VERŻJONI ELETTRONIKA

L.N. 332 of 2011

PRODUCT SAFETY ACT
(CAP. 427)

Transportable Pressure Equipment Regulations, 2011

IN exercise of the powers conferred by article 38 of the Product Safety Act, the Prime Minister on the advice of the Malta Competition and Consumer Affairs Authority, has made the following regulations:-

Citation, scope and commencement.

1. (1) The title of these regulations is the Transportable Pressure Equipment Regulations, 2011.

(2) These regulations transpose Directive 2010/35/EU and lay down rules concerning transportable pressure equipment to enhance safety and ensure free movement of such equipment within the Union.

(3) These regulations shall come into force on 1st July 2011.

(4) EEC pattern approval certificates for transportable pressure equipment issued pursuant to Schedules V, VI or VII to the Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002, and EC design-examination certificates issued pursuant to the Transportable Pressure Equipment Regulations, 2002, shall be recognised as equivalent to the type approval certificates referred to in the Annexes to Directive 2008/68/EC and shall be subject to the provisions on time-limited recognition of type approvals set out in those Annexes.

L.N. 146 of 2002.
L.N. 331 of 2002.

(5) Valves and accessories referred to in regulation 5.3 of the Transportable Pressure Equipment Regulations, 2002 and marked with the mark of the Pressure Equipment Regulations, 2002 according to regulation 5.4 of the Transportable Pressure Equipment Regulations, 2002 may still be used.

L.N. 248 of 2002.

Applicability.

2. (1) These regulations shall apply to:

(a) new transportable pressure equipment as defined in regulation 3, which does not bear the conformity markings provided for in Schedules V, VI or VII to the Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002, or in the Transportable Pressure Equipment Regulations, 2002, for the purpose of making it available on the market;

(b) transportable pressure equipment as defined in regulation 3, bearing the conformity markings provided for in these regulations or in Schedules V, VI or VII to the Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002, or in the Transportable Pressure Equipment Regulations, 2002, for the purposes of its periodic inspections, intermediate inspections, exceptional checks and use;

(c) transportable pressure equipment as defined in regulation 3, which does not bear the conformity markings provided for in the Transportable Pressure Equipment Regulations, 2002, for the purposes of reassessment of conformity.

(2) As from the 1st July 2013 at the latest, these regulations shall also apply to pressure receptacles, their valves and other accessories used for the carriage of dangerous substances of class UN No 1745, UN No 1746 or UN No 2495.

(3) These regulations shall not apply to:

(a) transportable pressure equipment which was placed on the market before the 1st January, 2003, and which has not been subject to a reassessment of conformity;

(b) transportable pressure equipment used exclusively for the transport of dangerous goods between Member States and third countries, carried out in accordance with Article 4 of Directive 2008/68/EC.

Definitions.

3. For the purposes of these regulations the following definitions shall apply:

"accreditation" means an attestation by the National Accreditation Board that a notified body meets the requirements set out in the second paragraph of 1.8.6.8 of

the Annexes to Directive 2008/68/EC and the Method for Designating Conformity Assessment Bodies Regulations, 2003; L.N. 136 of 2003.

"Annexes to Directive 2008/68/EC" means Section I.1 of Annex I, Section II.1 of Annex II, and Section III.1 of Annex III to Directive 2008/68/EC;

"authorised representative" means any natural or legal person established within the Union who has received a written mandate from the manufacturer to act on his behalf in relation to specified tasks;

"conformity assessment" means the assessment and the procedure for the assessment of conformity set out in the Annexes to Directive 2008/68/EC;

"distributor" means any natural or legal person established within the Union, other than the manufacturer or the importer, who makes transportable pressure equipment or parts thereof available on the market;

"economic operator" means the manufacturer, the authorised representative, the importer, the distributor, the owner or the operator acting in the course of a commercial or public service activity, whether in return for payment or free of charge;

"exceptional check" means the exceptional check and the procedures governing the exceptional check set out in the Annexes to Directive 2008/68/EC;

"importer" means any natural or legal person established within the Union, who places transportable pressure equipment or parts thereof from a third country on the Union market;

"intermediate inspection" means the intermediate inspection and the procedures governing the intermediate inspection as set out in the Annexes to Directive 2008/68/EC;

"making available on the market" means any supply of transportable pressure equipment for distribution or use on the Union market in the course of a commercial or public service activity, whether in return for payment or free of charge;

"manufacturer" means any natural or legal person who manufactures transportable pressure equipment, or parts thereof, or who has such equipment designed or manufactured and markets it under his name or trademark;

"market surveillance" means the activities carried out and measures taken by public authorities to ensure that transportable pressure equipment during its life cycle complies with the requirements set out in Directive 2008/68/EC and these regulations and does not endanger health, safety or any other aspect of public interest protection;

"Member States" means the Member States of the Union;

"National Accreditation Board (Malta)" means the National Accreditation Board (Malta) established in terms of regulation 3 of the National Accreditation Board (Malta) (Establishment) Regulations, 2007;

L.N. 306 of 2007.

"notification" is the process of awarding notified body status to an inspection body and includes communication of this information to the Commission and to the Member States;

"notified body" means an inspection body meeting the requirements set out in the Annexes to Directive 2008/68/EC and the conditions set out in regulation 15 and the Method for Designating Conformity Assessment Bodies Regulations, 2003, and has been notified in accordance with regulation 16;

"operator" means any natural or legal person established in the Union using transportable pressure equipment;

"owner" means any natural or legal person established within the Union who owns transportable pressure equipment;

"periodic inspection" means the periodic inspection and the procedures governing the periodic inspection as set out in the Annexes to Directive 2008/68/EC;

"Pi marking" means a marking which indicates that the transportable pressure equipment is in conformity with the applicable conformity assessment requirements set out in the Annexes to Directive 2008/68/EC and in these regulations;

"placing on the market" means the first making available of transportable pressure equipment on the Union market;

"reassessment of conformity" means the procedure undertaken, at the request of the owner or operator, for the subsequent assessment of the conformity of transportable pressure equipment manufactured and placed on the market before the 1st January, 2003;

"recall" means any measure aimed at achieving the return of transportable pressure equipment that has already been made available to the end user;

"transportable pressure equipment" means:

(a) all pressure receptacles, their valves and other accessories when appropriate, as covered in Chapter 6.2 of the Annexes to Directive 2008/68/EC,

(b) tanks, battery vehicles/wagons, multiple-element gas containers (MEGCs), their valves and other accessories when appropriate, as covered in Chapter 6.8 of the Annexes to Directive 2008/68/EC,

when the equipment under (a) or (b) is used in accordance with those Annexes for the transport of Class 2 gases, excluding gases or articles with figures 6 and 7 in the classification code, and for the transport of the dangerous substances of other classes specified in Schedule I to these regulations.

Transportable pressure equipment shall be understood as including gas cartridges (UN No 2037) and excluding aerosols (UN No 1950), open cryogenic receptacles, gas cylinders for breathing apparatus, fire extinguishers (UN No 1044), transportable pressure equipment exempted according to 1.1.3.2 of the Annexes to Directive 2008/68/EC and transportable pressure equipment exempted from the rules for construction and testing of packaging according to special provisions in 3.3 of the Annexes to Directive 2008/68/EC;

"Technical Regulations Division" means the Technical Regulations Division of the Malta Competition and Consumer Affairs Authority as established by the Malta Competition and Consumer Affairs Authority Act of 2011; Act No. VI of 2011.

"the Union" means the European Union;

"use" means filling, temporary storage linked to carriage, emptying and refilling of transportable pressure equipment;

"withdrawal" means any measure aimed at preventing transportable pressure equipment from being made available on the market or from being used.

Placing on the market.

4. (1) Only transportable pressure equipment complying with these regulations shall be placed on the market.

(2) Without prejudice to the safeguard procedures in regulation 17 and to the market surveillance framework set out in Regulation (EC) No 765/2008, the making available on the market and the use of transportable pressure equipment, which complies with these regulations shall not be prohibited, restricted or impeded.

Obligations of manufacturers.

5. (1) When placing their transportable pressure equipment on the market, manufacturers shall ensure that the equipment has been designed, manufactured and documented in accordance with the requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

(2) Where the compliance of the transportable pressure equipment with the applicable requirements has been demonstrated through the conformity assessment process set out in the Annexes to Directive 2008/68/EC and in these regulations, manufacturers shall affix the Pi marking in accordance with regulation 14.

(3) Manufacturers shall keep the technical documentation specified in the Annexes to Directive 2008/68/EC. This documentation shall be kept for the period specified therein.

(4) Manufacturers who consider or have reason to believe that transportable pressure equipment which they have placed on the market is not in conformity with the Annexes to Directive 2008/68/EC or with these regulations shall immediately take the corrective measures necessary to bring the transportable pressure equipment into conformity, to withdraw it or to recall it, if appropriate. Furthermore, where the transportable pressure equipment presents a risk, manufacturers shall immediately inform the Technical Regulations Division to that effect, giving details, in

particular, of the non-compliance and of any corrective measures taken.

(5) Manufacturers shall document all such instances of noncompliance and corrective measures.

(6) Manufacturers shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation necessary to demonstrate the conformity of the transportable pressure equipment, in at least the English or Maltese language. They shall cooperate with that Division, at its request, as regards any action taken to eliminate the risks posed by transportable pressure equipment which they have placed on the market.

(7) Manufacturers shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

Authorised representatives.

6. (1) Manufacturers may, by a written mandate, appoint an authorised representative.

The obligations set out in regulations 5(1) and 5(2) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

(2) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the technical documentation at the disposal of the Technical Regulations Division for at least the period as specified in the Annexes to Directive 2008/68/EC for manufacturers;

(b) further to a reasoned request from the Technical Regulations Division, provide that Division with all the information and documentation necessary to demonstrate the conformity of the transportable pressure equipment in at least the English or Maltese language;

(c) cooperate with the Technical Regulations Division, at their request, on any action taken to eliminate the risks posed by transportable pressure equipment covered by the mandate.

(3) The identity and address of the authorised representative shall be indicated on the certificate of conformity specified in the Annexes to Directive 2008/68/EC.

(4) Authorised representatives shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

Obligations of importers.

7. (1) Importers shall only place on the market transportable pressure equipment which is in conformity with the Annexes to Directive 2008/68/EC and with these regulations.

(2) Before placing transportable pressure equipment on the market, importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation and that the transportable pressure equipment bears the Pi marking and is accompanied by the certificate of conformity specified in the Annexes to Directive 2008/68/EC.

Where an importer considers or has reason to believe that the transportable pressure equipment is not in conformity with the Annexes to Directive 2008/68/EC or with these regulations, he shall not place the transportable pressure equipment on the market until it has been brought into conformity. Furthermore, where the transportable pressure equipment presents a risk, the importer shall inform the manufacturer and the Technical Regulations Division to that effect.

(3) Importers shall indicate their name and the address at which they can be contacted either in, or attached to, the certificate of conformity specified in the Annexes to Directive 2008/68/EC.

(4) Importers shall ensure that, while transportable pressure equipment is under their responsibility, storage or transport conditions do not jeopardize its compliance with the requirements set out in the Annexes to Directive 2008/68/EC.

(5) Importers who consider or have reason to believe that transportable pressure equipment which they have placed on the market is not in conformity with the Annexes to Directive 2008/68/EC or with these regulations shall immediately take the corrective measures necessary to bring the transportable

pressure equipment into conformity, to withdraw it or to recall it, if appropriate. Furthermore, where the transportable pressure equipment presents a risk, importers shall immediately inform the manufacturer and the Technical Regulations Division to that effect, giving details, in particular, of the noncompliance and of any corrective measures taken.

Importers shall document all such instances of non-compliance and corrective measures.

(6) Importers shall, for at least the period specified in the Annexes to Directive 2008/68/EC for manufacturers, keep a copy of the technical documentation at the disposal of the Technical Regulations Division and ensure that the technical documentation can be made available to that Division upon request.

(7) Importers shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation necessary to demonstrate the conformity of the transportable pressure equipment, in at least the English or Maltese language. They shall cooperate with the Technical Regulations Division, at its request, on any action taken to eliminate the risks posed by transportable pressure equipment which they have placed on the market.

(8) Importers shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

(9) An importer shall be considered a manufacturer for the purposes of these regulations and subject to the obligations of the manufacturer pursuant to regulation 5, where he places transportable pressure equipment on the market under his name or trademark or modifies transportable pressure equipment already placed on the market in such a way that compliance with the applicable requirements may be affected.

Obligations of distributors.

8. (1) Distributors shall only make available on the market transportable pressure equipment which is in conformity with the Annexes to Directive 2008/68/EC and with these regulations. Before making transportable pressure equipment available on the market distributors shall verify that the transportable pressure equipment bears the Pi marking, and that it is accompanied by the certificate of conformity and the contact address referred to in regulation 7(3).

Where a distributor considers or has reason to believe that transportable pressure equipment is not in conformity with the Annexes to Directive 2008/68/EC or with these regulations, he shall not make the transportable pressure equipment available on the market until it has been brought into conformity. Furthermore, where the transportable pressure equipment presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the Technical Regulations Division.

(2) Distributors shall ensure that, while transportable pressure equipment is under their responsibility, storage or transport conditions do not jeopardize its compliance with the requirements set out in the Annexes to Directive 2008/68/EC.

(3) Distributors who consider or have reason to believe that transportable pressure equipment which they have made available on the market is not in conformity with the Annexes to Directive 2008/68/EC or with these regulations shall make sure that the corrective measures necessary to bring that transportable pressure equipment into conformity, to withdraw it or to recall it, if appropriate, are taken. Furthermore, where the transportable pressure equipment presents a risk, distributors shall immediately inform the manufacturer, the importer, where relevant, and the Technical Regulations Division, giving details, in particular, of the non-compliance and of any corrective measures taken.

Distributors shall document all such instances of non-compliance and corrective measures.

(4) Distributors shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation necessary to demonstrate the conformity of the transportable pressure equipment in at least the English or Maltese language. They shall cooperate with the Technical Regulations Division, at its request, on any action taken to eliminate the risks posed by transportable pressure equipment which they have made available on the market.

(5) Distributors shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

(6) A distributor shall be considered a manufacturer for the purposes of these regulations and subject to the obligations of the manufacturer pursuant to regulation 5, where he places

transportable pressure equipment on the market under his name or trademark or modifies transportable pressure equipment already placed on the market in such a way that compliance with the applicable requirements may be affected.

Obligations of owners.

9. (1) Where an owner considers or has reason to believe that transportable pressure equipment is not in conformity with the Annexes to Directive 2008/68/EC, including the requirements for periodic inspection, and with these regulations, he shall not make it available or use it until it has been brought into conformity. Furthermore, where the transportable pressure equipment presents a risk, the owner shall inform the manufacturer or the importer or the distributor to that effect as well as the Technical Regulations Division.

Owners shall document all such instances of non-compliance and corrective measures.

(2) Owners shall ensure that, while transportable pressure equipment is under their responsibility, storage or transport conditions do not jeopardize its compliance with the requirements set out in the Annexes to Directive 2008/68/EC.

(3) Owners shall only provide information to operators which complies with the requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

(4) The preceding sub-regulations shall not apply to private individuals intending to use or using transportable pressure equipment for their personal or domestic use or for their leisure or sporting activities.

Obligations of operators.

10. (1) Operators shall only use transportable pressure equipment which is in conformity with the requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

(2) Where the transportable pressure equipment presents a risk, the operator shall inform the owner to that effect as well as the Technical Regulations Division.

Other responsibilities.

11. In addition to the preceding regulations, any economic operator shall, on request from the Technical Regulations Division, identify the following to it for a period of at least 10 years after the transportable pressure equipment has been placed on the market:

(a) any economic operator who has supplied them with transportable pressure equipment;

(b) any economic operator to whom they have supplied transportable pressure equipment.

Conformity assessment.

12. (1) The transportable pressure equipment referred to in regulation 2(1)(a) shall meet the relevant conformity assessment, periodic inspection, intermediate inspection and exceptional checks requirements set out in the Annexes to Directive 2008/68/EC and in regulations 4 and 12 to 16 of these regulations.

(2) The transportable pressure equipment referred to in regulation 2(1)(b) shall meet the specifications of the documentation according to which the equipment was manufactured. The equipment shall be subject to periodic inspections, intermediate inspections and exceptional checks in accordance with the Annexes to Directive 2008/68/EC and with the requirements of regulations 4 and 12 to 16 of these regulations.

(3) Certificates of conformity assessment and certificates of reassessment of conformity and reports of periodic inspections, intermediate inspections and exceptional checks issued by a notified body shall be valid in all Member States.

(4) For demountable parts of refillable transportable pressure equipment a separate conformity assessment may be carried out.

Reassessment of conformity.

13. (1) The reassessment of conformity of transportable pressure equipment referred to in regulation 2(1)(c) manufactured and put into service before the 1st January, 2003, shall be established in accordance with the conformity reassessment procedure set out in Schedule II to these regulations.

(2) The Pi marking shall be affixed in accordance with Schedule II to these regulations.

Rules and conditions for affixing the Pi marking.

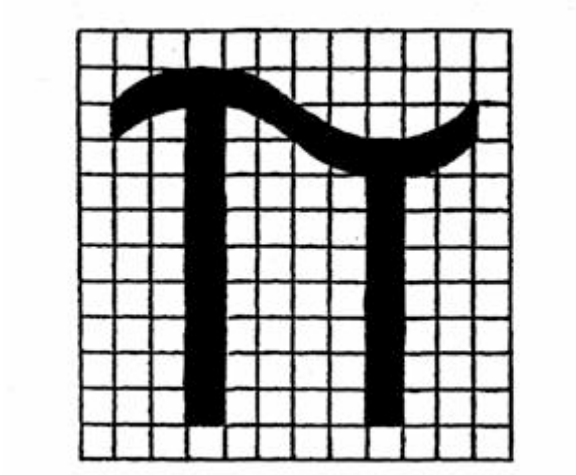
14. (1) The Pi marking shall be affixed only to transportable pressure equipment which:

(a) meets the conformity assessment requirements in the Annexes to Directive 2008/68/EC and in these regulations; or

(b) meets the reassessment of conformity requirements referred to in regulation 13.

It shall not be affixed to any other transportable pressure equipment.

(2) The Pi marking shall consist of the following symbol in the following form:



(3) The minimum height of the Pi marking shall be 5mm. For transportable pressure equipment with a diameter less than or equal to 140mm the minimum height shall be 2.5mm.

(4) The proportions given in the graduated drawing in sub-regulation (2) shall be respected. The grid does not form part of the marking.

(5) The Pi marking shall be affixed visibly, legibly and permanently to the transportable pressure equipment or to its data plate as well as to demountable parts of refillable transportable pressure equipment having a direct safety function.

(6) The Pi marking shall be affixed before the new transportable pressure equipment or demountable parts of refillable transportable pressure equipment having a direct safety function are placed on the market.

(7) The Pi marking shall be followed by the identification number of the notified body involved in the initial inspections and tests.

The identification number of the notified body shall be affixed by the body itself, or under its instructions, by the manufacturer.

(8) The Pi marking shall only be affixed by the manufacturer or, in cases of reassessment of conformity, as set out in Schedule II. For gas cylinders previously in compliance with Schedules V, VI or VII to the Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002, the Pi mark shall be affixed by or under the surveillance of the notified body.

(9) By affixing or having affixed the Pi marking, the manufacturer indicates that he takes responsibility for the conformity of the transportable pressure equipment with all applicable requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

(10) For the purposes of these regulations, the Pi marking shall be the only marking which attests conformity of the transportable pressure equipment with the applicable requirements set out in the Annexes to Directive 2008/68/EC and in these regulations.

(11) The affixing on transportable pressure equipment of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the Pi marking, is prohibited. Any other marking may be affixed to the transportable pressure equipment in such a way that the visibility, legibility and meaning of the Pi marking are not thereby impaired.

(12) Demountable parts of refillable transportable pressure equipment with a direct safety function shall be Pi-marked.

(13) The marking of the date of the periodic inspection or, where appropriate, the intermediate inspection shall be accompanied by the identification number of the notified body responsible for the periodic inspection.

(14) With regard to gas cylinders previously in compliance with Schedules V, VI or VII to the Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002, not bearing the Pi marking, when the first periodic inspection is carried out in accordance with these regulations, the identification

number of the notified body responsible shall be preceded by the Pi marking.

Notified bodies.

15. (1) For the purposes of notification under these regulations, a notified body shall meet the requirements set out in the Annexes to Directive 2008/68/EC, in these regulations and in the Method for Designating Conformity Assessment Bodies Regulations, 2003.

(2) A competent authority, within the meaning of the Annexes to Directive 2008/68/EC may be a notified body provided it meets the requirements set out in the Annexes to Directive 2008/68/EC, in these regulations, and in the Method for Designating Conformity Assessment Bodies Regulations, 2003, and that it does not also act as the notifying authority.

(3) The notified body shall participate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body coordination group established pursuant to regulation 15(8) and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

(4) Notified bodies shall carry out conformity assessments, periodic inspections, intermediate inspections and exceptional checks in accordance with the terms of their notification and the procedures set out in the Annexes to Directive 2008/68/EC and the Method for Designating Conformity Assessment Bodies Regulations, 2003.

(5) Notified bodies shall carry out reassessments of conformity in accordance with Schedule II.

(6) Notified bodies shall inform the Technical Regulations Division of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of and conditions for notification;

(c) any request for information on activities performed which they have received from market surveillance authorities;

(d) on request, activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(7) Notified bodies shall provide the other bodies notified under these regulations carrying out similar conformity assessment, periodic inspection, intermediate inspections and exceptional checks activities covering the same transportable pressure equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

(8) Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the Commission.

Notification of notified bodies procedure.

16. (1) The Technical Regulations Division shall be responsible for setting up and carrying out the necessary procedures for the assessment, notification and subsequent monitoring of notified bodies.

(2) The assessment and monitoring referred to in sub-regulation (1) shall be carried out by the National Accreditation Board (Malta).

(3) The Technical Regulations Division shall inform the Commission of its procedures for the assessment, notification and monitoring of notified bodies, and of any changes to that information.

(4) For the purposes of notification under these regulations, an inspection body shall submit an application for notification to the Technical Regulations Division. The application shall be accompanied by a description of:

(a) the activities relating to conformity assessment, periodic inspection, intermediate inspection, exceptional checks and reassessment of conformity;

(b) the procedures relating to such activities;

(c) the transportable pressure equipment for which the body claims to be competent;

(d) an accreditation certificate issued by the National Accreditation Board (Malta) attesting that the inspection body fulfils the requirements laid down in regulation 15 and the Method for Designating Conformity Assessment Bodies Regulations, 2003.

(5) The Technical Regulations Division shall notify only those bodies which have satisfied the requirements set out in regulation 15 and the Method for Designating Conformity Assessment Bodies Regulations, 2003.

(6) The Technical Regulations Division shall notify to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

The notification shall include the information required in sub-regulation (4).

(7) The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification.

Only such a body shall be considered a notified body for the purposes of these regulations.

(8) The Technical Regulations Division shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

(9) In–house inspection services of the applicant as defined in the Annexes to Directive 2008/68/EC shall not be notified.

(10) Where the Technical Regulations Division has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulation 15 or the Method for Designating Conformity Assessment Bodies Regulations, 2003, or that it is failing to fulfil its obligations, the Technical Regulations Division shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

(11) In the event of withdrawal, restriction or suspension of notification or where the notified body has ceased its activity, the Technical Regulations Division shall take the appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities on request.

(12) The Technical Regulations Division shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

(13) Notified bodies notified by the Technical Regulations Division shall be authorised to work in all Member States. The Technical Regulations Division, having carried out the initial assessment and notification, retains the responsibility for monitoring the ongoing activities of the notified body.

Market surveillance.

17. (1) Where the Technical Regulations Division takes any action pursuant to these regulations or Article 20 of Regulation (EC) No 765/2008 or where it has sufficient reason to believe that transportable pressure equipment covered by these regulations presents a risk to the health or safety of persons or to other aspects of public interest protection covered by these regulations, it shall carry out an evaluation in relation to the transportable pressure equipment concerned covering all the requirements laid down in these regulations.

(2) The relevant economic operators shall cooperate as necessary with the Technical Regulations Division, including granting access to their premises and providing samples as appropriate.

(3) Where, in the course of that evaluation, the Technical Regulations Division finds that the transportable pressure equipment does not comply with the requirements set out in the Annexes to Directive 2008/68/EC and in these regulations, it shall without delay require the relevant economic operator to take all appropriate corrective action to bring the transportable pressure equipment into compliance with those requirements, to withdraw the transportable pressure equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe. In such cases, Article 21 of Regulation (EC) No 765/2008 shall apply to such corrective actions and the

Technical Regulations Division shall inform the relevant notified body accordingly.

(4) Where the Technical Regulations Division considers that non-compliance is not restricted to the Maltese national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

(5) The economic operator shall ensure that all appropriate corrective action is taken in respect of transportable pressure equipment that it has made available on the market.

(6) Where the relevant economic operator does not take adequate corrective action within the period referred to in the sub-regulation (3), the Technical Regulations Division shall take all appropriate provisional measures to prohibit or restrict the transportable pressure equipment being made available on the market, to withdraw the equipment from that market or to recall it.

Technical Regulations Division shall inform the Commission and the other Member States, without delay, of those measures.

(7) The information referred to in sub-regulation (6) shall include all available details, in particular the data necessary for the identification of the non-compliant transportable pressure equipment, the origin of the equipment, the nature of the alleged noncompliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the Technical Regulations Division shall indicate whether the non-compliance is due to either:

(a) failure of the transportable pressure equipment to meet requirements relating to the health or safety of persons or to other aspects of public interest protection set out in the Annexes to Directive 2008/68/EC and in these regulations, or

(b) shortcomings in the standards or technical codes referred to in the Annexes to Directive 2008/68/EC or in other provisions of that Directive.

(8) Where procedures against the placing on the market of products are initiated in another Member State, the

Technical Regulations Division shall without delay take the measures necessary to ensure that the non-compliant transportable pressure equipment is withdrawn from the local market and shall inform the Commission and the other Member States of any such measures adopted locally and of any additional information at its disposal relating to the non-compliance of the transportable pressure equipment concerned, or, in the event of disagreement with the notified measure, of its objections.

(9) Where, within two months of receipt of the information referred to in sub-regulation (6), no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by the Technical Regulations Division, that measure shall be deemed justified.

(10) The Technical Regulations Division shall ensure that appropriate restrictive measures are taken in respect of the transportable pressure equipment concerned, such as withdrawal of the transportable pressure equipment from their market, without delay.

(11) (a) Where, having performed an evaluation pursuant to sub-regulations (1) to (3), the Technical Regulations Division finds that although transportable pressure equipment is in compliance with Directive 2008/68/EC and these regulations, it presents a risk to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the transportable pressure equipment concerned, when placed on the market, no longer presents that risk, to withdraw the equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

(b) The economic operator shall ensure that corrective action is taken in respect of all the transportable pressure equipment concerned that he has made available on the market or is using throughout the Union.

(c) Where sub-regulation (a) applies, the Technical Regulations Division shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the transportable pressure equipment concerned, the origin and the supply chain of the equipment, the nature of the

VERŻJONI ELETTRONIKA

risk involved and the nature and duration of the national measures taken.

(12) (a) Without prejudice to the preceding regulations, where the Technical Regulations Division makes any of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(i) that the Pi marking has been affixed in violation of these regulations;

(ii) that the Pi marking has not been affixed;

(iii) that the technical documentation is either not available or not complete;

(iv) that the requirements of the Annexes to Directive 2008/68/EC and of these regulations have not been complied with.

(b) Where such non-compliance persists, the Technical Regulations Division concerned shall take all appropriate measures to restrict or prohibit the transportable pressure equipment being made available on the market or shall ensure that it is recalled or withdrawn from the market.

18. The penalties applicable for the infringement of any of the provisions above shall be those provided for in Part IV of the Product Safety Act. Penalties.

19. The Transportable Pressure Equipment Regulations, 2002, and the Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002, are hereby being revoked. Revokes L.N. 331 of 2002 and L.N. 146 of 2002.

20. References to the revoked regulations shall be construed as references to these regulations. Saving.

Schedule I
LIST OF DANGEROUS GOODS OTHER THAN THOSE IN CLASS 2

UN Number:	Class:	Dangerous substance:
1051	6.1	HYDROGEN CYANIDE, STABILISED Containing less than 3% water
1052	8	HYDROGEN FLUORIDE, ANHYDROUS
1745	5.1	BROMINE PENTAFLUORIDE Exlucing carriage in tanks
1746	5.1	BROMINE TRIFLUORIDE Excluding carriage in tanks
1790	8	HYDROFLUORIC ACID With more than 85% hydrogen fluoride
2495	5.1	IODINE PENTAFLUORIDE Excluding carriage in tanks

VERŻJONI ELETTRONIKA

Schedule II
PROCEDURE FOR REASSESSMENT OF CONFORMITY

(1) The method for ensuring that the transportable pressure equipment referred to in regulation 2(1)(c) manufactured and put into service before the 1st January 2003 complies with the relevant provisions of the Annexes to Directive 2008/68/EC and of these regulations as applicable at the time of reassessment shall be as set out in this Schedule.

(2) The owner or operator must make available to a notified body conforming to EN ISO/IEC 17020:2004 type A, notified for reassessment of conformity, the information regarding the transportable pressure equipment which enables that body to identify the equipment precisely (origin, design rules, and for acetylene cylinders also details of the porous material). The information shall include, where appropriate, any prescribed restrictions on use, and any notes on possible damage or repairs which have been carried out.

(3) The type A notified body, notified for reassessment of conformity, shall assess whether the transportable pressure equipment affords at least the same degree of safety as the transportable pressure equipment referred to in the Annexes to Directive 2008/68/EC. The assessment shall be carried out on the basis of the information produced in accordance with paragraph 2 and, where appropriate, of further inspections.

(4) If the results of the assessment in paragraph 3 are satisfactory, the transportable pressure equipment shall be subject to the periodic inspection provided for in the Annexes to Directive 2008/68/EC. If the requirements of that periodic inspection are met the Pi marking shall be applied by or under the surveillance of the notified body responsible for the periodic inspection in accordance with regulations 14 and 15. The Pi marking shall be followed by the identification number of the notified body responsible for the periodic inspection. The notified body responsible for the periodic inspection shall issue a certificate of reassessment in accordance with paragraph 6.

(5) Where pressure receptacles were manufactured in series, the manufacturer may carry out the reassessment of conformity of individual pressure receptacles, including their valves and other accessories used for transport. Such reassessment is to be carried out by a notified body notified for periodic inspection of the relevant transportable pressure receptacles provided that conformity of the type has been assessed in accordance with paragraph 3 by a type A notified body, responsible for the reassessment of conformity, and a certificate of type reassessment issued. The Pi marking shall be followed by the identification number of the notified body responsible for the periodic inspection.

(6) In all cases the notified body responsible for the periodic inspection shall issue the certificate of reassessment containing as a minimum:

(a) the identification of the notified body issuing the certificate, and, if different, the identification number of the type A notified body responsible for the reassessment of conformity in accordance with paragraph 3;

(b) the name and address of owner or operator specified in paragraph 2;

(c) in the case of the application of the procedure in paragraph 5, the data identifying the certificate of type reassessment;

(d) the data for identification of the transportable pressure equipment to which Pi marking has been applied including at least the serial number or numbers; and

(e) the date of issue.

(7) A certificate of type reassessment shall be issued.

Where the procedure in paragraph 5 is applied the type A body, responsible for the reassessment of conformity, shall issue the certificate of type reassessment containing as a minimum:

(a) the identification of the notified body issuing the certificate;

(b) the name and address of the manufacturer and the holder of the original type approval for the transportable pressure equipment being reassessed when the holder is not the manufacturer;

(c) the data identifying the transportable pressure equipment belonging to the series;

(d) the date of issue; and

(e) the words: 'this certificate does not authorise manufacture of transportable pressure equipment or parts thereof'.

(8) By affixing or having affixed the Pi marking, the owner or operator indicates that he takes responsibility for the conformity of the transportable pressure equipment with all applicable requirements set out in the Annexes to Directive 2008/68/EC and in these regulations as applicable at the time of reassessment.

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