

A.L. 170 ta' l-2002

**ATT DWAR IL-PROTEZZJONI TA' L-AMBJENT, 2001
(ATT NRU. XX TA' L-2001)**

**Regolamenti ta' l-2002 dwar Tluq Deliberat t'Organizmi
Modifikati Ġenetikament fl-Ambjent.**

BIS-SAHHA tal-poteri moghtija bl-artikoli 9 u 11 ta' l-Att dwar il-Protezzjoni ta' l-Ambjent, minn hawn 'l quddiem imsejjah 'L-Att', il-Ministru għall-Affarijiet Interni u l-Ambjent għamel ir-regolamenti li ġejjin:

1. (1) It-titolu ta' dawn ir-regolamenti huwa **Regolamenti ta' l-2002 dwar Tluq Deliberat t'Organizmi Modifikati Ġenetikament fl-Ambjent.** Citazzjoni u bidu
fis-sehh.

(2) (a) Dawn ir-Regolamenti jidhlu fis-sehh f'tali data li l-Ministru responsabbli għall-ambjent jista' b'avviż fil-Gazzetta jahtar u f'dati differenti li jistgħu jkunu deċiżi għal dispożizzjonijiet differenti u għal skopijiet differenti ta' dawn ir-Regolamenti.

(b) Avviż taht il-paragrafu (a) ta' dan is-subregolament jista' jagħmel tali dispożizzjonijiet transizzjonali kif jidhru li hemm bżonn jew espedjenti lill-Ministru responsabbli għall-ambjent rigward id-dispożizzjonijiet hekk miġjuba fis-sehh.

(3) Dawn ir-regolamenti jipprovdu għall-protezzjoni tas-saħħa umana u għall-ambjent meta:

- jitwettaq it-tluq deliberat fl-ambjent ta' organizmi modifikati ġenetikament għal kwalunkwe skopijiet oħra milli jitpoġġew fis-suq f'Malta,

- jitpoġġew fis-suq organizmi modifikati ġenetikament bhala jew fi prodotti f'Malta.

Parti A: Dispożizzjonijiet ġenerali

2. (1) F'dawn ir-regolamenti, jekk kemm-il darba l-kuntest Interpretazzjoni. ma jkunx mehtieg xorta oħra:

'organizmu' tfisser kwalunkwe entita bijoloġika kapaċi ta' replika jew ta' trasferiment ta' materjal ġenetiku;

‘organizmu modifikat genetikament’ (GMO) tfisser organismu bl-eċċezzjoni ta’ bnedmin, li fih il-materjal ġenetiku ġie mibdul b’mod li ma jsehhx b’mod naturali permezz tat-tahlit u/jew rikombinazzjoni naturali;

Fit-termini ta’ din id-definizzjoni:

(a) modifikazzjoni ġenetika ssehh ta’ linqas permezz ta’ l-użu tat-tekniki llistjati fl-Iskeda I A, il-Parti 1;

(b) it-tekniki llistjati fl-Iskeda I A, il-Parti 2, mhumiex ikkonsidrati li jirrizultaw f’modifikazzjoni ġenetika;

‘tluq deliberat’ tfisser kwalunkwe introduzzjoni mhux intenzjonata ta’ GMO jew ta’ kombinazzjoni ta’ GMOs għal liema ma ntużaw ebda miżuri ta’ konteniment speċifiċi biex jillimitaw il-kuntatt tagħhom ma u biex jipprovdu livell ta’ sigurtà għoli għall-popolazzjoni ingenerali u għall-ambjent;

L.N. 107 ta’ l-2002.

‘Awtorita Kompetenti’ tfisser l-Awtorita għall-Ippjanar u l-Ambjent ta’ Malta Awtorita kif preskritta mill-avviż intitolat Nomina ta’ l-Awtorita ta’ Malta għall-Ambjent u l-Ippjanar bhala l-Awtorita Kompetenti, u tali korp iehor jew persuna li l-Ministru responsabbli għall-ambjent jista’ b’ordni fil-Gazzetta jinnomina u korpi jew persuni differenti jistghu jkunu nnominati mill-awtorita kompetenti għal dispożizzjonijiet differenti u skopijiet differenti ta’ dawn ir-regolamenti;

‘tpoġġija fis-suq’ tfisser li tagħmel ottenibbli għal terzi partijiet, jew permezz ta’ hlas inkella b’xejn;

L-operazzjonijiet li ġejjin m’għandhomx ikunu meqjusa bhala tpoġġija fis-suq:

- li tagħmel ottenibbli mikro-organizmi modifikati genetikament għal attivitajiet irregolati taħt ir-Regolamenti ta’ l-2002 li għandhom x’jaqsmu ma’ l-użu kontenut ta’ mikro organismi modifikati genetikament inklużi kollezzjonijiet ta’ kultura;

- li tagħmel ottenibbli GMOs minbarra mikro organismi li għalihom hemm referenza fl-ewwel indent, biex ikunu wżati esklussivament għal attivitajiet fejn xieraq miżuri ta’ konteniment stringenti għandhom jintużaw biex jillimitaw il-kuntatt tagħhom ma u biex jipprovdu livell għoli ta’ sigurtà għall-popolazzjoni in ġenerali u l-ambjent, il-miżuri għandhom ikunu bbażati fuq l-istess prinċipji ta’ konteniment

kif stabbiliti fir-Regolament ta' l-2002 li ghandhom x'jaqsmu ma' l-użu kontenut ta' mikro organiżmi modifikati ġenetikament inklużi kollezzjonijiet kulturali;

- li tagħmel ottenibbli GMOs li ghandhom jintużaw esklussivament għal tluq deliberat li jikkonforma mal-kondizzjonijiet stipulati fil-Parti B ta' dawn ir-regolamenti;

'notifika' tfisser is-sottomissjoni ta' l-informazzjoni rekwizita taht dawn ir-regolamenti lill-awtorita kompetenti.

'notifikant' tfisser il-persuna li tissottometti n-notifika;

'prodott' tfisser preparazzjoni li tikkonsisti minn, jew li jkun fiha, GMO jew kombinazzjoni ta' GMOs, li tkun poġġuta fis-suq;

'assessjar t'impatt ta' l-ambjent' tfisser l-evalwazzjoni tar-riskji lis-saħha umana u l-ambjent, kemm direttament kif ukoll indirettament, immedjata jew ittardjata, li t-tluq deliberat jew it-tqeghid fis-suq ta' GMOs jista' jimponi u jitwettaq skond l-Iskeda II.

3. (1) Dawn ir-regolamenti m'għandhomx japplikaw għal organiżmi miksuba permezz ta' tekniki ta' modifikazzjoni ġenetika llistjati fl-Iskeda I B. Eżenzjonijiet.

(2) Dawn ir-regolamenti m'għandhomx japplikaw għat-trasport ta' organiżmi modifikati ġenetikament bil-linja tal-ferrovija, bit-triq, il-baħar jew l-ajru.

4. (1) GMOs jistgħu biss jintelqu deliberatament jew jitqiegħdu fis-suq f'konformita mal-parti B jew il-parti C ta' dawn ir-regolamenti irrispettivament. Obligazzjonijiet Ġenerali.

(2) Kwalunkwe persuna qabel ma tissottometti notifika taht il-parti B jew il-parti C, għandha twettaq assessjar ta' l-impatt ta' l-ambjent. L-informazzjoni li tista' tkun meħtieġa biex jitwettaq l-assessjar ta' l-impatt ta' l-ambjent hija stipulata fl-Iskeda III.

Basta li GMOs li jkunu fihom *genes* li jesprimu reżistenza għall-antibijotiċi fl-użu fit-trattament mediku u veterinarju għandu jittieħdu in konsiderazzjoni partikulari waqt li jitwettaq l-assessjar tal-impatt ta' l-ambjent, bi skop li jidentifikaw u jiffaġġaw il-markers tar-reżistenza ta' l-antibijotiċi f'GMOs li jista' jkollhom effetti avversi fuq is-saħha umana u l-ambjent.

Basta li dan l-iffażjar isir sal-31 ta' Diċembru 2004 fil-każ ta' GMOs imqieghda fis-suq skond il-parti C u sal-31 ta' Diċembru 2008 fil-każ ta' GMOs awtorizzati taht il-parti B.

(3) (i) Effetti avversi potenzjali fuq is-saħha umana u l-ambjent, li jistgħu jseħħu direttament jew indirettament, permezz ta' trasferiment ta' *genes* minn GMOs għal organiżmi oħra, għandhom ikunu assessjati bir-reqqa fuq bażi ta' każ każ.

(ii) Dan l-assessjar għandu jitmexxa skond l-Iskeda II waqt li jittiehed f' konsiderazzjoni l-impatt ambjentali skond in-natura ta' l-organiżmu ntrodott u ta' l-ambjent riċeventi.

(4) L-awtorita kompetenti għandha tkun l-organu responsabbli li jassigura konformita mal-kondizzjonijiet ta' dawn ir-regolamenti, u hija għandha teżamina notifikasi taht il-parti B u l-parti C għal konformita mal-kondizzjonijiet ta' dawn ir-regolamenti u jekk l-assessjar ipprovdut għalih fis-sub-artikolu 2 huwiex addattat.

(5) L-awtorita kompetenti għandha torganizza spezzjonijiet u miżuri ta' kontroll oħra kif xieraq, biex tassigura l-konformita ma' dawn ir-regoli.

Basta li fil-każ ta' tluq ta' GMOs jew tqeghid fis-suq bħal jew fi prodotti li għalihom ma ngħatat ebda approvazzjoni, l-awtorita kompetenti għandha tassigura li jittiehdu l-miżuri mehtieġa biex twaqqaf it-tluq jew it-tqeghid fis-suq, biex tibda azzjoni ta' rimedju jekk ikun hemm bżonn, u biex tinforma lill-pubbliku, u lil stati oħra li jistgħu jkunu milquta avversament.

(6) L-awtorita kompetenti għandha tiehu l-miżuri mehtieġa biex tassigura traċċibilta, f'linja mal-kondizzjonijiet stipulati fl-Iskeda IV, fl-istadji kollha tat-tqeghid fis-suq ta' GMOs awtorizzati taht il-parti C.

Parti B: Tluq Deliberat ta' GMOs għal xi Skop ieħor minbarra dak tat-Tqeghid fis-Suq

Applikabilita ta' l-Artikoli 6 sa 10

5. (1) L-Artikoli 6 sa 10 m'għandhomx japplikaw għal sustanzi mediċi u għal komposti ntenzjonati għal konsum uman li jikkonsistu fi, jew li jkun fihom GMO jew kombinazzjoni ta' GMOs basta li t-tluq deliberat tagħhom għal xi skop ieħor minbarra dak li jitqieghdu fis-suq ikun awtorizzat minn kwalunkwe legislazzjoni rilevanti li tipprovidi:

(a) għal assessjar t'impatt ta' l-ambjent speċifiku skond l-Iskeda II u fuq il-baży tat-tip t'informazzjoni speċifikata fl-Iskeda III mingħajr preġudizzju għal kondizzjonijiet addizzjonali pprovdut għalihom bl-imsemmija legislazzjoni;

(b) għal kunsens espliċitu qabel ma jkun mitluq;

(c) għal pjan ta' immonitjar skond il-partijiet rilevanti ta' l-Iskeda III, bi skop li jkunu misjuba l-effetti tal-GMO jew GMOs fuq is-saħħa umana u fuq l-ambjent;

(d) b'mod li jixraq għal kondizzjonijiet relatati mat-trattament ta' items godda, informazzjoni lill-pubbliku, informazzjoni dwar ir-riżultati tat-tluq, u bdil t'informazzjoni ta' lingas ekwivalenti ma' daww kontenuti f'dawn ir-regolamenti u fil-mizuri meħuda skond l-istess.

(2) Assessjar tar-riskji għall-ambjent ipprezentati minn tali sustanzi u komposti għandu jitwettaq mill-awtorità kompetenti, skond il-proċeduri stipulati f'dawn ir-regolamenti.

6. (1) Mingħajr preġudizzju għall-Artikolu 5, kwalunkwe persuna għandha, qabel ma tidhol għal tluq deliberat ta' GMO jew ta' kombinazzjoni ta' GMOs f'Malta, jew fi kwalunkwe nħawi barra t-territorju ta' Malta, tissottometti notifika lill-awtoritajiet kompetenti.

Procedura
l'Awtorizzazzjoni
Standard

Izda wkoll meta t-tluq deliberat ta' GMO jew ta' kombinazzjoni ta' GMOs issir barra mit-Territorju ta' Malta, l-Awtorità Kompetenti għandha tinnotifika lill-Awtoritajiet konċernati li fit-territorju tagħhom ikun ser isir it-tluq.

(2) In-notifika li hemm riferenza għaliha fis-sub artikolu 1 għandha tinkludi:

(a) *dossier* tekniku li jforni l-informazzjoni speċifikata fl-Iskeda III meħtieġa għat-twettiq ta' l-assessjar tal-impatt ta' l-ambjent tat-tluq deliberat ta' GMO jew kombinazzjoni ta' GMOs, partikularment:

(i) informazzjoni ġenerali li tinkludi nformazzjoni fuq *personnel* u taħriġ,

(ii) informazzjoni relatata mal-GMO(s),

(iii) informazzjoni relatata mal-kondizzjonijiet ta' tluq u l-ambjent riċeventi potenzjali,

(iv) informazzjoni dwar interazzjonijiet bejn il-GMOs u l-ambjent,

(v) pjan għal immonitjar skond il-partijiet rilevanti ta' l-Iskeda III, bi skop li jkunu identifikati l-effetti tal-GMOs fuq is-saħħa umana u fuq l-ambjent;

(vi) informazzjoni dwar kontrolli, metodi ta' rimedju, trattament ta' skart u pjan ta' rispons t'emergenza,

(vii) sommarju tad-*dossier*;

(b) l-assessjar tal-impatt ta' l-ambjent u l-konkluzjonijiet meħtieġa fl-Iskeda II, sezzjoni D, flimkien ma' kwalunkwe referenza biblijografika u indikazzjonijiet tal-metodi wżati.

(3) In-notifikant jista' jirreferi għal data jew riżultati minn notifiċi sottomessi qabel minn notifikanti oħra, basta li l-informazzjoni, d-data u r-riżultati ma jkunux konfidenzjali jew dawn in-notifikanti kienu taw il-ftehim tagħhom bil-miktub, jew jista' jissottometti nformazzjoni addizzjonali li huwa jikkonsidra rilevanti.

(4) L-awtorita kompetenti tista' taċċetta li tluq ta' l-istess GMO jew ta' kombinazzjoni ta' GMOS fuq l-istess sit jew fuq siti differenti għall-istess skop u fi żmien perijodu definit jista' jkun notifikat fl-istess notifiċa.

(5) L-awtorita kompetenti għandha tagħraf id-data tar-riċeviment tan-notifiċa u għandha twieġed bil-miktub lin-notifikant fi żmien 90 jum mir-riċeviment tan-notifiċa billi jew:

(a) tindika li hija sodisfatta li n-notifiċa hija f'konformita ma' dawn ir-regolamenti u li t-tluq jista' jkompli miexi; jew

(b) tindika li t-tluq ma jwettaqx il-kondizzjonijiet ta' dawn ir-regolamenti u li n-notifiċa għalhekk ma gietx milqugħa.

(6) Għall-iskop tal-kalkolu tal-perijodu tad-90 jum li hemm referenza għalih fis-sub artikolu (5), ebda konsiderazzjoni m'għandha tittiehed ta' xi perijodi ta' żmien matul liema l-awtorita kompetenti:

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

(b) tkun qed twettaq inkjesta pubblika jew konsultazzjoni skond l-Artikolu 9; din l-inkjesta jew konsultazzjoni pubblika m'għandhiex ittawwal il-perijodu tad-90 jum li hemm referenza għalih fis-sub artikolu 5 b'iktar minn 30 jum.

(7) Jekk l-awtorita kompetenti titlob informazzjoni ġdida din għandha taghti simultanjament ir-raġunijiet tagħha għaliex għamlet hekk.

(8) In-notifikant jista' jipproċedi bit-tluq biss meta jkun irċieva l-kunsens bil-miktub ta' l-awtorita kompetenti, u f'konformita ma' kwalunkwe kondizzjonijiet mehtieġa għal dan il-kunsens.

(9) Ebda materjal derivat minn GMOs li jkunu deliberament mitluqa skond il-parti B m'għandhom jitqieghdu fis-suq, dement li ma jkunux skond il-Parti C.

7. (1) Jekk esperjenza biżżejjed tkun giet miksuba ta' tluq ta' ċerti GMOs f'ċerti ekosistemi, u l-GMOs konċernati jissodisfaw il-kriterja stipulata fl-Iskeda V, l-awtorita kompetenti tista' tapplika proċeduri differenzjati għal tali tipi ta' GMOs. Proċeduri
Differenzjati

(2) In-notifikant jista' jipproċedi bit-tluq biss meta jkun irċieva l-kunsens bil-miktub ta' l-awtorita kompetenti, u f'konformita ma' l-ammont minimu nformazzjoni teknika mehtieġa ta' l-Iskeda III għall-evalwazzjoni ta' kwalunkwe riskji prevedibbli mit-tluq, partikularment:

- (a) informazzjoni ralatata ma' GMOs;
- (b) informazzjoni relatata mal-kondizzjonijiet ta' tluq u l-ambjent riċeventi potenzjali,
- (c) informazzjoni dwar interazzjonijiet bejn GMOs u l-ambjent;
- (d) assessjar tar-riskju ambjentali.

(3) Minghajr preġudizzju għas-sub-artikoli (1) u (2), il-proċeduri simplifikati rigward it-tluq deliberat fl-ambjent ta' pjanti modifikati ġenetikament, fil-każ t'iktar minn tluq wiehed ta' pjanti modifikati ġenetikament li jkunu rriżultaw mill-istess speċi ta' prodott ta' pjanta imma li jista' jkunu differenti fi kwalunkwe waħda mis-sekwenzi inseriti/mhassra jew li għandhom l-istess sekwenza inseritaċ mhassra imma li huma differenti fil-*phenotypes* għandhom ikunu daww stipulati fl-Iskeda IX.

8. (1) Fil-każ ta' xi modifikazzjoni ta' jew bdil mhux intenzjonat għal, it-tluq deliberat ta' GMO jew ta' kombinazzjoni ta' GMOs li jistgħu jkollhom konsegwenzi rigward riskji lis-saħħa umana u l-ambjent wara li l-awtorita kompetenti tkun tat il-kunsens tagħha Trattament ta'
modifikazzjonijiet u
nformazzjoni ġdida

bil-miktub, jew jekk informazzjoni tkun saret ottenibbli dwar tali riskji, jew waqt li n-notifika tkun qed tkun eżaminata mill-awtorita kompetenti jew wara li l-awtorita kompetenti tkun tat bil-miktub il-kunsens tagħha, in-notifikant għandu immedjament:

(a) jiehu l-miżuri mehtieġa biex jipproteġi s-saħħa umana u l-ambjent;

(b) jinforma lill-awtorita kompetenti bil-quddiem dwar kwalunkwe modifika jew mill-iktar fis possibbli dwar kif il-bdil intenzjonat huwa magħruf jew l-informazzjoni il-ġdida hija ottenibbli;

(c) jirrivedi l-miżuri speċifika fin-notifika.

(2) Jekk l-informazzjoni ssir ottenibbli għall-awtorita kompetenti li hemm referenza għaliha fis-sub artikolu 1 li jista' jkollha konsegwenzi sinifikanti rigward riskji għas-saħħa umana u l-ambjent jew taht ċirkustanzi deskritti fis-sub artikolu 1, l-awtorita kompetenti għandha tevalwa tali nformazzjoni u tagħmilha ottenibbli għall-pubbliku.

Basta wkoll li hija tista' titlob lin-notifikant biex jimmodifika l-kondizzjonijiet ta, jissospendi jew iwaqqaf it-tluq deliberat u għandu jinforma lill-pubbliku bl-istess.

Konsultazzjoni ta' u informazzjoni lill-pubbliku

9. (1) L-awtorita kompetenti għandha, mingħajr preġudizzju għad-dispożizzjonijiet ta' l-Artikoli 7 u 20, tikkonsulta lill-pubbliku u, fejn xieraq, lill-gruppi dwar it-tluq deliberat propost. Basta li meta tagħmel dan, l-awtorita kompetenti għandha tistabilixxi arrangamenti għal din il-konsultazzjoni, inkluż perijodu raġjonevoli, sabiex il-pubbliku jew il-gruppi jingħataw l-opportunita li jesprimu l-opinjoni tagħhom.

(2) Mingħajr preġudizzju għad-dispożizzjonijiet ta' l-Artikolu 20, l-awtorita kompetenti għandha tagħmel ottenibbli lill-pubbliku nformazzjoni dwar it-tluq kollu tal-Parti B ta' GMOs f'Malta.

Rapportagg minn notifikanti dwar tluq.

10. Wara t-tweqqif ta' tluq, u minn hemm 'il quddiem, fi kwalunkwe intervalli stabbiliti fil-kunsens fuq il-bażi tar-riżultati ta' l-assessjar ta' l-impatt ta' l-ambjent, in-notifikant għandu jibgħat lill-awtorita kompetenti ir-riżultat tat-tluq rigward kwalunkwe riskju għas-saħħa umana jew l-ambjent ma', fejn xieraq, referenza partikulari għal kwalunkwe tip ta' prodott li n-notifikant għandu f'moħħu li jinnotifika iktar 'il quddiem.

Parti C: Tqeghid fis-Suq ta' GMOs bhala jew fi prodotti

11. (1) L-Artikoli 12 sa 19 m'ghandhomx japplikaw ghal xi Legislazzjoni settorjali GMO bhala jew fi prodotti, sa fejn huma awtorizzati minn kwalunkwe legislazzjoni rilevanti li ttiprovdi ghal assessjar ta' l-impatt ta' l-ambjent speċifiku, li ghandu jitwettaq skond il-prinċipji stabbiliti fl-Iskeda II u fuq il-bażi t'informazzjoni speċifikata fl-Iskeda III, mingħajr preġudizzju ghal kondizzjonijiet addizzjonali pprovdut ghalihom mil-legislazzjoni rilevanti, u ghal kondizzjonijiet rigward immanigġjar ta' riskju, tikkettjar, immoniterjar kif jixraq, informazzjoni lill-pubbliku u klawnsola ta' salvagwardja almenu ekwivalenti ghal dik stipulata f'dawn ir-Regolamenti, jew fi kwalunkwe regolamenti ohra rilevanti li jikkonċernaw prodotti mediċinali għall-użu uman u veterinarju.

(2) Kwalunkwe GMO bhala jew fi prodotti sakemm huwa awtorizzat minn legislazzjoni rilevanti ohra ghandu biss jitqiegħed fis-suq wara li jkun gie aċċettat għat-tqegħid fis-suq skond dawn ir-Regolamenti.

12. (1) (a) Qabel ma GMO jew kombinazzjoni ta' GMOs Proċedura ta' Notifika bhala jew fi prodotti jitqiegħdu fis-suq għall-ewwel darba, għandha tkun sottomessa notifika lill-awtorita kompetenti.

(b) L-Awtorita kompetenti għandha tagħraf id-data tar-riċeviment tan-notifika.

(c) L-awtorita kompetenti għandha teżamina bla telf ta' żmien jekk in-notifika hijiex skond is-sub artikolu 2 u għandha, jekk ikun meħtieġ, titlob lin-notifikant għal iktar informazzjoni.

(2) In-notifika għandu jkun fiha:

(a) l-informazzjoni mitluba fl-Iskedi III u IV. Din l-informazzjoni għandha tiehu f'konsiderazzjoni id-diversita tas-siti ta' l-użu tal-GMO bhala jew fi prodott u għandha tinkludi nformazzjoni dwar data u riżultati miksuba minn tluq ta' riċerka u żvilupp rigward l-impatt tat-tluq fuq is-saħħa umana u fuq l-ambjent;

(b) l-assessjar tal-impatt ta' l-ambjent u l-konklużjonijiet mitluba fl-Iskeda II, sezzjoni D;

(c) il-kondizzjonijiet għat-tqegħid fis-suq tal-prodott, inklużi kondizzjonijiet speċifiċi t'uzu u trattament;

(d) b'referenza għall-artikolu 14 (4), perijodu propost li m'għandux jaqbeż għaxar snin;

(e) pjan t'immoniterjar skond l-Iskeda VII, li jinkludi proposta għal perijodu ta' żmien tal-pjan t'immoniterjar; dan il-perijodu ta' żmien jista' jkun differenti mill-perijodu propost għall-kunsens;

(f) proposta għal ittikkettjar li jkun konformi mal-kondizzjonijiet stipulati fl-Iskeda IV u, l-ittikkettjar għandu jesprimi kjament li hemm GMO u, il-kliem 'dan il-prodott fih organiżmi modifikati ġenetikament' għandhom jidhru jew fuq it-tikketta jew fid-dokument akkompanjatur;

(g) proposta għal ippakkjar li għandu jkun fiha il-kondizzjonijiet stipulati fl-Iskeda IV;

(h) sommarju tad-*dossier* kif jista' jkun stabbilit mill-awtorita kompetenti minn żmien għal żmien.

Basta li jekk fuq il-bażi tar-riżultati ta' kwalunkwe tluq notifikat taht il-Parti B, jew dwar sustantiv ieħor, bażijiet xjentifiċi raġjonati, notifikant jikkonsidra li t-tqeghid fis-suq u l-użu ta' GMO bħala jew fi prodott ma jimponix riskju lis-saħħa umana u l-ambjent, huwa jista' jipproponi lill-awtorita kompetenti biex ma jipprovdix parti jew l-informazzjoni kollha mitluba fl-Iskeda IV, sezzjoni B.

(3) In-notifikant għandu jinkludi f'din in-notifika nformazzjoni dwar data jew riżultati minn tluq ta' l-istess GMOs jew l-istess kombinazzjoni ta' GMOs innotifikati qabel jew fil-preżent u/jew mwettqa min-notifikant jew Malta inkella barra.

(4) In-notifikant jista' jirreferi għal data jew riżultati minn notifiċi sottomessi qabel minn notifikanti oħra, basta li l-informazzjoni, d-data u r-riżultati ma jkunux konfidenzjali jew dawn in-notifikanti kienu taw il-ftehim tagħhom bil-miktub, jew jista' jissottometti nformazzjoni addizzjonali li huwa jikkonsidra rilevanti.

(5) Sabiex GMO jew kombinazzjoni ta' GMOs jintużaw għal skop differenti minn dak diġa speċifikat f'notifika, trid tkun sottomessa notifiċa separata.

(6) Jekk informazzjoni ġdida ssir ottenibbli rigward riskji tal-GMO għas-saħħa umana jew għall-ambjent, qabel ma jkun ingħata kunsens bil-miktub, in-notifikant għandu mmedjatement jiehu l-miżuri

mehtieġa biex jipproteġi s-saħħa umana u l-ambjent, u jinforma minnufih lill-awtorita kompetenti. Barra minn dan, in-notifikant għandu jirrivedi l-informazzjoni u l-kondizzjonijiet speċifikati fin-notifika.

13. (1) Mar-riċeviment u wara l-għarfien tan-notifika skond l-artikolu 12(2), l-awtorita kompetenti għandha teżaminha għal konformita ma' dawn ir-regolamenti. Rapport ta' l-assessjar

(2) (a) fi żmien 90 jum wara r-riċeviment tan-notifika l-awtorita kompetenti għandha thejji rapport ta' assessjar u tibagħtu lin-notifikant.

(b) Tnehhija sussegwenti min-notifikant għandha tkun mingħajr preġudizzju għal xi sottomissjonijiet ohra tan-notifika lil awtorita kompetenti ohra.

(3) Ir-rapport ta' l-assessjar għandu jindika jekk:

(a) il-GMO(s) in kwestjoni għandhomx jitqieghdu fis-suq u taht liema kondizzjonijiet; jew

(b) il-GMO(s) in kwestjoni m'għandhomx jitqieghdu fis-suq.

Ir-rapporti ta' l-assessjar għandhom jiġu stabbiliti bi qbil mal-linji ta' gwida stipulati fl-Iskeda VI.

(4) Għall-iskop tal-kalkolu tal-perijodu ta' 90 jum li għalih hemm referenza fis-sub artikolu 2, kwalunkwe perijodi ta' żmien li matulhom l-awtorita kompetenti tkun tistenna iktar informazzjoni li hija tista' tkun talbet mingħand in-notifikant m'għandhomx jittiehdu f'konsiderazzjoni u l-awtorita kompetenti għandha tgħid ir-raġunijiet fi kwalunkwe talba għal iktar informazzjoni.

14. (1) (a) Fil-kazijiet li għalihom hemm riferenza fl-artikolu 13(3), l-awtorita kompetenti tista' titlob għal iktar informazzjoni, tagħmel kummenti jew tippreżenta oġġezzjonijiet raġonevoli għat-tqegħid fis-suq tal-GMO(s) in kwestjoni fi żmien 60 jum mid-data taċ-ċirkulazzjoni tar-rapport ta' assessjar. Proċedura standard

(b) L-awtorita kompetenti tista' tagħti lin-notifikant iktar żmien biex jissottometti nformazzjoni iktar basta li r-raġunijiet ikunu mistqarri fi kwalunkwe talba għal tali nformazzjoni.

(c) Jekk l-awtorita kompetenti wara li tkun hejjiet ir-rapport ta' l-assessjar tiddeciedi li l-prodott jista' jitqieghed fis-suq, hija

għandha tagħti l-kunsens tagħha bil-miktub għat-tqegħid fis-suq tal-GMOs in kwestjoni u dan ikun trasmess lin-notifikant.

(2) Fil-każ li hemm referenza għalih fl-artikolu 13(3)(b), jekk l-awtorita kompetenti tiddeċiedi li l-GMO(s) m'għandhomx jitqiegħdu fis-suq, in-notifika għandha tkun miċhuda, u din id-deċiżjoni għandha tagħti r-raġunijiet.

(3) Jekk l-awtorita kompetenti tiddeċiedi li l-prodott jista' jitqiegħed fis-suq, l-awtorita kompetenti għandha tagħti l-kunsens tagħha bil-miktub għat-tqegħid fis-suq.

(4) (a) il-kunsens jingħata għal-perijodu massimu ta' għaxar snin li jibdwu mid-data li fiha nħareġ il-kunsens.

(b) Għall-iskop t'approvazzjoni ta' GMO jew ta' proġene ta' dak il-GMO intenzjonat biss għall-immarkettjar taż-żerriegħa tagħhom il-perijodu ta' l-ewwel kunsens għandu jintemm l-iktar tard għaxar snin wara d-data ta' l-ewwel inkluzjoni ta' l-ewwel varjeta ta' pjanta li jkun fiha l-GMO fuq katalogu nazzjonali ufficijali tal-varjetajiet tal-pjanta.

(c) fil-każ ta' materjal riproduttiv forestali, il-perijodu ta' l-ewwel kunsens għandu jintemm l-iktar tard għaxar snin wara d-data ta' l-ewwel inkluzjoni tal-materjal bażiku li jkun fih il-GMO fuq ir-reġistru nazzjonali ufficijali tal-materjal bażiku.

Rinnovament tal-kunsens

15. (1) Permezz ta' deroga mill-Artikoli 12, 13 u 14, il-proċedura stipulata fis-sub artikoli 2 sa 5 għandha tkun applikata għar-rinnovament tal-kunsensi mogħtija taħt il-parti C.

(2) L-iktar tard disa' xhur qabel l-għeluq tal-kunsens in-notifikant taħt dan l-Artikolu għandu jissottometti notifika lill-awtorita kompetenti li għandu jkun fiha:

(a) kopja tal-kunsens għat-tqegħid fis-suq tal-GMOs;

(b) rapport dwar ir-risultati ta' l-immoniterjar li jkun twettaq skond l-Artikolu 17;

(c) kwalunkwe nformazzjoni ġdida li tkun saret ottenibbli rigward ir-riskji tal-prodott għas-saħħa umana u/jew l-ambjent, u

(d) kif xieraq, proposta għal emendar jew ikkomplimentar tal-kondizzjonijiet tal-kunsens oriġinali, inter alia l-kondizzjonijiet rigward immoniterjar futur u l-limitu taż-żmien tal-kunsens.

Basta li l-Awtorita kompetenti għandha tagħraf id-data tar-riċeviment tan-notifika.

(3) Ir-rapport ta' l-assessjar għandu jindika jekk:

(a) il-GMO(s) in kwestjoni għandhomx jibqgħu fis-suq u taht liema kondizzjonijiet; jew

(b) il-GMO(s) in kwestjoni m'għandhomx jibqgħu fis-suq.

(4) (a) Fil-każ tas-sub artikolu 3(a) l-awtorita kompetenti għandha tittrasmetti lin-notifikant id-deċiżjoni finali bil-miktub.

(b) il-validita tal-kunsens m'għandhiex, bħala regola ġenerali, taqbez għaxar snin u tista' tkun limitata jew estiża kif jixraq għal raġunijiet speċifiċi.

(c) Il-validita tal-kunsens tista' tkun limitata kif ikun hemm bżonn.

(5) Wara notifika għal rinnovament ta' kunsens skond is-subartikolu (2), in-notifikant jista' jkompli jqiegħed il-GMOs fis-suq taht il-kondizzjonijiet speċifikati f'dak il-kunsens sa ma tittiehed id-deċiżjoni finali dwar in-notifika.

16. (1) Jekk ikun inġhata kunsens bil-miktub biss għal tqegħid fis-suq ta' GMO bħala jew fi prodott minn awtorita kompetenti ta' Stat Membru ta' l-Unjoni Ewropea jista' dak il-prodott ikun użat mingħajr iktar notifika ta' l-awtorita kompetenti sa fejn kondizzjonijiet speċifiċi t'użu u l-ambjenti u/jew inħawi ġeografiki stipulati f'dawn il-kondizzjonijiet għandhom jinżammu strettament. Kunsens.

(2) (a) In-notifikant jista' jipproċedi bit-tqegħid fis-suq ta' prodott biss meta jkun irċieva l-kunsens bil-miktub ta' l-awtorita kompetenti, skond l-Artikoli 14 u 15 u f'konformita ma' kwalunkwe kondizzjonijiet meħtieġa għal dan il-kunsens.

(b) L-awtorita kompetenti għandha tiehu l-miżuri meħtieġa kollha biex tassigura li d-deċiżjoni tal-kunsens miktuba, fejn applikabbli, għandhom ikunu aċċessibbli għall-pubbliku u li kondizzjonijiet speċifikati fil-kunsens miktub u d-deċiżjoni, fejn applikabbli, jkun konfermat magħhom.

(3) Il-kunsens bil-miktub li għalih hemm referenza fl-Artikoli 14 u 15, fil-każijiet kollha għandu jispeċifika espliċitament:

(a) l-iskop tal-kunsens, inkluża l-identita tal-GMO(s) li se jkunu mqiegħda fis-suq bhala jew fi prodotti, u l-identifikant uniku tagħhom;

(b) il-perijodu tal-validita tal-kunsens;

(c) il-kondizzjonijiet għat-tqegħid fis-suq tal-prodott, inklużi kwalunkwe kondizzjonijiet speċifiċi tal-użu, trattament u ippakkjar tal-GMO(s) bhala jew fi prodotti, u kondizzjonijiet għall-protezzjoni ta' ekosistemi ambjenti partikulari u/jew inhawi ġeografici;

(d) li, mingħajr preġudizzju għall-Artikolu 20, in-notifikant għandu jagħmel kampjonar ta' kontroll ottenibbli għall-awtorita kompetenti fuq talba;

(e) il-kondizzjonijiet ta' ittikkettjar, f'konformita mal-kondizzjonijiet stipulati fl-Iskeda IV. L-ittikkettjar għandu kjament juri li GMO huwa preżenti.

Il-kliem 'Dan il-prodott fih organiżmi modifikati genetikament' għandhom jidhru jew fuq it-tikketta jew f' dokument li jakkumpanja l-prodott jew prodotti oħra li jkun fihom il-GMO(s);

(f) Konduzzjonijiet t'immoniterjar skond l-Iskeda VII, il-perijodu ta' żmien tal-pjan t'immoniterjar u, fejn xieraq, kwalunkwe obligazzjonijiet dwar kwalunkwe persuna li tbigh il-prodott jew kwalunkwe utent tiegħu, inter alia, fil-każ ta' GMOs imkabbra, rigward livell t'informazzjoni meqjus xieraq fil-post tagħhom.

Immoniterjar u
Trattament ta'
informazzjoni.

17. (1) Wara t-tqegħid fis-suq ta' GMO bhala jew fi prodott, in-notifikant għandu jassigura li immoniterjar u rapportaġġ dwaru jitwettaq skond il-kondizzjonijiet speċifikati fil-kunsens.

Basta li r-rapporti ta' dan l-immoniterjar għandu jkun sottomess lill-awtorita kompetenti, u fuq il-bażi ta' dawn ir-rapporti, skond il-kunsens u fl-ambitu tal-pjan t'immoniterjar speċifikat fil-kunsens, l-awtorita kompetenti tista' taddotta il-pjan t'immoniterjar wara l-ewwel perijodu t'immoniterjar.

(2) Jekk informazzjoni ġdida ssir ottenibbli, mill-utenti jew minn sorsi oħra, rigward ir-riskji tal-GMO(s) għas-saħħa umana jew għall-ambjent, wara li jkun ingħata l-kunsens bil-miktub, in-notifikant għandu mmedjatement jiehu l-mizuri meħtieġa biex jipproteġi s-saħħa umana u l-ambjent, u jinforma minnufih lill-awtorita kompetenti. Barra

minn dan, in-notifikant għandu jirrive di l-informazzjoni u l-kondizzjonijiet speċifikati fin-notifika.

(3) Jekk informazzjoni ssir ottenibbli lill-awtorita kompetenti li jista' jkollha konsegwenzi għar-riskji tal-GMO(s) għas-saħħa umana jew l-ambjent, jew taħt ċirkustanzi deskritti fis-sub artikolu 2, din tista' tagħmel użu mid-dispożizzjonijiet ta' l-artikoli 14 (1) fejn xieraq, meta l-informazzjoni tkun saret ottenibbli qabel il-kunsens bil-miktub.

Basta li meta l-informazzjoni tkun saret ottenibbli wara li l-kunsens ikun ingħata, l-awtorita kompetenti tkun tista' temenda il-kunsens u tkun tista' tittrasmetti l-kunsens emendat lin-notifikant.

(4) L-awtorita kompetenti għandha tagħmel pubblikament ottenibbli ir-riżultati ta' l-immoniterjar imwettaq taħt il-parti C ta' dawn ir-regolamenti.

18. (1) Fl-istadji kollha tat-tqegħid fis-suq, l-ittikkettjar u l-ippakkjar ta' GMO imqiegħed fis-suq bħala jew fi prodotti għandu jikkonforma mal-kondizzjonijiet rilevanti speċifikati fil-kunsens bil-miktub li hemm referenza għalihom fl-Artikoli 14(3) u 16(3). Ittrikkettjar.

Basta li l-awtorita kompetenti tkun tista' tissettja livelli minimi għall-prodotti fejn traċċi avventużi u tekniki li ma tistax tevitahom ta' GMOs awtorizzati ma jkunux jistgħu ikunu esklużi.

19. (1) Mingħajr preġudizzju għal dan l-artikolu l-awtorita kompetenti ma tistax tipprojbixxi, tirrestringi jew timpedixxi tqegħid fis-suq ta' GMOs, bħala jew fi prodotti, li jikkonformaw ma' dawn ir-regolamenti minbarra, fejn, bħala riżultat ta' informazzjoni ġdida jew addizzjonali li ssir ottenibbli mid-data tal-kunsens u li taffettwa l-assessjar tar-riskju ambjentali jew ir-riassessjar t'informazzjoni eżistenti fuq il-bażi t'għarfien xjentifiku ġdid jew addizzjonali, l-awtorita kompetenti jkollha bażi dettaljat għal konsiderazzjoni li GMO bħala jew fi prodott li kien gie notifikat sewwa u li kien irċieva kunsens bil-miktub skond dawn ir-regolamenti jikkostitwixxi riskju għas-saħħa umana jew għall-ambjent, l-awtorita kompetenti tista' tirrestringi proviżjonalment jew tipprojbixxi l-użu jew il-bejgħ ta' dak il-GMO bħala jew fi prodott. Klawsole ta' salvagwardja.

(2) L-awtorita kompetenti għandha tassigura li fil-każ ta' riskju sever, miżuri t'emergenza, bhas-sospensjoni u t-terminu tat-tqegħid fis-suq, għandhom ikunu applikati, inkluża nformazzjoni lill-pubbliku.

Parti D

Konfidenzjalità.

20. (1) L-awtorita kompetenti m'għandhiex tghaddi lil terzi partijiet kwalunkwe nformazzjoni konfidenzjali notifikata jew skambjata taħt dawn ir-Regolamenti u għandha tipproteġi d-drittijiet ta' propjeta ntellektwali relatati mad-data riċevuta.

(2) In-notifikant jista' jindika l-informazzjoni fin-notifika sottomessa taħt dawn ir-Regolamenti, il-kixfa ta' liema tista' tagħmel hsara lill-pożizzjoni kompetittiva tiegħu u liema għalhekk għandha tkun ittrattata bħala konfidenzjali, u għandha tingħata ġustifikazzjoni verifikabbli f'tali każijiet.

(3) L-Awtorita għandha tiddeċiedi, wara konsultazzjoni man-notifikant, liema nformazzjoni għandha tinzamm konfidenzjali u għandha tinforma lin-notifikant bid-deċiżjonijiet tagħha.

(4) Fl-ebda każ m'għandha l-informazzjoni li ġeja tinzamm konfidenzjali, meta tkun sottomessa skond l-Artikoli 6, 7, 8, 12, 15, 17, u 19:

- deskrizzjoni ġenerali tal-GMO jew tal-GMOs, isem u indirizz tan-notifikant, skop tat-tluq, allokazżjoni tat-tluq u użi ntenzjonati.

- metodi u pjanijiet għal immoniterjar tal-GMO jew il-GMOs u għal rispons t'emergenza;

- assessjar t'impatt ambjentali.

(5) Jekk, għal kwalunkwe raġuni, in-notifikant jiġbed lura n-notifika, l-awtorita kompetenti għandha tirrispetta l-konfidenzjalità ta' l-informazzjoni fornuta.

Ittikketjat tal-GMOs li għalihom hemm referenza f'din id-definizzjoni ta' 'tqegħid fis-suq' fl-artikolu 2 (1).

21. Il-GMOs li għandhom isiru ottenibbli għal operazzjonijiet li għalihom hemm referenza fid-definizzjoni 'tqegħid fis-suq' fl-artikolu 2(1), għandhom ikunu suġġetti għal kondizzjonijiet t'ittikkettjar adegwati skond is-sezzjonijiet rilevanti ta' l-Iskeda IV sabiex jipprovdu nformazzjoni ċara, fuq it-tikketta jew f'dokument akkompanjatur, fil-preżenza ta' GMOs.

Għal dak l-effett il-kliem 'Dan il-prodott fih organiżmi modifikati ġenetikament' għandhom jidhru jew fuq it-tikketta inkella f'dokument akkompanjatur.

22. (1) Mingħajr preġudizzju għas-sub artikolu 2 u l-punt A Nru 7 ta' l-Iskeda IV l-awtorita kompetenti għandha: Stabbiliment ta' registri pubbliċi.

(a) tistabilixxi registri pubbliċi li fihom l-allokazzjoni tat-tluq tal-GMOs taht parti B tkun irregistrata.

(b) anke tistabilixxi registri li jirrekordjaw l-allokazzjoni ta GMOs imkabbra taht il-parti C, inter alia sabiex l-effetti possibbli ta' tali GMOs fuq l-ambjent ikunu jistgħu jkunu mmoniterjati skond id-dispożizzjonijiet ta' l-Artikoli 16(3)(f) u 17(1).

(2) Mingħajr preġudizzju għal tali dispożizzjonijiet fl-Artikoli 16 u 17, l-imsemmija allokazzjonijiet għandhom:

- ikunu nnotifikati lill-awtorita kompetenti, u
- jkunu mgharrfa lill-pubbliku bil-mod meqjus xieraq mill-awtorita kompetenti.

23. Kull persuna tista' tinstab hatja ta' reat taht dawn ir-regolamenti jekk: Reati.

(a) tonqos li tikkonforma ma' kwalunkwe dispożizzjoni ta' dawn ir-regolamenti jew tonqos li tikkonforma mal-kondizzjonijiet tal-permess jew ma' kwalunkwe ordni mogħtija legalment fit-termini ta' kwalunkwe dispożizzjoni ta' dawn ir-regolamenti; jew

(b) tikser kwalunkwe restrizzjoni, projbizzjoni jew kondizzjoni mposta minn jew taht dawn ir-regolamenti, jew

(c) taġixxi f'kontravvenzjoni ta' xi wahda mid-dispożizzjonijiet ta' dawn ir-regolamenti; jew

(d) tikkonfossa jew tipprova, jew tghin, inkella thegħegħ kwalunkwe persuna oħra bi kwalunkwe mezz, inklużi riklamar, parir jew ksib biex tikser id-dispożizzjonijiet jew biex tonqos li tikkonforma ma kwalunkwe tali dispożizzjoni (inkluża kwalunkwe ordni mogħtija legalment fit-termini ta' kwalunkwe dispożizzjoni ta' dawn ir-regolamenti) jew biex tikser kwalunkwe restrizzjoni, projbizzjoni jew kondizzjoni mposta minn jew taht l-imsemmija regolamenti.

24. Kwalunkwe persuna li tikkommetti reat kontra dawn ir-regolamenti tkun, wara li tinstab hatja, tista' tehel: Penalitajiet.

(a) l-ewwel darba li tinstab hatja multa ta' mhux inqas minn hames mitt lira Maltin imma mhux iżjed minn elf lira Maltija;

(b) it-tieni darba u fi drabi ohrajn wara, multa ta' mhux inqas minn elf lira Maltija, imma mhux iżjed minn elfejn lira Maltin jew prigunerija ghal żmien li ma jaqbiżx sentejn, jew inkella multa flimkien ma prigunerija:

Iżda wkoll li l-qorti ghandha tordna kwalunkwe persuna li nstabet hatja li kkommettiet offiża kontra dawn ir-regolamenti biex thallas ghall-ispejjeż maghmula mill-Awtorita Kompetenti msemmija f'dawn ir-regolamenti bhala riżultat ta' l-imsemmija offiża, ir-revoka tal-permess mahruġ mill-Awtorita Kompetenti u l-konfiska tal-*corpus delicti*, inkluża, jekk applikabbli, il-vettura

Applikabilità tal-Kodiċi Kriminali Kap.9.

25. (1) Id-dispożizzjonijiet ta' l-artikoli 23 sa 30 tal-Kodiċi Kriminali ghandhom japplikaw, *mutatis mutandis* ghall-proċedimenti rigward l-offiži kontra dawn ir-regolamenti, u ghalhekk l-iskwalifika mill-pussess u l-ksib ta' liċenzja, permess jew awtorita m'ghandhom f'ebda każ ma jkunu t'inqas minn sena.

(2) Minkejja d-dispożizzjonijiet tas-sezzjoni 370 tal-Kodiċi Kriminali, proċedimenti ghal offiża kontra dawn ir-regolamenti ghandhom jinżammu quddiem il-Qorti tal-Maġistrati (Malta) jew il-Qorti tal-Maġistrati (Ghawdex), kif ikun il-każ, u ghandhom ikunu skond id-dispożizzjonijiet tal-Kodiċi Kriminali li jirregola l-proċedura quddiem l-imsemmija qorti bhala qorti tal-ġudikatura kriminali.

(3) Minkejja d-dispożizzjonijiet tal-Kodiċi Kriminali, l-Avukat Ġenerali ghandu dejjem ikollu d-dritt li jappella lill-Qorti Kriminali ta' l-Appell minn kwalunkwe haqq moghti mill-Qorti tal-Maġistrati (Malta) jew il-Qorti tal-Maġistrati (Ghawdex) rigward proċedimenti ghal kwalunkwe reat kontra dawn ir-regolamenti.

Lingwa ta' Annessi.

26. L-Iskedi I sa VIII ghal dawn ir-Regolamenti qeghdin ikunu ppubblikati bil-lingwa Ingliża mat-test Ingliż ta' dawn ir-regolamenti.

SCHEDULE I A**Techniques referred to in the definition of GMO in article 2****PART 1**

Techniques of genetic modification referred to in sub-paragraph (a) in the definition of GMO in article 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 micro-injection, 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 article 5**

Techniques/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/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 impact 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 impact assessment (e.i.a) referred to in Articles 4 and 12. 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 impact 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 e.i.a. 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 e.i.a. 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 e.i.a.:

- 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 e.i.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;
- the e.i.a. 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, i.e., GMOs already in the environment;
- if new information on the GMO and its effects on human health or the environment becomes available, the e.i.a. 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 e.i.a. has to take into account the relevant technical and scientific details regarding characteristics of:

- the recipient or parental organism(s);
- the genetic modification(s), 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 e.i.a.

C.2. Steps in the e.i.a.

In drawing conclusions for the e.i.a. referred to in Articles 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 the GMO(s) 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 B 7 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 and/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 the GMO(s) 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 the GMO(s) is (are) 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 the GMO(s) is intended to be released, and the manner of the release.

4. Estimation of the risk posed by each identified characteristic of the GMO(s)

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 GMO(s)

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 the GMO(s)

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

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

On the basis of an e.i.a. 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 impact 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 the proposed release(s).
2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).
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 and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).
5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.
6. Possible immediate and/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(s).
7. Possible immediate and/or delayed effects on animal health and consequences for the feed/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 and/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 the GMO release(s).
9. Possible immediate and/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 and/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 and/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 and/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 the GMHP release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/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 and/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 the GMO release(s).

9. Possible immediate and/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 Spermatophytæ (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 the responsible scientist(s)

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 and/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 and/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 the insert(s) into the recipient or to delete a sequence;

(c) description of the insert and/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/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO;

(a) description of genetic trait(s) 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 and/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 the expressed protein(s);

(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 and/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 immunocompetent:

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

- communicability,

- infective dose,

B 2720

- 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 the purpose(s) 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. method(s) 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 the site(s) (in case of notifications under part C the site(s) 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 the region(s) 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 the proposed site(s) 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 and/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 parental organism(s),

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

11. anticipated mechanism and result of interaction between the released GMOs and the target organism(s) 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 and/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 the responsible scientist(s),
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/breeding line

(f) common name.

2. (a) Information concerning reproduction:

(i) mode(s) 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 and/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 donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted/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 the deleted region(s);

(c) copy number of the insert;

(d) location(s) of the insert(s) 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) mode(s) and/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 ARTICLES 6 AND 7)

1. Location and size of the release site(s).

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 ARTICLES 6 AND 7)

1. Purpose of the release.
2. Foreseen date(s) 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 ARTICLES 6 AND 7)

1. Any precautions taken:
 - (a) distance(s) from sexually compatible plant species, both wild relatives and crops
 - (b) any measures to minimise/prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).
2. Description of methods for postrelease treatment of the site.
3. Description of postrelease 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 Article 2 definition of "placing on the market". It may be supplemented by guidance notes, as regards the description of how the product is intended to be used, which may be issued by the Authority. The labelling of exempted organisms as required by Article 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 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 the supplier(s) 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 the geographical area(s) 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 Article 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 and/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 (Article 7)

The criteria referred to in Article 9(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, pathogenicity) 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 Articles 12, 15, 16 and 17 should include in particular the following:

1. Identification of the characteristics of the recipient organism which are relevant to the assessment of the GMO(s) 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 the release of the GMO(s) in question as compared to the release of the corresponding non-modified organism(s), based on the environment impact assessment carried out in accordance with Schedule II.

5. A conclusion on whether the GMO(s) in question should be placed on the market or as (a) product(s) 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 e.i.a.. 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 to design the monitoring plan referred to in Articles 12(2), 16(3) and 17. It may be supplemented by guidance notes to be issued by the competent authority.

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 e.i.a. 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 e.i.a.

B. General principles

Monitoring, as referred to in Articles 12, 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 e.i.a.,
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 e.i.a.:

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 e.i.a.,

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 VIII

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/deleted sequences or have the same inserted/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 sites, on the following conditions: the taxonomic 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 and/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 the GMO(s),

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

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

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

(b) a statement evaluating the impacts and risks posed by the GMO(s) 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 and/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/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 and/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 and/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 the release(s) 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.

