

LEĠISLAZZJONI SUSSIDJARJA 549.60

REGOLAMENTI DWAR RILAXX DELIBERAT TA' ORGANIŻMI MODIFIKATI ĠENETIKAMENT FL-AMBJENT

16 ta' Novembru, 2010

L-AVVIŻ LEGALI 485 tal-2010, kif emendat bl-Avviż Legali 182 tal-2019.

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

(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: Għanijiet.

(a) ikun qed isir rilaxx intenzjonat fl-ambjent ta' organiżmi ġenetikament modifikati għal xi skopijiet oħra għajr it-tqeghid 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 id-disposizzjonijiet 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 haġa waħda ma' dak l-istrument legali.

TAQSIMA A:

DISPOSIZZJONIJIET ĠENERALI

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

Tifsir.
Emendat:
A.L. 182 tal-2019.

"l-awtorità kompetenti" tfisser l-Awtorità għall-Ambjent u r-Riżorsi kif stipulat bl-Ordni dwar in- Nomina ta' 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 disposizzjonijiet differenti u għanijiet differenti ta' dawn ir-regolamenti:

L.S.549.19

Iżda l-awtoritajiet kompetenti għall-kwistjonijiet relatati mal-organiżmi modifikati ġenetikament għall-ikel u l-għalf u t-tqeghid tagħhom fis-suq għandhom ikunu l-istess entitajiet li huma responsabbli għall-implimentazzjoni tar-Regolament (KE) Nru 1829/2003 tal-Parlament Ewropew u tal-Kunsill tat-22 ta' Settembru 2003 dwar ikel u għalf modifikat ġenetikament f'Malta, skont ir-Regolamenti dwar l-Infurzar ta' Diversi Regolamenti tal-Unjoni Ewropea dwar is-Sigurtà fl-Ikel.

"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

thassar 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 l-Iskeda II;

"il-Kummissjoni" tfisser il-Kummissjoni Ewropea;

"notifika" tfisser il-prezentazzjoni, bil-miktub jew fil-format diġitali, tal-informazzjoni meħtieġa taħt dawn ir-regolamenti, lill-awtorità kompetenti;

"notifikant" tfisser kull persuna ġuridika jew fiżika li ttipprezenta 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;

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

"organizmu ġenetikament modifikat (GMO)" tfisser organismu, bl-eċċezzjoni tal-bnedmin, li fihom il-materjal ġenetiku ġie mibdul b'mod illi ma jseħx 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 fl-Iskeda I A, Parti 1;
- (b) it-tekniki elenkati fl-Iskeda I A, Parti 2, m'humie x 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' hażna biex jillimitaw il-kuntatt tagħhom ma', u jipprovdi livell għoli ta' sigurtà, għall-popolazzjoni b'mod 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 hlas kemm jekk bla hlas; l-operazzjonijiet li ġejjin ma għandhomx jitqiesu bħala tqegħid fis-suq:

- (a) li tagħmel disponibbli mikro-organismi ġenetikament modifikati għal attivitajiet regolati skont ir-Regolamenti dwar l-Użu Kontenut ta' Mikro-Organismi Modifikati Ġenetikament inklużi kollezzjonijiet ta' kultura;

- (b) li tagħmel disponibbli GMOs minbarra l-mikro-organizmi msemmija fil-paragrafu (a), biex jiġu użati esklużivament għal attivitajiet fejn jintużaw miżuri xierqa u stretti ta' hażna 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' hażna kif stabbilit fir-Regolamenti dwar l-Użu Kontenut ta' Mikro-Organizmi Modifikati Ġenetikament; L.S. 549.49
- (c) li tagħmel disponibbli GMOs biex jiġu użati esklużivament għal rilaxx intenzjonat u li jikkonformaw mal-htigijiet stabbiliti fit-Taqsima B ta' dawn ir-regolamenti.

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

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

4. (1) GMOs jistgħu jiġu rilaxxati jew jitqegħdu fis-suq intenzjonalment biss b'konformità mat-Taqsima B jew mat-Taqsima ~ ta' dawn ir-regolamenti rispettivament. Obbligi ġenerali.

(2) Kull persuna għandha, qabel ma tippreżenta notifika skont it-Taqsima B jew it-Taqsima ~, tagħmel evalwazzjoni ta' riskju ambjentali. L-informazzjoni li tista' tkun neċessarja biex tagħmel evalwazzjoni ta' riskju ambjentali hija stabbilita fl-Iskeda III.

Dawk il-GMOs li jkun fihom ġeni li għandhom reżistenza għall-antibijotiċi bl-użu għat-trattament mediku jew veterinarju, għandhom jittiehdu f'konsiderazzjoni meta ssir evalwazzjoni ta' riskju ambjentali, bil-ħsieb li jiġu identifikati u jitnehhew 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 it-Taqsima ~ u sal-31 ta' Diċembru 2008 fil-każ ta' GMOs awtorizzati skont it-Taqsima 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 għal organizmi oħra għandhom jiġu stmati akkuratament fuq bażi ta' każ b'każ. Din l-evalwazzjoni għandha ssir skont l-Iskeda II u tiegħu kont tal-impatt ambjentali skont in-natura tal-organizmu 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 skont it-Taqsima B u t-Taqsima ~ għal konformità mar-rekwiżiti ta' dawn ir-regolamenti u jekk l-evalwazzjoni li hemm provdut dwarha fis-subregolament (2) tkunx wahda 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 nġatitx awtorizzazzjoni, 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.

TAQSIMA B:

RILAXX INTENZJONAT TA' GMOs GĦAL KULL SKOP IEHOR
HLIEF BIEK JIQTQEGĦDU FIS-SUQ

Kif japplikaw ir-regolamenti 6 sa 10.

L.S. 458.34

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 hlief dak li jitqieghdu fis-suq hu awtorizzat mir-Regolamenti 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 tipprovd:

- (a) għal evalwazzjoni ta' riskju speċifiku ambjentali skond l-Iskeda II u fuq il-bażi tat-tip ta' informazzjoni speċifika fl-Iskeda III mingħajr preġudizzju għal rekwiżiti addizzjonali li hemm provdut dwarhom b'dawk il-liġijiet;
- (b) għal kunsens espliċitu qabel ir-rilaxx;
- (c) għal pjan ta' sorveljar skont il-partijiet rilevanti tal-Iskeda III, bil-ħsieb li tikkonferma l-effetti ta' GMO jew GMOs fuq is-saħħa tal-bniedem jew l-ambjent;
- (d) f'manjiera adatta għal rekwiżiti dwar trattament ta' oġġetti godda 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 ttiehdu skont dan.

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

Proċedura ta' awtorizzazzjoni standard.
Emendat:
A.L. 182 tal-2019.

6. (1) Mingħajr preġudizzju għall-artikolu 5, kull persuna għandha, qabel ma tirrilaxxa 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 fl-Iskeda 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 tal-Iskeda 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' emergenza,
 - (vii) sommarju tad-*dossier* fil-format stabbilit skont il-proċedura stabbilita fl-Artikolu 30(2) tad-Direttiva;
- (b) evalwazzjoni ta' riskju ambjentali u l-konklużjonijiet meħtieġa fl-Iskeda II, taqsima D, flimkien ma' riferenza biblijografika u indikazzjonijiet tal-metodi użati;
- (ċ) in-notifika għandha tkun akkumpanjata mid-dokumenti rilevanti u kwalunkwe informazzjoni oħra meħtieġa kif speċifikat u meħtieġ mill-awtorità kompetenti. In-notifikant għandu jindika b'mod ċar jekk in-notifika tkunx ser tippreġudika xi każ ta' infurzar, xi każ pendenti quddiem il-qorti jew xi kawża oħra li jkunu għandhom *sub-judice*.
- (3) In-notifikant jista' jirreferi għal *data* jew riżultati minn notifiċi 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 tal-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 skont l-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 tletin gurnata minn meta tasal in-notifika, kopja tas-sommarju tan-notifika riċevuta skont is-subartikolu (2)(a)(vii);
 - (ċ) teżamina jekk in-notifika tkun saret skont dawn ir-regolamenti;
 - (d) tikkunsidra kull osservazzjoni li tkun waslet għand awtorità kompetenti ta' Stat Membru ieħor skont l-Artikolu 11(2) tad-Direttiva;
 - (e) jekk tkun intalbet minn awtorità kompetenti ta' Stat Membru ieħor għall-finijiet tad-Direttiva, tibghat

kopja shiħa ta' notifika lill-awtorità imsemmija;

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

(g) tnizzel il-konklużjonijiet bil-miktub.

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

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

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

(7) Għall-iskop ta' kalkolu tal-perjodu ta' disgħin ġurnata msemmija fis-subregolament (6), ma għandux jittiehed f'konsiderazzjoni 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 tiżvolgi inkjesta jew konsultazzjoni pubblika skont ir-regolament 9; din l-inkjesta pubblika jew konsultazzjoni ma għandhiex ittawwal il-perjodu ta' disgħin ġurnata msemmi fis-subregolament (6), b'izjed 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 tal-awtorità kompetenti, u konformi ma' kull kondizzjoni meħtieġa f'dan il-kunsens.

(10) Ebda materjal li ġej minn GMOs li huma deliberatament rilaxxati skond it-Taqsima B ma għandhom jitqegħdu fis-suq, sakemm dan ma jsirx skont it-Taqsima ~.

Proċeduri
differenzjati.
Emendat:
A.L. 182 tal-2019.

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 fl-Iskeda V, l-awtorità kompetenti tista', skont 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 l-kunsens bil-miktub tal-awtorità kompetenti u skont l-inqas ammont stabbilit fl-Iskeda III ta' informazzjoni teknika neċessarja biex jiġu evalwati r-riskji previsti jkollha mir-rilaxx, b'mod partikolari:

(a) informazzjoni dwar kull GMO;

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

(c) 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 elenkati fl-Iskeda IX għandhom ikunu applikabbli għar-rilaxx intenzjonat fl-ambjent ta' pjanti ġenetikament modifikati li jaqgħu taħt it-tifsira ta' pjanti ġenetikament modifikati inklużi fil-partita 1 tal-Iskeda IX.

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:

Gestjoni ta' modifiki u informazzjoni ġdida.

- (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;
- (c) 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 lill-pubbliku b'dan kollu;
- (c) tista' titlob lin-notifikant sabiex iħallas jew jikontribwixxi għal xi spejjeż jew l-ispejjeż kollha li tkun għamlet sabiex tipproteġi s-saħħa tal-bniedem u l-ambjent.

(3) Fil-każ tas-subregolamenti (1) u (2), 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.

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

Konsultazzjoni u informazzjoni lill-pubbliku.

- (2) Bla hsara għas-subregolament (3), għall-għanijiet, hlief ta'

tqegħid fis-suq, in-notifikant ta' rilaxx intenzjonat propost għandu, mhux aktar minn erbatax-il ġurnata wara d-data tan-notifika lill-awtorità kompetenti, jippubblika f'gazzetta 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 tal-organizmu modifikat ġenetikament proposta li tiġi rilaxxata,
- (c) il-fatt li tkun ġiet 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-uffiċċju prinċipali tagħha,
- (g) il-fatt illi, skond is-subregolament (5), kull persuna jew għaqda tista', fi żmien tmienja u għoxrin ġurnata li jibdedew għaddejin fil-ġurnata tal-pubblikazzjoni tal-avviż, tagħmel ilmenti bil-miktub lill-awtorità kompetenti dwar in-notifika,

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

(3) L-informazzjoni fuq il-post tar-rilaxx intenzjonat propost pubblikat konformement mas-subregolament (2) għandha tkun l-istess bhall-informazzjoni fuq il-post inidikat fir-registru miżmum mill-awtorità kompetenti skont 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 registru.

(4) In-notifikant għandu, sa mhux aktar tard minn erbatax-il ġurnata minn meta tasal in-notifika għand l-awtorità kompetenti, jibgħat kopja tal-avviż pubblikat konformement mas-subregolament (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 tmienja u għoxrin ġurnata li jibdedew għaddejin mill-ġurnata tal-pubblikazzjoni tal-avviż skont 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-uffiċċju prinċipali tagħha,
- (c) jintbagħtu lill-awtorità kompetenti fi żmien tmienja u

ghoxrin 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 skont is-subregolament (5), hija għandha -

- (a) tikkonferma illi tkun irċeviet l-ilmenti, u
- (b) tikkunsidra l-ilmenti biex tiġi deċiża n-notifika.

10. (1) In-notifikant għandu -

- (a) fit-tmiem tar-rilaxx intenzjonat, u
- (b) f'kull intervall sussegwenti stipulat fil-kunsens,

Rapport minn
notifikant fuq
rilaxx.

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

(2) Ir-rapport imsemmi fis-subregolament (1) għandu jiġi provdut f'dak il-format jew formati li jistgħu jiġu stabbiliti skont il-proċedura stipulata fl-Artikolu 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 skont is-subregolament (1) għandu, wara l-wasla tiegħu, jintbqgħat mill-awtorità kompetenti lill-Kummissjoni skont l-Artikolu 11(3) tad-Direttiva.

TAQSIMA ~:

TQEGHID FIS-SUQ TA' GMOs BĦALA JEW FI PRODOTTI

11. (1) Ir-regolamenti 12 sa 19 ma japplikawx għal xi GMO bħal jew fi prodotti, sakemm dawn ikunu awtorizzati minn xi leġislazzjoni rilevanti li tipprovdi għall-evalwazzjoni ta' riskju ambjentali speċifiku li jsir skond il-prinċipji stabbiliti fl-Iskeda II u fuq il-baži ta' informazzjoni speċifikati fl-Iskeda III, mingħajr preġudizzju għal rekwiżiti addizzjonali provduti minn leġislazzjoni 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.

Leġislazzjoni
settorali.

(2) Mingħajr preġudizzju għall-Iskeda IB u bla ħsara għall-eskluzjonijiet 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:

Obbligu ta'
osservanza tat-
Taqsima ~.

- (a) l-awtorità kompetenti ma tkunx irċeviet il-kunsens bil-

miktub skont it-Taqsima ~, jew

- (b) ma jkunx wasal il-kunsens bil-miktub tal-awtorità kompetenti ta' Stat Membru iehor skont it-Taqsima ~ tad-Direttiva,

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

Proċedura ta'
notifika.
Emendat:
A.L.182 tal-2019.

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.

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

(2) In-notifika għandu jkun fiha:

- (a) l-informazzjoni meħtieġa fl-Iskedi III u IV. Din l-informazzjoni għandha tiegħu konsiderazzjoni 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 meħtieġa fl-Iskeda II;
- (c) il-konklużjonijiet milħuqa minn notifikant skont l-Iskeda II, flimkien ma' kull referenza bibliografika, u dettalji 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(5), perjodu propost għal kunsens li m'għandux jeċċedi l-għaxar snin;
- (f) pjan għal sorveljanza skont l-Iskeda VII, inkluża proposta għal perjodu ta' żmien għal pjan ta' monitoraġġ; dan il-perjodu ta' żmien jista' jkun differenti mill-perjodu propost għall-kunsens;
- (g) proposta għat-tikkettjar li tikkonforma mar-rekwiżiti stabbiliti fl-Iskeda 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 fl-Iskeda IV;
- (i) sommarju tan-notifika li tista' tiġi stabbilita mill-awtorità kompetenti minn żmien għal 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) in-notifikant għandu jindika b'mod ċar jekk in-notifika tkunx ser tippregudika xi każ ta' infurzar, xi każ pendenti quddiem il-qorti jew xi kawża oħra li jkunu għadhom *sub-judice*:

Iżda jekk, fuq il-bażi tar-riżultati ta' xi rilaxx notifikat skond it-Taqsima B, jew fuq raġunijiet oħra sostantivi, u motivati xjentifikament, notifikant jikkunsidra li t-tqeghid 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 tipprovdi parti jew l-informazzjoni kollha meħtieġa fl-Iskeda IV, taqsima B.

(3) In-notifikant għandu jinkludi f'din in-notifika informazzjoni fuq *data* jew riżultati minn rilaxx tal-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-notifikant jista' wkoll jirreferi għal *data* jew riżultati minn notifiċi li ġew mogħtija qabel minn notifikanti oħra jew jagħti informazzjoni addizzjonali li 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 li jipproponi tqeghid fis-suq ta' prodott li jkun fih jew li jkun jikkonsisti f'xi organiżmu ġenetikament modifikat għall-ewwel darba għandu jippubblika avviż skont ir-regolament 9 bil-kliem "TQEGHID FIS-SUQ PROPOST TA' PRODOTT LI GĦANDU JKUN FIH JIKKONSISTI F'ORGANIŻMU MODIFIKAT ĠENETIKAMENT". Flimkien mar-rekwiżiti rilevanti stipulati fir-regolament 9(2) l-avviż għandu jinkludi wkoll:

- (a) l-indirizz postali sħiħ tal-Kummissjoni,
- (b) fir-rigward tan-notifika preżentata skont 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 skont ir-regolament 13(1)(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.
Emendat:
A.L. 182 tal-2019.

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

- (a) tgħarraġ lin-notifikant bil-miktub bid-data ta' meta tkun irċeviet in-notifika,
- (b) għandha immedjatament tibgħat kopja ta' sommarju tan-notifika riċevuta skond ir-regolament 12(2)(i) lill-awtoritajiet kompetenti ta' Stati Membri oħra għall-iskop tad-Direttiva u lill-Kummissjoni,
- (c) teżamina n-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-awtorità 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' disghin 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 tibgħat lill-Kummissjoni kopja tar-rapport ta' evalwazzjoni imsemmi fis-subregolament (3) jew (4).

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

- (a) tipprepara skont l-Iskeda VI rapport ta' evalwazzjoni li għandu wkoll jindika jekk:
 - (i) l-organizmu modifikat ġenetikament involut għandux jitqieghed fis-suq u taht liema kondizzjonijiet (imsemmija bħala "evalwazzjoni favorevoli"); jew
 - (ii) l-organizmu modifikat ġenetikament involut m'għandux jitqieghed fis-suq (imsemmija 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 mal-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 hmistax-il ġurnata wara li tibgħat kopja tar-rapport ta' evalwazzjoni lin-notifikant u mhux iktar tard minn mija u hames ġranet 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.ħ

(5) Mingħajr preġudizzju għar-Regolament (KE) Nru 1829/2003 dwar ikel u għalf modifikat ġenetikament:

- (a) waqt il-proċedura ta' awtorizzazzjoni l-awtorità kompetenti jew Stati Membri oħra jistgħu jitolbu li l-ambitu ġeografiku tal-kunsens bil-miktub jiġi aġġustat bl-effett li t-territorju kollu jew parti mit-territorju ta' Malta jew l-Istat Membru konċernat, skont kif ikun il-każ, għandu jiġi eskluż mill-kultivazzjoni. Din it-talba għandha ssir skont l-Artikolu 26b (1) tad-Direttiva;
- (b) fi żmien tletin (30) ġurnata mill-preżentazzjoni tat-talba lin-notifikant mill-Kummissjoni, in-notifikant jista' jaġġusta jew jikkonferma l-ambitu ġeografiku tan-notifika inizzjali;
- (c) fin-nuqqas tal-konferma tal-ambitu ġeografiku inizzjali min-notifikant, l-aġġustament tal-ambitu ġeografiku għandu jiġi implimentat fil-kunsens bil-miktub mahruġ skont dawn ir-regolamenti;
- (d) fejn applikabbli, il-kunsens bil-miktub mahruġ taht dawn ir-regolamenti mill-awtorità kompetenti għandu imbagħad jinhareġ fuq il-bażi tal-ambitu ġeografiku aġġustat tan-notifika.

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

Proċedura
standard.
Emendat:
A.L. 182 tal-2019.

- (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-tqeghid tal-prodott fis-suq li tkun saret mill-Kummissjoni jew minn awtorità kompetenti ta' Stat Membru iehor għall-finijiet tad-Direttiva meta dawn il-kummenti jew oġġezzjonijiet isiru f'perjodu ta' sittin (60) ġurnata mid-data ta' meta d-dokumenti msemmija fir-regolament 13(3) ikunu ġew mibgħuta lil kull awtorità kompetenti bhal dik mill-Kummissjoni, u
- (c) tipparteċipa f'diskussjonijiet fir-rigward tar-rapport ta' evalwazzjoni li jkun ġie mibdi mill-Kummissjoni fuq il-bażi tal-oġġezzjonijiet motivati magħmula skont il-paragrafu (b) bil-ħsieb li jintlaħaq ftehim fi żmien mija u ħames granet, 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 jittiehed f'konsiderazzjoni għall-finijiet tal-kalkolu tal-perjodu finali ta'

hamsa u erbgħin ġurnata biex jintlaħaq ftehim.

(2) L-awtorità 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 għet magħmula mill-Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru skont is-subregolament (1)(b), jew
- (b) oġġezzjoni motivata għal evalwazzjoni favorevoli tkun għet magħmula mill-Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru skont is-subregolament (1)(b) imma l-kwistjonijiet involuti jkunu ġew solvuti skont id-disposizzjonijiet tal-Artikolu 15(1) tad-Direttiva, jew
- (c) oġġezzjoni motivata għal evalwazzjoni favorevoli tkun għet magħmula mill-Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru skont is-subregolament (1)(b) u dik il-Kummissjoni tkun adottat deċiżjoni favorevoli skont id-disposizzjonijiet tal-Artikolu 18(1) tad-Direttiva.

(3) Jekk l-awtorità kompetenti tiddeċiedi li l-prodott jista' jitqiegħed fis-suq, għandha tagħti kunsens bil-miktub, tibgħata lin-notifikant, u tinforma lill-Istati Membri l-oħra u lill-Kummissjoni b'dan fi żmien tletin (30) ġurnata:

Iżda meta talba, jew talbiet, skont ir-regolament 13(5) jiġu kkomunikati lill-Kummissjoni wara d-data taċ-ċirkolazzjoni tar-rapport ta' evalwazzjoni meħtieġ taht ir-regolament 13(2) l-iskeda ta' żmien sabiex joħroġ il-kunsens bil-miktub għandha tiġi estiża b'perjodu wieħed ta' hmistax-il (15) ġurnata, irrISPettivament għan-numru tat-talbiet ippreżentati. Din id-dispożizzjoni għandha tkun mingħajr preġudizzju għar-Regolament (KE) Nru 1829/2003 dwar ikel u għalf modifikat ġenetikament.

(4) L-awtorità kompetenti għandha, meta hija tkun għamlet evalwazzjoni sfavorevoli, jew meta l-Kummissjoni tkun adottat deċiżjoni sfavorevoli skont id-disposizzjonijiet tal-Artikolu 18(1) tad-Direttiva, tinforma lin-notifikant bil-miktub, li l-kunsens ikun ġie miċhud filwaqt li tagħti r-raġunijiet għal dak iċ-ċhid.

(5) Bla ħsara għad-disposizzjonijiet tas-subregolament (6), l-awtorità kompetenti ma għandhiex tagħti kunsens taht it-Taqsima ~ għal perjodu ta' żmien li jeċċedi l-ghaxar snin li jibda għaddej mill-ġurnata meta jinhareġ 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 taht il-liġijiet tal-Unjoni Ewropea li jkunu fis-seħħ, jew mal-materjal riproduttiv modifikat ġenetikament tal-foresti, il-perjodu tal-ewwel kunsens għandu jkun limitat skont id-disposizzjonijiet tal-Artikolu 15(4) tad-Direttiva.

tiġdid tal-kunsensi mogħtijin taħt it-Taqsima ~.

(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 jiġġedded,
- (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 tittiehed 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,
- (c) 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-kondizzjonijiet li jinsabu fil-kunsens oriġinali mogħti mill-awtorità kompetenti, inklużi kondizzjonijiet relatati mal-monitoraġġ futur u limitazzjoni ta' żmien tal-kunsens.

(4) Mal-wasla ta' notifikazzjoni taħt is-subregolament (2), l-awtorità 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),
- (c) 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, skont l-Iskeda VI, rapport ta' evalwazzjoni li għandu jindika:
 - (i) jekk l-organizmu modifikat ġenetikament inkwistjoni għandux jibqa' fis-suq u b'liema kondizzjonijiet (imsemmija bħala "evalwazzjoni favorevoli");
 - (ii) jew l-organizmu modifikat ġenetikament inkwistjoni m'għandux jibqa' fis-suq (indikati 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) Id-dispożizzjonijiet imsemmija fir-regolament 13(5) dwar talba jew talbiet biex l-ambitu ġeografiku tal-kunsens bil-miktub jiġi aġġustat għandhom japplikaw ukoll għat-tiġdid tal-kunsens.

(6) 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, thassib jew oġġezzjonijiet motivati għall-prodott li jibqa' fis-suq magħmulin mill-Kummissjoni jew minn awtorità kompetenti ta' Stat Membru għall-finijiet tad-Direttiva meta daww il-kummenti jew oġġezzjonijiet isiru fi żmien sittin ġurnata mid-data meta d-dokumenti msemmija fis-subregolament (4)(d) ikunu ġew mibgħuta lil kull awtorità kompetenti bħal dik mill-Kummissjoni, u
- (c) tipparteċipa f'diskussjonijiet li jkunu jirrigwardaw ir-rapport ta' evalwazzjoni li jkun l-ewwel tressaq mill-Kummissjoni minhabba fl-oġġezzjonijiet motivati magħmulin skont il-paragrafu (b) bil-hsieb li jintlaħaq ftehim fi żmien hamsa u sebgħin ġurnata, li jibdw għaddejin mid-data meta d-dokumenti msemmija fis-subregolament (4)(d) kienu mibgħutin lil kull awtorità kompetenti bħal dik mill-Kummissjoni.

(7) L-awtorità kompetenti għandha ggedded 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 skont is-subregolament (6)(b), jew
- (b) tkun saret oġġezzjoni motivata għal evalwazzjoni sfavorevoli mill-Kummissjoni jew minn awtorità kompetenti ta' xi Stat Membru skont is-subregolament (6)(b) imma l-kwistjonijiet involuti jkunu ġew solvuti skont id-dispożizzjonijiet tal-Artikolu 17(7) u (8) tad-Direttiva, jew
- (c) tkun saret oġġezzjoni motivata għal evalwazzjoni sfavorevoli tkun giet magħmula mill-Kummissjoni jew minn awtorità kompetenti ta' xi Stat Membru skont is-subregolament (4)(d) u dik il-Kummissjoni tkun adottat deċiżjoni favorevoli skont id-dispożizzjonijiet tal-Artikolu 18(1) tad-Direttiva.

(8) Meta l-awtorità kompetenti ggedded il-kunsens skont is-subregolament (7), l-awtorità għandha tibgħat lin-notifikant id-deċiżjoni finali bil-miktub u għandha tinforma lill-Istati Membri l-oħra u lill-Kummissjoni b'dan fi żmien tletin (30) ġurnata li jibdw jiddekoru mill-ġurnata li fiha l-kunsens ġie mgedded:

Iżda meta talba, jew talbiet, skont is-subregolament (5) jiġu kkomunikati lill-Kummissjoni wara d-data taċ-ċirkolazzjoni tar-rapport ta' evalwazzjoni, l-iskeda ta' żmien biex joħroġ it-tiġdid tal-kunsens bil-miktub għandu jiġi estiż b'perjodu wieħed ta' hmistax-il (15) ġurnata, irrispettivament għan-numru tat-talbiet ippreżentati. Din id-dispożizzjoni għandha tkun mingħajr preġudizzju għar-Regolament (KE) Nru 1829/2003 dwar ikel u għalf modifikat ġenetikament.

(9) L-awtorità kompetenti għandha, meta tkun għamlet evalwazzjoni sfavorevoli, jew meta l-Kummissjoni tkun adottat deċiżjoni sfavorevoli skond id-dispożizzjonijiet tal-Artikolu 18(1) tad-Direttiva, tinforma lin-notifikant illi t-tiġdid tal-kunsens ikun ġie miċhud u għandha tagħti r-raġunijiet għal dak iċ-ċhid.

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

16. (1) Prodott jista' jiġi użat mingħajr il-htieġa ta' notifika ulterjuri lill-awtorità kompetenti ta' Stat Membru f'dawk il-każijiet biss meta jkun inġhata 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.

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

(b) L-awtorità kompetenti għandha tiehu l-miżuri kollha neċessarji biex tiżgura li kull kunsens mogħti bil-miktub ikun aċċessibbli għall-pubbliku u li dawk il-kondizzjonijiet 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 esplicitu:

(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;

(c) il-kondizzjonijiet għat-tqegħid fis-suq tal-prodott, inkluża kull kondizzjoni speċifika ta' użu, maniġġar u pakkeġġar ta' kull GMO bħala jew fi prodotti, u kondizzjonijiet 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, skont ir-rekwiżiti stabbiliti fl-Iskeda IV. It-tikkettjar għandu jindika b'mod ċar il-preżenza ta' GMO. Il-kliem "Dan il-prodott fih

organizmi modifikati ġenetikament" għandhom jidhru jew fuq it-tikketta jew fuq dokument li jkun mal-prodott jew ma' prodotti oħra li jkun fihom xi GMO;

- (f) ir-rekwiżiti ta' sorveljar skont l-Iskeda VII, inklużi obbligi biex tirrapporta lill-Kummissjoni, il-perjodu ta' żmien tal-pjan ta' sorveljar u, fejn adatt, kull obbligu 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' informazzjoni li jitqies li jkun adatt fil-post tagħhom.

(4) (a) Stat Membru ieħor jista' jitlob lill-awtorità kompetenti biex tintegra mill-ġdid it-territorju kollu tagħha jew parti minnu fl-ambitu ġeografiku ta' kunsens minn liema ġie eskluż skont s-subregolamenti 13(5) u 15(5). L-awtorità kompetenti għandha imbagħad temenda l-ambitu ġeografiku tal-kunsens kif meħtieġ.

- (b) L-awtorità kompetenti tista', jekk ikun meħtieġ, terġa' tintegra l-Gżejjer Maltin kollha jew parti minnhom fl-ambitu ġeografiku tal-kunsens minn fejn ġiet eskluża skont is-subregolamenti 13(5) u 15(5).

- (c) Ladarba l-aġġustament skont il-paragrafu (a) jew (b) ikun komplut l-awtorità kompetenti għandha tinforma kif dovut lill-Kummissjoni, lill-Istati Membri u d-detentur tal-kunsens.

16A. Mingħajr preġudizzju għar-Regolament (KE) Nru 1829/2003 dwar ikel u għalf modifikat ġenetikament:

(1) Jekk l-ebda talba sabiex jiġi aġġustat l-ambitu ġeografiku ta' kunsens bil-miktub ma tkun saret skont id-Direttiva jew taħt dawn ir-regolamenti, skont kif ikun il-każ, jew fejn in-notifikant ikun ikkonferma l-ambitu ġeografiku tan-notifika inizzjali, l-awtorità kompetenti tista' tadotta miżuri li jirrestringu jew jipprojbixxu l-kultivazzjoni fit-territorju Malti kollu jew f'parti minnu, ta' GMO jew ta' grupp ta' GMOs imfissra skont il-prodott ta' raba' (għalla) jew il-karatteristika, ladarba it-tqegħid fis-suq huwa awtorizzat taħt id-Direttiva jew taħt dawn ir-regolamenti.

(2) (a) Miżuri adottati skont is-subregolament (1) għandhom ikunu konformi mal-liġi tal-Unjoni, raġonevoli, proporzjonali, mhux diskriminatorji u bbażati fuq raġunijiet konvinċenti, bħal dawk relatati mal-:

- (i) objettivi tal-politika ambjentali;
- (ii) ippjanar urban u rurali;
- (iii) użu tal-art;
- (iv) impatti soċjo-ekonomiċi;

(v) evitar tal-preżenza ta' GMOs fi prodotti oħra mingħajr preġudizzju għar-regolament 16B;

Miżuri li
jillimitaw jew
jipprojbixxu l-
kultivazzjoni fit-
territorju Malti
kollu jew f'parti
minnu.
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(vi) għanijiet tal-politika agrikola; u

(vii) politika pubblika.

(b) Ir-raġunijiet konvinċenti jistgħu jiġu invokati individwalment jew flimkien, bl-eċċezzjoni tas-subparagrafu (vii) tas-subregolament (2)(a) li ma jistax jiġi invokat b'mod individwali. Ir-raġunijiet jiddependu fuq iċ-ċirkostanzi partikolari ta' Malta, fuq ir-regġun jew iż-żona fejn il-miżuri ser japplikaw u m'għandhom fl-ebda każ ikunu f'kunflitt mal-evalwazzjoni ta' riskju ambjentali mwettaq skont id-Direttiva jew dawn ir-regolamenti.

(3) L-abbozz tal-miżuri li l-awtorità kompetenti tkun bi ħsiebha tadotta flimkien mar-raġunijiet rilevanti li ġew invokati għandhom jiġi debitament kkomunikati lil Kummissjoni. Din il-komunikazzjoni tista' ssir qabel il-proċedura ta' awtorizzazzjoni tal-GMO taht il-Parti Ċ tad-Direttiva jew dawn ir-regolamenti tkun tlestiet.

(4) L-awtorità kompetenti għandha toħroġ avviż fil-Gazzetta fejn għandu jiġi pprojbit it-thawwil tal-GMO jew GMOs li għalihom miżuri ġew abbozzati skont is-subregolament (3). Dan l-avviż għandu jkopri perjodu ta' ħamsa u sebghin (75) ġurnata li jibda mill-jum li l-abbozz tal-miżuri ikunu ġew kkomunikati lill-Kummissjoni.

(5) Meta jiskadi l-perjodu tal-ħamsa u sebghin (75) jum imsemmi fis-subregolament (4) l-awtorità kompetenti tista', għad-dureza kollha tal-kunsens għat-tqegħid fis-suq u mid-data tad-dhul fis-seħħ tal-awtorizzazzjoni konċernata, tadotta miżuri li jillimitaw jew jipprojbixxu l-kultivazzjoni tal-GMO jew il-grupp ta' GMOs imsemmija fis-subregolament (4). Dawn il-miżuri għandhom ikunu dawk oriġinarjament proposti mill-awtorità kompetenti jew kif emendati wara li l-Kummissjoni tibgħat il-kummenti tagħha.

(6) (a) Ladarba l-awtorità kompetenti tadotta miżuri skont dan ir-regolament għandha minnufih tikkomunika dawn il-miżuri lill-Kummissjoni, lill-Istati Membri l-oħra u lid-detentur tal-kunsens mingħajr dewmien.

(b) L-awtorità kompetenti għandha wkoll tippubblika kwalunkwe miżura adottata skont is-subregolament (5) fil-Gazzetta.

(7) L-awtorità kompetenti tista' tirrevoka l-miżuri meħuda skont dan ir-regolament fi kwalunkwe żmien. Din ir-revoka għandha minnufih tiġi kkomunikata lill-Kummissjoni u lill-Istati Membri l-oħra.

16B. L-awtorità kompetenti f'kollaborazzjoni mal-awtoritajiet rilevanti oħra tista' tiegħu miżuri xierqa fiż-żoni konfinali li jimmiraw li jevitaw tniġġis transkonfinali possibbli fl-Istati Membri ġirien li fihom il-kultivazzjoni ta' dawn il-GMOs hija

Miżuri biex
tiġievitata
kontaminazzjoni
transkonfinali.

Sorveljar u
maniġġar ta'
informazzjoni
ġdida.
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pprojbta, kif ikun xieraq. Dawn il-miżuri għandhom jiġu kkomunikati lill-Kummissjoni.

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

(2) Jekk informazzjoni ġdida ssir disponibbli mill-utenti jew minn sorsi oħra fir-rigward tar-riskji ta' kull GMO għas-saħħa tal-bniedem jew għall-ambjent wara li jingħata kunsens bil-miktub, in-notifikant għandu:

- (a) jirrevedi n-notifika kif meħtieġ; u
- (b) jieħu l-miżuri neċessarji minnufih biex jipproteġi s-saħħa tal-bniedem u l-ambjent u jinforma lill-awtorità kompetenti dwar dan.

(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 skont ċirkostanzi deskritti fis-subregolament (2), din tista' tħaddem id-dispożizzjonijiet tar-regolament 14 u 15 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 iġġedded il-kunsens taħt ir-regolament 15, l-awtorità kompetenti tkun giet 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 fis-subregolament (2), din għandha:

- (a) immedjatament tibgħat l-informazzjoni lill-Kummissjoni u lill-awtoritajiet kompetenti tal-Istati Membri għall-finijiet tad-Direttiva,
- (b) tipprepara rapport ta' evalwazzjoni skont l-Iskeda VI li għandu jindika:
 - (i) jekk l-organizmu modifikat ġenetikament inkwistjoni għandux jibqa' fis-suq u taħt liema kondizzjonijiet (imsemmija bħala "evalwazzjoni favorevoli");
 - (ii) jew l-organizmu modifikat ġenetikament inkwistjoni m'għandux jibqa' fis-suq (imsemmija bħala "evalwazzjoni sfavorevoli"),
- (c) fi żmien sittin 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 tipprovdidi bidliet konsiderevoli fin-notifika, l-

awtorità kompetenti tista' titlob lin-notifikant biex jiegqaf 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 garrbet 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 kument, tħassib jew oġġezzjonijiet motivati għar-rapport ta' evalwazzjoni riferiti fis-subregolament (4)(b) magħmula mill-Kummissjoni jew minn awtorità kompetenti ta' Stat Membru ieħor għall-finijiet tad-Direttiva meta daww il-kummenti jew oġġezzjonijiet ikunu ġew magħmulin f'perjodu ta' sittin gurnata li jibdeu għaddejin mid-data ta' meta r-rapport ta' evalwazzjoni jkun ġie mghoddi lil kull waħda mill-awtoritajiet kompetenti bħal daww mill-Kummissjoni; u
- (c) tipparteċipa f'diskusjonijiet li jkollhom x'jaqsmu mar-rapport ta' evalwazzjoni mibdijin mill-Kummissjoni tal-Komunitajiet Ewropej skont oġġezzjonijiet motivati li jsiru skont il-paragrafu (b) bil-għan li jintlaħaq ftehim fi żmien hamsa u sebgħin gurnata, mid-data li jibdeu għaddejin meta d-dokumenti msemmija fis-subregolament (4)(b) ikunu ġew mghoddija lil kull waħda minn daww l-awtoritajiet kompetenti mill-Kummissjoni.

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

- (a) ma' tkunx saret ebda oġġezzjoni motivata għal evalwazzjoni favorevoli mill-Kummissjoni jew minn xi awtorità kompetenti ta' Stat Membru skont is-subregolament (5)(b), jew
- (b) tkun saret oġġezzjoni motivata għal evalwazzjoni favorevoli mill-Kummissjoni jew minn awtorità kompetenti ta' Stat Membru skont is-subregolament (5)(b) imma kwistjonijiet involuti jkunu ġew solvuti skont id-disposizzjonijiet tal-Artikolu 20(3) tad-Direttiva, jew
- (c) tkun saret oġġezzjoni motivata għal evalwazzjoni favorevoli mill-Kummissjoni jew minn awtorità kompetenti ta' Stat Membru skont is-subregolament (5)(b) u dik il-Kummissjoni tkun adottat deċiżjoni favorevoli skont id-disposizzjonijiet tal-Artikolu 18(1)

tad-Direttiva.

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

(8) L-awtorità kompetenti għandha, meta tkun għamlet evalwazzjoni sfavorevoli, jew meta il-Kummissjoni tkun adottat deċiżjoni sfavorevoli skont id-disposizzjonijiet tal-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 skont 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 skont dan ir-regolament.

(11) L-awtorità kompetenti għandha tara li r-riżultati ta' sorveljanza li tkun saret taht it-Taqsima ~ ikunu disponnibli għall-pubbliku.

Tikkettjar.
Emendat:
A.L. 182 tal-2019.

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-rekwiziti rilevanti speċifikati fil-kunsens bil-miktub imsemmija fir-regolamenti 14(2), 15(7) u 16(3).

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

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

Riżerva.
Emendat:
A.L. 182 tal-2019.

19. (1) Fejn, b'riżultat ta' informazzjoni ġdida jew addizzjonali 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 taht dawn ir-regolamenti jikkostitwixxi riskju lis-saħħa tal-bniedem jew l-ambjent, dik l-awtorità kompetenti tista' proviżorjament tirrestringi jew tipprobixxi 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.

TAQSIMA D:

KUNFIDENZJALITÀ U R-REĠISTRU PUBBLIKU

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

(2) In-notifikant jista' jindika l-informazzjoni fin-notifika mogħtija taht dawn ir-regolamenti, li l-iżvelar tagħha jista' jkun ta' ħsara għall-pożizzjoni kompetittiva 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 skont 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;
- (c) evalwazzjoni ta' riskju ambjentali.

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

21. Kull GMO li għandhom ikunu disponibbli għall-operazzjonijiet imsemmija fit-tifsira "tqegħid fis-suq" fir-regolament 2, għandhom ikunu soġġetti għal rekwiżiti adegwati ta' tikkettjar skond it-taqsimiet rilevanti tal-Iskeda IV biex tipprovdi informazzjoni ċara, fuq tikketta jew f'dokument li jkun miegħu, dwar il-preżenza ta' xi GMO. Għal dak il-għan il-kliem "Dan il-prodott fih organiżmi modifikati ġenetikament" għandhom jidhru jew fuq it-tikketta jew fuq dokument li jkun miegħu. Tikkettjar ta' GMOs imsemmija fit-tifsira "tqegħid fis-suq" fir-regolament 2.
Emendat:
A.L. 182 tal-2019.

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

- (a) tistabbilixxi reġistri pubbliċi fejn il-post ta' rilaxx ta' xi GMO skont it-Taqsima B tiġi reġistrata;
- (b) għandha tistabbilixxi wkoll reġistri biex jiġu reġistrati fejn il-GMOs ikunu mkabbra skont it-Taqsima ~, fost l-oħrajn biex effetti possibbli ta' GMOs fuq l-ambjent jistgħu jkunu segwiti skont id-disposizzjonijiet tar-regolamenti 16(3)(f) u 17(1).

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

- (a) jiġu notifikati lill-awtoritajiet kompetenti, u
- (b) isiru magħrufa lill-pubbliku bil-mod li l-awtorità kompetenti tqis li jkun adatt.

TAQSIMA E:**REATI**

Reati.
Emendat:
A.L. 182 tal-2019.

- 23.** (1) Kull persuna li -
- (a) tonqos milli tosserva xi disposizzjoni ta' dawn ir-regolamenti jew xi ordni oħra mogħtija bis-saħħa ta' xi disposizzjoni ta' dawn ir-regolamenti; jew
 - (b) tikser xi restrizzjoni, projbizzjoni jew rekwiżit impost minn jew taħt dawn ir-regolamenti; jew
 - (c) tonqos milli tosserva xi kondizzjoni ta' permess jew kunsens mogħti taħt id-disposizzjonijiet ta' dawn ir-regolamenti; jew
 - (d) taġixxi f'kontravvenzjoni ta' xi disposizzjoni ta' dawn ir-regolamenti; jew
 - (e) tagħmel dikjarazzjoni jew tippreżenta informazzjoni jew dokumentazzjoni, li dik il-persuna tkun taf illi din hija informazzjoni falza bil-ghan illi tikseb l-approvazzjoni jew il-kontinwità ta' kunsens taħt dawn ir-regolamenti; jew
 - (f) tikkonfoffa jew tipprova tikkonfoffa, tgħin jew tinkoraġġixxi, lil xi persuna oħra, b'kull mod, fosthom bir-riklamar, li tagħti parir jew tgħin biex jinkisru d-disposizzjonijiet ta' dawn ir-regolamenti jew li tonqos milli tosserva d-disposizzjonijiet ta' dawn ir-regolamenti jew ordni leġittimament mogħtija taħt xi disposizzjoni ta' dawn ir-regolamenti jew li tikser xi restrizzjoni, projbizzjoni jew rekwiżit imposti b'dawn ir-regolamenti jew taħthom,

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

Pieni.

(2) Kull persuna li tagħmel reat kontra id-dispożizzjonijiet dwar ir-rilaxx intenzjonat ta' GMOs, għal kull skop iehor hlief biex jitqiegħdu fis-suq għandha, meta tinsab haġja, tehel:

- (a) meta tinsab haġja għall-ewwel darba, multa ta' mhux inqas minn ħamsin elf euro (€50,000), iżda mhux iżjed minn ħamsa u sebghin elf euro (€75,000);
- (b) meta tinsab haġja għat-tieni darba jew aktar, multa ta' mhux inqas minn ħamsa u sittin elf euro (€65,000), iżda mhux iżjed minn mitt elf euro (€100,000) jew prigunerija għal żmien mhux iżjed minn sentejn (2), jew għal dik il-multa u prigunerija flimkien.

(3) Kull persuna li tagħmel reat kontra id-dispożizzjonijiet dwar it-tqegħid fis-suq ta' GMOs għandha, meta tinsab haġja, tehel:

- (a) meta tinsab haġja għall-ewwel darba, multa ta' mhux inqas minn sittin elf euro (€60,000), iżda mhux iżjed minn disghin elf euro (€90,000);

- (b) meta tinsab ħatja għat-tieni darba jew aktar, multa ta' mhux inqas minn ħamsa u sebghin elf euro (€75,000), iżda mhux iżjed minn mija u għoxrin elf euro (€120,000) jew priġunerija għal żmien mhux iżjed minn sentejn (2), jew għal dik il-multa u priġunerija flimkien.

(4) Il-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 tan-notifika mahruġa mill-awtorità kompetenti u l-konfiska tal-*corpus delicti*.

(5) Il-Qorti għandha tordna lill-hati sabiex inehhi l-kawżi tar-reat u li jreġġa' lura kull haġa li tkun saret mingħajr permess fi żmien li jkun suffiġenti għal dan il-ghan skont ma' jiġi stabbilit mill-Qorti; u, jekk il-hati jonqos milli jikkonforma ruħu ma' xi ordni bħal dik fiż-żmien stipulat, jista' jeħel multa ta' mhux inqas minn sittin euro (€60) u mhux iżjed minn ħames mitt euro (€500), skont ma l-Qorti tista' tistabbilixxi, għal kull ġurnata li n-nuqqas ikompli wara li jiskadi dak it-terminu.

(6) 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-ħsarati u l-ksur.

(7) Id-disposizzjonijiet tal-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.

Applikabilità tal-Kodiċi Kriminali. Kap. 9.

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

Kap. 9.

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

Kap. 9.

TAQSIMA E:

DRITTIJET

24. (1) L-awtorità kompetenti għandha tithallas dritt għan-notifika skont ir-regolament 6 għal proposta għal rilaxx intenzjonat appart mill-ghan ta' tqeghid fis-suq.

Dritt għal notifika ta' proposta għal rilaxx intenzjonat.

(2) Id-dritt li jithallas taht is-subregolament (1) għandu jkun ta' sebgha u tletin elf euro (€37,000).

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

(3) L-awtorità kompetenti għandha tithallas 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' tigdid ta' kunsens.

(4) Id-dritt li jithallas taht is-subregolament (3) għandu f'kull każ ikun ta' sebgħa u erbghin elf euro (€47,000).

Dritt għal emenda ta' notifika relatata ma rilaxx intenzjonat.

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

(6) Id-dritt li jithallas taht is-subregolament (5) għandu jkun ta' hamest elef euro (€5,000).

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

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

(8) Id-dritt li jithallas taht is-subregolament (7) għandu f'kull każ ikun ta' erbatax-il elf euro (€14,000).

Spejjeż perjodiċi għal monitoraġġ.

25. L-awtorità kompetenti tista' titlob lil notifikant li jagħmel hlasijiet perjodiċi, li ma jkunux jeċċedu l-ispejjeż li tkun għamlet l-awtorità kompetenti, sabiex thallas 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 konnessi ma' dawn ir-regolamenti.

Investigazzjoniet mill-awtorità kompetenti u rkuprar tal-ispejjeż.

26. L-awtorità kompetenti tista' tagħmel, jew tirranga biex isiru, dawk l-investigazzjonijiet li tqis meħtieġa, bħala parti mill-eżami jew monitoraġġ ta' notifika ta' rilaxx intenzjonat, tqegħid fis-suq jew xi haġa oħra relatata ma' dawn ir-regolamenti, sabiex hija tkun tista' tevalwa sew in-notifika u tista' titlob lin-notifikant sabiex ihallas jew jikkontribwixxi għal xi spejjeż konnessi ma' dawn l-investigazzjonijiet.

Ċirkolazzjoni libera tal-GMOs awtorizzati.
Miżjud:
A.L. 182 tal-2019.

26A. Id-dispożizzjonijiet tar-regolamenti 13(5), 15(5) u 16A m'għandhomx jippreġudikaw iċ-ċirkolazzjoni libera tal-GMOs awtorizzati bħal jew fil-prodotti.

TAQSIMA F:

DISPOŻIZZJONIJIET OĦRA

Pubblikazzjoni ta' Skedi bl-ilsien Ingliż.

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

SKEDA I A

Techniques referred to in the definition of GMO in regulation 2

PART 1

Techniques of genetic modification referred to in 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 microencapsulation;
- (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.
-

*Emendata:
A.L. 182 tal-2019*

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 re-addressed in order to:
 - determine whether the risk has changed;
 - determine whether there is a need for amending the risk management accordingly.

C. Methodology

Guidance issued by the European Food Safety Authority is available for the implementation of this section for Part C notifications.

C.1. General and specific considerations for the e.r.a.

1. *Intended and unintended changes*

As part of the identification and evaluation of the potential adverse effects referred to in Section A, the e.r.a shall identify the intended and unintended changes resulting from the genetic modification and shall evaluate their potential to cause adverse effects on human health and on the environment.

Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

2. *Long-term adverse effects and cumulative long-term adverse effects in the e.r.a. of Part C notifications*

Long-term effects of a GMO are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space.

The identification and evaluation of the potential long-term adverse effects of a GMO on human health and on the environment shall take into account the following:

- (a) the long-term interactions of the GMO and the receiving environment;
- (b) the characteristics of the GMO which become important on a long-term basis;
- (c) data obtained from repeated deliberate releases or placings on the market of the GMO over a long period.

The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introductory part of Schedule II shall also take into account the GMOs deliberately released or placed on the market in the past.

3. *Quality of the data*

In order to carry out an e.r.a. for a notification under Part C, the notifier shall collate already available data from scientific literature or from other sources, including monitoring reports, and shall generate the necessary data by performing, where possible, appropriate studies. Where applicable, the notifier shall justify in the e.r.a. why generating data by studies is not possible.

The e.r.a. for notifications under Part B shall be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the notifier.

Where data generated outside Europe is provided in the e.r.a., its relevance to receiving environment(s) in the Union shall be justified.

Data provided in the e.r.a for notifications under Part C shall comply with the following requirements:

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the e.ra., the notifier shall provide evidence to demonstrate that they were conducted in facilities which comply with:

- (i) the requirements of Directive 2004/10/EC; or
- (ii) the "OECD Principles on Good Laboratory Practice" (GLP), if carried out outside the Union;

(b) where studies other than toxicological studies are provided in the e.r.a., they shall:

- (i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC, where relevant; or
- (ii) be conducted by organisations accredited under the relevant ISO standard; or
- (iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards;

(c) information on the results obtained from the studies referred to in items (a) and (b) and on the study protocols used shall be reliable and comprehensive and shall include the raw data in an electronic format suitable for carrying out statistical or other analysis;

(d) the notifier shall specify, where possible, the size of effect that each study performed intends to detect and justify it;

(e) the selection of sites for field studies shall be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the GMO may be released. The selection shall be justified in the e.r.a.;

(f) the non-genetically modified comparator shall be appropriate for the relevant receiving environment(s) and shall have a genetic background comparable to the GMO. The choice of the comparator shall be justified in the e.r.a.

4. *Stacked transformation events in Part C notifications*

The following shall apply to the e.r.a. of a GMO containing stacked transformation events in Part C notifications:

(a) the notifier shall provide an e.r.a. for each single transformation event in the GMO or refer to already submitted notifications for those single transformation events;

(b) the notifier shall provide an assessment of the following aspects:

(i) the stability of the transformation events;

(ii) the expression of the transformation events;

(iii) the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events;

(c) where the progeny of the GMO can contain various sub-combinations of the stacked transformation events, the notifier shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned sub-combinations, independently of their origin, or, in the absence of such scientific rationale, shall provide the relevant experimental data.

C.2. Characteristics of the GMO and of the releases

The e.r.a. shall take into account the relevant technical and scientific details regarding characteristics of:

(a) the recipient or parental organism(s);

(b) the genetic modification(s), be it insertion or deletion of genetic material, and relevant information on the vector and the donor;

(c) the GMO;

(d) the intended release or use including its scale;

(e) the potential receiving environment(s) into which the GMO will be released and into which the transgene may spread; and

(f) the interaction(s) between these characteristics.

Relevant information from previous releases of the same or similar GMOs and organisms with similar traits and their biotic and abiotic interaction with similar receiving environments, including information resulting from the monitoring of such organisms, shall be considered in the e.r.a., subject to regulation 6(3) or regulation 12(4).

C.3. Steps in the e.r.a.

The e.r.a. referred to in regulations 4, 6, 7 and 12 shall be conducted for each relevant area of risk referred to in Section D1 or in Section D2 of Part D in accordance with the following six steps:

1. *Problem formulation including hazard identification*

The problem formulation shall:

(a) identify any changes in the characteristics of the organism, linked to the genetic modification, by comparing the characteristics of the GMO with those of the chosen non-genetically modified comparator under corresponding conditions of release or use;

(b) identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under item (a) above.

Potential adverse effects shall not be discounted on the basis that they are unlikely to occur.

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

- (i) effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations leading to a potential decline in biodiversity;
- (ii) altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors;
- (iii) 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;
- (iv) effects on biogeochemistry (biogeochemical cycles), including carbon and nitrogen recycling through changes in soil decomposition of organic material;
- (v) disease affecting humans, including allergenic or toxic reactions;
- (vi) disease affecting animals and plants, including toxic, and, in the case of animals, allergenic reactions, where appropriate.

Where potential long-term adverse effects of a GMO are identified, they shall be assessed in the form of desk based studies using, where possible, one or more of the following:

- (aa) evidence from previous experiences;
- (bb) available data sets or literature;
- (cc) mathematical modelling;
- (c) identify relevant assessment endpoints.

Those potential adverse effects that could impact the identified assessment endpoints shall be considered in the next steps of the risk assessment;

- (d) identify and describe the exposure pathways or other mechanisms through which adverse effects may occur.

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

- (i) the spread of the GMO(s) in the environment;
- (ii) the transfer of the inserted genetic material to the same organism or other organisms, whether genetically modified or not;
- (iii) phenotypic and genetic instability;
- (iv) interactions with other organisms;
- (v) changes in management, including, where applicable, in agricultural practices;
- (e) formulate testable hypotheses, and define relevant measurement endpoints, to allow, where possible, a quantitative evaluation of the potential adverse effect(s);
- (f) consider possible uncertainties, including knowledge gaps and methodological limitations.

2. Hazard characterisation

The magnitude of each potential adverse effect shall be evaluated. This evaluation shall assume that such an adverse effect will occur. The e.r.a shall consider that the magnitude is likely to be influenced by the receiving environment(s) into which the GMO is intended to be released and by the scale and conditions of the release.

Where possible, the evaluation shall be expressed in quantitative terms.

Where the evaluation is expressed in qualitative terms, a categorical description ("high", "moderate", "low" or "negligible") shall be used and an explanation of the scale of effect represented by each category shall be provided.

3. *Exposure characterisation*

The likelihood or probability of each identified potential adverse effect occurring shall be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability, or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment(s) and the scope of the notification shall be taken into consideration.

Where the evaluation is expressed in qualitative terms, a categorical description ("high", "moderate", "low" or "negligible") of the exposure shall be used and an explanation of the scale of effect represented by each category shall be provided.

4. *Risk characterisation*

The risk shall be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi-quantitative estimation of the risk.

Where a quantitative or semi-quantitative estimation is not possible, a qualitative estimation of the risk shall be provided. In that case, a categorical description ("high", "moderate", "low" or "negligible") of the risk shall be used and an explanation of the scale of effect represented by each category shall be provided.

Where relevant, the uncertainty for each identified risk shall be described and, where possible, expressed in quantitative terms.

5. *Risk management strategies*

Where risks are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy shall be proposed.

The risk management strategies shall be described in terms of reducing the hazard or the exposure, or both, and shall be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the e.r.a.

The consequent reduction in overall risk shall be quantified where possible.

6. *Overall risk evaluation and conclusions*

A qualitative and, where possible, quantitative evaluation of the overall risk of the GMO shall be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

The overall risk evaluation shall include, where applicable, the risk management strategies proposed for each identified risk.

The overall risk evaluation and conclusions shall also propose specific requirements for the monitoring plan of the GMO and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

For notifications under Part C, the overall risk evaluation shall also include an explanation of the assumptions made during the e.r.a. and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management measures proposed.

D. *Conclusions on the specific areas of risk of the e.r.a.*

Conclusions on the potential environmental impact in relevant receiving environments

from the release or the placing on the market of GMOs shall be drawn for each relevant area of risk listed in Section D1 for GMOs other than higher plants or Section D2 for genetically modified higher plants, on the basis of an e.r.a. carried out in accordance with the principles outlined in Section B and following the methodology described in Section C, and on the basis of the information required pursuant to Schedule III.

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)

"Higher plants" means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

1. Persistence and invasiveness of the GMHP, including plant to plant gene transfer.
 2. Plant to micro-organisms gene transfer.
 3. Interactions of the GMHP with target organisms.
 4. Interactions of the GMHP with non-target organisms.
 5. Impacts of the specific cultivation, management and harvesting techniques.
 6. Effects on biogeochemical processes.
 7. Effects on human and animal health.
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SKEDA III
(Regolamenti 4, 5, 6, 7, 11 u 12)

INFORMATION REQUIRED IN THE NOTIFICATION

Notifications referred to in Parts B and C shall, as a rule, include the information set out in Schedule III A, for GMOs other than higher plants, or in Schedule III B, for genetically modified higher plants.

The provision of a given subset of information listed in Schedule III A or in Schedule III B shall not be required where it is not relevant or necessary for the purposes of risk assessment in the context of a specific notification, in view especially of the characteristics of the GMO, of the scale and conditions of the release or of its intended conditions of use.

The appropriate level of detail for each subset of information may also vary according to the nature and the scale of the proposed release.

For each required subset of information, the following shall be provided:

- (a) the summaries and results of the studies referred to in the notification, including an explanation about their relevance to e.r.a., where applicable;
- (b) for notifications referred to in Part C, Annexes with detailed information on those studies, including a description of the methods and materials used or the reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out the studies.

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 perennial plants and trees, 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 Union.

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 immunocompetent:
 - 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

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- 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) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
 - (b) post-release 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.
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SKEDA III B

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

I. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO REGULATIONS 6 AND 7

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.
4. Information relating to the release;
 - (a) purpose of the release;
 - (b) foreseen date(s) and duration of the release;
 - (c) method by which the GMHP will be released;
 - (d) method for preparing and managing the release site, prior to, during and post release, including cultivation practices and harvesting methods;
 - (e) approximate number of plants (or plants per m²).
5. Information relating to the site of release;
 - (a) location and size of the release site(s);
 - (b) description of the release site ecosystem, including climate, flora and fauna;
 - (c) presence of sexually compatible wild relatives or cultivated plant species;
 - (d) proximity to officially recognised biotopes or protected areas which may be affected.

B. Scientific Information

1. Information relating to the recipient plant or, where appropriate, to the parental plants;
 - (a) complete name:
 - (i) family name;
 - (ii) genus;
 - (iii) species;
 - (iv) sub-species;
 - (v) cultivar or breeding line;
 - (vi) common name;
 - (b) geographical distribution and cultivation of the plant within the Union;
 - (c) information concerning reproduction:
 - (i) mode(s) of reproduction;
 - (ii) specific factors affecting reproduction, if any;
 - (iii) generation time;
 - (d) sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species;
 - (e) survivability:
 - (i) ability to form structures for survival or dormancy;
 - (ii) specific factors affecting survivability, if any;
 - (f) dissemination:
 - (i) ways and extent of dissemination;

- (ii) specific factors affecting dissemination, if any;
 - (g) where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts;
 - (h) potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.
- 2. Molecular characterisation.
 - (a) Information relating to the genetic modification:
 - (i) description of the methods used for the genetic modification;
 - (ii) nature and source of the vector used;
 - (iii) source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.
 - (b) Information relating to the GMHP:
 - (i) general description of the trait(s) and characteristics which have been introduced or modified;
 - (ii) information on the sequences actually inserted/deleted:
 - (aa) size and copy number of all insert(s) and methods used for its/their characterisation;
 - (bb) in case of deletion, size and function of the deleted region(s);
 - (cc) sub-cellular location(s) of the insert(s) in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination;
 - (iii) parts of the plant where the insert is expressed;
 - (iv) genetic stability of the insert and phenotypic stability of the GMHP.
 - (c) Conclusions of the molecular characterisation.
- 3. Information on specific areas of risk.
 - (a) Any change to the persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.
 - (b) Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof.
 - (c) Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof.
 - (d) Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof.
 - (e) Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof.
 - (f) Potential interactions with the abiotic environment and the adverse

- environmental effects thereof.
- (g) Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification.
- (h) Conclusions on the specific areas of risk.
- 4. Information on control, monitoring, post-release and waste treatment plans
 - (a) Any measures taken, including:
 - (i) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops;
 - (ii) any measures to minimise or prevent the dispersal of any reproductive part of the GMHP.
 - (b) Description of methods for post-release treatment of the site.
 - (c) Description of post-release treatment methods for the genetically modified plant material including wastes.
 - (d) Description of monitoring plans and techniques.
 - (e) Description of any emergency plans.
 - (f) Description of the methods and procedures to:
 - (i) avoid or minimise the spread of the GMHPs beyond the site of release;
 - (ii) protect the site from intrusion by unauthorised individuals;
 - (iii) prevent other organisms from entering the site or minimise such entries.
- 5. Description of detection and identification techniques for the GMHP.
- 6. Information about previous releases of the GMHP, if applicable.

II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO REGULATION 12

A. General information.

- 1. Name and address of the notifier (company or institute).
- 2. Name, qualifications and experience of the responsible scientist(s).
- 3. Designation and specification of the GMHP.
- 4. Scope of the notification:
 - (a) cultivation;
 - (b) other uses (to be specified in the notification).

B. Scientific Information.

- 1. Information relating to the recipient plant or, where appropriate, to the parental plants.
 - (a) Complete name:
 - (i) family name;

- (ii) genus;
 - (iii) species;
 - (iv) subspecies;
 - (v) cultivar/breeding line;
 - (vi) common name.
 - (b) Geographical distribution and cultivation of the plant within the Union.
 - (c) Information concerning reproduction:
 - (i) mode(s) of reproduction;
 - (ii) specific factors affecting reproduction, if any;
 - (iii) generation time.
 - (d) Sexual compatibility with other cultivated or wild plant species, including the distribution in the Union of the compatible species.
 - (e) Survivability:
 - (i) ability to form structures for survival or dormancy;
 - (ii) specific factors affecting survivability, if any.
 - (f) Dissemination:
 - (i) ways and extent of dissemination;
 - (ii) specific factors affecting dissemination, if any.
 - (g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
 - (h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.
2. Molecular characterisation.
- (a) Information relating to the genetic modification.
 - (i) Description of the methods used for the genetic modification.
 - (ii) Nature and source of the vector used.
 - (iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.
 - (b) Information relating to the genetically modified plant.
 - (i) Description of the trait(s) and characteristics which have been introduced or modified.
 - (ii) Information on the sequences actually inserted or deleted:
 - (aa) size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation;
 - (bb) the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format;
 - (cc) in case of deletion, size and function of the deleted region(s);
 - (dd) sub-cellular location(s) of the insert(s) (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination;

- (ee) in the case of modifications other than insertion or deletion, function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification;
 - (ff) sequence information in a standardised electronic format for both 5' and 3' flanking regions at each insertion site;
 - (gg) bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes;
 - (hh) all Open Reading Frames, (hereafter referred to as "ORFs") within the insert (either due to rearrangement or not) and those created as a result of the genetic modification at the junction sites with genomic DNA. ORF is defined as a nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame;
 - (ii) bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects;
 - (jj) primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein;
 - (kk) bioinformatic analysis using up-to-date databases, to investigate possible sequence homologies and, if necessary, structural similarities between the newly expressed protein and known proteins or peptides which may have adverse effects.
- (iii) Information on the expression of the insert:
- (aa) method(s) used for expression analysis together with their performance characteristics;
 - (bb) information on the developmental expression of the insert during the life cycle of the plant;
 - (cc) parts of the plant where the insert/modified sequence is expressed;
 - (dd) potential unintended expression of new ORFs identified under sub-sub-paragraph (gg) of sub-paragraph (ii), which raise a safety concern;
 - (ee) protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown.
- (iv) Genetic stability of the insert and phenotypic stability of the GMHP.
- (c) Conclusions of molecular characterisation.
3. Comparative analysis of agronomic and phenotypic characteristics and of composition.
- (a) Choice of conventional counterpart and additional comparators.
 - (b) Choice of sites for field studies.
 - (c) Experimental design and statistical analysis of data from field trials for comparative analysis:
 - (i) description of field studies design;
 - (ii) description of relevant aspect of the receiving environments;

- (iii) statistical analysis.
 - (d) Selection of plant material for analysis, if relevant.
 - (e) Comparative analysis of agronomic and phenotypic characteristics.
 - (f) Comparative analysis of composition, if relevant.
 - (g) Conclusions of comparative analysis.
4. Specific information for each area of risk.

For each of the seven areas of risk referred to in Section D.2 of Schedule II the notifier shall first describe the pathway to harm explaining in a chain of cause and effect how the release of the GMHP could lead to harm, taking into account both hazard and exposure.

The notifier shall submit the following information, except where it is not relevant in view of the intended uses of the GMO:

- (a) Persistence and invasiveness including plant to plant gene transfer:
 - (i) assessment of the potential for the GMHP to become more persistent or invasive and the adverse environmental effects thereof;
 - (ii) assessment of the potential for the GMHP to transmit transgene(s) to sexually compatible relatives and the adverse environmental effects thereof;
 - (iii) conclusions on the adverse environmental effect(s) of persistence and invasiveness of the GMHP including the adverse environmental effect(s) of plant-to-plant gene transfer.
- (b) Plant to micro-organism gene transfer:
 - (i) assessment of the potential for transfer of newly inserted DNA from the GMHP to microorganisms and the adverse effects thereof;
 - (ii) conclusions on the adverse effect(s) of the transfer of newly inserted DNA from the GMHP to microorganisms for human and animal health and the environment.
- (c) Interactions of the GMHP with target organisms, if relevant:
 - (i) assessment of the potential for changes in the direct and indirect interactions between the GMHP and target organisms and the adverse environmental effect(s);
 - (ii) assessment of the potential for evolution of resistance of the target organism to the expressed protein (based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits) and any adverse environmental effect(s) thereof;
 - (iii) conclusions on adverse environmental effect(s) of interactions of the GMHP with target organisms.
- (d) Interactions of the GMHP with non-target organisms:
 - (i) assessment of the potential for direct and indirect interactions of the GMHP with non-target organisms, including protected species, and the adverse effect(s) thereof.

The assessment shall also take into account the potential adverse

- effect(s) on relevant ecosystem services and on the species providing those services;
- (ii) conclusions on adverse environmental effect(s) of interactions of the GMHP with non-target organisms.
- (e) Impacts of the specific cultivation, management and harvesting techniques:
 - (i) for GMHPs for cultivation, assessment of the changes in the specific cultivation, management and harvesting techniques used for the GMHP and the adverse environmental effect(s) thereof;
 - (ii) conclusions on adverse environmental effect(s) of the specific cultivation, management and harvesting techniques.
- (f) Effects on biogeochemical processes:
 - (i) assessment of the changes in the biogeochemical processes within the area in which the GMHP is to be grown and in the wider environment, and the adverse effects thereof;
 - (ii) conclusions on adverse effects on biogeochemical processes.
- (g) Effects on human and animal health:
 - (i) assessment of potential direct and indirect interactions between the GMHP and persons working with or coming into contact with the GMHPs, including through pollen or dust from a processed GMHP, and assessment of the adverse effects of those interactions on human health;
 - (ii) for GMHPs not destined for human consumption, but where the recipient or parental organism(s) may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake;
 - (iii) assessment of the potential adverse effects on animal health due to accidental consumption of the GMHP or of material from that plant by animals;
 - (iv) conclusions on the effects on human and animal health.
- (h) Overall risk evaluation and conclusions.

A summary of all the conclusions under each area of risk shall be provided.

The summary shall take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Schedule II and the risk management strategies proposed in accordance with item 5 of Section C.3 of Schedule II.

5. Description of detection and identification techniques for the GMHP.
 6. Information about previous releases of the GMHP, if applicable.
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Emendata:
A.L. 182 tal-2019

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 a proposal for a unique identifier for the GMO, developed in accordance with Commission Regulation (EC) No 65/2004*. 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. methods for detection, identification and, where appropriate, quantification of the transformation event; samples of the GMO(s) and their control samples, and information as to the place where the reference material can be accessed. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register(s) referred to in Article 31(2) of the Directive 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

* Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

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.

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 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 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 ninety 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 ninety-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 fifteen 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.
