Product regulation, safety and recall Q&A: Ireland

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Ireland specific information concerning product regulation, safety and recall issues.

This Q&A provides country-specific commentary on *Practice note, Product regulation, safety and recall: Cross-border*, and forms part of *Cross-border commercial transactions*.

Industry-specific regulation

1. Is there any industry-specific regulation as regards product safety?

Yes. Ireland is under an obligation to implement all EU Directives that deal with product safety. These have generally been transposed into Irish law with few or no amendments. The key pieces of legislation in Ireland transposing EU law in respect of product safety in specific industries include:

- The EU (Cosmetic Products) Regulations 2013 (as amended) (Cosmetic Products Regulations) transpose into Irish law EU Regulation 1223/2009 on Cosmetic Products.
- The European Communities (Food Supplements) Regulations 2007 (Food Supplements Regulations) transpose EU Directive 2002/46/EC relating to food supplements into Irish law.
- The European Communities (Safety of Toys) Regulations 2011, as amended by the European Communities (Safety of Toys) (Amendment) Regulations 2013 (together, the Toy Safety Regulations) transpose Council Directive 2009/48EC on the Safety of Toys into Irish law.
- The European Communities (Personal Protective Equipment) Regulations 1993 as amended (PPE Regulations) transpose into Irish law Directive 89/686 EC relating to personal protective equipment (PPE).
- The EU (Restriction of Certain Hazardous Substances in EEE) Regulations 2012 (RoHS Regulations) transpose Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) into Irish law.
- The EU (Textile Fibre Names and Related Labelling and Marking of the Fibre Composition of Textile Products) Regulations 2012 (Textile Labelling Regulations) transpose EU Regulation 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products.

- The EC (Labelling of Footwear) Regulations 1996 (Footwear Regulations) transpose EU Directive 94/11/EC relating to the labelling of the materials used in the main components of footwear for sale to consumers.
- The Chemicals Act 2008 and the Chemicals (Amendment) Act 2010, (together, the Chemicals Acts) provide a framework for the implementation and enforcement of a number of EU Regulations concerning chemicals in Ireland.

Consumer product legislation

2. How is general product safety regulated in the national jurisdiction? Does national law impose any product safety obligations over and above those contained in the 2001 General Product Safety Directive?

The European Communities (General Product Safety) Regulations 2004 (Product Safety Regulations), as amended, give effect to the 2001 General Product Safety Directive in Ireland and apply to all products which are not subject to specific safety requirements imposed by EU law (see *Question 1*).

The obligations imposed by the Product Safety Regulations largely mirror the obligations imposed by the 2001 General Product Safety Directive. They generally prohibit the placing of a product on the market "unless it is a safe product".

A "safe product" is defined in the Product Safety Regulations as "any 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 following factors should be taken into consideration in determining the safety of a product:

- The characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance.
- The effect of the product on other products, where it is reasonably foreseeable that it will be used with other products.
- The presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the products.
- The categories of consumers at risk when using the product, in particular children and the elderly.

A producer must provide consumers with all relevant information relating to a product placed on the market, to enable them to assess the risks inherent in the product and to take precautions against those risks (*Regulation 6, Product Safety Regulations*). A "producer" is defined as the manufacturer of a product (when the manufacturer is

established in the EU), the manufacturer's representative (when the manufacturer is not established in the EU, or if there is no representative in the EU, the importer of the product), or other professionals in the supply chain (in so far as their activities may affect the safety of the product).

A distributor must act with due care to ensure that any product they supply is a safe product (*Regulation 7, Product Safety Regulations*). A "distributor" is defined as "any professional in the supply chain whose activity does not affect the safety properties of a product".

Where a producer or distributor of a product knows that a product which they have placed on the market poses a safety risk to a consumer, the producer or distributor must inform the Competition and Consumer Protection Commission (CCPC). If a product which has been placed on more than one market (that is, two or more member states) is recalled, the CCPC must notify the European Commission via RAPEX. The RAPEX system was introduced by the 2001 General Product Safety Directive to allow for the rapid exchange of information between EU authorities if a non-food consumer product poses a serious risk to the healh and safety of consumers. The European Commission then transmits this information to all EU member states.

3. How is product safety legislation enforced in the national jurisdiction? What powers do the enforcement authorities have?

There is no single body with responsibility for enforcing consumer safety legislation in Ireland. Rather, particular product sectors have their own enforcement agencies.

Competition and Consumer Protection Commission (CCPC)

The CCPC is responsible for enforcing the Product Safety Regulations, the Textile Labelling Regulations and the Toy Safety Regulations. The CCPC is also the competent authority for the regulation of PPE for recreational use. However, the use of PPE in the workplace is the responsibility of the Health and Safety Authority (HSA).

Under the Product Safety Regulations, the CCPC may issue directions in respect of products which pose risks in certain conditions or to certain persons. The directions may require that the product is suitably marked with clear warnings on the risks it may present, or prohibit the placing of the product on the market.

Where a dangerous product has been placed on the market, the CCPC may issue a direction which requires the immediate withdrawal of the product from the marketplace and that consumers are alerted to the risks presented by the product.

Where a person contravenes the Toy Safety Regulations, the CCPC may:

- Issue a contravention notice, directing that person to either remedy the contravention or to remove the toy from the market by a specified date.
- Issue a prohibition notice in circumstances where there is, or is likely to be, a situation or activity relating to a toy that involves a serious risk to safety or health. The prohibition notice may include directions as to the

measures to be taken to remedy any contravention or to comply with the notice, and to bring the notice to the attention of any affected person or the public generally.

If a person fails to comply with a prohibition notice, an application may be made ex parte to the Irish High Court for an order prohibiting the continued contravention of the notice.

Under the Textile Labelling Regulations, the CCPC may issue a compliance notice directing the person to whom it is served to remedy a contravention of the Textile Labelling Regulations and to carry out any other requirements which may be considered appropriate. It is an offence to fail to comply with a compliance direction or a requirement specified in the compliance notice without reasonable excuse.

Health Products Regulatory Authority

The Health Products Regulatory Authority (HPRA) is the competent authority for, among other things, the regulation of cosmetics in Ireland.

Where an authorised officer of the HPRA is of the opinion that there is non-compliance with the Cosmetic Product Regulations, the authorised officer may serve a compliance notice on the person concerned, which may identify corrective actions to be taken or direct the person concerned to ensure that the cosmetic product is not placed or made available on the market until the product is in conformity with the Cosmetic Products Regulations.

Where a person fails to comply with a compliance notice, or where an authorised officer of the HPRA is of the opinion that a cosmetic product does not comply with the Cosmetic Product Regulations or poses a serious risk to human health, the officer may serve a prohibition order on the person which prohibits the product is not placed or made available on the market or directs the person to destroy the product within a specified time.

Food Safety Authority of Ireland

The Food Safety Authority of Ireland (FSAI) is the competent body responsible for the enforcement of the Food Supplement Regulations in Ireland.

Where an authorised officer of the FSAI suspects that a food supplement does not comply with the Food Supplements Regulations, the authorised officer may seize, remove, detain or direct the withdrawal of that food supplement from the market.

Environmental Protection Agency

The Environmental Protection Agency (EPA) is the designated market surveillance authority for the enforcement of the RoHS Regulations. Non-compliance with the RoHS Regulations may result in the EPA imposing a fine or ordering a product recall.

Health and Safety Authority

In relation to the Chemicals Acts, the HSA is the main competent authority for a number of EU Regulations concerning chemicals. However, five other national authorities also have administration or enforcement obligations under the Chemicals Acts: the Minister for Agriculture, Fisheries and Food, the EPA, Beaumont Hospital Board, the Revenue Commissioners and the Irish National Accreditation Board (INAB).

4. What sanctions are imposed under national law for breach of product safety legislation?

An offence under the Product Safety Regulations may be prosecuted summarily by the CCPC. There is no method by which an offence can be prosecuted on indictment under the Product Safety Regulations.

A person guilty of an offence under the Product Safety Regulations (for example, by placing a dangerous product on the market, failing to provide consumers with the relevant information to enable them to assess the risks inherent in a product or failing to act with due care to ensure the product supplied is safe) is liable on summary conviction to a fine not exceeding EUR3,000 or to imprisonment for a term not exceeding three months, or both.

5. Does national law imply any terms into a contract in relation to product safety? Can they be excluded?

The Sale of Goods Act 1893 and the Sale of Goods and Supply of Services Act 1980 (SGSSA) imply a number of terms into a contract for the sale of goods. The following relate to product safety:

- **Description.** It is an implied condition that goods will correspond with the description provided (*section 13, Sale of Goods Act 1893*). If goods are sold by description and sample, it is not sufficient that the bulk of the goods correspond with the sample if the goods do not also correspond with the description.
- **Merchantable quality.** It is an implied condition that the goods must be of merchantable quality unless:
    - defects have been specifically brought to the buyer's attention before the contract has been made; or
    - the buyer examines the goods before the contract has been made as regards defects which that examination ought to have revealed.

    (*Section 14(2), Sale of Goods Act 1893*.)
- **Fit for purpose.** Where the seller sells goods in the course of a business and the buyer, expressly or by implication, makes known to the seller a particular purpose for which the goods are being purchased, there is an implied condition that the goods are reasonably fit for that purpose, whether or not that is a purpose for which the goods are commonly supplied (*section 14(4), Sale of Goods Act 1893*). This condition is not implied where the circumstances show that the buyer does not rely, or that it is unreasonable for the buyer to rely, on the seller's skill or judgement.

- **Materials used.** A term is implied in a contract for the supply of a service that a supplier acting in the course of a business will use materials which are sound and reasonably fit for the purpose for which they are required (*section 39, SGSSA*).

The implied conditions with regards to merchantable quality and fitness for purpose may never be excluded where the buyer deals as a consumer. Any provisions attempting to do so will be deemed void. In any other case, attempts to exclude liability for these implied conditions will not be enforceable unless it is shown that it is fair and reasonable (*section 55, Sale of Goods Act 1893*).

6. Do product safety regulations apply equally to imported products?

Yes. The Product Safety Regulations apply to all products. Products cannot be placed on the market within the EU unless they conform to the relevant EU laws.

7. Does national law regulate the safety of packaging?

Yes. In determining the safety of a product, the "characteristics of the product, including its composition, packaging, instructions for assembly and where applicable, for installation and maintenance" must be taken into consideration (*Regulation 4(2)(a), Product Safety Regulations*).

In addition, the Packaging (Essential Requirements) Regulations 2014 (Packaging Regulations) implement Directive 94/62/EC on Packaging and Packaging Waste (as amended) in Ireland. The Packing Regulations set out the requirements that all items of packaging must meet before being placed on the Irish market. They are enforced by the EPA and local authorities.

Under the Packaging Regulations, the essential requirements in respect of packaging are as follows:

- Packaging must be manufactured so that the packaging volume and weight are limited to the minimum adequate amount to maintain the necessary level of safety, hygiene and acceptance for the packed product to the consumer.
- Packaging must be designed, produced and placed on the market in such a way as to permit its reuse or recovery, including recycling, and to minimise its impact on the environment when packaging waste or residues from packaging waste management operations are disposed of.
- Packaging must be manufactured so that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or any of the packaging components is minimised

with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled.

Schedule 4 of the Packaging Regulations sets out a number of requirements in relation to the reusable nature of packaging, including the requirement that "the physical properties and characteristics of the packaging must enable a number of trips or rotations in normally predictable conditions of use".

The Packing Regulations also set out a number of requirements specific to the recoverable nature of packaging:

- Packaging must be manufactured in such a way as to enable the recycling of a certain percentage by weight of the materials used into the manufacture of marketable products, in compliance with current standards in the EU. The establishment of this percentage may vary, depending on the type of material of which the packaging is composed.
- Packaging waste processed for the purpose of energy recovery must have a minimum inferior calorific value to allow optimisation of energy recovery.
- Packaging waste processed for the purpose of composting must be of such a biodegradable nature that it should not hinder the separate collection and the composting process or activity into which it is introduced.
- Biodegradable packaging waste must be of such a nature that it is capable of undergoing physical, chemical, thermal or biological decomposition so that most of the finished compost ultimately decomposes into carbon dioxide, biomass and water.

Packaging must also comply with certain heavy metal concentration limits (*Regulation 29, Packaging Regulations*).

8. What provision does national law make for product recall? Is it mandatory or voluntary?

Producers must adopt measures commensurate with the characteristics of the product, to enable the producer to:

> "(a) be informed of the risks which the product might pose, or
> (b) choose to take appropriate action, including, if necessary to avoid such risks, withdrawal of the product in question from the market, adequately and effectively warning consumers, or recall of the product from consumers. Recall shall take place as a last resort where other measures do not suffice to prevent the risks involved."

(*Regulation 6(3), Product Safety Regulations*.)

The decision to recall a product is determined on a case-by-case basis and must be assessed in the light of a risk assessment undertaken in accordance with the methodology contained in Commission Decision 2010/15/EU. A producer who does not undertake appropriate actions to avoid the risks posed by their product, which may include a product recall in appropriate circumstances, risks criminal sanctions.

In addition to the requirements under the Product Safety Regulations, an obligation to recall unsafe products may also exist under general civil liability principles, for example under the Liability for Defective Products Act 1991 (which was implemented to give effect to Directive 85/374/EEC on Product Liability). The Liability for Defective Products Act 1991 imposes a duty on those who supply products to ensure, as far as is reasonably practical, that users will not be harmed by them.

The CCPC has the express power to order a product recall (*Regulation 9(1)(f), Product Safety Regulations*). A person who fails to comply with a direction of the CCPC to recall a product is guilty of an offence.

9. Are there any sanctions for failure to initiate a product recall exercise?

While it is not an offence under the Product Safety Regulations to fail to initiate a product recall, it is an offence to fail to comply with a direction of the CCPC to recall a product.

An offence under the Product Safety Regulations may be prosecuted summarily by the CCPC (see *Question 4*). A person guilty of an offence under the Product Safety Regulations is liable on summary conviction to a fine not exceeding EUR3,000 or to imprisonment for a term not exceeding three months, or both.

In circumstances where a manufacturer or retailer is aware that a product it has supplied is dangerous but does not initiate a product recall, the manufacturer or retailer may be liable to anyone injured by the product under the Liability for Defective Products Act 1991 or under the common law tort of negligence.

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