

Products standards

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. These laws have evolved over time.

The effect of these standards is that once relevant goods comply with the standards in Ireland an exporter can know that they comply automatically with standards throughout the EU. There are harmonised European standards across a vast range of goods and products. There is a vast range of product categories involved.

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Most harmonised standards have evolved through industry groups and 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. 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.

The Directive states that legal objectives (i.e. the minimum essential health and safety requirements) (HSR) and 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 mandatory. Compliance gives a presumption of conformity with the required HSR.

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CE Marking

Products with harmonised standards must comply with the essential requirements of the Directives. CE Marking must be applied to many products in order to verify compliance with the essential requirements under the relevant Directives. The mark must be applied by manufacturers and importers 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. Conformity assessment procedures could involve self declaration, testing, inspection or quality system approval. However, they will create a presumption of conformity.

It is necessary to identify whether an independent assessment of conformity is needed from a notified body. This will depend on the product. CE marking must not be affixed until all necessary certifications have been obtained from the notified bodies. Compliance may be through a national standards body. The National Standards Authority of Ireland (NSAI) is the standards body for Ireland.

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.

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. There may be conformity assessment procedure or quality control system.

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

2008 EU Regulation

In 2008, the EU adapted a Regulation which has direct effect throughout the EU in order to remove the remaining obstacles to the free circulation of goods products throughout the EU. The regulation sets out the requirements for EU wide accreditation and marketing of products.

The new rules were also designed to protect the public from unsafe products, in particular those from 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.

Under the Regulation the objective is to ensure that denial of mutual recognition of each member state's standards becomes the exception by putting the onus on member states to objectively justify why they propose to deny recognition of another member state's standards.

Onus on Member States

The EU has gone very far to make it very difficult to deny real effect to the EU Treaty rights to market and sell goods and services by making it very difficult for member states to justify failure to recognise. The onus is on the member state to respond to the foreign business and to justify the failure to recognise the. It must do so within a short time frame. The purpose of these recent Regulations are to ensure member states do not use the very limited grounds for denying mutual recognition in a way that is unfair to businesses.

If a member state proposes to deny mutual 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 a 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 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.

Product Contact Points

Each member state must designate at least one Product Contact Point and inform the European Commission and other member states. This could be a new or existing public body. This body acts as the contact point in relation to recognition of standards under the 2008 Regulations.

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 between the authorities.

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 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.