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

TOYS (SAFETY) REGULATIONS 2011 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

September 2019
1. Introduction

The Toys (Safety) Regulations 2011 set out the essential safety requirements which must be met before toys can be placed on the UK market. The purpose of the legislation is to ensure safe products are placed on the market by requiring manufacturers to show how their toys meet the ‘essential safety requirements’.

This guidance is designed to help you understand the Toys (Safety) Regulations 2011 now the UK has left the EU, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (“2011 Regulations”).

2. Legislative Background

The Toys (Safety) Regulations 2011 transposed the requirements of Council and European Parliament Directive 2009/48/EC, whose purpose is to ensure a high level of toy safety. The EU Withdrawal Act 2018 preserves the Regulations and enables them to be amended so as to continue to function effectively now that 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 2011 Regulations apply to toys manufactured with the following characteristic: toys designed or intended (whether or not exclusively) for use in play by children under 14 years old. There are some products that are specifically excluded from the scope of the 2011 Regulations (e.g. toy steam engines - see Regulation 4).

Furthermore, Schedule 1 lists the products that are not considered to be toys; the 2011 Regulations do not apply to these listed products.

4. Requirements

Regulation 5 outlines the essential safety requirements which apply to toys. These are divided into general safety requirements and particular safety requirements.

General Safety Requirements

The general safety requirements are as follows.

Toys, including the chemicals they contain, must not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

The ability of the users and, where appropriate, their supervisors must be taken into account. In particular, this applies to toys intended for use by children under 36 months or by other specified age groups.

Information on hazards and risks involved in using the toy, and the ways of avoiding them, must be marked in English, in a clearly visible, easily legible, understandable and accurate manner. The information must be preceded by the word “Warning” or “Warnings”, and should be marked on the toy, a label affixed to the toy or the toy’s packaging and any accompanying instructions for use.
Particular Safety Requirements

There are also particular safety requirements which are set out in Schedule 2 (which was added to the Toys (Safety) Regulations 2011 by the the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019). These cover hazards relating to physical/mechanical properties, flammability, chemical properties, electrical properties, hygiene requirements and radioactivity. For example, Schedule 2 sets out a list of allergenic fragrances that toys must not contain and makes clear that toys must not constitute a dangerous flammable element in the child’s environment.

5. Obligations of manufacturers

A manufacturer is a person who manufactures toys, or has toys designed or manufactured, and markets those toys under their name or trademark.

The obligations of manufacturers of toys, which must be complied with before the toy is placed on the market, include:

1. Make sure the toy has been designed and manufactured to comply with the essential safety requirements during its foreseeable and normal period of use.
2. Carry out a safety assessment of the toy.
3. Follow the applicable conformity assessment procedure.
4. Draw up a declaration of conformity and affix the UKCA marking, or for a time limited period the CE marking.
5. Draw up the technical documentation and keep it for 10 years.
6. Apply information identifying the toy and manufacturer on the toy or, where not possible because of the size or nature of the toy, on its packaging or accompanying documentation.
7. Make sure the toy is accompanied by instructions for safe use, safety information and warnings as appropriate, which must be marked in a clearly visible, easily legible, understandable and accurate manner on the toy, a label affixed to the toy or the toy’s packaging and if appropriate on any instructions for use which accompany the toy.
8. Make sure that continuing production runs of the same toy remain in conformity.
9. Carry out sample testing of marketed toys.
10. Investigate and record any complaint made in relation to the toy and keep a register of complaints, non-compliant toys and recalled toys (and keep distributors informed of any of these actions).
11. Bring non-conforming toys into compliance (or if appropriate withdraw or recall the toy) and tell authorities if there is a safety risk and provide information to authorities following any requests.
12. Identify the other economic operators in the supply chain on request by an enforcement authority where the request is made within 10 years of the toy being supplied.
6. **Obligations of authorised representatives**

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

Mandated authorised representatives based in an EU Member State prior to the UK leaving the EU continue to be recognised by the UK to act in the UK. However, authorised representatives appointed after the UK left the EU to act in the UK must be based in the UK to be recognised under UK law.

Businesses with an existing authorised representative based in the EEA can 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 products being placed on the EU market. Therefore, a manufacturer exporting products to the EU, who wishes to appoint an authorised representative to carry out tasks for them in respect of those products, must appoint an authorised representative based in the EU.

There are certain obligations that the authorised representative’s mandate must include (for example keeping technical documentation) and some that it must not (for example, duty to design and manufacturer in accordance with the essential safety requirements).

The obligations of authorised representatives include:

1. An authorised representative must comply with all the duties imposed on the manufacturer under the 2011 Regulations that they are appointed by the manufacturer to perform. A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.

2. If an Authorised Representative does not comply with all the duties that they are appointed by the manufacturer to perform, they may be subject to penalties.

7. **Obligations of importers**

An importer is a person or business who places a toy on the UK market from a country outside the UK. UK businesses who used to act as a ‘distributor’ legally become an ‘importer’ if they place products from an EU 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 including their name, registered trade name or mark and a postal address on the toy or, where this is not possible, on its packaging or in accompanying documentation.

To assist with the transition, the UK is applying a transitional period of 18 months to allow UK suppliers of goods from the EEA or Switzerland (who post exit are importers) to provide their details on the accompanying documentation as an alternative to placing them on the product itself.

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

1. Make sure that the manufacturer has fulfilled their obligations before the importer places a toy on the market.
2. Make sure that the importer’s name and address is marked on the toy or (in the circumstances permitted – see above) on a document accompanying the toy.
3. Make sure that the compliance of the toy is not affected by the conditions of storage or transport.
4. Carry out sample testing of marketed toys.
5. Investigate and record any complaint made in relation to the toy and keep a register of complaints, non-compliant toys and recalled toys and keep distributors informed of any action taken.
6. Bring non-conforming toys into compliance (or if appropriate withdraw or recall the toy) and inform the authorities and other economic operators if there is a safety risk.
7. Keep a copy of the Declaration of Conformity and make sure the technical documentation is available to enforcement authorities on request, both for a period of 10 years.
8. Identify the other economic operators in the supply chain.

8. Obligations of distributors

UK businesses which were distributors of toys 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. A distributor is any person, other than the manufacturer or importer, who makes toys available on the market.

The obligations of distributors include:

1. Take due care to ensure that toys they make available on the market are compliant with the Regulations (and not make toys available if they believe the toy will not comply with the essential safety requirements during its foreseeable and normal use).
2. Verify that the manufacturer has applied information identifying the toy and manufacturer, applied the UKCA marking and that the toy is accompanied by instructions for safe use and safety information where appropriate.
3. Verify that the importer has applied their name and address on the toy or on a document accompanying the toy.
4. Make sure that the compliance of the toy is not affected by the conditions of storage or transport.
5. Bring non-conforming toys into compliance (or if appropriate withdraw or recall the toy) and inform the authorities and other economic operators if there is a safety risk.
6. Identify the other economic operators in the supply chain.
9. Transitional arrangements

‘Deeming’ provision

Products which have 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 products 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, products 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 products placed on the UK market which have been assessed by a UK approved body (or by non-EU 3rd country CABs, where an agreement exists). 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 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 goods on the UK market can alternatively affix the new UKCA conformity marking before placing a product 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. When exporting to the EU, the CE marking remains mandatory.

Placing CE marked goods on the UK market:

Goods that meet EU regulatory requirements, including those with a CE marking, which have been assessed by an EU recognised conformity assessment body or which have been self-declared 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 products assessed by EU recognised bodies are obliged to use the CE marking and cannot use the UKCA marking.

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

Toys exported to the EU Single Market must comply with EU Directive 2009/48/EC.
11. Approved Bodies

The UK has established a new framework for UK based bodies to assess products 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 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 safety requirements (which are substantially the same as EU essential safety requirements).

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 2016 Regulations as amended.

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 toy to assess the adequacy of the technical design.

Where an approved body finds that essential safety requirements have not been met by a manufacturer, 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

In Great Britain, local Trading Standards authorities are responsible for day-to-day enforcement of the 2011 Regulations. In Northern Ireland, district councils are responsible.

Enforcement action may be taken in cases of formal non-compliance such as inappropriate conformity marking or in cases where the enforcement authority has reason to believe that the toy presents a risk to the safety and health of persons.

The enforcement authority may issue a compliance notice in the case of a formal non-compliance or where this notice is not complied with. Where an enforcement authority has sufficient reason to believe that a toy presents a risk to the health and safety of persons, the operator may be required to withdraw the toys from the market or undertake a recall.

Enforcement authorities must take all appropriate measures to withdraw from the market, to prohibit or restrict the supply of toys which pose a serious risk to consumers.

Regulators’ Code

Enforcement authorities must continue to 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.

Penalties

Offences may result in unlimited fines (England and Wales), of up to £10,000 (Scotland), or of up to £5,000 (Northern Ireland), or a maximum prison term of 6 months, or both.

13. Charities and toy sales, second-hand toys

The duties in the Regulations apply when a person is “acting in the course of a commercial activity (whether in return for payment or free of charge)”. Many charities are subject to the Regulations because they run trading companies or bodies that are similar to businesses that are:

- money generating;
- have a degree of continuity; and
- keep regular business hours.

People organising events such as jumble sales and car boot sales - which are held at infrequent and irregular intervals - are unlikely to be considered as acting in the course of business. However, traders invited to sell toys there would not be exempt from the requirements of the regulations.

Individuals producing toys on an occasional basis to give to charities to sell are also likely to be exempt.


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/DomsRoom/documents/18027/

15. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a ‘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 EEA 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 include (amongst other things) the following:
  - The specific toy 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 and importer for a period of ten years from the date on which the toy was placed on the market. This declaration must be made available to the enforcing authority upon request.

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

- **Enforcement Authority** – In Great Britain, for toys for consumer use this is local Trading Standards authorities. In Northern Ireland, this is district councils. The Secretary of State is also an enforcement authority across the UK.

- **Importer** – A person established in the UK who places a toy from a country outside of the UK on the market. A person who before the UK left the EU distributed toys within the EU (including the UK) will now be an importer if they are bringing toy into the UK from another country (including EU Member States).

- **Manufacturer** – A person who manufactures a toy or has a toy designed or manufactured and markets that toy 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.