



Office for Product
Safety & Standards

Supply of Machinery (Safety) Regulations 2008

As they apply to machinery being supplied in or into Great
Britain from 1 January 2021

Guidance

January 2021



Contents

Guidance	3
1. Introduction	3
2. Legislative Background.....	3
3. Scope	4
4. Requirements	5
5. Obligations of ‘responsible persons’	5
6. Obligations of authorised representatives.....	6
7. Transitional arrangements	6
8. UKCA Marking	7
9. Qualifying Northern Ireland Goods	7
10. Approved Bodies	8
11. Enforcement	9
12. Glossary	9
ANNEXES	11
Annex A Machinery excluded from the Regulations.....	11
Annex B Essential Health and Safety Requirements relating to the design and construction of machinery.....	12

Guidance

1. Introduction

This Guide is for businesses placing machinery on the market in Great Britain from 1 January 2021¹. If you are placing machinery on the market in Northern Ireland, you should read separate guidance:

<https://www.gov.uk/government/publications/supply-of-machinery-safety-regulations-2008>

This Guide is designed to help you understand The Supply of Machinery (Safety) Regulations 2008 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (referred to in this document as the “2008 Regulations”). The 2008 Regulations set out the requirements that must be met before machinery can be placed on the GB market or put into service. The purpose of the legislation is to ensure safe machinery is placed on the market or put into service by requiring manufacturers to show how their machinery meet the ‘essential health and safety requirements’.

2. Legislative Background

The Supply of Machinery (Safety) Regulations 2008 implemented Directive 2006/42/EC on machinery. 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 Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019² fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the GB market.

The 2008 Regulations replaced the Supply of Machinery (Safety) Regulations 1995 and were amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 to apply solely to the GB market.

There is therefore one set of UK 2008 Regulations, but some of the provisions apply differently in NI for as long as the Northern Ireland Protocol is in force. References to the 2008 Regulations in this guidance are references to those Regulations as they apply in Great Britain. For guidance on placing on the Northern Ireland market, please see.

<https://www.gov.uk/government/publications/supply-of-machinery-safety-regulations-2008>

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

² The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were 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 Protocol of Ireland and Northern Ireland (“The Northern Ireland Protocol”). The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were further amended by the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 to provide for a 24 month transition period for importer labelling (for goods from the EEA), UKCA marking, to amend the definition of “authorised representative” as well as introducing an end (in 12 months from the end of the Transition Period) to the recognition of goods meeting EU requirements, as well as introducing provisions for qualifying Northern Ireland goods.

3. Scope

The Regulations apply to:

(a) machinery, described as:

- (i) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application
- (ii) an assembly as referred to in sub-paragraph (i), missing only the components to connect it on site or to sources of energy and motion
- (iii) an assembly as referred to in sub-paragraph (i) or (ii), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or structure
- (iv) assemblies of machinery as referred to in sub-paragraphs (i), (ii) and (iii) or partly completed machinery, which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole
- (v) an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort

(b) interchangeable equipment, described as:

devices which, after the putting into service of machinery or of a tractor, are assembled with that machinery or tractor by operators themselves in order to change its function or attribute a new function, in so far as they are not tools

(c) safety components, described as components:

- (i) which serve to fulfil a safety function
- (ii) which are independently placed on the market
- (iii) the failure or malfunction of which endangers the safety of persons; and
- (iv) which are not necessary in order for the machinery to function, or for which other components which do not fall within the previous sub-paragraphs may be substituted in order for the machinery to function

(d) lifting accessories, described as components or equipment that:

- (i) are not attached to lifting machinery
- (ii) allow a load to be held
- (iii) are placed between the machinery and the load or on the load itself, or are intended to constitute an integral part of the load; and
- (iv) are independently placed on the market

(e) chains, ropes and webbing, described as being:

designed and constructed for lifting purposes as part of lifting machinery or lifting accessories

(f) removable mechanical transmission devices, described as:

removable components for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing (when such components are placed on the market with a guard the components and the guard together shall be regarded as one product).

(g) partly completed machinery, described as:

drive systems and other assemblies which

- (a) are almost machinery
- (b) cannot in themselves perform a specific application; and
- (c) are only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery.

4. Requirements

The Regulations make it an offence for a 'responsible person' to supply machinery, partly completed machinery or safety components unless they comply with the 2008 Regulations.

Compliance with the 2008 Regulations includes ensuring that the essential health and safety requirements (EHSRs) are satisfied; carrying out the necessary conformity assessment procedures; drawing up a declaration of conformity; and ensuring the machinery has the UKCA or (alternatively until 31 December 2021 the CE marking) affixed.

5. Obligations of 'responsible persons'

A 'responsible person' under the Regulations means the manufacturer (see definition of 'manufacturer' in the glossary section 12) of the machinery or the manufacturer's authorised representative.

The obligations of responsible persons under the Regulations are:

1. No responsible person shall place machinery on the GB market or put it into service unless it is safe.
2. They must ensure that the essential health and safety requirements are satisfied in respect of it.
3. They must ensure that the technical file is compiled and made available on request.
4. They must provide information necessary to operate it safely.
5. They must ensure that the relevant conformity assessment procedure is carried out.
6. They must draw up a declaration of conformity and make sure that a copy of this accompanies the machinery.
7. They must affix the relevant conformity marking to the machinery.
8. For partly completed machinery, the responsible person must also ensure that assembly instructions are prepared, and a declaration of incorporation is drawn up and that both accompany the partly completed machinery until it is incorporated into machinery.

Manufacturers based in Northern Ireland can follow the legislation as it applies to Northern Ireland and place qualifying Northern Ireland goods on the GB market without any additional approvals. See further detail in Section 9 on Qualifying Northern Ireland Goods.

6. Obligations of authorised representatives

Manufacturers are able by written mandate to appoint authorised representatives to perform all or part of the obligations and formalities imposed on manufacturers (either as manufacturers or responsible persons) by the Regulations.

Mandated authorised representatives for the GB market can be based in GB or Northern Ireland but after 1 January 2021 cannot be based outside the UK. A manufacturer can only mandate an authorised representative established in the UK, under the 2008 Regulations as they apply in GB.

No GB-based authorised representatives are recognised under EU law. This means GB-based authorised representatives cannot carry out tasks on the manufacturer's behalf for machinery being placed on the Northern Ireland or EEA markets. Therefore, a GB manufacturer selling machinery to the EEA or placing on the NI market, who wishes to appoint an authorised representative to carry out tasks for them in respect of that machinery, must appoint an authorised representative based in Northern Ireland or the EEA.

7. 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 Northern Ireland or Great Britain) before 1 January 2021, you do not need to do anything new. 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; and
- documents concerning the shipping of goods for distribution.

The relevant responsible person (manufacturer, authorised representative or person placing on the market or putting into service) bears the burden of proof for demonstrating that the good was placed on the EEA or UK market before 1 January 2021.

Existing CE marked stock

The UK will allow CE marked machinery that has been either self-declared as compliant (where permissible) or where compliance must and has been demonstrated through assessment by an EU-recognised conformity assessment body (notified body) to be placed on the GB market until 31 December 2021.

Machinery lawfully placed on the market with a CE marking by 31 December 2021 can continue to circulate on the GB market after this date.

8. UKCA Marking

Assessment through third-party organisations:

From 1 January 2021, machinery that is conformity assessed by a UK approved body should be UKCA marked, not CE marked. If the conformity assessment was carried out by a UK notified body and the CE marking was affixed to the fully made product before 1 January 2021, the CE marking can still be used. But it can only be placed on the GB market and must be placed on the GB market before 31 December 2021.

Where the machinery has been assessed by an EU notified body, manufacturers must continue to use the CE marking. These products may be placed on the GB market until 31 December 2021. Qualifying Northern Ireland goods complying with the legislation as it applies in Northern Ireland, including affixing the CE marking, may be placed on the GB market after 31 December 2021. See further detail in Section 11 on Qualifying Northern Ireland Goods.

Rules around physically affixing the new UKCA marking mirror those which currently apply for the application of the CE marking although, until 31 December 2022, the UKCA marking may be affixed to a label affixed to the machinery or a document accompanying the machinery, rather than being affixed to the machinery itself (even where it is otherwise possible to affix it to the equipment itself).

Self-declaration:

Manufacturers selling machinery on the GB market can affix the new UKCA marking before placing machinery on the GB market. CE marking based on self-declaration of conformity by the manufacturer with the EU requirements is still possible until 31 December 2021 for the GB market.

It will also be possible to affix both the UKCA marking and the CE marking to the same product on the basis of self-declaration, where applicable, as long as the EU and GB requirements remain the same. When selling to the EU or placing on the NI market, the CE marking remains mandatory.

Further guidance on UKCA marking can be found here:

<https://www.gov.uk/guidance/using-the-ukca-marking>

9. Qualifying Northern Ireland Goods

The government has committed to providing unfettered access for qualifying Northern Ireland goods to the rest of the UK market after 1 January 2021. Products that can be placed on the market in Northern Ireland in accordance with the legislation, as it applies to Northern Ireland, can be sold in the rest of the UK without any additional approvals.

This means that products that are qualifying Northern Ireland goods can be sold in the rest of the UK if any of the following apply:

- the CE marking is lawfully applied to the good on the basis of self-declaration
- any mandatory third-party conformity assessment was carried out by an EU-recognised notified body (including a body in a country with which the EU has a relevant mutual recognition agreement) and a CE marking is affixed

- the certificate of conformity previously held by a UK approved body has been transferred to an EU-recognised notified body and a CE marking has been affixed
- any mandatory third-party conformity assessment was carried out by a UK-based body, and the good is therefore marked with the CE marking and with the new UKNI marking

This will be the case even if there are changes between the EU rules that the Northern Ireland Protocol applies to NI and the GB rules.

You can find more information about the UKNI marking here:

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

NI businesses that are importing products from the EEA and placing them on the GB market must ensure that the relevant conformity assessment procedure has been carried out, that the technical documentation has been drawn up and that the machinery bears the CE marking. They will also have to comply with the importer labelling duties (see Section 6 on obligations of importers).

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>

10. Approved Bodies

The UK has established a new framework for UK based bodies to assess machinery against GB rules. Existing UK notified bodies have been granted new UK 'approved body' status and are listed on a new UK database. They do not need to seek re-accreditation in order to benefit from UK approved body status. These approved bodies retain their 4-digit identification number. New approved bodies will be assigned a number by the Office for Product Safety and Standards on behalf of the Secretary of State.

Approved bodies can assess products for the GB market against GB essential requirements (which are, as yet, the same as EU essential requirements).

UK approved bodies are conformity assessment bodies which were UK based notified bodies before 1 January 2021 or have been approved by the Secretary of State to carry out the procedures for conformity assessment and certification for the GB market as set out in the 2008 Regulations as amended.

UK 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 machinery or partly completed machinery to assess the adequacy of the technical design.

Where, having issued a certificate or approval, an approved body finds that applicable requirements of the Regulations have not been met by a manufacturer, they must require the manufacturer to take corrective measures and/or suspend or withdraw the certificate or approval.

A register of UK Approved Bodies can be found on the UKMCAB system at the link here:

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

The register also contains details of bodies in other countries such as Australia, New Zealand, Canada, Japan, and the United States of America, which the UK is designating as Approved Bodies through Mutual Recognition Agreements.

11. Enforcement

For products intended for workplace use, the [Health and Safety Executive \(HSE\)](#) has a duty to enforce of the Regulations in Great Britain.

In Great Britain, local trading standards authorities have a duty to enforce the Regulations in relation to consumer goods.

Alternatively, the Office for Product Safety and Standards on behalf of the Secretary of State is able to enforce the Regulations. The Office of Rail Regulation is responsible for the enforcement of these Regulations in Great Britain where the Health and Safety (Enforcing Authority for Railways and Other Guided Transport Systems) Regulations 2006 make it the enforcing authority, within the meaning of section 18(7) of the 1974 Act, in relation to machinery or partly completed machinery for use in the operation of a railway, tramway or any other system of guided transport, as defined in those Regulations.

Regulators' Code

Enforcing 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 their regulatory functions.

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

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

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 two years 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.

12. Glossary

- **Approved Body** – A conformity assessment body which has been approved by the Secretary of State or was previously a UK based 'notified body' before 1 January 2021.
- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. From 1 January 2021, authorised representatives for the GB market must be based in the UK.
- **Declaration of conformity** – A document prepared by the manufacturer which must detail, among other things, the following:

- a. The business name and full address of the manufacturer and, where appropriate, the manufacturer's authorised representative
 - b. A description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name.
- **Designated standard** – A technical specification which is adopted by a recognised standardisation body or which is designated by the Secretary of State.
 - **Enforcement Authority** – In Great Britain, for machinery in use in the workplace, this is the Health and Safety Executive. For products for consumer use this is local trading standards authorities or the Secretary of State. In Great Britain, in relation to machinery for use on railways, it is the duty of the Office of Rail Regulation to enforce these Regulations.
 - **Manufacturer** – A person who designs or manufactures machinery or partly completed machinery, with a view to its being placed on the GB market under their own name or trademark or for their own use in the UK; or where there is no such person, the person who places the machinery or partly completed machinery on the GB market or puts it into service.
 - **Putting into service/Placing on the market** – References to placing machinery or partly completed machinery on the market are references to making it available in GB:
 - a. for the first time
 - b. with a view to distribution; and
 - c. whether for reward or free of charge.

References to putting any machinery or partly completed machinery into service are references to the first time that it is used for its intended purpose in GB.

- **Responsible Person** – The manufacturer or their authorised representative, or the person placing the product on the GB market or putting the product into service in GB.
- **Safe** – Machinery that, when properly installed and maintained, and used for the purposes for which it is intended, or under conditions which can be reasonably foreseen does not endanger the health of, or result in death or injury to, any person or domestic animal or endanger property.
- **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 Northern Ireland and the European Union.
- **UKNI Marking** (also known as the UK(NI) indication) – The UKNI marking is a new marking applied in addition to the CE marking, where a good requiring mandatory third-party conformity assessment has been tested against EU requirements by a UK body. The UKNI marking applies when placing such products on the Northern Ireland market. Under the Government's unfettered access commitments, products lawfully marked with the UKNI marking can also be placed on the GB market if they are also qualifying Northern Ireland goods.

ANNEXES

Annex A Machinery excluded from the Regulations

The Regulations do not apply to:

1. safety components which are:
 - (a) intended to be used as spare parts to replace identical components; and
 - (b) supplied by the manufacturer of the original machinery
2. equipment specifically for use in fairgrounds and/or amusement parks
3. machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity
4. weapons, including firearms
5. subject to paragraph 2 of Schedule 3, the following means of transport:
 - (a) agricultural and forestry tractors, in respect of the risks covered by Regulation 167/2013;
 - (b) motor vehicles as defined in regulation 4(1) of the Road Vehicles (Approvals) Regulations 2009;
 - (c) vehicles covered by Regulation 168/2013;
 - (d) motor vehicles exclusively intended for competition; and
 - (e) means of transport by air, on water and on rail networks.
6. seagoing vessels, mobile offshore units and machinery installed on board such vessels or units
7. machinery specially designed and constructed for military or police purposes
8. machinery specially designed and constructed for research purposes for temporary use in laboratories
9. mine winding gear
10. machinery intended to move performers during artistic performances
11. electrical and electronic products falling within the following areas, in so far as they are covered by the Electrical Equipment (Safety) Regulations 2016:
 - (a) household appliances intended for domestic use;
 - (b) audio and video equipment;
 - (c) information technology equipment;
 - (d) ordinary office machinery;
 - (e) low-voltage switchgear and control gear; and
 - (f) electric motors.
12. the following types of high voltage electrical equipment
 - a) switch gear and control gear; and
 - b) transformers.

Annex B Essential Health and Safety Requirements relating to the design and construction of machinery

For the purposes of this Annex, the term ‘machinery’ incorporates machinery; interchangeable equipment; safety components; chains, ropes, and webbing; lifting accessories; and removable transmission devices.

To comply with the Regulations, machinery must satisfy the essential health and safety requirements (EHSRs) which apply to it. The full list of EHSRs is laid out in Schedule 2, Part 1 of the 2008 Regulations as amended by the Product Safety and Metrology etc. (Amendment etc) (EU Exit) Regulations 2019.

The listing in Schedule 2, Part 1 of the 2008 Regulations, as amended, begins with a crucially important statement of ‘General Principles’, reproduced in full below. This, in turn, explicitly requires the carrying out of a risk assessment, meaning that the responsible person should determine which are the EHSRs applicable to their machinery and in respect of which they must take measures.

General Principles

The responsible person must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to above, the responsible person shall:

1. Determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof
2. Identify the hazards that can be generated by the machinery and the associated hazardous situations
3. Estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence
4. Evaluate the risks, with a view to determining whether risk reduction is required; and
5. Eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b) of Annex I to Directive 2006/42/EC as set out in Schedule 2 to the 2008 Regulations.

The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the responsible person or in foreseeable abnormal situations. In any event, the principles of safety integration referred to in section 1.1.2 of Annex I to Directive 2006/42/EC as set out in Schedule 2 to the 2008 Regulations and the obligations concerning marking of machinery and instructions referred to in sections 1.7.3 and 1.7.4 of Annex I to Directive 2006/42/EC as set out in Schedule 2 to the 2008 Regulations apply.

The essential health and safety requirements are mandatory. However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.

The list of essential requirements is organised into several sections. The first section has a general scope and is applicable to all kinds of machinery. The other sections refer to certain kinds of more specific hazards. Nevertheless, it is essential to examine the whole of the list in order to be sure of meeting all the applicable essential requirements. When machinery is being designed, the requirements of the general section and the requirements of one or more of the other sections shall be taken into account, depending on the results of the risk assessment carried out in accordance with the opening paragraph of these General Principles.

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

Office for Product Safety and Standards

Department for Business, Energy and Industrial Strategy
4th Floor, Cannon House, 18 The Priory Queensway, Birmingham B4 6BS
<https://www.gov.uk/government/organisations/office-for-product-safety-and-standards>