A.L. 127 ta' l-2008

ATT DWAR IL-ĦARSIEN TA' L-AMBJENT (KAP. 435)

Regolamenti ta' l-2008 dwar l-Użu Kontenut ta' Mikro-Organiżmi Ġenetikament Modifikati

BIS-SAĦĦA tas-setgħat mogħtija bl-artikoli 9, 10(2) u 11 ta' l-Att dwar il-Ħarsien ta' l-Ambjent, hawnhekk iżjed 'il quddiem imsejjaħ "l-Att", il-Prim Ministru għamel dawn ir-regolamenti li ġejjin:–

1. It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2008 dwar l-Użu Kontenut ta' Mikro-Organiżmi Modifikati Ġenetikament. Titolu.

2. (1) L-għan ta' dawn ir-regolamenti hu li jkunu stabbiliti miżuri għall-użu kontenut ta' mikro-organiżmi modifikati ġenetikament bl-iskop li tkun protetta s-saħħa umana u l-ambjent. Għanijiet.

(2) Dawn ir-regolamenti jipprovdu d-disposizzjonijiet neċessarji għall-implimentazzjoni tad-Direttiva 90/219/KE tal-Kunsill Ewropew tat-23 ta' April 1990, f'Malta, rigward l-użu kontenut ta' mikro-organiżmi modifikati ġenetikament u għandhom jinqraw u jiftiehmu bħala ħaġa waħda ma' dik id-Direttiva.

(3) Dawn ir-regolamenti għandhom jinqraw u jiftehmu ħaġa waħda mar-Regolamenti ta' l-2003 dwar il-Protezzjoni tal-Ħaddiema minn Riskji relatati ma' l-Espożizzjoni għal Aġenti Bijoloġiċi fuq il-Post tax-Xogħol, li għandhom x'jaqsmu ma' kwistjonijiet rigward is-saħħa u s-sigurtà fuq il-post tax-xogħol. A. L. 228 ta' l-2003.

DEFINIZZJONIJIET U EŻENZJONIJIET: PARTI I

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

"l-Awtorità Kompetenti" tfisser l-Awtorità ta' Malta dwar l-Ambjent u l-Ippjanar kif stipulat bl-avviż intitolat Nomina ta' l-Awtorità ta' Malta dwar l-Ambjent u l-Ippjanar bħala l-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 nnominati bħala l-awtorità kompetenti għal dispożizzjonijiet differenti u skopijiet differenti ta' dawn ir-regolamenti;

"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-saħħa umana jew l-ambjent;

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

Fil-kuntest ta' din it-tifsira:

(a) modifikazzjoni ġenetika isseħħ ta' l-inqas meta jintużaw it-tekniki msemmija fi Skeda I, Parti A;

(b) tekniki msemmija fi Skeda I, Parti B, ma jiġux ikkunsidrati li jirriżultaw f'modifikazzjoni ġenetika;

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

"notifika" tfisser meta l-informazzjoni meħtieġa tiġi ippreżentata mill-Awtorità Kompetenti;

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

"użu kontentut" tfisser kull attività li fiha mikro-organiżmi jiġu modifikati ġenetikament jew li fiha dawk il-GMM jiġu kultivati, maħżuna, trasportati, meqruda, isir minnhom jew jiġu użati b'kull mod ieħor, u li dwar dawk 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.

ASSESSJAR: PARTI II

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 stabbilità fi Skeda III, sezzjonijiet A u B.

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

Klassi 1: attivitajiet ta' ebda riskju jew ta' riskju negliġibbli, 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 strinġenti.

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

(5) L-utent għandu jżomm *record* ta' l-assessjar imsemmi fis-subregolament (1) ta' dan ir-regolament 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, ħlief meta l-paragrafu 2 ta' Skeda IV jippermetti li jkunu applikati miżuri oħra, il-prinċipji ġenerali

u l-konteniment adatt u miżuri protettivi oħra stipulati fi Skeda 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) ta' dan ir-regolament u l-konteniment u l-miżuri protettivi l-oħra applikati għandhom jiġu riveduti perjodikament, 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.

Eżenzjonijiet.

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

(a) meta modifikazzjoni ġenetika tirriżulta mill-użu ta' tekniki jew metodi msemmija fi Skeda II, Parti A, jew

(b) għal kull użu kontenut li jinvolvi biss tipi ta' GMM li jkunu konformi mal-kriterji elenkati fi Skeda II, Parti B li jistabbilixxu s-sigurtà tagħhom għas-saħħa umana u l-ambjent. Dawn it-tipi ta' GMM jinsabu elenkati fi Skeda II, Parti C.

(2) Ir-regolament 4 (2), 4(5), 4(6), 4 (7) u 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 ta' l-2002 dwar Tluq Deliberat ta' Organiżmi Modifikati Ġenetikament fl-Ambjent, jew konformement ma' leġislazzjoni relevanti 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-kundizzjonijiet, jekk tkun il-każ, għall-kunsens għat-tqegħid fis-suq.

A.L. 170 ta' l-2002.

PERMESSI U PENALI: PARTI III:

Post użat għall-ewwel darba.

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 fi Skeda V, Parti A.

7. (1) Meta xi użu kontenut ta' Klassi 1 ikun ser isiru għall-ewwel darba jew sussegwentement f'post notifikat skond ir-regolament 6, notifika li jkun fiha l-informazzjoni msemmija fi Skeda V, Parti B (minbarra s-sommarju ta' l-assessjar msemmi f'regolament 4 (1)), għandha tiġi ppreżentata lill-Awtorità Kompetenti. L-użu kontenut fi Klassi 1 jista' jkompli jsir minnufih wara li ssir in-notifika. Użu Kontenut ta' Klassi 1.

(2) L-utenti ta' GMM f'Użu Kontenut ta' Klassi 1 ikunu meħtieġa li jżommu *record* ta' kull assessjar kif imsemmi fis-subregolament 4 (5), li għandu jkun disponibbli għall-Awtorità Kompetenti meta jiġi hekk mitlub.

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 tigi ppreżentata notifika li jkun fiha l-informazzjoni msemmija fi Skeda V, Parti B, għandha tiġi ippreżentata lill-Awtorità Kompetenti. Użu Kontenut ta' Klassi 2.

(2) Jekk il-post kien soġġett għal notifika preċedenti biex jitwettaq xi użu kontenut ta' Klassi 2 jew ta' klassi ogħla u kull kunsens assoċjat meħtieġ ikun ġie sodisfatti, 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 izjed minn 45 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 ogħla, l-użu kontenut ta' Klassi 2 jista', fin-nuqqas ta' xi indikazzjoni kuntrarja mill-Awtorità Kompetenti, ikompli wara 45 jum minn meta tiġi ppreżentata n-notifika msemmija fis-subregolament (1), jew qabel bi qbil ma' l-Awtorità Kompetenti.

9. (1) Dwar l-ewwel użu kontenut ta' Klassi 3 u Klassi 4 u dawk li sussegwentement ikunu se jitwettqu f'post notifikat skond ir-regolament 6, notifika li jkun fiha l-informazzjoni msemmija fi Skeda V, Parti C, għandha tiġi ppreżentata lill-Awtorità Kompetenti. Użu Kontenut ta' Klassi 3 u Klassi 4.

(2) Użu kontenut ta' Klassi 3 jew ta' klassi ogħla 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 45 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 oġħla u meta xi ħtieġa ta' kunsens assoċjat tkun ġiet sodisfatta, għall-istess klassi jew għal klassi oġħla mill-użu kontenut li bih ikun hemm ħsieb li jitkompla;

(b) mhux aktar tard minn 90 jum minn meta tkun ġiet ippreżentata n-notifika, fil-każijiet l-oħra.

Notifiki lill-Awtorità Kompetenti.

10. (1) Il-persuna li tippreżenta notifika jew li titlob permess għal attivitajiet imsemmija fir-regolamenti 6, 7, 8 u 9, hawn aktar 'l isfel imsejjaħ l-applikant, għandu jippreżenta t-talba tiegħu bil-miktub lill-Awtorità Kompetenti qabel ma jwettaq dik l-attività.

(2) Sabiex l-Awtorità Kompetenti tkun tista' tassessja notifika jew talba għal permess b'mod adegwat, għandu jkun hemm mehmuż ma' l-applikazzjoni d-dokumenti rilevanti u kull informazzjoni meħtieġa kif speċifikat u meħtieġ mill-Awtorità Kompetenti. L-applikant għandu jindika b'mod ċar jekk l-applikazzjoni tippreġudikax xi każ ta' infurzar, kawża jew kawżi oħra li jkunu jinsabu *sub-judice*.

(3) L-Awtorità Kompetenti għandha teżamina l-konformità tan-notifiki mal-ħtiġiet ta' dawn ir-regolamenti, l-eżattezza u l-kompletezza ta' l-informazzjoni mogħtija, il-korrettezza ta' l-assessjar msemmi f'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-immaniġġar 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-kundizzjonijiet 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 għall-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 qegħda twettaq inkjesta jew konsultazzjoni pubblika skond ir-regolament 15, m'għandux jittieħed in konsiderazzjoni.

(6) Meta l-Awtorità Kompetenti toħroġ permess, hija tista' timponi dawk 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 tlett xhur mid-data ta' pubblikazzjoni.

(10) L-Awtorità Kompetenti m'għandhiex toħroġ jew iġġedded permess jekk l-applikant involut ma jkunx issodisfa jew onora dawk il-kondizzjonijiet jew l-obligazzjonijiet li joriġinaw minn xi permess ieħor maħruġ mill-Awtorità Kompetenti taħt dawn ir-regolamenti u, jew kull regolamenti oħra 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 jinħolqu bl-użu kontenut, l-Awtorità Kompetenti tista' teħtieġ 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 jinħolqu 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 is-subregolament 4(2), ta' dak ir-regolament; u

(b) jippreżenta notifika emendata lill-Awtorità Kompetenti.

(3) Għall-fini tas-subregolament (2) id-dispożizzjonijiet 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 ħatja ta' reat taħt dawn ir-regolamenti jekk:

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

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

(ċ) hija taġixxi f'kontravenzjoni ta' xi dispożizzjoni ta' dawn ir-regolamenti; jew

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

(e) hija tikkonfoffa jew tipprova tikkonfoffa, tgħin jew tipprova tgħin, tħajjar jew tipprova tħajjar, tagħti parir jew tipprova tagħti parir, tqabbad jew tipprova tqabbad, lil xi persuna oħra sabiex din tikser id-dispożizzjonijiet ta' dawn ir-regolamenti jew jekk hija tonqos milli tikkonforma ruħha ma' dawk id-dispożizzjonijiet, inkluża kull ordni mogħtija leġittimament skond xi dispożizzjoni ta' dawn ir-regolamenti, jew biex tikser xi restrizzjoni, projbizzjoni jew rekwiżit imposti minn jew taħt ir-regolamenti msemmija jew bħala riżultat ta'dan.

Penali.

(2) Kull persuna li tagħmel jew tipprova tagħmel xi reat kontra dawn ir-regolamenti għandha, meta tinstab ħatja, teħel il-penali li ġejjin:

(a) meta tinsab ħatja għall-ewwel darba ta' reat taħt Klassi 1, multa ta' mhux inqas minn ħames mitt euro, iżda mhux iżjed minn elf euro; meta tinsab ħatja għat-tieni darba jew aktar għal reat taħt Klassi 1, multa ta' mhux inqas minn elf euro, iżda mhux

iżjed minn elfejn u ħames mitt euro jew għal priġunerija għal żmien mhux iżjed minn sentejn jew għal dik il-multa u priġunerija flimkien;

(b) meta tinsab ħatja għall-ewwel darba ta' reat taħt Klassi 2, multa ta' mhux inqas minn elf euro, iżda mhux aktar minn elfejn euro; meta tinsab ħatja għat-tieni darba jew aktar għal reat taħt Klassi 2, multa ta' mhux inqas elfejn euro, iżda mhux iżjed minn tlett elef u ħames mitt euro jew għal priġunerija għal żmien mhux iżjed minn sentejn jew għal dik il-multa u priġunerija flimkien;

(ċ) meta tinstab ħatja għall-ewwel darba ta' reat taħt Klassi 3, multa ta' mhux inqas minn elfejn u ħames mitt euro, iżda mhux iżjed minn sitt elef euro; meta tinsab ħatja għat-tieni darba jew aktar għal reat taħt Klassi 3, multa ta' mhux inqas minn erbat elef u ħames mitt euro, iżda mhux iżjed minn ħamsa u għoxrin elf euro jew għal priġunerija għal żmien ta' mhux iżjed minn sentejn jew għal dik il-multa u priġunerija flimkien;

(d) meta tinsab ħatja għall-ewwel darba ta' reat taħt Klassi 4, multa ta' mhux inqas minn tnax-il elf euro, iżda mhux iżjed minn ħamsa u għoxrin elf euro; meta tinsab ħatja għat-tieni darba jew aktar għal reat taħt Klassi 4, multa ta' mhux inqas ħamsa u għoxrin elf euro, iżda mhux aktar minn ħamsa u tletin elf euro jew għal priġunerija għal żmien ta' mhux iżjed minn sentejn jew għal dik il-multa u priġunerija flimkien:

Iżda l-Qorti għandha tordna lil persuna li tinsab ħatja li tkun għamlet reat kontra dawn ir-regolamenti, tħallas l-ispejjeż li l-Awtorità Kompetenti tkun għamlet b'riżultat ta' dak ir-reat, inkluża kull azzjoni li ssir bħala rimedju għal danni kaġunati b'dak ir-reat, ir-revoka tal-permess maħruġ mill-Awtorità Kompetenti u l-konfiska tal-*corpus delicti*, inklużi wkoll l-ispejjeż kollha mġarrba għaż-żamma u t-trasport ta' dak il-*corpus delicti*.

(3) Il-Qorti għandha tordna lill-ħati biex ineħħi il-kawżi tar-reat u li jreġġa lura kull ħaġa li tkun saret mingħajr permess fi żmien li jkun suffiċjenti għal dan il-għan skond ma' jiġi stabbilit mill-Qorti; u, jekk il-ħati jonqos milli jikkonforma ruħu ma ordni bħal dik fiż-żmien stipulat, għandu jeħel multa ta' mhux inqas minn sittin euro u mhux iżjed minn ħames mitt euro, skond mal-Qorti tista' tistabbilixxi, għal kull ġurnata li n-nuqqas ikompli wara li jiskadi t-terminu msemmi.

(4) Id-dispożizzjonijiet 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-

Applikabilità tal-Kodiċi Kriminali. Kap. 9.

iskwalifika milli persuna jkollha jew tikseb liċenza jew permess mill-Awtorità Kompetenti m'għandha f'ebda każ tkun ta' inqas minn sena.

(5) Minkejja d-dispożizzjonijiet 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-dispożizzjonijiet tal-Kodiċi Kriminali li jirregolaw il-proċedura quddiem dawk il-qrati bħala qrati ta' ġudikatura kriminali.

(6) Minkejja d-dispożizzjonijiet 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 ta' Kontroll.

13. L-Awtorità Kompetenti tista' torganizza spezzjonijiet u miżuri oħra ta' kontroll sabiex tiżgura li l-utent ikun jikkonforma ruħu ma' dawn ir-regolamenti.

KONSULTAZZJONI PUBBLIKA U KUNFIDENZJALITÀ: PARTI IV

Kxif ta' *Data* Kunfidenzjali.

14. (1) Meta l-kxif ta' *data* li jkollha x'taqsam ma' dawn ir-regolamenti tkun taffetwa lil xi waħda 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,

(ċ) fatti li huma, jew li kienu, *sub-judice*, jew taħt inkjesta (inkluż inkjesti dixxiplinari), jew li jiffurmaw is-suġġett għal proċedimenti ta' investigazzjoni preliminari,

(d) kunfidenzjalità kummerċjali u industrijali, inkluża l-proprjetà intellettwali,

(e) il-kunfidenzjalità ta' *data* personali u, jew inkartamenti;

(f) materjal fornut minn terzi mingħajr ma dik il-parti tkun taħt obbligu legali li tagħmel 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 ippreżentati

f'konformità ma' dawn ir-regolamenti li għandhom jiġu trattati b'mod kunfidenzjali:

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

(2) L-Awtorità Kompetenti għandha tiddeċiedi, wara konsultazzjoni man-notifikant, liema informazzjoni għandha tinżamm bħala waħda kunfidenzjali u għandha tinforma lin-notifikant bid-deċiżjoni tagħha.

(3) F'ebda każ m'għandha l-informazzjoni li ġejja, tinżamm kunfidenzjali meta din tkun ġiet ippreżentata 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,

(ċ) 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'għanda 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 intellettwali 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.

Konsultazzjoni pubblika.

15. Minħajr 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.

INĊIDENTI U PJANIJIET TA' EMERĠENZA: PARTI V

Pjanijiet ta' Emerġenza.

16. (1) L-Awtorità Kompetenti għandha tiżgura li qabel ma jibda użu kontenut:

(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, ħlief meta dak il-pjan ta' emerġenza jkun diġà ġie mfassal taħt leġislazzjoni rilevanti oħra;

(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 disponnibli għall-pubbliku.

(2) Fl-istess ħin, l-Awtorità Kompetenti għandha tara li informazzjoni bħal dik li tkun tqassmet liċ-ċittadini tagħha għandha tkun disponibbli għal Stati Membri oħra involuti.

Okkorrenza ta' Inċidenti.

17. (1) F'każ ta' inċident, l-utent ikun minnufih meħtieġ jinforma lill-Awtorità Kompetenti u li jipprovdilha din l-informazzjoni li ġejja:

(a) iċ-ċirkustanzi ta' l-inċident,

(b) l-identità u l-kwantitajiet ta' kull GMM involut,

(ċ) kull informazzjoni meħtieġa biex jiġu valutati l-effetti ta' l-inċident fuq is-saħħa tal-popolazzjoni in ġenerali u ta' l-ambjent,

(d) il-miżuri li jkunu ttieħdu.

(2) L-utent għandu jinforma lill-Awtorità Kompetenti msemmija fir-Regolament ta' l-2003 dwar il-Protezzjoni tal-Ħaddiema 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 msemmija fis-subregolament (2), tkun meħtieġa:

(a) tiżgura li jittieħdu l-miżuri kollha meħtieġa, u minnufih tinforma lil Stati Membri oħra li jistgħu jkunu affettwati bl-inċident,

(b) tiġbor, meta dan ikun possibbli, l-informazzjoni meħtieġa għal analiżi sħiħ 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 msemmija fis-subregolament (2), tista' titlob lill-utent biex iħallas jew jikkontribwixxi għal xi jew kull spejjeż li joriġinaw minn dan l-inċident.

Komunikazzjoni ma' Stati Membri oħra.

18. L-Awtorità Kompetenti għandha tikkonsulta lil Stati Membri oħra, li x'aktarx li jiġu affettwati f'każ ta' inċident, fuq l-implimentazzjoni proposta tal-pjanijiet ta' emerġenza.

DRITTIJIET: PARTI VI

19. (1) Għandu jitħallas 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 taħt ir-regolament 6, skond id-drittijiet applikabbli mniżżla f'Parti A ta' Skeda VI, skond liema minnhom ikun japplika;

Dritt għal notifika għal użu kontenut individwali.

(b) notifika dwar użu kontenut individwali, mogħtija lill-Awtorità Kompetenti taħt ir-regolamenti 7, 8 u 9 skond id-drittijiet applikabbli mniżżla f'Parti B ta' Skeda VI, skond liema minnhom ikun japplika;

Dritt għal notifika emendata ta' użu kontenut.

(ċ) notifika emendata dwar użu kontenut, mogħtija lill-Awtorità Kompetenti taħt ir-regolament 11 skond id-drittijiet applikabbli mniżżla f'Parti Ċ ta' Skeda VI, skond liema minnhom ikun japplika;

Investigazzjonijiet.

(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.

Rkupru ta' spejjeż jew ħlasijiet.

(3) L-Awtorità Kompetenti tista' tirkupra l-ammont ta' kull ħlas lilha dovut minn xi ħtieġa taħt ir-regolament 17 (4).

DISPOŻIZZJONIJIET OĦRA: PARTI VII

L-iskeda I sa IV jinsabu pubblikati bil-lingwa Ingliza biss.

20. L-Iskedi I sa IV li jinsabu ma' dawn ir-regolamenti qegħdin jiġu pubblikati bil-lingwa Ingliża mat-test Ingliż ta' dawn ir-regolamenti.

Iħassar A.L. 169 ta' l-2002.

21. Ir-Regolamenti ta' l-2002 dwar l-Użu Kontenut ta' Mikro-Organiżmi Modifikati Ġenetikament, qegħdin b'dawn jiġu mħassra.

SCHEDULE 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.

SCHEDULE 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.

2. 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 Legal Notice 228 of 2003 on the protection of workers from risks related to exposure to biological agents at work.

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, 2003 (Legal Notice 228 of 2003).

SCHEDULE 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[(1)];
   (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 plants[(1)], or likely to cause deleterious effects in the environment;
   (iii) the GMM is unlikely to cause disease to humans, animals or plants[(1)] 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).

[1] This would only apply to animals and plants in the environment likely to be exposed

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).

SCHEDULE 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[1]	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[2]	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required except for [1]	Required
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	Required (HEPA)[4] – extract air except for [3]	Required (HEPA)[5] – input and extract air
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the Building	En suite[6]	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
12	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
18	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required

	Specifications	Containment levels			
		1	2	3	4
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

[1] Isolation = the laboratory is separated from other areas in the same building or is in a separated building.

[2] 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.

[3] Activities where transmission does nor occur via airborne route.

[4] HEPA = High efficiency particulate air.

[5] Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

[6] 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
Buildings					
1	Greenhouse: permanent structure [1]	Not required	Required	Required	Required
Equipment					
3	Entry via a separated room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise [2] run-off	Prevent run-off	Prevent run-off
System of work					
6	Measures to control undesired species such as insects, rodents, arthropods	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

[1] The glasshouse shall consist of a permanent structure with a continuous water proofed covering, located on a site graded to prevent entry of surface-water run-off having self-closing lockable doors.

[2] 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 [1]	Optional	Required	Required	Required
2	Animal facilities [2] 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 [3]	Not required	Optional	Required	Required

[1] 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.

[2] 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.

[3] 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, prevent 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, prevent 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 contamination	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
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

Specifications		Containment levels			
		1	2	3	4
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 handwashing sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GM Ms in contaminated material and waste including those in process eft1uent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

SCHEDULE 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).

SCHEDULE 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

L.N. 127 of 2008

ENVIRONMENT PROTECTION ACT (CAP. 435)

Contained Use of Genetically Modified Micro-organisms Regulations, 2008

BY virtue of the powers conferred by articles 9, 10(2) and 11 of the Environment Protection Act, hereinafter referred to as "the Act", the Prime Minister has made the following regulations:-

Citation.

1. The title of these regulations is the Contained Use of Genetically Modified Micro-organisms Regulations, 2008.

Objectives.

2. (1) The objective of these regulations is to lay down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment.

(2) These regulations provide the provisions required for the implementation in Malta of the European Council Directive 90/219/EEC of the 23rd of April 1990 on the contained use of genetically modified micro-organisms and shall be read and construed as one with such legal instrument.

(3) These regulations are to be read and construed with the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations, 2003, in relation to issues in connection with occupational health and safety. L.N. 228 of 2003.

PART I: DEFINITIONS AND EXEMPTIONS

Interpretation.

3. In these regulations, unless the context otherwise requires:

"accident" means any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;

"the Competent Authority" means the Malta Environment and Planning Authority as prescribed by the notice entitled Nomination of the Malta Environment and Planning Authority as the competent authority, and such other body or person as the Minister responsible for the environment may by order in the Gazette prescribe and different bodies or persons may be designated as the competent

authority for different provisions and different purposes of these regulations;

"contained use" means any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment;

"genetically modified micro-organism" or "GMM" means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and, or natural recombination.

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Schedule I, Part A;

(b) the techniques listed in Schedule I, Part B, are not considered to result in genetic modification;

"micro-organism" means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;

"the Minister" means the Minister responsible for the environment;

"notification" means the presentation of the requisite information to the Competent Authority;

"user" means any natural or legal person responsible for the contained use of GMMs.

PART II: ASSESSMENT

Assessment.

4. (1) In order to ensure that the contained use of GMMs does not produce adverse effects on human health and the environment the user shall carry out an assessment of the contained uses as regards the risks to human health and the environment that these contained uses may incur, using as a minimum the elements of assessment and the procedure set out in Schedule III, sections A and B.

(2) The assessment referred to in sub-regulation (1) shall result in the final classification of the contained uses in four classes applying the procedure set out in Schedule III, which will result in the assignment of containment levels in accordance with sub-regulations (6) and (7):

Class 1: activities of no or negligible risk, for which level 1 containment is appropriate.

Class 2: activities of low risk, for which level 2 containment is appropriate.

Class 3: activities of moderate risk, for which level 3 containment is appropriate.

Class 4: activities of high risk, for which level 4 containment is appropriate.

(3) Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless sufficient evidence, in agreement with the Competent Authority, justifies the application of less stringent measures.

(4) The assessment referred to in sub-regulation (1) hereof shall especially take into account the question of disposal of waste and effluents. Where appropriate, the necessary safety measures shall be implemented in order to protect human health and the environment.

(5) A record of the assessment referred to in sub-regulation (1) hereof shall be kept by the user and made available in an appropriate form to the Competent Authority as part of the notification pursuant to regulations 6, 8 and 9 or on request.

(6) The user shall apply, except to the extent that paragraph 2 of Schedule IV allows other measures to be applied, the general principles and the appropriate containment and other protective measures set out in Schedule IV corresponding to the class of the contained use, so as to keep workplace and environmental exposure to any GMMs to the lowest reasonably practicable level, and so that a high level of safety is ensured.

(7) The assessment referred to in sub-regulation (1) hereof and the containment and other protective measures applied shall be reviewed periodically, and forthwith if:

(a) the containment measures applied are no longer adequate or the class assigned to the contained uses is no longer correct, or

(b) there is reason to suspect that the assessment is no longer appropriately judged in the light of new scientific or technical knowledge.

Exemptions.

5. (1) Without prejudice to regulation 4 (1), these regulations shall not apply:

(a) where genetic modification is obtained through the use of the techniques or methods listed in Schedule II, Part A, or

(b) for contained uses involving only types of GMMs meeting the criteria listed in Schedule II, Part B which establish their safety to human health and the environment. These types of GMMs are listed in Schedule II, Part C.

(2) regulation 4(2), 4(5), 4(6), 4(7) and regulations 6 to 11 shall not apply to the transport of GMMs by road, sea or air.

(3) These regulations shall not apply to the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with the Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2002 or pursuant to other relevant legislation, which provides for a specific environmental risk assessment similar to that laid down in the said regulations, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

L.N. 170 of 2002.

PART III: PERMITTING AND PENALTIES

Premises used for the first time.

6. When premises are to be used for the first time for contained uses, the user shall be required to submit to the Competent Authority, before commencing such use, a notification containing at least the information listed in Schedule V, Part A.

Contained Use of Class 1.

7. (1) For the first time or subsequent Class 1 contained uses to be carried out in premises notified in accordance with regulation 6, a notification containing the information listed in Schedule V, Part B (excluding the summary of assessment referred to in regulation 4 (1)), shall be submitted to the Competent Authority. The Class 1 contained use may proceed immediately following notification.

(2) Users of GMMs in Class 1 Contained Use shall be required to keep a record of each assessment referred to in sub-regulation

4 (5), which shall be made available to the Competent Authority on request.

Contained Use of Class 2.

8. (1) For the first and subsequent class 2 contained uses to be carried out in premises notified in accordance with regulation 6, a notification containing the information listed in Schedule V, Part B shall be submitted to the Competent Authority.

(2) If the premises have been the subject of a previous notification to carry out class 2 or a higher class of contained uses and any associated consent requirements have been satisfied, the class 2 contained use may proceed immediately following the new notification:

Provided that the applicant can, however, himself request a decision on a formal authorisation from the Competent Authority. The decision must be made within a maximum of 45 days from the notification.

(3) If the premises have not been the subject of a previous notification to carry out class 2 or a higher class of contained uses, the class 2 contained use may, in the absence of any indication to the contrary from the Competent Authority, proceed 45 days after submission of the notification referred to in sub-regulation (1), or earlier with the agreement of the Competent Authority.

Contained Use of Class 3 and Class 4.

9. (1) For the first and subsequent class 3 or class 4 contained uses to be carried out in premises notified in accordance with regulation 6, a notification containing the information listed in Schedule V, Part C shall be submitted to the Competent Authority.

(2) A class 3 or higher class of contained use may not proceed without the prior consent of the Competent Authority which shall communicate its Decision in writing:

(a) at the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed;

(b) at the latest 90 days after submission of the notification, in other cases.

Notifications to the Competent Authority.

10. (1) The person submitting a notification or requesting a permit for activities referred to in regulations 6, 7, 8 and 9, hereinafter referred to as the applicant, shall submit his request in writing to the Competent Authority prior to carrying out such activities.

(2) In order to enable the Competent Authority to adequately assess a notification or a request for permission, the application shall be accompanied by the relevant documents and any other requisite information as specified and required by the Competent Authority. The applicant shall clearly indicate whether the application would prejudice any enforcement case, court case or other causes currently *sub-judice*.

(3) The Competent Authority shall examine the conformity of the notifications with the requirements of these regulations, the accuracy and completeness of the information given, the correctness of the assessment referred to in regulation 4 (1) and the class of contained uses and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures.

(4) If necessary, the Competent Authority may:

(a) ask the user to provide further information or to modify the conditions of the proposed contained use or to amend the class assigned to any contained use:

Provided that in this case the Competent Authority may require that the contained use, if proposed, does not begin, or, if in progress, is suspended or terminated, until the Competent Authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;

(b) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

(5) For the purpose of calculating the periods referred to in regulations 8 and 9, any period of time during which the Competent Authority:

(a) is awaiting any further information which it may have requested from the notifier in accordance with sub-regulation 4(a), or

(b) is carrying out a public inquiry or consultation in accordance with regulation 15, shall not be taken into account.

(6) Whenever the Competent Authority issues a permit, it may impose such conditions as it may deem fit and appropriate.

(7) Whenever the Competent Authority refuses such permit, it shall inform the applicant of the reasons for such refusal.

(8) The period of validity of such permit shall also be established at the discretion of the Competent Authority.

(9) The applicant shall provide a copy of any published results and other publications relevant to this permit to the Competent Authority within three months from the date of publication.

(10) The Competent Authority shall not issue or renew any permit if the applicant in question has not fulfilled or honoured any of the conditions or obligations arising from any other permit issued by the Competent Authority under these regulations and, or the related regulations.

New information on risks of contained use.

11. (1) (a) If new information subsequently becomes available to the Competent Authority which could have significant consequences for the risks posed by the contained use, the Competent Authority may require the user to modify the conditions of, or suspend or terminate, the contained use.

(b) Where a user becomes aware of new information or modifies the contained use in a way which could have significant consequences for the risks posed by it, the user shall discontinue the contained use and, as soon as practicable, inform the Competent Authority.

(2) Prior to resuming a contained use discontinued in accordance with sub-regulation (1), the user shall –

(a) review the assessment carried out in accordance with regulation 4, and the class and level of containment applied in accordance with sub-regulation 4(2) thereof; and

(b) submit an amended notification to the Competent Authority.

(3) For the purposes of sub-regulation (2) the provisions in relation to the submission of a notification by a user in accordance with regulations 6, 8 or 9, and to the processing and determination of such a notification by the Competent Authority in accordance with regulation

10, shall apply, as appropriate, to an amended notification as if it were a notification under regulations 6, 8 or 9.

Offences.

12. (1) Any person shall be guilty of an offence under these regulations if:

(a) he fails to comply with any provision of these regulations or fails to comply with permit conditions or with any order lawfully given in terms of any provision of these regulations; or

(b) he contravenes any restriction, prohibition or requirement imposed by or under these regulations; or

(c) he acts in contravention of any of the provisions of these regulations; or

(d) he makes a statement or presents information or documentation, which such person knows to be false for the purpose of obtaining the approval or continuation of a permit in line with regulations 6, 8, 9 or 11 2(b); or

(e) he conspires or attempts to conspire, aids or attempts to aid, abets or attempts to abet, counsel or attempt to counsel, procures or attempt to procure any other person to contravene the provisions of these regulations or to fail to comply with any such provisions, including any order lawfully given in terms of any of the provision of these regulations, or to contravene any restriction, prohibition or requirement imposed by or under the said regulations or by virtue thereof.

Penalties.

(2) Any person who commits, or attempts to commit an offence against these regulations shall, on conviction, be liable to the following range of penalties:

(a) on first conviction for an offence under Class 1 a fine (*multa*) of not less than five hundred euro but not exceeding one thousand euro; on a second or subsequent convictions for an offence under Class 1, a fine (*multa*) of not less than one thousand euro, but not exceeding two thousand five hundred euro or to imprisonment for a term not exceeding two years or to both such fine and imprisonment;

(b) on first conviction for an offence under Class 2 a fine (*multa*) of not less than one thousand euro but not exceeding two thousand euro; on a second or subsequent convictions for an offence under Class 2, a fine (*multa*) of not less than two thousand euro,

but not exceeding three thousand five hundred euro or to imprisonment for a term not exceeding two years or to both such fine and imprisonment;

(c) on first conviction for an offence under Class 3 a fine (*multa*) of not less than two thousand five hundred euro but not exceeding six thousand euro; on a second or subsequent convictions for an offence under Class 3, a fine (*multa*) of not less than four thousand five hundred euro, but not exceeding twenty-five thousand euro or to imprisonment for a term not exceeding two years or to both such fine and imprisonment;

(d) on first conviction for an offence under Class 4 a fine (*multa*) of not less than twelve thousand euro but not exceeding twenty-five thousand euro; on a second or subsequent convictions for an offence under Class 4, a fine (*multa*) of not less than twenty-five thousand euro, but not exceeding thirty-five thousand euro or to imprisonment for a term not exceeding two years or to both such fine and imprisonment:

Provided that the Court shall order any person who has been found guilty of committing an offence against these regulations to pay for the expenses incurred by the Competent Authority as a result of the said offence, including any remedying action for any damage caused by the said offence, the revocation of the permit issued by the Competent Authority and the confiscation of the *corpus delicti*, including any expenses incurred for the keeping and transport of the said *corpus delicti*.

(3) The Court shall order the offender to remove the causes of the offence and to undo anything which was done without a permit within a time sufficient for the purpose to be fixed by the Court; and, if the offender fails to comply with any such order within the time so fixed, he shall be liable to a fine (*multa*) of not less than sixty euro and not more than five hundred euro, as the Court may fix, for every day that the default continues after the expiration of the said time.

Applicability of the Criminal Code. Cap. 9.

(4) The provisions of articles 23 and 30 of the Criminal Code shall apply, *mutatis mutandis*, to proceedings in respect of offences against these regulations, so however that the disqualification from holding or obtaining a licence or permit from the Competent Authority shall in no case be for less than one year.

(5) Notwithstanding the provisions of Article 370 of the Criminal Code, proceedings for an offence against these regulations shall be held before the Court of Magistrates (Malta) or the Court of

Magistrates (Gozo), as the case may be, and shall be in accordance with the provisions of the Criminal Code regulating the procedure before the said courts as courts of criminal judicature.

(6) Notwithstanding the provisions of the Criminal Code, the Attorney General shall always have a right of appeal to the Court of Criminal Appeal from any judgement given by the Court of Magistrates (Malta) or the Court of Magistrates (Gozo) in respect of proceedings for any offence against these regulations.

Inspections and Control Measures.

13. The Competent Authority may organise inspections and other control measures to ensure user compliance with these regulations.

PART IV: PUBLIC CONSULTATION AND CONFIDENTIALITY

Disclosure of Confidential Data.

14. (1) Where disclosure of data related to these regulations, affects one or more of the following:

(a) the confidentiality of the proceedings of public authorities, international relations and national defence,

(b) public security,

(c) matters which are, or have been, *sub-judice*, or under enquiry (including disciplinary enquiries), or which are the subject of preliminary investigation proceedings,

(d) commercial and industrial confidentiality, including intellectual property,

(e) the confidentiality of personal data and/or files,

(f) material supplied by a third party without that party being under a legal obligation to do so,

(g) material, the disclosure of which would make it more likely that the environment to which such material is related would be damaged, the notifier may indicate the information in the notifications submitted pursuant to these regulations that should be treated as confidential:

Provided that a verifiable justification must be given in such cases.

(2) The Competent Authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.

(3) In no case may the following information, when submitted according to regulations 6, 8 or 9, be kept confidential:

(a) the general characteristics of the GMMs, name and address of the notifier, and location of use,

(b) class of contained use and measures of containment,

(c) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

(4) The Competent Authority shall not divulge to third parties any information decided to be confidential according to sub-regulation (2) and notified or otherwise provided pursuant to these regulations, and shall protect intellectual property rights relating to the data received.

(5) If, for whatever reasons, the notifier withdraws the notification, the Competent Authority must respect the confidentiality of the information supplied.

Public consultation.

15. Without prejudice to regulation 14, the Competent Authority may hold public consultations on aspects of the proposed contained use where it considers to be appropriate.

PART V: ACCIDENTS AND EMERGENCY PLANS

Emergency Plans.

16. (1) The Competent Authority shall ensure that before a contained use commences:

(a) an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and, or to the environment, except where such an emergency plan has been drawn up under other relevant legislation;

(b) information on such emergency plans, including the relevant safetymeasures to be applied, is supplied in an appropriate

manner, and without them having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.

(2) The Competent Authority shall at the same time make available to other Member States concerned, the same information as that which is disseminated to their nationals.

Occurrences of Accidents.

17. (1) In the event of an accident, the user shall be required to inform immediately the Competent Authority and provide the following information:

(a) the circumstances of the accident,

(b) the identity and quantities of the GMMs concerned,

(c) any information necessary to assess the effects of the accident on the health of the general population and the environment,

(d) the measures taken.

(2) The user shall also inform the Competent Authority cited in the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations, 2003, of such accident.

(3) Where information is given pursuant to sub-regulation (1), the Competent Authority, in collaboration with the Competent Authority cited in sub-regulation (2), shall be required to:

(a) ensure that any measures necessary are taken, and immediately alert other Member States which could be affected by the accident,

(b) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit the effects thereof.

(4) In the event of an accident, the Competent Authority in collaboration with the Competent Authority cited in sub-regulation (2), may require the user to defray or contribute towards any or all of the costs incurred by it arising from such accident.

Communication with other Member States.

18. The Competent Authority shall consult with other Member States, likely to be affected in the event of an accident, on the proposed implementation of emergency plans.

PART VI: FEES

19. (1) A fee shall be paid to the Competent Authority in respect of:

Fee for notification of first time use of a premises.

(a) a notification of a first time use of a premises given to the Competent Authority under regulation 6, in accordance with the applicable fees indicated in Part A of Schedule VI, whichever is appropriate;

Fee for notification of any individual contained use.

(b) a notification of an individual contained use given to the Competent Authority under regulations 7, 8 and 9, in accordance with the applicable fees indicated in Part B of Schedule VI, whichever is appropriate;

Fee for an amended notification of a contained use.

(c) An amended notification of a contained use given to the Competent Authority under regulation 11, in accordance with the applicable fees indicated in Part C of Schedule VI, whichever is appropriate;

Agency investigations.

(2) The Competent Authority may carry out, or arrange to have carried out, such additional investigations as it considers necessary, as part of its examination or monitoring of a notification of a contained use to enable it properly to assess the notification and may require the user to defray or contribute towards the cost of any such investigations.

Recovery of costs or charges.

(3) The Competent Authority may recover the amount of any payment due to it arising from a requirement under regulation 17 (4).

PART VII: OTHER PROVISIONS

Schedules I to IV published in English only.

20. The Schedules I to IV to these regulations are being published in the English language with the English text of these regulations.

Repeal of L.N. 169 of 2002.

21. The Contained use of genetically modified micro-organisms Regulations, 2002, is hereby repealed.

SCHEDULE 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.

SCHEDULE 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.

2. 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 Legal Notice 228 of 2003 on the protection of workers from risks related to exposure to biological agents at work.

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, 2003 (Legal Notice 228 of 2003).

SCHEDULE 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[(1)];
   (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 plants[(1)], or likely to cause deleterious effects in the environment;
   (iii) the GMM is unlikely to cause disease to humans, animals or plants[(1)] 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).

[1] This would only apply to animals and plants in the environment likely to be exposed

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).

SCHEDULE 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[1]	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[2]	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required except for [1]	Required
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	Required (HEPA)[4] – extract air except for [3]	Required (HEPA)[5] – input and extract air
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the Building	En suite[6]	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
12	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
18	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required

	Specifications	Containment levels			
		1	2	3	4
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

[1] Isolation = the laboratory is separated from other areas in the same building or is in a separated building.

[2] 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.

[3] Activities where transmission does nor occur via airborne route.

[4] HEPA = High efficiency particulate air.

[5] Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

[6] 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
Buildings					
1	Greenhouse: permanent structure [1]	Not required	Required	Required	Required
Equipment					
3	Entry via a separated room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise [2] run-off	Prevent run-off	Prevent run-off
System of work					
6	Measures to control undesired species such as insects, rodents, arthropods	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

[1] The glasshouse shall consist of a permanent structure with a continuous water proofed covering, located on a site graded to prevent entry of surface-water run-off having self-closing lockable doors.

[2] 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 [1]	Optional	Required	Required	Required
2	Animal facilities [2] 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 [3]	Not required	Optional	Required	Required

[1] 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.

[2] 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.

[3] 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, prevent 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, prevent 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 contamination	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
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

Specifications		Containment levels			
		1	2	3	4
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 handwashing sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GM Ms in contaminated material and waste including those in process eft1uent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

SCHEDULE 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).

SCHEDULE 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

Ippubblikat mid-Dipartiment ta' l-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugh fl-Istamperija tal-Gvern — *Printed at the Government Printing Press*

Prezz/*Price*
€2.98 (Lm1.28)