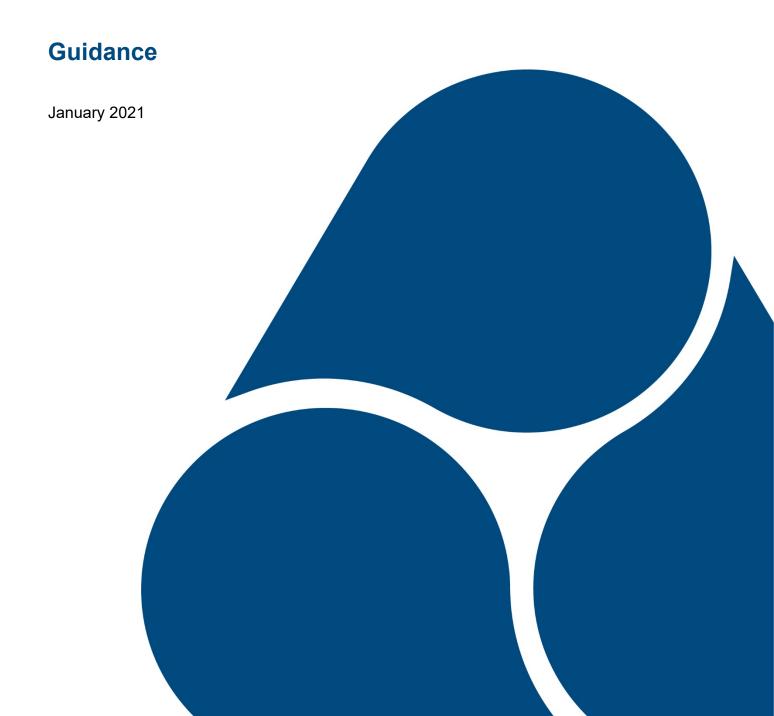


Toys (Safety) Regulations 2011

As they apply to toys being supplied in or into Northern Ireland from 1 January 2021



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Guidance

1. Introduction

This Guide is for businesses placing toys on the market in Northern Ireland from 1 January 2021¹.

While the Northern Ireland Protocol² ('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. Toys placed on the NI market must therefore follow UK law as it applies to NI. The relevant law is The Toys (Safety) Regulations 2011, which apply across the UK but some of their provisions apply differently in NI so that they implement in NI Directive 2009/48/EC on Toys, as required by the Protocol.

This Guide is designed to help you comply with The Toys (Safety) Regulations 2011, as they apply in NI. References to "the 2011 Regulations" in this document are references to The Toys (Safety) Regulations 2011, as they apply in NI.

The 2011 Regulations set out the essential safety requirements that must be met before toys can be placed on the NI 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'.

Toys placed on the Great Britain ("GB") market (GB comprises England, Scotland and Wales) must follow the separate rules for the GB market. If you are placing toys on the market in GB, you should read the relevant separate guidance.

The government has committed to providing unfettered access for qualifying NI goods to the rest of the UK market after 1 January 2021. Toys that can be placed on the market in NI in accordance with the 2011 Regulations, as they apply to NI, can be supplied in the rest of the UK without any additional approvals. The arrangements here are explained in detail in the separate guidance for placing toys on the market in GB.

https://www.gov.uk/guidance/toys-safety-regulations-2011

2. Legislative Background

The Toys (Safety) Regulations 2011 implemented the requirements of Directive 2009/48/EC, whose purpose is to ensure a high level of toy safety.

The Directive will continue to be implemented in NI, for as long as the Protocol on Ireland/ Northern Ireland is in force. However, the 2011 Regulations (as they apply in NI) 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 2011 Regulations, but some of the provisions apply differently in NI and GB. References to the 2011 Regulations in this guidance are references to those Regulations as they apply in NI.

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 31 December 2020.

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

The 2011 Regulations were amended by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 and The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020³ to give effect to The Protocol of Ireland and Northern Ireland ("The Northern Ireland Protocol") as it relates to the placing on the NI market of toys⁴.

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 Annex II of the Toys Directive, which the 2011 Regulations cross reference. These cover hazards relating to physical/mechanical properties, flammability, chemical properties, electrical properties, hygiene requirements and radioactivity. For example, Annex II 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.

At the time of writing the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 are subject to Parliamentary approval.

In 2019, the 2011 Regulations 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. These 2019 Regulations 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.

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 NI 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 an EC Declaration of Conformity and affix the CE marking, visibly, legibly and indelibly to the toy, a label affixed to the toy or the toy's packaging. When conformity assessment has been carried out by a UK notified body, the UKNI marking (also known as the UK(NI) indication) must be affixed as well as the CE marking. A product with both the CE and UKNI markings cannot be placed on the European Economic Area (EEA) market. There is separate guidance on when and how to use the UKNI marking:
 - https://www.gov.uk/guidance/using-the-ukni-marking-from-1-january-2021.
- 5. Where toys are too small or consist of small parts, the CE, or CE and UKNI, marking(s) may be affixed to a label which is not affixed to the toy or a leaflet which accompanies the toy.
- 6. Draw up the technical documentation and keep it for 10 years.
- 7. Apply information, identifying the toy (e.g. type/ batch/ serial/ model number) and manufacturer (e.g. name, registered trade name / trademark, contact address) on the toy or, where not possible because of the size or nature of the toy, on its packaging or in an accompanying document.
- 8. Make sure the toy is accompanied by instructions for safe use, safety information and warnings as appropriate. These 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.
- 9. Make sure that continuing production runs of the same toy remain in conformity.
- 10. Carry out sample testing of marketed toys.
- 11. 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).
- 12. 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.
- 13. 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

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

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 2011 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 2011 Regulations that they are appointed by the manufacturer to perform. There are some duties that a manufacturer cannot mandate an authorised representative to perform (e.g. conformity assessment) and some that must form part of the authorised representatives mandate (e.g. retention of technical documentation).

A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.

Any references in the 2011 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 2011 Regulations as they apply in NI (under the Protocol), an importer is a business or person established in NI or the EEA who places a toy 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 for sale or supply on the NI market will be an importer under the 2011 Regulations as they apply in NI.

The obligations of importers include to:

- 1. Make sure that the manufacturer has fulfilled their obligations before the importer places a toy on the NI market, including completing an EC Declaration of Conformity and relevant technical documentation, and affixing the CE marking.
- When conformity assessment has been carried out by a UK notified body, the UKNI marking (also known as the UK(NI) indication) must be affixed as well as the CE marking. A product with both the CE and 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-from-1-january-2021
- 3. Making sure that the importer's name and address is marked on the toy or, where not possible because of the size or nature of the toy on a document accompanying the toy or packaging, as well as the manufacturer's details.
- 4. Make sure that the compliance of the toy is not affected by the conditions of storage or transport.
- 5. Carry out sample testing of marketed toys.

- 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.
- 7. 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.
- 8. Keep a copy of the EC Declaration of Conformity and make sure the technical documentation is available to enforcement authorities on request, both for a period of 10 years.
- Identify the other economic operators in the NI supply chain on request by an enforcement authority where the request is made within 10 years of the toy being supplied.

8. Obligations of distributors

NI businesses which were distributors of toys supplied to them from GB should now consider whether they are classified as importers under the 2011 Regulations and therefore what additional requirements they need to comply with – see section 7 above. Under the 2011 Regulations an NI business placing a product from GB on the NI market does so as an importer, not as a distributor under the 2011 Regulations.

The obligations of distributors include:

- Take due care to ensure that toys they make available on the NI market are compliant with the 2011 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).
- Verify that the manufacturer has applied information identifying the toy and manufacturer, applied the CE marking and that the toy is accompanied by instructions for safe use and safety information where appropriate.
- 3. When conformity assessment has been carried out by a UK notified body, the UKNI 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-from-1-january-2021
- 4. Verify that the importer has applied their name and address on the toy or in certain circumstances on the toy's packaging or on a document accompanying the toy.
- 5. Make sure that the compliance of the toy is not affected by the conditions of storage or transport.
- 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. 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.

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 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
- 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 a toy is being placed on the market in NI, and the manufacturer chooses to have it conformity assessed by an 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 met. After 31 December 2021, the UKCA marking must be used for the GB market, but there are special rules under unfettered access that apply for qualifying NI goods.

For qualifying NI goods, toys meeting NI rules (the 2011 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 toys on the GB market).

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

From 1 January 2021, where the manufacturer chooses to have the toys conformity assessed by a UK notified body before placing on the NI market, 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-from-1-january-2021

11. 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. Toys that can be placed on the market in NI in accordance with the 2011 Regulations, can be sold in the rest of the UK without any additional approvals. The guide to placing toys on the GB market has further details on these arrangements.

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

 $\underline{https://www.gov.uk/guidance/moving-qualifying-goods-from-northern-ireland-to-the-rest-of-\underline{the-uk}}$

12. 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 2011 Regulations.

From 1 January 2021, all active UK Notified Bodies will remain Notified Bodies for the purpose of CE marking products for the NI market. 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 market in the EEA.

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

https://www.gov.uk/guidance/using-the-ukni-marking-from-1-january-2021.

A list of EU Notified Bodies can be found on the <u>NANDO</u> 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 both the CE and UKNI markings).

A list of UK Notified Bodies is available here:

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

13. Enforcement

In NI, district councils have a duty to enforce the 2011 Regulations. The Secretary of State is also an enforcement authority across the UK.

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 and take action 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 NI market or undertake a recall.

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

Safeguard procedure

Enforcement authorities are required under the 2011 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 in NI indicating the reasons justifying the action. This will enable Member States of the EU 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 NI market surveillance authorities and the Secretary of State. The European Commission will determine whether the action taken is justified; if so enforcement authorities must take necessary measures to ensure the toy is withdrawn from the market.

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.

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

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

Penalties

Offences may result in fines up to £5,000 or a maximum prison term of 6 months, or both.

14. Charities and toy sales, second-hand toys

The duties in the 2011 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.

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 the tasks undertaken by the authorised representative are carried out
 properly.
- CE marking the CE marking can 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.
- **EC 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 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.
- Enforcement Authority In NI, for toys for consumer use district councils enforce
 the 2011 Regulations. The Secretary of State is also an enforcement authority
 across the UK.
- 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 a toy or has a toy designed or manufactured and markets that toy under their name or trademark.
- Notified Body A conformity assessment body based in the EEA which has been approved by an EEA State to carry out conformity assessment for placing products on the EEA and NI markets; or a conformity assessment body that is based in the UK and have been notified to the Commission 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 (including toys) 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.

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