFIKATI ĠENETIKAMENT

29 ta' April, 2008

*L-AVVIZ LEGALI 127 tal-2008, kif emendat bl-Avviz Legali 265 tal-2010.*

1. It-titolu ta' dawn ir-regolamenti hu Regolamenti dwar l-Użu kontenut ta' Mikro-Organizmi Modifikati Ġenetikament. Titolu.

2. (1) L-ghan ta' dawn ir-regolamenti hu li jkunu stabbiliti miżuri għall-użu kontenut ta' mikro-organizmi modifikati ġenetikament bl-iskop li tkun protetta s-saħha umana u l-ambjent. Għan.  
Emendat:  
A.L. 265 tal-2010.

(2) Dawn ir-regolamenti jipprovdu d-disposizzjonijiet meħtieġa għall-implimentazzjoni f'Malta tad-Direttiva tal-Kunsill Ewropew 2009/41/KE tas-6 ta' Mejju, 2009 dwar l-użu kontenut ta' mikro-organizmi modifikati ġenetikament (*recast*) u għandhom jinqraw u jiftiehmu haġa wahda ma' dak l-istrument legali.

(3) Dawn ir-regolamenti għandhom jinqraw u jiftiehmu haġa wahda mar-Regolamenti dwar il-Protezzjoni tal-Haddiema minn Riskji relatati ma' l-Espożizzjoni għal Aġenti Bijoloġiċi fuq il-Post tax-Xogħol, li għandhom x'jaqsmu ma' kwistjonijiet rigward is-saħha u s-sigurtà fuq il-post tax-xogħol. L.S. 424.25

#### TAQSIMA I: DEFINIZZJONIJIET U EŻENZJONIJIET

3. F'dawn ir-regolamenti kemm-il darba r-rabta tal-kliem ma tkunx teħtieġ xort'ohra: Tifsir.

"l-awtorità kompetenti" tfisser l-Awtorità għall-Ambjent u r-Rizorsi kif stipulat bl-Ordni dwar in-Nomina ta' Awtorità Kompetenti, u tali korp jew persuna li l-Ministru responsabbli għall-ambjent jista' b'ordni fil-Gazzetta jinnomina u korpi jew persuni differenti jistgħu jiġu nominati bħala l-awtorità kompetenti għal disposizzjonijiet differenti u skopijiet differenti ta' dawn ir-regolamenti; L.S. 549.19

"inċident" tfisser kull inċident li jinvolvi ħelsien sinifikanti u mhux intenzjonat ta' GMM fil-kors ta' l-użu tagħhom kontenut li jista' jkun ta' perikolu immedjat jew ritardat għas-saħha umana jew l-ambjent;

"mikro-organizmu" tfisser entità mikrobijoloġika, kemm ċellulari kemm mhux ċellulari, kapaċi li tirreplika jew li tittrasferixxi materjal ġenetiku, inkluż kull *virus*, *viroid*, ċellula tal-pjanti u ta' l-annimali fil-kultura;

"mikro-organizmu modifikat ġenetikament" jew "GMM" tfisser mikro-organizmu li fih il-materjal ġenetiku ġie mibdul b'tali mod li ma jkunx naturali permezz ta' tahlit u, jew rikombinazzjoni naturali.

Fil-kuntest ta' din it-tifsira:

- (a) modifikazzjoni ġenetika ssehh ta' l-inqas meta jintużaw il-karatteristiċi tekniċi msemmija fl-Iskeda I, Parti A;
- (b) karatteristiċi tekniċi msemmija fl-Iskeda I, Parti B, ma jiġux ikkunsidrati li jirriżultaw f'modifikazzjoni ġenetika;

"il-Ministru" tfisser il-Ministru responsabbli għall-ambjent;

"notifika" tfisser meta l-informazzjoni mehtieġa tiġi ppreżentata mill-awtorità kompetenti;

"utent" tfisser persuna naturali jew legali li tkun responsabbli għall-użu kontenut ta' GMM;

"użu kontenut" tfisser kull attività li fiha mikro-organismi jiġu modifikati ġenetikament jew li fiha dawg il-GMM jiġu kultivati, mahżuna, trasportati, meqruda, isir minnhom jew jiġu użati b'kull mod ieħor, u li dwar dawg il-miżuri ta' konteniment speċifiċi dawn jiġu wżati biex jillimitaw il-kuntatt ma', u sabiex jiġi provdut livell għoli ta' sigurtà għal, popolazzjoni in ġenerali u għall-ambjent.

#### TAQSIMA II: ASSESSJAR

Assessjar.

4. (1) Sabiex jiġi żgurat li l-użu kontenut ta' GMM ma jkunx jipproduċi effetti kuntrarji fuq is-saħħa umana u l-ambjent, l-utent għandu jwettaq assessjar ta' kull użu kontenut rigward ir-riskji għas-saħħa umana u l-ambjent li użu kontenut bħal dan jista' jikkawża, billi juża bħala minimu l-elementi ta' assessjar u l-proċedura stabbilita fl-Iskeda III, sezzjonijiet A u B.

(2) L-assessjar imsemmi fis-subregolament (1) għandu jirriżulta fil-klassifikazzjoni finali ta' l-użu kontenut f'erba' klassijiet billi tiġi applikata l-proċedura stabbilita fl-Iskeda III, li għandha tirriżulta fl-assenjar ta' livelli kontenuti skond is-subregolamenti (6) u (7):

Klassi 1: attivitajiet ta' ebda riskju jew ta' riskju negligibbli, li dwarhom ikun adatt il-livell 1 ta' konteniment.

Klassi 2: attivitajiet ta' riskju baxx, li dwarhom ikun adatt il-livell 2 ta' konteniment.

Klassi 3: attivitajiet ta' riskju moderat, li dwarhom ikun adatt il-livell 3 ta' konteniment.

Klassi 4: attivitajiet ta' riskju għoli, li dwarhom ikun adatt il-livell 4 ta' konteniment.

(3) Meta jkun hemm xi dubju dwar liema klassi tkun adatta għall-użu kontenut propost, għandhom jiġu applikati l-aktar miżuri stretti, kemm-il darba prova suffiċjenti, bi qbil ma' l-awtorità kompetenti, ma tkunx tiġġustifika l-applikazzjoni ta' miżuri inqas stringenti.

(4) L-assessjar imsemmi fis-subregolament (1) għandu b'mod speċjali jiehu in konsiderazzjoni l-kwistjoni tar-rimi ta' skart u effluwenti. Meta jkun adatt, għandhom jiġu implimentati l-miżuri ta' sigurtà mehtieġa sabiex tkun protetta s-saħħa umana u l-ambjent.

(5) L-utent għandu jżomm *record* ta' l-assessjar imsemmi fis-subregolament (1) u dak ir-*record* għandu jkun disponibbli f'forma skond ma tkun trid l-awtorità kompetenti bħala parti min-notifika skond ir-regolamenti 6, 8 u 9 jew meta jiġi hekk mitlub.

(6) L-utent għandu japplika, hlief meta l-paragrafu 2 ta' l-Iskeda IV jippermetti li jkunu applikati miżuri oħra, il-prinċipji ġenerali u l-konteniment adatt u miżuri protettivi oħra stipulati fl-Iskeda IV li jikkorrispondu għall-klassi ta' użu kontenut, sabiex l-espożizzjoni għal kull GMM f'xi post tax-xogħol u l-ambjent tinżamm fl-inqas livell raġonevolment prattikabbli, u b'hekk jiġi żgurat livell għoli ta' sigurtà.

(7) L-assessjar msemmi fis-subregolament (1) u l-konteniment u l-miżuri protettivi l-oħra applikati għandhom jiġu riveduti perijodikament, u minnufih jekk:

- (a) il-miżuri ta' konteniment applikati ma jibqgħux aktar adegwati jew il-klassi assenjata lil dak l-użu kontenut ma tkunx aktar korretta, jew
- (b) ikun hemm suspett li l-assessjar m'għadux aktar valutat b'mod adattat fil-kuntest ta' għarfien xjentifiku u tekniku ġdid.

5. (1) Mingħajr preġudizzju għar-regolament 4(1), dawn ir-regolamenti m'għandhomx ikunu japplikaw: Eżenzjonijiet.

- (a) meta modifikazzjoni ġenetika tirriżulta mill-użu ta' teknika jew metodi msemmija fl-Iskeda II, Parti A, jew
- (b) għal kull użu kontenut li jinvolvi biss tipi ta' GMM li jkunu konformi mal-kriterji elenkati fl-Iskeda II, Parti B li jistabbilixxu s-sigurtà tagħhom għas-saħħa umana u l-ambjent. Dawn it-tipi ta' GMM jinsabu elenkati fl-Iskeda II, Parti Ċ.

(2) Ir-regolament 4(2), 4(5), 4(6), 4(7) u r-regolamenti 6 sa 11 m'għandhomx japplikaw għat-trasport ta' GMM bit-triq, bil-baħar jew bl-ajru.

(3) Dawn ir-regolamenti m'għandhomx japplikaw għall-ħażna, kultivar, trasport, qerda, rimi jew użu ta' GMM li jkunu tpoġġew fis-suq skond ir-Regolamenti dwar Tluq Deliberat ta' Organizmi Modifikati Ġenetikament fl-Ambjent, jew konformement ma' leġislazzjoni rilevanti oħra, li tipprovdi għall-assessjar ta' l-impatt ta' l-ambjent speċifiku, simili għal dak stabbilit fir-regolamenti msemmija, sakemm l-użu kontenut ikun skond il-kondizzjonijiet, jekk ikun il-każ, għall-kunsens għat-tqeghid fis-suq. L.S. 549.60

### TAQSIMA III: PERMESSI U PENALI

6. Meta xi post ikun ser jintuża għall-ewwel darba għal xi użu kontenut, qabel ma jibda tali użu, l-utent għandu jippreżenta notifika lill-awtorità kompetenti, li jkun fiha ta' l-inqas l-informazzjoni msemmija fl-Iskeda V, Parti A.

Post użat għall-ewwel darba.

7. (1) Meta xi użu kontenut ta' Klassi 1 ikun ser isir għall-ewwel darba jew sussegwentement f'post notifikat skond ir-

Użu kontenut ta' Klassi 1.

regolament 6, notifika li jkun fiha l-informazzjoni msemmija fl-Iskeda V, Parti B (minbarra s-sommarju ta' l-assessjar msemmi fir-regolament 4 (1)), għandha tiġi ppreżentata lill-awtorità kompetenti. L-użu kontenut fi Klassi 1 jista' jkompli jsir minnufih wara li ssir in-notifika.

(2) L-utenti ta' GMM f'użu kontenut ta' Klassi 1 ikunu meħtieġa li jzommu *record* ta' kull assessjar kif imsemmi fir-regolament 4(5), li għandu jkun disponibbli għall-awtorità kompetenti meta jiġi hekk mitlub.

Użu kontenut ta'  
Klassi 2.

**8.** (1) Meta xi użu kontenut ta' Klassi 2 ikun ser isiru għall-ewwel darba jew sussegwentement f'post notifikat skond ir-regolament 6, għandha tiġi ppreżentata notifika li jkun fiha l-informazzjoni msemmija fl-Iskeda V, Parti B, għandha tiġi ppreżentata lill-awtorità kompetenti.

(2) Jekk il-post kien soġġett għal notifika preċedenti biex jitwettaq xi użu kontenut ta' Klassi 2 jew ta' klassi oghla u kull kunsens assoċjat meħtieġ ikun ġie sodisfatt, l-użu kontenut ta' Klassi 2 jista' jkompli jsir minnufih wara li ssir in-notifika l-ġdida:

Iżda l-applikant jista' wkoll, madankollu, huwa stess jitlob deċiżjoni dwar awtorizzazzjoni formali mingħand l-awtorità kompetenti. Id-deċiżjoni għandha ssir fi żmien mhux iżjed minn hamsa u erbghin jum min-notifika.

(3) Jekk il-post ma kienx soġġett għal notifika preċedenti biex jitwettaq xi użu kontenut ta' Klassi 2 jew ta' xi klassi oghla, l-użu kontenut ta' Klassi 2 jista', fin-nuqqas ta' xi indikazzjoni kuntrarja mill-awtorità kompetenti, ikompli wara hamsa u erbghin jum minn meta tiġi ppreżentata n-notifika msemmija fis-subregolament (1), jew qabel bi qbil ma' l-awtorità kompetenti.

Użu kontenut ta'  
Klassi 3 u Klassi 4.

**9.** (1) Dwar l-ewwel użu kontenut ta' Klassi 3 u Klassi 4 u daww li sussegwentement ikunu ser jitwettqu f'post notifikat skond ir-regolament 6, notifika li jkun fiha l-informazzjoni msemmija fl-Iskeda V, Parti Ċ, għandha tiġi ppreżentata lill-awtorità kompetenti.

(2) Użu kontenut ta' Klassi 3 jew ta' klassi oghla ma jistax ikompli qabel ma jkun hemm il-kunsens bil-quddiem mill-awtorità kompetenti li għandha tikkomunika d-deċiżjoni tagħha bil-miktub:

- (a) mhux aktar tard minn hamsa u erbghin jum minn meta tiġi ppreżentata n-notifika l-ġdida, fil-każ ta' postijiet li kienu soġġetti għal notifika preċedenti biex jitwettaq xi użu kontenut ta' Klassi 3 jew ta' klassi oghla u meta xi hteġa ta' kunsens assoċjat tkun ġiet sodisfatta, għall-istess klassi jew għal klassi oghla mill-użu kontenut li bih ikun hemm hsieb li jitkompla;
- (b) mhux aktar tard minn disghin jum minn meta tkun ġiet ippreżentata n-notifika, fil-każijiet l-oħra.

10. (1) Il-persuna li tippreżenta notifika sabiex tikseb permess għall-attivitajiet msemmija fir-regolamenti 6, 7, 8 u 9, hawn aktar 'l isfel imsejha l-applikant, għandha tippreżenta t-talba tagħha bil-miktub lill-awtorità kompetenti qabel ma twettaq dik l-attività.

Notifiki lill-awtorità kompetenti.  
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(2) Sabiex l-awtorità kompetenti tkun tista' tivvaluta notifika u tohrog permess, għandu jkun hemm meħmuż ma' l-applikazzjoni d-dokumenti rilevanti u kull informazzjoni oħra meħtieġa mill-awtorità kompetenti. L-applikant għandu jindika b'mod ċar jekk l-applikazzjoni tkunx tippregudika xi każ ta' infurzar, kawża fil-qorti jew kawża oħra li jkunu jinsabu *sub-judice*.

(3) L-awtorità kompetenti għandha teżamina l-konformità tan-notifiki mal-htigiet ta' dawn ir-regolamenti, l-eżattezza u l-kompletezza ta' l-informazzjoni mogħtija, il-korrettezza ta' l-assessjar imsemmi fir-regolament 4(1) u l-klassi ta' kull użu kontenut kif ukoll, fejn ikun adatt, kemm ikun sar kif imissu l-konteniment u miżuri protettivi oħra, l-immanigġar ta' skart, u miżuri ta' rispons f'każ ta' emerġenza.

(4) Jekk ikun meħtieġ, l-awtorità kompetenti tista':

(a) titlob lill-utent jipprovdi aktar informazzjoni jew jimmodifika l-kondizzjonijiet ta' l-użu kontenut propost jew li jemenda l-klassi assenjata lil xi użu kontenut:

Iżda f'dan il-każ l-awtorità kompetenti tista' teħtieġ li l-użu kontenut, jekk ikun propost, ma jibdiex, jew, jekk ikun qed isir, jiġi sospiż jew terminat, sakemm l-awtorità kompetenti ma tagħtix l-approvazzjoni tagħha abbażi ta' aktar informazzjoni li tinkiseb jew tal-kondizzjonijiet modifikati ta' l-użu kontenut;

(b) tillimita ż-żmien sa meta jkun permess li jsir l-użu kontenut jew li dan ikun soġġett għal ċerti kondizzjonijiet speċifiċi.

(5) Għall-fini tal-kalkolu tal-perjodi msemmija fir-regolamenti 8 u 9, kull perjodu ta' żmien, li matulu, l-awtorità kompetenti -

(a) tkun qiegħda tistenna xi informazzjoni ulterjuri li hija tista' tkun ntalbet għalih mingħand in-notifikant skond is-subregolament (4)(a), jew

(b) tkun qiegħda twettaq inkjesta jew konsultazzjoni pubblika skond ir-regolament 15,

m'għandux jittiehed in konsiderazzjoni.

(6) Meta l-awtorità kompetenti tohrog permess, hija tista' timponi daww il-kondizzjonijiet li tista' tqis adatti u idonei.

(7) Meta l-awtorità kompetenti tirrifjuta dak il-permess, hija għandha tinforma lill-applikant bir-raġunijiet għal dak ir-rifjut.

(8) Il-perjodu ta' validità ta' dak il-permess għandu wkoll ikun stabbilit fid-diskrezzjoni ta' l-awtorità kompetenti.

(9) L-applikant għandu jipprovdi kopja ta' kull riżultat pubblikat u ta' kull pubblikazzjoni oħra, li jkunu rilevanti għal dan il-permess, lill-awtorità kompetenti fi żmien tliet xhur mid-data ta'

pubblikazzjoni.

(10) L-awtorità kompetenti m'għandhiex tohrōg jew iġġedded permess jekk l-applikant involut ma jkunx issodisfa jew onora dawk il-kondizzjonijiet jew l-obligazzjonijiet li joriġinaw minn xi permess ieħor mahruġ mill-awtorità kompetenti taht dawn ir-regolamenti u, jew kull regolament ieħor li jkollhom x'jaqsmu magħhom.

Informazzjoni  
ġdida dwar riskji  
ta' użu kontenut.

**11.(1)(a)** Jekk informazzjoni ġdida ssir sussegwentement disponibbli għall-awtorità kompetenti li jista' jkollha konsegwenzi sinifikanti għar-riskji li jinholqu bl-użu kontenut, l-awtorità kompetenti tista' tehtieg lill-utent jimmodifika l-kondizzjonijiet ta', jew li jissospendi jew iwaqqaf, l-użu kontenut.

(b) Meta utent isir jaf b'informazzjoni ġdida jew jimmodifika l-użu kontenut b'mod li jista' jkollu konsegwenzi sinifikanti għar-riskji li jinholqu b'dan, l-utent għandu jwaqqaf l-użu kontenut u, mill-aktar fis possibbli, jinforma lill-awtorità kompetenti.

(2) Qabel ma jerġa' jibda użu kontenut li jkun twaqqaf skond is-subregolament (1), l-utent għandu -

(a) jirrevedi l-assessjar mwettaq skond ir-regolament 4, u l-klassi u l-livell ta' konteniment applikati skond ir-regolament 4(2); u

(b) jippreżenta notifika emendata lill-awtorità kompetenti.

(3) Għall-fini tas-subregolament (2), id-disposizzjonijiet li jkollhom x'jaqsmu mal-preżentata ta' notifika minn utent skond ir-regolamenti 6, 8 jew 9, u għall-ipproċessar u deċiżjoni dwar notifika bħal dik mill-awtorità kompetenti skond ir-regolament 10, għandhom ikunu japplikaw, skond kif ikun adatt, għal notifika emendata bħal li kieku din kienet notifika skond ir-regolamenti 6, 8 jew 9.

Reati.

**12. (1)** Persuna tista' tinsab hatja ta' reat taht dawn ir-regolamenti jekk:

(a) hija tonqos milli tikkonforma ruhha ma' xi disposizzjoni ta' dawn ir-regolamenti jew tonqos milli tikkonforma mal-kondizzjonijiet tal-permess jew ma' xi ordni oħra mogħtija legittimament skond xi disposizzjoni ta' dawn ir-regolamenti; jew

(b) hija tikser xi restrizzjoni, projbizzjoni jew rekwiżit impost minn jew taht dawn ir-regolamenti; jew

(c) hija taġixxi f'kontravvenzjoni ta' xi disposizzjoni ta' dawn ir-regolamenti; jew

(d) hija tagħmel xi dikjarazzjoni jew tippreżenta informazzjoni jew dokumenti, li dik il-persuna tkun taf li huma foloz għall-fini li takkwista l-approvazzjoni jew it-komplija tal-permess skond ir-regolamenti 6, 8, 9 jew 11(2)(b); jew

(e) hija tikkonfoffa jew tipprova tikkonfoffa, tghin jew

tipprova tghin, thajjar jew tipprova thajjar, taghti parir jew tipprova taghti parir, tqabba jew tipprova tqabba, lil xi persuna ohra sabiex din tikser id-disposizzjonijiet ta' dawn ir-regolamenti jew jekk hija tonqos milli tikkonforma ruhha ma' daww id-disposizzjonijiet, inkluda kull ordni moghtija legittimament skond xi disposizzjoni ta' dawn ir-regolamenti, jew b'x tikser xi restrizzjoni, projbizzjoni jew rekwiżit imposti minn jew taht ir-regolamenti msemmija jew b'hala riżultat ta' dan.

(2) Kull persuna li taghmel jew tipprova taghmel xi reat kontra dawn ir-regolamenti ghandha, meta tinstab hatja, tehel il-penali li ġejjin: Penali.

- (a) meta tinsab hatja għall-ewwel darba ta' reat taht Klassi 1, multa ta' mhux inqas minn hames mitt euro (€500), iżda mhux iżjed minn elf euro (€1,000); meta tinsab hatja għat-tieni darba jew aktar għal reat taht Klassi 1, multa ta' mhux inqas minn elf euro (€1,000), iżda mhux iżjed minn elfejn u hames mitt euro (€2,500) jew għal priġunerija għal żmien mhux iżjed minn sentejn jew għal dik il-multa u priġunerija flimkien;
- (b) meta tinsab hatja għall-ewwel darba ta' reat taht Klassi 2, multa ta' mhux inqas minn elf euro (€1,000), iżda mhux aktar minn elfejn euro (€2,000); meta tinsab hatja għat-tieni darba jew aktar għal reat taht Klassi 2, multa ta' mhux inqas elfejn euro (€2,000), iżda mhux iżjed minn tliet elef u hames mitt euro (€3,500) jew għal priġunerija għal żmien mhux iżjed minn sentejn jew għal dik il-multa u priġunerija flimkien;
- (c) meta tinstab hatja għall-ewwel darba ta' reat taht Klassi 3, multa ta' mhux inqas minn elfejn u hames mitt euro (€2,500), iżda mhux iżjed minn sitt elef euro (€6,000); meta tinsab hatja għat-tieni darba jew aktar għal reat taht Klassi 3, multa ta' mhux inqas minn erbat elef u hames mitt euro (€4,500), iżda mhux iżjed minn hamsa u għoxrin elf euro (€25,000) jew għal priġunerija għal żmien ta' mhux iżjed minn sentejn jew għal dik il-multa u priġunerija flimkien;
- (d) meta tinsab hatja għall-ewwel darba ta' reat taht Klassi 4, multa ta' mhux inqas minn tnax-il elf euro (€12,000), iżda mhux iżjed minn hamsa u għoxrin elf euro (€25,000); meta tinsab hatja għat-tieni darba jew aktar għal reat taht Klassi 4, multa ta' mhux inqas hamsa u għoxrin elf euro (€25,000), iżda mhux aktar minn hamsa u tletin elf euro (€35,000) jew għal priġunerija għal żmien ta' mhux iżjed minn sentejn jew għal dik il-multa u priġunerija flimkien;

Iżda l-Qorti ghandha tordna lil persuna li tinsab hatja li tkun għamlet reat kontra dawn ir-regolamenti, thallas l-ispejjeż li l-awtorità kompetenti tkun għamlet b'riżultat ta' dak ir-reat, inkluda kull azzjoni li ssir b'hala rimedju għal danni kaġunati b'dak ir-reat, ir-revoka tal-permess mahruġ mill-awtorità kompetenti u l-konfiska

tal-*corpus delicti*, inklużi wkoll l-ispejjeż kollha mgarrba ghaż-  
żamma u t-trasport ta' dak il-*corpus delicti*.

(3) Il-Qorti ghandha tordna lill-hati biex inehhi l-kawzi tar-reat u li jregga lura kull haġa li tkun saret minghajr permess fi żmien li jkun suffiċjenti għal dan il-ghan skond ma' jiġi stabbilit mill-Qorti; u, jekk il-hati jonqos milli jikkonforma ruhu ma' ordni bħal dik fiż-  
żmien stipulat, għandu jehel multa ta' mhux inqas minn sittin euro (€60) u mhux iżjed minn hames mitt euro (€500), skond ma l-Qorti tista' tistabbilixxi, għal kull ġurnata li n-nuqqas ikompli wara li jiskadi t-terminu msemmi.

Applikabilità tal-  
Kodiċi Kriminali.  
Kap. 9.

(4) Id-disposizzjonijiet ta' l-artikoli 23 u 30 tal-Kodiċi Kriminali għandhom, *mutatis mutandis*, ikunu japplikaw għall-proċedimenti dwar reati kontra dawn ir-regolamenti, b'dan illi l-iskwalifika milli persuna jkollha jew tikseb liċenza jew permess mill-awtorità kompetenti m'għandha f'ebda każ tkun ta' inqas minn sena.

Kap. 9.

(5) Minkejja d-disposizzjonijiet ta' l-artikolu 370 tal-Kodiċi Kriminali, proċedimenti għal reat kontra dawn ir-regolamenti għandhom isiru quddiem il-Qorti tal-Maġistrati (Malta) jew il-Qorti tal-Maġistrati (Għawdex), skond kif ikun il-każ, u għandhom jkunu skond id-disposizzjonijiet tal-Kodiċi Kriminali li jirregolaw il-proċedura quddiem dawk il-qrati bħala qrati ta' ġudikatura kriminali.

Kap. 9.

(6) Minkejja d-disposizzjonijiet tal-Kodiċi Kriminali, l-Avukat Ġenerali għandu dejjem ikollu dritt ta' appell quddiem il-Qorti ta' l-Appell Kriminali minn kull sentenza mogħtija mill-Qorti tal-Maġistrati (Malta) jew mill-Qorti tal-Maġistrati (Għawdex) dwar proċedimenti għal xi reat kontra dawn ir-regolamenti.

Spezzjonijiet u  
miżuri oħra ta' kontroll.

**13.** L-awtorità kompetenti tista' torganizza spezzjonijiet u miżuri oħra ta' kontroll sabiex tiżgura li l-utent ikun jikkonforma ruhu ma' dawn ir-regolamenti.

#### TAQSIMA IV: KONSULTAZZJONI PUBBLIKA U KUNFIDENZJALITÀ

Kxif ta' *data*  
kunfidenzjali.

**14.** (1) Meta l-kxif ta' *data* li jkollha x'taqsam ma' dawn ir-regolamenti tkun taffetwa lil xi wahda jew aktar minn dawn li ġejjin -

- (a) il-kunfidenzjalità tal-proċedimenti ta' awtoritajiet pubbliċi, ir-relazzjonijiet internazzjonali u d-difiża nazzjonali,
- (b) is-sigurtà pubblika,
- (c) fatti li huma, jew li kienu, *sub judice*, jew taht inkjesta (inkluż inkjesti dixxiplinari), jew li jiffurmaw is-sugġett għal proċedimenti ta' investigazzjoni preliminari,
- (d) kunfidenzjalità kummerċjali u industrijali, inkluża l-proprietà intellettuali,
- (e) il-kunfidenzjalità ta' *data* personali u, jew inkartamenti;

- (f) materjal fornut minn terzi minghajr ma dik il-parti tkun taht obbligu legali li taghmel dan,
- (g) materjal, li l-kxif tiegħu x'aktarx li jista' jwassal għal dannu fl-ambjent li dak il-materjal ikollu kuntatt miegħu,

in-notifikant jista' jindika l-informazzjoni fin-notifiki pprezentati f'konformità ma' dawn ir-regolamenti li għandhom jiġu trattati b'mod kunfidenzjali:

Iżda f'dawn il-każijiet għandha tinghata ġustifikazzjoni li tista' tiġi verifikata.

(2) L-awtorità kompetenti għandha tiddeċiedi, wara konsultazzjoni man-notifikant, liema informazzjoni għandha tinzamm bħala wahda kunfidenzjali u għandha tinforma lin-notifikant bid-deċiżjoni tagħha.

(3) F'ebda każ m'għandha l-informazzjoni li ġejja, tinzamm kunfidenzjali meta din tkun ġiet ipprezentata skond ir-regolamenti 6, 8 jew 9:

- (a) il-karatteristiċi ġenerali tal-GMM, l-isem u l-indirizz tan-notifikant, u l-lok ta' l-użu,
- (b) il-klassi ta' l-użu kontenut u l-miżuri ta' konteniment,
- (c) l-evalwazzjoni ta' effetti prevedibbli, b'mod partikolari dawk l-effetti li jagħmlu l-ħsara lis-saħħa umana u l-ambjent.

(4) L-awtorità kompetenti m'għandha xxandar ebda informazzjoni lil terzi li tkun ġiet deċiża li tibqa' kunfidenzjali skond is-subregolament (2) u li tkun ġiet notifikata jew b'xi mod ieħor provduta b'mod konformi ma' dawn ir-regolamenti, u għandha tipproteġi d-drittijiet ta' proprjetà intellettuali li jkollhom x'jaqsmu mad-*data* li tkun ġiet mogħtija.

(5) Jekk, għal xi raġuni li tkun, in-notifikant jirtira n-notifika tiegħu, l-awtorità kompetenti għandha tirrispetta l-kunfidenzjalità ta' l-informazzjoni mogħtija.

**15.** Minghajr preġudizzju għar-regolament 14, l-awtorità kompetenti tista' tikkonsulta lill-pubbliku dwar xi aspetti ta' l-użu kontenut propost meta hija tqis li dan ikun adatt.

Konsultazzjoni pubblika.

#### TAQSIMA V: INĊIDENTI U PJANIJET TA' EMERĠENZA

**16.** (1) L-awtorità kompetenti għandha tiżgura li qabel ma jibda użu kontenut:

Pjanijiet ta' emerġenza.

- (a) jitfassal pjan ta' emerġenza għal kull użu kontenut f'dawk il-każijiet meta l-miżuri ta' konteniment jistgħu jfallu u jwasslu għal perikolu serju, kemm jekk immedjat kemm jekk ritardat, għal bnedmin barra mill-post u, jew għall-ambjent, hliet meta dak il-pjan ta' emerġenza jkun diġà ġie mfassal taht leġislazzjoni rilevanti ohra;
- (b) informazzjoni fuq pjanijiet ta' emerġenza, għal dawk inklużi l-miżuri ta' sigurtà rilevanti li għandhom jiġu

applikati, għandha tingħata b'mod adatt, u mingħajr ma din ikollha għalfejn tintalab, mingħand korpi u awtoritajiet li jistgħu jkunu affettwati bl-inċident. Din l-informazzjoni għandha tiġi aġġornata f'intervalli adatti. Din għandha tkun ukoll disponnibbli għall-pubbliku.

(2) Fl-istess hin, l-awtorità kompetenti għandha tara li informazzjoni bħal dik li tkun tqassmet liċ-ċittadini tagħha għandha tkun disponnibbli għal Stati Membri ohra involuti.

Okkorrenza ta' inċidenti.

**17.** (1) F'każ ta' inċident, l-utent ikun minnufih mehtieġ jinforma lill-awtorità kompetenti u li jipprovdiha din l-informazzjoni li ġejja:

- (a) iċ-ċirkostanzi ta' l-inċident,
- (b) l-identità u l-kwantitajiet ta' kull GMM involut,
- (c) kull informazzjoni mehtieġa biex jiġu valutati l-effetti ta' l-inċident fuq is-saħħa tal-popolazzjoni in ġenerali u ta' l-ambjent,
- (d) il-miżuri li jkunu ttiehdu.

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(2) L-utent għandu jinforma lill-awtorità kompetenti msemija fir-Regolamenti dwar il-Protezzjoni tal-Haddiema minn Riskji relatati ma' l-Espożizzjoni għal-Aġenti Bijoloġiċi fuq il-Post tax-Xogħol, b'xi inċident bħal dak.

(3) Meta tingħata informazzjoni b'konformità mas-subregolament (1), l-awtorità kompetenti, flimkien ma' l-awtorità kompetenti msemija fis-subregolament (2), tkun mehtieġa:

- (a) tiżgura li jittiehdu l-miżuri kollha mehtieġa, u minnufih tinforma lil Stati Membri ohra li jistgħu jkunu affettwati bl-inċident,
- (b) tiġbor, meta dan ikun possibbli, l-informazzjoni mehtieġa għal analiżi shiha ta' l-inċident u, meta jkun adatt, tagħmel ir-rakkomandazzjonijiet tagħha sabiex jiġu evitati inċidenti simili fil-futur u biex tillimita l-effetti tagħhom.

(4) F'każ ta' inċident, l-awtorità kompetenti flimkien ma' l-awtorità kompetenti msemija fis-subregolament (2), tista' titlob lill-utent biex iħallas jew jikkontribwixxi għal xi jew l-ispejjeż kollha li joriġinaw minn dan l-inċident.

Komunikazzjoni ma' Stati Membri ohra.

**18.** L-awtorità kompetenti għandha tikkonsulta lil Stati Membri ohra, li x'aktarx li jiġu affettwati f'każ ta' inċident, fuq l-implementazzjoni proposta tal-pjanijiet ta' emerġenza.

#### TAQSIMA VI: DRITTIJET

Dritt għal notifika dwar post li ser ikun użat.

**19.** (1) Għandu jithallas dritt lill-awtorità kompetenti għal:

Dritt għal notifika dwar post li ser ikun użat għall-ewwel darba.

- (a) notifika dwar post li jkun ser jintuża għall-ewwel darba mogħtija lill-awtorità kompetenti taht ir-regolament 6, skond id-drittijiet applikabbli mniżżla

- fil-Parti A ta' l-Iseda VI, skond liema minnhom ikun japplika;
- (b) notifika dwar użu kontenut individwali, mogħtija lill-awtorità kompetenti taht ir-regolamenti 7, 8 u 9 skond id-drittijiet applikabbli mnizzla fil-Parti B ta' l-Iskeda VI, skond liema minnhom ikun japplika; Dritt għal notifika għal użu kontenut individwali.
- (ċ) notifika emendata dwar użu kontenut, mogħtija lill-awtorità kompetenti taht ir-regolament 11 skond id-drittijiet applikabbli mnizzla fil-Parti Ċ ta' l-Iskeda VI, skond liema minnhom ikun japplika. Dritt għal notifika emendata ta' użu kontenut.
- (2) L-awtorità kompetenti tista' tagħmel, jew tirranġa li jsiru, dawk l-investigazzjonijiet addizzjonali li tqis meħtieġa, bħala parti mill-eżami jew monitorġġ tagħha ta' notifika ta' użu kontenut sabiex hija tkun tista' tivvaluta sew in-notifika u tista' titlob lill-utent iħallas jew jikkontribwixxi għal xi spejjeż ta' kull investigazzjoni bħal dik. Investigazzjonijiet.
- (3) L-awtorità kompetenti tista' tirkupra l-ammont ta' kull hlas lilha dovut minn xi hteġa taht ir-regolament 17(4). Rkupru ta' spejjeż jew hlasijiet.

#### TAQSIMA VII: DISPOSIZZJONIJIET OHRA

20. L-Iskedi I sa VI qegħdin jiġu pubblikati bil-lingwa Ingliża mat-test Ingliż ta' dawn ir-regolamenti. L-iskedi I sa VI jinsabu pubblikati bil-lingwa Ingliża biss.

## SKEDA I

## PART A

Techniques of genetic modification referred to in regulation 3 are, *inter alia*:

1. Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.
2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism including micro-injection, macro-injection and micro-encapsulation.
3. Cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

## PART B

Techniques referred to in regulation 3 which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than techniques/methods excluded by Schedule II, Part A:

- (1) in vitro fertilisation;
- (2) natural processes such as: conjugation, transduction, transformation;
- (3) polyploidy induction.

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SKEDA II

## PART A

Techniques or methods of genetic modification yielding micro-organisms to be excluded from the Regulation on the condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below

1. Mutagenesis.
2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.
3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.
4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

PART B

Criteria establishing the safety of GMMs for human health and the environment

This Schedule describes in general terms the criteria to be met when establishing the safety of types of GMMs for human health and the environment.

1. GENERAL CRITERIA

2.1. Strain verification/authentication

Identity of the strain must be precisely established. Modification must be known and verified.

2.2. Documented and established evidence of safety

Documented evidence of the safety of the organism must be provided.

2.3. Genetic stability

Where any instability could adversely affect safety, evidence of stability is required.

3. SPECIFIC CRITERIA

3.1. Non-pathogenic

The GMM should not be capable of causing disease or harm to a healthy human, plant or animal. Since pathogenicity includes both toxigenicity and allergenicity, the GMM should therefore be:

3.1.1. Non-toxigenic

The GMM should not produce increased toxigenicity as a result of the genetic modification nor be noted for its toxigenic properties.

3.1.2. Non-allergenic

The GMM should not produce increased allergenicity as a result of the genetic modification nor be a noted allergen, having, for example, allergenicity comparable in particular with that of the micro-organisms identified in the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations.

3.2. No harmful adventitious agents

The GMM should not harbour known harmful adventitious agents such as other micro-organisms, active or latent, existing alongside or inside the GMM that could cause harm to human health and the environment.

3.3. Transfer of genetic material

The modified genetic material must not give rise to harm if transferred nor should it be self-transmissible or transferable at a frequency greater than other genes of the recipient or parental micro-organism.

3.4. Safety for the environment in the event of a significant and unintended release GMMs must not produce adverse effects on the environment, immediate or delayed, should any incident involving a significant and unintended release occur.

PART C

Types of GMMs which meet the criteria listed in Part B can be referred to Schedule III of the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations.

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**SKEDA III****PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT  
REFERRED TO IN REGULATION 4(1)**

This Schedule describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in regulation 4(1). It may be supplemented, as regards in particular section B, by guidance notes which may be issued by the competent authority.

**A. ELEMENTS OF ASSESSMENT**

1. The following should be considered as potentially harmful effects:
  - disease to humans including allergenic or toxic effects,
  - disease to animals or plants,
  - deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,
  - deleterious effects due to establishment or dissemination in the environment,
  - deleterious effects due to the natural transfer of inserted genetic material to other organisms.
2. The assessment referred to in regulation 4(1) should be based on the following:
  - (a) the identification of any potentially harmful effects, in particular those associated with:
    - (i) the recipient micro-organism;
    - (ii) the genetic material inserted (originating from the donor organism);
    - (iii) the vector;
    - (iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);
    - (v) the resulting GMM;
  - (b) the characteristics of the activity;
  - (c) the severity of the potentially harmful effects;
  - (d) the likelihood of the potentially harmful effects being realised.

**B. PROCEDURE**

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.
4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in Class 1 as defined in regulation 4:
  - (i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants (\*);
  - (ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or

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\*This would only apply to animals and plants in the environment likely to be exposed.

- plants (\*), or likely to cause deleterious effects in the environment;
- (iii) the GMM is unlikely to cause disease to humans, animals or plants (\*) and is unlikely to have deleterious effects on the environment.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Council Directive 90/679/EEC). International or national classification schemes (e.g. WHO, NIH, etc.) and their revisions due to new scientific knowledge and technical progress may also be considered.

These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 90/679/EEC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance to the categorisation of the contained use activities in the four classes of risk referred to in regulation 4(2). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with paragraphs 3 to 5, should lead to the identification of the level of risk associated with the GMM.

7. Selection of the containment and other protective measures should then be made on the basis of the level or risk associated with the GMMs together with consideration of:

- (i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);
- (ii) the characteristics of the activity (e.g. its scale; nature);
- (iii) any non-standard operations (e.g. the inoculation of animals with GMMs; equipment likely to generate aerosols).

Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under paragraph 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in regulation 4(2).

9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in regulation 4(2).

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\*This would only apply to animals and plants in the environment likely to be exposed.

**SKEDA IV****CONTAINMENT AND OTHER PROTECTIVE MEASURES****General principles**

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene, shall apply:

- (i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;
- (ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;
- (iii) to test adequately and maintain control measures and equipment;
- (iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;
- (v) to provide appropriate training of personnel;
- (vi) to establish biological safety committees or subcommittees, if required;
- (vii) to formulate and implement local codes of practice for the safety of personnel, as required;
- (viii) where appropriate to display biohazard signs;
- (ix) to provide washing and decontamination facilities for personnel;
- (x) to keep adequate records;
- (xi) to prohibit eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area;
- (xii) to prohibit mouth pipetting;
- (xiii) to provide written standard operating procedures where appropriate to ensure safety;
- (xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;
- (xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level. In some cases users may,

with the agreement of the competent authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables "optional" means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in regulation 4(1).

Table I A

Containment and other protective measures for laboratory activities

| Specifications |                                            | Containment levels |              |          |          |
|----------------|--------------------------------------------|--------------------|--------------|----------|----------|
|                |                                            | 1                  | 2            | 3        | 4        |
| 1              | Laboratory suite: isolation <sup>(1)</sup> | Not required       | Not required | Required | Required |
| 2              | Laboratory: sealable for fumigation        | Not required       | Not required | Required | Required |

Equipment

|   |                                                                                                                |                  |                  |                                                                        |                                                        |
|---|----------------------------------------------------------------------------------------------------------------|------------------|------------------|------------------------------------------------------------------------|--------------------------------------------------------|
| 3 | Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean | Required (bench) | Required (bench) | Required (bench, floor)                                                | Required (bench, floor, ceiling, walls)                |
| 4 | Entry to lab via airlock <sup>(2)</sup>                                                                        | Not required     | Not required     | Optional                                                               | Required                                               |
| 5 | Negative pressure relative to the pressure of the immediate environment                                        | Not required     | Not required     | Required except for <sup>(1)</sup>                                     | Required                                               |
| 6 | Extract and input air from the laboratory should be HEPA-filtered                                              | Not required     | Not required     | Required (HEPA) <sup>(4)</sup> - extract air except for <sup>(3)</sup> | Required (HEPA) <sup>(5)</sup> - input and extract air |
| 7 | Microbiological safety post                                                                                    | Not required     | Optional         | Required                                                               | Required                                               |
| 8 | Autoclave                                                                                                      | On site          | In the building  | En suite <sup>(6)</sup>                                                | In lab = double-ended                                  |

System of work

|    |                                                    |                              |                                                      |                              |                                                                |
|----|----------------------------------------------------|------------------------------|------------------------------------------------------|------------------------------|----------------------------------------------------------------|
| 9  | Restricted access                                  | Not required                 | Required                                             | Required                     | Required                                                       |
| 10 | Biohazard sign on the door                         | Not required                 | Required                                             | Required                     | Required                                                       |
| 11 | Specific measures to control aerosol dissemination | Not required                 | Required minimise                                    | Required prevent             | Required prevent                                               |
| 13 | Shower                                             | Not required                 | Not required                                         | Optional                     | Required                                                       |
| 14 | Protective clothing                                | Suitable protective clothing | Suitable protective clothing and (optional) footwear | Suitable protective clothing | Complete change of clothing and footwear before entry and exit |
| 15 | Gloves                                             | Not required                 | Optional                                             | Required                     | Required                                                       |

| Specifications |                                                         | Containment levels |          |          |          |
|----------------|---------------------------------------------------------|--------------------|----------|----------|----------|
|                |                                                         | 1                  | 2        | 3        | 4        |
| 18             | Efficient vector control (e.g. for rodents and insects) | Optional           | Required | Required | Required |

## Waste

|    |                                                                                                      |              |              |          |          |
|----|------------------------------------------------------------------------------------------------------|--------------|--------------|----------|----------|
| 19 | Inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents | Not required | Not required | Optional | Required |
| 20 | Inactivation of GMMs in contaminated material and waste                                              | Optional     | Required     | Required | Required |

## Other measures

|    |                                                                                     |              |              |          |          |
|----|-------------------------------------------------------------------------------------|--------------|--------------|----------|----------|
| 21 | Laboratory to contain its own equipment                                             | Not required | Not required | Optional | Required |
| 23 | An observation window or alternative is to be present so that occupants can be seen | Optional     | Optional     | Optional | Required |

<sup>(1)</sup> Isolation = the laboratory is separated from other areas in the same building or is in a separated building.

<sup>(2)</sup> Airlock = entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

<sup>(3)</sup> Activities where transmission does not occur via airborne route.

<sup>(4)</sup> HEPA = High efficiency particulate air.

<sup>(5)</sup> Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

<sup>(6)</sup> With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

Table I B

Containment and other protective measures for glasshouses and growth-rooms

The terms "glasshouse" and "growth-room" refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment.

All provisions of Table I A shall apply with the following additions/modifications:

| Specifications        |                                                                                                                                                                                        | Containment levels     |                                   |                       |                       |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|-----------------------------------|-----------------------|-----------------------|
|                       |                                                                                                                                                                                        | 1                      | 2                                 | 3                     | 4                     |
| <b>Building</b>       |                                                                                                                                                                                        |                        |                                   |                       |                       |
| 1                     | Greenhouse:<br>permanent structure<br>( <sup>1</sup> )                                                                                                                                 | Not required           | Required                          | Required              | Required              |
| <b>Equipment</b>      |                                                                                                                                                                                        |                        |                                   |                       |                       |
| 3                     | Entry via a separated room with two interlocking doors                                                                                                                                 | Not required           | Optional                          | Optional              | Required              |
| 4                     | Control of contaminated run-off water                                                                                                                                                  | Optional               | Minimise run-off ( <sup>2</sup> ) | Prevent run-off       | Prevent run-off       |
| <b>System of work</b> |                                                                                                                                                                                        |                        |                                   |                       |                       |
| 6                     | Measures to control undesired species such as insects, rodents, anthropods                                                                                                             | Required               | Required                          | Required              | Required              |
| 7                     | Procedures for transfer of living material between the glasshouse/growth-room, protective structure and laboratory shall control dissemination of genetically modified micro-organisms | Minimise dissemination | Minimise dissemination            | Prevent dissemination | Prevent dissemination |

(<sup>1</sup>) The glasshouse shall consist of a permanent structure with a continuous waterproofed covering, located on a site graded to prevent entry of surface-water run-off having self-closing lockable doors.

(<sup>2</sup>) Where transmission can occur through the ground.

Table I C

Containment and other protective measures for activities in animal units

All provisions of Table I A shall apply with the following additions/modifications:

| Specifications |                                                                                                                  | Containment levels |                  |                            |                            |
|----------------|------------------------------------------------------------------------------------------------------------------|--------------------|------------------|----------------------------|----------------------------|
|                |                                                                                                                  | 1                  | 2                | 3                          | 4                          |
| Facilities     |                                                                                                                  |                    |                  |                            |                            |
| 1              | Isolation of animal unit <sup>(1)</sup>                                                                          | Optional           | Required         | Required                   | Required                   |
| 2              | Animal facilities <sup>(2)</sup> separated by lockable doors                                                     | Optional           | Required         | Required                   | Required                   |
| 3              | Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.)) | Optional           | Optional         | Required                   | Required                   |
| 4              | Floor and/or walls easily washable                                                                               | Optional           | Required (floor) | Required (floor and walls) | Required (floor and walls) |
| 5              | Animals kept in appropriate containment facilities such as cages, pens or tanks                                  | Optional           | Optional         | Optional                   | Optional                   |
| 6              | Filters on isolators or isolated room <sup>(3)</sup>                                                             | Not required       | Optional         | Required                   | Required                   |

<sup>(1)</sup> Animal unit: a building, or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc..

<sup>(2)</sup> Animal facility: a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.

<sup>(3)</sup> Isolators: transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table II  
Containment and other protective measures for other activities

| Specifications |                                                                                                                                        | Containment levels      |                                  |                                 |                                         |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------------------|---------------------------------|-----------------------------------------|
|                |                                                                                                                                        | 1                       | 2                                | 3                               | 4                                       |
| General        |                                                                                                                                        |                         |                                  |                                 |                                         |
| 1              | Viable micro-organisms should be contained in a system which separates the process from the environment (closed system)                | Optional                | Required                         | Required                        | Required                                |
| 2              | Control of exhaust gases from the closed system                                                                                        | Not required            | Required, minimise dissemination | Required, prevent dissemination | Required, prevent dissemination         |
| 3              | Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system | Optional                | Required, minimise dissemination | Required, prevent dissemination | Required, prevent dissemination         |
| 4              | Inactivation of bulk culture fluids before removal from the closed system                                                              | Optional                | Required, by validated means     | Required, by validated means    | Required, by validated means            |
| 5              | Seals should be designed so as to minimise or prevent release                                                                          | Minimise dissemination  | Minimise dissemination           | Prevent dissemination           | Prevent dissemination                   |
| 6              | The controlled area should be designed to contain spillage of the entire contents of the closed system                                 | Optional                | Optional                         | Required                        | Required                                |
| 7              | The controlled area should be sealable to permit fumigation                                                                            | Not required            | Optional                         | Optional                        | Required                                |
| Equipment      |                                                                                                                                        |                         |                                  |                                 |                                         |
| 8              | Entry via airlock                                                                                                                      | Not required            | Not required                     | Optional                        | Required                                |
| 9              | Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean                         | Required (bench if any) | Required (bench if any)          | Required (bench if any, floor)  | Required (bench, floor, ceiling, walls) |
| 10             | Specific measures to adequately ventilate the controlled area in order to minimise air ventilation                                     | Optional                | Optional                         | Optional                        | Required                                |
| 11             | The controlled area should be maintained at an air pressure negative to the immediate surroundings                                     | Not required            | Not required                     | Optional                        | Required                                |

| Specifications |                                                                        | Containment levels |              |                                                |                                  |
|----------------|------------------------------------------------------------------------|--------------------|--------------|------------------------------------------------|----------------------------------|
|                |                                                                        | 1                  | 2            | 3                                              | 4                                |
| 12             | Extract and input air from the controlled area should be HEPA filtered | Not required       | Not required | Required (extract air, optional for input air) | Required (input and extract air) |

**System of work**

|    |                                                            |                          |                          |          |                                       |
|----|------------------------------------------------------------|--------------------------|--------------------------|----------|---------------------------------------|
| 13 | Closed systems should be located within a controlled area  | Not required             | Optional                 | Required | Required                              |
| 14 | Access should be restricted to nominated personnel only    | Not required             | Required                 | Required | Required                              |
| 15 | Biohazard signs should be posted                           | Not required             | Required                 | Required | Required                              |
| 17 | Personnel should shower before leaving the controlled area | Not required             | Not required             | Optional | Required                              |
| 18 | Personnel should wear protective clothing                  | Required (work clothing) | Required (work clothing) | Required | Complete change before exit and entry |

**Waste**

|    |                                                                                                                    |              |                              |                              |                              |
|----|--------------------------------------------------------------------------------------------------------------------|--------------|------------------------------|------------------------------|------------------------------|
| 22 | Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents                          | Not required | Not required                 | Optional                     | Required                     |
| 23 | Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge | Optional     | Required, by validated means | Required, by validated means | Required, by validated means |

SKEDA V

PART A

Information required for the notification referred to in regulation 6:

- name of user(s) including those responsible for supervision and safety,
- information on the training and qualifications of the persons responsible for supervision and safety,
- details of any biological committees or subcommittees,
- address and general description of the premises,
- a description of the nature of the work which will be undertaken,
- the class of the contained uses,
- only for Class 1 contained uses, a summary of the assessment referred to in regulation 4(1) and information on waste management.

PART B

Information required for the notification referred to in regulation 8:

- the date of submission of the notification referred to in regulation 6,
- the name of the persons responsible for supervision and safety and information on the training and qualification,
- the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,
- the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),
- identity and characteristics of the GMM,
- the purpose of the contained use including the expected results,
- approximate culture volumes to be used,
- description of the containment and other protective measures to be applied, including information about waste management including the wastes to be generated, their treatment, final form and destination,
- a summary of the assessment referred to in regulation 4(1),
- the information necessary for the competent authority to evaluate any emergency response plans if required under regulation 16.

PART C

Information required for the notification referred to in regulation 9:

- (a) - the date of submission of the notification referred to in regulation 6,
  - the name of the persons responsible for supervision and safety and information on the training and qualification;
- (b) - the recipient or parental micro-organism(s) to be used,
  - the host-vector system(s) to be used (where applicable),
  - the source(s) and intended functions(s) of the genetic material(s) involved in the modification(s),
  - identity and characteristics of the GMM,
  - the culture volumes to be used;
- (c) - description of the containment and other protective measures to be

- applied, including information about waste management including the type and form of wastes to be generated, their treatment, final form and destination,
- the purpose of the contained use including the expected results,
- description of the parts of the installation;
- (d) information about accident prevention and emergency response plans, if any:
  - any specific hazards arising from the location of the installation,
  - the preventive measures applied such as safety equipment, alarm systems and containment methods,
  - procedures and plans for verifying the continuing effectiveness of the containment measures,
  - a description of information provided to workers,
  - the information necessary for the competent authority to evaluate any emergency response plans if required under regulation 16;
- (e) a copy of the assessment referred to in regulation 4(1).

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#### SKEDA VI

##### Fees

###### Part A: First time use of facility

Class 1 - €500

Class 2 - €1,200

Class 3 - €4,700

Class 4 - €15,000

###### Part B: Individual contained use activities

Class 1 - €30

Class 2 - €800

Class 3 - €4,500

Class 4 - €10,000

###### Part C: Amended Notification

Class 1 - €30

Class 2 - €500

Class 3 - €1,500

Class 4 - €7,000

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