A.L. 485 tal-2010

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

Regolamenti tal-2010 dwar Rilaxx Deliberat ta' Organiżmi Modifikati Ġenetikament fl-Ambjent

BIS-SAĦĦA tas-setgħat mogħtija bl-artikoli 9, 10, 11 u 23 ta' l-Att dwar il-Ħarsien ta' l-Ambjent, il-Prim Ministru għamel dawn ir-regolamenti li ġejjin:-

Titolu.

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2010 dwar Rilaxx Deliberat ta' Organiżmi Modifikati Ġenetikament fl-Ambjent.

Għanijiet.

(2) Skond il-prinċipju ta' prekawzjoni, l-għan ta' dawn ir-regolamenti huwa li dawn jipprovdu għall-protezzjoni tas-saħħa tal-bniedem u l-ambjent meta:

(a) ikun qed isir rilaxx intenzjonat fl-ambjent ta' organiżmi ġenetikament modifikati għal xi skopijiet oħra għajr it-tqegħid fis-suq f'Malta,

(b) ikunu qed jitqegħdu fis-suq organiżmi modifikati ġenetikament bħala prodott jew fi prodotti f'Malta,

(3) Dawn ir-regolamenti jipprovdu il-provvedimenti meħtieġa għall-implimentazzjoni f'Malta tad-Direttiva tal-Kunsill Ewropew 2001/18/KE tat-12 ta' Marzu 2001 dwar ir-rilaxx intenzjonat fl-ambjent ta' organiżmi modifikati ġenetikament u tirrevoka d-Direttiva 90/220/KEE u għandhom jinqraw u jiftiehmu bħala ħaġa waħda ma' dak l-instrument legali.

PARTI A :

DISPOŻIZZJONIJIET ĠENERALI

Tifsir.

2. F'dan l-Att, sakemm ir-rabta tal-kliem ma teħtieġx xort'oħra –

"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 kull korp ieħor jew persuna li l-Ministru responsabbli għall-ambjent jista' b'ordni fil-Gazzetta jinnomina u korpi jew persuni differenti jistgħu jiġu nominati bħala l-awtorità kompetenti għal dispożizzjonijiet differenti u għanijiet differenti ta' dawn ir-regolamenti;

"id-Direttiva" tfisser Direttiva 2001/18/KE tal-Parlament Ewropew u tal-Kunsill tat-12 ta' Marzu 2001 dwar ir-rilaxx intenzjonat fl-ambjent ta' organiżmi ġenetikament modifikati u li tħassar id-Direttiva tal-Kunsill 90/220/KEE;

"evalwazzjoni ta' riskju ambjentali" tfisser l-evalwazzjoni ta' riskji għas-saħħa tal-bniedem u l-ambjent, kemm dirett kif ukoll indirett, immedjat jew imdewwem, li jista' jimponi r-rilaxx intenzjonat jew it-tqegħid fis-suq ta' GMOs u li jsiru skond Skeda II;

"il-Kummisjoni" tfisser il-Kummisjoni Ewropeja;

"notifika" tfisser il-preżentazzjoni, bil-miktub jew fil-format diġitali, ta' l-informazzjoni meħtieġa taħt dawn ir-regolamenti, lill-awtorità kompetenti;

"notifikant" tfisser kull persuna ġuridika jew fiżika li tippreżenta notifika, jew meta r-rabta tal-kliem hekk teħtieġ, kull persuna ġuridika jew fiżika risponsabbli għal rilaxx intenzjonat jew tqegħid fis-suq, jew biex jintlaħaq kull rekwiżit ieħor ta' dawn ir-regolamenti fir-rigward ta' rilaxx deliberat jew tqegħid fis-suq;

"organiżmu" tfisser kull entità bijoloġika li kapaċi tirreplika ruħha jew li tittrasferixxi materjal ġenetiku;

"organiżmu ġenetikament modifikat (GMO)" tfisser organiżmu, bl-eċċezzjoni tal-bnedmin, li fihom il-materjal ġenetiku ġie mibdul b'mod illi ma jseħħx b'mod naturali bit-tgħammir jew rikombinazzjoni naturali, u għall-iskop ta' dawn ir-regolamenti:

(a) modifika ġenetika sseħħ mill-inqas bl-użu tat-tekniki elenkati fi Skeda I A, Parti 1;

(b) it-tekniki elenkati fi Skeda I A, Parti 2, m'humiex kunsidrati li jirriżultaw f'modifika ġenetika;

"prodott" tfisser preparazzjoni li tikkonsisti, jew li jkun fiha, GMO jew tagħqid ta' GMOs, li jitqiegħed fis-suq;

"rilaxx intenzjonat" tfisser kull introduzzjoni intenzjonata fl-ambjent ta' GMO jew tagħqid ta' GMOs li għalihom ma jintużawx miżuri ta' ħażna biex jillimitaw il-kuntatt tagħhom ma', u jipprovdi livell għoli ta' sigurtà, għall-popolazzjoni in ġenerali u l-ambjent;

"Stat Membru" tfisser Stat li hu membru tal-Komunità Ewropea;

"tqegħid fis-suq" tfisser li tagħmel disponibbli għal terzi persuni, kemm jekk bi ħlas kemm jekk bla ħlas; l-operazjonijiet li ġejjin ma għandhomx jitqiesu bħala tqegħid fis-suq:

(a) li tagħmel disponibbli mikro-organiżmi ġenetikament modifikati għal attivitajiet regolati skond ir-Regolamenti ta' l-2008 dwar l-Użu Kontenut ta' Mikro-Organiżmi Modifikati Ġenetikament inklużi kollezzjonijiet ta' kultura; A.L. 127 ta' l-2008.

(b) li tagħmel disponibbli GMOs minbarra l-mikro-organiżmi msemmija fil-paragrafu (a), biex jiġu użati esklussivament għal attivitajiet fejn jintużaw miżuri xierqa u stretti ta' ħażna biex jillimitaw il-kuntatt tagħhom ma', u jipprovdu livell għoli ta' sigurtà għall-popolazzjoni ġenerali u l-ambjent, il-miżuri għandhom jkunu bażati fuq l-istess prinċipji ta' ħażna kif stabbilit fir-Regolamenti ta' l-2008 dwar l-Użu Kontenut ta' Mikro-Organiżmi Modifikati Ġenetikament;

(ċ) li tagħmel disponibbli GMOs biex jiġu użati esklussivament għal rilaxx intenzjonat u li jikkonformaw mal-ħtiġijiet stabbiliti fil-Parti B ta' dawn ir-regolamenti.

3. (1) Dawn ir-regolamenti ma japplikawx għal organiżmi miksuba permezz tat-teknika ta' modifika ġenetika elenkati fi Skeda I B. Eżenzjonijiet.

(2) Dawn ir-regolamenti ma għandhomx japplikaw għall-ġarr ta' organiżmi ġenetikament modifikati bit-triq, bil-baħar jew bl-ajru.

Obbligi ġenerali.

4. (1) GMOs jistgħu jiġu rilaxxati jew jitqegħdu fis-suq intenzjonalment biss b'konformità mal-Parti B jew mal-Parti Ċ ta' dawn ir-regolamenti rispettivament.

(2) Kull persuna għandha, qabel ma tippreżenta notifika skond Parti B jew Parti Ċ, tagħmel evalwazzjoni ta' riskju ambjentali. L-informazzjoni li tista' tkun neċessarja biex tagħmel evalwazzjoni ta' riskju ambjentali hija stabbilita fi Skeda III.

Dawk il-GMOs li jkun fihom ġeni li għandhom reżistenza għall-antibijotiċi bl-użu għat-trattament mediku jew veterinarju, għandhom jittieħdu f'kunsiderazzjoni meta ssir evalwazzjoni ta' riskju ambjentali, bil-ħsieb li jiġu identifikati u jitneħħew b'mod gradwali dawk l-indikaturi ta' reżistenza antibijotika fil-GMOs li jista' jkollhom effetti ħżiena fuq is-saħħa u l-ambjent. Din l-eliminazzjoni kellha issir sal-31 ta' Diċembru 2004 fil-każ ta' GMOs li tqegħdu fis-suq skond il-Parti Ċ u sal-31 ta' Diċembru 2008 fil-każ ta' GMOs awtorizzati skond Parti B.

(3) L-effetti negattivi potenzjali fuq is-saħħa tal-bniedem u l-ambjent, li jistgħu jseħħu direttament jew indirettament permezz ta' trasferiment ta' ġeni minn GMOs għall-organiżmi oħra, għandhom jiġu stmati akkuratament fuq bażi ta' każ b'każ. Din l-evalwazzjoni għandha ssir skond Skeda II u tieħu kont ta' l-impatt ambjentali skond in-natura ta' l-organiżmu introdott u l-ambjent li jirċevieh.

(4) L-awtorità kompetenti jew awtoritajiet responsabbli għal konformità tar-rekwiżiti ta' dawn ir-regolamenti għandhom jeżaminaw in-notifikazzjonijiet skond Parti B u Parti Ċ għal konformità mar-rekwiżiti ta' dawn ir-regolamenti u jekk l-evalwazzjoni li hemm provdut dwarha fis-subregolament (2) tkunx waħda adatta.

(5) L-awtorità kompetenti għandha torganizza spezzjonijiet u miżuri oħra ta' kontroll kif adatt, biex tiżgura konformità ma' dawn ir-regolamenti. Fil-każ ta' rilaxx ta' xi GMO jew tat-tqegħid fis-suq bħala prodott jew fi prodotti li għalihom ma ngħatatx awtorizzazjoni, l-awtorità kompetenti għandha tiżgura li l-miżuri neċessarji huma meħuda biex jintemm ir-rilaxx jew tqegħid fis-suq, biex tibda azzjoni ta' rimedju, jekk neċessarju, u

biex jiġi mgħarraf il-pubbliku, il-Kummissjoni u Stati Membri oħra.

PARTI B:

RILAXX INTENZJONAT TA' GMOs GĦAL KULL SKOP IEĦOR ĦLIEF BIEX JITQEGĦDU FIS-SUQ

Kif japplikaw ir-regolamenti 6 sa 10.

5. (1) Ir-regolamenti 6 sa 10 m'għandhomx japplikaw għal sustanzi u komposti mediċinali għall-użu tal-bniedem li jikkonsistu, jew ikun fihom, xi GMO jew tagħqid ta' GMOs sakemm ir-rilaxx intenzjonat tagħhom għal skop ieħor ħlief dak li jitqiegħdu fis-suq hu awtorizzat mir-Regolamenti ta' l-2007 dwar l-Awtorizzazzjoni għat-Tqegħid fis-Suq ta' Mediċini, u d-Direttiva 2001/83/KE tal-Parlament Ewropew u tal-Kunsill tas-6 ta' Novembru, 2001 dwar il-Kodiċi tal-Komunità rigward il-prodotti mediċinali għall-użu mill-bniedem, li tipprovdi:

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(a) għal evalwazzjoni ta' riskju speċifiku ambjentali skond Skeda II u fuq il-bażi tat-tip ta' informazzjoni speċifikati fi Skeda III mingħajr preġudizzju għal rekwiżiti addizzjonali li hemm provdut dwarhom b'dawk il-liġijiet;

(b) għal kunsens espliċitu qabel ir-rilaxx;

(ċ) għal pjan ta' sorveljar skond il-partijiet rilevanti ta' Skeda III, bil-ħsieb li tikxef l-effetti ta' GMO jew GMOs fuq is-saħħa tal-bniedem jew l-ambjent;

(d) f'manjiera adatta għal rekwiżiti dwar trattament ta' oġġetti ġodda ta' informazzjoni, informazzjoni lill-pubbliku, informazzjoni dwar ir-riżultati ta' rilaxxi, u skambji ta' informazzjoni għall-inqas ekwivalenti għal dawk li jinsabu f'dawn ir-regolamenti u fil-miżuri li ttieħdu skond dan.

(2) Evalwazzjoni ta' riskji għal ambjent preżentati minn dawn is-sustanzi u l-komposti għandhom jitwettqu b'mod konformi mad-dispożizzjonijiet ta' l-Artikolu 5 tad-Direttiva.

Proċedura ta' awtorizzazzjoni *standard*.

6. (1) Mingħajr preġudizzju għall-artikolu 5, kull persuna għandha, qabel ma tirrilaxxja b'mod intenzjonat GMO jew tagħqid ta' GMOs, tippreżenta notifika lill-awtorità kompetenti.

(2) In-notifika msemmija fis-subregolament (1) għandha tinkludi:

(a) *dossier* tekniku li jagħti l-informazzjoni speċifikata fi Skeda III li tkun meħtieġa biex issir l-evalwazzjoni ta' riskju ambjentali ta' rilaxx intenzjonat ta' GMO jew tagħqid ta' GMOs, b'mod partikolari:

(i) informazzjoni ġenerali inkluża informazzjoni fuq impjegati u taħriġ,

(ii) informazzjoni dwar kull GMO,

(iii) informazzjoni dwar il-kondizzjonijiet ta' rilaxx u l-ambjent potenzjali li qiegħed jirċievi,

(iv) informazzjoni dwar interazzjonijiet bejn kull GMO u l-ambjent,

(v) pjan għas-sorveljar skond il-partijiet rilevanti ta' Skeda III biex jiġu identifikati l-effetti ta' kull GMO fuq is-saħħa tal-bniedem jew fuq l-ambjent,

(vi) informazzjoni fuq kontroll, metodi ta' rimedji, trattament ta' skart u pjanijiet ta' rispons ta' emerġenza,

(vii) sommarju tad-*dossier* fil-format stabbilit skond il-proċedura stabbilita f'Artikolu 30(2) tad-Direttiva;

(b) evalwazzjoni ta' riskju ambjentali u l-konklużjonijiet meħtieġa fi Skeda II, taqsima D, flimkien ma' riferenza bibljografika u indikazzjonijiet tal-metodi użati.

(3) In-notifikant jista' jirreferi għal data jew riżultati minn notifiki li ġew mogħtija qabel minn notifikanti oħra, sakemm l-informazzjoni, *data* u riżultati mhumiex kunfidenzjali jew dawn in-notifikanti jkunu taw il-kunsens tagħhom bil-miktub, jew jistgħu jippreżentaw informazzjoni addizzjonali li titqies bħala rilevanti.

(4) L-awtorità kompetenti tista' taċċetta li rilaxx ta' l-istess GMO jew tagħqid ta' GMOs fuq l-istess sit jew fuq siti differenti għall-istess skop u f'perijodu definit jistgħu jiġu notifikati b'notifika waħda.

(5) Mal-wasla tan-notifika skond artikolu 6(1), l-awtorità kompetenti, għandha:

(a) tikkonferma bil-miktub lin-notifikant bid-data ta' meta tkun saret in-notifika;

(b) tibghat lill-Kummissjoni, fi żmien 30 ġurnata minn meta tasal in-notifika, kopja tas-sommarju tan-notifika riċevuta skond is-subartikolu 2(a)(vii);

(ċ) teżamina jekk in-notifika tkun saret skond dawn ir-regolamenti;

(d) tikkunsidra kull osservazzjoni li tkun waslet għand awtorità kompetenti ta' Stat Membru ieħor skond Artikolu 11(2) tad-Direttiva;

(e) jekk tkun intalbet minn awtorità kompetenti ta' Membru Stat ieħor għall-finijiet tad-Direttiva, tibgħat kopja sħiħa ta' notifika lill-Awtorità imsemmija;

(f) tevalwa r-riskji imposti mill-proposta tar-rilaxx intenzjonat fuq is-saħħa tal-bniedem u l-ambjent; u

(ġ) tnizzel il-konklużjonijiet bil-miktub.

(6) L-awtorità kompetenti għandha twieġeb bil-miktub lin-notifikant fi żmien 90 ġurnata mill-wasla tan-notifika billi tindika li l-kunsens għar-rilaxx intenzjonat huwa -

(a) mogħti, bil-kundizzjonijiet jew mingħajrhom, jew

(b) rifjutat u r-raġunijiet għar-rifjut.

(7) Għall-iskop ta' kalkolu tal-perjodu ta' disgħin ġurnata msemmija fis-subregolament (5), ma għandux jittieħed in kunsiderazzjoni l-perjodu ta' żmien li matulu l-awtorità kompetenti:

(a) tkun qegħda tistenna aktar informazzjoni li tista' tkun talbet mingħand in-notifikant, jew

(b) tkun qegħda tiżvolġi inkjesta jew konsultazzjoni pubblika skond ir-regolament 9; din l-inkjesta pubblika jew konsultazzjoni ma għandhiex ittawwal il-perjodu ta' disgħin ġurnata msemmi fis-subregolament (5), b'iżjed minn tletin ġurnata.

(8) Jekk l-awtorità kompetenti titlob informazzjoni ġdida, hija għandha simultanjament tagħti r-raġunijiet tagħha għaliex tkun għamlet hekk.

(9) In-notifikant jista' jipproċedi bir-rilaxx biss meta jkun irċieva l-kunsens bil-miktub ta' l-awtorità kompetenti, u konformi ma' kull kondizzjoni meħtieġa f'dan il-kunsens.

(10) Ebda materjal li ġej minn GMOs li huma deliberatament rilaxxati skond il-Parti B ma għandhom jitqegħdu fis-suq, sakemm dan ma jsirx skond il-Parti Ċ.

Proċeduri differenzjati.

7. (1) F'każ illi tkun inkisbet esperjenza suffiċjenti minn rilaxxi ta' ċerti GMOs f'ċerti ekosistemi u l-GMOs konċernati jkunu jissodisfaw il-kriterji stabbiliti fi Skeda V, l-awtorità kompetenti tista', skond il-proċedura stabbilita fl-artikolu 7 tad-Direttiva, tapplika proċeduri differenti għal dawn it-tipi ta' GMOs.

(2) In-notifikant jista' jipproċedi bir-rilaxx biss meta jkun irċieva il-kunsens bil-miktub ta' l-awtorità kompetenti u skond l-inqas ammont stabbilit fi Skeda III ta' informazzjoni teknika neċessarja biex jiġu evalwati r-riskji previst ikollha mir-rilaxx, b'mod partikolari:

(a) informazjoni dwar kull GMO;

(b) informazzjoni dwar il-kondizzjonijiet ta' rilaxx u l-ambjent potenzjali li qiegħed jirċievi;

(ċ) informazzjoni dwar interazzjonijiet bejn kull GMO u l-ambjent;

(d) evalwazzjoni ta' riskju ambjentali.

(3) Mingħajr preġudizzju għas-subregolamenti (1) u (2), il-proċeduri simplifikati dwar rilaxx intenzjonat fl-ambjent ta' pjanti ġenetikament modifikati, fil-każ ta' aktar minn rilaxx wiehed ta' pjanti ġenetikament modifikati li rriżultaw mill-istess speċi ta' pjanta ta' xitla li tirċievi imma li jvarjaw minn sekwenzi inseriti jew imħassra jew li ikollhom l-istess sekwenza inseriti jew imħassra imma li jvarjaw fil-fenotipi skond dawk stabbiliti fi Skeda IX.

Ġestjoni ta' modifiki u informazzjoni ġdida.

8. (1) Fil-każ ta' xi modifika ta', jew bidla mhux mistennija, tar-rilaxx intenzjonat ta' xi GMO jew tagħqid ta' GMOs

li jista' jkollhom konsegwenzi dwar riskji għas-saħħa tal-bniedem u l-ambjent wara li l-awtorità kompetenti tkun tat il-kunsens tagħha bil-miktub, jew jekk informazzjoni ġdida issir disponibbli fuq dawn ir-riskji, jew waqt li qed tiġi eżaminata notifika mill-awtorità kompetenti jew wara li dik l-awtorità tkun tat il-kunsens tagħha bil-miktub, in-notifikant għandu minnufih:

(a) jieħu l-miżuri neċessarji biex jipproteġi s-saħħa tal-bniedem u l-ambjent;

(b) jinforma lill-awtorità kompetenti minn quddiem b'kull modifika jew hekk kif il-bidla mhux intenzjonata ssir magħrufa jew l-informazzjoni l-ġdida tkun disponibbli;

(ċ) jirrevedi l-miżuri speċifikati fin-notifika.

(2) Jekk informazzjoni ssir disponibbli lill-awtorità kompetenti msemmija fis-subregolament (1) li jista' jkollha konsegwenzi sinifikanti dwar riskji għas-saħħa tal-bniedem u l-ambjent jew f'ċirkostanzi deskritti fis-subregolament (1), l-awtorità kompetenti:

(a) għandha tevalwa dik l-informazzjoni u tagħmilha disponibbli għall-pubbliku;

(b) tista' tinħtieġ li n-notifikant jimmodifika l-kondizzjonijiet ta', jissospendi jew itemm ir-rilaxx intenzjonat u jinforma lil pubbliku b'dan kollu;

(ċ) tista' titlob lin-notifikant sabiex iħallas jew jikkontribwixxi għal xi jew kull spejjeż li tkun għamlet sabiex tipproteġi s-saħħa tal-bniedem u l-ambjent.

(3) Fil-każ tas-subregolamenti (1) u (2) ta' dan ir-regolament, in-notifikant għandu jemenda n-notifika li dwarha jkun ingħata l-kunsens u jibgħat in-notifika emendata lill-awtorità kompetenti.

(4) Meta l-awtorità kompetenti tirċievi notifika emendata skond is-subregolamenti (1) u (2), hija għandha tqis in-notifika emendata daqs li kieku kienet notifika ġdida taħt ir-regolament 6 fir-rigward tar-rilaxx intenzjonat modifikat propost.

(5) In-notifikant ma għandux jipproċedi bir-rilaxx intenzjonat propost sakemm jirċievi kunsens bil-miktub mill-awtorità kompetenti.

Konsultazzjoni u informazzjoni lill-pubbliku.

9. (1) L-awtorita' kompetenti għandha, mingħajr preġudizzju għad-dispożizzjonijiet tar-regolamenti 7 u 20, tikkonsulta lill-pubbliku u, fejn ikun adatt, lil gruppi, fuq ir-rilaxx intenzjonat li jkun ġie propost.

(2) Bla ħsara għas-subregolament (3), għall-għanijiet, ħlief ta' tqegħid fis-suq, in-notifikant ta' rilaxx intenzjonat propost għandu, mhux aktar minn 14-il ġurnata wara d-data tan-notifika lill-awtorità kompetenti, jippubblika f'ġazzetta lokali prominenti avviż bit-titolu "PROPOSTA DWAR RILAXX INTENZJONAT FL-AMBJENT TA' ORGANIŻMI MODIFIKATI ĠENETIKAMENT", u li jkun fihom l-informazzjoni segwenti -

(a) l-isem u l-indirizz tan-notifikant,

(b) id-deskrizzjoni ta' l-organiżmu modifikat ġenetikament proposta li tiġi rilaxxata,

(c) il-fatt li tkun giet ippreżentata notifika lill-awtorità kompetenti, u l-post u l-għan tar-rilaxx intenzjonat propost,

(d) il-perjodu ta' żmien li r-rilaxx intenzjonat propost għandu jsir fih,

(e) il-fatt li tista' tirriżulta aktar informazzjoni fuq ir-rilaxx intenzjonat propost mill-awtorità kompetenti,

.

(f) it-titolu sħiħ tal-awtorità kompetenti u l-indirizz sħiħ tal-uffiċju prinċipali tagħha,

(g) il-fatt illi, skond is-subregolament (5), kull persuna jew għaqda tista', fi żmien 28 ġurnata li jibdew għaddejin fil-ġurnata tal-pubblikazzjoni ta' l-avviż, tagħmel ilmenti bil-miktub lill-awtorità kompetenti dwar in-notifika,

u għandu jibgħat kopja tan-notifika lill-awtorità kompetenti fi żmien 14-il ġurnata.

(3) L-informazzjoni fuq il-post tar-rilaxx intenzjonat propost pubblikat konformement mas-subregolament (2) għandha tkun l-istess bħall-informazzjoni fuq il-post inidikat fir-reġistru mizmum mill-awtorità kompetenti skond ir-regolament 22, u, għal dak il-għan, in-notifikant għandu jiżgura li l-informazzjoni fuq il-post li jkollu mingħand l-awtorità kompetenti, tkun tqegħdet jew ikollha titqiegħed fl-imsemmi reġistru.

(4) In-notifikant għandu, sa mhux aktar tard minn 14-il ġurnata minn meta tasal in-notifika għand l-awtorità kompetenti, jibgħat kopja ta' l-avviż pubblikat konformement mas-sub-regolament (2) –

(a) lis-sid tal-post tar-rilaxx intenzjonat propost f'każ jekk dak is-sid ikun persuna li ma tkunx in-notifikant, u

(b) l-awtorità kompetenti.

(5) Kull persuna jew entità tista', fi żmien 28 ġurnata li jibdew għaddejin mill-ġurnata tal-pubblikazzjoni ta' l-avviż skond is-subregolament (2), tista' tagħmel ilmenti lill-awtorità kompetenti fir-rigward tan-notifika. L-ilmenti għandhom:-

(a) isiru bil-miktub,

(b) jiġu indirizzati lill-awtorità kompetenti fl-uffiċju prinċipali tagħha,

(ċ) jintbagħtu lill-awtorità kompetenti fi żmien 28 ġurnata li jibdew għaddejin mill-ġurnata tal-pubblikazzjoni tan-notifika konformement mas-subregolament (2),

(6) Ilmenti li ma jkunux konformi mas-subregolament (5) ma jkunux validi. Meta l-awtorità kompetenti tirċievi ilmenti skond is-subregolament (5), hija għandha-

(a) tikkonferma illi tkun irċeviet l-ilmenti, u

(b) tikkunsidra l-ilmenti biex tiġi deċiża n-notifika.

Rapport minn notifikant fuq rilaxx.

10. (1) In-notifikant għandu:

(a) fit-tmiem tar-rilaxx intenzjonat, u

(b) f'kull intervall sussegwenti stipulat fil-kunsens,

jippreżenta rapport lill-awtorità kompetenti dwar ir-riżultati tar-rilaxx intenzjonat.

(2) Ir-rapport imsemmi f'subregolament (1) għandu jiġi provdut f'dak il-format jew formati li jistgħu jiġu stabbiliti skond il-proċedura stipulata f'Artiklu 30(2) tad-Direttiva, jew

jekk dan ma jiġix hekk stabbilit dwar il-kunsens rilevanti, f'dak il-format li jista' jiġi speċifikat fil-kunsens u għandu jinkludi:

(a) evalwazzjoni wara r-rilaxx tar-riskji għas-saħħa tal-bniedem jew l-ambjent, u

(b) meta jkun adatt, dikjarazzjoni fuq ir-riżultati tar-rilaxx intenzjonat fl-rigward ta' kull prodott, jew tip ta' prodott, li dwaru jista' jinkiseb kunsens għat-tqegħid tiegħu.

(3) Kopja ta' kull rapport li l-awtorità kompetenti tkun irċeviet skond is-subregolament (1) għandu, wara l-wasla tiegħu, jintbgħat mill-awtorità kompetenti lill-Kummissjoni skond l-Artikolu 11(3) tad-Direttiva.

PARTI Ċ:

TQEGĦID FIS-SUQ TA' GMOs BĦALA JEW FI PRODOTTI

Leġiżlazzjoni settorali.

11. (1) Ir-regolamenti 12 sa 19 ma japplikawx għal xi GMO bħal jew fi prodotti, sakemm dawn ikunu awtorizzati minn xi leġiżlazzjoni rilevanti li tipprovdi għall-evalwazzjoni ta' riskju ambjentali speċifiku li jsir skond il-prinċipji stabbiliti fi Skeda II u fuq il-bażi ta' informazzjoni speċifikati fi Skeda III, mingħajr preġudizzju għal rekwiżiti addizjonali provduti minn leġiżlazzjoni rilevanti, u għal rekwiżiti fir-rigward tal-ġestjoni tar-riskju, tikkettjar, sorveljar kif adatt, informazzjoni lill-pubbliku u klawżola ta' salvagwardja mill-inqas ekwivalenti għal dak stabbilit f'dawn ir-regolamenti, jew f'kull regolamenti rilevanti oħra dwar prodotti mediċinali għall-użu uman u veterinarju.

Obbliġu ta' osservanza tal-Parti Ċ.

(2) Mingħajr preġudizzju għal Skeda IB u bla ħsara għall-esklużjonijiet fis-subregolament (1) persuna ma għandhiex tqiegħed fis-suq xi prodott li jkun fih jew ikun jikkonsisti f'xi organiżmu ġenetikament modifikat kemm-il darba:

(a) l-awtorità kompetenti ma tkunx irceviet il-kunsens bil-miktub skond il-Parti Ċ, jew

(b) ma jkunx wasal il-kunsens bil-miktub ta' l-awtorità kompetenti ta' Stat Membru ieħor skond il-Parti Ċ tad-Direttiva,

u l-kondizzjonijiet mehmuża mal-kunsens ikunu ġew imħarsa.

Proċedura ta' notifika.

12. (1) (a) Qabel xi GMO jew tagħqid ta' GMOs bħal jew fi prodotti jitqegħdu fis-suq għall-ewwel darba, għandha tiġi ppreżentata notifika lill-awtorità kompetenti.

(b) L-awtorità kompetenti għandha tgħarraf id-*data* tal-wasla tan-notifika.

(ċ) L-awtorità kompetenti għandha mingħajr dewmien teżamina jekk in-notifika tkunx skond is-subartikolu (2) u għandha, jekk ikun meħtieġ, titlob lin-notifikant jagħtiha informazzjoni addizzjonali.

(2) In-notifika għandu jkun fiha:

(a) l-informazzjoni meħtieġa fi Skedi III u IV. Din l-informazzjoni għandha tieħu akkont ta' diversità ta' siti ta' użu ta' GMO bħal jew fi prodott u tinkludi informazzjoni fuq *data* u riżultati miksuba minn riċerka u konklużjonijiet ta' żvilupp dwar l-impatt tar-rilaxx fuq is-saħħa tal-bniedem u l-ambjent;

(b) l-evalwazzjoni ta' riskju ambjentali u l-konklużjonijiet meħtieġha fi Skeda II;

(ċ) il-konklużjonijiet milħuqa minn notifikant skond Skeda II, flimkien ma' kull referenza bibliografika, u dettaliji tal-metodi użati.

(d) il-kondizzjonijiet għat-tqegħid fis-suq tal-prodott, inklużi kondizzjonijiet speċifiċi ta' użu u maniġġar;

(e) b'referenza għar-regolament 14(4), perjodu propost għal kunsens li m'għandux jeċċedi l-għaxar snin;

(f) pjan għal sorveljanza skond Skeda VII, inkluża proposta għal perjodu ta' żmien għal pjan ta' monitoraġġ; dan il-perijodu ta' żmien jista' jkun differenti mill-perjodu propost għall-kunsens;

(g) proposta għat-tikkettjar li tikkonforma mar-rekwiżiti stabbiliti fi Skeda IV u l-ittikkettjar għandhom jiddikjaraw b'mod ċar il-preżenza ta' GMO u l-kliem "dan il-

prodott fih organiżmi modifikati ġenetikament" jidhru jew fuq it-tikketta jew fuq dokument li jkun miegħu;

(h) proposta għall-imballaġġ li tikkonsisti fir-rekwiżiti stabbiliti fi Skeda IV;

(i) sommarju tan-notifika li tista' tiġi stabbilità mill-awtorità kompetenti minn żmien ghal żmien, fil-format stabbilit bi qbil mal-proċedura stabbilita fl-Artikolu 30(2) tad-Direttiva; dan għandu japplika wkoll f'każ li l-Artikolu 16 tad-Direttiva jkun japplika għalih;

(j) l-applikant għandu jindika b'mod ċar jekk l-applikazzjoni tkunx ser tippreġudika xi każ ta' infurzar, xi każ pendenti quddiem il-qorti jew xi kawżi oħra li jkunu għadhom *sub-judice*:

Iżda jekk, fuq il-bażi tar-riżultati ta' xi rilaxx notifikat skond il-parti B, jew fuq raġunijiet oħra sostantivi, u motivati xjentifikament, notifikant jikkunsidra li t-tqegħid fis-suq u l-użu ta' GMO bħala jew fi prodott ma humiex ta' riskju għas-saħħa tal-bniedem u għall-ambjent, huwa jista' jipproponi lill-awtorità kompetenti biex ma tipprovdix parti jew l-informazzjoni kollha meħtieġa fi Skeda IV, taqsima B.

(3) In-notifikant għandu jinkludi f'din in-notifika informazzjoni fuq *data* jew rizultati minn rilaxx ta' l-istesss GMOs jew l-istess tagħqid ta' GMOs notifikati qabel jew f'dak il-waqt jew li jkunu saru minn notifikant jew f'Malta jew barra minn Malta.

(4) In-notifkant jista' wkoll jirreferi għal *data* jew riżultati minn notifiki li ġew mogħtija qabel minn notifikanti oħra jew jagħti informazzjoni addizjonali huwa jikkonsidra rilevanti, sakemm l-informazzjoni, *data* u riżultati ma jkunux ta' xorta kunfidenzjali jew dawn in-notifikanti jkunu taw il-kunsens tagħhom bil-miktub.

(5) In-notifikant jipproponi li tqegħid fis-suq ta' prodott li jkun fih jew li jkun jikkonsisti f'xi organiżmu ġenetikament modifikat għall-ewwel darba għandu jippubblika avviż skond ir-regolament 9 bil-kliem "TQEGĦID FIS-SUQ PROPOST TA' PRODOTT LI GĦANDU JKUN FIH JIKKONSISTI F'ORGANIŻMU MODIFIKAT ĠENETIKAMENT'. Flimkien mar-rekwiżiti stipulati fir-regolament 9(2) l-avviż għandu jinkludi wkoll:-

(a) l-indirizz postali sħiħ tal-Kummissjoni,

(b) fir-rigward ta' applikazzjoni preżentata skond is-subartikolu (1), ir-regolament 9(2)(g) m'għandux japplika u għandu jkun sostitwit bis-subartikolu 5(ċ) hawn aktar 'l isfel.

(ċ) il-fatt li kull persuna jew korp jista' jressaq ilmenti bil-miktub lill-imsemmija Kummissjoni dwar in-notifika fi żmien tletin ġurnata li jibda fil-jum li l-Kummissjoni tagħmel disponibbli għall-pubbliku s-sommarju tan-notifika riċevuta minnha skond l-artikolu 13(b).

(6) Biex GMO jew tagħqid ta' GMOs jiġu użati għal skop differenti minn dak li diġà ġie speċifikat f'notifika, għandha tiġi ppreżentata notifika separata.

(7) Jekk l-informazzjoni ġdida ssir disponibbli dwar riskji ta' GMO lis-saħħa tal-bniedem jew għall-ambjent, qabel ma jingħata l-kunsens bil-miktub, in-notifikant għandu immedjatament jieħu l-miżuri neċessarji biex jipproteġi s-saħħa tal-bniedem u l-ambjent, u jinforma lill-awtorità kompetenti b'dan. Minbarra dan, in-notifikant għandu jirrevedi l-informazzjoni u l-kondizzjonijiet speċifikati fin-notifika u tippreżenta notifika emendata lill-awtorità kompetenti, u l-ewwel notifika taħt is-subregolament (1), ma għandhiex tibqa tiġi kkunsidrata aktar mill-awtorità kompetenti.

Rapport ta' evalwazzjoni.

13. (1) Mal-wasla tan-notifika skond ir-regolament 12(2), l-awtorità kompetenti għandha:

(a) tgħarraf lin-notifikant bil-miktub bid-data ta' meta tkun irċeviet in-notifika,

(b) għandha immedjatament tibgħat kopja ta' sommarju tan-notifika riċevuta skond l-Artikolu 12(2)(h) lill-awtoritajiet kompetenti ta' Stati Membri oħra għall-iskop tad-Direttiva u lill-Kummisjoni,

(ċ) teżamina in-notifika biex tara jekk hix konformi ma' dawn ir-regolamenti u b'mod partikolari mar-regolament 12,

(d) titlob bil-miktub lin-notifikant għal kull informazzjoni oħra li l-awtorita' kompetenti tikkunsidra neċessarja, u tindika r-raġunijiet tagħha għaldaqstant. Il-perjodu ta' żmien li fih l-awtorità kompetenti tkun qegħda

tistenna aktar informazzjoni m'għandux jitqies meta jiġi kalkolat il-perjodu ta' disgħin ġurnata msemmi fis-subartikolu (2),

(e) tibgħat kopja tan-notifika lill-Kummissjoni meta tkun sodisfatta li r-rekwiżiti tar-regolament 12 ġew sodisfatti, u mhux aktar tard miż-żmien li hija tibghat lill-Kummissjoni kopja tar-rapport ta' evalwazzjoni imsemmi skond is-subregolament (3) jew (4).

(2) Fi żmien 90 ġurnata minn meta tirċievi notifika taħt ir-regolament 12, l-awtorità kompetenti għandha:

(a) tipprepara skond Skeda VI rapport ta' evalwazzjoni li għandu wkoll jindika jekk:

(i) l-orġanżmu modifikat ġenetikament involut għandux jitqiegħed fis-suq u taħt liema kundizzjonijiet (imsemmija bħala "evalwazzjoni favorevoli"); jew

(ii) l-orġaniżmu modifikat ġenetikament involut m'għandux jitqiegħed fis-suq (imsemmiija bħala "evalwazzjoni sfavorevoli"), u

(b) tibgħat kopja tar-rapport ta' evalwazzjoni lin-notifikant.

(3) F'każ ta' evalwazzjoni favorevoli, l-awtorità kompetenti għandha tibgħat kopja tar-rapport ta' evalwazzjoni lin-notifikant u lill-Kummissjoni, flimkien ma' l-informazzjoni ulterjuri mingħand in-notifikant skond is-subregolament (1)(d), u kull informazzjoni oħra li fuqha l-awtorità kompetenti tkun ibbażat ir-rapport tagħha.

(4) Fil-każ ta' evalwazzjoni sfavorevoli, l-awtorità kompetenti għandha, mhux qabel 15-il ġurnata wara li tibgħat kopja tar-rapport ta' evalwazzjoni lin-notifikant u mhux iktar tard minn 105 ġurnata wara li tirċievi n-notifika, tibgħat lill-Kummissjoni kopja tar-rapport imsemmi, kull informazzjoni ulterjuri li tirċievi mingħand in-notifikant skond is-subregolament (1)(d), u kif ukoll informazzjoni oħra li fuqha l-awtorità kompetenti bbażat ir-rapport tagħha.

Proċedura *standard*.

14. (1) F'każ ta' evalwazzjoni favorevoli, l-awtorità kompetenti għandha:

(a) tipprovdi kull informazzjoni ulterjuri lill-Kummissjoni, meta dik l-informazzjoni tkun mitluba mill-istess Kummissjoni jew minn awtorità kompetenti ta' Stat Membru għall-finijiet tad-Direttiva,

(b) tikkunsidra kull kumment, jew oġġezzjonijiet motivati dwar it-tqegħid tal-prodott fis-suq li tkun saret mill-Kummisjoni jew minn awtorità kompetenti ta' Stat Membru ieħor għall-finijiet tad-Direttiva meta dawn il-kummenti jew oġġezzjonijiet isiru f'perjodu ta' 60 ġurnata mid-data ta' meta d-dokumenti msemmija fir-regolament 13(3) ikunu ġew mibgħuta lil kull awtorità kompetenti bħal dik mill-Kummissjoni, u

(ċ) tipparteċipa f'diskussjonijiet fir-rigward tar-rapport ta' evalwazzjoni li jkun ġie mibdi mill-Kummissjoni fuq il-bażi ta' l-oġġezzjonijiet motivati magħmula skond paragrafu (b) bil-ħsieb li jintlaħaq ftehim fi żmien 105 ġurnata, li jibdew għaddejin mid-data ta' meta d-dokumenti msemmija fir-regolament 13(3) kienu mibgħuta lil kull awtorità kompetenti mill-Kummissjoni:

Iżda kull perjodu ta' żmien li matulu tkun mistennija l-informazzjoni ulterjuri minn notifikant, m'għandux jittieħed in kunsiderazzjoni għall-finijiet tal-kalkolu tal-perjodu finali ta' 45 ġurnata biex jintlaħaq ftehim.

(2) L-awtorita kompetenti għandha tagħti l-kunsens tagħha bil-miktub lin-notifikant biex iqiegħed il-prodott fis-suq meta hija tkun għamlet evalwazzjoni favorevoli tal-proposta, u

(a) l-ebda oġġezzjoni motivata għall-evalwazzjoni favorevoli ma tkun ġiet magħmula mill-Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru skond is-subregolament 1(b), jew

(b) oġġezzjoni motivata għal evalwazzjoni favorevoli tkun ġiet magħmula mill-Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru skond is-subregolament 1(b) imma l-kwistjonijiet involuti jkunu ġew solvuti skond id-dispożizzjonijiet ta' l-Artikolu 15(1) tad-Direttiva, jew

(ċ) oġġezzjoni motivata għal evalwazzjoni favorevoli tkun ġiet magħmula mill-Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru skond is-subregolament 1(b) u

dik il-Kummissjoni tkun adottat deċiżjoni favorevoli skond id-dispożizzjonijiet ta' l-Artikolu 18(1) tad-Direttiva.

(3) L-awtorità kompetenti għandha, fi żmien 30 ġurnata mid-data ta' meta ingħata l-kunsens, tinforma lill-awtorità kompetenti ta' kull Stat Membru u lill-Kummisjoni li hiia tkun għamlet dan.

(4) L-awtorità kompetenti għandha, meta hija tkun għamlet evalwazzjoni sfavorevoli, jew meta l-Kummissjoni tkun adottat deċiżjoni sfavorevoli skond id-dispożizzjonijiet ta' l-Artikolu 18(1) tad-Direttiva, tinforma lin-notifikant bil-miktub, li l-kunsens ikun ġie miċħud filwaqt li tagħti r-raġunijiet għal dak iċ-ċħid.

(5) Bla ħsara għad-dispożizzjonijiet tas-subregolament (6), l-awtorità kompetenti ma għandhiex tagħti kunsens taħt il-Parti Ċ għal perjodu ta' żmien li jeċċedi l-għaxar snin li jibda għaddej mill-ġurnata meta jinħareġ il-kunsens.

(6) Fil-każijiet li għandhom x'jaqsmu ma' organiżmi modifikati ġenetikament jew nisel ta' dak l-organiżmu maħsuba biss għar-reklamar taż-żerriegħa tagħha taħt il-liġijiet ta' l-Unjoni Ewropea li jkunu fis-seħħ, jew mal-materjal riproduttiv modifikat ġenetikament tal-foresti, il-perjodu ta' l-ewwel kunsens għandu jkun limitat skond id-dispożizzjonijiet tal-Artikolu 15(4) tad-Direttiva.

Tiġdid tal-kunsens.

15. (1) B'deroga mir-regolamenti 12, 13 u 14, il-proċedura stabbilita fis-subartikoli (2) sa (5) għandha tiġi applikata għat-tiġdid tal-kunsensi mogħtijin taħt il-Parti Ċ.

(2) Persuna li tixtieq iġġedded kunsens mogħti mill-awtorità kompetenti taħt ir-regolament 14 jew kunsens li jkun ġie qabel imġedded taħt dan ir-regolament għandu:

(a) jippreżenta notifika lill-awtorità kompetenti mhux aktar tard minn disa' xhur qabel l-iskadenza tal-kunsens li jkun qiegħed jiġi propost li jiġġeded,

(b) persuna li tkun bagħtet in-notifika taħt dan ir-regolament tista' tkompli tmexxi fis-suq il-prodott involut bil-pattijiet u l-kondizzjonijiet rilevanti tal-kunsens rilevanti sakemm tittieħed deċiżjoni finali fuq in-notifika.

(3) In-notifika skond is-subregolament 2(a) għandha tinkludi:

(a) kopja tal-kunsens mogħti mill-awtorità kompetenti lill-prodott li jkun qed jitqiegħed fis-suq u ta' kull kunsens li jiġi mġedded,

(b) rapport dwar is-sorveljanza li ssir kif hemm fir-regolament 17,

(ċ) kull informazzjoni oħra ġdida li tkun saret disponibbli dwar ir-riskji tal-prodott għas-saħħa tal-bniedem jew l-ambjent, u

(d) kull proposta li n-notifikant jikkunsidra adatta biex jemenda jew iżid miżuri mal-kundizzjonijiet li jinsabu fil-kunsens oriġinali mogħti mill-awtorità kompetenti, inklużi kundizzjonijiet relatati mal-monitoraġġ futur u limitazzjoni ta' żmien tal-kunsens.

(4) Mal-wasla ta' notifikazzjoni taħt is-subregolament (2), l-awtortità kompetenti, għandha:

(a) tgħarraf lin-notifikant bil-miktub bid-data meta tkun waslet in-notifikazzjoni,

(b) teżaminaha biex tara jekk hijiex konformi mas-subregolament (3),

(ċ) titlob lin-notifikant bil-miktub għal kull informazzjoni oħra li l-awtorità kompetenti tqis li tkun meħtieġa, u tagħti r-raġunijiet tagħha għaldaqstant,

(d) tipprepara, skond Skeda V, rapport ta' evalwazzjoni li għandu jindika:

(i) jekk l-organiżmu modifikat ġenetikament in kwistjoni għandux jibqa' fis-suq u b' liema kondizzjonijiet (imsemmija bħala evalwazzjoni favorevoli);

(ii) jew l-organiżmu modifikat ġenetikament in kwistjoni m'għandux jibqa' fis-suq (indikat bħala evalwazzjoni sfavorevoli).

(e) tibgħat kopja tan-notifika u tar-rapport ta' evalwazzjoni lill-Kummissjoni, u

(f) tibgħat kopja tar-rapport ta' evalwazzjoni lin-notifikant.

(5) Fil-każ ta' evalwazzjoni favorevoli l-awtorità kompetenti għandha:

(a) tipprovdi kull informazzjoni ulterjuri lill-Kummissjoni, meta dik l-informazzjoni tkun mitluba mill-imsemmija Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru għall-finijiet tad-Direttiva,

(b) tikkunsidra kummenti, tħassib jew oġġezzjonijiet motivati għall-prodott li jibqa' fis-suq magħmulin mill-Kummisjoni jew minn awtorità kompetenti ta' Stat Membru għall-finijiet tad-Direttiva meta dawk il-kummenti jew oġġezzjonijiet isiru fi żmien 60 ġurnata mid-data meta d-dokumenti msemmija fis-subregolament 4(d) ikunu ġew mibgħuta lil kull awtorità kompetenti bħal dik mill-Kummissjoni, u

(ċ) tipparteċipa f'diskussjonijiet li jkunu jirrigwardaw ir-rapport ta' evalwazzjoni li jkun l-ewwel tressaq mill-Kummissjoni minħabba fl-oġġezzjonijiet motivati magħmulin skond il-paraġrafu (b) bil-ħsieb li jintlaħaq ftehim fi żmien 75 ġurnata, li jibdew għaddejin mid-data meta d-dokumenti msemmija fis-sub-regolament 4(d) kienu mibgħutin lil kull awtorità kompetenti bħal dik mill-Kummissjoni.

(6) L-awtorità kompetenti għandha ġġedded il-kunsens tagħha għat-tqegħid fis-suq ta' prodott meta tkun għamlet evalwazzjoni favorevoli tal-proposta, u -

(a) ma tkun saret ebda oġġezzjoni motivata għall-evalwazzjoni favorevoli mill-Kummissjoni jew minn awtorità kompetenti ta' xi Stat Membru skond is-subregolament 4(d), jew

(b) tkun saret oġġezzjoni motivata għal evalwazzjoni sfavorevoli mill-Kummissjoni jew minn awtorità kompetenti ta' xi Stat Membru skond is-subregolament 4(d) imma l-kwistjonijiet involuti jkunu ġew solvuti skond id-dispożizzjonijiet ta' Artikolu 17(7) u (8) tad-Direttiva, jew

(ċ) tkun saret oġġezzjoni motivata għal evalwazzjoni sfavorevoli tkun ġiet magħmula mill-Kummissjoni jew minn awtorità kompetenti ta' xi Stat Membru skond is-subregolament 4(d) u dik il-Kummissjoni tkun adottat deċizjoni favorevoli skond il-dispożizzjonijiet ta' l-Artikolu 18(1) tad-Direttiva.

(7) L-awtorità kompetenti għandha, fi żmien 30 ġurnata li jibdew għaddejin minn meta jiġedded il-kunsens, tinforma b'dan lill-awtorità kompetenti ta' kull Stat Membru u lill-Kummissjoni li tkun wettqet dan kollu.

(8) L-awtorità kompetenti għandha, meta tkun għamlet evalwazzjoni sfavorevoli, jew meta l-Kummissjoni tkun adottat deċiżjoni sfavorevoli skond id-dispożizzjonijiet ta Artikolu 18(1) tad-Direttiva, tinforma lin-notifikant illi it-tiġdid tal-kunsens ikun ġie miċħud u għandha tagħti r-raġunijet għal dak iċ-ċħid.

(9) L-awtorità kompetenti għandha tibgħat bil-miktub lin-notifikant it-tiġdid jew iċ-ċħid ta' kunsens taħt dan ir-regolament. Il-validità ta' tiġdid tal-kunsens m'għandhiex teċċedi l-għaxar snin u tista' tiġi limitata jew estiża kif adatt għal raġunijiet speċifiċi.

Kunsens.

16. (1) Prodott jista' jiġi użat mingħajr il-ħtieġa ta' notifika ulterjuri lill-awtorità kompetenti ta' Stat Membru f'dawk il-każijiet biss meta jkun ingħata kunsens bil-miktub għat-tqegħid fis-suq ta' GMO bħala jew f'dak il-prodott, u dan sakemm jiġu strettament osservati l-kondizzjonijiet speċifikati ta' użu u l-ambjent jew żoni ġeografiċi f'dawn il-kondizzjonijiet.

(2) (a) In-notifikant jista' jipproċedi bit-tqegħid fis-suq biss meta jkun irċieva l-kunsens bil-miktub ta' l-awtorità kompetenti skond ir-regolamenti 14 u 15 u konformi ma' kull kondizzjoni meħtieġa f'dak il-kunsens.

(b) L-awtorità kompetenti għandha tieħu l-miżuri kollha neċessarji biex tiżgura li kull kunsens mogħti bil-miktub ikun aċċessibli għall-pubbliku u li dawk il-kundizzjonijiet speċifikati fil-kunsens bil-miktub jiġu osservati.

(3) Il-kunsens bil-miktub imsemmi fir-regolamenti 14 u 15 għandu, fil-każijiet kollha, ikun jispeċifika b'mod espliċitu:

(a) l-iskop tal-kunsens, inkluża l-identità ta' kull GMO li jkun se jitqiegħed fis-suq bħala jew fi prodotti, u xi tkun dik il-ħaġa unika li tidentifikhom;

(b) il-perjodu ta' validità tal-kunsens;

(ċ) il-kondizzjonijiet għat-tqegħid fis-suq tal-prodott, inkluża kull kundizzjoni speċifika ta' użu, maniġġar u pakkeġġar ta' kull GMO bħala jew fi prodotti, u kundizzjonijiet għall-protezzjoni ta' ekosistemi, ambjenti jew żoni ġeografiċi partikolari;

(d) li, mingħajr preġudizzju għar-regolament 20, in-notifikant għandu jagħmel kampjuni ta' kontroll disponibbli lill-Awtorità Kompetenti fuq it-talba tagħha;

(e) ir-rekwiżiti ta' tikkettjar, skond ir-rekwiżiti stabbiliti fi Skeda IV. It-tikkettjar għandu jindika b'mod ċar il-preżenza ta' GMO. Il-kliem "Dan il-prodott fih organiżmi modifikati ġenetikament" għandhom jidhru jew fuq it-tikketta jew fuq dokument li jkun mal-prodottt jew ma' prodotti oħra li jkun fihom xi GMO;

(f) ir-rekwiżiti ta' sorveljar skond Skeda VII, inklużi obbligazzjonijiet biex tirraporta lill-Kummissjoni, il-perjodu ta' żmien tal-pjan ta' sorveljar u, fejn adatt, kull obligazzjoni li jkollha persuna li tkun qegħda tbiegħ il-prodott jew li tkun qegħda tagħmel użu minnu, fost l-oħrajn, fil-każ ta' kull GMO imkabbar, dwar livell ta' informazjoni li jitqies li jkun adatt fil-post tagħhom.

Sorveljar u maniġġar ta' informazzjoni ġdida.

17. (1) Wara t-tqegħid fis-suq ta' xi GMO bħala jew fi prodott, in-notifikant għandu jiżgura li s-sorveljar u r-rappurtaġġ fuqu jsiru skond il-kundizzjonijiet speċifikati fil-kunsens. Abbażi ta' dawn ir-rapporti, bi qbil mal-kunsens u fi ħdan il-qafas tal-pjan ta' sorveljanza speċifikat fil-kunsens, l-awtorità kompetenti tista' tadatta il-pjan ta' sorveljanza wara l-ewwel perjodu ta' sorveljar jew wara perjodi sussegwenti.

(2) F'każ li tkun saret disponibbli informazzjoni ġdida, mill-utenti jew minn sorsi oħra, dwar riskji ta' kull GMO għas-saħħa tal-bniedem jew l-ambjent wara li jingħata l-kunsens bil-miktub, in-notifikant għandu immedjatament jieħu l-miżuri neċessarji biex jipproteġi s-saħħa tal-bniedem u l-ambjent, u jinforma lill-awtorità kompetenti b'dan kollu.

(3) Jekk informazzjoni ssir disponibbli lill-awtorità kompetenti li jista' jkollha konsegwenzi għar-riskji ta' kull GMO għas-saħħa tal-bniedem jew l-ambjent, jew skond ċirkostanzi deskritti fis-subregolament (2), din tista' tħaddem id-dispożizzjonijiet tar-regolament 14 hekk kif ikun adatt, meta l-informazzjoni tkun saret disponibbli qabel il-kunsens bil-miktub.

(4) Jekk, wara li jingħata kunsens taħt ir-regolament 14, jew wara li jkun iġġeded il-kunsens taħt ir-regolament 15, l-awtorità kompetenti tkun ġiet infurmata jew issir taf, b'informazzjoni li jista' jkollha konsegwenzi ta' riskji għal xi GMO dwar is-saħħa tal-bniedem jew l-ambjent, jew f'ċirkostanzi deskritti f'subregolament (2), din għandha:

(a) immedjatament tibgħat l-informazzjoni lill-Kummissjoni u lill- awtoritajiet kompetenti ta' l-Istati Membri għall-finijiet tad-Direttiva,

(b) tipprepara rapport ta' evalwazzjoni skond Skeda V li għandu jindika:

(i) jekk l-orġanżmu modifikat ġenetikament in kwistjoni għandux jibqa' fis-suq u taħt liema kundizzjonijiet (imsemmija bħala "evalwazzjoni favorevoli");

(ii) jew l-orġaniżmu modifikat ġenetikament in kwistjoni m'għandux jibqa fis-suq (imsemmija bħala "evalwazzjoni sfavorevoli"),

(ċ) fi żmien 60 ġurnata wara li tirċievi l-informazzjoni, tibgħat kopja tar-rapport ta' evalwazzjoni lill-Kummissjoni, u

(d) tibgħat kopja tar-rapport ta' evalwazzjoni lin-notifikant. Jekk l- awtorità kompetenti jkun jidrilha mill-evalwazzjoni tar-rapport illi l-informazzjoni l-ġdida tipprovdi bidliet konsiderevoli fin-notifika, l-awtorità kompetenti tista' titlob lin-notifikant biex jieqaf milli jibqa' jqiegħed fis-suq taħt dan ir-regolament u jippreżenta notifika emendata:

Iżda jekk ikun hemm impatti fuq is-saħħa tal-bniedem u l-ambjent, in-notifikant jista' jiġi mitlub sabiex iħallas jew jikkontribwixxi għal parti mill-ispejjeż jew l-ispejjeż kollha li hija tkun ġarrbet biex tipproteġi s-saħħa tal-bniedem u l-ambjent.

(5) F'każ ta' evalwazzjoni favorevoli l-awtorità kompetenti għandha:

(a) tipprovdi kull informazzjoni ulterjuri lill-Kummissjoni, meta dik l-informazzjoni tkun mitluba mill-istess Kummissjoni jew minn awtorità kompetenti ta' Stat Membru ieħor għall-finijiet tad-Direttiva;

(b) tikkunsidra kull kumment, tħassib jew oġġezzjonijiet motivati għar-rapport ta' evalwazzjoni riferiti fis-subregolament 4(b)(i) magħmula mill-Kummisjoni jew minn awtorità kompetenti ta' Stat Membru ieħor għall-finijiet tad-Direttiva meta dawk il-kummenti jew oġġezzjonijiet ikunu ġew magħmulin f'perjodu ta' 60 ġurnata li jibdew għaddejin mid-data ta' meta r-rapport ta' evalwazzjoni ikun ġie mgħoddi lil kull waħda mill-awtoritajiet kompetenti bħal dawk mill-Kummissjoni; u

(ċ) tipparteċipa f'diskusjonijiet li jkollhom x'jaqsmu mar-rapport ta' evalwazzjoni mibdijin mill-Kummissjoni tal-Komunitajiet Ewropej skond oġġezzjonijiet motivati li jsiru skond il-paragrafu (b) bl-għan li jintlaħaq ftehim fi żmien 75 ġurnata, mid-data meta jibdew għaddejin id-dokumenti msemmijja fis-subregolament 4(b)(i) ikunu ġew mgħoddijja lil kull waħda minn dawk l-awtoritajiet kompetenti mill-Kummissjoni.

(6) L-awtorità kompetenti għandha tagħti l-kunsens tagħha għar-reklamar ta' prodott meta tkun għamlet evalwazzjoni favorevoli ta' l-informazzjoni, u -

(a) ma' tkunx saret ebda oġġezzjoni motivata għal evalwazzjoni favorevoli mill-Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru skond is-subregolament 5(b), jew

(b) tkun saret oġġezzjoni motivata għal evalwazzjoni favorevoli mill-Kummissjoni jew minn awtorità kompetenti ta' Stat Membru skond is-subregolament 5(b) imma kwistjonijiet involuti jkunu ġew solvuti skond id-dispożizzjonijiet ta' l-Artikolu 20(3) tad-Direttiva, jew

(ċ) tkun saret oġġezzjoni motivata għal evalwazzjoni favorevoli mill-Kummissjoni jew minn awtorità kompetenti ta' Stat Membru skond is-subregolament 5(b) u dik il-

Kummissjoni tkun adottat deċiżjoni favorabbli skond id-dispożizzjonijiet ta' l-Arikolu 18(1) tad-Direttiva.

(7) L-awtorità kompetenti għandha, fi żmien 30 ġurnata li jibdew għaddejin mill-ġurnata li fiha ngħata l-kunsens għat-tqegħid kontinwat fis-suq, għandha tinforma b'dan lill-awtorità kompetenti ta' kull Stat Membru u lill-Kummisjoni li tkun għamlet daqstant.

(8) L-awtorità kompetenti għandha, meta tkun għamlet evalwazzjoni sfavorevoli, jew meta il-Kummissjoni tkun adottat deċiżjoni sfavorevoli skond id-dispożizzjonijiet ta' l-Artikolu 18(1) tad-Direttiva, tordna lin-notifikant biex jieqaf milli jqiegħed fis-suq il-prodott u tagħti r-raġunijiet tagħha għal din l-ordni.

(9) In-notifikant għandu jikkonforma ma' kull direzzjoni mogħtija mill-awtorità kompetenti skond is-subregolament (8).

(10) L-awtorità kompetenti għandha tinforma bil-miktub lin-notifikant bil-kunsens tagħha biex ikompli bit-tqegħid fis-suq, jew b'ordni biex jieqaf mit-tqegħid fis-suq skond dan ir-regolament.

(11) L-awtorità kompetenti għandha tara li r-riżultati ta' sorveljanza li tkun saret taħt il-Parti Ċ tad-Direttiva ta' dawn ir-regolamenti, ikunu disponnibli għall-pubbliku.

Tikkettjar.

18. (1) Fl-istadji kollha ta' tqegħid fis-suq, it-tikkettjar u l-ippakkjar ta' kull GMO li jitqiegħed fis-suq bħala jew fi prodotti għandhom jikkonformaw mar-rekwiżiti rilevanti speċifikati fil-kunsens bil-miktub imsemmija fir-regolamenti 14(2) u 16(3).

(2) Meta prodotti fejn traċċi inevitabbli jew tekniċi aċċidentali ta' kull GMO awtorizzat ma jistgħux jiġu eskluż i, l-awtorità kompetenti tista' tistabbilixxi limitu minimu li nqas minnu dawn il-prodotti m'għandhomx għalfejn jiġu tikkettjati skond is-subregolament (1).

(3) Fir-rigward ta' prodotti intenzjonati għall-ipproċċesar dirett, is-subregolament (1) m'għandux japplika għal traċċi ta' xi GMO awtorizzat fi proporzjon mhux ogħla minn 0.9% jew f'xi limitu anqas, sakemm dawk it-traċċi huma aċċidentali jew teknikament inevitabbli.

Riżerva.

19. (1) Mingħajr preġudizzju għal dan ir-regolament l-awtorità kompetenti ma tistax tipprojbixxi, tirrestrinġi jew tfixkel it-tqegħid fis-suq ta' xi GMO, bħala jew fi prodotti, li jkunu konformi mar-rekwiżiti ta' dawn ir-regolamenti, ħlief meta, b'riżultat ta' informazzjoni ġdida jew addizjonali li ssir disponnibli mid-data tal-kunsens u taffetwa l-evalwazzjoni ta' riskju ambjentali jew eżami mill-ġdid ta' informazzjoni eżistenti abbażi ta' għarfien xjentifiku ġdid jew addizzjonali, l-awtorità kompetenti jkollha raġunijiet iktar dettaljati biex tikkunsidra li GMO bħala jew fi prodott li ġie proprjament notifikat u li rċieva l-kunsens bil-miktub taħt dawn ir-regolamenti jikkostitwixxi riskju lis-saħħa tal-bniedem jew l-ambjent, dik l-awtorità kompetenti tista' proviżorjament tirrestrinġi jew tipprojbixxi l-użu jew il-bejgħ ta' dik l-GMO bħala jew fi prodott.

(2) L-awtorità kompetenti għandha tiżgura li fil-każ ta' riskju gravi, għandhom jiġu applikati miżuri ta' emerġenza, bħal sospensjoni jew it-terminazzjoni ta' tqegħid fis-suq, inkluż li tingħata informazzjoni lill-pubbliku.

(3) Għall-finijiet tas-subregolament (1), għandhom japplikaw il-proċeduri msemmija fir-regolament 17.

PARTI D:

KUNFIDENZJALITÀ U R-REĠISTRU PUBBLIKU

Kunfidenzjalità.

20. (1) L-awtorità kompetenti m'għandhiex tgħaddi informazzjoni kunfidenzjali notifikata jew skambjata skond dawn ir-regolamenti lil terzi persuni u għandha tipproteġi drittijiet ta' proprjetà intelletwali relatati mad-*data* li tkun irċeviet.

(2) In-notifikant jista' jindika l-informazzjoni fin-notifika mogħtija taħt dawn ir-regolamenti, li l-iżvelar tagħha jista' jkun ta' ħsara għall-pożizzjoni kompettitiva tiegħu u li għalhekk għandha tkun meqjusa bħala kunfidenzjali, għandha tingħata f'dawn il-każijiet ġustifikazzjoni li tista' tiġi verifikata.

(3) L-awtorità kompetenti għandha, wara konsultazzjoni man-notifikant, tiddeċiedi liema informazzjoni għandha tinżamm kunfidenzjali u tinforma lin-notifikant bid-deċiżjonijiet tagħha.

(4) F'ebda każ ma tista', meta tingħata din l-informazzjoni skond ir-regolamenti 6, 7, 8, 12, 15, 17 jew 19, tinżamm kunfidenzjali:

(a) deskrizzjoni ġenerali ta' kull GMO, l-isem u l-indirizz tan-notifikant, skop tar-rilaxx, post tar-rilaxx u kull użu maħsub;

(b) metodi u pjanijiet għal sorveljar ta' kull GMO u għal kull rispons ta' emerġenza;

(ċ) evalwazzjoni ta' riskju ambjentali.

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

Tikkettjar ta' GMOs imsemmija fit-tifsira "tqegħid fis-suq" fir-regolament 2.

21. Kull GMO li għandhom ikunu disponibbli għall-operazzjonijiet imsemmija fit-tifsira "tqegħid fis-suq" fir-regolament 2(1), għandhom ikunu soġġetti għal rekwiżiti adegwati ta' tikkettjar skond it-taqsimiet rilevanti ta' Skeda IV biex tipprovdi informazzjoni ċara, fuq tikketta jew f'dokument li jkun miegħu, dwar il-preżenza ta' xi GMO. Għal dak l-għan il-kliem "Dan il-prodott fih organiżmi modifikati ġenetikament" jidhru jew fuq it-tikketta jew fuq dokument li jkun miegħu.

Twaqqif ta' reġistri pubbliċi.

22. (1) Mingħajr preġudizzju għas-subregolament (2) u punt A Nru. 7 ta' Skeda IV, l-awtorità kompetenti għandha:

(a) tistabbilixxi reġistri pubbliċi fejn il-post ta' rilaxx ta' xi GMO skond il-Parti B tiġi reġistrata;

(b) għandha tistabbilixxi wkoll reġistri biex jiġu reġistrati fejn il-GMOs ikunu mkabbra skond il-Parti Ċ, fost l-oħrajn biex effetti possibli ta' GMOs fuq l-ambjent jistgħu jkunu segwiti skond id-dispożizzjonijiet tar-regolamenti 16(3)(f) u 17(1).

(2) Mingħajr preġudizzju għal dawk id-dispożizzjonijiet fir-regolamenti 16 u 17, dawk il-postijiet għandhom:

(a) jiġu notifikati lill-awtoritajiet kompetenti, u

(b) isiru magħrufa lil pubbliku bil-mod li l-awtorità kompetenti tqis li jkun adatt.

PARTI E:

REATI

Reati.

23. (1) Kull persuna li:

(a) tonqos milli tosserva xi dispożizzjoni ta' dawn ir-regolamenti jew xi ordni oħra mogħtija bis-saħħa ta' xi dispożizzjoni ta' dawn ir-regolamenti; jew

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

(ċ) tonqos milli tosserva xi kundizzjoni ta' permess jew kunsens mogħti taħt id-dispożizzjonijiet ta' dawn ir-regolamenti; jew

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

(e) tagħmel dikjarazzjoni jew tippreżenta informazzjoni jew dokumentazzjoni, li dik il-persuna tkun taf illi din hija informazzjoni falza bl-għan illi tikseb l-approvazjoni jew il-kontinwità ta' kunsens taħt dawn ir-regolamenti; jew

(f) tikkonfoffa jew tipprova tikkonfoffa, tgħin jew tinkoraġixxi, lil xi persuna oħra, b'kull mod, fosthom bir-riklamar, li tagħti parir jew tgħin biex jinkisru d-dispożizzjonijiet ta' dawn ir-regolamenti jew li tonqos milli tosserva id-dispożizzjonijiet ta' dawn ir-regolamenti jew ordni leġittimament mogħtija taħt xi provvediment ta' dawn ir-regolamenti jew li tikser xi restrizzjoni, projbizzjoni jew rekwiżit imposti b'dawn ir-regolament jew taħthom,

għandha tkun ħatja ta' reat taħt dawn ir-regolamenti.

(2) Kull persuna li tagħmel reat taħt dawn ir-regolamenti tista', meta tinsab ħatja, teħel:

(a) meta tinsab ħatja għall-ewwel darba, multa ta' mhux inqas minn tnax-il elf euro, iżda mhux iżjed minn tmienja u ħamsin elf euro;

(b) meta tinsab ħatja għat-tieni darba jew aktar, multa ta' mhux inqas minn ħamsa u tletin elf euro, iżda mhux iżjed

minn tmienja u ħamsin elf euro jew priġunerija għal żmien 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, ir-revoka tal-permess maħruġ mill-awtorità kompetenti u l-konfiska tal-*corpus delicti*.

(3) Il-Qorti għandha tordna lill-ħati sabiex ineħħi il-kawzi 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' xi ordni bħal dik fiż-zmien stipulat, jista' jeħel multa ta' mhux inqas minn sittin euro u mhux iżjed minn ħames mitt euro, skond ma l-Qorti tista' tistabbilixxi, għal kull ġurnata li n-nuqqas ikompli wara li jiskadi dak it-terminu.

(4) Kull persuna li tinstab ħatja ta' reat kontra dawn ir-regolamenti għandha wkoll tħallas l-ispejjeż inkorsi sabiex jiġi miżmum, trasportat u tiġi rimedjata l-ħsara kaġunata bl-istess reat, kif ukoll għall-ispejjeż inkorsi jew miżuri oħra neċessarji biex jiġu rimedjati dawk il-ħsarat u l-ksur.

(5) 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-iskwalifika milli persuna jkollha jew tikseb liċenza jew permess mingħand awtorità kompetenti m'għandha f'ebda każ tkun ta' inqas minn sena.

(6) 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 ikunu skond id-dispożizzjonijiet tal-Kodiċi Kriminali li jirregolaw il-proċedura quddiem dawk il-qrati bħala qrati ta' ġudikatura kriminali.

(7) 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.

PARTI E:

DRITTIJIET

Dritt għal notifika ta' proposta għal rilaxx intenzjonat.

19. (1) L-awtorità kompetenti għandha titħallas dritt għan-notifika skond ir-regolament 6 għal proposta għal rilaxx intenzjonat apparti mill-għan ta' tqegħid fis-suq.

(2) Id-dritt li jitħallas taħt is-subregolament (1) għandu jkun ta €37,000.

Dritt għal notifika ta' proposta ta' tqegħid ta' prodott fis-suq u tiġdid ta' kunsens.

(3) L-awtorita' kompetenti għandha titħallas dritt għal notifika skond ir-regolament 12 għal proposta għal tqegħid ta' prodott fis-suq u għal notifika skond ir-regolament 15 għal proposta ta' tiġdid ta' kunsens.

(4) Id-dritt li jitħallas taħt is-subregolament (3) għandu f'kull każ ikun ta' €47,000.

Dritt għal emenda ta' notifika relatata ma rilaxx intenzjonat.

(5) L-awtorita' kompetenti għandha titħallas dritt għal notifika emendata taħt ir-regolament 8(3) dwar rilaxx intenzjonat għal għanijiet apparti minn dawk ta' tqegħid fis-suq.

(6) Id-dritt li jitħallas taħt is-subregolament (5) għandu jkun ta' €5,000.

Dritt għal emenda ta' notifika għat-tpoġġija fis-suq ta' prodott.

(7) L-awtorita' kompetenti għandha titħallas dritt għal notifika emendata taħt ir-regolamenti 12(6) u 17(4)(d) konness mar-rilaxx propost ta' prodott fis-suq.

(8) Id-dritt li jitħallas taħt is-subregolament (7) għandu f'kull każ ikun ta' €14,000.

Spejjeż perjodiċi għal monitoraġġ.

25. L-awtorità kompetenti tista' titlob lil notifikant li jagħmel ħlasijiet perjodiċi, li ma jkunux jeċċedu l-ispejjeż li tkun għamlet l-awtorità kompetenti, sabiex tħallas jew tikkontribwixxi għal xi spejjeż ta' monitoraġġ, investigazzjonijiet jew inkella biex jiżguraw konformità ma' dawn ir-regolamenti jew inkella spejjeż oħra relatati mal-kunsens, kundizzjonijiet jew rekwiżiti oħra konessi ma' dawn ir-regolamenti.

Investigazzjoniet mill-awtorità kompetenti u rkuprar ta' l-ispejjeż.

26. L-awtorità kompetenti tista' tagħmel, jew tirranġa biex isiru, dawk l-investigazzjonijiet li tqis meħtieġa, bħala parti mill-eżami jew monitoraġġ ta' notifika ta' rilaxx intenzjonat, tqegħid fis-suq jew xi ħaġa oħra relatata ma' dawn ir-regolamenti, sabiex

hija tkun tista' tevalwa sew in-notifika u tista' titlob lin-notifikant sabiex iħallas jew jikkontribwixxi għal xi spejjeż konessi ma' dawn l-investigazzjonijiet.

PARTI F:

DISPOŻIZZJONIJIET OĦRA

Pubblikazzjoni ta' Skedi bl-ilsien Ingliż.

27. Skedi I sa IX li jinsabu ma' dawn ir-regolamenti qegħdin jiġu pubblikati bl-ilsien Ingliż mat-test Ingliż ta' dawn ir-regolamenti.

Jirrevoka A.L. 170 ta' 1-2002.

28. Ir-Regolamenti ta' l-2002 dwar Tluq Deliberat ta' Organiżmi Modifikati Ġenetikament fl-Ambjent, qegħdin b'dawn jiġu revokati.

SKEDA I A

Techniques referred to in the definition of GMO in regulation 2

PART 1

Techniques of genetic modification referred to in sub-paragraph (a) in the definition of GMO in regulation 2 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 an organism of heritable material prepared outside the organism including microinjection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast 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 2

Techniques referred to in sub-paragraph (b) in the definition of GMO which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Schedule I B:

(1) in vitro fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.

SKEDA I B

Techniques referred to in regulation 3

Techniques or methods of genetic modification yielding organisms to be excluded from this regulation, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques or methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

SKEDA II

Principles for the Environment risk assessment

This Schedule describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environment risk assessment referred to in regulations 4 and 12. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) of the Directive, in order to facilitate the implementation and explanation of this Annex.

Without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, the following terms are described as follows:

- "direct effects" refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;

- "indirect effects" refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.

Observations of indirect effects are likely to be delayed;

- "immediate effects" refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

- "delayed effects" refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environment risk assessment is also that an analysis of the "cumulative long-term effects" relevant to the release and the placing on the market is to be carried out. "Cumulative long-term effects" refers to the accumulated effects of consents on human health and the environment, including *inter alia* flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

A. Objective

The objective of an environment risk assessment is, on a case-by-case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The environment risk assessment should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

B. General Principles

In accordance with the precautionary principle, the following general principles should be followed when performing the environment risk assessment:

- identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

- the environment risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

- the environment risk assessment should be carried out on a case-by-case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, *inter alia*, GMOs already in the environment;

- if new information on the GMO and its effects on human health or the environment becomes available, the environment risk assessment may need to be readdressed in order to:

    - determine whether the risk has changed;

    - determine whether there is a need for amending the risk management accordingly.

C. Methodology

C.1. Characteristics of GMOs and releases

Depending on the case the environment risk assessment has to take into account the relevant technical and scientific details regarding characteristics of:

- the recipient or any parental organism;

- any genetic modification, be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;

- the GMO;

- the intended release or use including its scale;

- the potential receiving environment; and

- the interaction between these.

Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the environment risk assessment

C.2. Steps in the environment risk assessment

In drawing conclusions for the environment risk assessment referred to in regulations 4, 6, 7 and 12 the following points should be addressed:

1. *Identification of characteristics which may cause adverse effects:*

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of any GMO with those of the non-modified organism under corresponding conditions of the release or use, will assist in identifying the particular potential adverse effects arising from the genetic modification. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

- disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C .2(i) in Schedule III A, and B7 in Schedule III B);

- disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2(i) in Schedule III A, and B 7 and D 8 in Schedule III B);

- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Schedule III A);

- altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors;

- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Schedule III A);

- effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Schedule III A, and D 11 in Schedule III B).

Adverse effects may occur directly or indirectly through mechanisms which may include:

- the spread of any GMO in the environment,

- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not,

- phenotypic and genetic instability,

- interactions with other organisms,

- changes in management, including, where applicable, in agricultural practices.

2. *Evaluation of the potential consequences of each adverse effect, if it occurs*

The magnitude of the consequences of each potential adverse effect should be evaluated.

This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which any GMO is intended to be released and the manner of the release.

3. *Evaluation of the likelihood of the occurrence of each identified potential adverse effect*

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which any GMO is intended to be released, and the manner of the release.

4. *Estimation of the risk posed by each identified characteristic of any GMO*

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

5. *Application of management strategies for risks from the deliberate release or marketing of any GMO*

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

6. *Determination of the overall risk of any GMO*

An evaluation of the overall risk of any GMO should be made taking into account any risk management strategies which are proposed.

D. Conclusions on the potential environmental risk from the release or the placing on the market of GMOs

On the basis of an environment risk assessment carried out in accordance with the principles and methodology outlined in sections B and C, information on the points listed in sections D1 or D2 should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental risk from the release or the placing on the market of GMOs:

D.1. In the case of GMOs other than higher plants

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of any proposed release.

2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of any proposed release.

3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.

4. Potential immediate or delayed environmental risk of the direct and indirect interactions between the GMO and target organisms (if applicable).

5. Potential immediate or delayed environmental risk of the direct and indirect interactions between the GMO with non-target organisms, including risk on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

6. Possible immediate or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release.

7. Possible immediate or delayed effects on animal health and consequences for the feed or food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of any GMO release.

9. Possible immediate or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

D.2. In the case of genetically modified higher plants (GMHP)

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to the GMHP.

3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.

4. Potential immediate or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).

5. Possible immediate or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

6. Possible immediate or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of any GMHP release.

7. Possible immediate or delayed effects on animal health and consequences for the feed or food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

8. Possible immediate or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of any GMO release.

9. Possible immediate or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

SKEDA III

Information Required in the Notification

A notification referred to in Part B or Part C of these regulations is to include, as appropriate, the information set out below in the sub-Schedules.

Not all the points included will apply to every case. It is to be expected that individual notifications will address only the particular subset of considerations which is appropriate to individual situations.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and the scale of the proposed release.

Future developments in genetic modification may necessitate adapting this Schedule to technical progress or developing guidance notes on this Schedule. Further differentiation of information requirements for different types of GMOs, for example single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Community.

The description of the methods used or the reference to standardised or internationally recognised methods shall also be mentioned in the dossier, together with the name of the body or bodies responsible for carrying out the studies.

Schedule III A applies to releases of all types of genetically modified organisms other than higher plants. Schedule III B applies to release of genetically modified higher plants.

The term “higher plants” means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

SKEDA III A

Information Required in Notifications concerning Releases of Genetically Modified Organisms other than Higher Plants

I. GENERAL INFORMATION

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of any responsible scientist

C. Title of the project

II. INFORMATION RELATING TO THE GMO

A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):

1. scientific name,

2. taxonomy,

3. other names (usual name, strain name, etc.),

4. phenotypic and genetic markers,

5. degree of relatedness between donor and recipient or between parental organisms,

6. description of identification and detection techniques,

7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,

8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,

9. organisms with which transfer of genetic material is known to occur under natural conditions,

10. verification of the genetic stability of the organisms and factors affecting it,

11. pathological, ecological and physiological traits:

(a) classification of hazard according to existing Community rules concerning the protection of human health or the environment;

(b) generation time in natural ecosystems, sexual and asexual reproductive cycle;

(c) information on survival, including seasonability and the ability to form survival structures;

(d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonise other organisms;

(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

(a) sequence;

(b) frequency of mobilisation;

(c) specificity;

(d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B. Characteristics of the vector

1. nature and source of the vector,

2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO,

3. frequency of mobilisation of inserted vector or genetic transfer capabilities and methods of determination,

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism

1. Information relating to the genetic modification:

(a) methods used for the modification;

(b) methods used to construct and introduce any insert into the recipient or to delete a sequence;

(c) description of the insert or vector construction;

(d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

(e) methods and criteria used for selection;

(f) sequence, functional identity and location of the altered or inserted or deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

(a) description of any genetic trait or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(b) structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism;

(c) stability of the organism in terms of genetic traits;

(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

(e) activity of any expressed protein;

(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

(g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(h) history of previous releases or uses of the GMO;

(i) considerations for human health and animal health, as well as plant health:

(i) toxic or allergenic effects of the GMOs or their metabolic products;

(ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(iii) capacity for colonisation;

(iv) if the organism is pathogenic to humans who are immuno-competent:

- diseases caused and mechanism of pathogenicity including invasiveness and virulence,

- communicability,

- infective dose,

- host range, possibility of alteration,

- possibility of survival outside of human host,

- presence of vectors or means of dissemination,

- biological stability,

- antibiotic resistance patterns,

- allergenicity,

- availability of appropriate therapies.

(v) other product hazards.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release

1. description of the proposed deliberate release, including any purpose and foreseen products,

2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases,

3. preparation of the site previous to the release,

4. size of the site,

5. any method to be used for the release,

6. quantities of GMOs to be released,

7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities),

8. worker protection measures taken during the release,

9. post-release treatment of the site,

10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment,

11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. Information on the environment (both on the site and in the wider environment):

1. geographical location and grid reference of any site (in case of notifications under Part C of any site of release will be the foreseen areas of use of the product),

2. physical or biological proximity to humans and other significant biota,

3. proximity to significant biotopes, protected areas, or drinking water supplies,

4. climatic characteristics of any region likely to be affected,

5. geographical, geological and pedological characteristics,

6. flora and fauna, including crops, livestock and migratory species,

7. description of target and non-target ecosystems likely to be affected,

8. a comparison of the natural habitat of the recipient organism with any proposed site of release,

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

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. biological features which affect survival, multiplication and dispersal,

2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.),

3. sensitivity to specific agents.

B. Interactions with the environment

1. predicted habitat of the GMOs,

2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses,

3. genetic transfer capability

   (a) postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;

   (b) postrelease transfer of genetic material from indigenous organisms to the GMOs;

4. likelihood of postrelease selection leading to the expression of unexpected or undesirable traits in the modified organism,

5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability,

6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.,

7. description of ecosystems to which the GMOs could be disseminated,

8. potential for excessive population increase in the environment,

9. competitive advantage of the GMOs in relation to the unmodified recipient or any parental organism,

10. identification and description of the target organisms if applicable,

11. anticipated mechanism and result of interaction between the released GMOs and any target organism if applicable,

12. identification and description of non -target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction,

13. likelihood of postrelease shifts in biological interactions or in host range,

14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,

15. known or predicted involvement in biogeochemical processes,

16. other potential interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring techniques

1. methods for tracing the GMOs, and for monitoring their effects,

2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques,

3. techniques for detecting transfer of the donated genetic material to other organisms,

4. duration and frequency of the monitoring.

B. Control of the release

1. methods and procedures to avoid or minimise the spread of the GMOs beyond the site of release or the designated area for use,

2. methods and procedures to protect the site from intrusion by unauthorised individuals,

3. methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. type of waste generated,

2. expected amount of waste,

3. description of treatment envisaged.

D. Emergency response plans

1. methods and procedures for controlling the GMOs in case of unexpected spread,

2. methods for decontamination of the areas affected, for example eradication of the GMOs,

3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread,

4. methods for the isolation of the area affected by the spread,

5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

SKEDA III B

Information Required in Notifications concerning Releases of Genetically Modified Higher Plants (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute),

2. Name, qualifications and experience of any responsible scientist,

3. Title of the project,

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:

   (a) family name

   (b) genus

   (c) species

   (d) subspecies

   (e) cultivar or breeding line

   (f) common name.

2. (a) Information concerning reproduction:

      (i) any mode of reproduction

      (ii) specific factors affecting reproduction, if any

      (iii) generation time.

   (b) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

3. Survivability:

   (a) ability to form structures for survival or dormancy

   (b) specific factors affecting survivability, if any.

4. Dissemination:

(a) ways and extent (for example an estimation of how viable pollen or seeds declines with distance) of dissemination

(b) specific factors affecting dissemination, if any.

5. Geographical distribution of the plant.

6. In the case of plant species not normally grown in any of the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

7. Other potential interactions, relevant to the GMO, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.

2. Nature and source of the vector used.

3. Size, source (name) of any donor organism and intended function of each constituent fragment of the region intended for insertion.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of any trait and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted or deleted:

(a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;

(b) in case of deletion, size and function of any deleted region;

(c) copy number of the insert;

(d) any location of any insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.

3. Information on the expression of the insert:

(a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation;

(b) parts of the plant where the insert is expressed (for example roots, stem, pollen, etc.).

4. Information on how the genetically modified plant differs from the recipient plant in:

(a) any mode or rate of reproduction;

(b) dissemination;

(c) survivability.

5. Genetic stability of the insert and phenotypic stability of the GMHP.

6. Any change to the ability of the GMHP to transfer genetic material to other organisms.

7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.

9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

10. Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification.

11. Potential interactions with the abiotic environment.

12. Description of detection and identification techniques for the genetically modified plant.

13. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO REGULATIONS 6 AND 7)

1. Location and size of any release site.

2. Description of the release site ecosystem, including climate, flora and fauna.

3. Presence of sexually compatible wild relatives or cultivated plant species.

4. Proximity to officially recognised biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO REGULATIONS 6 AND 7)

1. Purpose of the release.

2. Foreseen any date and duration of the release.

3. Method by which the genetically modified plants will be released.

4. Method for preparing and managing the release site, prior to, during and postrelease, including cultivation practices and harvesting methods.

5. Approximate number of plants (or plants per m2).

G. INFORMATION ON CONTROL, MONITORING, POSTRELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO REGULATIONS 6 AND 7)

1. Any precautions taken:

   (a) any distance from sexually compatible plant species, both wild relatives and crops

   (b) any measures to minimise or prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).

2. Description of methods for post release treatment of the site.

3. Description of post release treatment methods for the genetically modified plant material including wastes.

4. Description of monitoring plans and techniques.

5. Description of any emergency plans.

6. Methods and procedures to protect the site.

SKEDA IV

Additional Information

This Schedule describes in general terms the additional information to be provided in the case of notification for placing on the market and information for labelling requirements regarding GMOs as or in product to be placed on the market, and GMO exempted under regulation 2 definition of : "placing on the market". Technical guidance notes, as regards, *inter alia*, the description of how the product is intended to be used, may be developed in accordance with the regulatory procedure referred to Article 30 (2) of the Directive, in order to facilitate the implementation and explanation of this Schedule. The labelling of exempted organisms as required by regulation 21 shall be met by providing appropriate recommendations for, and restrictions on, use:

A. The following information shall be provided in the notification for placing on the market of GMOs as or in product in addition to that of Schedule III:

1. proposed commercial names of the products and names of GMOs contained therein, and any specific identification, name or code used by the notifier to identify the GMO. After the consent any new commercial names should be provided to the competent authority,

2. name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,

3. name and full address of any supplier of control samples,

4. description of how the product and the GMO as or in product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted,

5. description of any geographical area and types of environment where the product is intended to be used within the Community, including, where possible, estimated scale of use in each area,

6. intended categories of users of the product e.g. industry, agriculture and skilled trades, consumer use by public at large,

7. information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular GMO products to facilitate post-marketing control and inspection. This information should include where appropriate the lodging of samples of the GMO or its genetic material, with the competent authority and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny, for example the

methodology for detecting and identifying the GMO product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified,

8. proposed labelling on a label or in an accompanying document. This must include, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

B. The following information shall be provided in the notification, when relevant, in addition to that of point A, in accordance with regulation 12 of these regulations:

1. measures to take in case of unintended release or misuse,

2. specific instructions or recommendations for storage and handling,

3. specific instructions for carrying out monitoring and reporting to the notifier. These instructions should be consistent with Schedule VII Part C,

4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes,

5. proposed packaging,

6. estimated production in or imports to the Community,

7. proposed additional labelling. This may include, at least in summarised form, the information referred to in points A 4, A 5, B 1, B 2, B 3 and B 4.

SKEDA V

Criteria for the Application of Differentiated Procedures (Regulation 7)

The criteria referred to in regulation 7(1) are set out below.

1. The taxonomic status and the biology (for example mode of reproduction and pollination, ability to cross with related species, pathogenecity) of the non-modified (recipient) organism shall be well-known.

2. There shall be sufficient knowledge about the safety for human health and the environment of the parental, where appropriate, and recipient organisms in the environment of the release.

3. Information shall be available on any interaction of particular relevance for the risk assessment, involving the parental, where appropriate, and recipient organism and other organisms in the experimental release ecosystem.

4. Information shall be available to demonstrate that any inserted genetic material is well characterised. Information on the construction of any vector systems or sequences of genetic material used with the carrier DNA shall be available. Where a genetic modification involves the deletion of genetic material, the extent of the deletion shall be known. Sufficient information on the genetic modification shall also be available to enable identification of the GMO and its progeny during a release.

5. The GMO shall not present additional or increased risks to human health or the environment under the conditions of the experimental release that are not presented by releases of the corresponding parental, where appropriate, and recipient organisms. Any capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment shall not result in adverse effects.

SKEDA VI

Guidelines for the Assessment Reports

The assessment report provided for by regulations 13, 14, 15 and 17 should include in particular the following:

1. Identification of the characteristics of the recipient organism which are relevant to the assessment of any GMO in question. Identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism.

2. Description of the result of the genetic modification in the modified organism.

3. Assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.

4. Identification of any new risks to human health and the environment that may arise from any release of the GMO in question as compared to any release of the corresponding non-modified organism, based on the environment risk assessment carried out in accordance with Schedule II.

5. A conclusion on whether any GMO in question should be placed on the market or as any product and under which conditions, whether the GMOs in question shall not be placed on the market or whether the views of other competent authorities and the Commission are sought for on specific issues of the environment risk assessment. These aspects should be specified. The conclusion should clearly address the use proposed, risk management and the monitoring plan proposed. In the case that it has been concluded that the GMOs should not be placed on the market, the competent authority shall give reasons for its conclusion.

SKEDA VII

Monitoring Plan

This Schedule describes in general terms the objective to be achieved and the general principles to be followed in the design of the monitoring plan referred to in regulations 12(2), 15(3), 16 (3) and 17. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) of the Directive, in order to facilitate the implementation and explanation of this Schedule.

A. Objective

The objective of a monitoring plan is to:

- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environment risk assessment are correct, and

- identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environment risk assessment

B. General principles

Monitoring, as referred to in regulations 12, 15, 16 and 17, takes place after the consent to the placing of a GMO on the market.

The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the GMO or its use, as such changes may be the result of environmental factors other than the placing of the GMO on the market.

Experience and data gained through the monitoring of experimental releases of GMOs may assist in designing the post marketing monitoring regime required for the placing on the market of GMOs as or in products.

C. Design of the monitoring plan

The design of the monitoring plan should:

1. be detailed on a case by case basis taking into account the environment risk assessment,

2. take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released,

3. incorporate general surveillance for unanticipated adverse effects and, if necessary,

(case-) specific monitoring focusing on adverse effects identified in the environment risk assessment:

3.1. whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the environment risk assessment,

3.2. whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided.

4. facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment.

5. identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment. (Time points and intervals for reports on the results of the monitoring shall be indicated).

6. give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.

SKEDA IX

1. In the case of more than one release of genetically modified plants which have resulted from the same recipient crop plant species but which may differ in any of the inserted or deleted sequences or have the same inserted or deleted sequence but differ in phenotypes, a single notification dossier shall be submitted.

2. A notifier can submit in a single notification information on several releases of genetically modified crop plants, to be released on several different site on the following conditions:

- the taxononic status and biology of the recipient plants species is well known,

- information is available on the interactions of the recipient plant species in the ecosystems in which the experimental or agricultural releases are scheduled,

- scientific data is available on the safety to human health and the environment of experimental releases involving genetically modified plants of the same recipient plant species,

- the inserted sequences and their expression products should be safe for human health and the environment under the conditions of the experimental release,

- the inserted sequences have been well characterized,

- all the inserted sequences are integrated into the plant nuclear genome, all the releases are for an a priori specified programme of work,

- all the releases take place within an a priori specified time period.

4. Only one single consent is required for all the releases described in the single notification submitted to the competent authority. The procedure to be used in granting that consent is the following:

(1) any person, wishing to undertake a deliberate release of a GMO or a combination of GMOs in Malta for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority;

(2) the notification shall include:

(a) a technical dossier supplying the information specified in Schedule II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:

(i) general information including information on personnel and training,

(ii) information relating to any GMO,

(iii) information relating to the conditions of release and the receiving environment,

(iv) information on the interactions between any GMO and the environment,

(v) information on monitoring, control, waste treatment and emergency response plans;

(b) a statement evaluating the impacts and risks posed by any GMO to human health or the environment from the uses envisaged;

(3) the Competent Authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;

(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified or carried out by him either in Malta or abroad. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing;

(5) in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;

(6) in the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the risks for human health or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authority or after the competent authority has given its written consent, the notifier shall immediately:

(a) revise the measures specified in the notification,

(b) inform the competent authority in advance of any modification or as soon as the new information is available,

(c) take the measures necessary to protect human health and the environment.

(7)(i). On receipt and after acknowledgment of the notification the

competent authority shall:

- examine it for compliance with these regulations,

- evaluate the risks posed by the release,

- record its conclusions in writing, and, if necessary,

- carry out tests or inspections as may be necessary for control purposes.

(7) (ii). The competent authority, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with these regulations and that the release may proceed, or

(b) indicating that the release does not fulfil the conditions of these regulations and the notification is therefore rejected.

(7) (iii). For the purpose of calculating the 90-day period referred to in the preceding paragraph, any periods of time during which the competent authority:

- is awaiting further information which it may have requested from the notifier, or

- is carrying out a public inquiry or consultation in accordance with paragraph (8) shall not be taken into account.

(7) (iv). The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

(7) (v). If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

(8) Where the competent authority considers it appropriate, it may consult groups or the public on any aspect of the proposed deliberate release.

(9) After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at a later stage.

5. In order to obtain one single consent covering several releases, all the necessary information for each release should be indicated in the single notification, including sufficient information on the different sites of the releases and on the experimental design, as well as indication of any conditions for risk management for each different release. Clear reference to each release to be covered should be made in the notification, and the appropriate information should be included to allow completion of the summary notification information format.

6. A notifier can also submit a single notification covering a whole, a priori specified, programme of development work with a single specific recipient plant species and a specified range of inserts or deletions over several years and on several different sites, and receive a single consent for the whole programme of work.

6 (1). In such cases, detailed indications or descriptions of the different sites of the releases, subsequent intra-specific sexual crosses or the conditions of release need not be given in the notification, as would be required under the conditions indicated in paragraph 5. However, the notification must contain sufficient information to enable overall an evaluation of risk, and a detailed risk assessment to be made for at least the first release in the programme of work. The information that need not be given may only relate to the sites of the releases, the description of the sites and their surface area, the number of plants released, and the subsequent sexual crosses of the initially notified plants (including progenies) with themselves or with plant lines of the initially notified recipient plant species (including the progenies of these crossings).

7. In the cases referred to in paragraph 6 (1) the notifier will submit to the competent authority the additional information together with a statement indicating whether the original risk assessment remains valid and if not, provide further evaluation. This information should be sent before the specific release to which it refers is carried out, in the form of a simple additional notice for information only.

7 (1). The notifier can proceed with the release in question after 15 days from the date of receipt by the competent authority of this additional information, unless he receives written indication from the competent authority.

7 (2). If any new information submitted is such that the original consent under simplified procedures is no longer applicable, then it is for the competent authority to indicate to the notifier within 15 days of receipt of the notification that he may only proceed with the intended release if a consent is granted under the standard procedure laid down in these regulations.

8. When the single consent under simplified procedures is granted, conditions can be attached to each of the releases to which it refers. These conditions can subsequently be altered by the competent authority, as indicated in paragraph 4(7)(v).

9. On completion of one or more of the releases approved within the simplified procedure, the notifier shall submit to the competent authority a report with the results

of any release at the time specified in the consent. Such reports may be submitted separately, or as a clearly identifiable section in support of a notification for subsequent releases.

10. The competent authority may alter the conditions of the original consent or intervene to alter the conditions of specific subsequent releases on the basis of the results indicated in the reports or on the basis of information obtained during inspections.

L.N. 485 of 2010

ENVIRONMENT PROTECTION ACT
(CAP. 435)

Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2010

BY virtue of the powers conferred by articles 9, 10, 11 and 23 of the Environment Protection Act, the Prime Minister has made the following regulations:-

Citation.

1. (1) The title of these regulations is the Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2010.

Objectives.

(2) In accordance with the precautionary principle, the objective of these regulations is to provide for the protection of human health and the environment when:

(a) carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within Malta,

(b) placing on the market genetically modified organisms as or in products within Malta.

(3) These regulations provide the provisions required for the implementation in Malta of the European Council Directive 2001/18/EC of the 12th of March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and shall be read and construed as one with such legal instrument.

PART A : GENERAL PROVISIONS

Interpretation.

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

"the Commission" means the European Commission;

"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;

"deliberate release" means any intentional introduction into the environment of a GMO or a combination of GMOs for which no 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;

"the Directive" means Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC;

"environment risk assessment" means the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Schedule II;

"genetically modified organism" (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, and within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Schedule I A, part 1;

(b) the techniques listed in Schedule I A, part 2, are not considered to result in genetic modification;

"Member State" means Member State of the European Community;

"notification" means the submission, in writing and digital format, of the information required under these regulations to the Competent Authority;

"notifier" means any legal or physical person submitting a notification or, where the context so requires, any legal or physical person responsible for a deliberate release or for a placing on the market, or for meeting any other requirement of these regulations in relation to a deliberate release or a placing on the market;

"organism" means any biological entity capable of replication or of transferring genetic material;

"placing on the market" means making available to third parties, whether in return for payment or free of charge; the following operations shall not be regarded as placing on the market:

(a) making available genetically modified micro-organisms for activities regulated under the Contained use of Genetically Modified Micro-organisms Regulations, 2008 including culture collections;

L.N. 127 of 2008.

(b) making available GMOs other than micro-organisms referred to in paragraph (a), to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with, and to provide a high level of safety for the general population and the environment, the measures should be based on the same principles of containment as laid down in the Contained use of Genetically Modified Micro-organisms Regulations, 2008;

(c) making available GMOs to be used exclusively for deliberate releases complying with the requirements laid down in Part B of these regulations;

"product" means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market.

Exemptions.

3. (1) These regulations shall not apply to organisms obtained through the techniques of genetic modification listed in Schedule I B.

(2) These regulations shall not apply to the carriage of genetically modified organisms by road, sea or air.

General obligations.

4. (1) GMOs may only be deliberately released or placed on the market in conformity with Part B or Part C of these regulations respectively.

(2) Any person shall, before submitting a notification under Part B or Part C, carry out an environment risk assessment. The information which may be necessary to carry out the environment risk assessment is laid down in Schedule III. GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment shall be taken into particular consideration when carrying out an environment risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall have taken place by the 31st December 2004 in the case of GMOs placed on the market according to Part C and by 31st December 2008 in the case of GMOs authorised under Part B.

(3) Potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, shall be accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Schedule II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.

(4) The competent authority shall be responsible for ensuring compliance with the requirements of these regulations, and it shall examine notifications under Part B and Part C for compliance with the requirements of these regulations and whether the assessment provided for in sub-regulation (2) is appropriate.

(5) The competent authority shall organise inspections and other control measures as appropriate, to ensure compliance with these regulations. In the event of a release of any GMO or placing on the market as or in products for which no authorisation was given, the competent authority shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform the public, the Commission and other Member States.

PART B:

DELIBERATE RELEASE OF GMOs FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET

Applicability of regulations 6 to 10.

5. (1) Regulations 6 to 10 shall not apply to medicinal substances and compounds for human use consisting of, or containing, a GMO or combination of GMOs provided that their deliberate release for any purpose other than that of being placed on the market is authorised through the Medicines (Marketing Authorisation) Regulations, 2007 and Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, which provide:

L.N. 324 of 2007.

(a) for a specific environment risk assessment in accordance with Schedule II and on the basis of the type of information specified in Schedule III without prejudice to additional requirements provided for by the said legislation;

(b) for explicit consent prior to release;

(c) for a monitoring plan in accordance with the relevant parts of Schedule III, with a view to detecting the effects of the GMO or GMOs on human health or the environment;

(d) in an appropriate manner for requirements relating to treatment of new items of information, information to the public, information on the results of releases, and exchanges of information at least equivalent to those contained in these regulations and in the measures taken in accordance therewith.

(2) Assessment of the risks to the environment presented by such substances and compounds shall be carried out, in accordance with the provisions of Article 5 of the Directive.

Standard Authorisation Procedure.

6. (1) Without prejudice to regulation 5, any person shall, before undertaking a deliberate release of a GMO or of a combination of GMOs, submit a notification to the competent authority.

(2) The notification referred to in sub-regulation (1) shall include:

(a) a technical dossier supplying the information specified in Schedule III necessary for carrying out the environment risk assessment of the deliberate release of a GMO or combination of GMOs, in particular:

(i) general information including information on personnel and training,

(ii) information relating to any GMO,

(iii) information relating to the conditions of release and the potential receiving environment,

(iv) information on the interactions between any GMO and the environment,

(v) a plan for monitoring in accordance with the relevant parts of Schedule III in order to identify effects of any GMO on human health or the environment,

(vi) information on control, remediation methods, waste treatment and emergency response plans,

(vii) a summary of the dossier in the format established in accordance with the procedure laid down in Article 30 (2) of the Directive.

(b) the environment risk assessment and the conclusions required in Schedule II, section D, together with any bibliographic reference and indications of the methods used.

(c) 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 notifier may refer to data or results from notifications previously submitted by other notifiers, provided that the information, data and results are non confidential or these notifiers have given their agreement in writing, or may submit additional information he considers relevant.

(4) The competent authority may accept that releases of the same GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

(5) On receipt of the notification under regulation 6 (1) the competent authority shall :

(a) acknowledge to the notifier the date of such receipt in writing;

(b) forward to the Commission, within 30 days of receipt of the notification, a copy of the summary of the notification received in accordance with sub-regulation 2(a) (vii);

(c) examine it for compliance with these regulations;

(d) consider any observations received from a competent authority of another Member State in accordance with Article 11 (2) of the Directive;

(e) if requested by a competent authority of another Member State for the purposes of the Directive, forward a copy of the full notification to the said authority;

(f) evaluate the risks posed by the proposed deliberate release for human health and the environment, and;

(g) record its conclusions in writing.

(6) The competent authority shall respond in writing to the notifier within 90 days of receipt of the notification by indicating that consent to the deliberate release is either –

(a) granted, with or without, conditions, or

(b) refused and the reasons for the refusal.

(7) For the purpose of calculating the 90 day period referred to in sub-regulation 5, no account shall be taken of any periods of time during which the competent authority:

(a) is awaiting further information which it may have requested from the notifier, or

(b) is carrying out a public inquiry or consultation in accordance with regulation 9; this public inquiry or consultation shall not prolong the 90 day period referred to in sub-regulation (5) by more than 30 days.

(8) If the competent authority requests new information it shall simultaneously give its reasons for so doing.

(9) The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

(10) No material derived from GMOs which are deliberately released in accordance with Part B shall be placed on the market, unless in accordance with Part C.

Differentiated procedures.

7. (1) If sufficient experience has been obtained of releases of certain GMOs in certain ecosystems, and the GMOs concerned meet the criteria set out in Schedule V, the competent authority, in accordance with the procedure set through Article 7 of the Directive, may apply differentiated procedures to such types of GMOs.

(2) The notifier may proceed with the release only when he has received the written consent of the competent authority, and in accordance with the minimum amount of Schedule III technical information necessary for evaluating any foreseeable risks from release, in particular:

(a) information relating to GMOs;

(b) information relating to conditions of release and potential receiving environment;

(c) information on interactions between GMOs and environment;

(d) environment risk assessment.

(3) Without prejudice to sub-regulations (1) and (2), the simplified procedures concerning the deliberate release into the environment of genetically modified plants, in the case of more than one release of genetically modified plants which have resulted from the same recipient crop plant species but which

may differ in any of the inserted or deleted sequences or have the same inserted or deleted sequence but differ in phenotypes as shall be those laid down in Schedule IX.

Handling of modifications and new information.

8. (1) In the event of any modification of, or unintended change to, the deliberate release of a GMO or of a combination of GMOs which could have consequences with regard to risks for human health and the environment after the competent authority has given its written consent, or if new information has become available on such risks, either while the notification is being examined by the competent authority or after the competent authority has given its written consent, the notifier shall immediately:

(a) take the measures necessary to protect human health and the environment;

(b) inform the competent authority in advance of any modification or as soon as the unintended change is known or the new information is available;

(c) revise the measures specified in the notification.

(2) If information becomes available to the competent authority referred to in sub-regulation (1) which could have significant consequences with regard to risks for human health and the environment or under the circumstances described in sub-regulation (1), the competent authority:

(a) shall evaluate such information and make it available to the public;

(b) may require the notifier to modify the conditions of, suspend or terminate the deliberate release and shall inform the public thereof;

(c) may require the notifier to defray or contribute towards any or all of the costs incurred by it in order to protect human health and the environment.

(3) With respect to both sub-regulations (1) and (2) above, the notifier shall amend the notification on which consent was granted and submit the amended notification to the competent authority.

(4) Where the competent authority receives an amended notification in accordance with sub-regulations (1) and (2), it shall deal with the amended notification as if it were a new notification under regulation 6 in relation to the proposed modified deliberate release.

(5) The notifier shall not proceed with the proposed modified deliberate release unless he has received written consent from the competent authority.

Consultationing and informing the public.

9. (1) The competent authority shall, without prejudice to the provisions of regulations 7 and 20, consult the public and, where appropriate, groups on the proposed deliberate release.

(2) Subject to sub-regulation (3), the notifier of a proposed deliberate release for the purposes other than placing on the market shall, not more than 14 days after the date of receipt by the competent authority of the notification, cause to be published in a prominent local newspaper a notice with heading "PROPOSED DELIBERATE RELEASE OF A GENETICALLY MODIFIED ORGANISM" and containing the following information –

(a) the name and address of the notifier,

(b) the description of the genetically modified organism proposed to be released,

(c) the fact that a notification has been submitted to the competent authority, and the location and purpose of the proposed deliberate release,

(d) the period of time in which the proposed deliberate release is to be carried out,

(e) the fact that further information on the proposed deliberate release may be obtained from the competent authority,

(f) the full title of the competent authority and the full postal address of its headquarters,

(g) the fact that, in accordance with sub-regulation (5), any person or body may, within the period of 28 days beginning on the day of publication of the notice, make representations in writing to the competent authority regarding the notification,

and shall send a copy of the notice to the competent authority within the said 14 days.

(3) The information on the location of the proposed deliberate release published pursuant to sub-regulation (2) shall be the same as the information on its location which is placed on the register maintained by the competent authority in accordance with regulation 22, and, for that purpose, the notifier shall ascertain from the competent authority the information on the location which is to be or has been placed on the said register.

(4) The notifier shall, not more than 14 days after the date of receipt by the competent authority of the notification, send a copy of the notice published pursuant to sub-regulation (2) to –

(a) the owner of the site of the proposed deliberate release, if the said owner is a person other than the notifier, and

(b) the competent authority.

(5) Any person or body may, within the period of 28 days beginning on the day of publication of a notice pursuant to sub-regulation (2), make representations to the competent authority in relation to the notification. The representations shall be –

(a) made in writing,

(b) addressed to the competent authority at its headquarters,

(c) forwarded so as to reach the competent authority within the period of 28 days beginning on the day of publication of the notice pursuant to sub-regulation (2).

(6) Representations which do not comply with sub-regulation (5) shall be invalid. Where the competent authority receives representations in accordance with sub-regulation (5), it shall –

(a) acknowledge receipt of the representations, and

(b) consider the representations in determining the notification.

Reporting by notifiers on releases.

10. (1) The notifier shall:

(a) on completion of the deliberate release, and

(b) at any subsequent intervals specified in the consent,

submit a report to the competent authority on the results of the deliberate release.

(2) The report referred to in sub-regulation (1) shall be provided in such a format or formats as may be determined in accordance with the procedure laid down in Article 30(2) of the Directive, or in the absence of such a determination appropriate to the relevant consent, in such format as may be specified in the consent, and shall include:

(a) a post-release evaluation of the risks to human health or the environment, and

(b) where appropriate, a statement on the results of the deliberate release in relation to any product, or type of product, in respect of which consent to placing on the market may be sought.

(3) A copy of any report received by the competent authority pursuant to sub-regulation (1) shall, after its receipt, be sent by the competent authority to the Commission in accordance with Article 11 (3) of the Directive.

PART C:

PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS

Sectoral legislation.

11. (1) Regulations 12 to 19 shall not apply to any GMO as or in products, as far as they are authorised by any relevant legislation which provides for a specific environment risk assessment, to be carried out in accordance with the principles set out in Schedule II and on the basis of information specified in Schedule III, without prejudice to additional requirements provided for by the relevant legislation, and for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in these regulations, or in any other relevant regulations concerning medicinal products for human and veterinary use.

Duty to comply with Part C.

(2) Without prejudice to Schedule I B and subject to the exclusions in sub-regulation (1), a person shall not place on the market any product containing or consisting of a genetically modified organism unless:

(a) consent in writing has been received from the competent authority under Part C, or

(b) consent in writing has been received from the competent authority of another Member State in accordance with Part C of the Directive,

and the conditions attached to the consent have been complied with.

Notification procedure.

12. (1) (a) Before a GMO or a combination of GMOs as or in products is placed on the market for the first time, a notification shall be submitted to the competent authority.

(b) The competent authority shall acknowledge the date of receipt of the notification.

(c) The competent authority shall without delay examine whether the notification is in accordance with sub-regulation (2) and shall, if necessary, ask the notifier for additional information.

(2) The notification shall contain:

(a) the information required in Schedules III and IV. This information shall take into account the diversity of sites of use of the GMO as or in a product and shall include information on data and results obtained from research and developmental conclusions concerning the impact of the release on human health and the environment;

(b) the environment risk assessment and the conclusions required in Schedule II;

(c) the conclusions arrived at by the notifier in accordance with Schedule II, together with any bibliographic references and details of the methods used;

(d) the conditions for the placing on the market of the product, including specific conditions of use and handling;

(e) with reference to regulation 14(4), a proposed period for the consent which should not exceed ten years;

(f) a plan for monitoring in accordance with Schedule VII, including a proposal for the time-period of the monitoring plan; this time period may be different from the proposed period for the consent;

(g) a proposal for labelling which shall comply with the requirements laid down in Schedule IV and, the labelling shall clearly state that a GMO is present and, the words "this product contains genetically modified organisms" shall appear either on a label or in an accompanying document;

(h) a proposal for packaging which shall comprise the requirements laid down in Schedule IV;

(i) a summary of the notification as may be established by the competent authority from time to time in the format established in accordance with the procedure laid down in Article 30 (2) of the Directive; this shall also apply in a case to which Article 16 of the Directive applies;

(j) the applicant shall clearly indicate whether the application would prejudice any enforcement case, court case or other causes currently *sub-judice*.

Provided that if on the basis of the results of any release notified under part B, or on other substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a GMO as or in a product do not pose a risk to human health and the environment, he may propose to the competent authority not to provide part or all of the information required in Schedule IV, section B.

(3) The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified or carried out by the notifier either in Malta or abroad.

(4) The notifier may also refer to data or results from notifications previously submitted by other notifiers or submit additional information he considers relevant, provided that the information, data and results are non-confidential or these notifiers have given their agreement in writing.

(5) The notifier proposing to place a product containing or consisting of a genetically modified organism on the market for the first time shall publish a notice as per regulation 9 with the wording "PROPOSED PLACING ON THE MARKET OF A PRODUCT CONTAINING/CONSISTING OF A GENETICALLY MODIFIED ORGANISM". In addition to the requirements laid down in regulation 9 (2) the notice shall also include –

(a) the full postal address of the Commission,

(b) with respect to an application submitted in accordance with sub-regulation (1), regulation 9 (2)(g) shall not apply and shall be replaced by sub-regulation 5 (c) below,

(c) the fact that any person or body may make representations in writing to the said Commission regarding the notification within the period of 30 days beginning on the day that the Commission makes the summary of the notification received by it in accordance with regulation 13 (b) available to the public.

(6) In order for a GMO or combination of GMOs to be used for a purpose different from that already specified in a notification, a separate notification shall be submitted.

(7) If new information has become available with regard to the risks of the GMO to human health or the environment, before the written consent is granted, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof. In addition, the notifier shall revise the information and conditions specified in the notification and submit an amended notification to the competent authority, and the first notification under sub-regulation (1) shall not be further considered by the competent authority.

Assessment report.

13. (1) On receipt of a notification under regulation 12 (2) the competent authority shall:

(a) acknowledge to the notifier the date of such receipt in writing,

(b) immediately forward a copy of the summary notification received in accordance with regulation 12 (2)(h)

to the competent authorities of the other Member States for the purposes of the Directive and to the Commission,

(c) examine it for compliance with these regulations and in particular regulation 12,

(d) ask the notifier in writing for any further information which the competent authority considers necessary, stating its reasons for so doing. Any periods of time during which the competent authority is awaiting further information shall not be taken into account when calculating the 90 day period referred to in sub-regulation (2),

(e) send a copy of the notification to the Commission once it is satisfied that the requirements of regulation 12 have been complied with, and no later than the time at which it sends to the Commission a copy of the assessment report mentioned in accordance with sub-regulation (3) or (4).

(2) Within 90 days of the receipt of a notification under regulation 12, the competent authority shall:

(a) prepare, in accordance with Schedule VI, an assessment report which shall also indicate whether:

(i) the genetically modified organism concerned should be placed on the market and under which conditions (referred to as a "favourable assessment"); or

(ii) the genetically modified organism concerned should not be placed on the market (referred to as an "unfavourable assessment"), and

(b) send a copy of the assessment report to the notifier.

(3) In the case of a favourable assessment, the competent authority shall send a copy of the assessment report to the notifier and to the Commission, any further information obtained from the notifier in accordance with sub-regulation (l)(d), and any other information on which the competent authority has based its report.

(4) In the case of an unfavourable assessment, the competent authority shall, no sooner than 15 days after it sends a copy of the assessment report to the notifier and no later than 105

days after it received the notification, send to the Commission a copy of the said report, any further information obtained from the notifier in accordance with sub-regulation (1)(d), and any other information on which the competent authority has based its report.

Standard procedure.

14. (1) In the case of a favourable assessment, the competent authority shall:

(a) provide any further information to the Commission, where such information is requested by the said Commission or by a competent authority of a Member State for the purposes of the Directive,

(b) consider any comments, or reasoned objections concerning the placing of the product on the market made by the Commission or by a competent authority of another Member State for the purposes of the Directive where such comments or objections are made within a period of 60 days beginning on the day on which the documents referred to in regulation 13(3) were forwarded to each such competent authority by the Commission, and

(c) participate in any discussions in relation to the assessment report initiated by the Commission on grounds of reasoned objections made in accordance with paragraph (b) with a view to reaching an agreement within a period of 105 days, beginning on the day on which the documents referred to in regulation 13(3) were forwarded to each such competent authority by the Commission:

Provided that any periods of time during which further information from the notifier is awaited shall not be taken into account for the purpose of calculating the final 45 day period for arriving at an agreement.

(2) The competent authority shall grant consent to the notifier, in writing, to place the product on the market where it has concluded a favourable assessment of the proposal, and

(a) no reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation 1(b), or

(b) a reasoned objection to the favourable assessment

has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation 1(b) but the matters concerned have been resolved in accordance with the provisions of Article 15(1) of the Directive, or

(c) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation 1(b) and the said Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(3) The competent authority shall, within a period of 30 days beginning on the day that a consent is granted, inform the competent authority of each Member State and the Commission that it has done so.

(4) The competent authority shall, where it has concluded an unfavourable assessment, or where the Commission has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, inform the notifier in writing, that consent is refused and stating the reasons for the refusal.

(5) Subject to the provisions of sub-regulation (6), the competent authority shall not grant a consent under Part C for a period which exceeds 10 years beginning on the date on which the consent is issued.

(6) In cases relating to a genetically modified organism or a progeny of that organism intended only for the marketing of its seeds under legislation of the European Union for the time being in force, or to genetically modified forest reproductive material, the period of first consent shall be limited in accordance with the provisions of Article 15(4) of the Directive.

Renewal of consent.

15. (1) By way of derogation from regulations 12, 13 and 14, the procedure set out in sub-regulations (2) to (5) shall be applied to the renewal of consents granted under Part C.

(2) A person seeking to renew a consent granted by the competent authority under regulation 14 or a consent previously renewed under this regulation shall:

(a) submit a notification to the competent authority no later than 9 months before the expiry of the consent that it is proposed to have renewed,

(b) a person who has submitted a notification under this regulation may continue to market the product concerned in accordance with the terms and conditions of the relevant consent until a final decision has been made on the notification.

(3) A notification in accordance with sub-regulation 2 (a) shall include:

(a) a copy of the consent granted by the competent authority to the product being placed on the market and of any renewed consent,

(b) a report on the monitoring carried out in accordance with regulation 17,

(c) any new information that has become available with regard to the risks of the product to human health or to the environment, and

(d) any proposals the notifier considers appropriate for the amendment of, or measures additional to, the conditions contained in the original consent granted by the competent authority, including conditions relating to future monitoring and time limitation of the consent.

(4) On receipt of a notification under sub-regulation (2), the competent authority shall:

(a) acknowledge to the notifier the date of such receipt in writing,

(b) examine it for compliance with sub-regulation (3),

(c) ask the notifier in writing for any further information which the competent authority considers necessary, stating its reasons for so doing,

(d) prepare, in accordance with Schedule V, an assessment report which shall indicate:

(i) whether the genetically modified organism concerned should remain on the market and under which conditions (referred to as a "favourable assessment");

(ii) or the genetically modified organism concerned should not remain on the market (referred to as a "unfavourable assessment"),

(e) send a copy of the notification and of the assessment report to the Commission, and

(f) send a copy of the assessment report to the notifier.

(5) In the case of a favourable assessment, the competent authority shall:

(a) provide any further information to the Commission where such information is requested by the said Commission or by a competent authority of a Member State for the purposes of the Directive,

(b) consider any comments, concerns or reasoned objections to the product remaining on the market made by the Commission or by a competent authority of another Member State for the purposes of the Directive where such comments or objections are made within a period of 60 days beginning on the day on which the documents referred to in sub-regulation 4(d) were forwarded to each such competent authority by the Commission, and

(c) participate in any discussions in relation to the assessment report initiated by the Commission on the grounds of reasoned objections made in accordance with paragraph (b) with a view to reaching an agreement within a period of 75 days, beginning on the day on which the documents referred to in sub-regulation 4(d) were forwarded to each such competent authority by the Commission.

(6) The competent authority shall renew consent to market a product where it has concluded a favourable assessment of the proposal, and -

(a) no reasoned objection to the favourable assessment

has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation 4(d), or

(b) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation 4(d) but the matters concerned have been resolved in accordance with the provisions of Article 17(7) and (8) of the Directive, or

(c) a reasoned objection to the favourable assessment has been made raised by the Commission or by a competent authority of a Member State in accordance with sub-regulation 4(d) and the said Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(7) The competent authority shall, within a period of 30 days beginning on the day that consent is renewed, inform the competent authority of each Member State and the Commission that it has done so.

(8) The competent authority shall, where it has concluded an unfavourable assessment, or where the Commission has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, inform the notifier that renewal of the consent is refused and stating the reasons for the refusal.

(9) A renewal or a refusal of consent under this regulation shall be conveyed by the competent authority to the notifier in writing. In the case of a renewal of consent, its validity shall not exceed ten years and may be limited or extended as appropriate for specific reasons.

Consent.

16. (1) Only if a written consent has been given for the placing on the market of a GMO as or in a product by a competent authority of a Member State may that product be used without further notification to the competent authority in so far as the specific conditions of use and the environment or geographical areas stipulated in these conditions are strictly adhered to.

(2) (a) The notifier may proceed with the placing on the market only when he has received the written consent of

the competent authority in accordance with regulations 14 and 15 and in conformity with any conditions required in that consent.

(b) The competent authority shall take all necessary measures to ensure that any written consent is made accessible to the public and that conditions specified in the written consent are complied with.

(3) The written consent referred to in regulations 14 and 15 shall, in all cases, explicitly specify:

(a) the scope of the consent, including the identity of any GMO to be placed on the market as or in products, and their unique identifier;

(b) the period of validity of the consent;

(c) the conditions for the placing on the market of the product, including any specific condition of use, handling and packaging of any GMO as or in products, and conditions for the protection of particular ecosystems, environments or geographical areas;

(d) that, without prejudice to regulation 20, the notifier shall make control samples available to the competent authority on request;

(e) the labelling requirements, in compliance with the requirements laid down in Schedule IV. The labelling shall clearly state that a GMO is present. The words "This product contains genetically modified organisms" shall appear either on a label or in a document accompanying the product or other products containing any GMO;

(f) monitoring requirements in accordance with Schedule VII, including obligations to report to the Commission, the time period of the monitoring plan and, where appropriate, any obligations on any person selling the product or any user of it, *inter alia*, in the case of any GMO grown, concerning a level of information deemed appropriate on their location.

Monitoring and handling of new information.

17. (1) Following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent. On the basis of these reports, in accordance with the consent and within the framework for the monitoring plan specified in the consent, the competent authority may adapt the monitoring plan after the first or subsequent monitoring period.

(2) If new information has become available, from the users or other sources, with regard to the risks of any GMO to human health or the environment after the written consent has been given, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof.

(3) If information becomes available to the competent authority which could have consequences for the risks of any GMO to human health or the environment, or under the circumstances described in sub-regulation (2), it may avail itself of the provisions in regulation 14 where appropriate, when the information has become available before the written consent.

(4) If, after granting consent under regulation 14 or renewing a consent under regulation 15, the competent authority is informed or becomes aware, of information which could have consequences for the risks of any GMO to human health or the environment, or under the circumstances described in sub-regulation (2), it shall:

(a) immediately forward the information to the Commission and to the competent authorities of the Member States for the purposes of the Directive,

(b) prepare an assessment report in accordance with Schedule V which shall indicate:

(i) whether the genetically modified organism concerned should remain on the market and under which conditions (referred to as "favourable assessment");

(ii) or the genetically modified organism concerned should not remain on the market (referred to as "unfavourable assessment"),

(c) within 60 days of the receipt of the information,

forward a copy of the assessment report to the Commission, and

(d) send a copy of the assessment report to the notifier. If the competent authority deems through the assessment report, that the new information provides considerable changes to the notification, the competent authority may ask the notifier to cease marketing under this regulation and submit an amended notification:

Provided that in case of impacts to human health and the environment, the notifier may be asked to defray or contribute towards any or all of the costs incurred by it in order to protect human health and the environment.

(5) In the case of a favourable assessment, the competent authority shall:

(a) provide any further information to the Commission where such information is requested by the said Commission or by a competent authority of a Member State for the purposes of the Directive;

(b) consider any comments, concerns or reasoned objections to the assessment report referred to in sub-regulation 4(b)(i) made by the Commission or by a competent authority of another Member State for the purposes of the Directive where such comments or objections are made within a period of 60 days beginning on the day on which a copy of the said assessment report was forwarded to each such competent authority by the Commission, and

(c) participate in any discussions in relation to the assessment report initiated by the Commission on the grounds of reasoned objections made in accordance with paragraph (b) with a view to reaching an agreement within a period of 75 days, beginning on the day on which the documents referred to in sub-regulation 4(b)(i) were forwarded to each such competent authority by the Commission.

(6) The competent authority shall consent to the continued marketing of a product where it has concluded a favourable assessment of the information, and -

(a) no reasoned objection to the favourable assessment

has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation 5(b), or

(b) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation 5(b) but the matters concerned have been resolved in accordance with the provisions of Article 20 (3) of the Directive, or

(c) a reasoned objection to the favourable assessment has been made by the Commission or by a competent authority of a Member State in accordance with sub-regulation 5(b) and the said Commission has adopted a favourable decision in accordance with the provisions of Article 18(1) of the Directive.

(7) The competent authority shall, within a period of 30 days beginning on the day that consent to the continued marketing is granted, inform the competent authority of each Member State and the Commission that it has done so.

(8) The competent authority shall, where it has concluded an unfavourable assessment, or where the Commission has adopted an unfavourable decision in accordance with the provisions of Article 18(1) of the Directive, direct the notifier to cease marketing the product and stating the reasons for the direction.

(9) The notifier shall comply with any direction given by the competent authority under sub-regulation (8).

(10) A consent to continue, or a direction to cease, marketing under this regulation shall be conveyed by the competent authority to the notifier in writing.

(11) The competent authority shall make the results of the monitoring carried out under Part C of these regulations publicly available.

Labelling.

18. (1) At all stages of the placing on the market, the labelling and packaging of any GMO placed on the market as or in products shall comply with the relevant requirements specified in the written consent referred to in regulations 14(2), and 16(3).

(2) For products where adventitious or technically unavoidable traces of any authorised GMO cannot be excluded, the competent authority may establish a minimum threshold below which these products shall not have to be labelled in accordance with sub-regulation (1).

(3) For products intended for direct processing, sub-regulation (1) shall not apply to traces of any authorised GMO in proportions no higher than 0.9% or lower thresholds, provided that these traces are adventitious or technically unavoidable.

Saving.

19. (1) Without prejudice to this regulation the competent authority may not prohibit, restrict or impede placing on market of any GMO, as or in products, which comply with these regulations except where, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, the competent authority has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under these regulations constitutes a risk to human health or the environment, the competent authority may provisionally restrict or prohibit the use or sale of that GMO as or in a product.

(2) The competent authority shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including giving information to the public.

(3) For the purposes of sub-regulation (1), the procedures mentioned in regulation 17 shall be adopted.

PART D:

CONFIDENTIALITY AND PUBLIC REGISTER

Confidentiality.

20. (1) The competent authority shall not divulge to third parties any confidential information notified or exchanged under these regulations and shall protect intellectual property rights relating to the data received.

(2) The notifier may indicate the information in the notification submitted under these regulations, the disclosure of which might harm his competitive position and which should

therefore be treated as confidential, and verifiable justification must be given in such cases.

(3) The competent authority shall, after consultation with the notifier, decide which information will be kept confidential and shall inform the notifier of its decisions.

(4) In no case may the following information when submitted according to regulations 6, 7, 8, 12, 15, 17 or 19 be kept confidential:

(a) general description of any GMO, name and address of the notifier, purpose of the release, location of release and intended uses;

(b) methods and plans for monitoring of any GMO and for emergency response;

(c) environment risk assessment.

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

Labelling of GMOs referred to in the definition of "placing on the market" in regulation 2.

21. Any GMO to be made available for operations referred to in the definition of "placing on the market" in regulation 2 (1), shall be subject to adequate labelling requirements in accordance with the relevant sections of Schedule IV in order to provide for clear information, on a label or in an accompanying document, on the presence of GMOs. To that effect the words "This product contains genetically modified organisms" shall appear either on a label or in an accompanying document.

Establishment of public registers.

22. (1) Without prejudice to sub-regulation (2) and point A No 7 of Schedule IV, the competent authority shall:

(a) establish public registers in which the location of the release of any GMO under Part B is recorded;

(b) also establish registers for recording the location of GMOs grown under Part C, *inter alia* so that the possible effects of such GMOs on the environment may be monitored in accordance with the provisions of regulation 16(3)(f) and 17(1).

(2) Without prejudice to such provisions in regulation 16 and 17, the said locations shall:

- be notified to the competent authority, and

- be made known to the public in the manner deemed appropriate by the competent authority.

PART E:

OFFENCES

23. (1) Any person who: Offences.

(a) fails to observe any provision of these regulations or any other lawful order given by virtue of any provision of these regulations; or

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

(c) fails to observe any condition of a permit or consent granted under the provisions of these regulations; or

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

(e) 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 consent under these regulations; or

(d) conspires or attempts, or aids, or abets, any other person by whatever means, including advertising, counselling or procurement 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 provisions of these regulations, or to contravene any restriction, prohibition or requirement imposed by or under the said regulations,

shall be guilty of an offence under these regulations.

(2) Any person who commits an offence against these regulations shall, on conviction, be liable: Penalties.

(a) on a first conviction to a fine (*multa*) of not less than twelve thousand euro but not exceeding fifty-eight thousand euro;

(b) on a second or subsequent convictions, to a fine (*multa*) of not less than thirty-five thousand euro, but not exceeding fifty-eight 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, the revocation of the permit issued by the competent authority and the confiscation of the *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.

(4) Any person who has been found guilty of committing an offence against these regulations shall also pay for the expenses incurred for the keeping, transport and remedying the damage caused by the said infringement, and for any other expense incurred or mitigation measures required to remedy such doings, damage and infringement.

Applicability of the Criminal Code, Cap. 9.

(5) 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.

(6) 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.

(7) 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.

PART E:

FEES

Fee for notification of a proposed deliberate release.

24. (1) A fee shall be paid to the competent authority in respect of a notification under regulation 6 of a proposed deliberate release for purposes other than placing on the market.

(2) The fee payable under sub-regulation (1) shall be €37,000.

Fee for notification of a proposed placing of a product on the market and renewal of consent.

(3) A fee shall be paid to the competent authority in respect of a notification under regulation 12 of a proposed placing on the market of a product and a notification under regulation 15 of a proposal for renewal of a consent.

(4) The fee payable under sub-regulation (3) shall in each case be €47,000.

Fee for amended notification in relation to a deliberate release.

(5) A fee shall be paid to the competent authority in respect of an amended notification under regulation 8(3) in relation to a deliberate release for purposes other than placing on the market.

(6) The fee payable under sub-regulation (5) shall be €5,000.

Fee for amended notification of a proposed placing of a product on the market.

(7) A fee shall be paid to the competent authority in respect of an amended notification under regulation 12(6) and 17(4)(d) in connection with the proposed placing of a product on the market.

(8) The fee payable under sub-regulation (7) shall in each case be €14,000.

Periodic charges for monitoring.

25. The competent authority may require a notifier to make periodic payments, not exceeding the costs incurred by the competent authority, for the purpose of defraying or contributing towards the costs incurred by the competent

authority in monitoring, carrying out inspections, or otherwise ensuring compliance with the requirements of these regulations and any other expenses related to the consent, conditions or other requirements pursuant to these regulations.

Investigations by the competent authority and recovery of costs.

26. The competent authority may carry out, or arrange to have carried out, such investigations as it considers necessary, as part of its examination or monitoring of a notification of a deliberate release, placing on the market or other matter related to these regulations, to enable it properly to assess the notification and may require the notifier to defray or contribute towards the cost of any such investigations.

PART F:

OTHER PROVISIONS

Publication of Schedules in the English language.

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

Revokes L.N. 170 of 2002.

28. The Deliberate Release into the Environment of Genetically Modified Organisms Regulations, 2002, are hereby revoked.

SCHEDULE I A

Techniques referred to in the definition of GMO in regulation 2

PART 1

Techniques of genetic modification referred to in sub-paragraph (a) in the definition of GMO in regulation 2 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 an organism of heritable material prepared outside the organism including microinjection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast 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 2

Techniques referred to in sub-paragraph (b) in the definition of GMO which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Schedule I B:

(1) in vitro fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.

SCHEDULE I B

Techniques referred to in regulation 3

Techniques or methods of genetic modification yielding organisms to be excluded from this regulation, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques or methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

SCHEDULE II

Principles for the Environment risk assessment

This Schedule describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environment risk assessment referred to in regulations 4 and 12. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) of the Directive, in order to facilitate the implementation and explanation of this Annex.

Without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, the following terms are described as follows:

- "direct effects" refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;

- "indirect effects" refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.

Observations of indirect effects are likely to be delayed;

- "immediate effects" refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

- "delayed effects" refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environment risk assessment is also that an analysis of the "cumulative long-term effects" relevant to the release and the placing on the market is to be carried out. "Cumulative long-term effects" refers to the accumulated effects of consents on human health and the environment, including *inter alia* flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

A. Objective

The objective of an environment risk assessment is, on a case-by-case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The environment risk assessment should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

B. General Principles

In accordance with the precautionary principle, the following general principles should be followed when performing the environment risk assessment:

- identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

- the environment risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

- the environment risk assessment should be carried out on a case-by-case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, *inter alia*, GMOs already in the environment;

- if new information on the GMO and its effects on human health or the environment becomes available, the environment risk assessment may need to be readdressed in order to:

    • determine whether the risk has changed;

    • determine whether there is a need for amending the risk management accordingly.

C. Methodology

C.1. Characteristics of GMOs and releases

Depending on the case the environment risk assessment has to take into account the relevant technical and scientific details regarding characteristics of:

- the recipient or any parental organism;

- any genetic modification, be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;

- the GMO;

- the intended release or use including its scale;

- the potential receiving environment; and

- the interaction between these.

Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the environment risk assessment

C.2. Steps in the environment risk assessment

In drawing conclusions for the environment risk assessment referred to in regulations 4, 6, 7 and 12 the following points should be addressed:

1. *Identification of characteristics which may cause adverse effects:*

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of any GMO with those of the non-modified organism under corresponding conditions of the release or use, will assist in identifying the particular potential adverse effects arising from the genetic modification. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

- disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C .2(i) in Schedule III A, and B7 in Schedule III B);

- disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2(i) in Schedule III A, and B 7 and D 8 in Schedule III B);

- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Schedule III A);

- altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors;

- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Schedule III A);

- effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Schedule III A, and D 11 in Schedule III B).

Adverse effects may occur directly or indirectly through mechanisms which may include:

- the spread of any GMO in the environment,

- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not,

- phenotypic and genetic instability,

- interactions with other organisms,

- changes in management, including, where applicable, in agricultural practices.

2. *Evaluation of the potential consequences of each adverse effect, if it occurs*

The magnitude of the consequences of each potential adverse effect should be evaluated.

This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which any GMO is intended to be released and the manner of the release.

3. *Evaluation of the likelihood of the occurrence of each identified potential adverse effect*

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which any GMO is intended to be released, and the manner of the release.

4. *Estimation of the risk posed by each identified characteristic of any GMO*

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

5. *Application of management strategies for risks from the deliberate release or marketing of any GMO*

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

6. *Determination of the overall risk of any GMO*

An evaluation of the overall risk of any GMO should be made taking into account any risk management strategies which are proposed.

D. Conclusions on the potential environmental risk from the release or the placing on the market of GMOs

On the basis of an environment risk assessment carried out in accordance with the principles and methodology outlined in sections B and C, information on the points listed in sections D1 or D2 should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental risk from the release or the placing on the market of GMOs:

D.1. In the case of GMOs other than higher plants

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of any proposed release.

2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of any proposed release.

3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.

4. Potential immediate or delayed environmental risk of the direct and indirect interactions between the GMO and target organisms (if applicable).

5. Potential immediate or delayed environmental risk of the direct and indirect interactions between the GMO with non-target organisms, including risk on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

6. Possible immediate or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release.

7. Possible immediate or delayed effects on animal health and consequences for the feed or food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of any GMO release.

9. Possible immediate or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

D.2. In the case of genetically modified higher plants (GMHP)

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to the GMHP.

3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.

4. Potential immediate or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).

5. Possible immediate or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

6. Possible immediate or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of any GMHP release.

7. Possible immediate or delayed effects on animal health and consequences for the feed or food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

8. Possible immediate or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of any GMO release.

9. Possible immediate or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

SCHEDULE III

Information Required in the Notification

A notification referred to in Part B or Part C of these regulations is to include, as appropriate, the information set out below in the sub-Schedules.

Not all the points included will apply to every case. It is to be expected that individual notifications will address only the particular subset of considerations which is appropriate to individual situations.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and the scale of the proposed release.

Future developments in genetic modification may necessitate adapting this Schedule to technical progress or developing guidance notes on this Schedule. Further differentiation of information requirements for different types of GMOs, for example single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Community.

The description of the methods used or the reference to standardised or internationally recognised methods shall also be mentioned in the dossier, together with the name of the body or bodies responsible for carrying out the studies.

Schedule III A applies to releases of all types of genetically modified organisms other than higher plants. Schedule III B applies to release of genetically modified higher plants.

The term “higher plants” means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

SCHEDULE III A

Information Required in Notifications concerning Releases of Genetically Modified Organisms other than Higher Plants

I. GENERAL INFORMATION

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of any responsible scientist

C. Title of the project

II. INFORMATION RELATING TO THE GMO

A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):

1. scientific name,

2. taxonomy,

3. other names (usual name, strain name, etc.),

4. phenotypic and genetic markers,

5. degree of relatedness between donor and recipient or between parental organisms,

6. description of identification and detection techniques,

7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,

8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,

9. organisms with which transfer of genetic material is known to occur under natural conditions,

10. verification of the genetic stability of the organisms and factors affecting it,

11. pathological, ecological and physiological traits:

(a) classification of hazard according to existing Community rules concerning the protection of human health or the environment;

(b) generation time in natural ecosystems, sexual and asexual reproductive cycle;

(c) information on survival, including seasonability and the ability to form survival structures;

(d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonise other organisms;

(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

(a) sequence;

(b) frequency of mobilisation;

(c) specificity;

(d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B. Characteristics of the vector

1. nature and source of the vector,

2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO,

3. frequency of mobilisation of inserted vector or genetic transfer capabilities and methods of determination,

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism

1. Information relating to the genetic modification:

(a) methods used for the modification;

(b) methods used to construct and introduce any insert into the recipient or to delete a sequence;

(c) description of the insert or vector construction;

(d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

(e) methods and criteria used for selection;

(f) sequence, functional identity and location of the altered or inserted or deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

(a) description of any genetic trait or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(b) structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism;

(c) stability of the organism in terms of genetic traits;

(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

(e) activity of any expressed protein;

(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

(g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(h) history of previous releases or uses of the GMO;

(i) considerations for human health and animal health, as well as plant health:

(i) toxic or allergenic effects of the GMOs or their metabolic products;

(ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(iii) capacity for colonisation;

(iv) if the organism is pathogenic to humans who are immuno-competent:

- diseases caused and mechanism of pathogenicity including invasiveness and virulence,

- communicability,

- infective dose,

- host range, possibility of alteration,

- possibility of survival outside of human host,

- presence of vectors or means of dissemination,

- biological stability,

- antibiotic resistance patterns,

- allergenicity,

- availability of appropriate therapies.

(v) other product hazards.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release

1. description of the proposed deliberate release, including any purpose and foreseen products,

2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases,

3. preparation of the site previous to the release,

4. size of the site,

5. any method to be used for the release,

6. quantities of GMOs to be released,

7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities),

8. worker protection measures taken during the release,

9. post-release treatment of the site,

10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment,

11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. Information on the environment (both on the site and in the wider environment):

1. geographical location and grid reference of any site (in case of notifications under Part C of any site of release will be the foreseen areas of use of the product),

2. physical or biological proximity to humans and other significant biota,

3. proximity to significant biotopes, protected areas, or drinking water supplies,

4. climatic characteristics of any region likely to be affected,

5. geographical, geological and pedological characteristics,

6. flora and fauna, including crops, livestock and migratory species,

7. description of target and non-target ecosystems likely to be affected,

8. a comparison of the natural habitat of the recipient organism with any proposed site of release,

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

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination

1. biological features which affect survival, multiplication and dispersal,

2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.),

3. sensitivity to specific agents.

B. Interactions with the environment

1. predicted habitat of the GMOs,

2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses,

3. genetic transfer capability

   (a) postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;

   (b) postrelease transfer of genetic material from indigenous organisms to the GMOs;

4. likelihood of postrelease selection leading to the expression of unexpected or undesirable traits in the modified organism,

5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability,

6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.,

7. description of ecosystems to which the GMOs could be disseminated,

8. potential for excessive population increase in the environment,

9. competitive advantage of the GMOs in relation to the unmodified recipient or any parental organism,

10. identification and description of the target organisms if applicable,

11. anticipated mechanism and result of interaction between the released GMOs and any target organism if applicable,

12. identification and description of non -target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction,

13. likelihood of postrelease shifts in biological interactions or in host range,

14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,

15. known or predicted involvement in biogeochemical processes,

16. other potential interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring techniques

1. methods for tracing the GMOs, and for monitoring their effects,

2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques,

3. techniques for detecting transfer of the donated genetic material to other organisms,

4. duration and frequency of the monitoring.

B. Control of the release

1. methods and procedures to avoid or minimise the spread of the GMOs beyond the site of release or the designated area for use,

2. methods and procedures to protect the site from intrusion by unauthorised individuals,

3. methods and procedures to prevent other organisms from entering the site.

C. Waste treatment

1. type of waste generated,

2. expected amount of waste,

3. description of treatment envisaged.

D. Emergency response plans

1. methods and procedures for controlling the GMOs in case of unexpected spread,

2. methods for decontamination of the areas affected, for example eradication of the GMOs,

3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread,

4. methods for the isolation of the area affected by the spread,

5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

SCHEDULE III B

Information Required in Notifications concerning Releases of Genetically Modified Higher Plants (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute),

2. Name, qualifications and experience of any responsible scientist,

3. Title of the project,

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:

(a) family name

(b) genus

(c) species

(d) subspecies

(e) cultivar or breeding line

(f) common name.

2. (a) Information concerning reproduction:

(i) any mode of reproduction

(ii) specific factors affecting reproduction, if any

(iii) generation time.

(b) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.

3. Survivability:

(a) ability to form structures for survival or dormancy

(b) specific factors affecting survivability, if any.

4. Dissemination:

(a) ways and extent (for example an estimation of how viable pollen or seeds declines with distance) of dissemination

(b) specific factors affecting dissemination, if any.

5. Geographical distribution of the plant.

6. In the case of plant species not normally grown in any of the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

7. Other potential interactions, relevant to the GMO, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.

2. Nature and source of the vector used.

3. Size, source (name) of any donor organism and intended function of each constituent fragment of the region intended for insertion.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of any trait and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted or deleted:

(a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;

(b) in case of deletion, size and function of any deleted region;

(c) copy number of the insert;

(d) any location of any insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.

3. Information on the expression of the insert:

(a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation;

(b) parts of the plant where the insert is expressed (for example roots, stem, pollen, etc.).

4. Information on how the genetically modified plant differs from the recipient plant in:

(a) any mode or rate of reproduction;

(b) dissemination;

(c) survivability.

5. Genetic stability of the insert and phenotypic stability of the GMHP.

6. Any change to the ability of the GMHP to transfer genetic material to other organisms.

7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.

9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

10. Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification.

11. Potential interactions with the abiotic environment.

12. Description of detection and identification techniques for the genetically modified plant.

13. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO REGULATIONS 6 AND 7)

1. Location and size of any release site.

2. Description of the release site ecosystem, including climate, flora and fauna.

3. Presence of sexually compatible wild relatives or cultivated plant species.

4. Proximity to officially recognised biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO REGULATIONS 6 AND 7)

1. Purpose of the release.

2. Foreseen any date and duration of the release.

3. Method by which the genetically modified plants will be released.

4. Method for preparing and managing the release site, prior to, during and postrelease, including cultivation practices and harvesting methods.

5. Approximate number of plants (or plants per m2).

G. INFORMATION ON CONTROL, MONITORING, POSTRELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO REGULATIONS 6 AND 7)

1. Any precautions taken:

   (a) any distance from sexually compatible plant species, both wild relatives and crops

   (b) any measures to minimise or prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).

2. Description of methods for post release treatment of the site.

3. Description of post release treatment methods for the genetically modified plant material including wastes.

4. Description of monitoring plans and techniques.

5. Description of any emergency plans.

6. Methods and procedures to protect the site.

SCHEDULE IV

Additional Information

This Schedule describes in general terms the additional information to be provided in the case of notification for placing on the market and information for labelling requirements regarding GMOs as or in product to be placed on the market, and GMO exempted under regulation 2 definition of : "placing on the market". Technical guidance notes, as regards, *inter alia*, the description of how the product is intended to be used, may be developed in accordance with the regulatory procedure referred to Article 30 (2) of the Directive, in order to facilitate the implementation and explanation of this Schedule. The labelling of exempted organisms as required by regulation 21 shall be met by providing appropriate recommendations for, and restrictions on, use:

A. The following information shall be provided in the notification for placing on the market of GMOs as or in product in addition to that of Schedule III:

1. proposed commercial names of the products and names of GMOs contained therein, and any specific identification, name or code used by the notifier to identify the GMO. After the consent any new commercial names should be provided to the competent authority,

2. name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,

3. name and full address of any supplier of control samples,

4. description of how the product and the GMO as or in product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted,

5. description of any geographical area and types of environment where the product is intended to be used within the Community, including, where possible, estimated scale of use in each area,

6. intended categories of users of the product e.g. industry, agriculture and skilled trades, consumer use by public at large,

7. information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular GMO products to facilitate post-marketing control and inspection. This information should include where appropriate the lodging of samples of the GMO or its genetic material, with the competent authority and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny, for example the

methodology for detecting and identifying the GMO product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified,

8. proposed labelling on a label or in an accompanying document. This must include, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

B. The following information shall be provided in the notification, when relevant, in addition to that of point A, in accordance with regulation 12 of these regulations:

1. measures to take in case of unintended release or misuse,

2. specific instructions or recommendations for storage and handling,

3. specific instructions for carrying out monitoring and reporting to the notifier. These instructions should be consistent with Schedule VII Part C,

4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes,

5. proposed packaging,

6. estimated production in or imports to the Community,

7. proposed additional labelling. This may include, at least in summarised form, the information referred to in points A 4, A 5, B 1, B 2, B 3 and B 4.

SCHEDULE V

Criteria for the Application of Differentiated Procedures (Regulation 7)

The criteria referred to in regulation 7(1) are set out below.

1. The taxonomic status and the biology (for example mode of reproduction and pollination, ability to cross with related species, pathogenecity) of the non-modified (recipient) organism shall be well-known.

2. There shall be sufficient knowledge about the safety for human health and the environment of the parental, where appropriate, and recipient organisms in the environment of the release.

3. Information shall be available on any interaction of particular relevance for the risk assessment, involving the parental, where appropriate, and recipient organism and other organisms in the experimental release ecosystem.

4. Information shall be available to demonstrate that any inserted genetic material is well characterised. Information on the construction of any vector systems or sequences of genetic material used with the carrier DNA shall be available. Where a genetic modification involves the deletion of genetic material, the extent of the deletion shall be known. Sufficient information on the genetic modification shall also be available to enable identification of the GMO and its progeny during a release.

5. The GMO shall not present additional or increased risks to human health or the environment under the conditions of the experimental release that are not presented by releases of the corresponding parental, where appropriate, and recipient organisms. Any capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment shall not result in adverse effects.

SCHEDULE VI

Guidelines for the Assessment Reports

The assessment report provided for by regulations 13, 14, 15 and 17 should include in particular the following:

1. Identification of the characteristics of the recipient organism which are relevant to the assessment of any GMO in question. Identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism.

2. Description of the result of the genetic modification in the modified organism.

3. Assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.

4. Identification of any new risks to human health and the environment that may arise from any release of the GMO in question as compared to any release of the corresponding non-modified organism, based on the environment risk assessment carried out in accordance with Schedule II.

5. A conclusion on whether any GMO in question should be placed on the market or as any product and under which conditions, whether the GMOs in question shall not be placed on the market or whether the views of other competent authorities and the Commission are sought for on specific issues of the environment risk assessment. These aspects should be specified. The conclusion should clearly address the use proposed, risk management and the monitoring plan proposed. In the case that it has been concluded that the GMOs should not be placed on the market, the competent authority shall give reasons for its conclusion.

SCHEDULE VII

Monitoring Plan

This Schedule describes in general terms the objective to be achieved and the general principles to be followed in the design of the monitoring plan referred to in regulations 12(2), 15(3), 16 (3) and 17. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) of the Directive, in order to facilitate the implementation and explanation of this Schedule.

A. Objective

The objective of a monitoring plan is to:

- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environment risk assessment are correct, and

- identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environment risk assessment

B. General principles

Monitoring, as referred to in regulations 12, 15, 16 and 17, takes place after the consent to the placing of a GMO on the market.

The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the GMO or its use, as such changes may be the result of environmental factors other than the placing of the GMO on the market.

Experience and data gained through the monitoring of experimental releases of GMOs may assist in designing the post marketing monitoring regime required for the placing on the market of GMOs as or in products.

C. Design of the monitoring plan

The design of the monitoring plan should:

1. be detailed on a case by case basis taking into account the environment risk assessment,

2. take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released,

3. incorporate general surveillance for unanticipated adverse effects and, if necessary,

(case-) specific monitoring focusing on adverse effects identified in the environment risk assessment:

3.1. whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the environment risk assessment,

3.2. whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided.

4. facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment.

5. identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment. (Time points and intervals for reports on the results of the monitoring shall be indicated).

6. give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.

SCHEDULE IX

1. In the case of more than one release of genetically modified plants which have resulted from the same recipient crop plant species but which may differ in any of the inserted or deleted sequences or have the same inserted or deleted sequence but differ in phenotypes, a single notification dossier shall be submitted.

2. A notifier can submit in a single notification information on several releases of genetically modified crop plants, to be released on several different site on the following conditions:

- the taxononic status and biology of the recipient plants species is well known,

- information is available on the interactions of the recipient plant species in the ecosystems in which the experimental or agricultural releases are scheduled,

- scientific data is available on the safety to human health and the environment of experimental releases involving genetically modified plants of the same recipient plant species,

- the inserted sequences and their expression products should be safe for human health and the environment under the conditions of the experimental release,

- the inserted sequences have been well characterized,

- all the inserted sequences are integrated into the plant nuclear genome, all the releases are for an a priori specified programme of work,

- all the releases take place within an a priori specified time period.

4. Only one single consent is required for all the releases described in the single notification submitted to the competent authority. The procedure to be used in granting that consent is the following:

(1) any person, wishing to undertake a deliberate release of a GMO or a combination of GMOs in Malta for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority;

(2) the notification shall include:

(a) a technical dossier supplying the information specified in Schedule II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:

(i) general information including information on personnel and training,

(ii) information relating to any GMO,

(iii) information relating to the conditions of release and the receiving environment,

(iv) information on the interactions between any GMO and the environment,

(v) information on monitoring, control, waste treatment and emergency response plans;

(b) a statement evaluating the impacts and risks posed by any GMO to human health or the environment from the uses envisaged;

(3) the Competent Authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;

(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified or carried out by him either in Malta or abroad. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing;

(5) in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;

(6) in the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the risks for human health or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authority or after the competent authority has given its written consent, the notifier shall immediately:

(a) revise the measures specified in the notification,

(b) inform the competent authority in advance of any modification or as soon as the new information is available,

(c) take the measures necessary to protect human health and the environment.

(7)(i). On receipt and after acknowledgment of the notification the

competent authority shall:

- examine it for compliance with these regulations,

- evaluate the risks posed by the release,

- record its conclusions in writing, and, if necessary,

- carry out tests or inspections as may be necessary for control purposes.

(7) (ii). The competent authority, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with these regulations and that the release may proceed, or

(b) indicating that the release does not fulfil the conditions of these regulations and the notification is therefore rejected.

(7) (iii). For the purpose of calculating the 90-day period referred to in the preceding paragraph, any periods of time during which the competent authority:

- is awaiting further information which it may have requested from the notifier, or

- is carrying out a public inquiry or consultation in accordance with paragraph (8) shall not be taken into account.

(7) (iv). The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

(7) (v). If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

(8) Where the competent authority considers it appropriate, it may consult groups or the public on any aspect of the proposed deliberate release.

(9) After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at a later stage.

5. In order to obtain one single consent covering several releases, all the necessary information for each release should be indicated in the single notification, including sufficient information on the different sites of the releases and on the experimental design, as well as indication of any conditions for risk management for each different release. Clear reference to each release to be covered should be made in the notification, and the appropriate information should be included to allow completion of the summary notification information format.

6. A notifier can also submit a single notification covering a whole, a priori specified, programme of development work with a single specific recipient plant species and a specified range of inserts or deletions over several years and on several different sites, and receive a single consent for the whole programme of work.

6 (1). In such cases, detailed indications or descriptions of the different sites of the releases, subsequent intra-specific sexual crosses or the conditions of release need not be given in the notification, as would be required under the conditions indicated in paragraph 5. However, the notification must contain sufficient information to enable overall an evaluation of risk, and a detailed risk assessment to be made for at least the first release in the programme of work. The information that need not be given may only relate to the sites of the releases, the description of the sites and their surface area, the number of plants released, and the subsequent sexual crosses of the initially notified plants (including progenies) with themselves or with plant lines of the initially notified recipient plant species (including the progenies of these crossings).

7. In the cases referred to in paragraph 6 (1) the notifier will submit to the competent authority the additional information together with a statement indicating whether the original risk assessment remains valid and if not, provide further evaluation. This information should be sent before the specific release to which it refers is carried out, in the form of a simple additional notice for information only.

7 (1). The notifier can proceed with the release in question after 15 days from the date of receipt by the competent authority of this additional information, unless he receives written indication from the competent authority.

7 (2). If any new information submitted is such that the original consent under simplified procedures is no longer applicable, then it is for the competent authority to indicate to the notifier within 15 days of receipt of the notification that he may only proceed with the intended release if a consent is granted under the standard procedure laid down in these regulations.

8. When the single consent under simplified procedures is granted, conditions can be attached to each of the releases to which it refers. These conditions can subsequently be altered by the competent authority, as indicated in paragraph 4(7)(v).

9. On completion of one or more of the releases approved within the simplified procedure, the notifier shall submit to the competent authority a report with the results

of any release at the time specified in the consent. Such reports may be submitted separately, or as a clearly identifiable section in support of a notification for subsequent releases.

10. The competent authority may alter the conditions of the original consent or intervene to alter the conditions of specific subsequent releases on the basis of the results indicated in the reports or on the basis of information obtained during inspections.