

PRODUCTS STANDARDS

European Harmonisation

The European Union has harmonised product standards across numerous areas in order to facilitate free movement of goods throughout the EU. Numerous Directives have been made at EU level, which have become law in Ireland, setting out minimum of standards for products and goods over the last 35 years. The advantage of these common standards is that once goods comply with the standards in Ireland, an exporter can know that they comply automatically with standards throughout the EU.

Most harmonised standards have evolved through industry groups. The standards are not intended to be restrictive or prescriptive. Under the newer approach, EU Directives seek to harmonise the essential health and safety requirements of goods without prescribing detailed technical requirements in the law itself. The European standards bodies prepare and publish technical standards in support of the Directives known as harmonised standards in order to meet the essential health and safety requirements for the products.

The Directive for the relevant product type typically states the legal objectives (i.e. the minimum essential health and safety requirements) (HSR). The harmonised standards produced by the Standard Bodies identify the technical means to meet these objectives. Harmonised standards are one method of reaching the HSR but are not necessarily the only way to do so. Compliance gives a presumption of conformity with the required HSR.

There are harmonised standards across a vast range of products. They include, for example, motor vehicle, agricultural vehicles, construction, equipment and product. They also cover electrical products, machinery, food stuffs, ceramics, cosmetics, dangerous substances, equipment, pharmaceutical products and petroleum products.

CE Marking

CE marking must be applied by manufacturers and importers to many products to verify compliance with the essential requirements under the relevant product standards in order to market them in the EU or EFTA. In order to procure CE marking, it is necessary to verify which EU Regulations apply to the product. The manner of conformity verification differs between various types of product. Conformity assessment procedures could involve self declaration, testing, inspection or quality system approval. However, they will create a presumption of conformity.

It may be necessary that an independent assessment of conformity is issued by a standards body. This will depend on the product. CE marking must not be affixed, until all necessary certifications have been obtained from the standards body. Compliance may be through a national standards body. The National Standards Authority of Ireland is the notified standards body for Ireland.

In areas where EU law requires the manufacturer to affix the CE mark before marketing, suppliers must submit to conformity assessment procedures performed by the standards body. In order to be entitled to affix the CE mark the applicant must comply with the conditions relevant to the goods concerned. Certain fees are payable to the national standards body.

A declaration of conformity and the required supporting evidence must be available to the relevant authority in the member state upon request. Technical documentation required by the Directive must be maintained.

The certificate holder entitled to provide the CE mark must communicate changes to the product to the standards body. Certain adverse incidents must be notified to the standards body. Records must be maintained.

2008 Products Regulation

In 2008 the EU adapted a Regulation which has direct effect throughout the EU in order to remove the remaining obstacles to free the circulation of products. The regulation sets out the requirements for EU wide accreditation and marketing of products. The new rules were also designed to tackle unsafe products and third party imports. They enhance conformity and quality assessment of products and reinforce rules and requirements on notification to conformity assessment bodies. It increases use of accreditation. It enhances the "CE" marking.

The Regulation establishes a common legal framework for industrial products. It strengthens the free common market in products which are not yet subject to EU harmonisation such as certain food stuffs, furniture, bicycles, ladders, precious metals.

The EU has gone very far to make it very difficult to deny real effect to the Treaty rights to provide goods and services by making it very difficult for member states to justify failure to recognise. The Regulation's objective is to ensure that denial of recognition of one EU state's standards becomes the exception. It does this by putting the onus on the authorities in the member state of import to objectively justify why it purports to deny recognition of another member state's standards.

The member state must respond promptly to the exporting business and to justify the failure to recognise the product standard. It must do so within a short time frame. The purpose is to ensure that member states do not use the very limited bases for denying recognition in a way that is unfair to businesses.

If a member state proposes to deny recognition, it must give written notice to the business specifying the technical rule, setting out technical and scientific evidence proving that the proposed decision is justified by an overriding reason of public interest and that no less restrictive measure can be taken. The decision must be based on the characteristics of the product.

The business may submit comments to the member state within time limits. The member state must assess the exporter's comments before a decision is made. In giving a decision it must provide technical and scientific justification for the decision based on the limited grounds in the European Union Treaties.

Each member state must designate at least one Product Contact Centre and inform European Commission and other member states. This may be a new or existing public body. Various tasks must be performed free of charge by the member state within 15 days. These tasks include the following:

- providing the technical information applicable to a specific type of product in that state
- advise whether the marketing and sale product is subject to prior authorisation
- give contact details of the relevant regulatory authorities
- describe the remedies available in the event of a dispute with the authority.

This Guide is intended as an overview and broad outline of the matters covered in it. Its purpose is to inform and raise awareness. We are happy to offer specific legal advice on particular circumstances.

This Guide should not be relied on as a substitute for comprehensive legal advice with reference to the particular circumstances.

While we have taken due care in the preparation of this publication, we do not accept legal liability as a result of any reliance placed on anything in this Guide. The reader should rely only on specific legal or taxation advice.