A.L. 87 tal-2009

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

Regoli tal-2009 dwar il-Projbizzjoni tal-Użu ta' Ċerti Sustanzi fit-Trobbija tal-Bhejjem li jkollhom Effett Ormonali u Tireostatiku u ta' *Beta-agonists*

BIS-SAĦĦA tas-setgħat mogħtija permezz tal-artikolu 13(a) tal-Att dwar is-Servizzi Veterinarji, il-Ministru għar-Riżorsi u Affarijiet Rurali għamel dawn ir-regoli li ġejjin:-

Titolu, skop u dħul fis-seħħ.

1. (1) It-titolu ta' dawn ir-regoli hu Regoli tal-2009 dwar Il-Projbizzjoni tal-Użu ta' Ċerti Sustanzi fit-Trobbija tal-Bhejjem li jkollhom Effett Ormonali u Tireostatiku u ta' *Beta-agonists*.

(2) L-iskop ta' dawn ir-regoli hu li jimplimentaw ir-regoli mniżżla taħt id-Direttiva tal-Kunsill tal-Unjoni Ewropea 96/22/KEE li jistabbilixxu l-projbizzjoni tal-użu ta' ċerti sustanzi fit-trobbija tal-annimali, filwaqt li jemendaw dawn ir-regoli skond ir-regoli l-ġodda mniżżla taħt id-Direttiva tal-Parlament u tal-Kunsill tal-Unjoni Ewropea 2008/97/KE, fir-rigward tal-projbizzjoni tal-użu ta' ċerti sustanzi għall-annimali u li dik il-projbizzjoni għandha tiġi limitata.

Tifsir.

2. (1) Kemm–il darba ma jiġix stabbilit xort'oħra f'dawn ir-regoli, it-tifsiriet fl-Att dwar is-Servizzi Veterinarji għandhom japplikaw.

(2) Għall-finijiet ta' dawn ir-regoli u kemm–il darba r-rabta tal-kliem ma tkunx teħtieġ xort'oħra:-

"annimali tal-irziezet" tfisser annimali domestiċi tal-ispeċi bovina, porċina, ovina u kaprina, annimali domestiċi li għandhom difrejhom sodi (*solipeds*), tjur u fniek, kif ukoll annimali selvaġġi ta' dawk l-ispeċi u ruminanti selvaġġi li jkunu ġew imrobbija f'razzett;

"l-awtorità" tfisser l-Awtorità dwar is-Servizzi Veterinarji f'Malta kif stabbilit f'artikolu 2 tal-Att dwar is-Servizzi Veterinarji;

"Pajjiż terz" tfisser stat li m'huwiex membru tal-Komunità Ewropea;

"Stat Membru" tfisser Stat li huwa Membru fil-Komunità Ewropea;

"trattament illegali" tfisser l-użu ta' sustanzi jew prodotti mhux awtorizzati jew l-użu ta' sustanzi jew prodotti awtorizzati minn kull liġi oħra għal finijiet jew taħt kundizzjonijet differenti minn dawk stipulati f'kull liġi oħra;

"trattament terapewtiku" tfisser l-amministrazzjoni ta' sustanza awtorizzata, imsemmija f'regola 6 ta' dawn ir-regoli, lil annimal agrikolu individwali sabiex ifejjaq problema ta' fertilità, inkluż t-twaqqif tat-tqala mhux mixtieqa, wara eżaminazzjoni ta' veterinarju u fil-każ ta' *beta-agonists*, biex titqanqal tokolożi fil-baqar filwaqt li jwelldu u biex titratta l-problemi respiratorji, mard navikulari u l-*laminitis* u tqanqal it-tokolożi fl-*equidae*;

"trattament zootekniku" tfisser l-amministrazzjoni ta' kull sustanza lill-annimal tar-razzett individwali u fil-każ ta' annimali akwatici, lil grupp ta' annimali mrobbija għat-tnissil għall-inverżjoni tas-sess, fuq preskrizzjoni tal-veterinarju u taħt ir-responsabbilità tiegħu, u li hu projbit taħt ir-regola 7 (2) ta' dawn ir-regoli.

Applikabilità.

3. Dawn ir-regoli għandhom ikunu japplikaw għall-projbizzjoni tal-użu ta' ċerti sustanzi fit-trobbija tal-annimali u li dik l-applikazzjoni għandha tiġi limitata biss għal annimali maħsuba għall-produzzjoni alimentari u li l-projbizzjoni għall-annimali domestiċi tiġi rtirata.

Projbizzjonijiet.

4. It-tqegħid fis-suq tas-sustanzi elenkati fl-Iskeda, biex jingħataw lil kull annimal, li l-laħam u l-prodotti tagħhom huma maħsuba għall-konsum tal-bniedem, għal finijiet mhux stabbiliti fir-regola 5 qiegħed hawn jiġi projbit.

Projbizzjonijiet oħra.

5. F'Malta dawn li ġejjin għandhom jiġu wkoll projbiti -

(i) l-amministrazzjoni lill-annimali tar-razzett jew akwatiċi, permezz ta' kull metodu, ta' sustanzi li għandhom effetti tirostatiċi, ostroġeniċi, androġeniċi jew ġestaġeniċi u ta' *beta-agonists*;

(ii) iż-żamma, minbarra taħt kontroll uffiċjali, ta' annimali msemmija f'paragrafu (i) fir-razzett, it-tqegħid fis-suq jew qatla għal konsum mill-bniedem ta' annimali tar-razzett jew annimali akwatici li jkollhom sustanzi msemmija f'paragrafu (i) jew fejn il-preżenza ta' sustanzi bħal dawn tkun ġiet stabbilita, sakemm ma tingħatax prova illi l-annimali in kwistjoni ġew ikkurati skond ir-regoli 6 jew 7;

(iii) it-tqegħid fis-suq għal konsum mill-bniedem ta' annimali akwatiċi li ġew amministrati b'sustanzi msemmija f'paragrafu (i) u ta' prodotti proċessati derivanti minn annimali bħal dawn;

(iv) it-tqegħid fis-suq ta' laħam ta' annimali msemmija f'paragrafu (ii); u

(v) l-ipproċessar ta' laħam imsemmi f'paragrafu (iv).

Eżenzjonijiet minn projbizzjonijiet.

6. (1) Salv id-dispożizzjonijiet f'regoli 4 u 5, għandu jkun awtorizzat dan li ġej:-

(i) l-amministrazzjoni lill-annimali tar-razzett, għal finijiet terapewtici, ta' *ßoestradiol* 17, *testosterone* u *progesterone* u derivattivi li jirrilaxxaw f'ħin qasir il-kompost prinċipali ma' l-idrolisi wara li jiġi assorbit fil-lok ta' applikazzjoni:

Iżda prodotti mediċinali veterinarji wżati għat-trattament terapewtiku għandhom jaqblu mar-rekwiżiti għat-tqegħid fis-suq stabbiliti fid-Direttiva tal-Unjoni Ewropea 81/851/KEE u għandhom jiġu amministrati minn veterinarju biss, permezz ta' injezzjoni jew għat-trattament ta' malfunzjoni tal-ovarji permezz ta' spirali vaġinali, iżda mhux permezz ta' impjant, lill-annimali tar-razzett li jkunu ġew identifikati b'mod ċar. Trattament ta' annimali identifikati għandu jiġi reġistrat mill-veterinarju responsabbli. Dan tal-aħħar għandu jniżżel għall-inqas dawn id-dettalji li ġejjin f'reġistru, li jista' jkun dak stabbilit fid-Direttiva tal-Unjoni Ewropea 81/851/KEE:-

(a) it-tip ta' trattament;

(b) it-tip ta' prodotti awtorizzati;

(ċ) id-data tat-trattament;

(d) l-identità tal-annimali kkurati:

Iżda wkoll ir-reġistru għandu jkun disponibbli għas-Servizzi Veterinarji meta dawn jitolbuh;

(ii) l-amministrazzjoni għal raġunijiet terapewtiċi ta' prodotti mediċinali veterinarji awtorizzati li għandu jkun fihom:-

(a) *allyl trenbolone*, amministrat oralment, jew *beta-agonists* lil *equidae*, sakemm dawn ikunu wżati skond l-istruzzjonijiet tal-manifattur;

(b) *beta-agonists*, fl-għamla ta' injezzjoni sabiex jikkaġunaw tokolosi fil-baqar tqal. Sustanzi bħal dawn għandhom jiġu amministrati minn veterinarju jew, fil-każ tal-prodotti mediċinali veterinarji msemmija f'paragrafu (a) hawn qabel, taħt ir-responsabbiltà diretta tiegħu, trattament għandu jiġi reġistrat mill-veterinarju responsabbli, li għandu jniżżel għall-inqas id-dettalji msemmija f'partita (i). Il-bdiewa għandhom ikunu pprojbiti milli jżommu prodotti mediċinali veterinarji li jkollhom *beta-agonists* li jistgħu jiġu wżati għal raġunijiet ta' induzzjoni fit-trattament tat-tokolosi.

(2) Mingħajr preġudizzju għal dak imsemmi fil-paragrafu hawn qabel, it-trattament terapewtiku ta' annimali għall-produzzjoni, inkluż annimali għat-tnissil fl-aħħar tal-ħajja riproduttiva tagħhom, huwa projbit.

Ċertu trattament permessi.

7. (1) Fir-rigward tal-annimali fl-akwakultura, ħut li għadu żgħir jista' jiġi kkurat għall-ewwel tlett xhur għar-raġuni ta' inversjoni ta' sess permezz ta' prodotti mediċinali veterinarji li għandhom effetti androġeniċi u li huma awtorizzati skond id-Direttivi tal-Unjoni Ewropea 81/851/KEE u 81/852/KEE.

(2) Fil-każijiet stipulati f'din ir-regola, il-veterinarju għandu jagħmel riċetta li ma tistax tiġi mġedda, u għandu jispeċifika l-kura in kwistjoni u l-kwantità tal-prodott meħtieġ u għandu jniżżel il-prodotti preskritti:

Iżda trattament zootekniku ta' annimali tal-produzzjoni, inkluż matul il-perjodu ta' tħaxxin għall-annimali tat-tnissil fl-aħħar tal-ħajja riproduttiva tagħhom, huwa projbit.

8. (1) Prodotti ormonali u *Beta-agonists* li huma awtorizzati skond ir-regola 6 għandhom ikunu skond il-ħtiġijiet stabbiliti fid-Direttivi tal-Unjoni Ewropea 81/851/KEE u 81/852/KEE. Awtorizzazzjoni ta' amministrazzjoni ta' prodotti ormonali u *Beta-agonists*.

(2) Mingħajr preġudizzju għal subregola (1), is-segwenti mhumiex awtorizzati:-

(a) prodotti ormonali li ġejjin:

(i) prodotti li jaġixxu ta' depositi;

(ii) prodotti b'*withdrawal* period ta' iktar minn 15-il ġurnata wara t-tmiem tat-trattament;

(iii) prodotti li:

(1) huma awtorizzati taħt regoli li jippreċedu xi liġi nazzjonali li tistabbilixxi proċeduri in konformità ma' ftehim internazzjonali għall-awtorizazzjoni u s-superviżjoni ta' prodotti mediċinali għall-użu mill-bniedem u dak veterinarju;

(2) li l-kundizzjonijiet ta' użu tagħhom m'humiex magħrufa; jew

(3) fejn ma jeżistux reaġenti jew apparat għall-użu fit-tekniċi analitiċi sabiex tinstab il-preżenza ta' residwi li jeċċedu l-limiti permessi; u

(b) prodotti mediċinali veterinarji li fihom *beta-agonists* li għandhom *withdrawal period* ta' iktar minn 28 ġurnata wara li jkun spiċċa t-trattament.

9. (1) Għall-fini ta' kummerċ, huwa permess, it-tqegħid fis-suq ta' annimali għat-tnissil u annimali għat-tnissil fl-aħħar tal-ħajja riproduttiva tagħhom illi, matul dak il-perjodu tal-aħħar, ikunu ħadu trattament msemmi fir-regola 6 biex tiġi awtorizzata l-affissjoni ta' marki ta' saħħa ta' Anness I, Kapitolu XI, (50) tad-Direttiva tal-Unjoni Ewropea 64/433/KEE fuq laħam minn annimali bħal dawn fejn il-kundizzjonijiet stipulati fir-regola 6 u l-*withdrawal periods* minimi stipulati f'regola 8(2), taħt l-paragrafu (a) (ii) jew (b) rispettivament jew il-*withdrawal periods* stipulati fl-awtorizazzjoni għat-tqegħid fis-suq, jiġu mħarsa: Awtorizzazzjoni ta' tqegħid fis-suq ta' annimali għat-tnissil.

Iżda l-kummerċ fi żwiemel ta' valur għoli, u b'mod partikolari żwiemel tal-ġiri, żwiemel tal-kompetizzjonijiet, żwiemel taċ-ċirku u żwiemel intenzjonati għat-tnissil jew għall-esibizzjonijiet, inklużi *equidae* reġistrati li ġew amministrati bi prodotti mediċinali veterinarji li fihom *allyl trenbolone* jew *beta-agonists* għar-raġunijiet imsemmija f'regola 6, jista' jsir qabel it-tmiem tal-*withdrawal period*, sakemm il-kundizzjonijiet marbuta ma' l-amministrazzjoni jkunu mħarsa u t-tip u d-data tal-kura huma mniżżla fiċ-ċertifikat jew fil-passaport li jakkumpanja dawn l-annimali.

(2) Laħam jew prodotti minn annimali li ġew amministrati b'sustanzi li għandhom effett estroġeniku, androġeniku jew ġestaġeniku jew *beta-agonists* skond il-provvedimenti ta' dispensa ta' dawn ir-regoli ma jistgħux jitqegħdu fis-suq għall-konsum mill-bniedem, ħlief meta l-annimali in kwistjoni ikunu ġew kurati minn prodotti mediçinali veterinarji li jħarsu l-ħtiġijiet imsemmija f'regola 8 u sakemm il-*withdrawal period* stipulat ikun ġie osservat qabel ma l-annimali jkunu ġew maqtula.

Pussess u użu ta' sustanzi minn persuni awtorizzati.

10. (1) L-Awtorità kompetenti għandha tamministra l-pussess tas-sustanzi msemmija f'regoli 4 u 5(i) lil persuni awtorizzati minn kull liġi oħra skond l-Artiklu 1 (5) tad-Direttiva tal-Unjoni Ewropea 81/851/KEE, fil-perjodu tal-importazzjoni, manifattura, ħażna, distribuzzjoni, bejgħ u użu ta'dawk is-sustanzi.

(2) L-Awtorità għandha wkoll mingħajr preavviż, flimkien mal-kontrolli stabbiliti fl-Ordnijiet li jirregolaw it-tqegħid fis-suq tad-diversi prodotti relattivi, twettaq kontrolli uffiċjali stabbiliti fl-Artiklu 11 tad-Direttiva tal-Unjoni Ewropea 96/23/KEE, bil-ħsieb li jiġi żgurat:-

(a) il-pusses jew preżenza ta' sustanzi jew prodotti projbiti taħt ir-regola 5, intiżi biex jiġu amministrati lill-annimali sabiex jitħaxxnu;

(b) it-trattament illegali tal-annimali;

(c) in-nuqqas ta' osservazzjoni tal-*withdrawal periods* stipulati f'regola 8;

(d) in-nuqqas ta' osservazzjoni tar-restrizzjonijiet fuq l-użu ta' ċertu sustanzi jew prodotti stipulati f'regola 6.

(3) L-eżamijiet għall-preżenza ta' sustanzi msemmija fis-subregola (1) fl-annimali, fl-ilma tax-xorb tal-annimali u fil-

postijiet kollha fejn jitrabbew jew jinżammu l-annimali, residwi tas-sustanzi msemmija hawn qabel f'annimali ħajjin, fil-ħmieġ u fil-fluwidi tagħhom u fit-tessuti u fil-prodotti tal-annimali għandhom isiru skond l-Annessi III u IV tad-Direttiva 96/23/KEE.

(4) Meta l-kontrolli stabbiliti fis-sub-regoli (2) u (3) juru l-preżenza ta' sustanzi jew prodotti li l-użu jew pussess tagħhom huwa projbit, jew il-preżenza ta' residwi ta' sustanzi li l-amministrazzjoni tagħhom taqa' taħt il-kappa ta' trattament illegali, dawk is-sustanzi jew prodotti jkunu konfiskati, filwaqt illi kull annimal ikkurat jew il-laħam tiegħu jitqiegħed taħt superviżjoni uffiċjali sakemm jiġu applikati l-penali meħtieġa.

(5) Meta jirriżulta nuqqas ta' ħarsien mar-rekwiżiti ta' subregola (2) paragrafi (b) u (ċ) ta' din ir-regola, l-Awtorità għandha tieħu dawk il-miżuri adatti b'konformità mal-gravita' tal-ksur tal-liġi.

Żamma ta' reġistri ta' sustanzi.

11. (1) Mingħajr preġudizzju għad-Direttiva 81/851/KEE, persuni fi sħab li jixtru jew jipproduċu sustanzi li għandhom effett tirostatiku, estroġeniku, androġeniku jew ġestaġeniku u *beta-agonists*, persuni bi sħab awtorizzati f'kull kapaċità li jqegħdu fis-suq sustanzi bħal dawk u persuni fi sħab li jixtru jew jipproduċu prodotti mediċinali veterinarji u farmaċewtiċi minn sustanzi bħal dawn, għandhom iżommu reġistri li jkollhom dettalji, f'ordni kronoloġiku, tal-kwantitajiet prodotti jew akwistati u dawk mibjugħin jew użati għall-produzzjoni ta' prodotti mediċinali veterinarji u farmaċewtiċi u l-ismijiet tal-persuni li lilhom ikunu ġew mibjugħa dawn il-kwantitajiet jew mingħand min inxtraw.

(2) L-informazzjoni f'subregola (1) għandha tkun disponnibli għall-awtorità kompetenti meta din titlobhom u, fil-każ ta' informazzjoni li tinżamm f'kompjuter, fil-forma ta' karta stampata.

Nuqqas ta' ħarsien ta' dawn ir-regoli.

12. Meta r-rizultati ta' kontrolli li jkunu saru mill-Awtorità juru nuqqas ta' ħarsien tar-rekwiżiti ta' dawn ir-regoli fil-pajjiż ta' oriġini tal-annimali jew prodotti, l-awtorita' kompetenti għandha tirrikorri għall-provvedimenti meħuda skond il-proċedura stipulata f'Artiklu RE1 tal-Att dwar is-Servizzi Veterinarji dwar l-assistenza reċiproka bejn awtoritajiet amministrattivi ta' Malta u Stati Membri oħra sabiex tiġi żgurata l-applikazzjoni korretta tal-leġislazzjoni f'materji veterinarji.

Limitazzjoni ta' importazzjoni.

13. (1) Pajjiżi terzi li għandhom leġislazzjoni li tawtorizza t-tqegħid fis-suq u l-amministrazzjoni ta'stilbeni, derivattivi tal-istilbeni, l-imluħ u l-esteri tagħhom, jew ta' sustanzi tireostatiċi għall-amministrazzjoni lil annimali ta' kull speċi li l-laħam jew il-prodotti tagħhom huma maħsuba għall-konsum mill-bniedem ma jistgħu jidhru fuq ebda lista ta' pajjiżi li huma awtorizzati skond il-liġi li jimpurtaw annimali agrikoli jew ta' l-akkwakultura jew laħam u prodotti miksuba minn dawk l-annimali.

(2) Hija projbita l-importazzjoni ġewwa Malta minn pajjiżi terzi fuq xi lista minn dawk imsemmija f'subregola (1):

(a) fil-każ ta' annimali tar-razzett jew tal-akwakultura:-

(i) li jkunu ġew lilhom amministrati prodotti jew sustanzi msemmija f'regola 4 b'kull mezz ikun li jkun;

(ii) li jkunu ġew lilhom amministrati sustanzi jew prodotti msemmija f'punt (i) tar-regola 5, sakemm dawk is-sustanzi jew prodotti ikunu ġew amministrati f'konformità mad-dispożizzjonijiet u mar-rekwiżiti stipulati f'regoli 6 u 9 u l-*withdrawal periods* aċċettati skond rakkomandazzjonijiet internazzjonali jkunu ġew imħarsa; u

(b) laħam jew prodotti li ġejjin minn annimali li l-importazzjoni tagħhom hija projbita taħt il-paragrafu (a).

(3) Mingħajr preġudizzju għas-sub-regoli (1) u (2) ta' din ir-regola, annimali intizi għat-tnissil, annimali tat-tnissil fl-aħħar tal-ħajja riproduttiva tagħhom, jew laħam tagħhom, minn pajjizi terzi jistgħu jiġu impurtati jekk dawn jagħtu garanzija mill-inqas ekwikalenti għal dawk stipulati f'dawn ir-regoli jew li jkunu ġew stabbiliti għall-implimentazzjoni u l-infurzar tal-Kapitolu V tad-Direttiva tal-Unjoni Ewropea 96/23/KEE fuq miżuri li għandhom jittieħdu fil-każ ta' ksur ta' liġi.

(4) Kontrolli fuq importazzjoni minn pajjizi terzi ghandhom isiru skond l-artikolu 17 (2) and (3) tal-Att dwar is-Servizzi Veterinarji.

Tħassir ta' A.L. 96 tal-2005.

14. Ir-regoli tal-2005 dwar Projbizzjoni ta' l-Użu ta' Sustanzi li Għandhom Azzjoni Ormonali jew Tirostatika u ta' Betaagnosti fit-Trobbija ta' l-Annimali qegħdin b'dawn jiġu mħassra.

SKEDA

Regolament 4

Lista ta' Sustanzi Projbiti:

Lista A: sustanzi projbiti

- Sustanzi tireostatiċi,
- Stilbeni, derivattivi tal-istilbeni, l-imluħ u l-esteri tagħhom,
- Estradjol 17ß u d-derivattivi tiegħu li jixbħu l-esteri.

Lista B: sustanzi projbiti b'derogi

- *Beta-agonists*.

L.N. 87 of 2009

VETERINARY SERVICES ACT (CAP. 437)

Prohibition on the Use of Certain Substances in Stockfarming having a Hormonal or Thyrostatic Effect and of Beta-agonists Rules 2009

IN exercise of the powers conferred under article 13(a) of the Veterinary Services Act, the Minister for Resources and Rural Affairs has made the following rules:-

Title, scope and commencement.

1. (1) The title of these rules is Prohibition on the Use of Certain Substances in Stockfarming having a Hormonal or Thyrostatic Effect and of Beta-agonists Rules 2009.

(2) The scope of these regulations is to implement the rules found under the European Union Council Directive 96/22/EEC establishing the prohibition on the use of certain substances in stockfarming, while amending these rules according to the new rules found under the European Union Parliament and Council Directive 2008/97/EC, concerning the prohibition of the use of certain substances for animals whereby such prohibition shall be limited.

Interpretation.

2. (1) Unless otherwise stated in these rules, the definitions in the Veterinary Services Act shall apply.

(2) For the purpose of these rules, and unless the context otherwise requires:-

"the authority" means the Veterinary Services Authority in Malta as provided under article 2 of the Veterinary Services Act;

"farm animals" means domestic animals of the bovine, porcine, ovine and caprine species, domestic solipeds, poultry and rabbits, as well as wild animals of those species and wild ruminants which have been raised on a holding;

"illegal treatment" means the use of unauthorised substances or products or the use of substances or products authorised by any other law for purposes or under conditions other than those laid down in any other law;

"Member State" means a State which is a Member within the European Community;

"therapeutic treatment" means the administering prescribed under rule 6 of these rules, to an individual farm animal of an authorised substance to treat, after examination by a veterinarian, a fertility problem, including the termination of unwanted gestation, and in the case of beta-agonists, to induce tocolysis in cows when claving as well as to treat respiratory problems, navicular desease and laminitis and to induce tocolysis in equidae;

"Third country" means a state which is not a member within the European Community;

"zootechnical treatment" means the administering of any substance to an individual farm animal and in the case of aquaculture animals to a group of breeding animals for sex inversion on a veterinarian's prescription and under his responsibility and which is prohibited under rule 7 (2) hereof.

Applicability.

3. These rules shall apply to the prohibition of the use of certain substances in stockfarming whereby such application shall be limited only to animals intended for food-producing and that the prohibition for pet animals shall be withdrawn.

Prohibitions.

4. The placing on the market of the substances listed in the Schedule for administering to any animals, the meat and products of which are intended for human consumption, for purposes other than those provided in rule 5 is hereby being prohibited.

Other prohibitions.

5. In Malta, the following shall also be prohibited –

(i) the administering to a farm or aquaculture animal, by any means whatsoever, of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and of beta-agonists;

(ii) the holding, except under official control, of animals referred to in paragraph (i) on a farm, the placing on the market or slaughter for human consumption of farm animals or of aquaculture animals which contain the substances referred to in paragraph (i) or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with rules 6 or 7;

(iii) the placing on the market for human consumption of aquaculture animals to which substances referred to in paragraph (i) have been administered and of processed products derived from such animals;

(iv) the placing on the market of meat of the animals referred to in paragraph (ii); and

(v) the processing of the meat referred to in paragraph (iv).

Exemptions from prohibitions.

6. (1) Saving the provisions in rules 4 and 5, the following shall be authorised:-

(i) the administering to farm animals, for therapeutic purposes, of ßoestradiol 17, testosterone and progesterone and derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application:

Provided that, veterinary medicinal products used for therapeutic treatment must comply with the requirements for placing on the market laid down in European Union Directive 81/851/EEC and they must be administered only by a veterinarian, by injection or for the treatment of ovarian disfunction in the form of vaginal spirals, but not by implant, to farm animals which have been clearly identified. Treatment of identified animals must be registered by the veterinarian responsible. The latter must record at least the following details in a register, which may be the one provided for in European Union Directive 81/851/EEC:-

(a) type of treatment;

(b) the type of products authorised;

(c) the date of treatment;

(d) the identity of the animals treated:

Provided also that the register must be made available to the Veterinary Services at its request:-

(ii) the administering for therapeutic purposes of authorised veterinary medicinal products containing:-

(a) allyl trenbolone, administered orally, or beta-agonists to equidae, provided they are used in accordance with the manufacturer's instructions;

(b) beta-agonists, in the form of an injection to induce tocolysis in cows when calving. Such substances must be administered by a veterinarian or, in the case of the veterinary medicinal products referred to in paragraph (a) hereof, under his direct responsibility, treatment must be registered by the veterinarian responsible, who shall record at least the details referred to in item (i). Farmers shall be prohibited from holding veterinary medicinal products containing beta-agonists which may be used for induction purposes in the treatment of tocolysis.

(2) Without prejudice to that mentioned in the previous paragraph, therapeutic treatment of production animals, including breeding animals at the end of their reproductive life, shall be prohibited.

Certain authorised treatments.

7. (1) With regard to aquaculture animals, young fish may be treated for the first three months for the purpose of sex inversion with veterinary medicinal products that have an androgenous action and are authorised in accordance with European Union Directives 81/851/EEC and 81/852/EEC.

(2) In the cases provided for in this rule, the veterinarian shall make out a non-renewable prescription, specifying the treatment in question and the quantity of the product required and shall record the products prescribed:

Provided that zootechnical treatment of production animals, including during the fattening period for breeding animals at the end of their reproductive life, shall be prohibited.

Authorisation of administration of hormonal products and Beta-agonists.

8. (1) Hormonal products and Beta-agonists which are authorised in accordance with rule 6 shall be in accordance with the requirements established in European Directives 81/851/EEC and 81/852/EEC.

(2) Without prejudice to sub-rule (1), the following are not authorised:-

(a) the following hormonal products:

(i) products acting as a deposit;

(ii) products with a withdrawal period of more than 15 days after the end of treatment;

(iii) products which:

(1) were authorised under rules that preceded the national legislation laying down procedures in conformity with international agreement for the authorisation and supervision of medicinal products for human and veterinary use;

(2) whose conditions of use are not known; or

(3) which no reagents or equipment exist for use in the analytical techniques for detecting the presence of residues in excess of the permitted limits; and

(b) veterinary medicinal products containing beta-agonists which have a withdrawal period of more than 28 days after the end of treatment.

Authorisation for the placing on the market of animals for breeding.

9. (1) For the purpose of trade, it is permitted, the placing on the market of animals for breeding and breeding animals at the end of their reproductive life which, during the latter period, have undergone a treatment referred to in rule 6 in order to be authorised the affixing of the health mark of Annex I, Chapter XI, (50) of Directive 64/433/EEC to meat from such animals where the conditions laid down in rule 6 and the minimum withdrawal periods laid down in rule 8 (2), under paragraph (a) (ii) or (b) respectively or the withdrawal periods provided for in the authorisation to place on the market are complied with:

Provided that, trade in highvalue horses, and in particular racehorses, competition horses, circus horses or horses intended for stud purposes or for exhibitions, including registered equidae to which veterinary medicinal products containing allyl trenbolone or betaagonists have been administered for the purposes referred to in rule 6, may take place before the end of the withdrawal period, provided that the conditions governing administration are fulfilled and that the type and date of treatment are entered on the certificate or passport accompanying these animals.

(2) Meat or products from animals to which substances having an oestrogenic, androgenic or gestagenic effect or beta-agonists have been administered in accordance with the dispensatory provisions of these regulations may not be placed on the market for human consumption unless the animals in question have been treated with veterinary medicinal products complying with the requirements of rule 8 and in so far as the withdrawal period laid down was observed before the animals were slaughtered.

Possession and use of substances by authorised persons.

10. (1) The competent Authority shall administer the possession of substances referred to in rules 4 and 5 (i) to the persons authorised by any other law in accordance with Article 1 (5) of European Directive 81/851EEC during the period of importation, manufacture, storage, distribution, sale and use of such substances.

(2) The Authority shall also without prior notice, in addition to the checks provided for in the Orders governing the placing on the market of the various products in question, carry out official checks provided for in Article 11 of Directive 96/23/EEC with a view to ascertaining:-

(a) the possession or presence of substances or products prohibited under rule 5, intended to be administered to animals for the purpose of fattening;

(b) the illegal treatment of animals;

(c) failure to observe the withdrawal periods provided for in regulation 8;

(d) failure to observe the restrictions on the use of certain substances or products laid down in rule 6.

(3) The tests for the presence of the substances referred to in sub-rule (1) in animals, in the drinking water of animals and in all places where animals are bred or kept, residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products, shall be carried out in accordance with Annexes III and IV to Directive 96/23/EEC.

(4) Where the checks provided for in sub-rules (2) and (3) reveal the presence of substances or products the use or possession of which is prohibited, or the presence of residues of substances the administering of which comes under the heading of illegal treatment, such substances or products are confiscated, while

any animals treated or the meat therefrom is placed under official supervision until the requisite penalties have been applied.

(5) Where failure to comply with the requirements of sub-rule (2) paragraphs (b) and (c) of this rule results, the Authority shall take such appropriate measures in conformity with the gravity of the law infringement.

Keeping of registers of substances.

11. (1) Without prejudice to Directive 81/851/EEC, undertakings buying or producing substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and betaagonists, undertakings authorised in any capacity to market such substances and undertakings buying or producing pharmaceutical and veterinary medicinal products from such substances shall be required to keep registers detailing, in chronological order, quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary medicinal products and the names of the persons to whom such quantities were sold or from whom they were purchased.

(2) The information in sub-rule (1) hereof shall be made available to the competent Authority at its request and, in the case of computerised records, in the form of a print-out.

Failure to comply with these rules.

12. Where the results of checks carried out by the Authority show failure to comply with the requirements of these rules in the country of origin of the animals or products, the competent authority shall have recourse to provisions taken according to the procedure laid down in Article RE1 of the Veterinary Services Act on mutual assistance between the administrative authorities of Malta and of the Member States to ensure the correct application of legislation on veterinary.

Limitation of importation.

13. (1) Third countries whose legislation authorizes the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to animals of all species may not appear on any of the lists of countries provided for under veterinary legislation from which Malta authorizes to import farm or aquaculture animals or meat or products obtained from such animals.

(2) In Malta, it is prohibited to import from third countries on any of the lists referred to in sub-rule (1) of:

(a) farm or aquaculture animals:

(i) to which products or substances referred to in rule 4 have been administered by any means whatsoever;

(ii) to which substances or products referred to in point (i) of rule 5 have been administered, unless those substances or products have been administered in compliance with the provisions and requirements laid down in rules 6 and 9 and the withdrawal periods allowed in international recommendations have been observed; and

(b) meat or products obtained from animals the importation of which is prohibited under paragraph (a).

(3) Without prejudice to sub-rules (1) and (2) of this rule, animals intended for breeding, breeding animals at the end of their reproductive life, or meat there from, from third countries may be imported subject to their affording guarantees at least equivalent to those laid down in these regulations or which have been established for the implementation and enforcement of Chapter V of Directive 96/23/EEC on measures to be taken in the event of law infringement.

(4) Checks on imports from third countries shall be carried out in accordance with Article 17 (2) and (3) of the Veterinary Services Act.

14. Prohibition on the Use in Stock-Farming of Substances having a Hormonal or Thyrostatic Action and of Betaagonists Rules, 2005 are hereby being repealed.

Repeal of L.N. 96 of 2005.

SCHEDULE

Regulation 4

List of Prohibited Substances

List A: prohibited substances

- Thyrostatic Substances,

- Stilbenes, stilbene derivatives, their salts and esters,

- Oestradiol 17ß and its ester-like derivatives.

List B: prohibited substances with derogations

- Beta-agonists

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — ***Printed at the Government Printing Press on recycled paper***

Prezz/*Price*
€0.84