

England and Wales

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1. Product safety regulation

1.1 Regulatory framework – an overview

Product safety is highly regulated, and various regulatory techniques are used to increase the probability that products reaching the market are acceptably safe. Those methods include domestic and international product safety regulations, which impose safety requirements as well as criminal penalties for failure to comply with those requirements. For certain classes of product, typically ones that could pose serious risks to great numbers of people, such as medicines and automotive vehicles, regulations also impose requirements to obtain official authority to supply new products within those classes.

There are regulations of general application, and regulations that apply only to specific categories of products. The Consumer Protection Act 1987 is important 'general' legislation. It set out a general safety requirement (now superseded) and provides for the making of safety regulations for specific types of product (see below for some examples). The general safety requirement in the act was largely superseded by the General Product Safety Regulations 1994. For almost all products, the General Product Safety Regulations 2005 now apply, except to the extent of more specific regulations.

In addition to regulations, there are many product safety standards, which are of great practical importance. Safety standards relate to the design and/or performance of products. Although compliance with applicable safety standards does not conclusively determine the issue of 'safety', the General Product Safety Regulations 2005 provide that, where a product conforms to certain types of standard, it is presumed to comply with the general safety requirement.

Before the General Product Safety Regulations 2005 came into force, certain specific products had safety regimes requiring notification and corrective actions. The 2005 regulations introduced measures of general application to almost all products, including a notification duty, and powers of enforcement authorities to order or perform corrective actions.

The Consumer Protection Act 1987 remains the key source of 'strict liability' for claims by consumers for injury and property damage caused by a product defect (see "Product liability" below).

1.2 Safety regulation – safety requirements, offences and penalties

There is a wide range of safety regulations, governing production, distribution,

record-keeping, and corrective actions. Unsurprisingly, products that carry significant safety risks, or are consumed or used universally or by a great proportion of the public, are subject to more detailed regulation.

Safety regulations can be broadly classified into two categories:

- 'general' provisions, which apply generally to all products, except to the extent that more specific regulations apply; and
- 'special' provisions, which apply only to specified types of product.

Provisions of general application impose a general requirement that products be 'safe'. Special regulations set out additional, more detailed, requirements concerning safety. The various regulations use different language in imposing obligations and prohibitions.

(a) *General provisions – the General Product Safety Regulations 2005*

The General Product Safety Regulations 2005 apply to all new and used products, except secondhand products supplied as needing repair or reconditioning before use (provided that the buyer is clearly informed of this), and except where products are subject to other specific safety requirements.

The regulations set out a 'general safety requirement'. Regulation 5 provides that "No producer shall place a product on the market unless it is a safe product". For the meaning of 'safe,' see below.) 'Producer' is defined to include own-branders, persons who recondition products, and others whose activity may affect the safety properties of a product. For products manufactured outside the EEA, 'producer' also includes an EEA representative or party importing the product into the EEA.

Regulation 29 provides for the defence of 'due diligence'; in relation to any offence under the General Product Safety Regulations 2005, it is a defence that the relevant party took all reasonable steps and exercised all due diligence to avoid committing an offence.

Under Regulation 20, contravention of Regulation 5 is an offence, punishable when tried summarily by a term of imprisonment of up to three months, and/or by the statutory maximum fine (currently £5,000). If convicted on indictment, the maximum penalty is 12 months' imprisonment and/or a fine of £20,000.

(b) *Special provisions*

Section 10 of the Consumer Protection Act 1987 set out a 'general safety requirement', but this requirement has been replaced by Regulation 5 of the General Product Safety Regulations,.

Section 11 of the Consumer Protection Act 1987 provides for the making of "safety regulations", except for certain specified products including food and medicines. Below, we refer to examples of such safety regulations, relating to toys, cosmetic products and electrical equipment.

The supply of goods in contravention of such safety regulations is an offence (Consumer Protection Act 1987, Section 12). Generally, a person convicted after summary trial is liable to imprisonment for a term not exceeding six months and/or to a fine not exceeding level 5 on the standard scale (currently £5,000). There are exceptions, however, some of which are noted below.

The Consumer Protection Act 1987 provides (in Section 39) for the defence of 'due diligence', which applies where a defendant shows that it "took all reasonable steps and exercised due diligence to avoid committing the offence".

Toys (Safety) Regulations 2011: These regulations replaced the Toys (Safety) Regulations 1995, and came into force on August 19 2011. Regulation 5 sets out the 'essential safety requirements' of a toy. These requirements consist of the general safety requirements (set out at Regulation 5(2) to 5(5)), and the particular safety requirements, set out at Annex II of Directive 2009/48/EC. The particular safety requirements cover physical, mechanical, chemical and electrical properties of toys, as well as their flammability, hygiene and radioactivity. The new requirements as to chemical properties of toys are subject to a transitional provision for toys placed on the market before July 20 2013.

Regulation 10 prohibits manufacturers from placing a toy on the market unless the toy complies with the essential safety requirements, and the manufacturer has complied with Regulations 11 to 13, 15, 17(1) to (3), and 19 to 21. These impose obligations regarding design and manufacture (Regulation 11), safety assessment (Regulation 12), conformity assessment procedure (Regulation 13), EC declarations of conformity (Regulations 15 and 16), CE marking (Regulations 15 and 18), technical information (Regulation 17), information identifying the manufacturer (Regulation 19), instructions, safety information and warnings (Regulation 20), and compliance procedures for series production (Regulation 21).

Under Regulation 26, importers must not place a toy on the market unless the importer has complied with Regulations 27 (identifying the importer) and 28 (storage and transport conditions), and has ensured that the manufacturer has complied with Regulations 13, and 17 to 20. Under Regulation 33, distributors must not make a toy available unless they have complied with Regulation 34 (storage and transport conditions), verified that the manufacturer has complied with regulations 18 to 20, and verified that any importer has complied with Regulation 27.

A breach of these regulations is an offence under Section 12 of the Consumer Protection Act 1987, and the penalty is as set out above.

Cosmetic Products (Safety) Regulations 2008: These regulations contain 'general' and 'particular' safety requirements. The general safety requirement is set out in Regulation 4, which requires that no person supply a cosmetic product that "may cause damage to human health when applied under normal or reasonably foreseeable conditions of use".

More particularly, the regulations prohibit the supply of certain cosmetic products that contain prohibited substances set out in Schedule 3 to the regulations. The inclusion of other specified substances, including certain colouring agents, preservatives and UV filters, is permitted, subject to conditions.

Regulation 22 sets out various penalties, applicable according to the specific regulation has been breached.

Electrical Equipment (Safety) Regulations 1994: Electrical equipment must be safe

(Regulation 5), and bear the CE marking (Regulation 9). 'Safe' is defined to have generally the same meaning set out in Section 19(1) of the Consumer Protection Act 1987. Schedule 3 sets out the principal elements of the safety objectives, including general conditions regarding design and manufacture, as well as protection against particular hazards, including those caused by external influences on the equipment.

Regulation 14 makes it an offence to supply any electrical equipment that does not comply with Regulations 5 and 9. The penalty for contravention is as set out above. As an exception, where the supplied equipment creates a risk of property damage or injury to animals, but no risk of injury to persons, the maximum penalty on summary conviction is imprisonment for a term not exceeding three months and/or a fine not exceeding level 5 on the standard scale (currently £5,000).

Food – Regulation (EC) 178/2002: There are many regulations relating to aspects of food safety, including licensing, processing, production, labelling, packaging, distribution and marketing.

Article 14 of EC Regulation 178/2002 sets out the 'food safety requirements', including that "food shall not be placed on the market if it is unsafe". Article 14 also provides that food is deemed to be unsafe if it is injurious to health, or unfit for human consumption (see below).

By the General Food Regulations 2004 (Regulation 4(a)), contravention of Article 14 is an offence. Under Regulation 5, a person convicted on indictment is liable to imprisonment for a term not exceeding two years, and/or to an unlimited fine. On summary conviction, the maximum penalty is a term of six months and/or a fine of £20,000. Regulation 7 applies certain provisions of the Food Safety Act 1990, including the defence of due diligence.

Human Medicines Regulations 2012: The Human Medicines Regulations 2012 came into force on August 14 2012, and set out the consolidated legal framework for the control of medicinal products for human use.

The regulatory method is, for any new product, to require the following:

- authority to conduct clinical trials to test safety (and quality and efficacy); and
- authority to market the product; and
- operation of a pharmacovigilance system, involving ongoing monitoring and reporting of safety issues, eg suspected adverse reactions (Part 11 of the regulations).

The Medicines and Healthcare Products Regulatory Agency (MHRA), an agency of the Department of Health, remains the responsible regulating authority. Before a marketing authorisation is granted, it is necessary to obtain the MHRA's permission to conduct clinical trials. The MHRA assesses subsequent licensing applications and, if necessary, obtains independent expert advice from the Commission of Human Medicines. If the MHRA is satisfied that a medicine is effective, and acceptably safe, it may issue a marketing authorisation.

Under Regulation 17 of the Human Medicines Regulations 2012, a person

without a licence may not manufacture any medicinal product. Regulation 18 imposes similar obligations for licences to distribute ('wholesale dealer's licences'). Under Regulation 34(1), breach of either obligation is an offence.

Under Regulation 46, a person may not sell or supply an unauthorised medicinal product, or an authorised product otherwise than in accordance with the terms of an authorisation or registration.

In the event of breach of the above duties concerning manufacture and supply, Regulations 35 and 47 state that the penalty is, on summary conviction, a fine not exceeding the statutory maximum (currently £5,000), or, on conviction on indictment, an unlimited fine and/or imprisonment for a term not exceeding two years. There are numerous other relevant duties and offences, including those relating to pharmacovigilance.

Automotive vehicles, systems and components: The General Product Safety Regulations 2005 and other safety regulations apply to automotive products. It should also be noted that vehicles, and their component systems and parts, are subject to detailed regimes of 'type approval'. For new products, this involves testing by reference to certain performance requirements. Once all systems and components have been approved, a whole vehicle is assessed. A satisfactory assessment will lead to whole vehicle type approval, and documentary evidence of approval, depending on the approval regime concerned. Generally, approval is valid until the point of any change in design, or change in the applicable standards.

As an example of legislation regarding type approvals, Directive 92/23/EEC requires member states to give type approval to tyre types that satisfy the requirements of Annex II of the directive.

In addition to the General Product Safety Regulations 2005, other safety regulations may apply. For example, the Motor Vehicle Tyres (Safety) Regulations 1994, made under Section 11 of the Consumer Protection Act 1987, prohibit the supply of tyres that do not bear a valid approval mark. In addition, Section 75 of the Road Traffic Act 1988 prohibits the sale of vehicles that are in an unroadworthy condition.

1.3 Compliance with safety requirements

The examples above show that there are different safety requirements for different products. Some products must be 'safe', while others (such as toys) have detailed particular safety requirements.

Below, we set out further detail on the general meaning of 'safe', as well as specific safety requirements for foods, medicinal products, and automotive products.

If an unsafe product has been put onto the market, in addition to possible criminal penalties, producers and distributors have obligations to notify the authorities and to conduct corrective actions.

1.4 Statutory definition of 'safe'

The Consumer Protection Act 1987, Section 19(1), defines 'safe' as:

such that there is no risk, or no risk apart from one reduced to a minimum, that any of

the following [essentially use or consumption] will (whether immediately or after a definite or indefinite period) cause the death of, or any personal injury to, any person whatsoever

The General Product Safety Regulations 2005 define 'safe product', and provide guidance by listing the factors to be considered when assessing whether a product is safe. Regulation 2(1) provides:

'safe product' means a product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.

The Consumer Protection Act 1987 definition permits only minimum risk, and the General Product Safety Regulations' definition permits the minimum risks that are acceptable and consistent with a high level of consumer protection. These definitions are similar, each requiring a judgement as to whether a risk is acceptable.

It should also be noted that, for the purposes of the General Product Safety Regulations 2005, a producer should anticipate 'abnormal' uses of a product: it is likely this will apply particularly to products that might be misused by children.

1.5 **Presumption of conformity**

Regulation 6 of the General Product Safety Regulations 2005 sets out presumptions of conformity, by reference to compliance with certain national and international product safety standards. For example, Regulation 6(2) provides that:

Where a product conforms to a voluntary national standard of the United Kingdom giving effect to a European standard the reference of which has been published in the Official Journal of the European Union in accordance with Article 4 of the GPS Directive, the product shall be presumed to be a safe product so far as concerns the risks and categories of risk covered by that national standard. The Secretary of State shall publish the reference number of such national standards in such manner as he considers appropriate.

Compliance with such standards is not equivalent to the product being 'safe', so is not a bar to enforcement action. However, it is unlikely that a court would decide that a product which complies with standards is nevertheless unsafe, unless, for example, aggravating factors are present. More detailed official guidance is available to assist with risk assessment, some of which is summarised below.

2. **Other obligations of producers and distributors**

Regulation 7 of the General Product Safety Regulations sets out other important general obligations relating to safety issues and corrective actions:

- (3) *Within the limits of his activities, a producer shall adopt measures commensurate with the characteristics of the products which he supplies to enable him to—*
 - (a) *be informed of the risks which the products might pose, and*
 - (b) *take appropriate action including, where necessary to avoid such risks, withdrawal, adequately and effectively warning consumers as to the risks or, as a last resort, recall.*
- (4) *The measures referred to in paragraph (3) include—*