

A.L. 525 tal-2010**ATT DWAR IL-KONTROLL TAL-PESTIČIDI
(KAP. 430)****Regolamenti ta' l-2010 dwar il-Bijoċidi**

BIS-SAHHA tas-setgħat mogħtija bl-artikoli 4 u 5 ta' l-Att dwar il-Kontroll tal-Pestiċidi, il-Ministru għar-Riżorsi u Affarijiet Rurali, wara li kkonsulta lill-Prim Ministru u lill-Ministru għas-Saħħa, l-Anzjani u Kura fil-Komunità, għamel dawn ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2010 dwar il-Bijoċidi**, u għandhom jidhlu fis-seħħ kif jidher hawn taħt: Titolu.

2. (1) Dawn ir-regolamenti jirrigwardaw: Skop.

(a) l-awtorizzazzjoni u t-tqegħid fis-suq għall-użu ta' prodotti bijoċidali;

(b) ir-rikonoxximent reċiproku ta' l-awtorizzazzjonijiet;

(ċ) kif tiġi stabbilita fil-livell Komunitarju lista pozittiva tas-sustanzi attivi li jistgħu jintużaw fil-prodotti bijoċidali.

(2) Dawn ir-regolamenti għandhom japplikaw għall-prodotti bijoċidali kif imfissra taħt regolament 3(1)(a) jew li jidhlu fl-iskop ta' l-istrumenti li ġejjin għall-għanijiet ta' dawn ir-regolamenti:

(a) Regolamenti ta' l-2005 dwar it-Tqegħid ta' Tikketti u Ppakkettjar ta' Prodotti Mediċinali; A.L. 393 ta' l-2005.

(b) Regolamenti ta' l-2005 dwar Prodotti ta' Hxejjex Mediċinali; A.L. 379 ta' l-2005.

(ċ) Regolamenti ta' l-2004 dwar Prodotti Mediċinali Veterinarji; A.L. 469 ta' l-2004.

(d) Ir-Regolament (KE) Nru 726/2004 tal-Parlament Ewropew u tal-Kunsill tal-31 ta' Marzu 2004 li jistabbilixxi proċeduri Komunitarji għall-awtorizzazzjoni u s-sorveljanza ta' prodotti mediċinali għall-użu mill-bniedem u veterinarji u li jistabbilixxi l-Aġenzija Ewropea għall-Mediċini;

A.L. 211 ta' l-2008.

(e) Regolamenti ta' l-2008 dwar Tagħmir Mediku Attiv li jista' jkun Impjantat;

A.L. 210 ta' l-2008.

(f) Regolamenti ta' l-2008 dwar Tagħmir Mediku, 2008;

A.L. 89 ta' l-1994.

(g) Regolamenti ta' l-1994 dwar l-Additivi fi Hwejjeg ta' l-Ikel;

A.L. 257 ta' l-1998.

(h) Regolamenti ta' l-1998 dwar Sapuri li Jintużaw fi Hwejjeg ta' l-Ikel u Materjali Ewlenin għall-Produzzjoni Tagħhom;

A.L. 54 ta' l-2005.

(i) Regolamenti ta' l-2005 dwar Additivi Permessi biex jintużaw ma' l-Ikel;

(j) Ir-Regolament (KE) Nru 1935/2004 tal-Parlament Ewropew u tal-Kunsill tas-27 ta' Ottubru 2004 dwar materjali u oġġetti maħsuba biex jiġu f'kuntatt ma' l-ikel u li jħassar id-Direttivi 80/590/KEE u 89/109/KEE;

A.L. 83 ta' l-2006.

(k) Regoli ta' l-2006 dwar l-Iġjene ta' l-Ikel u Kundizzjonijiet tas-Saħħa għall-Produzzjoni u t-Tqegħid fis-Suq ta' Ċertu Prodotti li joriginaw mill-Annimali u intiżi għall-Konsum mill-Bniedem (Emendi u Tħassir);

A.L. 225 ta' l-2005.

(l) Regoli ta' l-2005 dwar Kondizzjonijiet li Jirregolaw il-Preparazzjoni, t-Tpoġġiegħ fis-Suq u l-Użu ta' Għalf Medikat;

(m) Ir-Regolament (KE) Nru 1831/2003 tal-Parlament Ewropew u L-Kunsill ta' 22 ta' Settembru 2003 fuq l-additivi għall-użu fl-għalf ta' l-annimali;

A.L. 89 ta' l-2005.

(n) Regoli ta' l-2005 dwar Prodotti li Jintużaw fl-Għalf ta' l-Annimali;

A.L. 374 ta' l-2005.

(o) Regoli ta' l-2005 dwar iċ-Ċirkolazzjoni u l-Użu ta' Materjal ta' l-Għalf;

(p) Regolamenti ta' l-2004 dwar prodotti kosmetiċi; A.L. 424 ta' l-2004.

(q) Id-Direttiva tal-Kunsill 95/5/KE tas-27 ta' Frar 1995 li temenda d-Direttiva 92/120/KEE dwar il-kondizzjonijiet sabiex jiġu konċessi derogi temporanji u limitati minn regoli Komunitarji speċifiċi tas-saħħa rigward il-produzzjoni u t-tqegħid fis-suq ta' ċerti prodotti ta' oriġini mill-annimali;

(r) Regolamenti ta' l-2009 dwar Prodotti għall-harsien tal-pjanti; minbarra Skeda VII li tinsab ma' dawh ir-regolamenti; A.L. 358 ta' l-2009.

(s) Regolamenti ta' l-2002 dwar Tagħmir Mediku Dijanjostiku In Vitro; A.L. 61 ta' l-2002.

(3) Dawn ir-regolamenti jitrosponu l-proviżjonijiet tad- Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali.

(4) Dawn ir-regolamenti għandhom japplikaw, mingħajr preġudizzju għad-dispożizzjonijiet jew il-miżuri rilevanti Komunitarji meħuda, b'mod partikolari, skond:

(a) Regolament (KE) Nru 1907/2006 tal-Parlament Ewropew u tal-Kunsill tat- 18 ta' Diċembru 2006 dwar ir-Registrazzjoni, il-Valutazzjoni, l-Awtorizzazzjoni u r-Restrizzjoni ta' Sustanzi Kimiċi, li jistabbilixxi Aġenzija Ewropea għas-Sustanzi Kimiċi (REACH), li jemenda d-Direttiva 1999/45/KE u li jhassar ir-Regolament (KEE) Nru 793/93 tal-Kunsill u r-Regolament (KE) Nru 1488/94 tal-Kummissjoni kif ukoll id-Direttiva 76/769/KEE tal-Kunsill u d-Direttivi 91/155/KEE, 93/67/KEE, 93/105/KE u 2000/21/KE tal-Kummissjoni;

(b) Skeda VII tar-Regolamenti ta' l-2009 dwar Prodotti għall-harsien tal-pjanti; A.L. 358 ta' l-2009.

(ċ) Ir-Regolament (KE) Nru 304/2003 tal-Parlament Ewropew u tal-Kunsill tat-28 ta' Jannar 2003 dwar l-esportazzjoni u l-importazzjoni tal-kimiċi perikolużi;

(d) Regolamenti ta' l-2003 dwar il-Protezzjoni tas-Saħħa u s-Sigurtà tal-Haddiema minn Riskji relatati ma' l-aġenti kimiċi fuq il-Post tax-Xogħol u Regolamenti ta' A.L. 227 ta' l-2003.
A.L. 36 ta' l-2003.

l-2003 dwar Disposizzjonijiet Generali dwar is-Saħħa u s-Sigurtà fuq il-Post tax-Xogħol;

(e) artikolu 32 tal-Kodiċi Kummerċjali dwar ir-reklamar li jqarraq u komparattiv.

A.L. 306 ta' l-2008.

(5) Regolament 21 ta' dawn ir-regolamenti m'għandux japplika għall-garr tal-prodotti bijoċidali bil-ferrovija, bit-triq, fuq l-ibhra interni, bil-baħar jew bl-ajru.

Tifsiriet.

3. Għall-iskopijiet ta' dawn ir-regolamenti għandhom japplikaw it-tifsiriet li ġejjin:

“awtorizzazzjoni” tfisser att amministrattiv li bih l-awtorità kompetenti ta' Stat Membru tawtorizza, wara applikazzjoni sottomessa minn applikant, it-tqegħid fis-sug ta' prodott bijoċidali fit-territorju tiegħu jew f'parti minnu;

Kap. 13.

“direttur” tfisser il-kap tad-Direttorat għall-Affarijiet Regolatorji stabbilit taħt l-Att dwar l-Awtorità Maltija dwar l-iStandards jew kap ta' kull Direttorat ieħor skond ma jista' l-Ministru jahtar minfloku b'Ordni u, sal-limitu tal-funzjonijiet mogħtija, tinkludi kull uffiċjal pubbliku awtorizzat mid-Direttur għal hekk bil-miktub għal xi wieħed mill-għanijiet ta' dan l-Att;

“fdalijiet” tfisser waħda jew aktar mis-sustanzi preżenti fi prodott bijoċidali li jifdlu bħala riżultat ta' l-użu tagħhom inklużi l-metaboliti ta' ċerti sustanzi u prodotti li jirriżultaw middegradazzjoni jew mir-reazzjoni tagħhom;

“il-formolazzjoni tal-kwadru” l-ispeċifikazzjonijiet għal grupp ta' prodotti bijoċidali li jkollhom l-istess użu u tip ta' utenti. Dan il-grupp ta' prodotti jrid ikun fih l-istess sustanzi attivi ta' l-istess speċifikazzjonijiet, u l-kompożizzjoni tagħhom trid tippreżenta biss varjazzjonijiet minn prodott bioċidali awtorizzat qabel li ma jaffettwawx il-livell tar-riskju assoċjat magħhom u l-effiċjenza tagħhom. F'dan il-kuntest, il-varjazzjoni hija l-konċessjoni ta' tnaqqis fil-perċentwal tas-sustanza attiva u/jew bidla fil-perċentwal tal-kompożizzjoni ta' sustanza jew iktar mhux attivi u/jew is-sostituzzjoni ta' pigment, żebgħa, fwieħa jew aktar minn oħrajn li jipprezentaw l-istess riskju jew riskju iktar baxx, u li ma' jnaqqsux l-effikaċja;

“ittra ta’ aċċess” tfisser dokument, iffirmat mis-sid jew mis-sidien ta’ l-informazzjoni rilevanti protetta skond id-dispożizzjonijiet ta’ dawn ir-regolamenti, li jiddikjara illi din l-informazzjoni tista’ tintuża mid-Direttur bl-iskop li tagħti awtorizzazzjoni jew registrazzjoni lil prodott bijoċidal skond dawn ir-regolamenti;

“organizmu ta’ ħsara” tfisser kull organismu li għandu preżenza mhux mixtieqa jew ta’ effett determinali fuq il-bniedem, l-attivitajiet tiegħu jew il-prodotti li juża jew jipproduċi, jew fuq l-annimali jew l-ambjent;

“preparat” tfisser taħlita jew soluzzjoni komposta minn żewġ sustanzi jew aktar;

“prodotti bijoċidal” tfisser is-sustanzi attivi u t-tnejjijiet li jkun fihom sustanza attiva jew aktar, esibiti fil-għamla li fiha jkunu forniti lill-utent, maħsuba sabiex jeqirdu, igerrxu, jirrendu bla ħsara, jipprevjenu l-azzjoni, jew jeżerċitaw xorta oħra kontroll effettiv fuq kull organismu ta’ perikolu b’mezzi kimiċi jew bioloġiċi; lista eżawrjenti ta’ 23 tip ta’ prodotti b’sett indikattiv ta’ deskrizzjonijiet ġewwa kull tip hija mogħtija fil-Skeda V ta’ dawn ir-regolamenti.

“prodott bijoċidal b’riskju baxx” tfisser prodott bijoċidali li jkunu fih bħala sustanza/i attiva/i waħda biss jew iktar min dawk elenkati fil-Skeda I – Taksima B u li ma jkun fihom l-ebda sustanza/i ta’ tħassib; skond il-kondizzjonijiet ta’ l-użu, il-prodott bijoċidali għandu jippreżenta biss riskju baxx għall-bniedem, l-annimali u l-ambjent;

“registrazzjoni” tfisser att amministrattiv li bih id-Direttur, wara applikazzjoni sottomessa minn applikant, wara l-verifika li d-dossier jissodisfa l-htigiet rilevanti ta’ dawn ir-regolamenti, jippermetti t-tqegħid fis-suq ta’ prodott bijoċidali fit-territorju tiegħu jew f’parti minnu;

“riċerka u żvilupp orjentati lejn prodotti u proċessi” tfisser kwalunkwe żvilupp xjentifiku relatat ma’ żvilupp ta’ prodott, jew żvilupp ulterjuri ta’ sustanza, waħidha, fi preparati jew f’oġġetti li fil-kors tiegħu jintużaw provi pilota ta’ l-impjant jew tal-produzzjoni sabiex jiġi żviluppat il-proċess tal-produzzjoni u/jew sabiex jiġu testjati l-oqsma ta’ l-applikazzjoni tas-sustanza;

“riċerka u żvilupp xjentifiċi” tfisser kwalunkwe sperimentazzjoni xjentifika, analiżi jew riċerka kimika li ssir taħt kondizzjonijiet kontrollati f’volum ta’ anqas minn tunnellata metrika fis-sena;

“sustanza” tfisser element kimiku u l-komposti tiegħu fl-istat naturali jew miksub bi kwalunkwe proċess ta’ manifattura, inkluż kwalunkwe addittiv meħtieġ sabiex jippreżerva l-istabbiltà tiegħu u kwalunkwe impurità li tiġi mill-proċess użat, iżda eskluż kwalunkwe solvent li jista’ jiġi separat mingħajr ma tkun milquta l-istabbiltà tas-sustanza jew tinbidel il-kompożizzjoni tagħha;

“sustanza attiva” tfisser sustanza jew mikro-organizmu, inkluż mikrobu jew fungu, li jkollhom azzjoni ġenerali jew speċifika fuq jew kontra organiżmi ta’ ħsara;

“sustanza bażika” tfisser sustanza li hija elenkata fis-Skeda I – Taqsima Ċ, li l-użu magġuri tagħha mhux ta’ pesticida imma li għandha xi użu minuri bħala bijoċida jew direttament jew fi prodott li jikkonsisti minn sustanza u dilwent sempliċi li minnhom infushom mhumix sustanzi ta’ tħassib u li mhumix imqiegħda fis-suq direttament għal dan l-użu bijoċidali; is-sustanzi, li jistgħu potenzjalment jidhru fis-Skeda I – Parti Ċ skond il-proċeduri stabbilita fir-regolamenti 11 u 12, huma fost oħrajn dawn li ġejjin:

- (i) Id-dijossidu tal-karbonju,
- (ii) in-nitroġenu,
- (iii) l-etanol,
- (iv) it-2-propanol,
- (v) l-aċidu aċetiku,
- (vi) il-kieselguhr;

“sustanza ta’ tħassib” tfisser kull sustanza, għajr is-sustanza attiva, li għandha kapacità inerenti li tikkawża effett żvantaġġuż fuq il-bniedem, l-annimali jew l-ambjent u li tkun preżenti jew prodotta f’konċentrazzjoni bizzżejġed sabiex tohloq dan l-effett; din is-sustanza, għajr jekk ikun hemm raġunijiet oħra ta’ tħassib, normalment tkun sustanza

klassifikata bħala perikoluża skond Regolamenti ta' l-2008 dwar is-Sustanzi Perikolużi u preżenti fil-prodott bijoċidali f'konċentrazzjoni li twassal illi l-prodott jitqies bħala perikoluż fit-tifsira ta' r-regolamenti 6 u 7 ta' r-Regolamenti ta' l-2007 dwar Sustanzi u Preparazzjonijiet Perikolużi. A.L. 10 ta' l-2007.

“tqegħid fis-suq” tfisser kull provvista, sewwa jekk bħala għotja għall-ħlas jew bla flus, jew il-ħażna sossegwenti għajr għall-ħażna segwita minn kunsinna mit-territorju tad-dwana tal-Komunità jew għad-disponiment minnha. L-importazzjoni ta' prodott bijoċidali fit-territorju tad-dwana tal-Komunità għandu jiġi meqjus li jikkostitwixxi tqegħid fis-suq għall-iskopijiet ta' dawn ir-regolamenti;

4. (1) Prodott bijoċidali m'għandux jitqiegħed fis-suq u jiġi wżat fit-territorju għajr jekk ikun gie awtorizzat skond dawn ir-regolamenti. Awtorizzazzjoni għat-tqegħid fis-suq tal-prodotti bijoċidali.

(2) Bħala deroga mis-sub-regolament (1):

(a) bla ħsara għar-reġistrazzjoni, t-tqegħid fis-suq u l-użu ta' prodott bijoċidali ta' riskju baxx huwa permess, sakemm ikun gie ssottomess u vverifikat dossier skond r-regolament 9(3) mid-Direttur; għajr jekk speċifikat xorta oħra, id-dispożizzjonijiet kollha li għandhom x'jaqsmu mal-awtorizzazzjoni taħt dawn ir-regolamenti għandhom japplikw ukoll għar-reġistrazzjoni; u

(b) t-tqegħid fis-suq u l-użu tas-sustanzi li huma oġġetti tad-dar għal skopijiet bijoċidali għandhom jiġu permessi għaladarba jkun gw imdahħla fis-Skeda I – Taqsima C.

(3) (a) Kull applikazzjoni għal awtorizzazzjoni għandha tiġi deċiża mingħajr dewmien mhux misthoqq.

(b) rigward l-applikazzjonijiet għall-prodotti bijoċidali li jeħtieġu reġistrazzjoni, d-Direttur għandu jieħu deċiżjoni f'perjodu taż-żmien ta' 60 jum.

(4) Id- Direttur għandu, fuq talba, jew jista', fuq l-inizjattiva tiegħu innifsu, u meta rilevanti, jistabilixxi formolazzjoni ta' kwadru u jikkomunikaha lill-applikant meta joħorġu awtorizzazzjoni għal prodott bijoċidali partikolari.

Izda mingħajr preġudizzju għar-regolamenti 9 u 13 u

sakemm l-applikant ikollu d-dritt għall-aċċess tal-formolazzjoni tal-kwadru fil-għamla ta' ittra ta' l-aċċess, meta applikazzjoni sossegwenti għal awtorizzazzjoni għal prodott bijoċidali gdid tkun imsejsa fuq din l-formolazzjoni tal-kwadru, id-Direttur għandu jieħu deċiżjoni fir-rigward ta' din l-applikazzjoni f'perjodu taż-żmien ta' 60 jum.

(5) Prodotti bijoċidali jridu jiġu klasifikati, pakkjati u tikkettjati skond id-dispożizzjonijiet ta' dawn ir-regolamenti.

(6) Mingħajr preġudizzju għar-regolament 8(1), awtorizzazzjonijiet għandhom jiġu konċessi għal perjodu massimu ta' żmien ta' 10 snin mid-data ta' l-ewwel tidħil tas-sustanza attiva fis-Skedi I – Taqsima A jew Taqsima B għat-tip tal-prodott jew għat-tigdid tagħha, mingħajr ma tiġi maqbuża t-temma taż-żmien speċifikata għas-sustanza attiva fis-Skeda I – Taqsima A jew Taqsima B; dawn jistgħu jiġġeddu wara verifika illi l-kondizzjonijiet imposti fir-regolament 6(1) u (2) għadhom jiġu ssodisfatti. It-tigdid jista', meta meħtieġ, jiġi konċess biss għall-perjodu taż-żmien meħtieġ sabiex jippermetti lid-Direttur jagħmel din il-verifika, meta tkun giet magħmula applikazzjoni għat-tigdid.

(7) Prodotti bijoċidali għandhom jintużaw kif jixraq. L-użu kif jixraq għandu jinkludi l-konformità mal-kondizzjonijiet stabbiliti skond r-regolament 6 u speċifikat fid-dispożizzjonijiet tat-tikkettjar ta' dawn ir-regolamenti. L-użu kif jixraq għandu jinvolvi wkoll l-applikazzjoni razzjonali ta' għaqda fiżika, bijoloġika, kimika jew ta' miżuri oħra xierqa, li bihom l-użu tal-prodotti bijoċidali jiġi limitat għall-minimu meħtieġ. Meta l-prodotti bijoċidali jiġu wżati fuq ix-xogħol, l-użu għandu wkoll ikun skond il-htigiet tar-regolamenti għall-protezzjoni tal-ħaddiema.

Ir-Rikonoxximent
reċiproku ta'
l-awtorizzazzjonijiet.

5. (1) (a) Mingħajr preġudizzju għar-regolament 13 ta' dawn ir-regolamenti, prodott bijoċidali li jkun diġà awtorizzat jew irregistrat f'wieħed mill-Istati Membri għandu jkun awtorizzat jew irregistrat f'Malta għal 120 jum, jew 60 jum rispettivament, għal applikazzjoni li tkun waslet għand id-Direttur, sakemm is-sustanza attiva tal-prodott bijoċidali tkun inkluża fis-Skeda I – Taqsima A jew Taqsima B u tikkonforma mal-htigiet tagħhom. Rigward ir-rikonoxximent reċiproku ta' l-awtorizzazzjonijiet, l-applikazzjoni għandha tinkludi sommarju tad-dossier kif meħtieġ fir-regolament 9(2)(a) u Skeda II – Taqsima B, s-Sezzjoni X u kopja attestata ta' l-ewwel awtorizzazzjoni konċessa. Għar-rikonoxximent reċiproku tar-registrazzjoni ta' prodotti bijoċidali ta' riskju baxx, l-applikazzjoni għandha tinkludi l-htigiet ta' l-informazzjoni tar-

regolament 9(3), għajr l-informazzjoni dwar l-effikaċja li għaliha sommarju għandu jkun bizzejjed.

(b) L-awtorizzazzjoni trid tkun bla ħsara għad-dispożizzjonijiet li jirriżultaw mill-implimentazzjoni ta' miżuri oħra skond illiġijiet Komunitarji li għandhom x'jaqsmu mal-kondizzjonijiet tad-distribuzzjoni u l-użu tal-prodotti bijoċidali maħsuba sabiex jipproteġu s-saħħa tad-distributuri, l-utenti u l-haddiema interessati.

(2) Jekk, skond regolament 6, jiġi stabbilit illi:

(a) l-ispeċje fil-mira ma tkunx preżenti fi kwantitajiet li jagħmlu ħsara,

(b) jiġu murija tolleranza jew reżistenza mhux aċċettabbli fl-organizmu fil-mira għall-prodott bijoċidali, jew

(ċ) iċ-ċirkostanzi rilevanti ta' l-użu, bħalma huma l-klima jew il-perjodu taż-żmien tat-tnissil ta' l-ispeċje fil-mira, jiddifferixxu b'mod sinifikati minn daww ta' l-Istati Membri fejn kien l-ewwel awtorizzat il-prodott bijoċidali, u awtorizzazzjoni mhux mibdula tista' għalhekk tippreżenta riskji mhux aċċettabbli għall-bniedem jew għall-ambjent, ċerti kondizzjonijiet riferiti fir-regolament 21(3)(e), (f), (h), (j) u (l) jistgħu jiġu aġġustati għaċ-ċirkostanzi differenti, sabiex jiġu sodisfatti l-kondizzjonijiet għall-ħruġ ta' awtorizzazzjoni stabbilita fir-regolament 6.

(3) (a) Meta d-Direttur ikun tal-fehma li prodott bijoċidali li kien irregistrati minn Stat Membru ieħor ma' jħarisx id-definizzjoni ta' "prodott bijoċidal b'riskju baxx" fir-regolament 3(1), d-Direttur jista' jirrifjuta tempornjament ir-registrazzjoni ta' dan u jista' jikkomunika minnufih it-thassib tiegħu lill-awtorità kompetenti responsabbli mill-verifika tad-dossier.

(b) Jekk, f'perjodu massimu taż-żmien ta' 90 jum, ma jintlaħaqx ftehim bejn l-awtoritajiet interessati, il-każ għandha titressaq quddiem il-Kummissjoni għal deċiżjoni skond il-proċedura stabbilita fir-regolament (5)4.

(4) Minkejja r-regolamenti 5(2) u (3), meta d-Direttur ikun tal-fehma li prodott bijoċidali awtorizzat minn Stat Membru ieħor ma' jistax jissodisfa l-kondizzjonijiet iddikjarati fir-regolament 6(1) u b'konsegwenza ta' dan jipproponi li

jirrifjuta l-awtorizzazzjoni jew ir-reġistrazzjoni jew li jirrestringi l-awtorizzazzjoni fuq ċerti kondizzjonijiet, d-Direttur għandu jinnotifika lill-Kummissjoni, lill-Istat Membru l-iehor u lill-applikant u għandu jipprovdilhom dokument ta' spjega li jkun fih l-isem tal-prodott u l-ispeċifikazzjoni tiegħu u li jiddikjara r-raġunijiet li għalihom jipproponi li jirrifjuta jew jirrestringi l-awtorizzazzjoni.

(5) (a) Jekk il-proċedura stabbilita fir-regolament 5(4) twassal għall-konferma tar-rifjut tat-tieni reġistrazzjoni jew ta' reġistrazzjoni sossegwenti, l-Istat Membru li jkun qabel irreġistra l-prodott bijoċidali ta' riskju baxx għandu, meta meqjus li jkun adatt mill-Kumitat Permanenti, jieħu dan ir-rifjut f'konsiderazzjoni u jirrevedi din ir-reġistrazzjoni skond r-regolament 7.

(b) Jekk din il-proċedura tikkonferma r-reġistrazzjoni inizjali, l-Istat Membru li jkun ressaq il-proċedura għandu jirreġistra l-prodott bijoċidali ta' riskju baxx interessat.

(6) Bħala deroga mir-regolament 5(1), d-Direttur jista' jirrifjuta, bla ħsara għat-Trattat, ir-rikonoxximent reċiproku ta' l-awtorizzazzjonijiet konċessi għat-tipi tal-prodotti 15, 17 u 23 ta' lis-Skeda V sakemm din il-limitazzjoni tista' tiġi ġustifikata u ma tqegħidx fil-periklu l-iskop ta' dawn ir-regolamenti.

Il-Kondizzjonijiet
għall-ħruġ ta'
awtorizzazzjoni.

6. (1) Prodott bijoċidali għandhom jiġu awtorizzati biss jekk -

(a) is-sustanza/i attiva/i inkluż/i fiha tkun/ikunu elenkati fis- Skeda I – Taqsima A jew Taqsima B u titwettag kull htieġa stabbilita f'dawn lis-Skedi;

(b) jiġi stabbilit, fid-dawl tal-għerf xjentifiku u tekniku korrenti, u jiġi muri mill-istima tad-dossier provdut fir-regolament 9, skond il-prinċipji komuni għall-valutazzjoni tad-dossiers kif stabbilit flis-Skedi VI, illi, meta wżati kif awtorizzati u wara li jitqiesu:

(1) il-kondizzjonijiet normali kollha li fuqhom jista' jintuza l-prodott bijoċidali,

(2) kif jista' jintuza l-materjal ittrattat bih,

(3) il-konsegwenzi mill-użu u mid-disponiment, il-prodotti bijoċidali:

(i) huwa effettiv suffiċjentement,

(ii) m'għandu l-ebda effett mhux aċċettabbli fuq organiżmi fil-mira, bħalma huma r-reżistenza mhux aċċettabbli jew ir-reżistenza inkroċjata jew sofferenza mhux meħtieġa u wġiġh għall-vertebrati,

(iii) m'għandu l-ebda effett mhux aċċettabbli minnu nnifsu jew bħala riżultat tal-fdalijiet tiegħu, fuq is-saħħa tal-bniedem jew ta' l-annimali, direttament jew indirettament, inklużi permezz ta' l-ilma tax-xorb, l-ikel jew il-għalf, l-arja ta' ġewwa jew konsegwenzi fuq il-post tax-xogħol, jew fuq l-ilma tal-wiċċ u ilma ta' taħt l-art,

(iv) m'għandu l-ebda effett mhux aċċettabbli minnu nnifsu, jew bħala riżultat tal-fdalijiet tiegħu, fuq l-ambjent b'rigward partikolari għall-konsiderazzjonijiet li ġejjin:

(1) id-destin jew id-distribuzzjoni tiegħu fl-ambjent; b'mod partikolari l-kontaminazzjoni ta' l-ilma tal-wiċċ, inklużi l-ilma ta' l-estwarji u dak tal-baħar, l-ilma ta' taħt l-art u l-ilma tax-xorb,

(2) l-impatt tiegħu fuq l-organiżmi mhux fil-mira;

(ċ) in-natura u l-kwantità tas-sustanzi attivi u, meta approprijat, kull impurità tossikoloġika jew ekotossikoloġika sinifikanti u ko-formolanti, u l-fdalijiet tiegħu ta' sinifikat tossikoloġiku għall-ambjent, li jirriżulta min utenti mhux awtorizzati, jistgħu jiġu stabbiliti skond il-htigiet rilevanti fis-Skedi II – Taqsima A, II – Taqsima B, III – Taqsima A, III – Taqsima B, IV – Taqsima A jew IV – Taqsima B;

(d) il-proprjetajiet fiżiċi u kimiċi tiegħu jkunu ġew stabbiliti u meqjusa aċċettabbli għall-iskop ta' l-użu approprijat, il-ħażna u t-trasport tal-prodott.

(2) Prodott bijoċidali klassifikat skond r-regolament 21(1) bħala tossiku, tossiku ħafna jew karcinoġenus tal-kategoriji 1 jew 2, jew mutaġenu tal-kategoriji 1 jew 2 jew ikklassifikat tossiku

għar-riproduzzjoni tal-kategoriji 1 jew 2, m'għandux jiġi awtorizzat għall-marketing, jew għall-użu mill-pubbliku ġenerali.

(3) L-awtorizzazzjoni tista' tkun ikkondizzjonata bil-kondizzjonijiet li għandhom x'jaqsmu mal-marketing u l-użu meħtieġ biex tiżgura l-konformità mad-dispożizzjonijiet ta' subregolament 6(1).

(4) Meta dispożizzjonijiet legali oħra jimponu htigiet rilevanti għall-kondizzjonijiet tal-ħruġ ta' awtorizzazzjoni u ta' l-użu ta' prodott bijoċidali, u b'mod partikolari meta dawn ikunu maħsuba sabiex jipproteġu s-saħħa tad-distributuri, ta' l-utenti, tal-haddiema u tal-konsumaturi jew is-saħħa ta' l-annimali jew l-ambjent, d-Direttur għandu jieħu dawn f'konsiderazzjoni meta tinħareġ awtorizzazzjoni u, meta meħtieġ, għandha toħroġ l-awtorizzazzjoni bla ħsara għal dawn il-htigiet.

Ir-Revizjoni ta' awtorizzazzjoni.

7. Matul il-perjodu taż-żmien li għalih tkun giet konċessa awtorizzazzjoni, din tista tiġi riveduta f'kull waqt, inklużi t-tagħrif li jkun wasal skond r-regolament 15, jekk ikun hemm indikazzjonijiet illi ma tkunx għadha tiġi sodisfatta xi waħda mill-kondizzjonijiet riferiti fir-regolament 6. F'dawn il-każijiet id-detentur ta' l-awtorizzazzjoni, jew lill-applikant li lilu kienet konċessa modifika għall-awtorizzazzjoni skond r-regolament 8, jistgħu jigu meħtieġa li jagħtu iktar tagħrif meħtieġ għar-reviżjoni. Jekk ikun hemm il-htieġa, l-awtorizzazzjoni tista' tiġi mtawla għall-perjodu taż-żmien meħtieġ biss sabiex titlesta r-reviżjoni, imma għandha tiġi mtawla għall-perjodu taż-żmien meħtieġ sabiex jiġi provvdut iktar tagħrif.

Il-Kanċellazzjoni jew il-modifika ta' awtorizzazzjoni.

8. (1) Awtorizzazzjoni għandha tiġi kanċellata jekk:

(a) is-sustanza attiva ma tibqax inkluża iktar fis-Skedi I – Taksima A jew Taksima B kif meħtieġa mir-regolament 6(1)(a);

(b) ma jibqgħux sodisfatti iktar il-kondizzjonijiet fit-tifsira ta' r-regolament 6(1) sabiex tinkiseb l-awtorizzazzjoni;

(ċ) jiġi mikxuf illi kienu forniti partikolaritajiet foloz jew li jqarrqu li jirrigardaw il-fatti li fuq il-bażi tagħhom kienet konċessa l-awtorizzazzjoni.

(2) Awtorizzazzjoni tista' tiġi kanċellata wkoll jekk id-detentur ta' l-awtorizzazzjoni jitlob dan u jiddikjara r-raġuni għall-

kancellazzjoni.

(3) Meta d-Direttur jahseb biex jikkancella awtorizzazzjoni, għandu jgħarraf u jisma' lid-detentur ta' l-awtorizzazzjoni. Meta tiġi kancellata awtorizzazzjoni, d-Direttur jista' jikkonċedi perjodu ta' żmien ta' grazzja għad-disponiment mill-ħażniet eżistenti jew mill-ħażna, mill-marketing u l-użu tagħhom, għal tul taż-żmien skond ir-raġuni għall-kancellazzjoni mingħajr preġudizzju għal kull perjodu ta' żmien ipprovdut għal deċiżjoni meħuda skond ir-Regolament (KE) Nu. 1907/2006 jew b' konnessjoni mar-regolament 8(1)(a).

(4) Il-kondizzjonijiet ta' l-użu ta' awtorizzazzjoni u, b'mod partikolari, il-manjiera ta' l-użu jew ta' l-ammonti wżati għandhom jiġu modifikati mid-Direttur meta jkun meħtieġ, fuq il-bażi ta' l-iżviluppi fil-għerf xjentifiku u tekniku u sabiex jiġu protetti s-saħħa u l-ambjent,.

(5) Awtorizzazzjoni tista' tiġi modifikata wkoll jekk jitlobha d-detentur ta' l-awtorizzazzjoni u jiddikjara r-raġunijiet għall-modifika.

(6) Meta modifika proposta tirrigwarda estensjoni ta' l-użi, d-Direttur għandu jestendi l-awtorizzazzjoni bla ħsara għall-kondizzjonijiet partikolari mqiegħda fuq is-sustanza attiva elenkata fis-Skedi I – Taqsima A jew Taqsima B.

(7) Meta modifika proposta għal awtorizzazzjoni tinvolvi bidliet fil-kondizzjonijiet partikolari mqiegħda fuq sustanza attiva elenkata fis-Skedi I – Taqsima A jew Taqsima B, ċerti bidliet jistgħu jsiru biss wara valutazzjoni tas-sustanza attiva, rigward il-bidliet proposti, skond il-proċeduri stabbiliti fir-regolament 12.

(8) Il-modifiki għandhom jiġu konċessi biss jekk jiġi stabbilit illi jissoktaw jiġu sodisfatti l-kondizzjonijiet fit-tifsira ta' r-regolament 6.

9. (1) Applikazzjoni għall-awtorizzazzjoni għandha ssir biss, mill-persuna responsabbli mill-ewwel tqegħid fis-suq ta' prodott bjoċidali fi Stat Membru partikolari, jew f'ismu, u għandha ssir lill-awtorità kompetenti ta' dan l-Istat Membru. Kull applicant għandu jkun meħtieġ li jkollu ufficiċju permanenti ġewwa l-Komunità.

Il-Ħtiġiet għall-awtorizzazzjoni.

(2) L-Istati Membri għandhom jeħtieġu illi applikant

għal awtorizzazzjoni ta' prodotti bijoċidali għandhom jissottomettu lid-Direttur:

(a) dossier jew ittra ta' l-aċċess għall-prodott bijoċidali li jissodisfaw, fid-dawl tal-għerf xjentifiku u tekniku korrenti, il-ħtigiet iddikjarati fis-Skedi II – Taqsima B u, meta speċifikati, il-partijiet rilevanti ta' lis-Skedi III – Taqsima B, u

(b) għal kull sustanza attiva fil-prodott bijoċidali, dossier jew ittra ta' aċċess li jissodisfaw, fid-dawl tal-għerf xjentifiku u tekniku korrenti, il-ħtigiet iddikjarati fis-Skedi II – Taqsima A u, meta speċifikati, il-partijiet rilevanti ta' lis-Skedi III – Taqsima A.

(3) Bħala deroga mis-subregolament 9(2)(a), dossier li jkun fih l-informazzjoni li ġejja rigward prodott bijoċidali ta' riskju baxx huwa meħtieġ:

(i) l-applikant:

(1) l-isem u l-indirizz,

(2) il-fabbrikanti tal-prodott bijoċidali u s-sustanzi attivi, (l-ismijiet u l-indirizzi inkluża l-lokazzjoni tal-fabbrikant tas-sustanza attiva),

(3) meta jkun adatt, ittra ta' aċċess għal kull informazzjoni rilevanti meħtieġa,

(ii) l-identità tal-prodott bijoċidali:

(1) l-isem kummerċjali,

(2) il-kompożizzjoni sħiħa tal-prodott bijoċidali,

(3) il-proprietajiet fiżiċi u kimiċi kif referiti fir-regolament 6(1)(d);

(iii) l-użi maħsuba:

(1) it-tip tal-prodotti (s-Skeda V) u l-kamp ta' l-użu tiegħu,

(2) il-kategoriji ta' l-utenti,

- (3) il-metodu ta' l-użu,
- (iv) l-informazzjoni dwar l-effikaċja,
- (v) il-metodi analitiċi,
- (vi) il-klassifika, il-pakkjar u t-tikkettjar, inkluż abożz tat-tikketta, skond r-regolament 21 ta' dawn ir-regolamenti,
- (vii) il-folja ta' informazzjoni dwar is-sigurtà mhejjija skond r-regolament 17 ta' r-Regolamenti ta' l-2007 dwar Sustanzi u Preparazzjonijiet Perikolużi, jew l-Artikolu 31 tar-Regolament (KE) 1907/2006. A.L. 10 ta' 2007.

(4) Id-dossiers għandhom jinkludu deskrizzjoni dettaljata u sħiħa dwar l-istudji kondotti u dwar il-metodi wżati jew referenza biblijografika ta' dawn il-metodi. It-tagħrif fid-dossiers fornit skond r-regolament 9(2) għandu jkun biżżejjed għal valutazzjoni li trid issir dwar l-effetti u l-proprjetajiet referiti fir-regolament 6(1)(b), (ċ) u (d). Għandu jiġi sottomess lid-Direttur fil-ġhamla ta' dossiers tekniċi, li jkun fihom it-tagħrif u r-riżultati ta' l-istudji referiti fis-Skedi II – Taqsima A u II – Taqsima B u, meta speċifikat, il-partijiet rilevanti fis-Skedi III – Taqsima A u III – Taqsima B.

(5) It-tagħrif li mhux meħtieġ minhabba n-natura tal-prodott bijoċidali jew l-użi proposti tiegħu m'għandux jiġi fornit. L-istess japplika meta ma jkunx xjentifikament jew teknikament possibli li jiġi fornit it-tagħrif. F'dawn il-każijiet, trid tiġi sottomessa ġustifikazzjoni, aċċettabli għad-Direttur. Din il-ġustifikazzjoni tista' tkun l-eżistenza ta' formolazzjoni ta' kwadru li l-applikant ikollu d-dritt għall-aċċess tagħha.

(6) Jekk il-valutazzjoni tad-dossier turi illi huwa meħtieġ iktar tagħrif, inklużi l-informazzjoni u r-riżultati minn iktar testijiet, sabiex jiġu valutati r-riskji fuq il-prodotti bijoċidali, l-awtorità kompetenti għandha titlob lill-applikant li jissottometti dan it-tagħrif. Il-perjodu taż-żmien għall-valutazzjoni tad-dossier għandu jibda biss wara li jimtela d-dossier.

(7) L-isem tas-sustanza attiva jrid jiġi mogħti kif irreġistrat fil-lista li tinsab fis-Skeda I tar-Regolamenti tal-2008 dwar Sustanzi Perikolużi, jew, jekk l-isem ma jkunx inkluż hawnhekk, kif mogħti fl-Inventarju Ewropew tas-Sustanzi Kimiċi Eżistenti (l-Einecs), jew, jekk l-isem mhux inkluż f'dan, A.L. 306 ta' 2008.

is-sustanza attiva trid tigi mogħtija l-isem komuni tagħha skond l-Organizzazzjoni Internazzjonali ta' l-Istandards (l-ISO). Jekk dan l-aħħar ma jkunx disponibbli, is-sustanza għandha tigi deżinjata bid-denominazzjoni kimika tagħha skond ir-regoli ta' l-Unjoni Internazzjonali tal-Kimika Pura u Applikata (il-IUPAK).

(8) Bħala prinċipju ġenerali, għandhom jiġu kondotti testijiet skond il-metodi deskritti fl-Regolament tal-Kummissjoni (KE) 465/2008 u Regolament tal-Kummissjoni (KE) 466/2008. Fl-eventwalità li metodu ma jkunx adatt jew mhux deskritt, metodi oħra wżati għandhom, kull meta possibli, jiġu rikkonossuti internazzjonalment u jridu jkunu ġustifikati. Meta jkun adatt, it-testijiet iridu jiġu kondotti skond id-dispożizzjonijiet stabbiliti fir-Regolamenti ta' l-2008 dwar l-Esperimenti li jsiru fuq l-Annimali, u r-Regolamenti ta' l-2004 dwar l-Ispezzjoni u l-Verifika ta' Prassi Tajba ta' Laboratorji.

(9) Meta teżisti informazzjoni dwar it-testijiet li tkun giet iġġenerata qabel l-adozzjoni ta' din id-Direttiva b'metodi oħra għajr dawk stabbiliti fir-Regolament tal-Kummissjoni (KE) 465/2008 u Regolament Kummissjoni (KE) 466/2008, l-adekwatezza ta' din l-informazzjoni għall-iskopijiet ta' dawn r-regolamenti u l-htieġa li jiġu kondotti testijiet ġodda skond lis-Skeda V iridu jiġu deċiżi każ b'każ, billi titqies, fost hwejjeg oħra, il-htieġa li jiġu minimizzati t-testijiet fuq l-annimali vertebrati.

(10) Id-Direttur għandu jiżgura illi jiġi kumpilat fajl għal kull applikazzjoni. Kull fajl irid ikun fih mill-inqas kopja ta' l-applikazzjoni, ir-registrazzjoni tad-deċiżjonijiet amministrattivi meħuda mill-Istati Membri li jirrigwardaw l-applikazzjoni u li jirrigwardaw id-dossiers sottomessi skond ir-regolament 9(2), flimkien ma' sommarju ta' dawn ta' l-aħħar. Fuq talba, d-Direttur għandu jagħmel disponibbli lill-awtoritajiet kompetenti l-oħra u lill-Kummissjoni l-fajls provduti f'dan ir-regolament; għandu ifornihom, fuq talba, bit-tagħrif kollu meħtieġ sabiex jifhmu bis-sħiħ l-applikazzjonijiet u għandu, meta mitluba, jiżgura illi l-applikanti jipprovdu kopja tad-dokumentazzjoni teknika stabbilita fir-regolament 9(2).

(11) Kampjuni tat-tħejjija u ta' l-ingredjenti tagħha jistgħu jeħtieġu li jiġu provvduti.

(12) L-applikazzjonijiet għall-awtorizzazzjoni għandhom jiġu sottomessi jew bl-Ingliż jew bil-Malti.

10. (1) Meta sustanza tkun sustanza attiva għall-użu fil-prodotti bijoċidali, ma tistax titqiegħed fis-suq għal dan l-użu għajr jekk:

It-tqegħid fis-suq tas-sustanzi attivi.

(a) meta s-sustanza attiva ma kinetx fis-suq qabel it-8 ta' Marzu 2000, id-dossier ikun gie mibgħut lil Stat Membru, li jissodisfa l-htigiet ta' r-regolament 12(1) u jkun akkumpanjat b'dikjarazzjoni illi s-sustanza attiva hija maħsuba sabiex tiġi mdaħħla fi prodotti bijoċidali. Dan m'għandux japplika għas-sustanzi għall-użu skond r-regolament 18;

(b) tiġi klassifikata, ippakkjata u t-tikkettjata skond id-dispożizzjonijiet tar-Regolamenti ta' l-2008 dwar Sustanzi Perikolużi, 2008.

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11. (1) Fid-dawl tal-għerf xjentifiku u tekniku korrenti, sustanza attiva għandha tiġi mdaħħla fis-Skeda I għal perjodu inizjali taż-żmien li ma jaqbiżx l-10 snin jekk jista' jiġi mistenni li –

L-inkluzjoni ta' sustanza attiva fi Skeda I.

(a) il-prodotti bijoċidali li jkun fihom is-sustanza attiva,

(b) il-prodotti bijoċidal ta' riskju baxx li jharsu d-definizzjoni “prodott bijoċidal b'riskju baxx” fir-regolament 3(1),

(ċ) is-sustanzi ta' l-oġġetti tad-dar li jharsu t-tifsira “sustanza bażika” fir-regolament 3(1),

iridu jwettqu l-kondizzjonijiet stabbiliti fir-regolament 6(1)(b), (ċ) u (d), filwaqt li jitqiesu, meta rilevanti, l-effetti kumulattivi mill-użu tal-prodotti bijoċidali li jkun fihom l-istess sustanzi attivi.

Sustanza attiva ma' tistax tiddaħħal fis-Skeda I – Taqsima B jekk tkun klassifikata skond r-Regolamenti ta' 2008 dwar Sustanzi Perikolużi, 2008 bħala:

A.L. 306 ta' l-2008.

(i) karċinogenika,

(ii) mutaġenika,

(iii) tossika għar-riproduzzjoni,

(iv) li tissensitizza, jew

(v) hija bijo-kumulattiva u ma tiddegradax ruħha minnufih:

Iżda meta jkun adatt, id-dħul tas-sustanza attiva fis-Skeda I – Taksima B għandu jirreferi għall-firxiet tal-koncentrazzjoni li bejniethom tista' tintuża s-sustanza.

(2) It-tidħil ta' sustanza attiva fis-Skeda I għandha, meta jkun adatt, tkun bla ħsara għal dan li ġej:

(a) il-ħtiġiet dwar:

(i) il-grad minimu tas-safa tas-sustanza attiva,

(ii) in-natura u l-kontenut massimu ta' ċerti impuritajiet,

(iii) it-tip ta' prodott li fih tista' tintuża,

(iv) il-manjiera u ż-żona ta' l-użu,

(v) id-denominazzjoni tal-kategoriji ta' l-utenti, inklużi industrijali, professjonali jew mhux professjonali,

(vi) il-kondizzjonijiet l-oħra partikolari mill-valutazzjoni tat-tagħrif li jkun ġie magħmul disponibbli fil-kuntest ta' dawn ir-regolamenti;

(b) il-mod li bih jiġu stabbiliti dawn li ġejjin:

(i) il-livell aċċettabli ta' l-espożizzjoni ta' l-operatur (l-LAEO), jekk meħtieġ,

(ii) meta rilevanti, it-tidħil ta' kuljum aċċettabli għall-bniedem (l-ADI) u limitu massimu tal-fdalijiet (l-LMF),

(iii) id-destin u l-imġiba fl-ambjent u l-impatt fuq l-organizmi mhux fil-mira.

(3) L-inklużjoni fis-Skeda I ta' sustanza attiva għandha tiġi ristretta għal daww it-tipi ta' prodotti fl-Anness V li għalihom kienet sottomesa l-informazzjoni rilevanti skond r-regolament 9.

(4) L-inklużjoni ta' sustanza attiva fis-Skeda I tista' tigi mġedda f'okkażjoni jew aktar għal perjodi taż-żmien li ma' jaqbżux l- 10 snin. L-inklużjoni inizjali, kif ukoll kull inklużjoni mġedda, jistgħu jiġu riveduti f'kull hin jekk ikun hemm indikazzjonijiet illi ma tibqax tigi sodisfatta xi waħda mill-htigiet riferiti fir-regolament 11(1). It-tiġdid jista', meta meħtieġ, jiġi konċess biss għall-perjodu minimu taż-żmien meħtieġ sabiex titlesta reviżjoni, meta tkun giet magħmula applikazzjoni għal dan it-tiġdid, u għandu jiġi konċess għall-perjodu taż-żmien meħtieġ sabiex jiġi provvdut iktar tagħrif mitlub skond r-regolament 12(2).

(5) (a) It-tidħil ta' sustanza attiva fis-Skeda I – Taksima A u, meta rilevanti, fit- Taksima B jew it-Taksima Ċ jista' jiġi rifjutat jew imneħhi,

(i) jekk il-valutazzjoni tas-sustanza attiva skond r-regolament 12(2) turi illi, taħt kondizzjonijiet normali li fuqhom tista' tintuża fil-prodotti bjoċidali awtorizzati, ir-riskji għas-saħħa jew għall-ambjent jissoktaw iqajmu tħassib, u

(ii) jekk ikun hemm sustanza attiva oħra fis-Skeda I – Taksima A għall-istess tip ta' prodott li, fid-dawl tal-għerf xjentifiku jew tekniku, jippreżenta b'mod sinifikanti inqas riskju għas-saħħa jew għall-ambjent:

Iżda meta jiġu kunsidrat dan ir-rifjut jew din it-tneħħija, għandha ssir stima ta' sustanza attiva alternattiva jew sustanzi attivi alternattivi sabiex jiġi muri illi jistgħu jintużaw b'effett simili fuq l-organizmu fil-mira mingħajr żvantagġi ekonomiċi u prattiċi sinifikanti għall-utent u mingħajr riskju miżjud għas-saħħa u għall-ambjent.

(b) Ir-rifjut jew it-tneħħija ta' tidħil fis-Skeda I – Taksima A u, meta rilevanti, fit-Taksima B jew fit-Taksima Ċ għandhom jitwettqu skond il-kondizzjonijiet li ġejjin:

(i) id-diversità kimika tas-sustanzi attivi għandha tkun adegwata sabiex timminimizza l-okkorrenza tar-reżistenza fl-organizmu fil-mira;

(ii) għandhom jitwettqu biss għas-sustanzi attivi li, meta wżati taħt il-kondizzjonijiet normali fil-prodotti bjoċidali awtorizzati, jippreżentaw livell ta' riskju differenti b'mod sinifikanti;

(iii) għandhom jiġu applikati biss għas-sustanzi attivi wżati fil-prodotti ta' l-istess tip ta' prodott;

(iv) għandhom jiġu applikati biss wara titħalla l-possibbiltà, meta meħtieġa, li tiġi miksuba l-esperjenza mill-użu fil-prattika, jekk ma tkunx diġà disponibbli;

(v) id-dossiers kompleti tad-data ta' l-evalwazzjoni li jservu jew li servew għar-reġistrazzjoni fis-Skeda I għandhom jiġu mqiegħda għad-dispożizzjoni tal-Kumitat imsemmi fl-Artikolu 28(1) tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali.

(ċ) Deċiżjoni biex jitneħħa d-dhul fis-Skeda I – Taqsima A m'għandux ikollha effett immedjat imma għandha tiġi posposta għal perjodu taż-żmien sa massimu ta' erba' snin mid-data ta' din id-deċiżjoni.

Il-Proċedura għall-inklużjoni ta' sustanza attiva fis-Skeda I.

12. (1) It-tidħil, jew il-bidliet sossegwenti għall-inklużjoni, ta' sustanza attiva fis-Skeda I għandhom jiġu kunsidrati meta:

(a) applikant ikun bagħat lid-Direttur:

(i) dossier dwar is-sustanza attiva li jissodisfa l-htigiet ta' s-Skeda IV – Taqsima A jew il-htigiet ta' lis-Skeda II – Taqsima A u, meta speċifikata, il-parti rilevanti ta' lis-Skeda III – Taqsima A;

(ii) dossier għal mill-inqas prodott bijoċidali wieħed li jkun fih is-sustanza attiva li tissodisfa l-htigiet ta' r-regolament 9, bl-eċċezzjoni tar-regolament 12(3) tiegħu;

(b) d-Direttur riċevitur ikun ivverifika id-dossiers u għandu għax jaħseb li jissodisfaw il-htigiet ta' l is-Skeda IV – Taqsima A u lis-Skeda IV – Taqsima B jew il-htigiet ta' lis-Skeda II – Taqsima A u lis-Skeda II – Taqsima B u, meta rilevanti, ta' lis-Skedi IIIA u IIIB, jaċettahom u jaqbel li l-applikant jibgħat sommarju tad-dossiers lill-Kummissjoni u lill-Istati Membri l-oħra.

(2) Id-Direttur riċevitur għandu, fi żmien 12-il xahar minn meta jaċetta d-dossiers, iwettaq valutazzjoni tagħhom. Kopja tal-valutazzjoni għandha tintbagħat mid-Direttur lill-Kummissjoni,

lill-Istati Membri l-oħra u lill-applikant, flimkien mar-rakkommandazzjoni sabiex tiddaħħal, jew xorta oħra, is-sustanza attiva fis-Skeda I:

Iżda jekk, meta jiġu valutati d-dossiers, jidher li jkun meħtieġ iktar tagħrif sabiex issir valutazzjoni sħiħa, d-Direttur riċevitur għandu jitlob lill-applikant li jissottometti dan it-tagħrif. Il-perjodu taż-żmien ta' 12-il xahar għandu jiġi sospiż mid-data tal-ħruġ tat-talba tad-Direttur sad-data li fiha jiġi rċevut it-tagħrif. Id-Direttur għandu jgħarraf lill-Istati Membri l-oħra u lill-Kummissjoni bl-azzjoni tagħha meta tgħarraf lill-applikant.

13. (1) Id-Direttur m'għandux jagħmel użu mit-tagħrif riferit fir-regolament 9 għall-benefiċċji ta' tieni applikant jew applikant sossegwenti:

L-użu ta' l-informazzjoni miżmuma mill-awtoritajiet kompetenti għall-applikanti l-oħra.

(a) għajr jekk it-tieni applikant jew l-applikant sossegwenti ikollhom il-qbil bil-miktub fil-għamla ta' ittra ta' aċċess ta' l-ewwel applikant illi jista' jsir użu minn dan it-tagħrif, jew

(b) fil-każ ta' sustanza attiva mhux fis-suq fit-8 ta' Marzu 2000, għall-perjodu taż-żmien ta' 15-il sena mid-data ta' l-ewwel tidħil fis-Skedi I – Taqsima A jew Taqsima B, jew

(ċ) fil-każ ta' sustanza attiva diġà fis-suq fit-8 ta' Marzu 2000:

(i) sal-14 ta' Mejju 2014 għal kwalunkwe informazzjoni li tingħata għall-iskopijiet ta' dawn ir-regolamenti, għajr għal meta t-tali informazzjoni tkun diġà protetta permezz tar-regoli nazzjonali eżistenti li jirrigwardaw il-prodotti bijoċidali. F'dawn il-każijiet, l-informazzjoni għandha tibqa' tiġi protetta lokalment sat-tmiem ta' kwalunkwe perjodu li jkun fadal għall-protezzjoni tad-data kif previst mir-regoli nazzjonali, iżda mhux wara l- 14 ta' Mejju 2014 jew, jekk applikabbli, mhux wara d-data sa meta ġie estiż il-perjodu tranżizzjonali msemmi fir-regolament 17(1) b'konformità mar-regolament 17(2);

(ii) għal perjodu taż-żmien ta' 10 snin mid-data tad-dħul tas-sustanza attiva fis-Skedi I – Taqsima A jew Taqsima B għat-tagħrif is-sottomess għal l-ewwel darba bħala appoġġ għall-ewwel inkluzjoni fis- Skedi I –

Taqsim A jew Taqsim B ta' jew is-sustanza attiva jew ta' tip ta' prodott addizzjonali għal din is-sustanza attiva,

(d) fil-każ ta' tagħrif iktar sottomess għall-ewwel darba għal waħda minn dawn li ġejjin:

(i) il-varjazzjoni tal-ħtiġiet għat-tidħil ta' lis-Skedi I – Taqsim A jew Taqsim B;

(ii) iż-żamma fil-post tat-tidħil fis-Skedi I – Taqsim A jew Taqsim B

għal perjodu taż-żmien ta' ħames snin mid-data tad-deċiżjoni wara l-irċevuta ta' iktar tagħrif għajr jekk jiskadi l-perjodu taż-żmien ta' ħames snin qabel il-perjodu taż-żmien provdut fir-regolament 13(1) (b) u (ċ), f'liema każ il-perjodu taż-żmien ta' ħames snin għandu jiġi mtawwal sabiex jiskadi fl-istess data bħal dawn il-perjodi taż-żmien.

(2) Id-Direttur m'għandux jagħmel użu mit-tagħrif riferit fir-regolament 9, għall-benefiċċju ta' applikant tat-tieni jew ta' applikant sossegwenti:

(a) għajr jekk it-tieni applikant jew l-applikant sossegwenti jkollhom il-qbil bil-miktub fil-għamla ta' ittra ta' aċċess mill-ewwel applikant illi jista' jsir użu minn dan it-tagħrif; jew

(b) fil-każ ta' prodott bijoċidali jkun fih sustanza attiva li ma tkunx fis-suq fit-8 ta' Marzu 2000, għal perjodu taż-żmien ta' 10 snin mid-data ta' l-ewwel awtorizzazzjoni f'kull Stat Membru, jew;

(ċ) fil-każ ta' prodott bijoċidali li jkun fih sustanza attiva diġà fis-suq fit-8 ta' Marzu 2000;

(i) sal-14 ta' Mejju 2014 għal kwalunkwe informazzjoni li tingħata għall-iskopijiet ta' dawn ir-regolamenti, għajr għal meta d-data tkun diġà protetta permezz tar-regoli nazzjonali eżistenti li jirrigwardaw il-prodotti bijoċidali, f'liema każ it-tali data għandha tibqa' tiġi protetta lokalment sat-tmiem ta' kwalunkwe perjodu li jkun fadal għall-protezzjoni tad-data kif previst mir-regoli nazzjonali, iżda mhux wara l-14 ta' Mejju 2014 jew, jekk applikabbli, mhux wara d-data sa meta ġie

estiz il-perjodu tranżizzjonali msemmi fir-regolament 17(1) b'konformità mar-regolament 17(2);

(ii) għal perjodu taż-żmien ta' 10 snin mid-data tat-tidhila tas-sustanza attiva fis- Skedi I – Taqsima A jew Taqsima B għat-tagħrif li jiġi sottomess għall-ewwel darba bħala appoġġ għall-inklużjoni fis- Skedi I – Taqsima A jew Taqsima B jew tas-sustanza attiva jew ta' tip ta' prodott addizzjonali għal din is-sustanza attiva;

(d) fil-każ ta' kull informazzjoni sottomessa għall-ewwel darba għall-waħda jew l-oħra ta' dawn li ġejjin:

(i) il-varjazzjoni fil-kondizzjonijiet ta' l-awtorizzazzjoni ta' prodott bjoċidali;

(ii) is-sottomissjoni ta' l-informazzjoni meħtieġa sabiex jinżamm it-tidhila tas-sustanza attiva fis- Skedi I – Taqsima A jew Taqsima B għal perjodu taż-żmien ta' hames snin mid-data ta' l-ewwel irċevuta ta' iktar informazzjoni, għajr jekk il-perjodu taż-żmien ta' hames snin jiskadi qabel il-perjodu taż-żmien provdut fir-regolament 13(2) (b) u (ċ), f'liema każ il-perjodu taż-żmien ta' hames għandu jiġi mtawwal sabiex jiskadi fl-istess data bħal dawn il-perjodi taż-żmien.

(3) Għad-deċiżjonijiet meħuda skond r-regolament 11(5), it-tagħrif riferit fis-subregolament 13(1) u (2) jista' jintuża mill-Kummissjoni, mill-Kumitati Xjentifiċi kif referit fl-Artikolu 27 tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bjoċidali u mill-Istati Membri.

14. (1) Fil-każ ta' prodott bjoċidali li jkun diġà ġie awtorizzat skond r-regolamenti 4 u 6, u mingħajr preġudizzju għal obbligi imposti skond r-regolament 13, l-awtorità kompetenti tista' jaqbel li t-tieni applikant jew applikant sossegwenti għal awtorizzazzjoni jistgħu jirreferu għall-informazzjoni pprovduta mill-ewwel applikant safejn u sakemm it-tieni l-applikant jew applikant sossegwenti jistgħu jipprovdu xiehda illi l-prodott bjoċidali jixbah lil wieħed awtorizzat minn qabel, inklużi l-grad tas-safa u n-natura ta' l-impuritajiet u li s-sustanzi attivi huma l-istess bħal dan.

Il-ko-operazzjoni fl-użu ta' l-informazzjoni għat-tieni applikazzjoni u l-applikazzjonijiet sossegwenti għal awtorizzazzjoni.

(2) Minkejja r-regolament 9(2):

(a) applikant għal awtorizzazzjoni ta' prodotti bijoċidali jrid, qabel iwettaq l-esperimenti li jinvolvu l-annimali vertebrati, jistaqsu lid-Direttur beħsiebu jagħmel l-applikazzjoni:

(i) jekk il-prodott bijoċidali li għalih trid issir l-applikazzjoni tkunx simili għal prodott bijoċidali li għalih tkun giet konċessa awtorizzazzjoni, u

(ii) rigward l-isem u l-indirizz tad-detentur jew tad-detenturi ta' l-awtorizzazzjoni jew ta' l-awtorizzazzjonijiet:

Izda l-mistoqsija għandha tiġi appoġġjata b'xiehda illi l-applikant prospettiv ikun beħsiebu japplika għall-awtorizzazzjoni f'ismu u li jkun disponibbli t-tagħrif l-ieħor speċifikat fir-regolament 9(2);

(b) id-Direttur, jekk sodisfat illi l-applikant ikun beħsiebu japplika, għandu jipprovdli l-isem u l-indirizz tad-detentur jew tad-detenturi ta' l-awtorizzazzjonijiet rilevanti ta' qabel u għandha fl-istess żmien tgħarraf lid-detenturi ta' l-awtorizzazzjonijiet bl-isem u l-indirizz ta' l-applikant.

Izda –

(i) id-detentur jew id-detenturi ta' l-awtorizzazzjonijiet ta' qabel u l-applikant għandhom jieħdu l-passi kollha raġjonevoli sabiex jilhqu ftehim dwar it-tqassim bejniethom tat-tagħrif, sabiex jevitaw, jekk possibbli, it-tennija tat-testijiet fuq annimali vertebrati;

(ii) id-Direttur għandu jinkoraġġixxi lid-detenturi ta' l-informazzjoni sabiex jikkooperaw fil-provvediment ta' l-informazzjoni mitluba, bil-ħsieb li jillimitaw it-tennija tat-testijiet fuq annimali vertebrati; u

(iii) jekk jibqa' ma jkunx possibbli illi l-applikant u d-detenturi ta' l-awtorizzazzjonijiet ta' qabel għall-istess prodott jilhqu ftehim dwar it-tqassim bejniethom ta' l-informazzjoni, id-Direttur jista' jintroduċi miżuri nazzjonali li jobbligaw lill-applikant u lid-detenturi ta' l-awtorizzazzjonijiet ta' qabel lokati fit-territorju tagħhom biex jaqsmu bejniethom l-informazzjoni bil-

hsieb li jevitaw it-tennija tat-testijiet fuq annimali vertebrati u biex jistabbilixxu kemm il-proċedura għall-utilizzazzjoni tat-tagħrif, u kemm il-bilanċ raġjonevoli ta' l-interessi tal-partijiet interessati.

15. (1) Id-detentur ta' awtorizzazzjoni għal prodott bijoċidali għandu jinnotifika minnufih lid-Direttur bit-tagħrif li hu jew hi jkunu jafu bih jew li hu jew hi jistgħu raġjonevolment ikunu mistennija li jkunu jafu bih rigward sustanza attiva jew prodott bijoċidali li jkun fih minnha u li jistgħu' jaffettwaw il-kontinwazzjoni ta' l-awtorizzazzjoni. B'mod partikolari, għandu jiġi notifikat b'dan li ġej:

It-Tagħrif ġdid u l-obbligazzjonijiet tal-pussessur tal-awtorizzazzjoni.

(a) it-tagħrif jew l-informazzjoni godda fuq l-effetti tas-sustanza attiva jew tal-prodott bijoċidali fuq il-bniedem jew fuq l-ambjent,

(b) il-bidliet fis-sors jew fil-kompożizzjoni tas-sustanza attiva,

(ċ) il-bidliet fil-kompożizzjoni ta' prodott bijoċidali,

(d) l-iżvilupp tar-reżistenza,

(e) il-bidliet ta' natura amministrattiva jew aspetti oħra, bħalma hija l-kwalità tal-pakkjar.

(2) Id-Direttur għandu jinnotifika minnufih lill-Istati Membri l-oħra u lill-Kummissjoni b'kull tagħrif minn dan li jirċievu dwar l-effetti potenzjalment ta' ħsara għall-bniedem jew għall-ambjent jew il-kompożizzjoni ġdida ta' prodott bijoċidali, is-sustanzi attivi tiegħu, l-impuritajiet, il-ko-formolanti jew il-fdalijiet.

16. (1) Bħala deroga mir-regolamenti 4 u 6, it-tqegħid fis-suq ta' prodotti bijoċidali li ma jikkonformawx mad-dispożizzjonijiet ta' dawn ir-regolamenti, jistgħu jiġu awtorizzazzati temporanjament għal perjodu taż-żmien ta' mhux aktar minn 120 jum, għal użu limitat u kontrollat jekk din il-miżura tidher meħtieġa minħabba periklu imprevist li ma jistax jiġi kontrollat b'mezzi oħra. F'dan il-każ, id-Direttur interessat għandu jgħarraf minnufih lill-Istati Membri l-oħra u lill-Kummissjoni bl-azzjoni tiegħu u bil-ġustifikazzjoni għaliha.

Id-Deroga mill-htigiet.

(2) Bħala deroga mir-regolament 6(1)(a) u sakemm

sustanza attiva tibqa' elenkata fis- Skedi I – Taqsima A jew Taqsima B, Direttur jista' jawtorizza proviżorjament, għal perjodu taż-żmien ta' mhux aktar minn tliet snin, li jitqiegħed fis-suq prodott bijoċidali li jkun fih sustanza attiva li mhix elenkata fis- Skedi I – Taqsima A jew Taqsima B u li tkun għadha mhix disponibbli fis-suq fit-8 ta' Marzu, 2000 għal skopijiet oħra għajr dawk mfissra fir-regolament 3(2)(ċ) u (d). Din l-awtorizzazzjoni tista' tinħareġ biss jekk, wara li d-dossiers ikunu ġew ivvalutati skond r-regolament 12, ikun jemmen li:

(a) is-sustanza attiva tissodisfa l-htigiet ta' r-regolament 11, u

(b) il-prodott bijoċidali jista' jkun mistenni li jissodisfa l-kondizzjonijiet tar-regolamenti 6(1)(b), (ċ) u (d)

u l-ebda Stat Membru ieħor, fuq il-bazi tas-sommarju li jirċievi, ma jagħmel oġġezzjoni leġittima, skond r-regolament 19(2), dwar il-kompletezza tad-dossiers. Meta ssir oġġezzjoni, għandha tittieħed deċizjoni dwar il-kompletezza tad-dossiers skond il-proċedura fl-Artikolu 28(2) tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali mingħajr dewmien mhux misthoqq:

Iżda -

(a) jekk, wara l-proċeduri stabbiliti fl-Artikoli 27 u 28(2) tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali, jiġi deċiż illi s-sustanza attiva ma tissodisfax il-htigiet speċifikati fir-regolament 11, d-Direttur għandu jiżgura illi tiġi kanċellata l-awtorizzazzjoni proviżorja;

(b) fil-kazijiet meta l-valutazzjoni tad-dossiers bil-għan li tiġi inkluża sustanza attiva fis-Skeda I – Taqsima A jew Taqsima B ma tkunx kompletata meta jiskadi l-perjodu taż-żmien ta' tliet snin, d-Direttur jista' jerga' jawtorizza proviżorjament il-prodott għal mhux aktar minn sena, sakemm ikun hemm raġunijiet validi sabiex temmen illi s-sustanza attiva trid tissodisfa l-htigiet ta' r-regolament 11.

Miżuri Transitorji.

17. (1) B'deroga oħra mir-regolamenti 4(1), 6(1), 9(2) u 9(4), u mingħajr preġudizzju għas-subregolament 17(3), id-Direttur jista', sal-14 ta' Mejju 2014, ikompli japplika s-sistema jew il-prattika attwali tiegħu li jqiegħed fis-suq il-prodotti bijoċidali. Jekk

deċiżjoni sabiex sustanza attiva tigi inkluża fis- Skedi I – Taqsima A jew Taqsima B tistabbilixxi data iktar tard mill-14 ta' Mejju 2014 għall-konformità mar-regolament 17(3), din id-deroga għandha tibqa' tapplika għall-prodotti li fihom dik is-sustanza attiva sad-data stabbilita fid-deċiżjoni. Id-Direttur jista', b'mod partikolari, skont r-regoli nazzjonali tiegħu, jawtorizza t-tqegħid fis-suq fit-territorju tiegħu prodott bijoċidali li jkun fih sustanzi attivi li mhux elenkati fi Skedi I – Taqsima A jew Taqsima B għal dan it-tip ta' prodott. Dawn is-sustanzi attivi jridu jkunu fis-suq fit-8 ta' Marzu 2000 bħala sustanzi attivi ta' prodott bijoċidali għal finijiet oħra għajr dawk mfissra fir-regolament 3(2)(ċ) u (d).

(2) Wara din id-deċiżjoni sabiex tiddaħhal jew le sustanza attiva fis-Skeda I, id-Direttur għandu jiżgura illi jiġu konċessi, modifikati jew kanċellati kif ikun adatt l-awtorizzazzjonijiet jew, fejn rilevanti, ir-registrazzjonijiet tal-prodotti bijoċidali li jkun fihom is-sustanzi attivi u li jharsu d-dispożizzjonijiet ta' dawn ir-regolamenti.

18. (1) Bħala deroga mir-regolament 4, kull esperiment jew test għall-finijiet tar-riċerka u l-iżvilupp li jinvolvu t-tqegħid fis-suq ta' prodotti bijoċidali mhux awtorizzati jew sustanza attiva maħsuba biss għall-użu fi prodott bijoċidali m'għandomx isiru għajr jekk:

Ir-riċerka u l-iżvilupp.

(a) fil-każ tar-riċerka xjentifika u l-iżvilupp, il-persuni interessati jfasslu u jzommu registri li jagħtu fid-dettal l-identità tal-prodott bijoċidali jew tas-sustanza attiva, li jagħtu t-tikketta lill-informazzjoni, lill-kwantitajiet provvduti u lill-ismijiet u l-indirizzi ta' dawk il-persuni li jirċievu l-prodott bijoċidali jew is-sustanza attiva u jikkompilaw dossier li jkun fih l-informazzjoni kollha disponibbli dwar l-effetti possibbli fuq is-saħħa tal-bniedem jew ta' l-animali jew dwar l-impatt fuq l-ambjent. Dan it-tagħrif għandu, jekk mitlub, jkun disponibbli lid-Direttur;

(b) fil-każ ta' riċerka u żvilupp orjentati fuq il-proċess, it-tagħrif meħtieġ fir-regolament 18(1)(a) jiġi notifikat lid-Direttur qabel ma jiġri t-tqegħid fis-suq u lill-awtorità kompetenti ta' l-Istat Membru fejn irid jiġi kondott l-esperiment.

(2) Prodott bijoċidali mhux awtorizzat jew sustanza attiva għall-użu esklussiv fi prodott bijoċidali, ma jisgħux jitqiegħdu fis-suq għall-finijiet ta' kull esperiment jew test li jistgħu

jinvolve, jew jirriżultaw fir-rilaxx fl-ambjent għajr jekk d-Direttur ikun stmat l-informazzjoni disponibbli u ħarġet awtorizzazzjoni għal dan il-għan li tillimita l-kwantitajiet li jridu jiġu wżati u ż-żoni li jridu jiġu trattati u tista' timponi iktar kondizzjonijiet.

(3) Meta kull esperiment jew test isiru fi Stat Membru għajr Malta, l-applikant għandu jikseb awtorizzazzjoni għall-esperimenti jew it-testijiet li fit-territorju jridu jiġu kondotti l-esperimenti jew it-testijiet:

Iżda jekk l-esperimenti jew it-testijiet proposti riferiti fir-regolamenti 18(1) u (2) jistgħu jagħmlu ħsara lis-saħħa tal-bniedem jew ta' l-annimali jew jista' jkollhom influwenza negattiva u mhux aċċettabbli fuq l-ambjent, d-Direttur jista' jew jipprojbixxuhom jew iħalluhom biss bla ħsara għall-kondizzjonijiet meħtieġa sabiex jipprevjenu dawn il-konsegwenzi.

(4) Regolament 18(2) m'għandux japplika jekk d-Direttur jkun konċeda lill-persuna interessata d-dritt illi tindaħal għal ċerti esperimenti u testijiet u jkun stabbilixxa l-kondizzjonijiet li fuqhom iridu jiġu mwettqa l-esperimenti u t-testijiet.

(5) Għandhom jiġu adottati kundizzjonijiet komuni għall-applikazzjoni ta' r-regolament 18, b'mod partikolari l-kwantitajiet massimi ta' sustanzi attivi jew prodotti bijoċidali tagħhom ikun hemm ċans ta' rilaxx waqt esperimenti u d-data minima li trid tiġi preżentata sabiex tippermetti evalwazzjoni skond ir-regolament 18(2). Dawn il-miżuri, imfassla sabiex jemendaw elementi mhux essenzjali ta' dawn ir-regolamenti billi jissupplimentawha, għandhom jiġi adottati skond il-proċedura regolatorja bi skrutinju msemija fl-Artikolu 28(4) tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali.

L-iskambju tat-tagħrif.

19. (1) Fi żmien xahar mit-tmien ta' kull kwart tas-sena, d-Direttur għandu jgħarraf lil Istat Membri oħra u lill-Kummissjoni dwar kull prodott bijoċidali li jkun ġie awtorizzat jew registrat fit-territorju tagħhom jew li għalih ikunu ġew rifjutati, immodifikati, rinnovati jew kanċellati l-awtorizzazzjoni jew ir-registrazzjoni, billi mill-inqas jindikaw:

(a) l-isem jew l-isem kummerċjali ta' l-applikant għall-awtorizzazzjoni jew ir-registrazzjoni, jew id-detentur tagħhom;

(b) l-isem kummerċjali tal-prodotti bijoċidali;

(ċ) l-isem u l-ammont ta' kull sustanza attiva li jkun fiha, kif ukoll l-isem u l-ammont ta' kull sustanza perikoluża fit-tifsira ta' r-regolament 3(2) tar-Regolamenti ta' l-2008 A.L. 306 ta' l-2008. dwar Sustanzi Perikolużi u l-klassifika tagħha;

(d) it-tip ta' prodott u l-użu jew l-użi li għalihom tkun awtorizzata;

(e) it-tip tal-formolazzjoni;

(f) kull limitu propost dwar il-fdalijiet li jkun għew stabbiliti;

(g) il-kondizzjonijiet ta' l-awtorizzazzjoni u, meta rilevanti, ir-raġunijiet għall-modifika jew il-kanċellazzjoni ta' l-awtorizzazzjoni;

(h) indikazzjoni dwar jekk il-prodott huwiex ta' tip speċjali inklużi fi prodott bijoċidali ta' formolazzjoni ta' kwadru ta' riskju baxx.

(2) Meta Direttur jirċievi sommarju tad-dossiers skond r-regolamenti 12(1)(b) u 16(2) u għandu raġuni legittima biex jemmen illi d-dossiers mhumiex kompletati, għandu jikkomunika minnufih it-tfassil tiegħu lill-awtorità kompetenti responsabbli mill-valutazzjoni tad-dossiers u għandu jgħarraf lill-Kummissjoni u lill-Istati Membri l-oħra bit-tfassil tiegħu mingħajr dewmien mhux misthoqq.

(3) Id-Direttur għandu jfassal lista ta' kull sena tal-prodotti bijoċidali awtorizzati jew registrati fit-territorju tiegħu u għandu jikkomunika din il-lista lill-Istati Membri l-oħra u lill-Kummissjoni.

(4) Skond il-proċedura stabbilita fl-Artikolu 28(2) tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali, għandha tiġi stabbilita sistema standardizzata ta' tagħrif sabiex tiffaċilita l-applikazzjoni tar-regolamenti 19 (1) u (2).

20. (1) Mingħajr preġudizzju għar-Regolamenti ta' l-2005 dwar il-Libertà ta' Aċċess għal-Infurmazzjoni dwar l-Ambjent, applikant jista' jindika lid-Direttur t-tagħrif li huwa Il-Kunfidenzjalità.

A.L. 116 ta' l-2005.

A.L. 306 ta' l-2008.

A.L. 10 ta' l-2007.

jikkunsidra bħala sensittiv kummerċjalment u li l-iżvelar tiegħu jista' jikkawżalu ħsara industrijalment jew kummerċjalment u li għalhekk ikun jixtieq li jibqa' kunfidenzjali minn persuni oħra għajr l-awtoritajiet kompetenti u l-Kummissjoni. Trid tinħtieg ġustifikazzjoni sħiħa f'kull każ. Mingħajr preġudizzju għat-tagħrif msemmi fir-regolament 20(3) u fid-dispożizzjonijiet tar-Regolamenti ta' l-2008 dwar Sustanzi Perikolużi u tar-Regolamenti ta' l-2007 dwar Sustanzi u Preparazzjonijiet Perikolużi, d-Direttur għandu jieħu l-passi meħtieġa sabiex jiżgura il-kunfidenzjalità tal-kompożizzjoni sħiħa tal-formolazzjonijiet tal-prodott jekk mitluba mill-applikant.

(2) Id-Direttur li jirċievi l-applikazzjoni għandu jiddeċiedi, fuq il-bażi tax-xhieda dokumentarja prodotta mill-applikant, liema tagħrif għandu jkun kunfidenzjali fit-termini tar-regolament 20(1):

Iżda t-tagħrif aċċettat bħala kunfidenzjali mid-Direttur li jirċievi l-applikazzjoni għandu jiġi ttrattat bħala kunfidenzjali mill-awtoritajiet kompetenti l-oħra, mill-Istati Membri u mill-Kummissjoni.

(3) Wara li tkun ġiet konċessa l-awtorizzazzjoni, il-kunfidenzjalità m'għandha fl-ebda każ tapplika għal:

(a) l-isem u l-indirizz ta' l-applikant;

(b) l-isem u l-indirizz tal-fabbrikant tal-prodott bijoċidali;

(ċ) l-isem u l-indirizz tal-fabbrikant tas-sustanza attiva;

(d) l-ismijiet u l-kontenut tas-sustanza jew is-sustanzi attiva/i fil-prodott bijoċidali u l-isem tal-prodott bijoċidali;

A.L. 306 ta' l-2008.

(e) l-ismijiet ta' sustanzi oħra li jiġu meqjusa bħala perikolużi fit-tifsira tar-Regolament ta' l-2008 dwar Sustanzi Perikolużi u li jikkontribwixxu għall-klassifika tal-prodott;

(f) l-informazzjoni fiżika u kimika li tirrigwarda s-sustanza attiva u l-prodott bijoċidali;

(g) kull manjiera li tirrendi s-sustanza attiva jew il-prodott bijoċidali bħala mingħajr ħsara;

(h) sommarju tar-riżultati tat-testijiet meħtieġa skond r-regolament 9 sabiex tigi stabbilita l-effikaċja tas-sustanza jew tal-prodott u l-effetti fuq il-bniedem, l-annimali u l-ambjent u, meta tapplika, l-abbiltà tagħhom li jippromwovi reżistenza;

(i) il-metodi u l-prekawzzjonijiet rakkommandati sabiex inaqqsu l-periklu mit-tqandil, il-ħażna, it-trasport u l-użu kif ukoll minn nar jew riskji oħra;

(j) il-folji ta' l-informazzjoni dwar is-sigurtà;

(k) il-metodi ta' l-analiżi riferiti fir-regolament 6(1)(ċ);

(l) il-metodi tad-disponiment mill-prodott u tal-pakkjar tiegħu;

(m) il-proċeduri li jridu jiġu segwiti u l-miżuri li jridu jittieħdu fil-każ ta' tixrid jew tnixxija;

(n) l-ewwel għajnuna u l-pariri mediċi li għandhom jingħataw fil-każ tal-korriment ta' persuni.

Iżda jekk l-applikant jew il-fabbrikant jew l-importatur ta' prodott bijoċidali jew ta' sustanza attiva għandhom iktar tard jiżvelaw it-tagħrif preċedentement kunfidenzjali, id-Direttur għandu jiġi mgħarraf kif jixraq.

(4) Id-dispożizzjonijiet iddettaljati u l-format sabiex ikun disponibbli għall-pubbliku t-tagħrif u sabiex jiġi implimentat regolament 20 għandhom jiġu deċiżi skond il-proċeduri stabbiliti fl-Artikolu 28(2) tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali.

21. (1) Il-prodotti bijoċidali għandhom jiġu kklassifikati skond id-dispożizzjonijiet li għandhom x'jaqsmu mal-klassifika fir-Regolamenti ta' l-2007 dwar is-Sustanzi u Preparazzjonijiet Perikolużi.

Il-Klassifika, il-pakkjar u t-tikkettjar tal-prodotti bijoċidali. A.L. 10 ta' l-2007.

(2) Il-prodotti bijoċidali għandhom jiġu ppakkjati skond r-regolament 12 tar-Regolamenti ta' l-2007 dwar is-Sustanzi u Preparazzjonijiet Perikolużi. B'żieda ma' dan:

A.L. 10 ta' l-2007.

(a) il-prodotti li jistgħu jittieħdu bi zball bħala ikel,

xorb jew oġġetti ta' l-ikel għandhom jiġu ppakkjati hekk illi titnaqqas l-okkorrenza possibbli li jsir dan l-iżball;

(b) il-prodotti disponibbli għall-pubbliku ġenerali li jistgħu jiġu mittieħda bi żball bħala ikel, xorb jew oġġetti ta' l-ikel għandu jkun fihom komponenti li jiskoraġġixxu l-konsum tagħhom.

A.L. 10 ta' l-2007.

(3) Il-prodotti bijoċidali għandhom ikunu ttikkettjati skond id-dispożizzjonijiet li għandhom x'jaqsmu mat-tikkettjar fir-Regolamenti ta' l-2007 dwar is-Sustanzi u Preparazzjonijiet Perikolużi. It-tikketti m'għandhomx iqarrqu jew jagħtu impressjoni esagerata tal-prodott, u, f'kull każ, m'għandhomx isemmu l-indikazzjonijiet ta' "prodott bijoċidali ta' riskju baxx", "mhux tossiku", "ma jagħmilx ħsara" jew indikazzjonijiet bħal dawn. B'zieda ma' dan, it-tikketta trid turi b'mod ċar u li ma jithassarx dan li ġej:

(a) l-identità ta' kull sustanza attiva u l-konċentrazzjoni tagħha f'unitajiet metriċi;

(b) in-numru ta' l-awtorizzazzjoni allokat lill-prodott bijoċidali mill-awtorità kompetenti;

(ċ) it-tip ta' thejjija, inklużi konċentrati likwidi, gerbub, trab, solidi;

(d) l-użu li għalihom il-prodott bijoċidali huwa awtorizzat inklużi il-priservazzjoni ta' l-injam, id-dizinfettazzjoni, bijoċida tal-wieċ, kontra t-tkabbir tal-ħaxix tal-baħar mal-karini;

(e) l-istruzzjonijiet għall-użu u r-rata tad-doża, espressa f'unitajiet metriċi, għal kull użu pprovdut fit-termini ta' l-awtorizzazzjoni;

(f) il-partikolaritajiet ta' l-effetti possibbilment żvantagġużi b'modi diretti jew indiretti u kull istruzzjoni dwar l-ewwel għajnuna;

(g) jekk akkumpanjata b'fuljett, is-sentenza "Aqra l-istruzzjonijiet meħmuża qabel l-użu";

(h) l-istruzzjonijiet dwar id-disponiment fis-sigurtà mill-prodott bijoċidali u l-pakkjar tiegħu, inkluża, meta

rilevanti, kull projbizzjoni ta' l-użu mill-gdid tal-pakkjar;

(i) in-numru tal-lott tal-formolazzjoni jew tad-denominazzjoni u d-data ta' l-iskadenza rilevanti għall-kondizzjonijiet normali tal-ħażna;

(j) il-perjodu taż-żmien meħtieġ għall-effett bijoċidali, l-intervall taż-żmien li jrid jiġi osservat bejn l-applikazzjonijiet ta' prodott bijoċidali jew bejn applikazzjoni u l-użu li jkun imiss tal-prodott ittrattat, jew l-aċċess li jkun imiss mill-bniedem jew l-annimali għaž-żona fejn ikun gie wżat il-prodott bijoċidali, inklużi l-partikolaritajiet li jirrigwardaw il-mezzi u l-miżuri tad-dekontaminazzjoni u t-tul taż-żmien tal-ventilazzjoni meħtieġa fiż-żoni trattati; il-partikolaritajiet għat-tindif adegwat tat-tagħmir; il-partikolaritajiet dwar il-miżuri prekawzjonarji matul l-użu, il-ħażna u t-trasport (p.e. l-ilbies u t-tagħmir protettivi, il-miżuri għall-protezzjoni kontra n-nar, il-kisi tal-għamara, it-tneħħija ta' l-ikel jew tal-għalf u l-istruzzjonijiet sabiex jipprevjenu li l-annimali jiġu esposti);

u meta japplikaw:

(k) il-kategoriji ta' l-utenti li għalihom ikun ristrett il-prodott bijoċidali;

(l) it-tagħrif dwar kull perikolu speċifiku għall-ambjent b'mod partikolari dwar il-protezzjoni ta' organiżmi mhux fil-mira u li tiġi evitata l-kontaminazzjoni ta' l-ilma;

(m) għall-prodotti bijoċidali mikro-bijoloġiċi, il-ħtiġiet tat-tikkettjar skond r-Regolamenti ta' l-2008 dwar il-Protezzjoni tal-Ħaddiema minn Riskji relatati ma' l-Espożizzjoni għal Aġenti Bijoloġiċi fuq il-Post tax-Xogħol:

Iżda –

(a) l-intestaturi tas-sub-regolament 3(a), (b), (d) u meta japplikaw il-(g) u l-(k) għandhom dejjem jingarru fuq it-tikketta tal-prodott;

(b) d-Direttur għandu jippermetti l-intestaturi tas-sub-regolament 3(ċ), (e), (f), (h), (i), (j) u (l) li jingarru xi mkien ieħor fuq il-pakkjar jew fuq fuljett akkumpanjanti integrali għall-pakkjar. Dawn l-intestaturi

ta' tagħrif għandhom jitqiesu bħala t-tagħrif tat-tikketta għall-finijiet ta' dawn ir-regolamenti.

A.L. 228 ta' l-2003.

A.L. 10 ta' l-2007.

(4) Meta prodott bijoċidali identifikat bħala insettiċida, akariċida, rodentiċida, aviċida jew molluskiċida jiġi awtorizzat skond daw ir-regolamenti u huwa wkoll bla ħsara għall-klassifik, il-pakkjar u t-tikkettjar skond r-Regolamenti ta' l-2007 dwar is-Sustanzi u Preparazzjonijiet Perikolużi, bis-saħħa ta' dispożizzjonijiet oħra Komunitarji, id-Direttur għandu jippermetti bidliet fil-pakkjar u t-tikkettjar ta' dan il-prodott li jistgħu jkunu meħtieġa bħala konsegwenza ta' dawn id-dispożizzjonijiet safejn u sakemm dawn ma jmorrux kontra l-kondizzjonijiet ta' awtorizzazzjoni maħruġa skond dawn ir-regolamenti.

(5) Id-Direttur jista' jeħtieġ l-forniment ta' kampjuni, mudelli jew abbozzi tal-pakkjar, tat-tikkettjar u tal-fuljetti.

(6) It-tikkettjar tat-tqegħid fis-suq tal-prodotti bijoċidali għandu jkun bl-Ingliż u bil-Malti. Fuq raġunijiet validi u dipendenti fuq x'tip ta' prodott hu, id-Direttur jista' jagħti permess bil-miktub li t-tikketta tkun biss b-lingwa waħda, jew bl-Ingliż jew bil-Malti.

(7) It-tikketta għandha tkun resistenti għall-espożizzjonijiet għal kundizzjonijiet normali tal-ħażniet, immaniġġjar u użu u jkun żgurat li l-kontenituri jibqgħu ċari u legibbli matul il-mistenni ħajja fuq l-ixkaffa tal-prodott.

Il-folja ta' l-informazzjoni dwar is-sigurtà.

22. (1) Id-Direttur għandu jieħu l-mizuri meħtieġa sabiex jiżgura illi tiġi stabbilita sistema ta' tagħrif speċifiku sabiex tippermetti lill-utenti professjonali u industrijali u, kif approprjat, lil utenti oħra tal-prodotti bijoċidali li jieħdu l-mizuri meħtieġa għall-protezzjoni ta' l-ambjent u s-saħħa kif ukoll is-saħħa u s-sigurtà fuq il-post tax-xogħol. Dan għandu jsir fil-għamla ta' folja ta' l-informazzjoni dwar is-sigurtà provduta minn dawk responsabbli għat-tqegħid tal-prodott fis-suq.

Iżda l-folji ta' l-informazzjoni dwar is-sigurtà għandhom ikunu mhejjija:

A.L. 10 ta' l-2007.

(a) għall-prodotti bijoċidali kklassifikati bħala perikolużi u skond r-regolament 17 tar- Regolamenti ta' l-2007 dwar is-Sustanzi u Preparazzjonijiet Perikolużi, u

(b) għas-sustanzi attivi wżati esklussivament fi prodotti

bijoċidali skond il-ħtiġiet fl-Artikolu 31 ta' Regolament (KE) 1907/2006.

23. (1) Kull pubbliċità għall-prodott bijoċidali tkun Ir-Reklamar. akkumpanjata bis-sentenzi “Uża l-bijoċidi mingħajr periklu. Dejjem aqra t-tikketta u t-tagħrif dwar il-prodott qabel l-użu”.

(2) Is-sentenzi għandhom ikunu jintgħarfu minn oħrajn b'mod ċar f'relazzjoni mar-reklam kollu. Dawk li jirreklamaw jistgħu jibdlu l-kelma “Bijoċidi” fis-sentenzi stabbiliti b'deskrizzjoni preċiża tat-tip ta' prodott li jkun qiegħed jiġi rreklamat, bħal per eżempju priservattivi ta' l-injam, diżinfettanti, bijoċidi għall-wieċ u kontra t-tkabbir tal-ħaxix tal-baħar mal-karini.

(3) Ir-reklami tal-prodotti bijoċidali ma jistgħux jirreferu għall-prodott f'manjera li tqarraq rigward ir-riskji mill-prodott għall-bniedem jew l-ambjent. Taħt l-ebda ċirkostanzi ma jista' r-reklamar ta' prodott bijoċidali jsemmi “prodott bijoċidali b'riskju baxx”, “mhux tossiku”, “mhux ta' ħsara” jew indikazzjonijiet bħal dawn.

24. (1) (a) L-Awtorità ta' Malta dwar l-iStandards hija responsabbli sabiex tirċievi t-tagħrif dwar il-prodotti bijoċidali li jkunu ġew imqiegħda fis-suq, inkluż it-tagħrif dwar il-kompożizzjoni kimika ta' dawn il-prodotti, u sabiex jagħmlu dan it-tagħrif disponibbli f'każijiet meta jinħoloq is-suspett ta' avvelenament li jirriżulta mill-prodotti bijoċidali. Dan it-tagħrif jista' jintuża biss biex jissodisfa kull domanda medika billi jiġu f-formolati miżuri preventivi u kurattivi, b'mod partikolari f'emergenzi. Id-Direttur għandu jiżgura illi dan it-tagħrif ma tintużax għal skopijiet oħra. Il-Kontroll tal-velenu.

(b) Id-Direttur għandu jieħu l-passi meħtieġa sabiex jiżgura illi l-korpi maħtura jipprovdu l-garanziji meħtieġa kollha sabiex tinzamm il-kunfidenzjalità tat-tagħrif irċevut. Id-Direttur għandu jiżgura illi l-korpi maħtura jkollhom għad-dispożizzjoni tagħhom it-tagħrif kollu meħtieġ għalbiex iwettqu l-kompiti li għalihom huma responsabbli minn għand il-fabbrikant jew minn għand il-persuna responsabbli mill-marketing.

(ċ) Rigward il-prodotti bijoċidali diġà fis-suq fit-8 ta' Marzu 2000, id-Direttur għandu jieħu miżuri sabiex iħarsu r-regolament 24 fi żmien tliet snin mit-8 ta' Marzu 2000.

Il-Konformità mal-
htigiet.

25. (1) Id-Direttur għandu jagħmel l-arrangamenti meħtieġa sabiex il-prodotti bijoċidali li jkunu ġew imqiegħda fis-suq jiġu monitorjati sabiex jiġi stabbilit jekk dawn jikkonformawx mal-htigiet ta' dawn ir-regolamenti.

(b) Kull tliet snin wara t-8 ta' Marzu 2000, id-Direttur għandu jibgħat lill-Kummissjoni sat-30 ta' Novembru tat-tielet sena rapport dwar l-azzjoni tagħhom f'dawn il-materji flimkien ma' tagħrif dwar kull avvelenament li jinvolvi l-prodotti bijoċidali. Il-Kummissjoni għandha, fi żmien sena minn meta tircievi dan it-tagħrif, thejji u tippubblika rapport kompost.

L-Imposti.

26. (1) Id-Direttur għandu jistabbilixxi sistemi li jobbligaw lil daww li jkunu qiegħdu, jew ifittxu li jqiegħdu, prodotti bijoċidali fis-suq u daww li jappoġġjaw it-tidħil ta' sustanzi attivi fis-Skeda I, sabiex iħallsu imposti, li jikkorrispondu safejn u sakemm jista' jkun ma' l-ispejjeż tagħhom fit-twettiq tal-proċeduri differenti kollha assoċjati mal-proċeduri ta' dawn ir-regolamenti.

L-Awtoritajiet
Kompetenti.

27. (1) L-Awtorita' ta' Malta dwar l-iStandards hija l-awtorita' kompetenti responsabbli mid-dmirijiet imposti skond dawn ir-regolamenti.

Adattament għall-
progress tekniku.

28. (1) Għandhom jiġu adottati il-miżuri meħtieġa sabiex lis-Skedi II – Taqsima A, II – Taqsima B, III – Taqsima A, III – Taqsima B, IV – Taqsima A jew IV – Taqsima B jew id-deskrizzjonijiet tat-tipi ta' prodotti fis-Skeda V jiġu adattati għall-progress tekniku jew sabiex jiġu speċifikati rekwiżiti ta' data għal kull wieħed minn dawn it-tipi ta' prodotti. Dawn il-miżuri, imfassla sabiex jemendaw elementi mhux essenzjali ta' dawn ir-regolamenti inter alia billi jissupplimentawha, għandhom jiġi adottati skond il-proċedura regolatorja bi skrutinju msemmija fl-Artikolu 28(4) tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali.

Ir-Responsabbiltà
Ċivili u Kriminali.

29. (1) Il-konċessjoni ta' awtorizzazzjoni u l-miżuri l-oħra kollha f'konformità ma' dawn ir-regolamenti għandhom ikunu mingħajr preġudizzju għar-responsabbiltà ċivili u kriminali generali fl-Istati Membri tal-fabbrikant u, meta japplika, tal-persuna responsabbli mit-tqegħid tal-prodott bijoċidali fis-suq jew jużawh. Is-sanzjonijiet li japplikaw għall-ksur tad-dispożizzjonijiet ta' dawn ir-regolamenti għandhom ikunu daww provduti f'Parti 9 ta' l-Att tal-Kontroll tal-Pesticidi.

Kap. 430.

30. (1) Meta d-Direttur jkollu raġunijiet validi sabiex jikkunsidra illi prodott bijoċidali li huwa jkun awtorizza, irregistra jew li hu obbligat illi jawtorizza jew jirregistra skond r-regolamenti 4 jew 5, jikkostitwixxi riskju mhux aċċettabbli għas-saħħa tal-bniedem jew ta' l-annimali jew ta' l-ambjent, huwa jista' jirrestringi proviżorjament jew jipprojbixxi l-użu jew il-bejgħ ta' dan il-prodott fit-territorju tiegħu. Id-Direttur għandu jgħarraf lill- Kummissjoni u lill-Istati Membri l-oħra minnufih b'din l-azzjoni u għandu jagħti r-raġunijiet għad-deċiżjoni tiegħu. Deċiżjoni għandha tittiehed fuq il-materja fi żmien 90 jum skond il-proċedura stabbilita fl-Artikolu 28(3) tad-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill tas-16 ta' Frar 1998 dwar it-tqegħid fis-suq tal-prodotti bijoċidali.

Il-Klawsola tas-Salvagwardja.

31. (1) Ebda persuna ma tista' tinnegożja jew tiddisponi minn xi:

Negożju fi Prodotti Bijoċidali.

(a) sustanza attiva jekk din ma tkunx reġistrata skond dawn ir-regolamenti;

(b) prodott bijoċidali jekk din ma tkunx awtorizzata biex titqiegħed fis-suq f'Malta skond ir-regolament 32 ta' dawn ir-regolamenti.

(2) Ebda persuna ma tista' tinnegożja xi sustanza attiva jew prodott bijoċidali jekk m'għandhiex awtorizzazzjoni biex tinnegożja f'sustanzi attivi jew prodotti bijoċidali mogħtija lilha skond ir-regolament 32 ta' dawn ir-regolamenti.

32. (1) Kull applikazzjoni għall-għoti ta' awtorizzazzjoni biex wiehed jinnegożja prodotti bijoċidali jew sustanzi attivi għandha ssir bil-miktub lid-Direttur u għandu jkollha dik l-informazzjoni, dokumenti, kampjuni u materjal ieħor kif provdut mill-Att jew tahtu.

Applikazzjoni għal awtorizzazzjoni għan-negożju.

(2) Kull applikazzjoni għandha, bħala minimu, tissodisfa r-rekwiżiti li ġejjin:

(a) in-natura ta' kull attività relatata man-negożjar ta' prodotti bijoċidali li l-applikant jixtieq jidhol għaliha;

(b) il-post fejn din l-attività se ssir, u informazzjoni adattata, dokumentazzjoni u evidenza skond kif ikun meħtieġ biex jintwera li dak il-post hu adattat u suffiċjenti għal dak l-iskop;

(c) evidenza li turi li l-post fejn din l-attività se ssir għandha t-tagħmir meħtieġ u faċilitajiet ta' kontroll kif jista' jkun meħtieġ mill-Att jew taħtu;

(d) evidenza li turi li s-saħħa u s-sigurtà ta' l-impjegati għandha tiġi u tkun żgurata l-hin kollu;

(e) l-isem u l-indirizz postali u dettalji oħra kif l-applikant jista' jkun kuntattjat;

(f) fil-każ ta' applikazzjoni għall-manifattura ta' prodott bijoċidali, l-isem tal-prodott bijoċidali u kull formulazzjoni li se tkun, jew hemm il-ħsieb li tkun, manifatturata, immuntata jew b'xi mod modifikata inklużi dettalji tat-tip u konċentrament ta' xi sustanza attiva li tinsab f'dik il-formulazzjoni.

(3) Id-Direttur għandu jiddetermina l-applikazzjoni f'perijodu ta' żmien raġjonevoli li ma jaqbiżx l-45 ġurnata xogħol mid-data meta tasal applikazzjoni:

B'dan iżda li dan iż-żmien jista' jkun sospiż sakemm tasal l-informazzjoni rilevanti.

(4) Meta applikazzjoni tkun saret lid-Direttur għall-għoti ta' awtorizzazzjoni biex wieħed jinnegozja skond dan ir-regolament, id-Direttur jista', qabel jiddetermina l-applikazzjoni, jitlob lill-applikant jissottometti informazzjoni ulterjuri dwar l-applikazzjoni skond kif jidhirlu meħtieġ u meta tkun saret xi talba ta' din ix-xorta d-dispożizzjoni tar-regolament 32(5) għandha tkun sospiża sakemm l-informazzjoni addizzjonali tkun giet sottomessa.

(5) Kull awtorizzazzjoni maħruġa skond dan ir-regolament għandha ssir bil-miktub u tkun soġġetta għal kull kondizzjoni li d-Direttur jista' jqis neċessarja biex in-negozju jsir skond id-dispożizzjonijiet magħmulin mill-Att jew taħtu.

Tul ta' validità ta' awtorizzazzjoni.

33. (1) Kull awtorizzazzjoni maħruġa mid-Direttur skond ir-regolament 32 ta' dawn ir-Regolamenti għandha tkun valida għal perijodu ta' mhux aktar minn tliet snin hekk kif speċifikat fl-awtorizzazzjoni:

Izda li d-Direttur jista' jestendi l-validità ta' xi awtorizzazzjoni ta' din ix-xorta wara s-sottomissjonni ta' applikazzjoni għat-tigdid ta' l-awtorizzazzjoni sottomessa lillu

skond ir-regolament 36 ta' dawn ir-regolamenti u d-Direttur hu sodisfatt li l-kondizzjonijiet stabbiliti mir-regolament 32 ta' dawn ir-regolamenti għadhom jitharsu.

34. (1) Mingħajr preġudizzju għar-regolament 35 ta' dawn ir-regolamenti, u jekk id-Direttur jissuspetta li xi kondizzjoni minn dawk stabbiliti mir-regolament 31 ta' dawn ir-regolamenti m'għadhiex imħarsa, id-Direttur:

Verifika ta' awtorizzazzjoni.

(a) għandu jitlob lill-applikant għall-awtorizzazzjoni jew lid-detentur ta' l-awtorizzazzjoni biex jissottomettu informazzjoni ulterjuri neċessarja biex tistabbilixxi konformità mad-disposizzjonijiet tar-regolament 32 ta' dawn ir-regolamenti u kull tali informazzjoni li tista' tenħtieg raġonevolment;

(b) jista' jagħmel kull spezzjoni, verifika jew test neċessarji li jidhrulu meħtieġa;

(ċ) jista' jissospendi l-awtorizzazzjoni skond ir-regolament 35 ta' dawn ir-regolamenti.

35. (1) Kull awtorizzazzjoni maħruġa skond ir-regolament 31 ta' dawn ir-regolamenti tista' tkun sospiża jew revokata mid-Direttur jekk ikun stabbilit li:

Sospensjoni jew revoka ta' awtorizzazzjoni.

(a) xi informazzjoni jew dettall li jsostnu l-applikazzjoni għal awtorizzazzjoni kienu inkorretti, foloz jew qarrieqa; jew

(b) xi rekiwizit kif dettaljat fir-regolament 31 ta' dawn ir-regolamenti mhux imħares aktar; jew

(ċ) l-applikant għal awtorizzazzjoni jitlob li d-Direttur jirrevoka l-awtorizzazzjoni biex jinnegozja prodotti bijoġidali jew sustanzi attivi; jew

(d) jekk l-attività tkun qed issir bi ksur ta' xi dispożizzjoni magħmula mill-Att jew taħtu.

(2) Meta d-Direttur jissospendi jew jirrevoka awtorizzazzjoni, hu għandu jinnotifika bil-miktub lid-detentur ta' l-awtorizzazzjoni b'din is-sospensjoni jew revoka u jagħti r-raġunijiet li fuqhom kienet ibbażata dik id-deċiżjoni.

Tiġdid
ta' awtorizzazzjoni.

36. Meta awtorizzazzjoni tiskadi, id-Direttur għandu jgedded l-awtorizzazzjoni jekk:

(a) hu jkun irċieva applikazzjoni għal tiġdid f'dik il-forma u f'dik il-manjiera u f'tali żmien li hu jista', minn żmien għal żmien;

(b) hu sodisfatt li l-kondizzjonijiet iddettaljati fir-regolament 32 ta' dawn ir-regolamenti għadhom qed jiġiharsu:

Izda li d-Direttur jista' jitlob lill-applikant għal xi informazzjoni addizzjonali li jista' jqis meħtieġa qabel it-tiġdid jew le ta' l-awtorizzazzjoni:

Izda wkoll li d-Direttur jista' jassoġġetta l-awtorizzazzjoni għal dik il-kondizzjoni jew għal dawk il-kondizzjonijiet li hu jista' jqis adatti u meħtieġa.

Modifika ta'
awtorizzazzjoni.

37. (1) Mingħajr preġudizzju għad-dispożizzjonijiet tar-regolament 34 ta' dawn ir-regolamenti, id-Direttur jista', wara talba bil-miktub tad-detentur ta' l-awtorizzazzjoni, jimmodifika awtorizzazzjoni biex wiehded jagħmel attività ta' negozju jekk id-Direttur hu sodisfatt li din il-modifika hi ġustifikata u adattata, u, meta rilevanti, tirrifletti l-opinjoni xjentifika kurrenti.

(2) Mingħajr preġudizzju għar-regolament 35 ta' dawn ir-regolamenti, id-Direttur jista' jimmodifika l-awtorizzazzjoni oriġinali jekk hu jqis li xi kondizzjoni li fuqha kienet ibbażata dik l-awtorizzazzjoni skond ir-regolament 31 ta' dawn ir-regolamenti kienet mibdula sostanzjalment.

(3) Kull talba għal modifika ta' awtorizzazzjoni skond r-regolament 37(1) għandha ssir mid-detentur ta' l-awtorizzazzjoni f'dik il-forma u f'dik il-manjiera u f'tali żmien li hu jista', minn żmien għal żmien, jitlob.

Obbligi tad-detentur
ta' awtorizzazzjoni.

38. (1) Mingħajr preġudizzju għal kull dispożizzjoni oħra magħmula minn jew taħt l-Att, għandu jkun id-dmir ta' kull persuna li jkollha awtorizzazzjoni mogħtija lilha skond ir-regolament 32 ta' dawn ir-regolamenti li:

(a) żżomm dik id-dokumentazzjoni u b'dak il-mod kif id-Direttur minn żmien għal żmien jista' jistabbilixxi:

Izda d-Direttur jista' jistabbilixxi dokumentazzjoni

differenti għal tipi differenti ta' attivitajiet ta' negozju;

(b) jinforma bil-miktub lid-Direttur, kemm jista' jkun malajr u prattikabbli, b'kull bidla fl-informazzjoni mghoddija lid-Direttur għall-ghoti ta' l-awtorizzazzjoni;

(ċ) jippermetti lid-Direttur jew lir-rappreżentant awtorizzat tiegħu aċċess għall-art jew bini f'kull hin raġonevoli;

(d) jagħti aċċess lid-Direttur jew lir-rappreżentant awtorizzat tiegħu daww ir-records li hu jista' jeħtieġ; u

(e) jikkonforma ruħu ma' kull dispożizzjoni magħmula mill-Att jew tahtu.

(2) Safejn dan jista' jkun applikabbli, persuna li jkollha awtorizzazzjoni taht ir-regolament 31 ta' dawn ir-regolamenti għandha teżerċita superviżjoni ġenerali fuq l-impjegati tagħha u għandha, qabel titlob jew tippermetti li kwalunkwe impjegat minnhom li jmiss jew japplika xi prodott bijoċidali:

(a) tagħti lil dawn l-impjegati taħriġ adatt fl-immaniġġjar u l-applikazzjoni ta' bijoċidi;

(b) tiżgura li kull prekawzjoni ta' sigurtà mnizzla fuq it-tikketta, jew preskritta b'xi mod ieħor, tinftiehem u titħares; u

(ċ) tiżgura li dawn il-ħaddiema jilbsu lbies protettiv adatt ipprovdut minnu.

(3) Meta persuna li jkollha awtorizzazzjoni ta' prodotti bijoċidali għandha mqar l-iċken suspett li xi prodott bijoċidali kkaguna xi avvelenament, hi għandha tinnotifika immedjatament lill-awtorità tas-saħħa.

39. (1) Kull persuna awtorizzata biex tinnegozja fi prodotti bijoċidali għandha tinnotifika lid-Direttur b'kull konsenja ta' xi prodott bijoċidali jew ta' xi sustanza attiva li hi d-daħħal f'Malta.

Notifika ta' dhul f'Malta.

(2) L-informazzjoni mogħtija fir-rigward ta' prodott bijoċidali jew sustanza attiva għandha tinkludi dan li ġej bħala minimu:

- (a) l-isem tal-prodott u n-numru tal-grupp;
- (b) in-numru ta' l-awtorizzazzjoni;
- (ċ) il-pajjiż ta' l-origini;
- (d) il-kwantità tal-konsenja; u
- (e) id-data u l-post tad-dhul f'Malta.

(3) Il-Liċenzja ta' Importazzjoni għandha tasal għand id-Direttur minn ta' l-anqas gimgħa qabel l-importazzjoni tal-prodotti tal-bijoċidi flimkien ma' dokumenti oħra li d-Direttur jara neċessarji.

Jirrevoka A.L. 294 ta' l-2004.

40. (1) Ir-Regolamenti ta' l-2004 dwar il-Bijoċidi qegħdin b'dawn jiġu revokati.

SCHEDULE I

PART A

List of Active Substances with Requirements Agreed At Community Level for Inclusion in Biocidal Products

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
1	sulfuryl fluoride	sulfuryl difluoride EC No: 220-281-5 CAS No: 2699-79-8	> 994 g/kg	1 January 2009	31 December 2010	31 December 2018	8	Member States shall ensure that authorizations are subject to the following conditions: (1) the product may only be sold to and used by professionals trained to use it; (2) appropriate risk mitigation measures are included for operators and bystanders; (3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored. Member States shall also ensure that reports of the monitoring referred to in point (3) are

		EC No: 214-118-7 CAS No: 1085-98-9							industrial and/or professional use must be used with appropriate personal protective equipment. (2) In view of the risks identified for the soil compartment appropriate risk mitigation measures must be taken to protect that compartment. (3) Labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for re-use or disposal.
3	clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-Nitroguanidine EC No: 433-460-1 CAS No: 210880-92-5	950 g/kg	1 February 2010	31 January 2012	31 January 2020	8		When assessing, in accordance with Article 5 and Annex VI, the application for authorization of a product, Member States shall assess those use/exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to

								acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: In view of the risk identified for the soil, surface water and groundwater compartments, products cannot be authorised for the treatment of wood that will be used outdoors unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for reuse or disposal.
4	Difethialone	3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one EC No: n/a CAS No: 104653-34-1	976 g/kg	1 November 2009	31 October 2011	31 October 2014	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed.

5	etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether EC No: 407-980-2 CAS No: 80844-07-1	970 g/kg	1 February 2010	31 January 2012	31 January 2020	8	Member States shall ensure that authorizations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 0,0025 % w/w and only ready-for-use baits shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes. When assessing, in accordance with Article 5 and Annex VI, the application for authorisation of a product, Member States shall assess those use and/or exposure scenarios and/or populations that have not been representatively addressed in the Community level risk
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									assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: In view of the risk identified for workers, products cannot be used year round unless dermal absorption data is provided to demonstrate that there are no unacceptable risks from chronic exposure. In addition, products intended for industrial use must be used with appropriate personal protective equipment
6	tebuconazole	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC No: 403-640-2 CAS No: 107534-96-3	950 g/kg	1 April 2010	31 March 2012	31 March 2020	8		Member States shall ensure that authorizations are subject to the following conditions: In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products

7	carbon dioxide	carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	authorised for industrial use indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. In addition, products cannot be authorised for the <i>in situ</i> treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in
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9	Difenacoum	3-(3-biphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	In addition, products cannot be authorised for the <i>in situ</i> treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder.
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10	K-HDO	Cyclohexylhydroxydiazene 1-oxide, potassium salt EC No: n/a CAS No: 66603-10-9 (This entry also covers the hydrated forms of K-HDO)	977 g/kg	1 July 2010	30 June 2012	30 June 2020	8	(4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. Member States shall ensure that authorizations are subject to the following conditions: (1) in view of the possible risks for the environment and workers, products shall not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in
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								accordance with Article 5 and Annex VI; (2) in view of the assumptions made during the risk assessment, products must be used with appropriate personal protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means; (3) in view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.
11	IPBC	3-iodo-2-propynyl butylcarbamate EC No: 259-627-5 CAS No: 55406-53-6	980 g/kg	1 July 2010	2010 30 June 2012	30 June 2020	8	Member States shall ensure that authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to

							protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hardstanding to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
12	Chlorophacinone	Chlorophacinone EC No: 223-003-0	978 g/kg	1 July 2011	30 June 2013	30 June 2016	14 In view of the identified risks for non-target animals, the active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products other than tracking powder shall not exceed 50 mg/kg and only ready-for use products shall be authorised. 2. Products to be used as tracking powder shall only be placed on the market for use by trained professionals. 3. Products shall contain an aversive agent and, where appropriate, a dye. 4. Primary as well as secondary exposure of humans, non-target

13	Thiabendazole	2-thiazol-4-yl-1H-benzimidazole EC No: 205-725-8 CAS No: 148-79-8	985 g/kg	1 July 2010	30 June 2012	30 June 2020	8	animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes. Member States shall ensure that authorizations are subject to the following conditions: in view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, with respect to the double-vacuum and dipping application tasks, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application that for product authorization that risks to industrial and/or professional users can be reduced to an acceptable level by others means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorized for industrial use shall indicate that freshly treated timber must be
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14	thiamethoxam	thiamethoxam EC No: 428-650-4 CAS No: 153719-23-4	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorizations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels
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15	alphachloralose	(R)-1,2-O-(2,2,2-Trichloroethy/lidene)- α -D-glucofuranose	825 g/kg	1 July 2011	30 June 2013	30 June 2021	14	and/or safety data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Products shall not be authorised for the <i>in situ</i> treatment of wood outdoors or for wood that will be exposed to weathering, unless data have been submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate
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16	brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin EC No: 259-980-5	950 g/kg	1 February 2012	31 January 2014	31 January 2017	14	measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. In particular, products cannot be authorised for outdoor use unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 40 g/kg. 2. Products shall contain an aversive agent and a dye. 3. Only products for use in tamper resistant and securely closed bait boxes shall be authorised. In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a
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17	bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	969 g/kg	1 July 2011	30 June 2013	30 June 2016	14	comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes. In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to
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18	Thiacloprid	(Z)-3-(6-chloro-3-pyridylmethyl)-	975 g/kg	1 January 2010	n/a	31 December 2019	8	bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes. When assessing the application for authorization of a product in
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					1,3-thiazolidin-2-ylidenecyanamide EC No: n/a CAS No: 111988-49-9	accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorization that risks to industrial and/or professional users can be reduced to an acceptable level by other means.
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19	Indoxacarb (enantiomeric reaction mass S:R 75:25)	Reaction mass of methyl (S)- and methyl(R)-7- chloro-2,3,4a,5-tetrahydro- 2-[methoxycarbonyl-(4- trifluoromethoxyphenyl)] carbamoyl]indeno[1,2-e] [1,3,4]oxadiazine- 4acarboxylate (This entry	796 g/kg	1 January 2010	n/a	31 December 2019	18	2. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. 3. Products shall not be authorised for the <i>in situ</i> treatment of wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be in contact with surface water, unless data have been submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or
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						exposure scenarios that have not been representatively addressed at the Community level risk assessment When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans, of non-target species and of the aquatic environment. In particular, labels and/or safety-data sheets of products authorized shall indicate that: 1. Products shall not be placed in areas accessible to infants, children and companion animals. 2. Products shall be positioned away from external drains. 3. Unused products shall be disposed of properly and not washed down the drain.
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20	aluminium phosphide releasing phosphine	aluminium phosphide EC No: 244-088-0 CAS No: 20859-73-8	830 g/kg	1 September 2011	31 August 2013	31 August 2021	14	For amateur uses, only ready-to-use products shall be authorised. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. In particular, products cannot be authorised for indoor use unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorizations are subject to the
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							following conditions: 1. Products shall only be sold to and used by specifically trained professionals. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. These include, amongst others, the use of appropriate personal protective equipment, the use of applicators and the presentation of the product in a form designed to reduce operator exposure to an acceptable level. 3. In view of the risks identified for terrestrial non-target species, appropriate risk reduction measures must be applied. These include, amongst others, the non-treatment of areas where other burrowing mammals than the target species are present.
						830 g/kg	1 February 2012 31 January 2014 31 January 2022 18 When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product

authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.							
Member States shall ensure that authorizations are subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas. 3. For products containing aluminium phosphide that may lead to residues in food or feed,							

21	fenpropimorph	(+/-)-cis-4-[3-(p-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine EC No: 266-719-9 CAS No: 67564-91-4	930 g/kg	1 July 2011	30 June 2013	30 June 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the	labels and/or safety data sheets for authorized products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).
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22	boric acid	boric acid EC No: 233-139-2 CAS No: 10043-35-3	990 g/kg	1 September 2011	31 August 2013	31 August 2021	8	following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, he populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.
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When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.							
Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.							
Member States shall ensure that authorizations are subject to the following conditions:							
1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.							
2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation							

23	boric oxide	Diboron trioxide EC No: 215-125-8 CAS No: 1303-86-2	975 g/kg	1 September 2011	31 August 2013	31 August 2021	8	measures. In particular, labels and/or safety-data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions:
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24	disodium tetraborate	disodium tetraborate EC No: 215-540-4 CAS No (anhydrous): 1330-43-4 CAS No (pentahydrate):	990 g/kg	1 September 2011	31 August 2013	31 August 2021	8	1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the
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								product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.
								When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.
								Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.
								Member States shall ensure that authorisations are subject to the following conditions:
								1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.
								2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that

25	disodium octaborate tetrahydrate	disodium octaborate tetrahydrate EC No: 234-541-0 CAS No: 12280-03-4	975 g/kg	1 September 2011	31 August 2013	31 August 2021	8	the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.
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26	Magnesium phosphide releasing	Trimagnesium diphosphide EC No: 235-023-7	880 g/kg	1 February 2012	31 January 2014	31 January 2022	18	Member States shall ensure that authorizations are subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. When assessing the application for authorization of a product in accordance with Article 5 and
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phosphine	CAS No: 12057-74-8					Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorizations are subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level.
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27	Nitrogen	Nitrogen EC No: 231-783-9 CAS No: 7727-37-9	999 g/kg	1 September 2011	31 August 2013	31 August 2021	18	For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas. 3. For products containing magnesium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1). When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the
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28	Coumatetralyl	Coumatetralyl EC No: 227-424-0 CAS No: 5836-29-3	980 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the identified risks for non-target animals, the active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products other than tracking powder shall not exceed 375 mg/kg and only ready-for use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation	following conditions: 1. Products may only be sold to and used by professionals trained to use them. 2. Safe working practices and safe systems of work must be in place to ensure minimum risk, including the availability of personal protective equipment if necessary.
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29	tolyfluamid	Dichloro-N- [(dimethylamino) sulphonyl]fluoro-N- (p- tolyl)methanesulphenamide EC No: 211-986-9 CAS No: 731-27-1	960 g/kg	1 October 2011	30 September 2013	30 September 2021	8	measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes. Products shall not be authorised for the <i>in situ</i> treatment of wood outdoors or for wood that will be exposed to weathering. Member States shall ensure that authorizations are subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorization that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial or professional use shall indicate that freshly treated timber must be stored after treatment under
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30	Acrolein	Acrylaldehyde EC No: 203-453-4 CAS No: 107-02-8	913 g/kg	1 September 2010	Not applicable	31 August 2020	12	shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: 1. Waste waters containing acrolein shall be monitored prior to discharge, unless it can be demonstrated that risks for the environment can be reduced by other means. Where necessary in view of the risks to marine environment, waste waters shall be held in suitable tanks or reservoirs or appropriately treated before discharge. 2. Products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, and safe operational procedures shall be established, unless it can be demonstrated in the application for product
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31	Flocoumafen	4-hydroxy-3- [(1 <i>RS</i> ,3 <i>RS</i> ;1 <i>RS</i> ,3 <i>RS</i>)- 1,2,3,4-tetrahydro-3-[4-(4- trifluoromethylbenzyloxy) phenyl]-1-naphthyl] coumarin EC No 421-960-0 CAS No 90035-08-8	955 g/kg	1 October 2011	30 September 2013	30 September 2016	14	authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means. In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation
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32	Warfarin	(R _S)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin EC No: 201-377-6 CAS No: 81-81-2	990 g/kg	1 February 2012	31 January 2014	31 January 2017	14	measures. Those include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes. The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper
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33	Warfarin sodium	Sodium 2-oxo-3-(3-oxo-1-phenylbutyl)chromen-4-olate EC No: 204-929-4 CAS No: 129-06-6	910 g/kg	1 February 2012	31 January 2014	31 January 2017	14	resistant and secured bait boxes. The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
34	Dazomet	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione EC No: 208-576-7	960 g/kg	1 August 2012	31 July 2014	31 July 2022	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the

35	N,N-diethyl- meta-toluamide	N,N-diethyl-l-m- toluamide EC No: 205-149-7 CAS No: 134-62-3	970 g/kg	1 August 2012	31 July 2014	31 July 2022	19	particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. In particular, where relevant, Member States shall assess any other use than professional use outdoors for the remedial treatment of wooden poles by insertion of granules. Member States shall ensure that authorisations are subject to the following condition: Products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means. Member States shall ensure that authorisations are subject to the following conditions: 1. primary exposure of humans shall be minimized by considering and applying appropriate risk mitigation measures, including, where applicable, instructions for the amount and frequency of application of the product on human skin; 2. labels on products intended for application on human skin, hair or clothing shall indicate that the product is intended only for restricted use on children between two and twelve years old, and that
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								it is not intended for use on children less than two years old, unless it can be demonstrated in the application for product authorisation that the product will meet the requirements of Article 5 and Annex VI without such measures;	
3. products must contain deterrents for ingestion.									

For the implementation of the common principles of Schedule VI, the content and conclusions of assessment reports are available on the Commission website:
<http://ec.europa.eu/comm/environment/biocides/index.htm>

PART B

List of Active Substances with Requirements agreed at Community Level for Inclusion in Low-Risk Biocidal Products

No	Common name	IUPAC name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions
1	Carbon dioxide	Carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	Only for use in ready-for-use gas canisters functioning together with a trapping device.

Note: For the implementation of the common principles of Schedule VI, the content and conclusions of assessment reports are available on the Commission website:
<http://ec.europa.eu/comm/environment/biocides/index.htm>

PART C

List of Basic Substances with Requirements agreed at Community Level

SCHEDULE II**PART A****COMMON CORE DATA SET FOR ACTIVE SUBSTANCES****CHEMICAL SUBSTANCES**

1. Dossiers on active substances are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.
2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

Dossier requirements

- I. Applicant
- II. Identity of the active substance
- III. Physical and chemical properties of the active substance
- IV. Methods of detection and identification
- V. Effectiveness against target organisms and intended uses
- VI. Toxicological profile for man and animals including metabolism
- VII. Ecotoxicological profile including environmental fate and behaviour
- VIII. Measures necessary to protect man, animals and the environment
- IX. Classification and labelling
- X. Summary and evaluation of Sections II to IX

The following data will be required to support submission on the above points.

I. APPLICANT

- 1.1. Name and address, etc.
- 1.2. Active substance manufacturer (name, address, location of plant)

II. IDENTITY

- 2.1. Common name proposed or accepted by ISO and synonyms
- 2.2. Chemical name (IUPAC nomenclature)
- 2.3. Manufacturer's development code number(s)
- 2.4. CAS and EC numbers (if available)
- 2.5. Molecular and structural formula (including full details of any isomeric composition), molecular mass
- 2.6. Method of manufacture (syntheses pathway in brief terms) of active substance
- 2.7. Specification of purity of the active substance in g/kg or g/l, as appropriate
- 2.8. Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate
- 2.9. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower
- 2.10. Exposure data in conformity with Annex VI of Regulation (EC) No. 1907/2006.

III. PHYSICAL AND CHEMICAL PROPERTIES

- 3.1. Melting point, boiling point, relative density¹
- 3.2. Vapour pressure (in Pa)¹ above

¹ These data must be submitted for the purified active substance of stated specification

- 3.3. Appearance (physical state, colour)²
- 3.4. Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant¹
- 3.5. Solubility in water including effect of pH (5 to 9) and temperature on solubility, where relevant¹
- 3.6. Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature¹
- 3.7. Thermal stability, identity of relevant breakdown products
- 3.8. Flammability including auto-flammability and identity of combustion products
- 3.9. Flash-point
- 3.10. Surface tension
- 3.11. Explosive properties
- 3.12. Oxidising properties
- 3.13. Reactivity towards container material

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

- 4.1. Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of the active substance and additives (e.g. stabilisers)
- 4.2. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:
 - (a) Soil
 - (b) Air
 - (c) Water: the applicant should confirm that the substance itself and any of its degradation products which fall within the definition of pesticides given for “pesticides” and “pesticides – total” under Part B of Annex I Parameters and Parametric Values Of Legal Notice 17 of 2009 Water Intended for Human

² These data must be submitted for the active substance of stated specification

Consumption Regulations can be estimated with adequate reliability at the MAC specified in those Regulations for individual pesticides

(d) Animal and human body fluids and tissues

V. EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

- 5.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide
- 5.2. Organism(s) to be controlled and products, organisms or objects to be protected
- 5.3. Effects on target organisms, and likely concentration at which the active substance will be used
- 5.4. Mode of action (including time delay)
- 5.5. Field of use envisaged
- 5.6. User: industrial, professional, general public (non-professional)
- 5.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies
- 5.8. Likely tonnage to be placed on the market per year

VI. TOXICOLOGICAL AND METABOLIC STUDIES

- 6.1. Acute toxicity

For studies 6.1.1 to 6.1.3, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

- 6.1.1. Oral
- 6.1.2. Dermal
- 6.1.3. Inhalation

6.1.4. Skin and eye irritation³

6.1.5. Skin sensitisation

6.2. Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study

For the following studies, 6.3 (where necessary), 6.4, 6.5, 6.7 and 6.8, the required route of administration is the oral route unless it can be justified that an alternative route is more appropriate

6.3. Short-term repeated dose toxicity (28 days)

This study is not required when a sub-chronic toxicity study is available in a rodent

6.4. Subchronic toxicity 90-day study, two species, one rodent and one non-rodent

6.5. Chronic toxicity⁽⁴⁾

One rodent and one other mammalian species

6.6. Mutagenicity studies

6.6.1. *In-vitro* gene mutation study in bacteria

6.6.2. *In-vitro* cytogenicity study in mammalian cells

6.6.3. *In-vitro* gene mutation assay in mammalian cells

6.6.4. If positive in 6.6.1, 6.6.2 or 6.6.3, then an *in-vivo* mutagenicity study will be required (bone marrow assay for chromosomal damage or a micronucleus test)

6.6.5. If negative in 6.6.4 but positive *in-vitro* tests then undertake a second *in-vivo* study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow

6.6.6. If positive in 6.6.4 then a test to assess possible germ cell effects may be required

³ Eye irritation test shall not be necessary where the active substance has been shown to have potential corrosive properties.

6.7. Carcinogenicity study⁴

One rodent and one other mammalian species. These studies may be combined with those in 6.5

6.8. Reproductive toxicity⁵

6.8.1. Teratogenicity test — rabbit and one rodent species

6.8.2. Fertility study — at least two generations, one species, male and female

6.9. Medical data in anonymous form

6.9.1. Medical surveillance data on manufacturing plant personnel if available

6.9.2. Direct observation, e.g. clinical cases, poisoning incidents if available

6.9.3. Health records, both from industry and any other available sources

6.9.4. Epidemiological studies on the general population, if available

6.9.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available

6.9.6. Sensitisation/allergenicity observations, if available

6.9.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known

6.9.8. Prognosis following poisoning

6.10. Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning the active substances. Where possible any suggested worker protection measures should be included in summary form

VII. ECOTOXICOLOGICAL STUDIES

7.1. Acute toxicity to fish

⁴ The long-term toxicity and carcinogenicity of an active substance may not be required where a full justification demonstrates that these tests are not necessary

⁵ If, in exceptional circumstances, it is claimed that such testing is unnecessary, that claim must be fully justified.

- 7.2. Acute toxicity to *Daphnia magna*
- 7.3. Growth inhibition test on algae
- 7.4. Inhibition to microbiological activity
- 7.5. Bioconcentration
- Fate and behaviour in the environment
- 7.6. Degradation
 - 7.6.1. Biotic
 - 7.6.1.1. Ready biodegradability
 - 7.6.1.2. Inherent biodegradability, where appropriate
 - 7.6.2. Abiotic
 - 7.6.2.1. Hydrolysis as a function of pH and identification of breakdown products
 - 7.6.2.2. Phototransformation in water including identity of the products of transformation¹
- 7.7. Adsorption/desorption screening test
 - Where the results of this test indicate the need to do so, the test described in Schedule III – Part A Section XII.1 paragraph 1.2 shall be required, and/or the test described in Schedule III – Part A Section XII.2 paragraph 2.2
- 7.8. Summary of ecotoxicological effects and fate and behaviour in the environment

VIII. MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

- 8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire
- 8.2. In case of fire, nature of reaction products, combustion gases, etc.
- 8.3. Emergency measures in case of an accident
- 8.4. Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil

- 8.5. Procedures for waste management of the active substance for industry or professional users
 - 8.5.1. Possibility of reuse or recycling
 - 8.5.2. Possibility of neutralisation of effects
 - 8.5.3. Conditions for controlled discharge including leachate qualities on disposal
 - 8.5.4. Conditions for controlled incineration
- 8.6. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms

IX. CLASSIFICATION AND LABELLING

Proposals including justification for the proposals for the classification and labelling of the active substance according to L.N 306 of 2008.

Hazard symbol(s)

Indications of danger

Risk phrases

Safety phrases

X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

PART B**COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS****CHEMICAL PRODUCTS**

1. Dossiers on biocidal products are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.
2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.
3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Legal Notice 10 of 2007 should be used wherever possible to minimise animal testing.

Dossier requirements

- I. Applicant
- II. Identity of the biocidal product
- III. Physical and chemical properties of the biocidal product
- IV. Methods for identification and analysis of the biocidal product
- V. Intended uses of the biocidal product and efficacy for these uses
- VI. Toxicology data for the biocidal product (additional to that for the active substance)
- VII. Ecotoxicology data for the biocidal product (additional to that for the active substance)
- VIII. Measures necessary to protect man, animals and the environment

- IX. Classification, packaging and labelling
- X. Summary and evaluation of Sections II to IX

The following data will be required to support submission on the above points.

I. APPLICANT

- 1.1. Name and address, etc.
- 1.2. Formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))

II. IDENTITY

- 2.1. Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate
- 2.2. Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjutants, inert components
- 2.3. Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution

III. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

- 3.1. Appearance (physical state, colour)
- 3.2. Explosive properties
- 3.3. Oxidising properties
- 3.4. Flash-point and other indications of flammability or spontaneous ignition
- 3.5. Acidity/alkalinity and if necessary pH value (1% in water)
- 3.6. Relative density
- 3.7. Storage stability — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material

- 3.8. Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability
- 3.9. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised

IV. METHODS OF IDENTIFICATION AND ANALYSIS

- 4.1. Analytical method for determining the concentration of the active substance(s) in the biocidal product
- 4.2. In so far as not covered by Schedule II – Part A, paragraph 4.2, analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:
 - (a) Soil
 - (b) Air
 - (c) Water (including drinking water)
 - (d) Animal and human body fluids and tissues
 - (e) Treated food or feedingstuffs

V. INTENDED USES AND EFFICACY

- 5.1. Product type and field of use envisaged
- 5.2. Method of application including description of system used
- 5.3. Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes
- 5.4. Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals
- 5.5. Function, e.g. fungicide, rodenticide, insecticide, bactericide

- 5.6. Pest organism(s) to be controlled and products, organisms or objects to be protected
- 5.7. Effects on target organisms
- 5.8. Mode of action (including time delay) in so far as not covered by Schedule II – Part A, paragraph 5.4
- 5.9. User: industrial, professional, general public (non-professional)

Efficacy data
- 5.10. The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate
- 5.11. Any other known limitations on efficacy including resistance

VI. TOXICOLOGICAL STUDIES

6.1. Acute toxicity

For studies 6.1.1 to 6.1.3, biocidal products other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the product and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route

6.1.1. Oral

6.1.2. Dermal

6.1.3. Inhalation

- 6.1.4. For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate

6.2. Skin and eye irritation⁽¹⁾

6.3. Skin sensitisation

6.4. Information on dermal absorption

- 6.5. Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)
- 6.6. Information related to the exposure of the biocidal product to man and the operator

Where necessary, the test(s) described in Schedule II – Part A, shall be required for the toxicologically relevant non-active substances of the preparation

VII. ECOTOXICOLOGICAL STUDIES

- 7.1. Foreseeable routes of entry into the environment on the basis of the use envisaged
- 7.2. Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself
- 7.3. Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets

VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

- 8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire
- 8.2. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by Schedule II – Part A, paragraph 8.3
- 8.3. Procedures, if any, for cleaning application equipment
- 8.4. Identity of relevant combustion products in cases of fire
- 8.5. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration
- 8.6. Possibility of destruction or decontamination following release in or on the following:
 - (a) Air

- (b) Water, including drinking water
 - (c) Soil
- 8.7. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms
- 8.8. Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms

IX. CLASSIFICATION, PACKAGING AND LABELLING

- Proposals for packaging and labelling
- Proposals for safety-data sheets, where appropriate
- Justification for the classification and labelling according to the principles of regulation 21 of these Regulations
- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases
- Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials to be included

X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

Notes

(¹) Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

SCHEDULE III**PART A****ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES****CHEMICAL SUBSTANCES**

1. Dossiers on active substances are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.
2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

III. PHYSICAL AND CHEMICAL PROPERTIES

1. Solubility in organic solvents, including effect of temperature on solubility¹
2. Stability in organic solvents used in biocidal products and identity of relevant breakdown products²

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

1. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant

VI. TOXICOLOGICAL AND METABOLIC STUDIES

1. Neurotoxicity study

¹ These data must be submitted for the purified active substance of stated specification.

² These data must be submitted for the active substance of stated specification.

If the active substance is an organophosphorus compound or if there are any other indications that the active substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another test species is justified to be more appropriate. If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected a test for response to reactivating agents should be considered

2. Toxic effects on livestock and pets
3. Studies related to the exposure of the active substance to humans
4. Food and feedingstuffs

If the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Section XI, part 1 shall be required

5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section XI, part 2 shall be required
6. If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required
7. Mechanistic study — any studies necessary to clarify effects reported in toxicity studies

VII. ECOTOXICOLOGICAL STUDIES

1. Acute toxicity test on one other, non-aquatic, non-target organism
2. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Sections XII and XIII shall be required
3. If the result of the test in paragraph 7.6.1.2 of Schedule II – Part A is negative and if the likely route of disposal of the active substance is by sewage treatment then the test described in Section XIII, part 4.1 shall be required
4. Any other biodegradability tests that are relevant from the results in paragraphs 7.6.1.1 and 7.6.1.2 of Schedule II – Part A

5. Phototransformation in air (estimation method), including identification of breakdown products¹
6. If the results from paragraphs 7.6.1.2 in Schedule II – Part A or from paragraph 4, above, indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in Section XII, part 1.1, part 2.1 and, where appropriate, part 3 shall be required

VIII. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

1. Identification of any substances falling within the scope of List I or List II of the Schedule of Legal Notice 203 of 2002 Regulations for the Protection of Groundwater against Pollution caused by Certain Dangerous Substances on the protection of groundwater against pollution caused by certain dangerous substances

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies
 - 1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedstuffs
 - 1.2. Behaviour of the residue of the active substance, its degradation products and, where relevant, its metabolites on the treated or contaminated food or feedstuffs including the kinetics of disappearance
 - 1.3. Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health
 - 1.4. Estimation of potential or actual exposure of the active substance to humans through diet and other means
 - 1.5. If residues of the active substance remain on feedingstuffs for a significant period of time then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin
 - 1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance
 - 1.7. Proposed acceptable residues and the justification of their acceptability

- 1.8. Any other available information that is relevant
- 1.9. Summary and evaluation of data submitted under 1.1 to 1.8
2. Other test(s) related to the exposure to humans
Suitable test(s) and a reasoned case will be required

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Fate and behaviour in soil
 - 1.1. Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions
 - 1.2. Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products
 - 1.3. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products
 - 1.4. Extent and nature of bound residues
2. Fate and behaviour in water
 - 2.1. Rate and route of degradation in aquatic systems (as far as is not covered by Schedule II – Part A, paragraph 7.6) including identification of metabolites and degradation products
 - 2.2. Absorption and desorption in water (soil sediment systems) and, where relevant, absorption and desorption of metabolites and degradation products
3. Fate and behaviour in air

If the active substance is to be used in preparations for fumigants, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that this is relevant, then the rate and route of degradation in air shall be determined as far as is not covered by Section VII, part 5
4. Summary and evaluation of parts 1, 2 and 3

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds
 - 1.1. Acute oral toxicity — this need not be done if an avian species was selected for study in Section VII, part 1
 - 1.2. Short-term toxicity — eight-day dietary study in at least one species (other than chickens)
 - 1.3. Effects on reproduction
2. Effects on aquatic organisms
 - 2.1. Prolonged toxicity to an appropriate species of fish
 - 2.2. Effects on reproduction and growth rate on an appropriate species of fish
 - 2.3. Bioaccumulation in an appropriate species of fish
 - 2.4. *Daphnia magna* reproduction and growth rate
3. Effects on other non-target organisms
 - 3.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators. A different test organism shall be chosen from that used in Section VII, part 1
 - 3.2. Toxicity to earthworms and to other soil non-target macro-organisms
 - 3.3. Effects on soil non-target micro-organisms
 - 3.4. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
4. Other effects
 - 4.1. Activated sludge respiration inhibition test
5. Summary and evaluation of parts 1, 2, 3 and 4

PART B**ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS****CHEMICAL PRODUCTS**

1. Dossiers on biocidal products are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.
2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.
3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Legal Notice 10 of 2007 should be used wherever possible to minimise animal testing.

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies
 - 1.1. If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin
 - 1.2. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product
1. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required for the biocidal product

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Where relevant all the information required in Schedule III – Part A, Section XII
2. Testing for distribution and dissipation in the following:
 - (a) Soil
 - (b) Water
 - (c) Air

Test requirements 1 and 2 above are applicable only to ecotoxicologically relevant components of the biocidal product

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds
 - 1.1. Acute oral toxicity, if not already done in accordance with Schedule II – Part B, Section VII
2. Effects on aquatic organisms
 - 2.1. In case of application on, in, or near to surface waters
 - 2.1.1. Particular studies with fish and other aquatic organisms
 - 2.1.2. Residue data in fish concerning the active substance and including toxicologically relevant metabolites
 - 2.1.3. The studies referred to in Schedule III – Part A, Section XIII, parts 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product
 - 2.2. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions
3. Effects on other non-target organisms
 - 3.1. Toxicity to terrestrial vertebrates other than birds
 - 3.2. Acute toxicity to honeybees

- 3.3. Effects on beneficial arthropods other than bees
- 3.4. Effects on earthworms and other soil non-target macro-organisms, believed to be at risk
- 3.5. Effects on soil non-target micro-organisms
- 3.6. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
- 3.7. If the biocidal product is in the form of bait or granules
 - 3.7.1. Supervised trials to assess risks to non-target organisms under field conditions
 - 3.7.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
- 4. Summary and evaluation of parts 1, 2, and 3

SCHEDULE IV**PART A****DATA SET FOR ACTIVE SUBSTANCES****MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI**

1. For the purposes of these regulations, the term micro-organisms shall be understood as including also viruses and fungi. Dossiers on active micro-organisms shall address at least all the points listed under 'Dossier requirements' below. For all micro-organisms subject to an application for inclusion into Schedule I – Part A or Part B, all available relevant knowledge and information in literature must be provided. The information related to the identification and characterization of a micro-organism including mode of action is particularly important and must be entered in sections I to IV and provides the bases for an assessment of potential impacts on human health and of environmental effects.
2. Where information is not necessary owing to the nature of the micro-organism regulation 9(5) shall apply.
3. A dossier within the meaning of regulation 12(1) shall be prepared on strain level of the micro-organism unless information is submitted that shows that the species is known to be sufficiently homogenous regarding all characteristics, or the applicant provides other arguments in accordance with regulation 9(5).
4. Where the micro-organism has been genetically modified within the meaning of regulation 2(1) of Legal Notice 170 of 2002 concerning the Deliberate Release into the Environment of Genetically Modified Organisms Regulations, a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in regulation 4(2) of that Legal Notice, shall also be submitted.
5. If the biocidal product action is known to be partly or entirely due to the effect of a toxin/metabolite, or if significant residues of toxins/metabolites are to be expected not related to the effect of the active micro-organism, a dossier for the toxin/metabolite shall be submitted in accordance with the requirements of Schedules II – Part A and, where specified, the relevant parts of Schedule III – Part A.

Dossier requirements

SECTIONS:

- I. Identity of the micro-organism
- II. Biological properties of the micro-organism
- III. Further information on the micro-organism
- IV. Analytical methods
- V. Effects on human health
- VI. Residues in or on treated materials, food and feed
- VII. Fate and behaviour in the environment
- VIII. Effects on non-target organisms
- IX. Classification and labeling
- X. Summary and evaluation of sections I to IX including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE MICRO-ORGANISM

- 1.1. Applicant
- 1.2. Manufacturer
- 1.3. Name and species description, strain characterization
 - 1.3.1. Common name of the micro-organism (including alternative and superseded names)
 - 1.3.2. Taxonomic name and strain indicating whether it is a stock variant, a mutant strain or a genetically modified organism (GMO); for viruses, taxonomic designation of the agent, serotype, strain or mutant
 - 1.3.3. Collection and culture reference number where the culture is deposited

1.3.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism (e.g. morphology, biochemistry, serology, etc.)

1.4. Specification of the material used for manufacturing of formulated products

1.4.1. Content of the micro-organism

1.4.2. Identity and content of impurities, additives, contaminating microorganisms

1.4.3. Analytical profile of batches

II. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

2.1. History of the micro-organism and its uses. Natural occurrence and geographical distribution

2.1.1. Historical background

2.1.2. Origin and natural occurrence

2.2. Information on target organism(s)

2.2.1. Description of the target organism(s)

2.2.2. Mode of action

2.3. Host specificity range and effects on species other than the target organism

2.4. Development stages/life cycle of the micro-organism

2.5. Infectiveness, dispersal and colonisation ability

2.6. Relationships to known plant or animal or human pathogens

2.7. Genetic stability and factors affecting it

2.8. Information on the production of metabolites (especially toxins)

2.9. Antibiotics and other anti-microbial agents

2.10. Robustness to environmental factors

2.11. Effects on materials, substances and products

III. FURTHER INFORMATION ON THE MICRO-ORGANISM

3.1. Function

3.2. Field of use envisaged

3.3. Product type(s) and category of users for which the micro-organism should be listed in Schedule I

3.4. Method of production and quality control

3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)

3.6. Methods to prevent loss of virulence of seed stock of the microorganism

3.7. Recommended methods and precautions concerning handling, storage, transport or fire

3.8. Procedures for destruction or decontamination

3.9. Measures in case of an accident

3.10. Procedures for waste management

3.11. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use

IV. ANALYTICAL METHODS

4.1. Methods for the analysis of the micro-organism as manufactured

4.2. Methods to determine and quantify residues (viable or non-viable)

V. EFFECTS ON HUMAN HEALTH

TIER I

5.1. Basic information

5.1.1. Medical data

5.1.2. Medical surveillance on manufacturing plant personnel

5.1.3. Sensitisation/allergenicity observations

5.1.4. Direct observation, e.g. clinical cases

5.2. Basic studies

5.2.1. Sensitisation

5.2.2. Acute toxicity, pathogenicity, and infectiveness

5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness

5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness

5.2.2.3. Intraperitoneal/subcutaneous single dose

5.2.3. *In vitro* genotoxicity testing

5.2.4. Cell culture study

5.2.5. Information on short-term toxicity and pathogenicity

5.2.5.1. Health effects after repeated inhalatory exposure

5.2.6. Proposed treatment: first aid measures, medical treatment

5.2.7. Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression

END OF TIER I

TIER II

5.3. Specific toxicity, pathogenicity and infectiveness studies

5.4. Genotoxicity — *In vivo* studies in somatic cells

5.5. Genotoxicity — *In vivo* studies in germ cells

END OF TIER II

5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation

VI. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

6.1. Persistence and likelihood of multiplication in or on treated materials, feedingstuffs or foodstuffs

6.2. Further information required

6.2.1. Non-viable residues

6.2.2. Viable residues

6.3. Summary and evaluation of residues in or on treated materials, food and feed

VII. FATE AND BEHAVIOUR IN THE ENVIRONMENT

7.1. Persistence and multiplication

7.1.1. Soil

7.1.2. Water

7.1.3. Air

7.2. Mobility

7.3. Summary and evaluation of fate and behaviour in the environment

VIII. EFFECTS ON NON-TARGET ORGANISMS

8.1. Effects on birds

8.2. Effects on aquatic organisms

8.2.1. Effects on fish

8.2.2. Effects on freshwater invertebrates

8.2.3. Effects on algae growth

8.2.4. Effects on plants other than algae

8.3. Effects on bees

8.4. Effects on arthropods other than bees

8.5. Effects on earthworms

8.6. Effects on soil micro-organisms

8.7. Further studies

8.7.1. Terrestrial plants

8.7.2. Mammals

8.7.3. Other relevant species and processes

8.8. Summary and evaluation of effects on non-target organisms

IX. CLASSIFICATION AND LABELLING

The dossier shall be accompanied by a reasoned proposals for allocating an active substance which is a micro-organism to one of the risk groups specified in regulation 2 of Legal Notice 228 of 2003 on the protection of workers from risks related to exposure to biological agents at work together with indications on the need for products to carry the biohazard sign specified in Schedule II to that Legal Notice.

X. SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS

PART B**DATA SET FOR BIOCIDAL PRODUCTS****MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI**

1. For the purposes of these Regulations, the term micro-organisms shall be understood as including also viruses and fungi. This Schedule provides the requirements for the authorization of a biocidal product based on preparations of micro-organisms. For all biocidal products based on preparations containing micro-organisms that are subject to application, all available relevant knowledge and information should be provided. The information related to the identification and characterization of all components in a biocidal product is particularly important and must be entered in sections I to IV and provides the basis for an assessment of possible impacts on human health and environment.
2. Where information is not necessary owing to the nature of the micro-organism regulation 9(5) shall apply.
3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Legal Notice 306 of 2008 and Legal Notice 10 of 2007 concerning the Dangerous Substances and Preparations Regulations shall be used wherever possible to minimize animal testing.
4. Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of Section II, must be provided. Where necessary, data as established in Schedules II – Part B, II – Part B shall be required for all the toxicologically/eco-toxicologically relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in regulation 3(1)(e).
5. In cases where a new preparation is to be dealt with, extrapolation from Schedules IV – Part A, could be acceptable, provided that all the possible effects of the components, especially on pathogenicity and infectiveness, are evaluated.

Dossier requirements

SECTIONS:

- I. Identity of the biocidal product
- II. Physical, chemical and technical properties of the biocidal product
- III. Data on application
- IV. Further information on the biocidal product
- V. Analytical methods
- VI. Efficacy data
- VII. Effects on human health
- VIII. Residues in or on treated materials, food and feed
- IX. Fate and behaviour in the environment
- X. Effects on non-target organisms
- XI. Classification, packaging and labelling of the biocidal product
- XII. Summary and evaluation of sections I to XI including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE BIOCIDAL PRODUCTS

- 1.1. Applicant
- 1.2. Manufacturer of the biocidal product and the micro-organism(s)
- 1.3. Trade name or proposed trade name, and manufacturer's development code number of the biocidal product
- 1.4. Detailed quantitative and qualitative information on the composition of the biocidal product
- 1.5. Physical state and nature of the biocidal product

1.6. Function

II. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

2.1. Appearance (colour and odour)

2.2. Storage stability and shelf-life

2.2.1. Effects of light, temperature and humidity on technical characteristics of the biocidal product

2.2.2. Other factors affecting stability

2.3. Explosivity and oxidising properties

2.4. Flash point and other indications of flammability or spontaneous ignition

2.5. Acidity, alkalinity and pH value

2.6. Viscosity and surface tension

2.7. Technical characteristics of the biocidal product

2.7.1. Wettability

2.7.2. Persistent foaming

2.7.3. Suspensibility and suspension stability

2.7.4. Dry sieve test and wet sieve test

2.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)

2.7.6. Emulsifiability, re-emulsifiability, emulsion stability

2.7.7. Flowability, pourability (rinsability) and dustability

2.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered

2.8.1. Physical compatibility

2.8.2. Chemical compatibility

2.8.3. Biological compatibility

2.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product

III. DATA ON APPLICATION

3.1. Field of use envisaged

3.2. Mode of action

3.3. Details of intended use

3.4. Application rate

3.5. Content of micro-organism in material used (e.g. in the application device or bait)

3.6. Method of application

3.7. Number and timing of applications and duration of protection

3.8. Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment

3.9. Proposed instructions for use

3.10. Category of users

3.11. Information on the possible occurrence of the development of resistance

3.12. Effects on the materials or products treated with the biocidal product

IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT

4.1. Packaging and compatibility of the biocidal product with proposed packaging materials

4.2. Procedures for cleaning application equipment

4.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

4.4. Recommended methods and precautions concerning: handling, storage, transport or fire

4.5. Measures in the case of an accident

4.6. Procedures for destruction or decontamination of the biocidal product and its packaging

4.6.1. Controlled incineration

4.6.2. Others

4.7. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use

V. ANALYTICAL METHODS

5.1. Methods for the analysis of the biocidal product

5.2. Methods to determine and quantify residues

VI. EFFICACY DATA

VII. EFFECTS ON HUMAN HEALTH

7.1. Basic acute toxicity studies

7.1.1. Acute oral toxicity

7.1.2. Acute inhalation toxicity

7.1.3. Acute percutaneous toxicity

7.2. Additional acute toxicity studies

7.2.1. Skin irritation

7.2.2. Eye irritation

7.2.3. Skin sensitisation

7.3. Data on exposure

7.4. Available toxicological data relating to non-active substances

7.5. Supplementary studies for combinations of biocidal products

7.6. Summary and evaluation of effects on human health

VIII. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

IX. FATE AND BEHAVIOUR IN THE ENVIRONMENT

X. EFFECTS ON NON-TARGET ORGANISMS

10.1. Effects on birds

10.2. Effects on aquatic organisms

10.3. Effects on bees

10.4. Effects on arthropods other than bees

10.5. Effects on earthworms

10.6. Effects on soil micro-organisms

10.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms

10.7.1. Terrestrial plants

10.7.2. Mammals

10.7.3. Other relevant species and processes

10.8. Summary and evaluation of effects on non-target organisms

XI. CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT

As established in regulation 21, proposals including justification for the classification and labelling of the biocidal product in accordance with the provisions set in Legal Notice 306 of 2008 and Legal Notice 10 of 2007 must be submitted. The classification comprises of the description of the category/categories of danger and qualifying risk phrases for all dangerous properties. On the basis of the classification, a proposal for labelling including the hazard symbol(s) and indications of danger, risk phrases and safety phrases should be given. The classification and labelling shall be in regard to the chemical substances contained in the biocidal product. If necessary, specimens of proposed packaging shall be submitted to the competent authority of a Member State.

The dossier shall be accompanied by a reasoned proposal for allocation to one of the risk groups specified in regulation 2 of Legal Notice 228 of 2003 together with

indications on the need for products to carry the biohazard sign specified in Schedule II to that Legal Notice.

**XII. SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING
CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS**

*SCHEDULE V***BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED
TO IN REGULATION 3(1)(a) OF THESE REGULATIONS**

These product-types exclude products where they are covered by the regulations mentioned in regulation 2(2) of these regulations for the purposes of these regulations and their subsequent modifications.

MAIN GROUP 1: Disinfectants and general biocidal products

These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene biocidal products

Products in this group are biocidal products used for human hygiene purposes.

Product-type 2: Private area and public health area disinfectants and other biocidal products

Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algacides.

Usage areas include, *inter alia*, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).

Product-type 3: Veterinary hygiene biocidal products

Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

Product-type 4: Food and feed area disinfectants

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.

Product-type 5: Drinking water disinfectants

Products used for the disinfection of drinking water (for both humans and animals).

MAIN GROUP 2: Preservatives

Product-type 6: In-can preservatives

Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.

Product-type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

Product-type 8: Wood preservatives

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.

This product type includes both preventive and curative products.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

Product-type 10: Masonry preservatives

Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

Product-type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the preservation of drinking water are not included in this product type.

Product-type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Product-type 13: Metalworking-fluid preservatives

Products used for the preservation of metalworking fluids by the control of microbial deterioration.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents.

Product-type 15: Avicides

Products used for the control of birds.

Product-type 16: Molluscicides

Products used for the control of molluscs.

Product-type 17: Piscicides

Products used for the control of fish; these products exclude products for the treatment of fish diseases.

Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

MAIN GROUP 4: Other biocidal products

Product-type 20: Preservatives for food or feedstocks

Products used for the preservation of food or feedstocks by the control of harmful organisms.

Product-type 21: Antifouling products

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

Product-type 23: Control of other vertebrates

Products used for the control of vermin.

*SCHEDULE VI***COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR
BIOCIDAL PRODUCTS****CONTENTS****Definitions****Introduction****Evaluation**

- General principles
- Effects on humans
- Effects on animals
- Effects on the environment
- Unacceptable effects
- Efficacy
- Summary

Decision-making

- General principles
- Effects on humans
- Effects on animals
- Effects on the environment
- Unacceptable effects
- Efficacy

— Summary

Overall integration of conclusions

DEFINITIONS

(a) *Hazard identification*

This is the identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) *Dose (concentration) — response (effect) assessment*

This is the estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) *Exposure assessment*

This is the determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

(d) *Risk characterisation*

This is the estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include 'risk estimation' i.e. the quantification of that likelihood.

(e) *Environment*

Water, including sediment, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Schedule lays down principles to ensure that evaluations made and decisions taken by a Member State concerning the authorisation of a biocidal product providing it is a chemical preparation results in

a harmonised high level of protection for humans, animals and the environment in accordance with regulation 6(1)(b) of these regulations.

2. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks identified during the proposed normal use of the biocidal product. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product.
3. A risk assessment on the active substance or substances present in the biocidal product is always required. This will already have been carried out for the purpose of Schedule I. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.
4. Additional risk assessments shall be carried out, in the same manner as described above, on any other substance of concern present in the biocidal product where relevant for the use of the biocidal product.
5. In order to carry out a risk assessment data are required. These data are detailed in Schedules II, III and IV and, recognising that there are a wide variety of product types, are flexible according to the product type and associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. Member States should take due consideration of the requirements of regulations 13 and 14 of these regulations in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type, however, shall be that detailed in Annex VI to Regulation 1907/2006; these data will already have been submitted and assessed as part of the risk assessment required for entry of the active substance into Schedule I to these regulations. Data may also be required on a substance of concern present in a biocidal product.
6. The results of the risk assessments carried out on an active substance and on a substance of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.
7. When making evaluations and taking decisions concerning the authorisation of a biocidal product the Member State shall:

(a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

(b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

8. The Member State shall comply with the requirements of mutual recognition as stated in regulation 5(1), (2) and (6) of these regulations.
9. It is known that many biocidal products present only minor differences in composition and this should be taken into account when evaluating dossiers. The concept of 'frame-formulations' is relevant here.
10. It is known that certain biocidal products are considered as posing only a low risk, these biocidal products, while complying with the requirements of this Schedule, are subject to a simplified procedure as detailed in regulation 4 of these regulations.
11. The application of these common principles shall lead to the Member State deciding whether or not a biocidal product can be authorised, such authorisation may include restrictions on use or other conditions. In certain cases the Member State may conclude that more data are required before an authorisation decision can be made.
12. During the process of evaluation and decision-making, Member States and applicants shall cooperate in order to resolve any questions on the data requirements quickly or to identify at an early stage any additional studies required, or to amend any proposed conditions for the use of the biocidal product or to modify its nature or its composition in order to ensure full compliance with the requirements of this Schedule or of these regulations. The administrative burden, especially for small and medium-sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.
13. The judgments made by the Member State during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

EVALUATION

General principles

14. The data submitted in support of an application for authorisation of a biocidal product shall be examined for completeness and overall scientific value by the receiving Member State. After acceptance of these data the Member State shall utilise them by carrying out a risk assessment based on the proposed use of the biocidal product.
15. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product together with a realistic worst-case scenario including any relevant production and disposal issue either of the biocidal product itself or any material treated with it.
16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail a hazard identification and the establishment of appropriate no-observed-adverse-effect levels (NOAEL), where possible. It shall also include, as appropriate, a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.
17. The results arrived at from a comparison of the exposure to the no-effect level concentrations for each of the active substances and any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.
18. The risk assessment shall determine:
 - (a) the risk to humans and animals,
 - (b) the risk to the environment,
 - (c) the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst-case situation.
19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

Effects on humans

20. The risk assessment shall take account of the following potential effects arising from the use of the biocidal product and the populations liable to exposure.
21. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:
 - acute and chronic toxicity,
 - irritation,
 - corrosivity,
 - sensitisation,
 - repeated dose toxicity,
 - mutagenicity,
 - carcinogenicity,
 - reproduction toxicity,
 - neurotoxicity,
 - any other special properties of the active substance or substance of concern,
 - other effects due to physico-chemical properties.
22. The populations previously mentioned are:
 - professional users,
 - non-professional users,
 - humans exposed indirectly via the environment.
23. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of regulation 21 of these Regulations then dose (concentration) —

response (effect) assessment, exposure assessment and risk characterisation shall be required.

24. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not lead to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues.
25. The Member State shall apply paragraphs 26 to 29 when carrying out a dose (concentration) — response (effect) assessment on an active substance or a substance of concern present in a biocidal product.
26. For repeated dose toxicity and reproductive toxicity the dose response relationship shall be assessed for each active substance or substance of concern and, where possible, the no-observed-adverse-effect level (NOAEL) identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified.
27. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of these Regulations. For acute toxicity, the LD50 (median lethal dose) or LC50 (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the product.
28. For mutagenicity and carcinogenicity it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product. However, if it can be demonstrated that an active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a N(L)OAEL as described in paragraph 26.
29. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

30. Where toxicity data derived from observations of human exposure, e.g. information gained from manufacture, from poison centres or epidemiology surveys, are available special consideration shall be given to those data when carrying out the risk assessment.
31. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.
32. The exposure assessment shall be based on the information in the technical dossier provided in conformity with regulation 9 of these regulations and on any other available and relevant information.

Particular account shall be taken, as appropriate, of:

- adequately measured exposure data,
- the form in which the product is marketed,
- the type of biocidal product,
- the application method and application rate,
- the physico-chemical properties of the product,
- the likely routes of exposure and potential for absorption,
- the frequency and duration of exposure,
- the type and size of specific exposed populations where such information is available.

33. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

- make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,
- be subjected to an analysis taking into account possible elements of uncertainty,
- be reliably validated with measurements carried out under circumstances relevant for the use of the model,
- be relevant to the conditions in the area of use.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

34. Where, for any of the effects set out in paragraph 21 a NOAEL or LOAEL had been identified, the risk characterisation shall entail comparison of the NOAEL or LOAEL with the evaluation of the dose/concentration to which the population will be exposed. Where a NOAEL or LOAEL cannot be established a qualitative comparison shall be made.

Effects on animals

35. Using the same relevant principles as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product.

Effects on the environment

36. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota following the use of the biocidal product.
37. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of these regulations then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.
38. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been

conducted but the results have not led to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:

- any indications of bioaccumulation potential,
- the persistence characteristics,
- the shape of the toxicity/time curve in ecotoxicity testing,
- indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),
- data on structurally analogous substances,
- endocrine effects.

39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.
40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of regulation 9 of these regulations. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50% inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).
41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in Subsidiary Legislation 427.15 – Legal Notice 40 of 2002 Dangerous Substances (Risk Assessment) Regulations.

42. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.
43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.
44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:
 - adequately measured exposure data,
 - the form in which the product is marketed,
 - the type of biocidal product,
 - the application method and application rate,
 - the physico-chemical properties,
 - breakdown/transformation products,
 - likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
 - the frequency and duration of exposure.
45. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in paragraph 33. Where appropriate, on a case-by-case basis, relevant

monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.
47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

Unacceptable effects

48. Data shall be submitted to and evaluated by the Member State to assess whether the biocidal product does not cause unnecessary suffering in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.
49. The Member State shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.
50. If there are indications that any other unacceptable effects may occur the Member State shall evaluate the possibility of such effects occurring. An example of such an unacceptable effect would be an adverse reaction to fastenings and fittings used in wood following the application of a wood preservative.

Efficacy

51. Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the applicant or held by the Member State must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.
52. Testing should be carried out according to Community guidelines if these are available and applicable. Where appropriate, other methods can

be used as shown in the list below. If relevant acceptable field data exist, these can be used.

- ISO, CEN or other international standard method
- national standard method
- industry standard method (accepted by Member State)
- individual producer standard method (accepted by Member State)
- data from the actual development of the biocidal product (accepted by Member State).

Summary

53. In each of the areas where risk assessments have been carried out, i.e. effects on man, animals, and the environment, the Member State shall combine the results for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This should take account of any likely synergistic effects of the active substance(s) and substances of concern in the biocidal product.
54. For biocidal products containing more than one active substance any adverse effects shall also be combined to produce an overall effect for the biocidal product itself.

DECISION MAKING

General principles

55. Subject to paragraph 96, the Member State shall come to a decision regarding the authorisation for use of a biocidal product as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product. The risk assessments shall cover normal use of the biocidal product together with a realistic worst-case scenario including any relevant disposal issue either of the biocidal product itself or any material treated with it.
56. In making a decision concerning authorisation, the Member State shall arrive at one of the following conclusions for each product type and for

each area of use of the biocidal product for which application has been made:

1. the biocidal product cannot be authorised;
 2. the biocidal product can be authorised subject to specific conditions/restrictions;
 3. more data is required before a decision on authorisation can be made.
57. If the conclusion arrived at by the Member State is that additional information or data are required before an authorisation decision can be made, then the need for any such information or data shall be justified. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.
58. The Member State shall comply with the principles of mutual recognition as detailed in regulation 4 of these Regulations.
59. The Member State shall apply the rules concerning the concept of 'frame formulations' when making an authorisation decision on a biocidal product.
60. The Member State shall apply the rules concerning the concept of 'low risk' products when making an authorisation decision on such a biocidal product.
61. The Member State shall only grant authorisation to those biocidal products which, when used according to their conditions of authorisation, do not present an unacceptable risk to humans, animals or the environment, are efficacious and which contain active substances permitted at Community level to be used in such biocidal products.
62. The Member State shall impose, where appropriate, conditions or restrictions when giving authorisations. The nature and severity of these shall be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise from the use of the biocidal product.
63. In the decision-making process the Member State shall take into consideration the following:
- the results of the risk assessment, in particular the relationship between exposure and effect,

- the nature and severity of the effect,
 - the risk management which can be applied,
 - the field of use of the biocidal product,
 - the efficacy of the biocidal product,
 - the physical properties of the biocidal product,
 - the benefits of using the biocidal product.
64. The Member State shall, when taking a decision concerning the authorisation of a biocidal product, take into account the uncertainty arising from the variability in the data used in the evaluation and decision-making process.
65. The Member State shall prescribe that biocidal products shall be used properly. Proper use shall include application at an efficacious dose and minimisation of use of biocidal products where possible.
66. The Member State shall take the necessary measures to ensure that the applicant proposes a label, and, where relevant, the safety-data sheet, for the biocidal product which:
- fulfils the requirements of regulation 19 and 20 of these Regulations,
 - contains the information on the protection of users required by Community legislation on worker protection,
 - specifies in particular the conditions or restrictions under which the biocidal product may or may not be used.
- Before issuing an authorisation the Member State shall confirm that these requirements must be satisfied.
67. The Member State shall take the necessary measures to ensure that the applicant proposes packaging and, where appropriate, the procedures for destruction or decontamination of the biocidal product and its packaging or any other relevant material associated with the biocidal product, which conforms to the relevant regulatory provisions.

Effects on humans

68. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in foreseeable application including a realistic worst possible scenario, the product presents an unacceptable risk to humans.
69. The Member State shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment when making a decision on the authorisation of a biocidal product.
70. The Member State shall examine the relationship between the exposure and the effect, and use this in the decision-making process. A number of factors need to be considered when examining this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern.
71. The Member State shall, where possible, compare the results obtained with those obtained from previous risk assessments for an identical or similar adverse effect and decide on an appropriate margin of safety (MOS) when making an authorisation decision.

An appropriate MOS is typically 100 but an MOS higher or lower than this may be appropriate depending on, among other things, the nature of the critical toxicological effect.

72. The Member State shall, if appropriate, impose, as a condition of authorisation, the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators. Such equipment must be readily available to them.
73. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure, the product shall not normally be authorised.
74. If the relationship between the exposure and the effect cannot be reduced to an acceptable level then no authorisation can be given by the Member State for the biocidal product.
75. No biocidal product classified according to regulation 21(1) of these regulations as toxic, very toxic or as a category 1 or 2 carcinogen, or as a

category 1 or 2 mutagen, or classified as toxic for reproduction category 1 or 2, shall be authorised for use by the general public.

Effects on animals

76. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in normal use, the biocidal product presents an unacceptable risk to non-target animals.
77. Using the same relevant criteria as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product when making an authorisation decision.

Effects on the environment

78. The Member State shall not authorise a biocidal product if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil and air. This shall include the assessment of risks to non-target organisms in these compartments.

In considering whether there is an unacceptable risk Member States shall, when coming to a final decision in accordance with paragraph 96, take into account the criteria in paragraphs 81 to 91.

79. The basic tool used in the decision making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.

In the determination of the PEC the most appropriate model should be used taking into account the environmental fate and behaviour of the biocidal product.

80. For any given environmental compartment if the PEC/PNEC ratio is equal to or less than 1 the risk characterisation shall be that no further information and/or testing are necessary.

If the PEC/PNEC ratio is greater than 1 the Member State shall judge, on the basis of the size of that ratio and on other relevant factors, if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary or if the product cannot be

given an authorisation at all. Relevant factors to be considered are those previously mentioned in paragraph 38.

Water

81. The Member State shall not authorise a biocidal product, if under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target species in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.
82. The Member State shall not authorise a biocidal product if, under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:
 - (a) the maximum permissible concentration laid down by Legal Notice 17 of 2009, or
 - (b) the maximum concentration as laid down following the procedure for including the active substance in Schedule I to these regulations, on the basis of appropriate data, in particular toxicological data unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.
83. The Member State shall not authorise a biocidal product if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:
 - exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by
 - Subsidiary Legislation 435.36 - Legal Notice 339 of 2001, as amended by Legal Notice 426 of 2007, Quality Required of Surface Water intended for the Abstraction of Drinking Water Regulations,
 - Legal Notice 17 of 2009 or

— has an impact deemed unacceptable on non-target species unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

84. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of water or its sediments is minimised.

Soil

85. Where unacceptable contamination of soil is likely to occur, the Member State shall not authorise a biocidal product if the active substance or substance of concern contained in it, after use of the biocidal product:

— during tests in the field, persists in soil for more than one year, or

— during laboratory tests, forms non-extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralisation rate of less than 5% in 100 days,

— has unacceptable consequences or effects on non-target organisms,

unless it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil.

Air

86. The Member State shall not authorise a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on non-target organisms

87. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product if for any active substance or substance of concern:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur

after use of the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) related to fat tissues in non-target vertebrates is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur, either directly or indirectly, after use of the product according to the proposed conditions of use.

88. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product if for any active substance or substance of concern in it:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms including marine and estuarine organisms is not threatened by the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) is greater than 1 000 for substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of exposed organisms including marine and estuarine organisms after use of the biocidal product according to the proposed conditions of use.

of By way of derogation from this paragraph, Member States may, however, authorise an anti-fouling product used on commercial, public service and naval seagoing vessels for a period of up to 10 years from the date on which Directive 98/8/EC of the European Parliament and the Council of 16 February 1998 concerning the placing of biocidal products on the market enter into force if similar fouling control cannot be achieved by other practicable means. When implementing this provision, Member States shall, if appropriate, take into account relevant International Maritime Organisation (IMO) resolutions and recommendations.

89. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Unacceptable effects

90. If the development of resistance to the active substance in the biocidal product is likely the Member State shall take steps to minimise the consequences of this resistance. This may involve modification of the conditions of authorisation or even refusal of any authorisation.
91. An authorisation for a biocidal product intended to control vertebrates shall not be given unless:
- death is synchronous with the extinction of consciousness, or,
 - death occurs immediately, or,
 - vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

Efficacy

92. Member States shall not authorise a biocidal product which does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of authorisation.
93. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in the Member State except where the proposed label prescribes that the biocidal product is intended for use in specific circumstances. Member States shall evaluate dose response data generated in trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

Summary

94. In each of the areas where risk assessments have been carried out, i.e. effects on humans, animals, and the environment, the Member State shall combine the conclusions arrived at for the active substance and the substances of concern to produce an overall conclusion for the biocidal product itself. A summary should also be made of the efficacy assessment and of the unacceptable effects.

The result shall be:

- a summary of the effects of the biocidal product on humans,
- a summary of the effects of the biocidal product on animals,
- a summary of the effects of the biocidal product on the environment,
- a summary of the efficacy assessment,
- a summary of the unacceptable effects.

OVERALL INTEGRATION OF CONCLUSIONS

95. The Member State shall combine the individual conclusions arrived at with regard to effects of the biocidal product on the three sectors namely, humans, animals and the environment to arrive at an overall conclusion for the global effect of the biocidal product.
96. The Member State shall then take due consideration of any relevant unacceptable effects, the efficacy of the biocidal product and the benefits of using the biocidal product before taking an authorisation decision on the biocidal product.
97. The Member State shall ultimately decide whether or not the biocidal product can be authorised and whether this authorisation shall be subject to any restrictions or conditions in conformity with this Schedule and these regulations.