Office for Product Safety & Standards

Pressure Equipment (Safety) Regulations 2016

As they apply to equipment being supplied in or into Northern Ireland

Guidance

January 2021

Contents

Guidance

1. Introduction

This Guide is for businesses placing pressure equipment on the market in Northern Ireland from 1 January 2021[1].

While the Northern Ireland Protocol[2] ('the Protocol') is in force, from 1 January 2021, Northern Ireland ("NI") will align with relevant EU rules relating to the placing on the market of manufactured goods. Pressure equipment placed on the NI market must follow UK law as it applies to NI. The relevant law is the Pressure Equipment (Safety) Regulations 2016, which apply across the UK but some of their provisions apply differently in NI so that they continue to implement in NI the Directive 2014/68/EU on Pressure Equipment.

This Guide is designed to help you comply with the Pressure Equipment (Safety) Regulations 2016, as they apply in NI. References to "The 2016 Regulations" in this document are references to the Pressure Equipment (Safety) Regulations 2016, as they apply in Northern Ireland.

The 2016 Regulations set out the requirements that must be met before pressure equipment can be placed on the NI market. The purpose of the legislation is to ensure safe equipment is placed on the market by requiring manufacturers to show how the equipment meet the 'essential safety requirements'.

Pressure equipment placed on the GB ("GB") market (GB comprises England, Scotland and Wales) must follow the separate rules for the GB market. If you are placing pressure equipment on the market in GB, you should read the relevant separate guidance:

https://www.gov.uk/government/publications/pressure-equipment-safety-regulations-2016

The government has committed to providing unfettered access for qualifying NI goods to the rest of the UK market after 1 January 2021. Pressure equipment that can be placed on the market in NI in accordance with the 2016 Regulations, as they apply to NI, can be sold in the rest of the UK without any additional approvals. The arrangements here are explained in detail in the separate guidance for placing pressure equipment on the market in GB.

2. Legislative Background

The Directive on Pressure Equipment (PED – 2014/68/EU) was implemented into UK law by the Pressure Equipment (Safety) Regulations 2016 (SI 2016 No.1105).

The Directive will continue to apply in NI, for as long as the Protocol on Ireland/ Northern Ireland is in force. However, the 2016 Regulations (as they apply in Northern Ireland) also implement parts of the Protocol which have particular provisions in them, recognising that the UK has left the EU.

There is therefore one set of UK 2016 Regulations, but some of the provisions apply differently in NI and GB. References to the 2016 Regulations in this guidance are references to those Regulations as they apply in NI.

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1 The Implementation or Transition Period officially ends at 11pm on 31 December 2020; therefore references to 1 January 2021 should be read as meaning 11pm on 31st December 2020

2 The Protocol on Ireland/Northern Ireland (also known as 'The Northern Ireland Protocol' and referred to in this document as 'the Protocol'.

The 2016 Regulations were amended by Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020, the Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 and the Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 to give effect to The Protocol as it relates to the placing on the NI market of pressure equipment[3].

3. Scope

The 2016 Regulations apply to pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar, although there are a number of exclusions, which are set out in regulation 4 and Schedule 1 to the 2016 Regulations. “Pressure equipment” means vessels, piping, safety accessories and pressure accessories. “Assembly” means several pieces of pressure equipment assembled by a manufacturer to form an integrated, functional whole.

These regulations do not apply to pressure equipment placed on the market before 8 December 2016.

For the avoidance of doubt, the manufacture of pressure equipment by private individuals for their own use is excluded from the scope of the 2016 Regulations.

4. Product classification

In order to know how the 2016 Regulations apply to specific items of pressure equipment, the manufacturer will need to know:

a) the type of equipment concerned, i.e. vessel, steam generator or piping;
b) the state of the intended fluid contents – gas or liquid; and
c) the fluid group of the intended contents – Group 1 or Group 2.

Group 1 comprises those substances and mixtures, as defined in points (7) and (8) of Article 2 of Regulation (EC) No 1272/2008 of the European Parliament and the Council on classification, labelling and packaging of substances and mixtures (“the CLP Regulation”), that are classified in accordance with the following physical or health hazard classes laid down in Parts 2 and 3 of Annex I to that Regulation:

(i) unstable explosives or explosives of Divisions 1.1, 1.2, 1.3, 1.4 and 1.5;
(ii) flammable gases, category 1 and 2;
(iii) oxidising gases, category 1;
(iv) flammable liquids, category 1 and 2;
(v) flammable liquids, category 3 where the maximum allowable temperature is above the flashpoint;
(vi) flammable solids, category 1 and 2;
(vii) self-reactive substances and mixtures, type A to F;
(viii) pyrophoric liquids, category 1;
(ix) pyrophoric solids, category 1;
(x) substances and mixtures which in contact with water emit flammable gases, category 1, 2 and 3;

[3] In 2019, the Simple Pressure Vessels Regulations 2016 were amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 to 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. The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were then amended by the Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 to apply to Great Britain only, and not to Northern Ireland, in support of implementing The Northern Ireland Protocol.

(xi) oxidising liquids, category 1, 2 and 3;
(xii) oxidising solids, category 1, 2 and 3;
(xiii) organic peroxides types A to F;
(xiv) acute oral toxicity, category 1 and 2;
(xv) acute dermal toxicity, category 1 and 2;
(xvi) acute inhalation toxicity, category 1, 2 and 3; and
(xvii) specific target organ toxicity - single exposure, category 1.

Assistance with identifying the hazard classes of substances can be found on the European Chemicals Agency (ECHA) website.

Group 1 also comprises substances and mixtures contained in pressure equipment with a maximum allowable temperature TS which exceeds the flashpoint of the fluid.

Group 2 comprises substances and mixtures not referred to under group 1, within the definition of a fluid, including steam.

With this information the manufacturer can identify the relevant chart in Annex II of the Directive and determine the correct classification of the equipment by plotting the maximum allowable pressure and, in the case of vessels, the volume in litres or, for piping, the nominal size (DN).

The obligations of economic operators with regard to pressure equipment and assemblies depend on their classification. Equipment and assemblies within scope which are below or equal to the limits set out in the 2016 Regulations (see regulation 6(a)-(c) and 7) must be; designed and manufactured in accordance with the principals of sound engineering practice of Northern Ireland or an European Economic Area (EEA) State in order to ensure safe use and must be accompanied by adequate instructions for use. Unless required by other applicable EU legislation, this second category of equipment and assembly must not bear the CE marking. This is set out in regulation 8 of the 2016 Regulations.

In the paragraphs below, unless indicated otherwise, the references to pressure equipment or assemblies does not include those under the limits referred to in regulation 8.

5. Obligations of manufacturers

A manufacturer is a person who manufactures pressure equipment or an assembly, or has pressure equipment designed or manufactured, and markets that equipment under their name or trademark.

The obligations of manufacturers of pressure equipment include:

1. Before placing relevant pressure equipment on the NI market or using it for their own purposes, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential safety requirements.
2. The manufacturer then must classify the equipment or assembly into the appropriate category, determine the conformity procedure that applies and carry out the relevant conformity assessment procedure and draw up the relevant technical documentation.

3. Once this has been done, a manufacturer must draw up an EU Declaration of Conformity, ensure that declaration accompanies the product and affix the CE marking visibly, legibly and indelibly to the equipment[4]. Where it is not possible or warranted, on account of the nature of the equipment, to affix the CE marking to the equipment, it must be affixed to the packaging and the accompanying documents. Where applicable, they must also ensure that the identification number of the notified body is affixed to the equipment or assembly.

3. When conformity assessment has been carried out by a UK notified body, the UK marking (also known as the UK(NI) indication) must be affixed as well as the CE marking. A product with the both the CE and the UKNI markings cannot be placed on the EEA market. There is separate guidance on when and how to use the UKNI marking:

   https://www.gov.uk/guidance/using-the-ukni-marking

4. Manufacturers must keep the EU Declaration of Conformity up to date and keep it and the relevant technical documentation for 10 years.

5. Manufacturers must also label their products with their name, registered trade name or registered trademark and address; the type batch or serial number (or other identification) in a language that is easily understood by the end user. If the end user is in NI, the language must be English. This applies to all products (including those to which regulation 8 refers).

6. When placing pressure equipment or an assembly on the NI market, a manufacturer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by the end user. If the end user is in NI, the language must be English. This applies to all products (including those to which regulation 8 applies).

7. Manufacturers must ensure that procedures are in place for series production to remain in conformity with Part 2 of the 2016 Regulations. In doing so, they must take account of any changes in pressure equipment or assembly design or characteristics, and any change in a harmonised standard or in another technical specification by reference to which the EU Declaration of Conformity was drawn up.

8. When appropriate, with regard to the risks to the health and safety of consumers and other users, they must carry out sample testing and they must investigate any complaints that the pressure equipment is not in conformity and keep records of these complaints.

9. They must take action where they have reason to believe that any product is not in conformity with the 2016 Regulations.

6. Obligations of authorised representatives

A manufacturer can appoint an authorised representative to perform certain tasks on their behalf.

[4] There are exceptions to conformity marking the equipment or assembly. Regulation 11(2) excludes conformity marking under modules A2, C2 F or G, and where conformity assessment is carried out by a user inspectorate.

An authorised representative appointed by a manufacturer to represent them in either the NI or EEA markets cannot be based in GB. This means that GB based authorised representatives cannot carry out tasks on the manufacturer's behalf for products being placed on the NI or EEA markets.

An authorised representative based in NI can, under the 2016 Regulations as they apply in NI, carry out tasks on the manufacturer's behalf for products placed on the NI or EEA markets.

An authorised representative must comply with all the duties imposed on the manufacturer under the 2016 Regulations that they are appointed in writing 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.

Any references in the 2016 Regulations to the manufacturer are to be taken to include a reference to the authorised representative including in relation to penalties for failure to comply with those duties.

7. Obligations of importers

For the purposes of the 2016 Regulations as they apply in NI (under the Protocol), an importer is a business or person established in NI or the EEA who places equipment from outside of the EEA or NI on the NI or EEA market. Therefore, a business or person based in NI who is supplied with a product from GB will be an importer under the 2016 Regulations as they apply in NI, if they then sell that product on the NI (or EEA) markets.

The obligations of importers include:

1. Before pressure equipment is placed on the NI market, an importer must ensure that it is conformity with the essential safety requirements.
2. The importer must ensure the manufacturer has only placed equipment on the GB market that is in conformity with Part 2 of the 2016 Regulations and has drawn up technical documentation; the pressure equipment or assembly is CE marked, where required, and is accompanied by the required documents and that the manufacturer has complied with the labelling requirements imposed on the manufacturer.
3. When conformity assessment has been carried out by a UK notified body, the UK marking (also known as the UK(NI) indication) must be affixed as well as the CE marking. A product with both the CE and the UKNI markings cannot be placed on the EEA market. There is separate guidance on when and how to use the UKNI marking:

   https://www.gov.uk/guidance/using-the-ukni-marking
4. The importer must keep a copy of the EU Declaration of Conformity and technical documentation for a period of 10 years after the pressure equipment or assembly has been placed on the NI market and must co-operate with and provide information to the enforcing authorities when requested.
5. When an importer has reason to believe that pressure equipment or an assembly is not in conformity with the essential safety requirements, the importer must not place the pressure equipment or assembly on the NI market.

6. The importer must provide their name trade, registered trade name and a postal address at which they can be contacted on the pressure equipment or assembly, where it is not possible to put this information on the equipment or assembly itself, it must be on its packaging or in a document accompanying the equipment or assembly.
7. The importer must ensure that when placing pressure equipment or assembly on the market, they must ensure that it is accompanied by instructions which can be easily understood by the end user where it is to be made available. If that is NI, the language is English.
8. The importer when appropriate, having regard to the risks to the health and safety of consumers and other users, must carry out sample testing of the pressure equipment or assembly and must investigate complaints about pressure equipment or assemblies that are not in conformity with the 2016 Regulations and keep a register of those complaints.
9. The importer must take action where they have reason to believe that the pressure equipment or assembly that they have placed on the NI market are not in conformity with the 2016 Regulations.
10. The importer must ensure that pressure equipment or assembly under their responsibility must be transported and stored in conditions that do not affect their conformity with the essential safety requirements.

8. Obligations of distributors

A distributor is any person, other than the manufacturer or importer, who makes equipment or an assembly available on the NI market.

NI businesses which were distributors of pressure equipment supplied to them from GB should now consider whether they are classified as importers under the 2016 Regulations and therefore what additional requirements they need to comply with – see section 7 above. Under the 2016 Regulations an NI business placing a product from GB on the NI market does so as an importer, not as a distributor.

The obligations of distributors include:

1. Before making pressure equipment or an assembly available on the NI market a distributor must ensure that it is in conformity with Part 2 of the 2016 Regulations, meaning that it conforms with the essential safety requirements and that each economic operator has complied or is complying with the obligations imposed on them under Part 2.
2. Before making pressure equipment or an assembly available on the NI market, a distributor must verify that the pressure equipment or assembly bears the CE marking (for pressure equipment under regulations 6 or 7), is accompanied by the required documents, the instructions and safety information and that the manufacturer and importer have complied with their labelling and identification requirements.

3. When conformity assessment has been carried out by a UK notified body, the UK marking (also known as the UK(NI) indication) must be affixed as well as the CE marking. A product with both the CE and the UKNI markings cannot be placed on the EU market. There is separate guidance on when and how to use the UKNI marking:

   https://www.gov.uk/guidance/using-the-ukni-marking

4. They must ensure that pressure equipment or assemblies under their responsibility must be transported and stored in conditions that do not affect their conformity with the essential safety requirements.
5. Where the distributor has reason to believe that the pressure equipment or assembly which the distributor has made available on the NI market is not in conformity with Part 2, they must not make it available on the NI market until it is brought into conformity.
6. The distributor must take action where they have reason to believe that the pressure equipment that they have made available on the NI market is not in conformity with the 2016 Regulations.
7. The distributor must also cooperate with and provide information to enforcing authorities when requested.

9. Transitional arrangements

Products placed on the market before 1 January 2021

If you have already placed an individual fully manufactured product on the EEA or the UK market (either in NI or GB) before 1 January 2021, you do not need to do take an additional action. These individual goods can continue to circulate on either market until they reach their end user and do not need to comply with the changes that take effect from 1 January 2021.

A fully manufactured good is ‘placed on the market’ when there is a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other rights in the product. This does not require physical transfer of the good.

You can usually provide proof of placing on the market on the basis of any relevant document ordinarily used in business transactions, including:

- contracts of sale concerning goods which have already been manufactured and meet the legal requirements
- invoices
- documents concerning the shipping of goods for distribution

The relevant economic operator (whether manufacturer, importer or distributor) bears the burden of proof for demonstrating that the good was placed on the market before 1 January 2021.

10. Conformity Marking

Where pressure equipment is being placed on the NI market, and the manufacturer chooses to have it conformity assessed by a EU recognised body, the marking for the NI and EEA markets continues to be the CE marking.

The CE marking can continue to be used for the GB market until 31 December 2021, as long as all the other rules have been complied with. After 31 December 2021, the UKCA marking must be used for the GB market, but there are specific rules relating to unfettered access that apply for qualifying NI goods.

For qualifying NI goods, equipment meeting NI rules (the 2016 Regulations as they apply in NI), which are CE or both CE and UKNI marked, can be placed on the GB market from 1 January 2021 and on an ongoing basis thereafter (there is further information on the reasons for this below and this arrangement is explained further in the separate guide to placing pressure equipment and assemblies on the GB market).

Equipment that does not fall within the definition of qualifying Northern Ireland goods will need to meet the GB rules, including being UKCA marked where applicable, if placed on the GB market after 31 December 2021.

From 1 January 2021, where the manufacturer chooses to have the equipment conformity assessed by a UK notified body, the CE marking must be accompanied by the UKNI marking (also known as the UK(NI) indication). Products with the UKNI marking cannot be placed on the EEA market.

There is separate guidance on when and how to use the UKNI marking:

https://www.gov.uk/guidance/using-the-ukni-marking

11. Notified Bodies

Notified Bodies are independent organisations notified to the European Commission to carry out the procedures for conformity assessment and certification set out in the 2016 Regulations.

From 1 January 2021, all UK Notified Bodies will remain Notified Bodies for the purpose of CE marked products for the NI market. This includes recognised third-party organisations (RTPO) and user inspectorates (UI). When these UK bodies are used for mandatory conformity assessment activity, then the manufacturer will need to affix both the CE and the UKNI markings. A product with both the CE and the UKNI markings cannot then be placed on the EEA market. There is separate guidance on when and how to use the UKNI marking:

https://www.gov.uk/guidance/using-the-ukni-marking

A list of EU Notified Bodies can be found on the NANDO website. Economic operators requiring conformity assessment and CE marking are free to select any suitable Notified Body from any Member State. If a manufacturer uses a Notified Body from this list, then they apply only the CE marking to their product (not the CE UKNI marking).

A list of UK Notified Bodies is available here:

https://www.gov.uk/uk-market-conformity-assessment-bodies

12. Qualifying Northern Ireland Goods

The government has committed to providing unfettered access for qualifying NI goods to the rest of the UK market after 1 January 2021. Pressure equipment that can be placed on the NI market in accordance with the 2016 Regulations can be sold in the rest of the UK without any additional approvals. The guide to placing pressure equipment on the GB market has further details on these arrangements.

You can find out more about qualifying Northern Ireland goods here:

https://www.gov.uk/guidance/moving-qualifying-goods-from-northern-ireland-to-the-rest-of-the-uk

13. Enforcement

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

In NI district councils, are responsible for enforcing the 2016 Regulations in relation to private use or consumption.

The 2016 Regulations provides powers to market surveillance authorities to take action against economic operators for products that present a risk or are not in conformity with the 2016 Regulations as set out in Regulation 71. Economic operators are also required to co-operate with the enforcement authority and on request, must provide information and take action as appropriate.

Safeguard procedure

Enforcement authorities are required under the 2016 Regulations to take all appropriate measures to withdraw from the NI market or to prohibit, and restrict the supply of products bearing CE Marking which may endanger the health and safety of persons, property or the environment if the relevant economic operator does not do so. Under the safeguard procedure, the UK must inform the European Commission and EU Member States immediately of any enforcement action taken indicating the reasons justifying the action. This will enable Member States to take action against similar products placed on the market on their territories. Similarly, if an EU Member State initiates the procedure with respect to action taken on their territories, certain actions are required of UK market surveillance authorities and the Secretary of State. The European Commission will determine whether the action taken is justified; if so UK enforcement authorities must take necessary measures to ensure the equipment is withdrawn from the market.

Regulator's 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 risk 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 Regulator's Code can be found here:

https://www.gov.uk/government/publications/regulators-code

Penalties

Penalties can include:

- a fine or prison sentence of up to three months or to both on summary conviction or:
- a fine or prison sentence of up to two years or both on conviction on indictment

While it is matter for the enforcement authority to decide whether prosecution is appropriate in each case, should a prosecution take place, and the economic operator is found to be in breach, it is at discretion of the court to decide the penalties imposed on the offender.

14. European Commission Guidance

The European Commission has produced detailed guidance on the provisions of the Directive and its requirements:

https://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment/directive_en

The Commission has produced guidance called the Blue Guide intended to contribute to a better understanding of EU product safety rules and to their more uniform and coherent application across different sectors and throughout the single market. A copy can be found at this link:

Blue Guide: http://ec.europa.eu/DocsRoom/documents/18027

15. Glossary

- **Approved Body** – A conformity assessment body which has been approved by the Secretary of State or was a UK 'Notified Body' prior to 1 January 2021 able to carry out conformity assessment of products with a view to UKCA marking. They are not recognised by the EU (unless they have a presence in the EU) and cannot approve CE marking.
- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. An authorised representative can be based anywhere in the EEA or NI, but cannot be based in GB, in respect of products being supplied on the NI market. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.
- **CE marking** – the CE marking must be placed on products which have been conformity assessed by an EU Notified Body and are intended for the EU or NI markets. CE marked products can only be placed on the GB market until 31 December 2021, although special arrangements have been agreed to ensure NI's unfettered access to the rest of the UK.
- **EU Declaration of conformity** – A document prepared by the manufacturer which must detail, amongst other things, the following:
  - The specific product 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 product was placed on the NI market. This declaration must be made available to the enforcing authority upon request.

- **Distributor** – Any person in the EEA or NI supply chains, other than the manufacturer or the importer, who makes a product available in the EEA or NI markets.
- **Enforcing Authority** – In NI, for products in the use in the workplace, the enforcing authority is the Health and Safety Executive for Northern Ireland (HSENI). For products for private use it is district councils.
- **Importer** – A person established in NI who places a product from a country outside of the EEA or NI on the NI market. A person based in NI who before 1 January 2021 distributed a product from GB on the NI (or EEA) market, will now be an importer if they are bringing products into NI from the GB.
- **Manufacturer** – A person who manufactures pressure equipment or assemblies or has them designed or manufactured and markets that product under their name or trademark.
- **Notified Body** – A conformity assessment body based in the EEA which has been approved and notified by an EEA Member State to carry out conformity assessment for placing products on the EU and NI markets; or a conformity assessment body that is based in the UK and have been approved and notified by the Secretary of State, including bodies which were notified bodies whilst the UK followed EU rules. If these UK based Notified Bodies are used, the CE marking must be accompanied by the UKNI marking and cannot be placed on the EEA market (just the NI market, or, where it is also a qualifying NI good, the GB market)
- **UKCA marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the GB market, in place of the CE marking, which is the conformity marking used in the European Union. All products placed on the GB market from 1 January 2022 must be UKCA marked, but there are special arrangements in place to ensure NI's unfettered access to the rest of the UK. Products being placed on the NI market cannot be UKCA marked but must continue to be CE marked.
- **UKNI marking** (also known as the UK(NI) indication) – The UKNI marking must be used along with the CE marking if manufacturers wish to use a UK Notified Body for conformity assessment. The UKNI marking allows the product to be placed on the NI market (and, under the Government's unfettered access commitments, where the product is also a qualifying NI good, on the GB market), but not the EEA market.

This publication is available at https://www.gov.uk/government/publications/pressure-equipment-safety-regulations-2016

Contact us if you have any enquiries about this publication, including requests for alternative formats, at: OPSS.enquiries@beis.gov.uk

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