# Product safety roadmap

#### **Consumer Products**

European Union and Great Britain





## How to place products on the EU and GB markets

Product launch roadmap European Union and Great Britain

We have set out the considerations manufacturers need to keep in mind when launching a product on both the EU and GB markets (ie England, Scotland and Wales), and what you will need to consider once your product has launched.

This roadmap focuses on consumer products which fall under the European Union's Directive 2001/95/EC (the "Directive"), which has been transposed into national law in all EU Member States.

On top of this, numerous EU Member States (and the UK) have introduced further specific regulations on individual areas, such as special regulations relating to labelling, safety instructions and maintenance instructions. Our team would be happy to advise you on these issues.

The Directive was introduced while the UK (England/Scotland/Wales and Northern Ireland) was an EU Member State and it was implemented by the General Product Safety Regulations 2005 (the "UK Regulations"). This means that the key national regulations in EU Member States and the UK stem from the Directive in the same way and enshrine the Directive's requirements in national law.

#### After Brexit – Great Britain

The regulations affecting products are currently the same as they were before Brexit in many circumstances, meaning that there is still significant symmetry between EU and GB rules. However, since Brexit there are some important changes that you need to be aware of before launching your product on the GB market.

The UK government now has the authority to make its own laws to change the regulatory requirements for products on or entering the GB Market. This means that over time there is likely to be greater divergence from the requirements set out in EU regulations. We can help to keep you updated of any changes on the horizon and explain how these will affect your business.

To find out more, please go to our Product Launch Q&A, which you can access <u>here</u>

#### **Northern Ireland**

The UK left the European Union (EU) on 31 January 2020. In accordance with the Northern Ireland Protocol, Northern Ireland ("NI") will follow the previous regulatory regime set out by the EU. Please contact our UK team for specialist advice if you are looking to place products on the market in NI.

## What has changed since Brexit?

As set out on the previous page, Brexit has already resulted in a few important differences emerging between the product safety rules governing GB and the existing EU regime.

#### Economic operator status – new UK based producers

The Directive requires product safety obligations to be placed on different actors in the supply chain. Most of these obligations fall on 'producers'.

Before Brexit, the UK Regulations implementing the Directive set out that a producer was the manufacturer of the product if that manufacturer was based in the EU. If the manufacturer was not based in the EU and did not have a manufacturer's representative, the producer would be the person placing the products on the EU market from a country outside of the EU. This person is generally known for product safety purposes as the 'importer'.

However, since Brexit, the UK Regulations have been amended so that producers, including importers placing goods on the GB market, must be based in the UK.

To take a practical example, this means that if a German company has a UK subsidiary and this UK subsidiary is placing products on the GB market, i.e. selling to consumers in GB, the UK entity will now be considered the producer and have these product safety obligations.

It also means that companies based in the UK who would previously have been considered distributors under the UK Regulations, and therefore had fewer obligations than producers, could now be considered producers if they are the person placing the goods on the GB market.

#### Manufacturer's Representatives

Producers are still able to appoint manufacturer's representatives to take on their obligations as producers. However, the UK Regulations have been amended so that for the purposes of products being placed on the GB market, these authorised representatives must be based in the UK, rather than anywhere in the EU as was previously permitted.

Please <u>contact</u> our team for more details about manufacturer's representatives.

#### **UKCA** marking

While the UK was a member of the EU, it was a part of the EU's CE marking system. This is the system which applies to certain product types (outside the scope of the Directive) such as toys and electrical goods. These goods must go through a conformity assessment, in which, depending on the type of product, the manufacturer has to self declare that the product meets all the applicable regulatory requirements and standards or submit the product to a third party conformity assessment body who will make this assessment. Once this process has been completed, the manufacturer has to draw up a declaration of conformity, and affix the CE marking to the product. Since Brexit, the UK has introduced its own UK conformity assessment and UKCA marking system for the Great Britain market (NI will continue to use the CE mark).

The focus of this roadmap is products which fall within the remit of the Directive and these products do not need to go through a conformity assessment procedure. A CE/UKCA marking should not be displayed on your goods if they are general consumer goods covered by the Directive.

## The roadmap

#### Stop

If your product is one of the below, the Directive and the regulations which implemented the Directive in each Member State and in the UK (together the "Regulations") do not apply.

We have expertise in dealing with the specialist regulatory regimes for these products:



Pharmaceuticals

**Medical devices** 

Machinery

Construction products

## Proceed with caution

The Regulations work so that the requirements/obligations they set out apply to a product unless the product is subject to more specific regulations, and those specific regulations include an obligation which is different to that set out in the Regulations.

This usually works so that the specific regulations impose a more onerous requirement than that which is applied to all products generally, on the basis that there is a particular need to adhere to a higher standard because of the nature of the product (and enforcement is usually by different regulators). This means there will be instances in which manufacturers need to take account of both the Regulations and more specific legislation covering their product type. In some cases, for example toys, the relevant product safety requirements will be substantially set out in other specific regulations, but manufacturers should still be aware of the obligations under the Regulations. Examples of common types of products in this category are below (this is not an exhaustive list):



Cosmetics

– Fertilisers

Chemicals

7 Tobacco products

Aerospace products

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### **Green light**

For products which will be covered by the Regulations, the first thing that manufacturers must consider is the general safety requirement:

Producers shall be obliged to place only safe products on the market (Article 3 of the Directive)

Although this may seem vague and obvious, the Regulations go on to provide more detail about how manufacturers can comply with this general requirement.

# What is a safe product?

The full definition is set out in the Directive, but the considerations in this section are relevant to deciding if a product will be considered safe.

When taking account of these considerations, if the product is one which presents no risks or only minimal risks which cannot be removed then it will be a safe product.

In terms of the minimum risks associated with a product, there will be some products which will always carry an element of risk, eg a chain saw. The risks these products pose need to be compatible with the 'high level of protection for safety and the health of persons' required by the Directive.



## Relevant considerations for a safe product



## What you need to action

The previous section can be summarised as an obligation to ensure that you only place safe products on the market. Taking the actions in this section can help you comply with this.



# **Additional obligations**

## The Regulations also set out two further broad obligations for manufacturers:

## 1. Providing consumers with all relevant information to use the product safely.

Manufacturers need to provide consumers with all the information they need to assess the risk posed by your product through its normal period of use and to allow the consumer to take precautions against these risks.

#### 2. Responding to a product safety incident

If you become aware that a product you have placed on the market poses a risk to consumers and therefore does not meet the general product safety requirement, you must take action. There are things you can do to make sure you are prepared for any product safety incident.





## Obligation to provide relevant consumer information



## Responding to a product safety incident



## How we can help

#### Taking these steps outlined in the roadmap should ensure that you are launching your product on the EU and GB markets with the right considerations in mind.

This roadmap gives an overview of the EU/GB regulatory landscape for consumer products, for specialist advice for your product please contact our international Product Liability and Safety Team.

We act for 35 of the world's 50 biggest brands.

Safeguarding the value of our clients' products and brand is our priority. Products businesses constantly face new and complex issues relating to liability, regulatory compliance and safety. We provide a truly international deep sector expertise in the markets of our clients' products. We understand the key variations of product laws and safety regulations between different jurisdictions.

#### We advise on all product-related issues including:

- product compliance (including labelling, testing, conformity assessments and UKCA/CE marking)
- regulatory investigations (including criminal investigations and enforcement actions by product regulators worldwide)
- co-ordinating and managing worldwide product recalls (including EU RAPEX notifications, UK/OPSS notifications, corrective action and risk assessments)
- defending cross-border product liability litigation

   (including collective, multi-claimant and group actions).



## Your team

This roadmap gives an overview of the EU and GB regulatory landscape for consumer products, for specialist advice for your product please contact our Product Liability and Safety team.

#### For the UK



Katie Chandler Partner Disputes & Investigations +44 20 7300 4163 k.chandler@taylorwessing.com London



Disputes & Investigations

e.spencer@taylorwessing.com

Senior Counsel

London

+44 20 7300 7064



**Matthew Caskie** Associate Disputes & Investigations +44 20 3077 7530 m.caskie@taylorwessing.com London

Joe Pengelly Associate **Disputes & Investigations** +44 20 7300 4265 j.pengelly@taylorwessing.com l ondon

#### For the EU



**Phillipp Behrendt** Partner **Disputes & Investigations** +49 40 36803 0 p.behrendt@taylorwessing.com Hamburg



**Dr Henning Moelle Evelyne Friedel** Partner Partner Commercial law disputes Commercial & distribution law +49 69 97130 0 +33172740340 h.moelle@taylorwessing.com e.friedel@taylorwessing.com Frankfurt Paris



**Nick Kampschreur** Partner **Disputes & Investigations** +31 88 024 3156 n.kampschreur@taylorwessing.com Eindhoven



Stefan Turic Partner Disputes & Investigations +431716550 s.turic@taylorwessing.com Vienna



Dr Benedikt Rohrben Partner Commercial & distribution law +49 89 21038-204 b.rohrssen@taylorwessing.com Munich



Partner Civil & commercial law +49 89 21038-241 m.kieffer@taylorwessing.com Munich



Civil & commercial law +49 40 36803-192 d.enzberg@taylorwessing.com Hamburg



Partner

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