

Naghti l-kunsens tieghi.

(L.S.)

EDWARD FENECH ADAMI  
President

21 ta' Dicembru, 2007

**ATT Nru. XXIX ta' l-2007**

*Att biex jemenda l-Att dwar l-Awtorità Maltija dwar l-iStandards u Diversi Liġijiet.*

IL-PRESIDENT bil-parir u l-kunsens tal-Kamra tad-Deputati, imlaqqgħa f'dan il-Parlament, u bl-awtorità ta' l-istess, hareġ b'liġi dan li ġej:

**1.** (1) It-titolu fil-qosor ta' dan l-Att hu Att ta' l-2007 li jemenda l-Att dwar l-Awtorità Maltija dwar l-iStandards u Diversi Liġijiet. Titolu fil-qosor u bidu fis-sehh.

(2) Dan l-Att għandu jiġi fis-sehh fid-data li l-Ministru responsabbli għall-Awtorità Maltija dwar l-iStandards jista' jistablixxi b'avviż fil-Gazzetta u jistgħu jiġu hekk ukoll stabbiliti dati differenti għal disposizzjonijiet differenti u għal għanijiet differenti ta' dan l-Att.

**Taqsimha I**

**2.** Din it-taqsimha temenda u għandha tinqara u tiftiehem haġa wahda ma' l-Att dwar l-Awtorità Maltija dwar l-iStandards, hawn iżjed 'il quddiem f'din it-Taqsimha msejjah "l-Att prinċipali". Emenda ta' l-Att dwar l-Awtorità Maltija dwar l-iStandards, Kap. 419.

**3.** L-artikolu 3 ta' l-Att prinċipali għandu jiġi emendat kif ġej: Emenda ta' l-artikolu 3 ta' l-Att prinċipali.

(a) fis-subartikolu (2), minflok il-kliem "L-Awtorità titmexxa minn Kunsill" għandhom jidhlu l-kliem "l-Awtorità

ghandu jkollha Kunsill li jkollu l-funzjonijiet imsemmija fis-subartikolu (2A) ta' dan l-artikolu u"; u

(b) minnufih wara s-subartikolu (2), ghandhom jigu miżjuda dawn is-subartikoli godda li ġejjin:-

“(2A) Il-Kunsill ghandu jkollu dawn il-funzjonijiet li ġejjin:-

(a) li jiddetermina l-*policy* generali u l-ghanijiet ta' l-Awtorità fil-kuntest tal-*policies* kwadri stabbiliti mill-Gvern;

(b) li jkun il-punt ta' kuntatt bejn l-Awtorità u s-setturi li din tirrappreżenta, u persuni ohra li jkollhom xi interess f'dawn;

(c) li japprova kull ftehim propost taht is-subartikolu (11) ta' dan l-artikolu qabel ma dan il-ftehim jiġi moghti lill-Ministru biex japprovah skond dan is-subartikolu;

(d) li japprova d-dikjarazzjonijiet finanzjarji ta' l-Awtorità;

(e) li jiggarantixxi l-indipendenza tal-funzjonijiet tad-Direttorati.

(2B) Bl-eċċezzjoni taç-*Chairman*, li ghandu jiehu azzjoni fuq ġudizzju individwali tieghu fl-interess ta' l-Awtorità, il-membri tal-Kunsill ghandhom jigu appuntati bhala rappreżentanti tas-setturi li jkunu jirrappreżentaw.”.

Emenda ta' l-artikolu 16 ta' l-Att prinċipali.

**4.** Fis-subparagrafu (ii) tal-paragrafu (b) ta' l-artikolu 16 ta' l-Att prinċipali, minflok il-kliem “l-iżgurar tad-disponibilità” ghandhom jidhlu l-kliem “id-disponibilità jew l-iżgurar tad-disponibilità”.

Emenda ta' l-artikolu 19 ta' l-Att prinċipali.

**5.** Fis-subartikolu (1) ta' l-artikolu 19 ta' l-Att prinċipali, minflok il-kliem “l-*iStandards* u jwettqu l-kondizzjonijiet preskritti fl-*iStandards*” ghandhom jidhlu l-kliem “l-*iStandards* u r-regolamenti tekniċi u jwettqu l-kondizzjonijiet stipulati fihom”.

## Taqsimha II

6. Din it-Taqsimha temenda u ghandha tinqara u tiftiehem haġa wahda ma' l-Att dwar is-Sigurezza tal-Prodotti, hawn iżjed 'il quddiem f' din it-Taqsimha msejjah "l-Att prinċipali".

Emenda ta' l-Att  
dwar is-Sigurezza  
tal-Prodotti,  
Kap. 427.

7. Artikolu 2 ta' l-Att prinċipali ghandu jiġi emendat kif ġej :

Emenda ta' l-  
artikolu 2 ta' l-Att  
prinċipali.

(a) minflok it-tifsira tal-kelma "Direttur" f' dan l-artikolu ghandu jidhol dan li ġej:-

“ “id-Direttur” tfisser il-Kap tad-Direttorat tas-Sorveljanza fuq is-Suq ta' l-Awtorità Maltija dwar l-*Standards* stabbilit taht l-artikolu 3 ta' l-Att dwar l-Awtorità Maltija dwar l-*Standards* jew kull kap ta' kull Direttorat iehor skond ma jista' l-Ministru jahtar minflok b'Ordni u tinkludi, fil-limitu ta' l-awtorità mogħtija, kull uffiċjal li jiġi awtorizzat għaldaqshekk minn dak il-Kap, bil-miktub, biex jaġixxi f' ismu għal xi wiehed mill-ghanijiet ta' dan l-Att;”;

(b) It-tifsira tal-kelma "Dipartiment" f' dan l-artikolu ghandha tithassar; u

(ċ) minflok it-tifsira tal-kelma "prodott mhux perikoluż" f' dan l-artikolu ghandu jidhol dan li ġej:-

“ “prodott mhux perikoluż” tfisser kull prodott li, taht kondizzjonijiet ta' użu normali jew li jkunu raġonevolment prevedibbli, inkluża l-hajja ta' dak il-prodott, u, fejn applikabbli, tqegħid għas-servizz, rekwiżiti ta' installazzjoni u manutenzjoni, ma johloqx riskju jew johloq biss ir-riskji minimi, li huma kompatibbli ma' l-użu tal-prodott, li huma kkunsidrati bħala aċċettabbli u konsistenti ma' livell għoli ta' protezzjoni għas-sigurtà u s-saħħa tal-bniedem, meta wiehed iqis partikolarment il-fatturi li ġejjin:

(a) il-karatteristiċi tal-prodott, inklużi l-kompożizzjoni, l-ippakkjar, l-istruzzjonijiet biex jingħaqad f'haġa wahda u l-manutenzjoni tiegħu;

(b) l-effett li jkollu fuq prodotti oħra, meta jkun raġonevolment prevedibbli li jiġi wżat ma' prodotti oħra;

(ċ) il-preżentazzjoni tal-prodott, l-immarkar fuqu, kull istruzzjoni għall-użu u għat-tnehhija tiegħu u kull indikazzjoni jew informazzjoni oħra mogħtija mill-produttur;

(d) il-kategoriji ta' konsumaturi li jkunu taht riskju meta jużaw il-prodott, partikolarment tfal, persuni b'dizabilità u anzjani:

Iżda l-possibbiltà li jistghu jintlahqu livelli oghla ta' sigurtà jew id-disponibilità ta' prodotti oħra li jkollhom livell aktar baxx ta' riskju ma jikkostitwux bażi biex prodott jiġi meqjus bhala prodott perikoluż;”.

Sostituzzjoni ta' l-artikolu 27 ta' l-Att prinċipali.

**8.** Minflok l-artikolu 27 ta' l-Att prinċipali għandu jidhol dan li ġej:-

“Funzjonijiet ta' l-Awtorità Maltija dwar l-*Standards*.

27. Mingħajr preġudizzju għal kull funzjoni oħra assenjata lilha minn xi liġi oħra, l-Awtorità Maltija dwar l-*Standards*, għandu jkollha wkoll dawn il-funzjonijiet li ġejjin:

(a) li tistabilixxi u perjodikament taġġorna l-programmi tas-sorveljanza settorali fir-rigward tal-kategoriji kollha ta' prodotti u riskji;

(b) li ssegwi u tagħmel aġġornament tat-tagħrif xjentifiku li jirrigwarda s-sigurezza tal-prodotti, kif ukoll rapporti perjodiċi dwar attivitajiet ta' sorveljanza, riżultanzi u riżultati miksuba;

(ċ) li perjodikament tirrevedi u tevalwa t-twettiq tal-attivitajiet tal-kontroll u l-effettività tagħhom, u, jekk ikun meħtieġ, tirrevedi l-approċ tas-sorveljanza u l-organizzazzjoni opportuna.”.

Emenda ta' l-artikolu 22 ta' l-Att prinċipali

**9.** Fl-artikolu 22 ta' l-Att prinċipali, il-kliem “tad-Dipartiment,” għandu jiġi mħassar.

Emenda ta' l-artikolu 28 ta' l-Att prinċipali.

**10.** Fis-subartikolu (1) ta' l-artikolu 28 ta' l-Att prinċipali, minflok il-kliem “jista', bi ftehim mad-Direttur ta' Sorveljanza fuq is-Suq, jagħmel jew” għandhom jidhlu l-kliem “jista', bi ftehim mal-kap tad-Direttorat għall-Affarijiet Regolatorji stabbilit taht l-Att dwar l-Awtorità Maltija dwar l-*Standards* jew kull kap iehor ta' xi Direttorat iehor skond ma jista' l-Ministru jahtar minfloku b'Ordni”.

Emenda ta' l-artikolu 38 ta' l-Att prinċipali.

**11.** Minnufih wara l-paragrafu (k) fl-artikolu 38 ta' l-Att prinċipali għandu jidjed dan il-paragrafu ġdid li ġej:

“(l) biex isemmi kull haġa, oġġett jew sustanza manifatturati bhala “prodott” għal xi jew kull raġuni skond dan l-Att.”.

### Taqsimha III

**12.** Din it-Taqsimha temenda u ghandha tinqara u tiftiehem haġa wahda ma' l-Att dwar il-Kontroll tal-Pesticidi, hawn iżjed 'il quddiem f' din it-Taqsimha msejjha "l-Att prinċipali".

Emenda ta' l-Att  
dwar il-Kontroll tal-  
Pesticidi, Kap. 430.

**13.** L-artikolu 2 ta' l-Att prinċipali, ghandu jiġi emendat kif ġej:-

Emenda ta' l-  
artikolu 2 ta' l-Att  
prinċipali.

(a) minnufih wara t-tifsira tal-kelma "awtorizzazzjoni" f' dan l-artikolu ghandha tidhol din it-tifsira ġdida li ġejja:-

“ “l-Awtorità” tfisser l-Awtorità Maltija dwar l-*Standards* stabbilita permezz ta' l-artikolu 3(1) ta' l-Att dwar l-Awtorità Maltija dwar l-*Standards* jew Direttorat ieħor skond ma jista' l-Ministru jahtar minfloku b'Ordni”;

Kap. 419.

(b) fit-tifsira tal-kelma “Direttur” f' dan l-artikolu minflok il-kliem “Direttur tad-Dipartiment” ghandhom jiġu sostitwiti l-kliem “kap tad-Direttorat għall-Affarijiet Regolatorji stabbilit taħt l-Att dwar l-Awtorità Maltija dwar l-*Standards* jew kap ta' kull Direttorat ieħor skond ma jista' l-Ministru jahtar minfloku b'Ordni”; u

(ċ) it-tifsira tal-kelma “Dipartiment” ghandha tiġi mħassra.

**14.** F'paragrafu (d) tas-subartikolu (2) ta' l-artikolu 10 ta' l-Att prinċipali, minflok il-kliem “Awtorità Maltija dwar l-*Standards*” ghandhom jidhlu l-kliem “Dipartiment tas-Sahha tal-Pjanti”.

Emenda ta' l-  
artikolu 10 ta' l-Att  
prinċipali.

### Taqsimha IV

**15.** Din it-Taqsimha temenda u ghandha tinqara u tiftiehem haġa wahda ma' l-Att dwar is-Sigurtà fl-Ikel, hawn iżjed 'il quddiem f' din it-Taqsimha msejjha “l-Att prinċipali”.

Emenda ta' l-Att  
dwar is-Sigurtà fl-  
Ikel, Kap. 449.

**16.** Minnufih wara l-artikolu 7 ta' l-Att prinċipali ghandu jidhol dan l-artikolu ġdid li ġej:

Emenda ta'  
l-artikolu 7 dwar  
l-Att prinċipali.

“Il-Kummissjoni teżerċita l-funzjonijiet tagħha permezz ta' l-Awtorità. 7A. (1) Il-Kummissjoni ghandha teżerċita l-funzjonijiet tagħha taħt l-artikolu 7(1) (b), (ċ), (d), (e), (g), (h), (j) u (l) permezz ta' l-Awtorità Maltija dwar l-*Standards* kif stabbilita bl-artikolu 3 ta' l-Att dwar l-Awtorità Maltija dwar l-*Standards*.”

Kap. 419.

(2) L-Awtorità Maltija dwar l-*Standards* ghandha wkoll toħroġ dawk il-linji ta' gwida li jistghu jkunu

mehtieġa rigward il-funzjonijiet imsemmija fis-subartikolu (1) ta' dan l-artikolu.

(3) Il-Kummissjoni tista' titlob lil l-Awtorità Maltija dwar l-*Standards* għal kull informazzjoni akkwistata jew rapport preparat mill-Awtorità waqt l-eżerċizzju tal-funzjonijiet tagħha taht dan l-artikolu u l-Awtorità għandha tikkonforma ruhha ma' din it-talba.

(4) Il-funzjonijiet ta' l-Awtorità Maltija dwar l-*Standards* taht dan l-artikolu għandhom ikunu mingħajr preġudizzju għal kull funzjoni oħra assenjata lilha taht xi liġi oħra.”.

Emenda ta' l-artikolu 9 ta' l-Att prinċipali.

**17.** Fis-subartikolu (1) ta' l-artikolu 9 ta' l-Att prinċipali, minflok il-kliem “id-Direttur tas-Sorveljanza fuq is-Suq” għandhom jidhlu l-kliem “il-Kap tad-Direttorat tas-Sorveljanza fuq is-Suq tal-Awtorità Maltija dwar l-*Standards* stabbilit taht l-Att dwar l-Awtorità Maltija dwar l-*Standards* jew kull kap ta' kull Direttorat iehor skond ma l-Ministru jista' jahtar minfloku b'Ordni.”.

## Taqsimha V

Emenda ta' l-Att dwar il-Mediċini, Kap. 458.

**18.** Din it-Taqsimha temenda u għandha tinqara u tiftiehem haġa waħda ma' l-Att dwar il-Mediċini, hawn iżjed 'il quddiem f'din it-Taqsimha msejjah “l-Att prinċipali”.

Sostituzzjoni ta' l-artikolu 4 ta' l-Att prinċipali.

**19.** Minflok l-artikolu 4 ta' l-Att prinċipali għandu jidhol dan li ġej:-

“Twaqqif ta' l-Awtorità dwar il-Mediċini jew Awtorità oħra.

4. Għandha tiġi stabbilita Awtorità dwar il-Mediċini, jew dik l-awtorità oħra li l-Prim Ministru jista', wara konsultazzjoni mal-Ministru responsabbli għas-saħħa, jahtar skond l-artikolu 110 ta' dan l-Att.”.

Emenda ta' l-artikolu 103 ta' l-Att prinċipali.

**20.** Minflok is-subartikolu (5) ta' l-artikolu 103 ta' l-Att prinċipali għandu jidhol dan li ġej:

“(5) (a) Meta jkun ġie elevat xi prodott mediċinali taht id-disposizzjonijiet ta' dan l-Att u sid il-prodott jagħti l-kunsens tiegħu bil-miktub għall-qirda ta' dak il-prodott mediċinali, l-Awtorità dwar il-Liċenzjar tista', wara li tiegħu dawk il-kampjuni li tista' tkun tehtieġ biex tingieb prova tar-reat, tordna li dak il-prodott mediċinali jiġi meqrud mingħajr preġudizzju għal kull proċediment li jista' jsir kontra l-persuna responsabbli għar-reat,

u l-imsemmija Awtorità dwar il-Liċenzjar ghandha tirrimborsa l-ispejjeż kollha li jkunu saru fil-qirda tal-prodott mediċinali.

(b) F'dawk il-każijiet fejn is-sid jonqos milli jaghti l-kunsens tiegħu għall-qirda tal-prodott mediċinali, l-Awtorità dwar il-Liċenzjar tista' wara li tippreżenta rikors fejn titlob lill-Qorti tordna l-qirda għas-spejjeż tas-sid, tghaddi biex twettaq dik il-qirda.

**21.** Minnufih wara l-artikolu 109 ta' l-Att prinċipali għandu jżidded dan li ġej:

Żjieda ta' l-artikolu 110 ġdid ma' l-Att prinċipali.

“Hatra ta' awtorità kompetenti.

110. (1) Il-Prim Ministru jista', wara konsultazzjoni mal-Ministru responsabbli għas-saħħa, b'Ordni fil-Gazzetta jsemmi lil kull awtorità biex twettaq il-funzjonijiet li kienu jiġu esegwiti mill-Awtorità dwar il-Mediċini taht dan l-Att.

(2) Ordni bhal dan jista' jhassar kull disposizzjoni ta' l-artikoli 5 u 7 sa 13 ta' dan l-Att.

(3) Ordni bhal dan jista' wkoll jemenda jew ihassar is-subartikolu (3) ta' l-artikolu 3 u l-artikoli 4 u 6 ta' dan l-Att.”.

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Mghoddi mill-Kamra tad-Deputati fis-Seduta Nru. 602 tat-12 ta' Diċembru, 2007.

ANTON TABONE  
*Speaker*

RICHARD J. CAUCHI  
*Skrivan tal-Kamra tad-Deputati*

I assent.

(L.S.)

EDWARD FENECH ADAMI  
President

21st December, 2007

**ACT No. XXIX of 2007**

*An ACT to amend the Malta Standards Authority Act and Various Laws.*

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives, in this present Parliament assembled, and by the authority of the same, as follows:

Short title and commencement.

**1.** (1) The short title of this Act is the Malta Standards Authority and Various Laws (Amendment) Act, 2007.

(2) This Act shall come into force on such date as the Minister responsible for the Malta Standards Authority may by notice in the Gazette establish, and different dates may be so established for different provisions and for different purposes of the Act.

**Part I**

Amendment of the Malta Standards Authority Act, Cap. 419.

**2.** This Part amends and shall be read and construed as one with the Malta Standards Authority Act, hereinafter in this Part referred to as “the principal Act”.

Amendment of article 3 of the principal Act.

**3.** Article 3 of the principal Act shall be amended as follows:

(a) in subarticle (2) thereof, for the words “The Authority shall be governed by a Council” there shall be substituted the words “The Authority shall have a Council which shall have the functions set out in subarticle (2A) hereof and”; and

(b) immediately after subarticle (2) thereof, there shall be added the following new subarticles:-

“(2A) The Council shall have the following functions:-

(a) to determine the general policy and objectives of the Authority within the context of the framework policies established by Government;

(b) to act as a liaison point between the Authority and the sectors it represents, and other persons having an interest therein;

(c) to approve any agreement proposed under subarticle (11) of this article before such agreement is forwarded for the concurrence of the Minister in terms of the said subarticle;

(d) to approve the financial statements of the Authority;

(e) to guarantee the functional independence of the Directorates.

(2B) With the exception of the Chairman, who shall act in his own individual judgement in the interests of the Authority, the members of the Council shall be appointed as representatives of the sectors they represent.”.

4. In sub-paragraph (ii) of paragraph (b) of article 16 of the principal Act, for the words “ensuring the availability” there shall be substituted the words “the availability or ensuring the availability”. Amendment of article 16 of the principal Act.

5. In subarticle (1) of article 19 of the principal Act, for the words “the standards and fulfil the conditions prescribed in the standards” there shall be substituted words “the standards and technical regulations and fulfil the conditions prescribed therein”. Amendment of article 19 of the principal Act.

## Part II

6. This Part amends and shall be read and construed as one with the Product Safety Act, hereinafter in this Part referred to as “the principal Act”. Amendment to the Product Safety Act, Cap. 427.

7. Article 2 of the principal Act shall be amended as follows:

(a) for the definition of the expression “Director” therein there shall be substituted the following:-

““Director” means the Head of the Market Surveillance Directorate of the Malta Standards Authority established by article 3 of the Malta Standards Authority Act or such other head of any Directorate as the Minister may by Order designate in his stead and includes, to the extent of the authority given, any officer authorised by such head, in writing, to act in that behalf for any of the purposes of this Act;”;

(b) the definition of the expression “Department” therein shall be deleted; and

(c) for the definition “safe product” therein there shall be substituted the following:-

“safe product” means any product which, under normal or reasonably foreseeable conditions of use, including duration, and, where applicable, putting into service, installation and maintenance requirements does not present any risk or only the minimum risks, compatible with the product’s use, which are considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account in particular the following factors:

(a) the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance;

(b) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(c) the presentation of the product, the labelling, any instructions for its use and disposal and any other indication or information provided by the producer;

(d) the categories of consumers at risk when using the product, in particular children, the disabled and the elderly;

Provided that the possibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be an unsafe product;”.

**8.** For article 27 of the principal Act that shall be substituted the following:- Substitution of article 27 of the principal Act.

“Functions of the Malta Standards Authority. **“27.** Without prejudice to any other functions assigned to it by any other law, the Malta Standards Authority, shall also have the following functions:

(a) to establish and periodically update sectoral surveillance programmes in respect of all categories of products and risks;

(b) to follow up and update scientific knowledge concerning the safety of products, as well as periodical reports on surveillance activities, findings and results achieved;

(c) to periodically review and assess the functioning of the control activities and their effectiveness, and, if necessary, revise the surveillance approach and organisation put in place.”.

**9.** In article 22 of the principal Act, the words “of the Department,” shall be deleted. Amendment of article 22 of the principal Act.

**10.** In subarticle (1) of article 28 of the principal Act, for the words “may, with the concurrence of the Director of Market Surveillance, make or” there shall be substituted words “may, with the concurrence of the head of the Regulatory Affairs Directorate established under the Malta Standards Authority Act or such other head of any Directorate as the Minister may by Order designate in his stead”. Amendment of article 28 of the principal Act.

**11.** Immediately after paragraph (k) of article 38 of the principal Act there shall be added the following new paragraph: Amendment of article 38 of the principal Act.

“(l) designating any manufactured article, item or substance as a ‘product’ for all or any purposes of this Act.”.

### Part III

Amendment to the Pesticides Control Act, Cap. 430.

**12.** This Part amends and shall be read and construed as one with the Pesticides Control Act, hereinafter in this Part referred to as “the principal Act”.

Amendment of Article 2 of the principal Act.

**13.** Article 2 of the principal Act, shall be amended as follows:-

(a) immediately after the definition of the expression “authorisation” therein there shall be added the following new definition:-

Cap. 419.

““the Authority” means the Malta Standards Authority established by article 3(1) of the Malta Standards Authority Act or such other Directorate as the Minister may by Order designate in its stead;”;

(b) in the definition of the expression “Director” therein, for the words “Director of the Department” there shall be substituted the words “the head of the Regulatory Affairs Directorate established under the Malta Standards Authority Act or such other head of any Directorate as the Minister may by Order designate in his stead”; and

(c) the definition of the expression “Department” shall be deleted.

Amendment of article 10 of the principal Act.

**14.** In paragraph (d) of sub-article (2) of article 10 of the principal Act, for the words “Malta Standards Authority” there shall be substituted the words “Plant Health Department”.

### Part IV

Amendment to the Food Safety Act, Cap. 449.

**15.** This Part amends and shall be read and construed as one with the Food Safety Act, hereinafter in this Part referred to as “the principal Act”.

Amendment of article 7 of the principal Act.

**16.** Immediately after Article 7 of the principal Act there shall be inserted the following new article:

Cap. 419.

“The Commission to exercise functions through the Authority.

7A. (1) The Commission shall exercise its functions under article 7(1) (b), (c), (d), (e), (g), (h), (j) and (l) through the Malta Standards Authority as established by article 3 of the Malta Standards Authority Act.

(2) The Malta Standards Authority shall also issue such guidelines as may be necessary in relation to the functions mentioned in subarticle (1) of this article.

(3) The Commission may demand from the Malta Standards Authority any information obtained or report drawn up by the Authority in the exercise of its functions under this article and the Authority shall comply with any such demand.

(4) The functions of the Malta Standards Authority under this article shall be without prejudice to any other functions assigned to it by any other law.”.

**17.** In subarticle (1) of article 9 of the principal Act, for the words “the Director of the Market Surveillance Directorate” there shall be substituted the words “the head of the Market Surveillance Directorate of the Malta Standards Authority established under the Malta Standards Authority Act or such other head of any Directorate as the Minister may by Order designate in his stead.”. Amendment of article 9 of the principal Act.

## Part V

**18.** This Part amends and shall be read and construed as one with the Medicines Act, hereinafter in this Part referred to as “the principal Act”. Amendment to the Medicines Act, Cap. 458.

**19.** For article 4 of the principal Act there shall be substituted the following:- Substitution of article 4 of the principal Act.

“4. There shall be established a Medicines Authority, or such other authority as the Prime Minister may, after consultation with the Minister responsible for health, designate in terms of article 110 of this Act.”.

**20.** For subarticle (5) of article 103 of the principal Act there shall be substituted the following: Amendment of article 103 of the principal Act.

“(5) (a) Where any medicinal product has been seized under the provisions of this Act, and the owner thereof consents in writing to the destruction of such medicinal product, the Licensing Authority may, after taking such samples as may be required to prove the offence, direct that the said medicinal product be destroyed without prejudice to the taking of any proceedings against the person responsible for the offence, and the said Licensing Authority shall recoup all the expenses involved in the destruction of the medicinal product.

(b) In those cases where the owner fails to consent to the destruction of the medicinal product, the Licensing Authority may, after filing an application requesting the Court to order the destruction at the expense of the owner, proceed with such destruction.”.

Addition of new article 110 to the principal Act.

**21.** Immediately after article 109 of the principal Act there shall be added the following:

“Designation of competent authority.

110. (1) The Prime Minister may, following consultation with the Minister responsible for health, by Order in the Gazette designate any authority to carry out the functions carried out by the Medicines Authority under this Act.

(2) Any such Order may delete any of the provisions of articles 5 and 7 to 13 of this Act.

(3) Any such Order may also amend or delete subarticle (3) of article 3 and articles 4 and 6 of this Act.”.

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Passed by the House of Representatives at Sitting No. 602 of 12th December, 2007.

ANTON TABONE  
*Speaker*

RICHARD J. CAUCHI  
*Clerk to the House of Representatives*