For use only if the UK has left the EU without a deal

SIMPLE PRESSURE VESSELS (SAFETY) REGULATIONS 2016 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

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1. Introduction

The Simple Pressure Vessels Regulations 2016 set out the essential safety requirements which must be met before simple pressure vessels can be placed on the UK market. The purpose of the legislation is to ensure safe vessels are placed on the market by requiring manufacturers to show how their vessels meet the ‘essential safety requirements’.

This guidance is designed to help you understand the Simple Pressure Vessels Regulations 2016, now the UK has left the EU, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (“2016 Regulations”).

2. Legislative Background

The Simple Pressure Vessels (Safety) Regulations 2016 implemented Directive 2014/29/EU on simple pressure vessels. The EU Withdrawal Act 2018 preserves the Regulations and enables them to be amended so as to continue to function effectively now the UK has left the EU. Accordingly, the 2019 Amendment Regulations fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the UK market.

3. Scope

The Regulations apply to simple pressure vessels manufactured in series with the following characteristics:

- the vessels are welded, intended to be subjected to an internal gauge pressure greater than 0.5 bar and to contain air or nitrogen, and are not intended to be fired;
- the parts and assemblies contributing to the strength of the vessel under pressure are made either of non-alloy quality steel or of non-alloy aluminium or non-age hardening aluminium alloys;
- the vessel is made of either of the following elements:
  - a cylindrical part of circular cross-section closed by outwardly dished and/or flat ends which revolve around the same axis as the cylindrical part; and
  - two dished ends revolving around the same axis;
- the maximum working pressure of the vessel does not exceed 30 bar and the product of that pressure and the capacity of the vessel (PS × V) does not exceed 10 000 bar·L; and
- the minimum working temperature is no lower than – 50 °C and the maximum working temperature is not higher than 300 °C for vessels constructed of steel and 100 °C for aluminium or aluminium alloy vessels.

4. Requirements

There are different requirements according to the category of vessel.
Category A vessels must meet the ‘essential safety requirements’ before being placed on the market. Compliance with the terms outlined in a designated standard is one way to demonstrate compliance with the essential safety requirements of the 2016 Regulations. A “designated standard” means a technical specification which has been adopted by a recognised standardisation body¹ for repeated or continuous application and which has been designated by the Secretary of State by publishing its reference. A “technical specification” is a document listing the technical requirements which a product must meet.

Category B vessels (of a lower capacity and pressure and therefore a lower risk than Category A) must be designed and manufactured in accordance with sound engineering practice.

- Category A vessels are simple pressure vessels of which the product of PS x V exceeds 50 bar.L.
- Category B vessels are simple pressure vessels of which the product of PS x V is 50 bar.L or less.

5. **Obligations of manufacturers**

A manufacturer is a person who manufactures a simple pressure vessel, or has simple pressure vessels designed or manufactured, and markets that simple pressure vessel under their name or trade mark.

The obligations of manufacturers of simple pressure vessels include:

1. Before placing a Category A vessel on the market, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential safety requirements. These are set out in Schedule 1 to the Regulations. They must also have had a relevant conformity assessment procedure carried out and technical documentation drawn up.

2. Once this has been done for Category A vessels, before placing a vessel on the market, a manufacturer must draw up a declaration of conformity, ensure that declaration accompanies the product and affix the UKCA marking to the vessel or its data plate and the last two digits of the year in which the UKCA marking is affixed. They must also affix the inscriptions (that is, the maximum working pressure and temperature, the minimum working temperature and the capacity of the vessel).

3. Before placing a Category B vessel on the market, a manufacturer must ensure that the vessel has been designed and manufactured in accordance with sound engineering practice.

4. For Category B vessels, the manufacturer must affix the inscriptions (that is, the maximum working pressure and temperature, the minimum working temperature and the capacity of the vessel).

5. For Category A vessels, manufacturers must keep the declaration of conformity up to date and must keep it and the technical documentation for 10 years after the vessel has been placed on the market.

¹ Standardisation bodies recognised by this legislation are: the European Committee for Standardisation (CEN); the European Committee for Electrotechnical Standardisation (Cenelec); the European Telecommunications Standardisation (Cenelec); the British Standards Institute (BSI).
6. Manufacturers must also label vessels or their data plates with the type and serial or batch identification, the manufacturer’s name, registered trade name or registered trade mark and address and ensure that they are accompanied by instructions and safety information which are clear, legible and in easily understandable English.

7. Manufacturers must, when appropriate with regard to any risk posed to end-users, carry out sample testing of vessels that they have placed on the market and investigate any complaints that the vessels are not in conformity with the relevant legal requirements in the Regulations and keep records of these complaints.

8. Manufacturers must take action where they have reason to believe that the vessels are not in conformity with the relevant legal requirements in the Regulations.

9. Manufacturers must also cooperate with and provide information to enforcing authorities following any requests.

6. Obligations of authorised representatives

Manufacturers are able to appoint authorised representatives to perform certain tasks on their behalf.

Mandated authorised representatives established in the EEA of Switzerland prior to the UK leaving the EU continue to be recognised as authorised representatives by the UK to act in the UK for the purposes of the 2016 Regulations. However, any authorised representatives appointed and mandated after the UK left the EU must be established in the UK to act in the UK to be recognised under UK law.

Businesses with an existing authorised representative based in the EEA or Switzerland can therefore continue to use the same authorised representative in respect of the UK.

No UK-based authorised representatives are recognised under EU law. This means that UK based authorised representatives cannot carry out tasks on the manufacturer’s behalf for products being placed on the EU market. Therefore, a manufacturer exporting simple pressure vessels to the EU, who wishes to appoint an authorised representative to carry out tasks for them in respect of those vessels, must appoint an authorised representative based in the EU.

The obligations of authorised representatives include:

1. An authorised representative must comply with all the duties imposed on the manufacturer under the 2016 Regulations that they are appointed by the manufacturer to perform. There are some duties that a manufacturer cannot mandate an authorised representative to perform (e.g. conformity assessment) and some that must form part of the authorised representatives mandate (e.g. retention of technical documentation). A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.

2. As far as those duties are concerned as well as penalties for failure to comply with those duties any references in the 2016 Regulations to the manufacturer are to be taken to include a reference to the authorised representative.
7. Obligations of importers

An importer is a person or business based in the UK who places a simple pressure vessel on the UK market from a country outside the UK. This means that UK businesses who used to act as a ‘distributor’ legally become an ‘importer’ if they place products from an EEA country on the UK market.

Importers have additional legal obligations which go beyond those of distributors, such as checking that manufacturers have carried out the right conformity assessment procedures and included their name, registered trade name or mark and a postal address on the equipment or, where this is not possible, on the accompanying documentation.

To assist with the transition, the UK is applying a transitional period of 18 months to allow UK businesses who import from EEA states or Switzerland (and therefore are importers) to provide their details on the accompanying documentation as an alternative to placing them on the vessel itself.

The EU does not have any such transitional provision. In the absence of this, vessels being exported from the UK to the EU must be labelled with the EU-based importer’s address.

The obligations of importers include:

1. Before placing a Category A vessel on the market, an importer must ensure that it is in conformity Part 2 of the 2016 Regulations. This means that the vessel must comply with the essential safety requirements set out in Schedule 1 and that each economic operator has complied or is complying with their obligations under Part 2 of the 2016 Regulations.

2. For Category A vessels, the importer must ensure that the relevant conformity assessment has been carried out by or on behalf the manufacturer; the manufacturer has drawn up technical documentation; the vessel bears the UKCA marking and is accompanied by the Declaration of Conformity. For Category B vessels, the importer must ensure the vessel has been designed and manufactured in accordance with sound engineering practice and that the manufacturer has complied with their labelling obligations.

3. The importer must keep a copy of the Declaration of Conformity and technical documentation for a period of 10 years after the vessel has been placed on the market.

4. The importer must provide their name, registered trade name and a postal address at which they can be contacted on the vessel or (in certain circumstances – see above) on documentation accompanying the vessel.

5. The importer must ensure that when placing vessels on the UK market, it is accompanied by instructions and safety information which are clear, legible and in easily understandable English.

6. The importer must ensure that Category A vessels under their responsibility are safely stored and transported.

7. The importer must, when appropriate with regard to any risk posed to consumers, carry out sample testing of vessels and investigate complaints about vessels that are not in conformity with the 2016 Regulations and keep a register of those complaints.
8. The importer must take action where they have reason to believe that the vessels that they have placed on the market are not in conformity with the 2016 Regulations.

9. The importer must also cooperate with and provide information to enforcing authorities following any requests.

8. Obligations of distributors

UK businesses which were distributors of simple pressure vessels within the EU single market should now consider whether they are importers from the EU single market and therefore what additional requirements they might face – see section 7 above. The same applies to distributors of vessels from the EEA and Switzerland.

A distributor is any person, other than the manufacturer or importer, who makes a simple pressure vessel available on the market.

The obligations of distributors include:

1. Before making a simple pressure vessel available on the market a distributor must act with due care to ensure that it is in conformity with Part 2 of the Regulations.

2. Before making a Category A vessel available on the market a distributor must ensure that it bears the relevant marking and for all vessels subject to the Regulations the distributor must ensure that the vessel bears the inscriptions, that it is accompanied by instructions and safety information, that the manufacturer has complied with the requirements as to labelling and the importer has complied with the requirements as to identification.

3. The distributor must ensure that the Category A vessels under their responsibility are safely stored and transported.

4. The distributor must take action where they have reason to believe that the vessels that they have made available on the market are not in conformity with the Regulations.

5. The distributor must also cooperate with and provide information to enforcing authorities following any requests.

9. Transitional arrangements

‘Deeming’ provision

Simple pressure vessels which have undergone full conformity assessment under the equivalent EU requirements and bear the CE marking will be deemed compliant with the UK legislation and can be placed on the UK market as if they had been UK conformity marked.

The UK continues to recognise the competency of EU recognised conformity assessment bodies (notified bodies) to assess vessels for the UK market. Products assessed by an EU recognised notified body prior to the UK leaving the EU do not need reassessment before being placed on the UK market. Furthermore, for a time-limited period, vessels assessed by an EU recognised notified body can be placed on the UK market.

This ‘deeming provision’ will be available for a time-limited period. This will be the subject of amending legislation in the future at a time yet to be decided. The Government will consult with industry and provide notice before ending this time-limited period.
10. UK Conformity Mark

Assessment through third-party organisations:

The UKCA conformity mark will replace the CE marking for simple pressure vessels placed on the UK market which have been assessed by a UK approved body. In all other cases, manufacturers will be able to continue using the CE marking for products being placed on the UK market instead of the new UKCA marking for a time-limited period. The Government will engage with industry before making any decision on when this period will end.

Rules around physically affixing the new UKCA conformity marking mirror those currently apply for the application of the CE marking.

Placing CE marked goods on the UK market:

Simple pressure vessels that meet EU regulatory requirements, including those with a CE marking, which have been assessed by an EU recognised conformity assessment body can still be placed on the UK market for a time-limited period. ‘EU-recognised’ does not include UK approved bodies. Manufacturers which have had their vessels assessed by EU recognised bodies are obliged to use the CE marking and cannot use the UKCA marking.

Testing Certificates:

Where conformity assessment is a 2-stage process, it is possible for simple pressure vessels to have an EU-type-examination certification (1st stage) followed by a UK declaration by the manufacturer or third party of the production process under the responsibility of a UK Approved Body (2nd stage). Such vessels should have the UK conformity mark followed by the UK Approved Body Number.

Further guidance on UKCA marking can be found here: https://www.gov.uk/government/publications/prepare-to-use-the-ukca-mark-after-brexit/using-the-ukca-marking-if-the-uk-leaves-the-eu-without-a-deal

Simple Pressure Vessels exported to the EU Single Market must comply with EU Directive 2014/29/EU.

11. Approved Bodies

The UK has established a new framework for UK based bodies to assess simple pressure vessels against UK rules. Existing UK notified bodies have been granted new UK ‘approved body’ status and are listed on a new UK database. There is no need for existing notified bodies to seek re-accreditation in order to benefit from UK approved body status. These approved bodies have been given a 4-digit approved body number.

Approved bodies can assess vessels for the UK market against UK essential safety requirements (which are the same as EU essential requirements).

UK Approved Bodies are conformity assessment bodies which were UK notified bodies before the UK left the EU or have been approved by the Secretary of State to carry out the procedures for conformity assessment and certification for the UK market as set out in the 2016 Regulations.

Approved bodies must be established in the UK and be independent of the manufacturer. Approved bodies must examine the technical documentation and supporting evidence in respect of a vessel to assess the adequacy of the technical design.
Where an approved body finds that essential safety requirements have not been met, they must not issue a certificate of conformity and they must require the manufacturer to take corrective measures.

A list of UK approved bodies can be found [link to be added].

12. Enforcement

For products intended for workplace use, the Health and Safety Executive (HSE) is responsible for the enforcement of the Regulations in Great Britain. In Northern Ireland, enforcement is the responsibility of the Health and Safety Executive for Northern Ireland (HSENI).

In Great Britain trading standards authorities, and in Northern Ireland district councils, are responsible for enforcing the Regulations in relation to private use or consumption.

Where the vessels are intended to be used on nuclear sites (either primarily or exclusively), the Office for Nuclear Regulation is responsible for enforcing these Regulations (http://www.onr.org.uk/).

The Regulations also provide powers to the Secretary of State or a person appointed to act on their behalf to enforce the Regulations and RAMS in its application to vessels (Regulation (EC 765/2008, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, which sets out requirements for market surveillance of products).

The Regulations provides the power to enforcing authorities to take action against economic operators for vessels that present a risk or are not in conformity with the Regulations. There are requirements on economic operators to co-operate with the enforcement authority as appropriate on request.

The UK market surveillance authorities will take all appropriate measures and ultimately to withdraw from the market or to prohibit and restrict the supply of vessels which may endanger the health and safety of persons, property or the environment.

Regulators’ Code

Market surveillance authorities must have regard to the Regulators’ Code when developing the policies and operational procedures that guide their regulatory activities in this area. They should carry out their activities in a way that supports those they regulate to comply and grow, including choosing proportionate approaches that reflect risk.

In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required, or decisions taken, and the reasons for these. Unless immediate action is needed to prevent a serious breach, regulators should provide an opportunity for dialogue in relation to the advice, requirements or decisions, with a view to ensuring that they are acting in a way that is proportionate and consistent. The Secretary of State takes account of the provisions of both the Regulators’ Code and the Growth Duty in exercising his regulatory functions.

A link to the Regulators’ Code can be found here:

Penalties

A person committing an offence under the Regulations may be liable to a penalty. Penalties can include a fine or a prison sentence of up to three months for the most serious offences. It is matter for the enforcement authority to decide what action is appropriate in each case taking into account the circumstances of the case and the enforcement authorities’ own policies, operational procedures and practices in line with the Regulators Code. Should a prosecution take place, it is at the discretion of the court to decide the penalties imposed on the offender.


The European Commission’s ‘Blue Guide’ aims to give a better understanding of EU product safety rules and to their application across different sectors and throughout the EU single market. You can view that here http://ec.europa.eu/DocsRoom/documents/18027/These documents set out the rules in relation to products on the EU market.

14. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a UK ‘Notified Body’ prior to the UK leaving the EU.

- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. This includes persons who are based in the EU or Switzerland, if they were appointed before the UK left the EU. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.

- **Declaration of conformity** – A document prepared by the manufacturer which must detail, amongst other things, the following:
  - The specific vessel to which the declaration is referring;
  - The name and address of the manufacturer and, where applicable, their authorised representative.

  This must be kept by the manufacturer for a period of ten years from the date on which the vessel was placed on the market. This declaration must be made available to the enforcing authority upon request.

- **Distributor** – Any person in the UK supply chain, other than the manufacturer or the importer, who makes a vessel available on the UK market.

- **Enforcing Authority** – In Great Britain, for vessels in the use in the workplace, this is the Health and Safety Executive (apart from when used on nuclear sites). For products for private use this is local Trading Standards authorities. In Northern Ireland, for vessels in use in the workplace, this is the Health and Safety Executive Northern Ireland. For products for consumer use this is district councils. For vessels in use on nuclear sites, this is the Office for Nuclear Regulation.
• **Importer** – A person established in the UK who places a vessel from a country outside of the UK on the market. A person who before the UK left the EU distributed vessels within the EU (including the UK) will now be an importer if they are bringing vessels into the UK from another country (including EU Member States, the EEA or Switzerland).

• **Manufacturer** – A person who manufactures a vessel or has a vessel designed or manufactured and markets that vessel under their name or trademark.

• **UK Conformity Marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the UK market, in place of the CE marking which is the conformity marking used in the European Union.