

# **PROTECTION OF RIGHTFUL INTEREST IN THE EU - BASIC - PRINCIPLES**



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## Structure of the protection of rightful interest

- The protection of rightful interest especially means protection of consumer rights, health or safety of persons, property or environment or another public interest.
- The set of legislative regulations protecting the rightful interest comprises documents amending:
  - consumer protection
  - technical harmonisation (requirements for safety and sanitary properties of products etc.)

# Legal regulations of the EU related to consumer protection

- General product safety directive (2001/95/ES)
- Defect products responsibility directive (85/374/EHS)
- False advertising directive (84/450/EHS)
- Consumer protection directive for agreements concluded beyond trade territories (85/577/EHS)
- Consumer credit directive (87/102/EHS)
- Directive on collective services for trips, stays and tours (90/314/EH)
- Directive on inadequate terms and conditions in consumer agreements (93/13/EHS)
- Directive on transferee protection in relation to certain aspects of agreements acquisition of the right for temporary property utilisation (the so called timesharing) (94/47/ES)
- Directive on consumer protection in case of distant agreements (97/7/ES)

# Legal regulations of the EU related to consumer protection

- Directive on certain aspects of services in information society, especially the electronic commerce, within the intra Community market (2000/31/ES)
- Directive on consumer protection for price labelling of products offered to consumers (98/6/ES)
- Directive on penal actions and forbearance for the sake of consumer protection (98/27/ES)
- Directive on certain aspects of sale of consumer goods and warranties for these goods (1999/44/ES)
- Directive on tobacco products advertising and sponsoring related to tobacco products (2003/33/ES)
- Directive on unfair trade practices (2005/29/ES)
- Cooperation order in the field of consumer protection (2006/2004)

# “New Approach” directives scope of validity

- Directives are legally-technical tools to be implemented into the legal order of particular member state. These directives define technical requirements for products and also amend methods and conditions for launching the products covered by relevant directives on the EU market.

# “New Approach” directives

- The New Approach directives relate to products to be launched on the market for the first time (or launched into operation) in the EU. For this reason directives relate both to new products manufactured in member states as well as new and used products and second hand products imported from third party countries.
- The directive relates to such products, whose nature places them under definitions stated in directives or products incurring specific risks and hazards, which the directive is intended to prevent.
- The term product as defined in New Approach directives is not uniform, the particular manufacturer is obliged to verify, whether his products falls within the scope of one or more directives.
- Those products, which have undergone substantial adaptation, can be considered new products, therefore those must comply with all the provisions of relevant directives at the launch of such products on the Community market. It is necessary to consider every single case, unless stated otherwise.

## “New Approach” directives

- Those products, which have been repaired without alterations to their initial function, purpose or type, shall not be subject to conformity assessment in accordance with New Approach directives.
- Products designed mainly or exclusively for military or police purposes are literally excluded from the scope of competency of certain New Approach directives. As far as other directives are concerned, member states may, under certain conditions stipulated in the article 296 of the EC Treaty, exclude products designed solely for military purposes from their scope of competency.

# Simultaneous use of directives

- Basic requirements defined in New Approach directives may be mutually overlapping or supplemented depending on risks related to certain products, which cover these requirements.
- A product may be launched on the market or into operation only in case, when it has been found compliant with provisions of all the relevant directives and if it has been subject to the conformity assessment procedure in accordance with all the relevant directives.

# New Approach directives and further consumer protection regulations

- The product general safety directive relates to consumer products supplied in relation with commercial activity, if:
  - The particular product is not amended by the New Approach directives nor any other EU legal regulations
- or
  - The New Approach directives and other EU legal regulations do not cover all the aspects of safety or all the risk categories.
- The product liability directive relates to all the products within the competency of New Approach directives.

# Current review of New Approach directive

Low voltage equipment	2006/95/EC
Simple pressure vessels	87/404/EEC
Toys	88/378/EEC
Construction products	87/404/EEC
Electromagnetic compatibility	2004/108/EC
Machinery	98/37/EC
Personal protective equipment	89/686/EEC
Non-automatic weighing instruments	90/384/EEC
Active implantable medical devices	90/385/EEC
Gas appliances	90/396/EEC
Hot water boilers	92/42/EEC
Civil explosives	93/15/EEC
Medical devices	93/42/EEC
Potentially explosive atmospheres	94/9/EC
Recreational craft	94/25/EC
Lifts	95/16/EC
Refrigeration appliances	96/57/EC
Pressure equipment	97/23/EC
Telecommunications terminal equipment	98/13/EC
<i>In vitro</i> diagnostic	98/79/EC
Radio and telecommunications terminal equipment	99/5/EC

# Market introduction and launching into operation

- Launching on the market is the first step towards making the product available on the EU market aimed at distribution or utilisation of the product within the Community. Such availability can be established against payment or free of charge.
- Launching into operation will take place at the moment of first use by end user within the EU.
- Any product, which is launched on the EU market for the first time, shall comply with relevant New Approach directives.
- Member states are obliged to
  - not impose bans, restrictions or barriers to launching of such products on the market for such items compliant with all the relevant New Approach directives,
  - take all the measures necessary for launching products into operation only in such cases, if their design, installation, maintenance and utilisation comply with their purpose, unless these products impose hazard to human health or other interests included in particular standards.

# Basic requirements

- The term “basic requirements“ refers to the set of technical requirements for products, which are included in the directive and which are subject to conformity assessment using an appropriate module (see the conformity assessment procedure). Basic requirements are defined in general, i.e. they determine objectives to be achieved or risks to be considered, yet these do not predetermine solutions to these issues.
  - Basic requirements are usually defined in annexes to directives and they contain all the features necessary for achievement of objectives defined in particular directives.
  - Products may be launched on the market or into operation only if compliant with basic requirements.
  - Basic requirements must be adequate to risks associated with particular products imposing risk to rightful and public interests

# Assumption of conformity – harmonized standards

- Those products, which comply with the so called harmonized standards, shall be considered compliant with relevant basic requirements implied by New Approach directives. If the manufacturer chooses not to use such standard, or to use it to a certain limited extent only, it is necessary to make records of measures taken in order to meet basic requirements imposed by directives. The use of harmonized standards is voluntary.
- European standardisation organisations are responsible for identification and processing of harmonized standards in terms of New Approach and for submission of a list of harmonized standards approved by the Commission. Technical contents of such standards shall be the full responsibility of European standardisation organisations.
- A harmonized standard may include provisions related not only to basic requirements yet also to other measures. In such case these provisions shall be clearly differentiated from those related to basic requirements.
- Above that, the harmonized standard does not have to cover all the basic requirements. In such case the manufacturer shall be obliged to use further relevant technical specifications in order to meet all the basic requirements imposed by directive.

# Assessment of conformity

- Prior to launching his product on the EU market, the manufacturer must submit his product to the procedure of conformity assessment stipulated in the relevant directive in order to provide the product with CE mark. The conformity assessment process is divided into modules, which contain a limited number of various procedures applicable to the widest range of products.
- Modules, depending on product type and relevant risks, allow law makers to provide background needed for determination of adequate procedures used by manufacturers to prove the conformity of his product with provisions of particular directive. The high level of protection, as defined in the article 95 section 3 of the EC Treaty, has been assured during establishment of the wide range of various modules by recognition, especially following the proportionality principle, of various aspects, for example product type, the nature of assumed risks, economic infrastructure of particular sector (e.g. the absence of third parties), the type and importance of production. Even though these procedures are not identical, the procedures used for conformity assessment must be applicable in accordance with the particular directive and these shall be also trustworthy with respect to assurance of product conformity with basic requirements. The principle of proportionality also requires that directives do not include unreasonable procedures too complicated in comparison with objectives as defined especially in basic requirements. Factors, which have been taken into account during determination of procedure applicability, are described in relevant directives.

# Technical documentation

- The New Approach directives impose the duty on manufacturers (not only from the EU) to not only process the technical documentation containing information to prove the product conformity with relevant requirements. This duty arises at the moment of product being launched on the market, regardless of geographic origin of the product.
- Technical documentation must be kept for the minimum period of ten years from the last date of manufacture, unless expressly stated otherwise in the directive. This is the liability of the manufacturer or his authorised representative based within the Community. In some cases, this liability must be adopted by the importer or the person, who launches the product on the EU market.

# Technical documentation

- Requirements for contents of technical documentation for various directives differ depending on particular products. In general, a technical directive shall contain information about product design, production and product functioning. The extent of documentation details depend on the nature of product, which is, from the technical point of view, necessary to prove the conformity of such product with basic requirements imposed by relevant directives, and if there were harmonized standards used to prove the conformity with these standards instead of basic requirement included in these standards.

# ES declaration of conformity

- The New Approach directives impose that the manufacturer or his authorised representative based in the EU process the EC declaration of conformity for the product being launched on the market. Depending on the procedure, the EC declaration of conformity shall include the affirmation that:
  - a) the product either complies with basic requirements implied by relevant directives
- *or*
  - b) the product complies with the type issued with the type re-test certificate and that it complies with basic requirements implied by relevant directives.

# ES declaration of conformity

- The EC declaration of conformity must be field for the minimum period of ten years from the last date of manufacture of the product, unless otherwise stated in the directive. It is the responsibility of manufacturer or his authorised representative based in the EU. In some cases, this responsibility shall be adopted by the importer or the persons responsible for launching the product on EU market.
- The contents of the EC declaration of conformity for particular directives are defined depending on particular product. The EN 45014 standard was created to define general criteria concerning the declaration of conformity and it can be also used as an auxiliary document for the New Approach directives.
- According to this standard, the declaration may be executed in form of a document, plate etc. and it shall contain sufficient information to enable identification of all the products it relates to.

# ES declaration of conformity

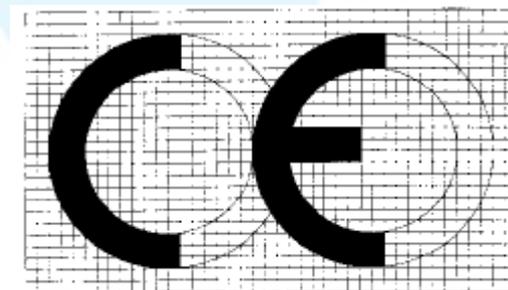
- name and address of the manufacturer or his authorised representative, who issues the declaration,
- product identification (name, type, or model number and any other additional information, e.g. order number, batch number or series, origin and the number of units),
- all the relevant provisions, which have been fulfilled, exact, complete and clear links to standards or other standardisation documents (e.g. national technical standards and specifications),
- all the additional information, which can be required if applicable (e.g. class. category),
- date of declaration issuance,
- signature and position corresponding to the identification authorised person
- a statement saying that the declaration is issued exclusively at the own and sole responsibility of the manufacturer or his authorised representative.

# Conformity mark (CE)

- The CE conformity mark expresses the compliance of product parameters with all the requirements in relevant directives related to the product and states that such product was subject to all the defined conformity assessment procedures prior to its launch on the market.
- The CE mark is compulsory and it must be attached before the launch of the relevant product on the market or into operation, besides cases, where specific directives require something else.
- The CE mark relates to all the products, which fall into the scope of applicability of directives defining its attachment and which are intended for the EU market. The CE mark then has to be provided on
  - all the new products, whether manufactured in member states or third party countries,
  - used products and second hand products imported from third party countries
  - substantially altered products, which are subject to directives as new products

# Conformity mark (CE)

- Member states can not restrict launching of new products with CE mark on the market and into operation, unless they are found incompliant with defined requirements
- The CE mark is usually used for products, which fall under directives of the New and Global Approach. However, it is acceptable that the CE mark be required by other legal regulations, if these are fully harmonised at the EU level and contain procedures for conformity assessment in accordance with the resolution 93/465/EHS
- The CE mark shall be attached to products by their manufacturer or his authorised representative based within the EU
- If the CE mark is magnified or reduced, the size proportions shall be maintained



# Conformity mark (CE)

- The CE mark must be visible, legible (min. height of 5mm) and indelible on a product or its plate with data. If not possible or legal with respect to the product nature, the CE mark shall be provided on the packaging, if there is any, and documents attached, if defined in the particular directive
- If the notified body is involved in the stage of production control as defined in particular directives, the CE mark shall be accompanied with its identification number
- The CE mark replaces all the compulsory product labels of the same meaning as the CE mark, which existed before the completion of harmonization. The national labelling of product conformity is incompatible with the CE mark and they represent violation of relevant directives within the New Approach.

# Notified (authorized) Bodies, notification (authorisation)

- Notified entities are professional entities announced by the European Commission, who have been authorised by the notification authority (the ÚNMZ in Czech Republic) for activities associated with conformity assessment at selected products with basic requirements imposed by European directives. The notified entities system assures uniform and coordinated procedures for application of technical requirements for products contained in European directives.

# Notified (authorized) Bodies, notification (authorisation)

- In the Czech Republic, the term Notified Body is replaced, in connection with terminology of the Act No. 22/1997 Coll. on technical product requirements, with the term Authorised Body.
- Member states are responsible for notification processes and they can choose appropriate authorities – notifying authorities, who have the competency to provide selected professional bodies with competencies – the so called notifications – enabling to carry out conformity assessment activities. During the act of authorisation, the notifying authority shall assess, whether the notified body is technically able to carry out relevant procedures for conformity assessment. There is a simultaneous assessment aimed at the fact, whether such Body can prove sufficient independence, neutrality and integrity. Besides that the ability of notified entity shall be subject to regular supervision and that should focus on higher implementation of principles of accreditation into its activity.

# Notified (authorized) Bodies

- Updated information about notified entities and their competencies (changes or restriction of the scope, changes of notification and restriction validity or abolition of notification) are published in the Official Bulletin of European Communities. Updated reviews of notified entities for particular directives are available at the following website:  
*[http://ec.europa.eu/enterprise/newapproach/legislation/nb/notified\\_bodies.htm](http://ec.europa.eu/enterprise/newapproach/legislation/nb/notified_bodies.htm)*

# Accredited laboratories

- Accreditation is a procedure, where the accrediting authority verifies and acknowledges that the accredited body conducts a certain activity in accordance with relevant regulations, usually international standards, directives and other generally acknowledged documents.  
The national accreditation body in the Czech Republic to administer the accreditation system in terms of the Act No. 22/1997 Coll. is the Czech Accreditation Institute (ČIA).
- Testing laboratory – a workplace dealing with evaluation and testing of raw materials, chemicals, various substances and materials, products, water, air, etc., with respect to their properties. Testing laboratories can be operated by various entities – manufacturers, state control institutions, research entities, education entities, etc.
- Accredited testing laboratory – a testing laboratory, where the testing authority has confirmed fulfilment of requirements imposed by the ČSN EN ISO/IEC 17025 standard (general requirements for the capability of testing and calibration laboratories), therefore it is competent for issuance of testing reports within the scope stipulated in the attachment to the accreditation certificate.

# Market supervision

- The market supervision is the essential tool for implementation of New Approach directives. The market supervision is conducted by inspection authorities, who verify the fulfilment of requirements laid on products by particular directives to ensure adoption of measures aimed at correct establishment of non-conformant products in conformity and the use of sanctions, if needed.
- Every member state may select its own infrastructure for market supervision, if the market supervision is efficient and covers the whole territory. This implies that the legal and administrative infrastructure of the supervision differs in various member states.

# Market supervision

- If the supervision authorities are to be able to monitor products launched on the market, they must have proper competency and features for the following activities:
  - regular visits of business, industrial and storage premises, in case of necessary visits to workplaces and other premises, where products are launched into operation
  - performance of random local checks
  - extraction of products samples and their examination and testing
  - request for technical documentation and other relevant information

# Market supervision

- The authority responsible for market supervision is entitled to ask for the following:
  - immediate submission of EC declaration of product conformity (if required by the directive)
  - submission of technical documentation within the period defined by the supervision authority and under conditions, which are adequate the level of risk involved (many kinds of technical documentation comprise very extensive documents). The request for technical documentation must be based on serious reasons.
  - certificates and other outputs from the notified authority
  - translations of technical documentation and EC declaration of product conformity into official language of the relevant state. However, that should not be done, if the documentation is available in language, which the personnel of national authority understand.

# Manufacturer

- The manufacturer is responsible:
  - for the conformity of the design and production of product with basic requirements stipulated in the directive (directives)
  - for performance of the conformity assessment in accordance with the procedure (procedures) stipulated in the directive

# Authorised representative

- The manufacturer may authorise any physical or legal entity to act on his behalf as an authorised representative
- As defined in purposes of the New Approach directives, the authorised representative shall have his seat within the EC
- The authorised representative has been expressly nominated by the manufacturer and authorities from member states can approach him, instead of the manufacturer, to discuss matters of obligation arising from the act of launching on market in terms of relevant directives in the New Approach
- The manufacturer shall remain generally responsible for steps taken by the authorised representative on manufacturer's behalf.

# Importer

- An importer (= an entity responsible for launching an item on the market), in terms of the New Approach directives, shall be every physical or legal entity based within the EC, which launches a product made by third party country on the EC market.
- The importer must be able to provide the market supervision authority with information about the product (a copy of EC declaration of conformity, and to submit technical documentation in case the manufacturer is not based within the EC or has no authorised representative therein. The importer (as the entity responsible for launching an item on the market) should observe these requirements and to obtain an official statement in writing from the manufacturer saying that these documents be made available to the supervision authority upon request.
- A physical or a legal entity importing the product to EC may be, in some situations, considered an entity obliged to take over responsibility of the manufacturer in accordance with relevant New Approach directives.

# Person assembling and installing the product

- Some products can be only used after assembly, installation or other kind of handling – this applies e.g. to machinery, personal protection equipment, measuring devices, gas fuel appliances and telecommunication end devices, etc.
- The person assembling and installing the product already launched on the market shall take necessary steps to maintain the product conformant to basic requirements at the time of its use within the EC. Handling may not represent a cause for non-conformity of the product with basic requirements.

# Distributor

- Provisions related to distribution are not generally included in the New Approach directives, even though these represent a frequently discussed issue.
- A distributor is every physical or legal entity within the supply chain performing subsequent trade activity following the launch of product on the EC market
- The distributor shall act with sufficient care in order to prevent selling such product on the EC market, which is evidently not in compliance with regulations. For, example, the distributor must know, which product needs to bear the CE label, what information shall accompany such product (e.g. the EC declaration of conformity), what language requirements are laid on users manuals and what is an evident sign of product non-conformity with regulations. Therefore, the distributor may not supply such products, about which he knows or should know, in accordance with his level of professional qualifications, that these items are non-compliant with regulations. He also has to cooperate during activities aimed at prevention and reduction of these risks.
- During the communication with supervision authority, the distributor must be able to prove that the products sold are compliant with requirements stipulated in relevant directives

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