SUPPLY OF MACHINERY (SAFETY) REGULATIONS 2008
as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

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1. Introduction

The Supply of Machinery (Safety) Regulations 2008 set out the essential health and safety requirements which must be met before machinery can be placed on the UK 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’.

This guidance is designed to help you understand the Supply of Machinery (Safety) Regulations 2008, now the UK has left the EU, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (“2008 Regulations amended”).

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 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.

The 2008 Regulations replaced the Supply of Machinery (Safety) Regulations 1995 and were amended by the 2019 Amendment Regulations to apply solely to the UK market.

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 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;

(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 as amended.
Compliance with the 2008 Regulations as amended 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 UK or CE mark 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 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.

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

Businesses with an existing authorised representative based in the EEA can therefore continue to use the same authorised representative.

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

7. Transitional arrangements

‘Deeming’ provision

Machinery which has undergone full conformity assessment under the equivalent EU requirements and bear the CE conformity mark will be deemed compliant with the UK legislation and can be placed on the UK market as if they had been UKCA conformity marked.

The UK continues to recognise the competency of EU recognised conformity assessment bodies (notified bodies) to assess machinery for the UK market. Machinery 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, machinery assessed by an EU recognised notified body can be placed on the UK market. (For the status of UK notified bodies, please see section 10 below).
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.

8. **UK Conformity Mark**

**Assessment through third-party organisations:**

The UKCA conformity mark will replace the CE marking for machinery placed on the UK market which has been assessed by a UK approved body. In all other cases, manufacturers will be able to continue using the CE marking for machinery 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 which currently apply for the application of the CE marking.

**Self-assessment:**

CE marking based on self-declaration of conformity by the manufacturer is still possible where it was pre-exit, including when exporting to the EU.

Manufacturers selling machinery on the UK market can alternatively affix the new UKCA conformity marking before placing machinery on the UK 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. When exporting to the EU, the CE marking remains mandatory.

**Placing CE marked goods on the UK market:**

Machinery that meets EU regulatory requirements, including those with a CE marking, which has been assessed by an EU recognised conformity assessment body or which has been self-declared (where permissible) 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 machinery assessed by EU recognised bodies are obliged to use the CE marking and cannot use the UKCA marking.


Machinery in the scope of these Regulations exported to the EU Single Market must comply with EU Directive 2006/42/EC.

9. **Approved Bodies**

The UK has established a new framework for UK based bodies to assess machinery 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 UK based 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 products for the UK market against UK essential requirements (which are substantially the same as EU essential requirements).
UK Approved bodies are conformity assessment bodies which were UK based 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 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 list of UK approved bodies can be found [link to be added].

10. 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 consumer goods. Alternatively, 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 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 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.

11. Where to find guidance about Directive 2006/42/EC


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/

12. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a UK based ‘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.

- **Declaration of conformity** – A document prepared by the manufacturer which must detail, among other things, the following:
  I. The business name and full address of the manufacturer and, where appropriate, the manufacturer’s authorised representative;
  II. 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 Northern Ireland, for machinery in use in the workplace, this is the Health and Safety Executive Northern Ireland. For products for consumer use this is district councils 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 manufactures machinery or partly completed machinery, with a view to its being placed on the 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 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 the UK:

  I. for the first time;
  II. with a view to distribution; and
  III. 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 the UK.

• **Responsible Person** – The manufacturer or their authorised representative, or if neither are in the UK then the person placing the product on the market or putting the product into service in the UK.

• **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.

• **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.
13. 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, insofar 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,
   (f) electric motors; and
   I. the following types of high voltage electrical equipment
   II. switch gear and control gear, and
   III. transformers.

(g) lifts which serve specific levels (i.e. of buildings and constructions) with a speed greater than 0.15 metres per second having a carrier, which must be a car*, moving between guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal and designed for the transport of:
   i. persons
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ii. persons and goods
iii. goods alone if the car is accessible, that is to say, a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier.

* note that the EHSRs now make clear that such a ‘car’ must be fully enclosed.

There are also several specific inclusions in paragraph 2 of Schedule 13.

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 his machinery and in respect of which he 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 amended.
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 amended 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 amended 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.