



# Product standards

**Keeping your product  
on the market**

**December 1999**

**dti**

Department of Trade and Industry

**URN 99/1118**

# Contents

	<b>Page</b>
Free movement of goods	<b>2</b>
The challenge for you	<b>3</b>
Investigate	<b>4</b>
Influence	<b>5</b>
Implement	<b>6</b>
Products covered by the rules	<b>8</b>
The rules - what they contain	<b>19</b>
How European standards are agreed	<b>21</b>
Directive 98/34/EC and the prevention of technical barriers to trade	<b>22</b>
Action Single Market	<b>23</b>
Further information and advice	<b>24</b>
DTI Government Offices (GOs)	<b>27</b>
Business Links	<b>27</b>

# Free movement of goods

Achieving the free movement of goods lies at the heart of achieving an open market for business in Europe.

In May 1985, European Community<sup>1</sup> Ministers agreed on a 'New Approach to Technical Harmonisation and Standards' in order to fulfil this objective.

'New Approach' Directives (that is, Community laws) set out 'essential requirements' (for health and safety, for example), written in general terms. For these Directives - with some specific exceptions - this means that products must meet essential requirements before they may be sold in the UK or anywhere else in the Community. European standards fill in the detail and are the main way for businesses to meet these requirements. The Directives also state how manufacturers are to show that products comply. Products meeting the requirements are to carry the CE marking, which indicates that they can be sold anywhere in the Community.

Under the European Economic Area (EEA) Agreement the provisions of the Directives now additionally apply in three of the member States of the European Free Trade Association (EFTA): Norway, Iceland and Liechtenstein.

---

<sup>(1)</sup> There are fifteen members of the Community - Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom.

# The challenge for you

In this freer Single Market there are new opportunities.

But your competitors have the same new opportunities - including in the United Kingdom.

To succeed, you need to act now:

Investigate

Influence

Implement

# Investigate

First, you need **information** relevant to your business - as it is now **and** as you intend it to develop in the United Kingdom and elsewhere in the Single Market.

- Do you make, import, use or sell a product covered by any of the rules (Directives) listed on pages 8 to 18?

Remember that products may have to comply with more than one set of rules. For example, machinery in a building may have to conform to the Machinery Directive **and** the Construction Products Directive.

- Which standards will you use to comply with the rules?
- Most of those rules have been adopted as UK law, and many standards have been agreed. If not, what stage have they reached? When will they come into effect?
- What tests and checks will you have to make on your product?

For sources of further information and advice turn to page 24.

# Influence

Many decisions have still to be taken - particularly about individual standards.

You can help shape those decisions, especially by taking an active part in European standards work.

- ❑ Identify any changes that would open major opportunities for your business - or pose threats to it.
  
- ❑ Ring the BSI number on page 24 if you are concerned about a standard.

Argue your case, through your trade association, in the BSI Technical Committee and help represent BSI in its European standards work. **The more you contribute the more likely you are to get the standards that meet your business needs.**

- ❑ Remember, a spread of opinion carries more weight than a lone voice. Work with others in your industry (perhaps through your trade association). Involve both users and producers. Team up with your counterparts elsewhere in the Community.

The DTI's booklet *The Single Market - making it work for you* describes how the Community reaches its decisions, and how you can influence that process, and is available from the DTI's Publications Orderline (see page 24). All DTI publications listed in this booklet are available from the Orderline unless otherwise indicated.

# Implement

The new rules and standards could well affect every aspect of your business.

- ❑ Plan to exploit the opportunities - and to counter the threats.
- ❑ Identify the changes you need to make in your business - then implement them.
  - Ring your local Government Office (see page 27) or the DTI general Enquiry Unit on 020 7215 5000 for details of help, advice and publications available from the DTI.
  - Ring the DTI Publications Orderline for copies of DTI publications.
  - Ring your local Business Link (see page 27). Business Links provide a single point of contact for business support services from Training & Enterprise Councils (TECs), Chambers of Commerce, Enterprise Agencies, Local Authorities, the DTI and others. They can advise on how to raise money for growth, how to get into export markets, what grants are available, how to source the most suitable training packages, and how to manage change.

Remember, every Community country is obliged to adopt these rules in its national law. So it is an offence to sell unfit or non-conforming products **in the United Kingdom** just as much as elsewhere in the Community.

**So...**

**A**rm yourself with information

**C**onsider the implications for your business

**T**ake part in standards work

**N**ote down changes you decide to make

**O**rganise their implementation

**W**atch out for new developments

# Products covered by the rules

## Active Implantable Medical Devices Directive (90/385/EEC) as amended by the Medical Devices Directive 93/42/EEC and the CE Marking Directive 93/68/EEC

<b>United Kingdom Law:</b>	<b>Active Implantable Medical Devices Regulations 1992 (SI 1992/3146) as amended by the Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995 (SI 1995/1671)</b>
<b>Entry into force:</b>	<b>1 January 1993</b>
<b>Products</b>	Powered medical devices, that is any equipment together with its accessories and operating software which is permanently implanted in the human body by surgical operation.
<b>Requirements</b>	Relate to safety and performance, including sterility, clinical and technical evaluation of the effects of the device and clinical evaluation of its implantation.
<b>Literature information</b>	There is no title in the <i>Product standards</i> series for this Directive. Medical Devices Directives Bulletins and Guidance Notes are available from Miss Alison Daykin, Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ. Tel: 020 7972 8300, Fax: 020 7972 8112.  The Medical Devices Agency's web site is at <a href="http://www.medical-devices.gov.uk">http://www.medical-devices.gov.uk</a>

## Construction Products Directive (89/106/EEC) as amended by Council Directive 93/68/EEC on CE Marking

<b>United Kingdom Law:</b>	<b>Construction Products Regulations 1991 (SI 1991/1620) as amended by the Construction Products (Amendment) Regulations 1994 (SI 1994/3051)</b>
<b>Entry into force:</b>	<b>27 December 1991 (original Regulations)</b>
<b>Products</b>	Products produced for incorporation in a permanent manner in construction works, including building and civil engineering works.
<b>Requirements</b>	Relate to mechanical resistance and stability; fire safety; hygiene, health and the environment; safety in use; protection against noise; energy economy and heat retention.
<b>Literature information</b>	<i>Product standards: Construction Products.</i>

*Note: The Construction Products Directive is unique for two reasons. Firstly, the essential requirements relate to construction works, and not construction products. Secondly, CE marking is not mandatory for construction products to be sold in the UK (and in Portugal, Sweden and the Republic of Ireland). It will be mandatory for products exported to countries which have made CE marking mandatory for construction products. Should a manufacturer wish to CE mark his products, he must demonstrate that they have the characteristics to allow the works to meet the essential requirements. For further information on the Construction Products Directive please contact Mr Tony Pillai, Building Regulations Division, Department of the Environment, Transport & the Regions (DETR), Room 3/E2, Eland House, Bressenden Place, London SW1E 5DU. Tel: 020 7890 5727, Fax: 020 7890 5719, or visit the DETR's web site at <http://www.construction.detr.gov.uk/br/index.htm>*

## **Efficiency requirements for New Hot-Water Boilers fired with liquid or gaseous fuels Directive (92/42/EEC) amended by Directive 93/68/EEC on CE Marking**

<b>United Kingdom Law:</b>	<b>The Boiler (Efficiency) Regulations 1993 (SI 1993/3083) and the Boiler (Efficiency) (Amendment) Regulations 1994 (SI 1994/3083)</b>
<b>Entry into force:</b>	<b>1 January 1994 for requirements relating to efficiency and 1 January 1995 for the amended requirements for CE marking.</b>
<b>Products</b>	New hot-water boilers, or boiler bodies and burners, fired by liquid or gaseous fuels with a rated output between 4kW and 400kW.
<b>Requirements</b>	Relate to improving the energy efficiency of boilers. Boilers are required to meet minimum standards for energy efficiency whilst running at full load and part load conditions.
<b>Literature information</b>	<i>Product standards: Hot water boilers - Guidance notes on UK Regulations.</i>

## **Electromagnetic Compatibility Directive (89/336/EEC) as amended by Council Directive 92/31/EEC**

<b>United Kingdom Law:</b>	<b>Electromagnetic Compatibility Regulations 1992 (SI 1992/2372)</b>
<b>Entry into force:</b>	<b>28 October 1992</b>
<b>Products</b>	Applies to almost all electrical and electronic appliances, equipment and apparatus.
<b>Requirements</b>	Relate to the non-generation of electromagnetic disturbance and immunity from such disturbance.
<b>Literature information</b>	<i>Product standards: Electromagnetic Compatibility - Guidance notes on UK Regulations; and Electromagnetic Compatibility - Sources of Information, Electromagnetic Compatibility - Minimising the Cost.</i>

## Energy efficiency requirements for household electric refrigerators, freezers and combinations thereof (Directive 96/57/EC)

<b>United Kingdom Law:</b>	<b>The Energy Efficiency (Refrigerators and Freezers) Regulations 1997</b>
<b>Entry into force:</b>	<b>3 September 1999</b>
<b>Products</b>	All new domestic electrical fridges, freezers and fridge-freezers.
<b>Requirements</b>	Relates to improving the energy efficiency of domestic electrical fridges, freezers and fridge-freezers.
<b>Literature information</b>	There is no title in the <i>Products standards</i> series for this Directive. Further information can be obtained from the Market Transformation Unit, Environment Business and Consumers Division, Department of the Environment Transport and the Regions, Zone 6/D10, Ashdown House, 123 Victoria Street, London, SW1E 6DE. Tel: 020 7944 6584, Fax: 020 7944 6559.

## Equipment and protective systems intended for use in potentially explosive atmospheres Directive (94/9/EC)

<b>United Kingdom Law:</b>	<b>The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996 (SI 1996/192)</b>
<b>Entry into force:</b>	<b>1 March 1996</b>
<b>Products</b>	Electrotechnical and mechanical plant for use on the surface, below ground and on fixed offshore installations where potentially explosive atmospheres are likely to occur.
<b>Requirements</b>	Relate to materials, design and construction; steps to prevent the formation and ignition of explosive atmospheres.
<b>Literature information</b>	<i>Product standards: Equipment and protective systems intended for use in potentially explosive atmospheres - Guidance notes on the UK Regulations</i>

## Gas Appliances Directive (90/396/EEC)

<b>United Kingdom Law:</b>	<b>Gas Appliances (Safety) Regulations 1995 (SI 1995/1629 consolidating original Regulations SI 1992/711)</b>
<b>Entry into force:</b>	<b>6 April 1992 (original Regulations)</b>
<b>Products</b>	Appliances, other than those specifically designed for industrial processes, used for cooking, heating, hot water production, refrigeration, lighting or washing, that burn gaseous fuels and have, where appropriate, a water temperature not exceeding 105°C.
<b>Requirements</b>	Relate to materials; design and construction; combustion and temperatures.
<b>Literature information</b>	<i>Product standards: Gas Appliances - Guidance notes on UK Regulations.</i>

## Lifts Directive (95/16/EC)

<b>United Kingdom Law:</b>	<b>The Lift Regulations 1997</b>
<b>Entry into force:</b>	<b>1 July 1997</b>
<b>Products</b>	Lifts (and safety components for lifts) defined as any appliance having a car intended for the transport of persons and/or goods and moving along a fixed course inclined at 15 degrees or greater to the horizontal.
<b>Requirements</b>	Relate to design, construction and health and safety requirements.
<b>Literature information</b>	<i>Product standards: Lifts - Guidance notes on the UK Regulations, and</i>  <i>Lifts: UK Approved Bodies</i>  <i>Lifts: Transposed Harmonised Standards</i>

## The Low Voltage Directive (73/23/EEC)

<b>United Kingdom Law:</b>	<b>The Electrical Equipment (Safety) Regulations 1994 (SI 1994/3260)</b>
<b>Entry into force:</b>	<b>9 January 1995</b>
<b>Products</b>	Most electrical equipment that is designed for use with a voltage rating of between 50 and 1000 volts (alternating current) and between 75 and 1500 volts (direct current).
<b>Requirements</b>	Relate to the provision that electrical equipment must be constructed in accordance with good engineering practice so that it does not endanger the safety of people, domestic animals or property.
<b>Literature information</b>	<i>Product standards: Electrical Equipment (implementing the Low Voltage Directive) - Guidance notes on UK Regulations.</i>

## Machinery Directive (89/392/EEC) as amended by 91/368/EEC, 93/44/EEC and 93/68/EEC

<b>United Kingdom Law:</b>	<b>Supply of Machinery (Safety) Regulations 1992 (SI 1992/3073) as amended by the Supply of Machinery (Safety) (Amendment) Regulations 1994 (SI 1994/2063)</b>
<b>Entry into force:</b>	<b>1 January 1993</b>
<b>Products</b>	'Functioning machines', that is assemblies of mechanically linked parts, at least one of which moves.
<b>Requirements</b>	Relate to materials and products used in construction; lighting; design for handling purposes; stability; hazards relating to mobility and lifting; fire; noise; vibration; emission of dust, gases, etc.; maintenance; indicators and instruction handbooks.
<b>Literature information</b>	<i>Product standards: Machinery - Guidance notes on UK Regulations, and Machinery: Independent sources of advice; Machinery: Transposed harmonised standards; Machinery: UK Approved Bodies; Machinery: Frequently Asked Questions</i>

## Medical Devices Directive (93/42/EEC)

<b>United Kingdom Law:</b>	<b>The Medical Devices Regulations 1994 (SI 1994/3017)</b>
<b>Entry into force:</b>	<b>1 January 1995</b>
<b>Products</b>	Most medical devices, including single-use products and equipment (but not active implantable medical devices or in vitro diagnostic medical devices) from syringes to ECGs.
<b>Requirements</b>	Relate to safety and performance requirements, such as minimising the risk of infection, safety when in contact with the human body and the provision of information.
<b>Literature information</b>	There is no title in the 'Product standards' series for this New Approach Directive. Bulletins and Guidance Notes are available from Miss Alison Daykin, Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ. Tel: 020 7972 8300, Fax: 020 7972 8112.  The Medical Devices Agency's web site is at <a href="http://www.medical-devices.gov.uk">http://www.medical-devices.gov.uk</a>

## Noise limits for earth moving machines Directive 95/27/EC (amending Directive 86/662/EEC)

<b>United Kingdom Law:</b>	<b>Construction Plant and Equipment (Harmonisation of Noise Emission Standards ) Regulations 1988 (SI 1988/361) as amended by SI 1992/488 and the Construction Plant and Equipment (Harmonisation of Noise Emission Standards) (Amendment) Regulations 1995 (SI 1995/2357)</b>
<b>Entry into force:</b>	<b>29 September 1995</b>
<b>Products</b>	Hydraulic excavators, rope-operated excavators, dozers, loaders and excavators-loaders (earth moving machines) with engine power up to 500kW.
<b>Requirements</b>	Relate to noise limits, noise test methods, marking and certification.
<b>Literature information</b>	<i>Product standards: Noise limits for earth moving machines - Guidance notes on UK Regulations.</i>

*Note: CE Marking of Earth Moving Machines is not required by this Directive.*

## **Non-automatic Weighing Instruments Directive (90/384/EEC) as amended by the CE Marking Directive (93/68/EEC)**

<b>United Kingdom Law:</b>	<b>Non-automatic Weighing Instruments (EEC Requirements) Regulations 1995 (SI 1995/1907 as amended by SI 1997/3035 and SI 1998/2994)</b>
<b>Entry into force:</b>	<b>1 January 1993 (the original Regulations)</b>
<b>Products</b>	Instruments (for example shop scales, balances, platform machines and weighbridges), particularly those used for: commercial transactions; determining tolls, tariffs, taxes, bonuses etc; law enforcement; health monitoring in medical practice, making up of medicines in pharmacies and making up of prepackages.
<b>Requirements</b>	Relate to basic metrological requirements such as units of mass, accuracy, classification and influence qualities, and design and construction requirements, such as quality, security and printing, levelling, zeroing and taring devices.  Relevant harmonised standards are EN 29002 and EN 45501.
<b>Literature information</b>	<i>Product standards: Non-automatic Weighing Instruments.</i>

## **Personal Protective Equipment Directive (89/686/EEC)**

<b>United Kingdom Law:</b>	<b>Personal Protective Equipment (EC Directive) Regulations 1992 (SI 1992/3139 as amended by SI 1993/3074 and SI 1994/2326, and the Personal Protective Equipment (EC Directive)(Amendment) Regulations 1996 (SI 1996/3039)</b>
<b>Entry into force:</b>	<b>1 July 1992 (original Regulations)</b>
<b>Products</b>	Any device or appliance designed to be worn or held for protection against any safety or health hazard - from safety helmets to cricket pads.
<b>Requirements</b>	Relate to the suitability of the constituent components and other such general requirements together with requirements specific to particular risks such as fire, heat, cold, radiation, noise and unbreathable atmospheres.
<b>Literature information</b>	<i>Product standards: Personal Protective Equipment - Guidance notes on UK Regulations, and Personal Protective Equipment - Approved Bodies.</i>

## Pressure Equipment Directive (97/23/EC)

<b>United Kingdom Law:</b>	<b>The Pressure Equipment Regulations 1999 (SI 1999/2001)</b>
<b>Entry into force:</b>	<b>29 November 1999</b>
<b>Products</b>	Pressure equipment and assemblies subject to an internal pressure greater than 0.5 bar. The Regulations therefore concern manufacturers of items such as shell and water tube boilers, heat exchangers, vessels, pressurised storage containers, industrial pipework and accessories.
<b>Requirements</b>	Relate to the design, manufacture and conformity assessment of pressure equipment and assemblies.
<b>Literature Information</b>	<i>Product standards: Pressure Equipment : Guidance notes on the UK Regulations</i>

## Recreational Craft Directive (94/25/EC)

<b>United Kingdom Law:</b>	<b>The Recreational Craft Regulations 1996 (SI 1996/1353)</b>
<b>Entry into force:</b>	<b>16 June 1996</b>
<b>Products</b>	Recreational craft intended for sports and leisure purposes, regardless of the means of propulsion, and measuring between 2.5 and 24 metres in hull length, partly completed recreational craft, and components.
<b>Requirements</b>	Relate to the safety and health of persons, property and the environment.
<b>Literature information</b>	<i>Product standards: Recreational Craft - Guidance notes on UK Regulations.</i>

## Simple Pressure Vessels Directive (87/404/EEC)

<b>United Kingdom Law:</b>	<b>Simple Pressure Vessels (Safety) Regulations 1991 (SI 1991/2749 as amended by SI 1994/3098)</b>
<b>Entry into force:</b>	<b>31 December 1991</b>
<b>Products</b>	Welded vessels made of certain types of steel or aluminium and intended to contain air or nitrogen under pressure, not exceeding 30 bar, e.g. reservoirs for compressor units; automotive and rail braking systems.
<b>Requirements</b>	Relate to raw materials and welding materials used; accessories contributing to the strength of the vessel; vessel design, including wall thickness; manufacturing processes and the manufacturers' instructions to users.
<b>Literature information</b>	<i>Product standards: Simple Pressure Vessels, and Simple Pressure Vessels - Approved Bodies</i>

## Telecommunications Terminal Equipment

A new directive on radio and telecommunications terminal equipment is due to be fully implemented in Member States from 8th April 2000. At the moment, however, terminal equipment in the European Community is governed by Directive 98/13/EC.

**Telecommunications Terminal Equipment and Satellite Earth Station Equipment Directive 98/13/EC.** (NB this is a consolidating directive, bringing satellite earth station equipment into the scope of the preceding directive 91/263/EEC on terminal equipment):

<b>United Kingdom Law:</b>	<b>Telecommunications Terminal Equipment Regulations 1992 (SI 1992/2324 amended by SI 1994/3129 and 1995/144)</b>
<b>Entry into force:</b>	<b>4 March 1998</b>
<b>Products</b>	Telecommunications Terminal Equipment which can be connected directly or indirectly to the public telecommunications network.

**Requirements** Relate to the safety of users and operators; electromagnetic compatibility requirements specific to terminal equipment; protection of the networks; effective use of the radio frequency spectrum and interworking with the network and other equipment attached to it.

**Literature information** There is no title in the *Product standards* series for this New Approach directive. Further information can be obtained from the UK's Terminals Approvals Policy Committee (TAPC) website at <http://www.tapc.org.uk>, or the Communications & Information Industries Directorate, Department of Trade & Industry, Terminal Equipment Unit, 151 Buckingham Palace Road, London SW1W 9SS, Tel: 020 7215 1773, Fax: 020 7931 7194.

### **The Radio and Telecommunications Terminal Equipment Directive 99/5/EC**

**United Kingdom Law:** Currently being formulated

**Implementation date:** 8 April 2000

**Products** Radio and telecommunications terminal equipment that can be connected directly or indirectly to the public telecommunications network.

**Requirements** Relate to the safety of users, third parties and operators; electromagnetic compatibility requirements specific to terminal equipment; protection of the networks; effective use of the radio frequency spectrum and interworking with the network and other equipment attached to it.

**Literature information** Guidance information is expected to become available in 2000 following full implementation of the RTTE Directive. Information on the directive is available now at the same contact points given above for 98/13/EC.

### **Summary of transitional arrangements**

The UK and European type approval regimes performed under Directive 98/13/EC for telecommunications terminal equipment will end on 7 April 2000. Directive 98/13/EC will be repealed from 8 April 2000. There are transitional arrangements for telecommunications terminal equipment approved before this date, but all equipment placed on the market from 8 April 2001 onwards must conform to the requirements of the RTTE Directive. Items of apparatus that are not sold by 7 April 2001 can remain on the market until sold, and can subsequently be installed and used.

## Toy Safety Directive (88/378/EEC)

<b>United Kingdom Law:</b>	<b>The Toys (Safety) Regulations 1995 - these Regulations continue the provisions first set out in the Toys (Safety) Regulations 1989 and implement those provisions of the CE Marking Directive which relate to toys - (SI 1995/204)</b>
<b>Entry into force:</b>	<b>24 February 1995</b>
<b>Products</b>	Almost all toys - that is products and materials designed or clearly intended for use in play by children under 14 years of age.
<b>Requirements</b>	Relate to physical and mechanical properties; flammability; hygiene; radioactivity; chemical and electrical properties.
<b>Literature information</b>	<i>Product standards: Toy Safety - Guidance notes on UK Regulations.</i>

## Transportable Pressure Equipment Directive (1999/36/EC)

This Directive covers pressure equipment approved for the inland transport of dangerous goods by road or rail, and falls to the Department of Environment, Transport and the Regions (DETR).

There is no *Product standards* publication available. Further information can be obtained from Mr Paul Quinn, Department of Environment, Transport and the Regions, Zone 2/34, Great Minster House, 76 Marsham Street, London SW1P 4DR. Tel: 020-7676 2768 Fax: 020-7676 2039.

# The rules - what they contain

A 'New Approach' Directive typically includes the following elements:

- ❑ **coverage:** this sets out the range of products, generally wide, covered by the Directive;
- ❑ **essential requirements:** these are the requirements relating, for example, to safety, that products must satisfy before they may be sold in the United Kingdom or anywhere else in the Community. They usually focus on what is to be achieved, rather than how;

The Single European Act specifies that Directives under the 'New Approach' must take as a base a high level of protection, thus ensuring that the new rules do not mean a lowering of safeguards;

'New Approach' Directives essentially deal with a class of risks, so more than one Directive (and indeed a more traditional 'Article 100' Directive) may apply to any particular product;

Generally speaking, all products must satisfy the 'essential requirements', not just products intended to be traded across national boundaries.

- ❑ **methods of satisfying the 'essential requirements':** the usual method is to manufacture in accordance with a specified European standard. But in order to allow for innovation and unusual circumstances, the manufacturer may have the choice of using other methods provided that the essential requirements are met;

The use of standards therefore remains voluntary;

In the United Kingdom, these European standards are published as identically worded British Standards;

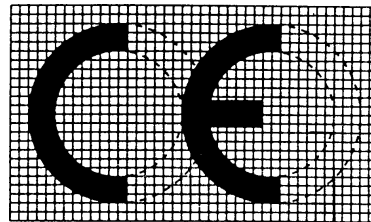
- ❑ **how to show the essential requirements are satisfied ('attestation'):** this sets out how manufacturers must show that products meet the 'essential requirements'. Normally, one of the following methods is specified:
  - a) a declaration by the manufacturer (backed up by his own, or independent, test results);
  - b) the certificate of an independent body; or
  - c) the test results of an independent body.

Manufacturers not using the specified European standard usually have to obtain a report from an independent body;

- ❑ **transitional arrangements:** if a relevant European standard does not yet exist, some Directives provide that national standards approved for that purpose by the European Commission may be used instead;
- ❑ **CE marking:** products meeting the requirements are also to carry CE marking. In simple terms CE marking denotes that a product conforms to a New Approach Directive. The marking is as illustrated in diagram 1, below \*. It may not be smaller than 5mm in its vertical height, and the proportions in diagram 2, below, must be maintained whatever its size. **The grid does not form part of the marking and is for information only;**



**Diagram 1**



**Diagram 2**

- This mark looks the same as some previous marks, but there are subtle changes, and diagram 2 should be studied closely. It should be noted, for example, that the C and E are not formed by perfect semi-circles, i.e. the top and bottom arms extend one square beyond the semi-circles, and the middle arm of the E stops one square short;

Where a product is covered by more than one New Approach Directive, CE marking denotes compliance with the relevant provisions of **all** relevant directives. However, where one or more of these Directives is in a transitional period, the marking may denote compliance with only one, so long as the manufacturer states this clearly in accompanying documents, notices or instructions required by the Directive.

United Kingdom policy is that the manufacturer should be free to decide whether or not to involve an independent body, unless the compulsory involvement of such a body is clearly justified by the nature or extent of the risks involved;

- ❑ **free circulation:** a product which conforms to the 'essential requirements' and which also carries the CE mark is to be presumed to have the right to be put on sale anywhere in the Community;
- ❑ **safeguard procedure:** the Directives, however, also require Community countries to take off the market products which bear CE marking but are unsafe. They must immediately tell the European Commission what they have done, and why. The Commission will consult those concerned. If it finds the action justified, the Commission will tell all the Community countries. In other cases, the action may be brought before the European Court of Justice.

\* Note that particular Directives may have additional CE Marking components to show that other requirements have been met, i.e. the 'crossed hockey sticks' symbol for TTE.

# How European standards are agreed

- ❑ 'New Approach' Directives depend heavily on the availability of European standards which are usually prepared by the European standards bodies, CEN (European Committee for Standardisation), CENELEC (European Committee for Electrotechnical Standardisation), and ETSI (European Telecommunications Standards Institute) on the basis of 'mandates' agreed with the European Commission.
- ❑ CEN and CENELEC bring together the national standards bodies of the Community and the European Free Trade Association (EFTA). BSI is the United Kingdom member. Setting standards in CEN and CENELEC is essentially a process of seeking consensus among the national members. Once an acceptable text has been developed in the relevant Committee, it is circulated to all the members for comment.
- ❑ The European Organisation for Technical Approvals (EOTA) is responsible for writing mandates for European Technical Approvals (ETAs) under the Construction Products Directive. ETAs will be issued for construction products where national standards do not exist, for example where the product is innovative. The UK representative on EOTA is the British Board of Agrément (BBA).
- ❑ The Committee reviews any resulting comments and the draft standard is circulated to national members for adoption by weighted majority voting. Alternatively, particularly if the proposal is to adopt an existing international or national standard as a European standard, a questionnaire procedure can be used to secure endorsement for a text, without the need for a meeting.
- ❑ All the national members have agreed to adopt the resulting European standard as their national standard (in the case of the United Kingdom, as a British Standard), and to withdraw any existing conflicting national standard.
- ❑ The United Kingdom's position at all stages of this process is developed by consensus in the corresponding BSI Technical Committee, which is made up of representatives of interested parties, and then argued, through BSI, in CEN and CENELEC.
- ❑ BSI has moreover developed a systematic methodology that will enable it and its members to prioritise its standards-making programmes, including those for European standards, and so allocate resources appropriately.

Those who participate most actively tend to have the greatest influence on the outcome. If a particular proposed standard affects your interests and you wish to take part, through BSI, in determining that outcome or to have your views taken into account, you (or your trade association or Chamber of Commerce) should contact BSI at 389 Chiswick High Road, Chiswick, London W4 4AL. Tel: 020 8996 9000, Fax: 020 8996 7400.

Those with an interest in European Technical Approvals (ETAs), or in products covered by ETAs, should contact the British Board of Agrément (BBA) at PO Box 195, Bucknalls Lane, Garston, Watford WD2 7NG. Tel: 01923 670844, Fax: 01923 662133.

# **Directive 98/34/EC and the prevention of new technical barriers to trade**

As well as removing existing barriers to trade, the Community, through Directive 98/34/EC, is seeking to prevent the creation of new technical barriers to trade. The Directive lays down a procedure for the provision of information in the field of technical standards and regulations and applies to all industrially manufactured products and agricultural products.

Directive 98/34/EC requires the European Economic Area (EEA) States' Governments to notify the European Commission in draft of any new national technical regulations, and to observe a minimum three-month standstill period before the regulation is made or comes into effect. This is to provide an opportunity for the Commission and/or another EEA State to comment if they feel that the proposed regulation has the potential to create a technical barrier to trade (the Commission circulates the notified drafts to all EEA States).

The Official Journal of the European Communities gives brief details of technical regulations that the UK and other EEA States are planning to make. This gives industry a chance to comment on any notifications. However, Government Departments, who are the usual recipients of notifications in their particular areas of responsibilities, will normally consult the relevant trade associations in the areas concerned before sending their comments to the Commission.

The European Commission intends to publish fuller details of new notifications in a more transparent manner on the internet. The site is currently under construction, but in due course a link will be provided to this site from the DTI's own web site (<http://www.dti.gov.uk/strd/>).

## **The European Economic Area**

The European Economic Area further strengthens business relations in Europe. In effect, it extends the European Union's Single Market to three non-member states: Iceland, Liechtenstein and Norway, so that European Union rules on fair competition and state aids apply there as well.

## **The European Free Trade Association**

Iceland, Liechtenstein, Norway and Switzerland are members of the European Free Trade Association (EFTA). Free trade agreements between the European Union and EFTA have resulted in the abolition of tariffs and quotas on most industrial goods, and a limited range of agricultural goods, and allowed trade between member countries to flourish. (The EFTA members, for example, took over £8.5 billion of goods and services from the UK in 1998).

# Action Single Market

Barriers to trade come in various forms, such as failure to recognise national standards or to comply with public procurement rules. Problems can arise as much from a lack of understanding at local level of Single Market obligations, as from any calculated protectionism. Whatever the cause, when this happens it still has the effect of making it more difficult for British firms to take full advantage of the Single Market.

So, if you are facing a barrier to trade in another EU or EEA country, the DTI's Action Single Market unit may be able to help overcome this. The unit is very keen to hear from British companies in this situation. They will talk through with you what information is available to back up your complaint and what the options are for action, and would be happy to visit you if this would be more helpful. They have scored successes in overcoming barriers across a range of sectors and problem areas. For further details, contact Action Single Market at Bay 211, Kingsgate House, 66-74 Victoria Street, London SW1E 6SW. Tel: 020-7215 4212. Fax: 020-7215 4489.

# Further information and advice

## GENERAL; SECTOR SPECIFIC; COMPANY SPECIFIC

- ❑ Trade associations, federations and similar representative organisations; professional bodies; chambers of commerce etc.

## CONTENT AND PROGRESS OF THE NEW RULES

- ❑ The DTI's Spearhead database provides a unique commentary on European Community single market legislation and other EC legislation relevant to the operation of businesses in the EC. The database includes implemented and adopted measures as well as proposed and projected EC legislation currently under consideration. The greatest strength of Spearhead is that it provides up-to-date UK Departmental contacts on every featured measure who are willing to advise on individual enquiries. Spearhead also provides details of the impact on UK law that each featured measure will have. An explanatory folder is available from the DTI Publications Orderline (see below).

General Enquiries:

Christopher Griffin, DTI Spearhead Manager, Tel: 020 7215 4486

The Spearhead web page is at <http://www.dti.gov.uk/support/spear.htm>

## STANDARDS

- ❑ BSI, 389 Chiswick High Road, Chiswick, London W4 4AL.  
Tel: 020 8996 9000, Fax: 020 8996 7400 for all enquiries including standards sales, subscriptions, and library. BSI's website is at <http://www.bsi.org.uk>

## TECHNICAL HELP TO EXPORTERS

- ❑ Help to exporters on overseas standards, regulations and markets is available from Technical Help to Exporters (THE), a part of BSI, at 389 Chiswick High Road, London W4 4AL. Tel: 020 8996 9000.

## REGULATIONS

- ❑ The Regulations themselves are obtainable from The Stationery Office, Publications Centre, Tel: 020 7873 9090. Statutory Instruments can be found on HMSO's website at <http://www.hmso.gov.uk/stat.htm> and orders for printed copies can be placed via the Stationery Office online site at <http://www.tsonline.co.uk>

## THE DTI PUBLICATIONS ORDERLINE

- ❑ The DTI Publications Orderline, open during business hours on weekdays, offers the full range of DTI's publications, and can also help to identify further sources of help and advice on both exporting and standards questions.

Telephone 0870 1502 500 (national rate), Fax 0870 1502 333  
Minicom 0870 1501 100 E-mail [dtipubs@echristian.co.uk](mailto:dtipubs@echristian.co.uk)

## WORLD WIDE WEB

- ❑ Further information on the Department of Trade & Industry is available from the DTI's World Wide Web site on the Internet, which can be visited at <http://www.dti.gov.uk> (or its mirror site at <http://www2.dti.gov.uk>).

The DTI's Standards and Technical Regulations Directorate (STRD) has its own homepage within the main DTI site, at <http://www.dti.gov.uk/strd/>

- ❑ European Commission documents can be found at <http://europa.eu.int>

Lists of harmonised standards relating to New Approach Directives can be found at <http://europa.eu.int/comm/dg03/directs/dg3b/newapproa/eurstd/harmstds/reflist.html>

- ❑ The Commission has set up a dedicated website for Electrical Engineering at <http://europa.eu.int/comm/dg03/directs/dg3d/d1/eleng/index.htm>. This has pages covering the Electromagnetic Compatibility, Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres, and Low Voltage Directives. The Low Voltage Directive pages contain the text of the Directive itself, the Commission's guidelines, a list of Notified Bodies, and the harmonised standards relating to this Directive, as well as other useful information.

- ❑ Further information on the Construction Products Directive can be found at the Department of the Environment, Transport & the Regions (DETR) website at <http://www.construction.detr.gov.uk/br/index.htm>.

- ❑ The Medical Devices Agency's web site is at <http://www.medical-devices.gov.uk>, where further information can be found on the Active Implantable Medical Devices Directive and the Medical Devices Directive.

- ❑ Non-automatic Weighing Instruments: Guidance notes on the UK's implementing Regulations can be found on the National Weights and Measures Laboratory's web site at <http://www.nwml.gov.uk>

WELMEC - the European Cooperation in Legal Metrology - has published various guides to the Directive on non-automatic weighing instruments. These can be found on its web site (<http://www.welmec.org>) together with a database of Notified Bodies and brief descriptions of legal metrology arrangements in each of the member States including reference to the Directive.

- ❑ Information on the Telecommunications Terminal Equipment Directive can be found at <http://www.tapc.org.uk>

## EXPORTS TO WESTERN EUROPE

The *Business in Europe Directorate*, within *British Trade International*, is responsible for trade promotion and development work in Western Europe.

It aims to identify the best opportunities in other Western European countries and help UK businesses take full advantage of them.

It can help UK businesses by:

- Providing practical help, including advice and assistance, from Export Promoters;
- Providing information on individual markets and opportunities;
- Signposting to sources of detailed advice, both within Government and the private sector;
- Managing the Export Explorer scheme that helps UK businesses take the first steps into finding new customers overseas;
- Organising various promotional projects, often on a sectoral basis, to help UK business take advantage of the many opportunities to be found in the European markets.

To find out more about the above visit the British Trade International web site ([www.brittrade.com](http://www.brittrade.com)) and select the market/sector which interests you most.

Alternatively telephone the Business in Europe enquiry desk on 020 7215 8885. They will be able to assist with your enquiry about exporting to the Western European countries.

# DTI Government Offices (GOs)

## G O EASTERN REGION

Cambridge 01223 346 700

## G O SOUTH WEST

Bristol 0117 900 1700  
Plymouth 01752 635 000  
Redruth 01209 312 662

## G O EAST MIDLANDS

Nottingham 0115 971 9971

## G O WEST MIDLANDS

Birmingham 0121 212 5050

## GO LONDON

London 020 7217 3328

## G O YORKSHIRE & THE HUMBER

Leeds 0113 280 0600

## G O NORTH EAST

Newcastle  
upon Tyne 0191 201 3300

## SCOTTISH EXECUTIVE

Glasgow 0141 248 2855

## G O NORTH WEST

Manchester 0161 952 4000  
Liverpool 0151 224 6300

## THE NATIONAL ASSEMBLY FOR WALES

Cardiff 029 20 825111

## G O SOUTH EAST

Guildford 01483 882 255

## NORTHERN IRELAND OFFICE

Belfast 028 9052 9900

## BUSINESS LINKS

To locate your nearest Business Link Office please call the Business Link Signpost line on 0345 567765 (or in Wales, Business Connect on 0345 969798, or in Scotland, Scottish Business Shops on 0800 787878).