

Background and guidance to the Transportable Pressure Equipment Directive

2010/35/EU (TPED)



Definitions

The definitions in this section are sourced from the ADR, the 2010 TPED and from our national regulations (the 'regulations'). The text in italics is not part of the definition as provided in legislation, it is additional text added for information purposes.

The 'ADR' means the European Agreement Concerning the International Carriage of Dangerous Goods by Road, the Annexes to it and the protocol of signature thereto done at Geneva on 30 September 1957, as amended. The ADR is referred to directly in the Annexes to Directive 2008/68/EC on the inland transport of dangerous goods, specifically Annex I. The current version of the ADR can be accessed and downloaded from the [UNECE website](#).

'2010 TPED' means Directive 2010/35/EU of the European Parliament and of the Council on Transportable Pressure Equipment.

'The Regulations' mean the European Communities (Carriage of Dangerous Goods by Road and use of Transportable Pressure Equipment) Regulations 2011, as amended.

'Conformity assessment' means the process of verifying the conformity of a product according to the provisions of ADR 1.8.6 and 1.8.7 related to type approval, supervision of manufacture and initial inspection and testing.

'Periodic inspection' means the periodic inspection and the procedures governing the periodic inspection as set out in the ADR. *Applicable to pressure receptacles and tanks, relevant sections of ADR are P200 in 4.1.4.1, 6.2.1.6, 6.2.2.4, 6.2.3.5, 6.2.4.2, 6.8.2.4.2 and 6.8.3.4.6.*

'Intermediate inspection' means the intermediate inspection and the procedures governing the intermediate inspection as set out in the ADR. *Applicable to tanks only, intermediate inspection is carried out in accordance with ADR 6.8.2.4.3.*

'Exceptional check' means the exceptional check and the procedures governing the exceptional check as set out in the ADR. *Applicable to tanks only, exceptional check has the meaning provided in ADR 6.8.2.4.4.*

'Reassessment of conformity' means the procedure undertaken, at the request of the owner or operator, for the subsequent assessment of conformity of transportable pressure equipment manufactured and placed on the market before the implementation of Directive 1999/36/EC.

'Inspection body' means an inspection and testing body, appointed by a competent authority for that purpose and which shall be accredited to carry out the inspections, checks and tests in accordance with IS/EN/IEC/17020 entitled 'General criteria for the operation of various types of bodies performing inspection' and published by the International Organisation for Standards (ISO).

'Notified body (NB)' means a conformity assessment body or inspection body meeting the requirements set out in the ADR and conditions set out in Articles 20 and 26 of Directive 2010/35/EU and notified in accordance with Article 22 of Directive 2010/35/EU.

'Type A notified body' means a notified body conforming to ADR 1.8.6.2, 1.8.6.4, 1.8.6.5 and 1.8.6.8 and accredited to standard EN ISO/IEC 17020 type A.

'Type B notified body' means a notified body conforming to ADR 1.8.6.2, 1.8.6.4, 1.8.6.5 and 1.8.6.8 and accredited to standard EN ISO/IEC 17020 type B.

'Transportable Pressure Equipment (TPE)' has the meaning provided in Article 2(1) and Annex 1 of Directive 2010/35/EU on transportable pressure equipment.

1 Introduction

The aim of **Directive 2010/35/EU** of the European Parliament and of the Council on Transportable Pressure Equipment (2010 TPED) is to promote the free movement of transportable pressure equipment (TPE) within the European Community (EC). It provides for a legal structure whereby TPE can be manufactured and sold and used throughout the EC without having to go through a local approval regime in every Member State.

Under the new legislative framework (NLF)¹ adopted in July 2008, the 2010 TPED includes accreditation and market surveillance and takes account of the existence of all the 'economic operators' in the supply chain, thus providing for their specific obligations in relation to TPE. It also recognises the different responsibilities of the various national authorities such as the notifying authority, national accreditation body and market surveillance authority, and provides criteria for the notification of conformity assessment and inspection bodies (notified bodies), and rules for the notification process.

Under the 2010 TPED, conformity assessment bodies and inspection bodies must seek specific authorisation to carry out the activities of conformity assessment, periodic inspection, intermediate inspection, exceptional checks and reassessment of conformity of TPE. Such activities must be carried out in accordance with the requirements set out in the ADR and in Chapters 3 and 4 of the 2010 TPED.

It should be noted that various parts of Council **Directive 1999/36/EC** (the '1999 TPED') were transferred into the ADR in 2009. A transitional measure was provided to allow Contracting Parties to change over to the new provisions of the ADR by 1 July 2011, and this coincided with the implementation date of the 2010 TPED.

The 2010 TPED, however, continues to refer to the implementation dates of the 1999 TPED (see Section 2.3).

The ADR and the 2010 TPED are given effect in Ireland by means of the European Communities (Carriage of Dangerous Goods by Road and use of Transportable Pressure Equipment) Regulations, 2011, as amended ('the Regulations'). Up to date regulations are available from the Health and Safety Authority's [ADR web pages](#).

This guidance must be read in conjunction with the Regulations (specifically, Part 9), the current edition of the ADR and the 2010 TPED, as all will be referred to throughout the text.



¹ Decision 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products and Regulation 765/2008/EC of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to products.

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Transportable Pressure Equipment Directive (TPED)

2.1 Scope

The 2010 TPED applies to the design, manufacture, conformity assessment, periodic inspection, intermediate inspection, exceptional checks and reassessment of conformity of **pressure receptacles and tanks** used for the transport of **Class 2** gases, covered respectively in:

- Chapter 6.2 of the ADR (for example, transportable cylinders, tubes, pressure drums and bundles of cylinders, chemicals under pressure, closed cryogenic receptacles, small receptacles containing gas [gas cartridges]), and

- Chapter 6.8 of the ADR (for example, fixed tanks, demountable tanks, battery vehicles, tank containers, tank swap bodies and multiple-element gas containers [MEGCs]).

It includes associated valves and other accessories, when appropriate, and includes both refillable and non-refillable pressure receptacles.

The directive also covers the carriage of specific dangerous goods other than those in Class 2, as listed in Annex 1 of the 2010 TPED, reproduced here in Table 1:

Table 1: 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 Excluding 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

The 2010 TPED applies to:

- All new TPE, not bearing the conformity markings epsilon (ϵ) or pi (π) mark as provided for in Directives 84/525-7/EEC and 1999/36/EC for the purposes of placing it on the market;
- Existing TPE, which has the conformity markings ϵ or π as provided for in Directives 84/525-7/EEC and the 1999 TPED, for the purposes of periodic inspections, intermediate inspections, exceptional checks and use. In the case of gas cylinders in compliance with Directive

84/525-7/EEC, and thus bearing the ϵ marking, when the first periodic inspection is carried out under the 1999 TPED or the 2010 TPED, the π mark is applied along with the identification number of the notified body carrying out the inspection;²

- Existing TPE, which does not have the conformity marking π as provided for in the 1999 TPED, for the purpose of reassessment of conformity.

² Article 6(3) and Article 10(3) of the 1999 TPED; Article 15(8) and Article 16 of the 2010 TPED.

2.2 Exclusions

Equipment that is specifically **excluded** from the 2010 TPED is as follows:

- Aerosols (UN No. 1950)
- Open cryogenic receptacles
- Gas cylinders for breathing apparatus
- Fire extinguishers (UN No. 1044)
- TPE exempted under ADR 1.1.3.2, exemptions related to the carriage of gases
- TPE exempted under ADR Chapter 3.3, special provisions applicable to certain articles or substances

Pressure vessels and apparatus used for non-transport related applications will usually be within the scope of the Pressure Equipment Directive 2014/68/EU (PED).

2.3 Implementation dates

The implementation date for the 1999 TPED in the EU was 1 July 2001. In Ireland, however, in accordance with Article 18 of the 1999 TPED, the implementation date was **1 July 2003**.

For pressure drums, bundles of cylinders and tanks, the date of implementation of the 1999 TPED was deferred to 1 July 2005 by means of [Commission Decision 2003/525/EC of 18 July 2003](#). In Ireland, in accordance with Article 2 of this decision, the implementation date for the placing on the market of such equipment was **1 July 2007**.

TPE placed on the market before the dates specified above does not require initial conformity assessment but can be reassessed for conformity at the time of its periodic inspection (see Section 4).

The implementation dates of the 1999 TPED are clarified in Table 2:

Table 2: Implementation dates of the TPED

Type of TPE	Directive 1999/36/EC	National Regulations (for the purposes of placing on the market)
Cylinders, tubes, cryogenic receptacles	1 July 2001	1 July 2003
Pressure drums, bundles of cylinders, tanks, battery vehicles, MEGCs	1 July 2005	1 July 2007

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Conformity assessment, periodic inspection, intermediate inspection and exceptional checks

All TPE as defined in Section 2 must meet the conformity assessment, periodic inspection, intermediate inspection, exceptional checks and reassessment of conformity requirements as set out in the ADR (1.8.6, 1.8.7, 6.2.2.11, 6.2.3.6 and 6.8.4, TA4 and TT9) and in Chapters 3 and 4 of the 2010 TPED.

Conformity assessment bodies and inspection bodies (in ADR the term 'relevant body' is used) must be **notified to the Commission** in accordance with Chapter 4 of the 2010 TPED. Such bodies must apply to the notifying authority to become a notified body.

'Notifying authority' means, in relation to transportable pressure equipment for the purposes of Part 9 of the Regulations, the Minister.

The [procedure](#) for applying for such notification is available from the Irish notifying authority which is the Department of Business, Enterprise and Innovation (DBEI).

In Ireland notification is based on accreditation by the Irish National Accreditation Board ([INAB](#)).

3.1 Pressure receptacles

For pressure receptacles (both UN and ADR pressure receptacles), relevant bodies are defined in ADR 6.2.2.11 and 6.2.3.6 in accordance with Table 3.

For gas cartridges the functions of the relevant bodies are outlined in ADR 1.8.8.

Table 3: Activities of relevant bodies

Procedure	Relevant Body
Type Approval (1.8.7.2)	Xa
Supervision of manufacture (1.8.7.3)	Xa or IS
Initial inspection and test (1.8.7.4)	Xa or IS
Periodic inspection (1.8.7.5)	Xa or Xb or IS

Xa' means conformity assessment body or inspection body conforming to ADR 1.8.6.2, 1.8.6.4, 1.8.6.5 and 1.8.6.8 and accredited according to EN ISO/IEC 17020 (except clause 8.1.3) type A (referred to as a 'type A conformity assessment body or inspection body').

'Xb' means inspection body conforming to ADR 1.8.6.2, 1.8.6.4, 1.8.6.5 and 1.8.6.8 and accredited according to EN ISO/IEC 17020 (except clause 8.1.3) type B (referred to as a 'type B inspection body').

'IS' means an in-house inspection service under the surveillance of a type A inspection body, which must be independent from design process, manufacturing operations, repair and maintenance.

Type A inspection bodies may approve a quality system for the 'in house inspection service (IS)' and can then delegate some of the in house inspection activity (but not type approval) to the IS. In accordance with ADR 1.8.7.6, the type A inspection body must carry out twice yearly audits of the quality system.

Once notified to the Commission, type A and type B conformity assessment bodies and inspection bodies will become, respectively, type A and type B notified bodies.

3.2 Tanks

For tanks, the only bodies which can carry out conformity assessment or inspection activity are those which are accredited to EN ISO/IEC 17020 (except clause 8.1.3) **type A**.

For the type approval of tanks, the conformity assessment procedures of ADR 1.8.7 must be applied by a conformity assessment body or inspection body conforming to ADR 1.8.6.2, 1.8.6.4, 1.8.6.5 and 1.8.6.8 and accredited to EN ISO/IEC 17020 (except clause 8.1.3) type A.³

For tank inspections and tests (including supervision of manufacture), the procedures of ADR 1.8.7 must be applied by an inspection body conforming to ADR 1.8.6.2, 1.8.6.4, 1.8.6.5 and 1.8.6.8 and accredited to EN ISO/IEC 17020 (except clause 8.1.3) type A.⁴

Once notified to the Commission, a type A conformity assessment body or a type A inspection body will become a type A notified body.

³ ADR 6.8.4, TA4

⁴ ADR 6.8.4, TT9



4 Reassessment of conformity

For TPE (both pressure receptacles and tanks) that was placed on the market before the date of implementation of the 1999 TPED (see Table 2), there is an option for relevant bodies to reassess TPE for conformity in accordance with the procedure provided in **Annex III** of the 2010 TPED (Annex III is reproduced as Schedule 5 of the Regulations).

The owner or operator of the TPE must make available to a **notified body**, conforming to EN ISO/IEC 17020 Type A, notified for reassessment of conformity, the information regarding the TPE 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 carried out.

The Type A notified body, based on the information provided and where appropriate, on further inspection, will assess whether the TPE affords at

least the same degree of safety as the TPE that is in compliance with the ADR. If the results of this assessment are deemed to be satisfactory, the TPE will be subject to periodic inspection in accordance with the ADR, and if the requirements are met the π marking can be applied in accordance with Section 5 below.

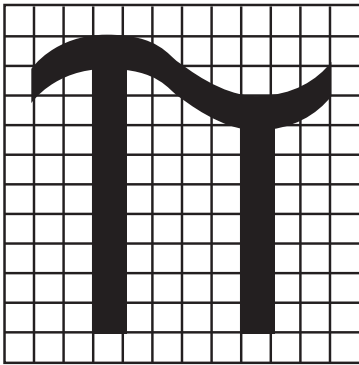
For **pressure receptacles manufactured in series**, as provided in the 2010 TPED, Annex III, paragraph 5, the receptacles can be reassessed by a Type B notified body, notified for periodic inspection of the relevant pressure receptacles, provided that conformity of 'the type' has been reassessed by a Type A notified body. The π mark must be followed by the identification number of the Type B notified body responsible for the periodic inspection.

The particulars for the certificates of reassessment are provided in Annex III of the 2010 TPED.



5 Pi marking of TPE

Transportable pressure equipment must bear a mark indicating its compliance with the ADR and the TPED to ensure its free movement and free use. The pi mark (π) must be applied in accordance with Chapter 3 of the 2010 TPED, and will be in the form of a symbol as follows:



The dimensions of the marking must be as laid out in Article 15 of the 2010 TPED.

TPE which was placed on the market before the implementation date of the 1999 TPED (see Table 2) does not need to bear the π mark. However, if the TPE is reassessed for conformity, the π mark will be applied as described above.

For pressure receptacles that were in compliance with Directives 84/525-7/EEC (see also Section 2), the π mark must be affixed by or under the surveillance of the notified body responsible for the periodic inspection of the relevant receptacles (Xa or Xb), and must be followed by the identification number of the notified body.

Certificates of conformity assessment, reports of periodic inspections, intermediate inspection and exceptional checks, and certificates of reassessment of conformity issued by a notified body are valid in all Member States.

6 Market Surveillance

The Health and Safety Authority is the market surveillance authority in Ireland in relation to TPE and for the purposes of Part 9 of the Regulations.

Where there is sufficient reason to believe that particular TPE presents a risk to the health and safety of persons or to other aspects of public interest protection, the market surveillance authority may carry out an **evaluation** of the TPE.

The relevant economic operator, which under the 2010 TPED, may be the manufacturer, the authorised representative, the importer, the distributor or the owner of the TPE (all of which are defined in Article 2 of the directive), must co-operate with the market surveillance authority, including granting access to their premises or providing samples on request.

Depending on the outcome of the evaluation, if the TPE is found either

- › not to be compliant with the requirements of the ADR and the 2010 TPED, or
- › to be compliant with the requirements of the ADR and the 2010 TPED but still presents a risk,

the market surveillance authority may require the relevant economic operator to take corrective action in relation to the TPE, to withdraw it from the market, or to recall it within a reasonable period.

Where the economic operator does not take adequate corrective action, the market surveillance authority will take provisional measures to ensure that the TPE is removed from the market, and will inform the EU Commission and other EU member states of those measures.⁵ The Commission, in consultation with member states, will then decide whether a national measure is justified or not, and will, where necessary, propose appropriate measures to be taken either by the member state concerned or the economic operator.

⁵ Tools that can be used by market surveillance authorities and the EU Commission are

1. the internet-supported information and communication system for the pan-European market surveillance (ICSMS), and
2. the rapid alert system for dangerous non-food products, RAPEX.

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Further Information

Market Surveillance Authority:

Health and Safety Authority,

The Metropolitan Building, James Joyce Street, Dublin 1, D01 K0Y8

Tel: 1890 289 389 / 00353 1 614 7000

Email: chemicals@hsa.ie

Web: www.hsa.ie

“Use www.besmart.ie – the HSA’s free online risk assessment tool”

Accreditation Body:

Irish National Accreditation Board (INAB),

The Metropolitan Building, James Joyce Street, Dublin 1, D01 K0Y8

Tel: 1890 289 389 / 00353 1 614 7000

Web: www.inab.ie

Notifying Authority

Product Safety Section

Department of Business, Enterprise and Innovation

Earlsfort Centre, Lower Hatch Street, Dublin 2, D02 PW01

Tel: + 353 1 6313189

Email: chemicals@dbei.gov.ie

Web: www.dbei.gov.ie

Further Information and Guidance:

Visit our website at www.hsa.ie, telephone our contact centre on **1890 289 389** or email wcu@hsa.ie

Use BeSMART, our free online risk assessment tool at www.besmart.ie

Check out our range of free online courses at www.hslearning.ie

