THE IMPACT OF THE EU "NEW APPROACH" ON THE SAFETY OF PRODUCTS AND SERVICES

Free movement of goods is a fundamental objective of the single market. The mechanisms in place to achieve this aim are based on the prevention of new barriers to trade, mutual recognition and technical harmonisation. 'New Approach' directives are in effect Community laws that must be transposed into the national law of each member state. This process should allow products legally manufactured or marketed in one country to move freely throughout all member states of the European Union.

PLACING ON THE MARKET AND PUTTING INTO SERVICE

Member States are obliged to take the necessary measures to ensure that products are placed on the market and put into service only if they do not endanger the safety and health of persons, or other public interests covered by the directive, when properly installed, maintained and used for the intended purposes. This entails an obligation for market surveillance on the part of the Member States.

ESSENTIAL REQUIREMENTS

Essential safety requirements are set out in the annexes to the directives and lay down the necessary elements for protecting the public interest. These essential requirements are often written in general terms and producers may need to look to standards to fill in the detail. ***Essential requirements are mandatory.*** Only products complying with essential requirements may be placed on the market and put into service. Essential requirements must be applied as a function of the hazards inherent to a given product.

PRESUMPTION OF CONFORMITY

Products that comply with national standards transposing harmonised standards, the reference numbers of which have been published in the *Official Journal of the European Communities*, are presumed to comply with the corresponding essential requirements. Where the producer has not applied, or has only partially applied, such a standard, the measures taken and their adequacy must be documented in order to comply with the essential requirements.

HARMONISED STANDARDS

Member States must publish the reference number of the national standard that transposes a harmonised standard. It is useful to indicate in the publication the link with the legislation in question. The application of harmonised standards, which give a presumption of conformity, remains voluntary in the field of New Approach directives. Thus, the product may be manufactured directly on the basis of the essential requirements.
The Commission can withdraw the presumption of conformity, if it has been established that a harmonised standard does not fully meet the essential requirements.

CONFORMITY ASSESSMENT

Conformity assessment is the means of ensuring that the product meets the essential requirements and subdivided into modules, which comprise a limited number of different procedures applicable to the widest range of products. The modules relate to the design phase of products, their production phase or both. The eight basic modules and their eight possible variants can be combined with each other in a variety of ways in order to establish complete conformity assessment procedures.

As a general rule, a product is subject to conformity assessment according to a module during the design as well as the production phase. Each New Approach directive describes the range and contents of possible conformity assessment procedures, which are considered to give the necessary level of protection. The directives also set out the criteria governing the conditions under which the manufacturer can make a choice, if more than one option is provided for.

EC DECLARATION OF CONFORMITY

The manufacturer or his authorised representative established within the Community must draw up an EC declaration of conformity as part of the conformity assessment procedure provided for in the New Approach directives. The EC declaration of conformity should contain all relevant information to identify the directives according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other normative documents.

The EC declaration of conformity must be kept for at least ten years from the last date of manufacture of the product, unless the directive expressly provides for any other duration. This is the responsibility of the manufacturer or the authorised representative established within the Community. In some cases the importer or the person responsible for placing on the market must take on this responsibility.

The EC declaration of conformity and other technical documentation are intended to provide the surveillance authorities with necessary information about the product.

CE MARKING

The Directives also state how producers should demonstrate that products meet the 'Essential Requirements'. Products in compliance with all provisions of the applicable directives providing for the CE marking must bear this marking. Thus, the CE marking is an indication that the products comply with the essential requirements of all applicable directives and that the products have been subject to a conformity assessment procedure provided for in the directives. Further, Member States are obliged to take appropriate measures to protect the CE marking.

The CE marking is mandatory and must be affixed before any product subject to it is placed on the market and put into service, except where specific directives require otherwise. Where products are subject to several directives, which all provide for the affixing of the CE marking, the

marking indicates that the products are presumed to conform to the provisions of all these directives. A product may not be CE marked, unless it is covered by a directive providing for its affixing.

The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents. Where a notified body is involved in the production control phase according to the applicable directives, its identification number must follow the CE marking. The manufacturer or the authorised representative established in the Community affixes the identification number, under the responsibility of the notified body.

FREE MOVEMENT

Member States must presume that products bearing the CE marking comply with all the provisions of the applicable directives providing for its affixing. Accordingly, Member States may not prohibit, restrict or impede the placing on the market and putting into service in their territory of products bearing the CE marking, unless the provisions relating to CE marking are incorrectly applied.

PRODUCER

A manufacturer, in the meaning of New Approach, is the person who is responsible for designing and manufacturing a product with a view to placing it on the Community market on his own behalf. The manufacturer has an obligation to ensure that a product intended to be placed on the Community market is designed and manufactured, and its conformity assessed, to the essential requirements in accordance with the provisions of the applicable New Approach directives. The manufacturer may use finished products, ready-made parts or components, or may subcontract these tasks. However, he must always retain the overall control and have the necessary competence to take the responsibility for the product.

The Directive on general product safety requires manufacturers to place only safe products on the market. They are obliged, within the limits of their respective activities, to provide consumers with the relevant information to enable them to assess the risks inherent in a product, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. They are also obliged to adopt measures commensurate with the characteristics of the product in order to be informed of possible risks, and to take appropriate action including, if necessary, withdrawing the product from the market

AUTHORISED REPRESENTATIVE

The manufacturer may appoint any natural or legal person to act on his behalf as an authorised representative. For the purposes of New Approach directives the authorised representative must be established inside the Community. The authorised representative must be explicitly designated by the manufacturer, and he may be addressed by the authorities of the Member States instead of the manufacturer with regard to the latter's obligations under the New Approach directive in question. The manufacturer remains generally responsible for actions carried out by an authorised representative on his behalf.

The authorised representative can also at the same time act as an importer or a person responsible for placing on the market in the meaning of New Approach directives. His responsibilities are extended accordingly.

Depending on the conformity assessment procedure and the directive in question, the authorised representative can, for instance, be appointed to ensure and declare that the product complies with the requirements, to affix the CE marking and the notified body's number to the product, to draw up and sign the EC declaration of conformity, or to keep the declaration and the technical documentation at the disposal of national market surveillance authorities.

IMPORTER

An importer, who is a person responsible for placing on the market in the meaning of New Approach directives, is any natural or legal person established in the Community who places a product from a third country on the Community market. The importer must ensure that he is able to provide the market surveillance authority with the necessary information regarding the product if the manufacturer is not established in the Community and has no authorised representative in the Community. The natural or legal person who imports a product into the Community may, in some situations, be considered as the person who must assume some of the responsibilities placed on the manufacturer according to the applicable New Approach directives.

The importer needs neither a mandate from the manufacturer, nor a preferential relationship with the manufacturer like the authorised representative. However, the importer must ensure, in order to fulfil his responsibilities, that a contact with the manufacturer can be established.

DISTRIBUTOR

Provisions regarding distribution are in general not included in New Approach directives. A distributor is to be considered as any natural or legal person in the supply chain who takes subsequent commercial actions after the product has been placed on the Community market. The distributor shall act with due care in order not to place clearly non-compliant products on the Community market. He shall also be capable of demonstrating this to the national market surveillance authority [CRPC].

The Directive on general product safety requires distributors to act with due care to help to ensure compliance with the general safety requirement of the Directive, in particular by not supplying products that they know or should have presumed, on the basis of the information in their possession and as professionals, not to comply with this requirement. In particular, within the limits of their activities, they must participate in monitoring the safety of products placed on the market, especially by passing on information on product risks and cooperating in the action taken to avoid these risks.

PRODUCT LIABILITY

The Directive on product liability covers any product manufactured or imported into the Community, which causes damage to individuals or private property. Thus, the Directive applies also to products that fall within the scope of a New Approach directive. The Directive on product liability establishes a strict liability regime on manufacturers and importers in the Community.

The producer is not automatically liable for damages caused by the product. The injured person, whether or not he is the buyer or user of the defective product, must claim his rights to obtain compensation. The victim will be paid only if he proves that he has suffered damage, the product was defective, and this product caused the damage. If the injured person contributes to the damage, the producer's liability may be reduced or even disallowed. However, the victim does not need to prove that the producer was negligent, because the Directive on product liability is based on the principle of liability without fault of the producer. Thus, the producer will not be exonerated even if he proves he was not negligent, if an act or omission of a third person contributes to the damage caused, if he has applied standards, or if his product has been tested.

MARKET SURVEILLANCE

Market surveillance is an essential tool for the enforcement of New Approach directives. The purpose of market surveillance is to ensure that the provisions of applicable directives are complied with across the EU. Citizens are entitled to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the benefit of economic operators, because it helps to eliminate unfair competition.

Member States must nominate or establish authorities to be responsible for market surveillance. Market surveillance is the responsibility of public authorities. The nominated authorities need to have the necessary resources and powers for their surveillance activities, ensure technical competence and professional integrity of their personnel, and act in an independent and non-discriminatory way respecting the principle of proportionality.

MARKET SURVEILLANCE ACTIVITIES

Market surveillance involves the national surveillance authorities monitoring that products placed on the market comply with the provisions of the applicable national legislation transposing the New Approach directives; and subsequently, when necessary, they take a range of enforcement actions to establish conformity.

Although market surveillance operations cannot take place during the design and production stages, efficient enforcement usually requires that market surveillance authorities act in collaboration with manufacturers and suppliers in order to prevent the placing on the market of non-compliant products.

Market surveillance authorities control the market by regularly visiting commercial, industrial and storage premises in an annual programme of random and spot checks to examine products and take samples of suspect products for additional testing. They have the legal powers to require all necessary information.

ENFORCEMENT ACTION

Before any legal action is taken, the producer, importer or supplier will be notified and — unless the matter is urgent — given the opportunity of being consulted. The necessary corrective action depends on the level of non-compliance, which has to be established on a case by case basis, and it has to be in accordance with the principle of proportionality.

Normally the manufacturer, or the authorised representative, is obliged to make the product comply with the provisions and to remedy the infringement; but where other measures have failed or they are not considered as sufficient, the market surveillance authority is required to take all appropriate measures to restrict or prohibit the placing on the market and putting into service of the product in question, and to ensure that it is withdrawn from the market.

Enforcement action to prohibit or restrict the placing on the market may first be temporary to allow the market surveillance authority to obtain sufficient evidence about the danger or other substantial non-compliance of the product.

COMPLEMENTARY ACTIVITIES

Efficient enforcement of directives usually requires that, in addition to their market surveillance operations authorities try to act in collaboration with manufacturers and suppliers; take appropriate action against the person who has affixed the CE marking to a non-compliant product, and against those who are responsible for the non-compliance of the product. They also have the duty to warn persons who might be at risk; to prohibit the use of dangerous products; ban their export and to destroy such products.

INFORMATION EXCHANGE SYSTEMS

A rapid information exchange system, RAPEX, has been set up by the Directive on general product safety to handle emergency situations caused by consumer products that present a serious and immediate danger. It is designed for handling urgent situations caused by new, used or repaired products that present a serious and immediate risk to the health and safety of consumers. Its essential aim is to provide information in order to allow market surveillance authorities of all Member States to take immediate and appropriate action when a serious risk arising from a product has been detected.

FURTHER INFORMATION

Detailed information regarding the New Approach can be found in:

- "***Guide to the implementation of directives based on the New Approach and the Global Approach***"
- "***ACQUIS of the EUROPEAN UNION under the management of DG ENTERPRISE***"

Both of these documents can be accessed or downloaded from:
http://ec.europa.eu/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf
http://ec.europa.eu/enterprise/newapproach/pdf/pink_book_2007.pdf

OTHER WEB BASED INFORMATION

NEWS AND UPDATES
HTTP://EC.EUROPA.EU/ENTERPRISE/NEWAPPROACH/STANDARDIZATION/HARMSTDS/WHATSNEW.HTML#NEW_APPROACH

NEW APPROACH - DIRECTIVES & STANDARDS
HTTP://WWW.NEWAPPROACH.ORG/DIRECTIVES/DIRECTIVELIST.ASP

TECHNICAL HARMONISATION
HTTP://EC.EUROPA.EU/ENTERPRISE/NEWAPPROACH/INDEX_EN.HTM

NEW INTERNAL MARKET RULES FOR CONSUMER GOODS
HTTP://EC.EUROPA.EU/ENTERPRISE/REGULATION/INTERNAL_MARKET_PACKAGE/INDEX_EN.HTM#INTRODUCTION#INTRODUCTION

ACCESS TO EUROPEAN UNION LEGISLATION
HTTP://EC.EUROPA.EU/ENTERPRISE/NEWAPPROACH/STANDARDIZATION/HARMSTDS/EU_LEX_ACCESS.HTML

NEW APPROACH DIRECTIVES

- Directives providing for CE marking
- Directives based on the principles of the New Approach or the Global Approach, but which do not provide for CE marking
- Directives based on some principles of the New Approach and the Global Approach
- Other standards-receptive directives

HTTP://EC.EUROPA.EU/ENTERPRISE/NEWAPPROACH/STANDARDIZATION/HARMSTDS/REFLIST.HTML

EU CONSUMER LAW ACQUIS DATABASE

The Database is an output of an EU research project called "EC Consumer Law Compendium", which is being conducted by an international research group. It provides access information on eight consumer law directives, their transposition into the laws of 27 EU Member States, including case-law, bibliography and a comparative study**.** - http://www.eu-consumer-law.org/index_en.cfm.