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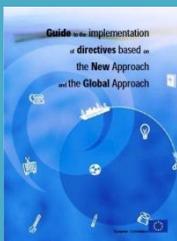
on the implementation of EU product rules

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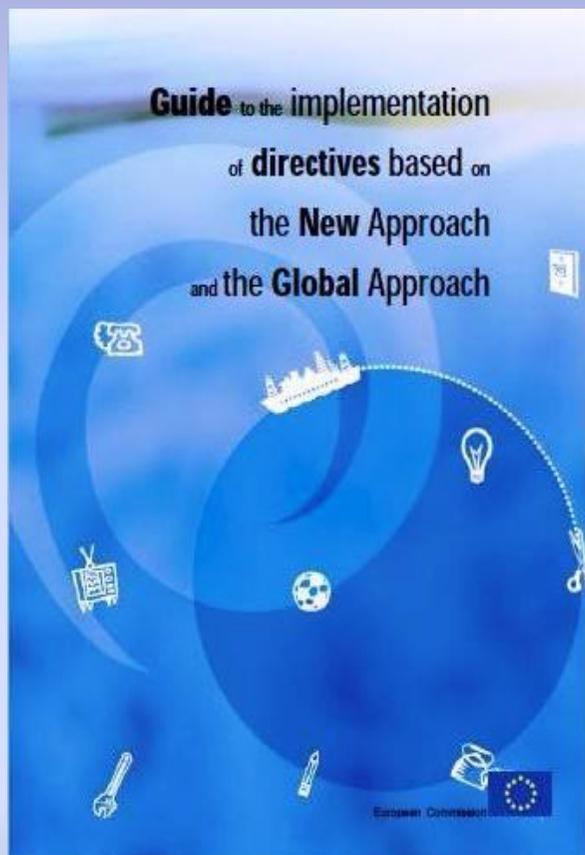


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The Guide to the implementation of Directives based on the New Approach and the Global Approach (the “Blue Guide”) was first published in 2000.

intentions:

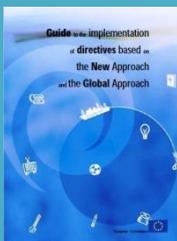
better understanding of directives based on the New Approach and the Global Approach

Uniform and coherent application across different sectors and throughout the single market

Since then, it has become one of the main reference documents explaining how to implement the legislation based on the New Approach, now covered by the New Legislative Framework

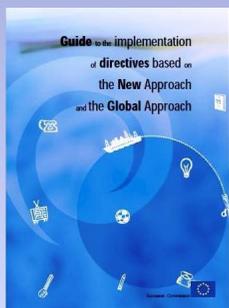


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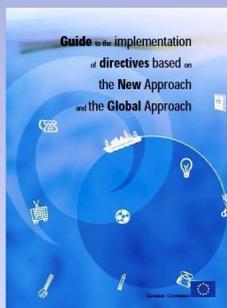
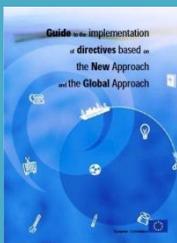
Provisions about:

- the scope of New Approach directives
- the responsibilities of the main actors, such as:
 - manufactures
 - authorised representative
 - importer / person responsible for placing on the market
 - distributor
 - assembler or installer
- essential requirements and harmonised standards
- conformity assessment procedures
- notified bodies
- CE marking
- market surveillance
- external aspects such as safeguard clause procedure

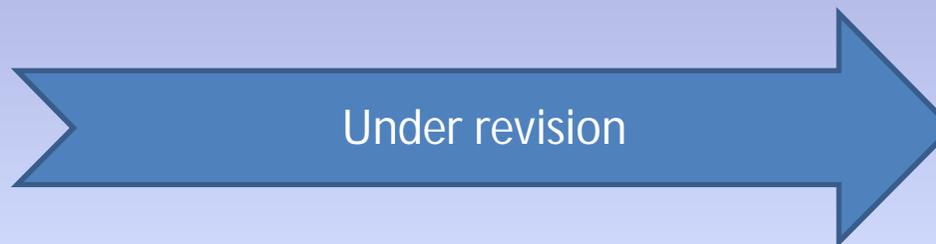


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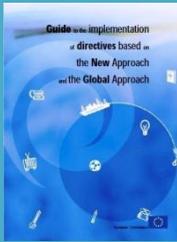


new 2014 edition
Blue Guide

In order to take into account the new developments in the New Legislative Framework for the marketing of products and the Lisbon Treaty for its legal references and terminology, the Blue Guide was under revision until March 2014.



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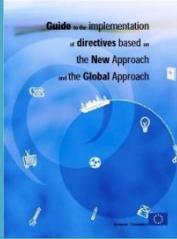
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The Package of measures known as the "New legislative framework" was adopted in Council on 9 July 2008 and published in the Official Journal on 13 August 2008. The measures are designed to help the internal market for goods work better and to strengthen and modernise the conditions for placing a wide range of industrial products on the EU market.

The package builds on existing systems to reinforce the application and enforcement of internal market legislation.





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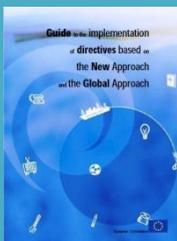
2000 vs. 2014



New Legislative Framework

- **improves market surveillance rules**, to better protect both consumers and professionals from unsafe products, including imports from third countries. This particularly applies to procedures for products which can be a hazard to, health or the environment, which will be withdrawn from the market.
- boost the quality of (and hence confidence in) the **conformity assessment of products** through **stronger clearer rules** on the requirements for the notification of conformity assessment bodies (testing, certification and inspection laboratories) including the increased use of accreditation; a system to ensure that assessment bodies provide the high quality services that manufacturers, consumers and public authorities need





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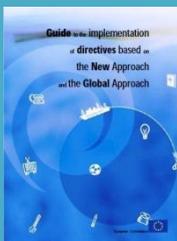
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New Legislative Framework

- clarifies the meaning of **CE marking** and so enhances its credibility. In addition the CE marking is to be protected as a trade mark, which will give authorities and competitors additional means to take legal action against abuse
- establishes a **common legal framework for industrial products** in the form of a toolbox of measures for use in future legislation. This includes provisions to support market surveillance and the application of the CE marking, definitions of terms commonly used in product legislation (but sometimes used differently at present) and procedures which will allow future sectoral legislation to become more consistent and easier to implement





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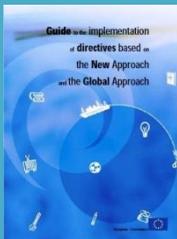


IMPLEMENTATION OF THE "NEW LEGISLATIVE FRAMEWORK"

In view of bringing product harmonisation legislation into line with the reference provisions of Decision 768/2008/EC, on 26 February 2014 an “Alignment Package” consisting of the following eight directives (which would not otherwise have been revised in the near future) was adopted, and published in the Official Journal of the European Union on 29 March 2014:

- Low Voltage Directive: [2014/35/EU](#)
- Electromagnetic Compatibility Directive: [2014/30/EU](#)
- ATEX Directive: [2014/34/EU](#)
- Lifts Directive: [2014/33/EU](#)
- Simple Pressure Vessels Directive: [2014/29/EU](#)
- Measuring Instruments Directive: [2014/32/EU](#)
- Non-automatic Weighing Instruments Directive: [2014/31/EU](#)
- Civil Explosives Directive: [2014/28/EU](#)





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The new Blue Guide, published in april 2014, includes new chapters, for example on the obligations of economic operators or accreditation, or completely revised chapters such as those on standardisation or market surveillance.

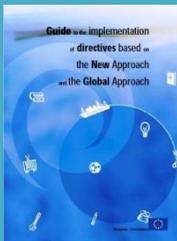
The new Blue Guide is a living document, meaning that it will be continuously updated to take into account the latest regulatory developments.

It is available in English on the [European Union's website](http://ec.europa.eu/DocsRoom/documents/4942)

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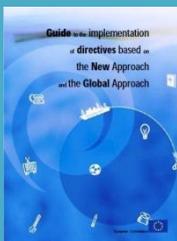


It is addressed to the Member States and others who need to be informed of the provisions designed to ensure:

- the free circulation of products
- high level of protection throughout the Union

(e.g. trade and consumer associations, standardisation bodies, manufacturers, importers, distributors, conformity assessment bodies and trade unions).





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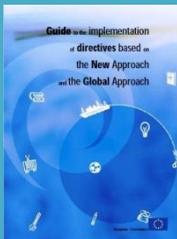
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Main actors: MANUFACTURER

- *The manufacturer is any natural or legal person who manufactures a product or has a product designed or manufactured and places it on the market under his own name or trademark. (new definition)*
- *The manufacturer is responsible for the conformity assessment of the product and is subject to a series of obligations including traceability requirements.*
- *When placing a product on the Union market, the responsibilities of a manufacturer are the same whether he is established outside the European Union or in a Member State.*
- *The manufacturer must cooperate with the competent national authorities in charge of market surveillance in case of a product presenting a risk or being non-compliant.*





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Main actors: AUTHORISED REPRESENTATIVE

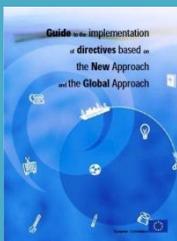
- *irrespectively of whether he is established in the EU or not, the manufacturer may appoint an authorised representative in the Union to act on his behalf in carrying out certain tasks*

A manufacturer established outside the European Union is not obliged to have an authorised representative.

- *to be able to act on behalf of the manufacturer, the authorised representative must be established inside the Union*

Commercial representatives of the manufacturer (such as authorised distributors or agents), are not to be confused with the authorised representative in the meaning of Union harmonisation legislation.. The delegation of tasks from the manufacturer to the authorised representative must be explicit and set out in writing





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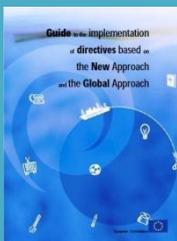
Main actors: IMPORTER

- *the importer is a natural or legal person established in the Union who places a product from a third country on the EU market.*
- *his obligations build on the obligation of the manufacturer.*

The importer must ensure:

1. that the appropriate conformity assessment procedure has been carried out by the manufacturer.
If he has any doubt about the conformity of the product, he must refrain from placing it on the market.
2. that the manufacturer has drawn up the technical documentation, affixed the relevant conformity marking (e.g. CE marking), fulfilled his traceability obligations and accompanied, where relevant, the product by the instructions and safety information in a language easily understood by consumers and other end-users, as determined by the Member State concerned





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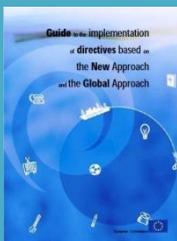
Main actors: DISTRIBUTOR

- *the distributor is a natural or a legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.*
- *distributors are subject to specific obligations and have a key role to play in the context of market surveillance.*

Distributor must act with due care in relation to the applicable requirements. They have to know, for instance, ***which products must bear the CE marking, what information is to accompany the product*** (for example the EU Declaration of Conformity), what are the ***language requirements*** for labelling, user instructions or other accompanying documents, and what is a ***clear indication of the product being non-compliant***.

Distributors have an ***obligation to demonstrate to the national market surveillance*** authority that they have acted with due care and ensure that the manufacturer, or his authorised representative, or the person who provided him with the product has taken the measures required by the applicable Union harmonisation legislation as listed in the obligations for distributors.





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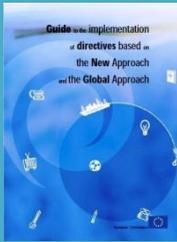
Main actors: DISTRIBUTOR

Before making a product available on the market, the distributor must verify:

- that the product bears the required conformity marking(s) (e.g. *CE marking*)
- that the product is accompanied by the relevant documents (e.g. *EU Declaration of Conformity*) and by instructions and safety information in a language which can be easily understood by consumers and other end-users if required by the applicable legislation
- that the manufacturer and importer have indicated their name, registered trade name or trademark and the address at which they can be contacted on the product or when not possible because of the size or physical characteristics of the products, on its packaging and/or on the accompanying documentation, and that the product bears a type, batch or serial number or other element allowing the identification of the product

Distributor **must not supply** products that they know or should have assumed, on the basis of information in their possession, not to be in compliance with the legislation.





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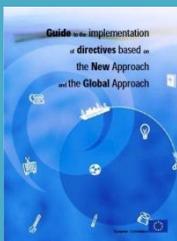


Main actors: DISTRIBUTOR

The distributor must :

- initiate corrective measures where there is suspicion of a non-conformity
- assist market surveillance authorities in identifying the manufacturer or importer responsible for the product
- upon a reasoned request from a competent authority, cooperate with that authority and provide it with all the information and documentation necessary to demonstrate the conformity of a product
- on request by market surveillance authorities, identify any economic operator who has supplied them and to whom they have supplied the product. They must be able to present this information for a period of 10 years after they have supplied the product





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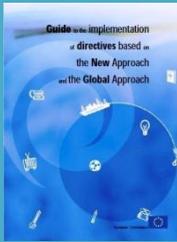


Main actors: END-USER

- *contrary to economic operators, end-users are not defined in Union harmonisation legislation and **are not subject to obligations***

Many products covered by Union harmonisation legislation are used at work. According to legislation based on Article 153 TFEU, **employers** have obligations as regards the use of work equipment by workers at the workplace.





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**Compliances with
the directives**

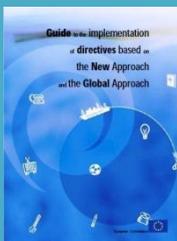


**Essential
product requirement**

Essential product requirement

- *a large part of Union harmonisation legislation limits legislative harmonisation to a number of essential requirements that are of **public interest**.*
- *essential requirements define the results to be attained, or the hazards to be dealt with, but **do not specify the technical solutions** for doing so..*





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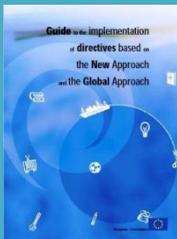
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Harmonised standards

- *Standards are of voluntary application.*
- *Harmonised standards provide a presumption of conformity with the essential requirements they aim to cover.*
- *“Harmonised standards” are “European standards” adopted, upon a request made by the Commission for the application of Union harmonisation legislation.*





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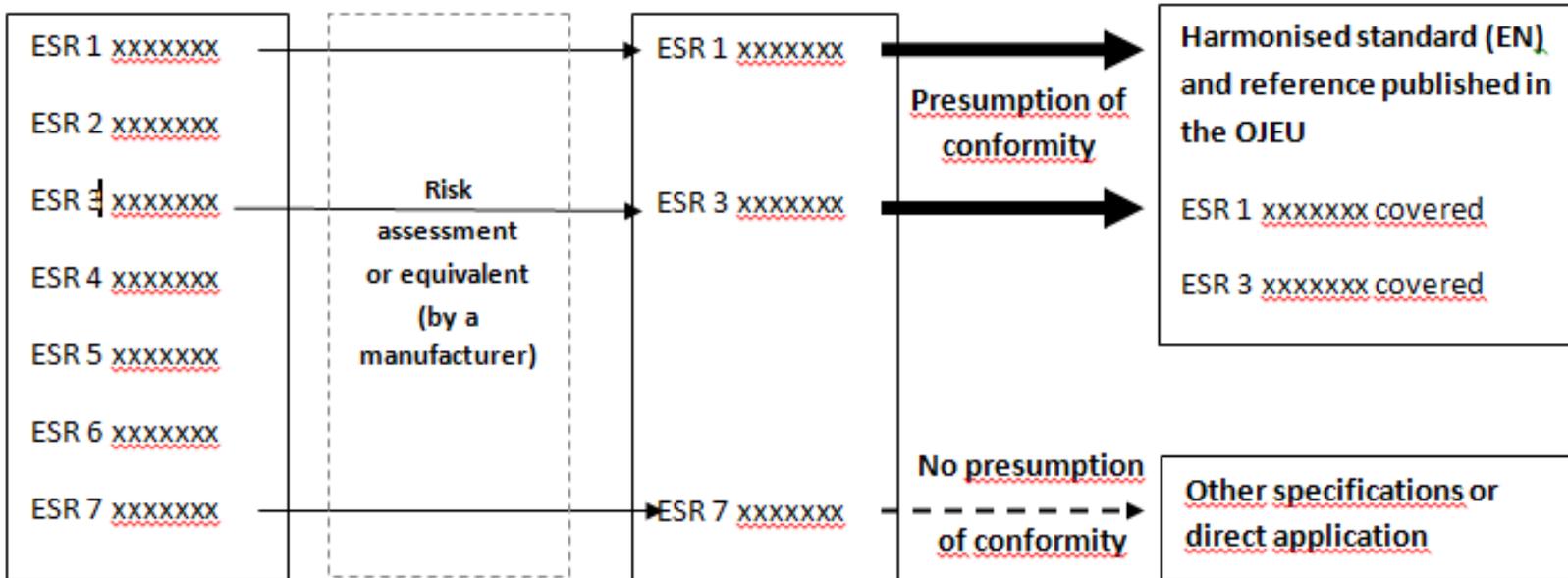


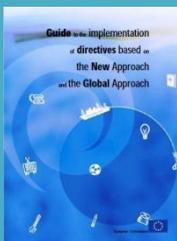
Harmonised standards

**All essential requirements
(legally binding,
given in legislation)**

**Applicable essential requirements
to be complied with
(identified by a manufacturer)**

**Specifications to comply with
applicable ESRs
(selected by a manufacturer)**





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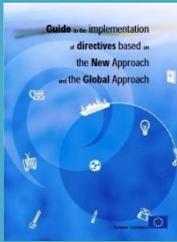
Traceability

- *The traceability requirements allow tracing the history of the product and support market surveillance. It allows market surveillance authorities to **find the liable economic operators** and obtain **evidence of the product compliance**.*
- *The traceability requirements include **labelling the product** and identifying the economic operators in the distribution chain.*

The manufacturers must indicate the following three elements:

 - ✓ their name,
 - ✓ registered trade name or registered trade mark
 - ✓ the address at which they can be contacted on the product





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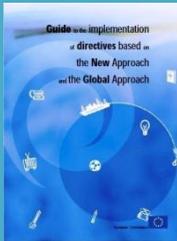
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Technical documentation

- *The manufacturer **must** draw up a technical documentation.*
- *The technical documentation is intended to provide information on the design, manufacture and operation of the product.*





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EU Declaration of conformity

➤ *The manufacturer or the authorised representative established within the Union **must draw up and sign an EU Declaration of Conformity** as part of the conformity assessment procedure provided for in the Union harmonisation legislation.*

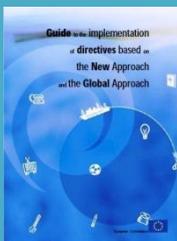
For imported products, the importer must take on this responsibility for the DoC

➤ *The EU Declaration of Conformity must contain all relevant information to identify the Union harmonisation legislation 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 technical specifications.*

➤ ***A single declaration** of conformity is required whenever a product is covered by **several pieces of Union harmonisation legislation** requiring an EU Declaration of Conformity*

➤ *The single declaration of conformity can be made up of a dossier containing all relevant individual declarations of conformity..*





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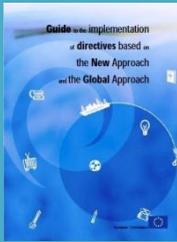


EU Declaration of conformity

The model declaration of Decision No 768/2008/EC contains:

1. A number identifying the product. This number does not need to be unique to each product. It could refer to a product, batch, type or a serial number. This is left to the discretion of the manufacturer
2. The name and address of the manufacturer or the authorised representative issuing the declaration
3. A statement that the declaration is issued under the sole responsibility of the manufacturer
4. The identification of the product allowing traceability. This is basically any relevant information supplementary to point 1 describing the product and allowing for its traceability. It may where relevant for the identification of the product contain an image, but unless specified as a requirement in the Union harmonisation legislation this is left to the discretion of the manufacturer





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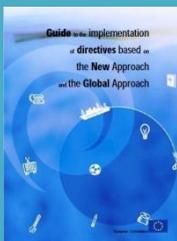


EU Declaration of conformity

The model declaration of Decision No 768/2008/EC contains: *(continued)*

5. All relevant Union harmonisation legislation complied with; the referenced standards or other technical specifications (such as national technical standards and specifications) in a precise, complete and clearly defined way; this implies that the version and/or date of the relevant standard is specified
6. The name and identification number of the notified body when it has been involved in the conformity assessment procedure
7. All supplementary information that may be required (for example grade, category), if applicable
8. The date of issue of the declaration; signature and title or an equivalent marking of authorised person; this could be any date **after** the completion of the conformity assessment





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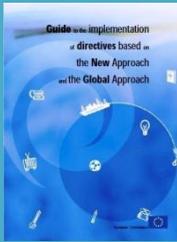
CE marking

- *The CE marking indicates the conformity of the product with the Union legislation applying to the product and providing for CE marking.*
- *The CE marking is affixed on products that will be placed on the EEA and Turkish market, whether they are manufactured in the EEA, in Turkey or in another country*
- *The CE marking is a **key indicator (but not proof)** of a product's compliance with EU legislation and enables the free movement of products within the European market*

The CE marking is affixed by the manufacturer (established inside or outside the Union), or by his authorised representative established within the Union.

By affixing the CE Marking the manufacturer declares on his sole responsibility that the product conforms to all applicable Union legislative requirements, and that the appropriate conformity assessment procedures have been successfully completed.



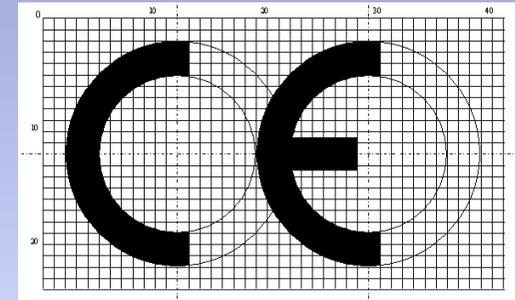


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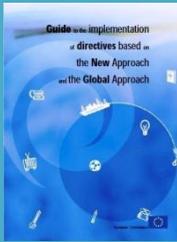
CE marking



- *Where a notified body is involved in the production control phase according to the applicable Union harmonisation legislation, its identification number must follow the CE marking*
- *The manufacturer or the authorised representative affixes the identification number if the legislation so requires, under the responsibility of the notified body*

A product may bear additional markings and marks, provided that they fulfill a different function from that of the CE marking, are not liable to cause confusion with it, and do not reduce its legibility and visibility



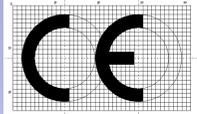


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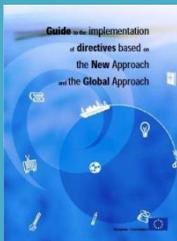
CE marking



Several pieces of Union harmonisation legislation foresee additional markings that are complementary and non-overlapping to the CE marking

- the EU energy label for energy-related products
- the specific marking of explosion protection required for equipment and protective systems intended for use in potentially explosive atmospheres;
- the specific conformity mark (in the form of a ship's wheel) of the marine equipment directive (instead of the CE marking)
- the equipment class identifier required for radio equipment (Class 2)
- the “Pi” marking required for transportable pressure equipment (instead of the CE marking);
- the supplementary metrology marking required for measuring instruments and non-automatic weighing instruments.



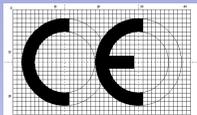


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CE marking



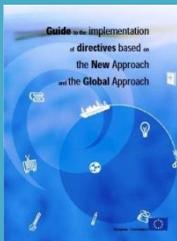
the supplementary metrology marking
for non-automatic weighing instruments



for measuring instruments



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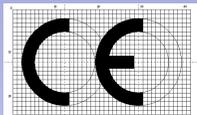


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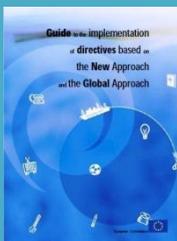
CE marking



Possible supplementary marking when several directives applies:



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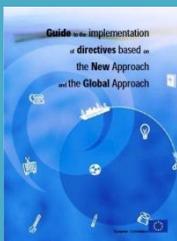
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CE marking SANCTIONS

- *Member States have to ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking.*
- *Member States have to also provide for penalties for infringements, which may include criminal sanctions for serious infringements*
- *A Member State must notify to the Commission and to the other Member States when it decides to restrict free movement due to incorrect affixing of the CE marking, or when it takes action against those who are responsible for a non-compliant product bearing the CE marking*





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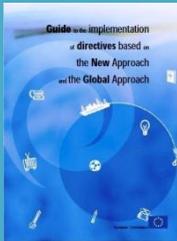
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Conformity assessment

- *Conformity assessment is the process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled*
- *A product is subjected to conformity assessment both during the design and production phase*
- *Decision No 768/2008/EC lays down the “horizontal menu” of conformity assessment modules and the ways procedures are built of modules*
- *The legislator selects from the menu of conformity assessment modules/procedures (laid down under Decision No 768/2008/EC) the most appropriate ones for the concerned sector*



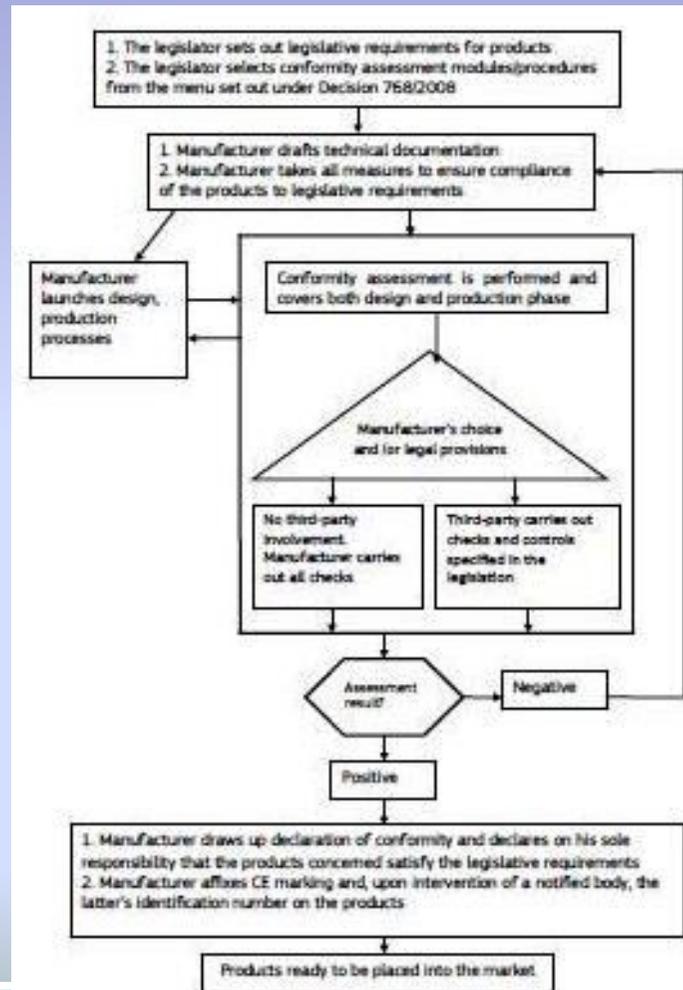


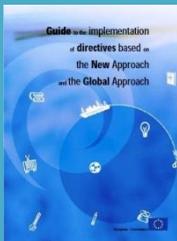
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Conformity assessment





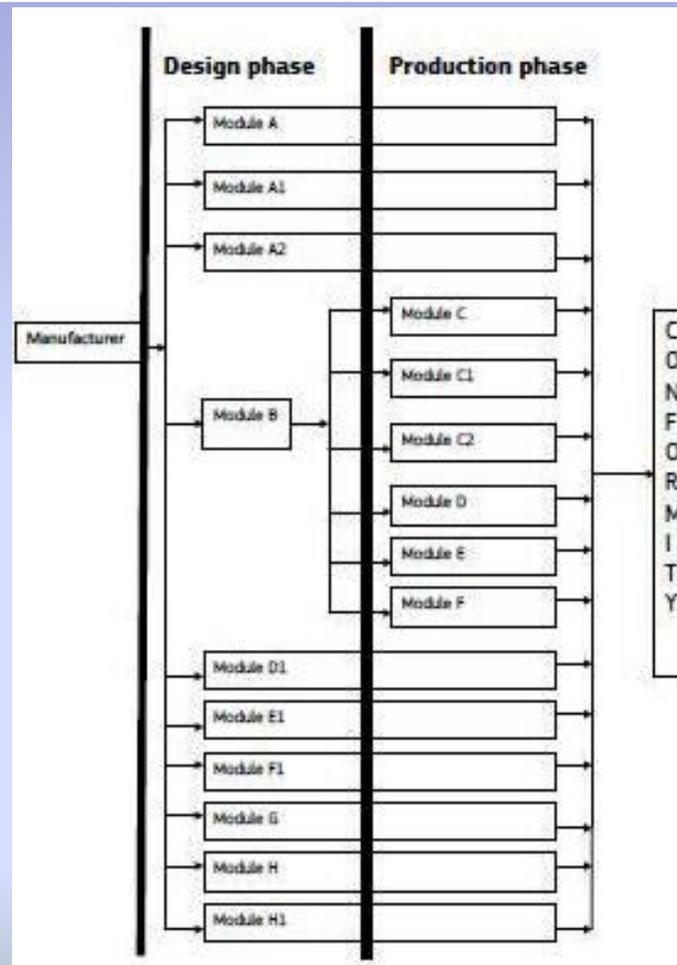
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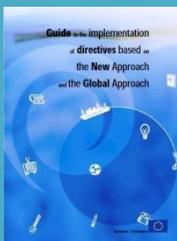
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Conformity assessment

Modules and variants





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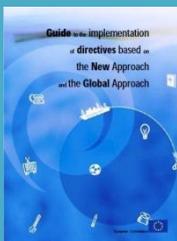


Conformity assessment

The following procedures are possible:

- A - Internal production control
- A1 - Internal production control plus supervised product testing
- A2 - Internal production control plus supervised product checks at random intervals
- B+C - EU-type examination (B) followed by Conformity to EU-type based on internal production control (C)
- B+C1- EU-type examination (B) followed by Conformity to EU-type based on internal production control plus supervised product testing (C1)
- B+C2 - EU-type examination (B) followed by Conformity to EU-type based on internal production control plus supervised product checks at random intervals (C2)
- B+D - EU-type examination (B) followed by Conformity to EU-type based on quality assurance of the production process (D)





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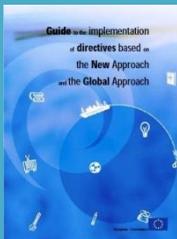


Conformity assessment

The following procedures are possible: *(continued)*

- D1 - Quality assurance of the production process.
- B+E - EU-type examination (B) followed by Conformity to EU-type based on product quality assurance (E)
- E1 - Quality assurance of final product inspection and testing
- B+F - EU-type examination (B) followed by Conformity to EU-type based on product verification (F)
- F1 - Conformity based on product verification
- G - Conformity based on unit verification
- H - Conformity based on full quality assurance
- H1 - Conformity based on full quality assurance plus design examination





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Conformity assessment bodies and notified bodies

For information purposes, the Commission makes the lists of notified bodies (and other categories of conformity assessment bodies such as User Inspectorates and Recognised Third Party Organisations) publicly available on the NANDO web site on its Europa server.

<http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=notifiedbody.main>

European Commission > Growth > Single Market and Standards > Tools and Databases > Notified bodies Nando > Body

Single Market and Standards | Industry | Entrepreneurship and SMEs | Access to finance for SMEs | Sectors

Notified bodies Nando

Country | Legislation | **Body**

Construction products | Free search | Mutual Recognition Agreements | Notifying Authority - Notification procedures

Bodies

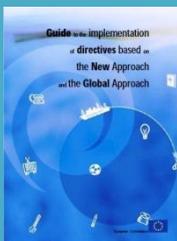
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Technical Assessment Body | Approved body Art. 9
LVD body | Recognised third-party organisation PED Art. 20
User inspectorate PED Art. 16 | Withdrawn/Expired/Suspended Notifications/NBs

Notified body

0001-0100	0101-0200	0201-0300	0301-0400	0401-0500
0501-0600	0601-0700	0701-0800	0801-0900	0901-1000
1001-1100	1101-1200	1201-1300	1301-1400	1401-1500
1501-1600	1601-1700	1701-1800	1801-1900	1901-2000
2001-2100	2101-2200	2201-2300	2301-2400	2401-2500
2501-2600	2601-2700			





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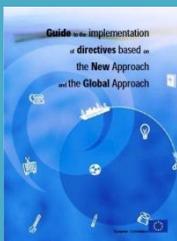
Accreditation

Accreditation provides the last level of public control in a quality chain underpinning the free movement of goods in the Union.

Regulation (EC) No 765/2008 introduced a legal framework for accreditation for the first time

Accreditation is the attestation by a national accreditation body based on harmonised standards that a conformity assessment body has the technical competence to perform a specific conformity assessment activity.





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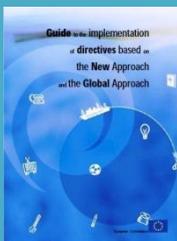
Accreditation according to Regulation (EC) No. 765/2008

- *Each Member State may appoint one single national accreditation body.*
- *Accreditation is to be operated as a public authority activity*
- *The responsibilities and tasks of the national accreditation body have to be clearly distinguished from those of other national authorities.*
- *Accreditation is to be provided on a not-for-profit basis.*
- *Within the EU, accreditation bodies are not allowed to compete with other accreditation bodies*
- *Within the EU, accreditation bodies are only to be active on the territory of their own Member State*

The European Cooperation for Accreditation (EA) is the organisation of European national accreditation bodies.

At international level, cooperation between accreditation bodies takes place within the International Accreditation Forum (IAF) and within the International Laboratory Accreditation Cooperation (ILAC).





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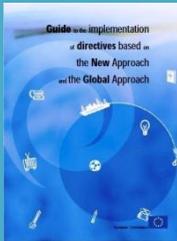
Chapter 7. MARKET SURVEILLANCE

Under Regulation (EC) No 765/2008 national market surveillance authorities have clear **obligations to proactively control** products placed on the market, to organise themselves and ensure coordination between themselves at the national level and to cooperate at the EU level

Member States have to take appropriate measures to prevent the placing on the market and use of non-compliant products.

According to Article 16 of Regulation (EC) No 765/2008 “Market surveillance shall ensure that products covered by Union harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Union harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly. Member States shall ensure that effective measures can be taken in relation to any product category subject to Union harmonisation legislation”.





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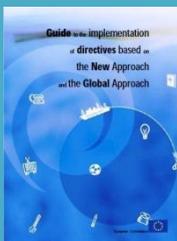
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MARKET SURVEILLANCE - activities

- *Market surveillance occurs at the post-marketing stage of the products*
- *Market surveillance activities may be organised differently depending on the nature of the product and may range from control of formal requirements to profound laboratory examinations*
- *All economic operators have a role and obligations in market surveillance.*
 - ✓ to regularly visit commercial, industrial and storage premises
 - ✓ to regularly visit, if appropriate, work places and other premises where products are put into service
 - ✓ to organise random and spot checks
 - ✓ to take samples of products, and to subject them to examination and testing
 - ✓ to require, upon reasoned request, all necessary information.





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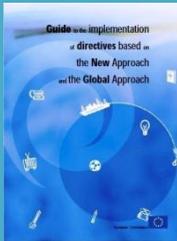
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MARKET SURVEILLANCE – member states responsibilities

- ✓ *Market surveillance is organised at national level and Member States are the primary actors in that activity. Consequently, they are required to ensure an appropriate set of infrastructures for that purpose and prepare national market surveillance programmes*
- ✓ *One major task for market surveillance authorities is to keep the public informed against potential risks*
- ✓ *The Market surveillance process is subject to strict procedures*
- ✓ *Non-compliant products are subject to corrective measures, bans withdrawals or recalls*
- ✓ *The level of the sanctions is determined at national level*





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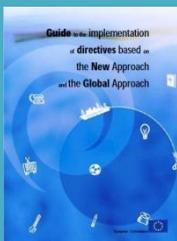


MARKET SURVEILLANCE – national infrastructure

Market surveillance is the responsibility of public authorities. This is, in particular, to guarantee the impartiality of market surveillance activities.

Each Member State can decide upon the market surveillance infrastructure, for example there is no limitation on the allocation of responsibilities between authorities on a functional or geographical basis as long as surveillance is ***efficient*** and ***covers the whole territory***.





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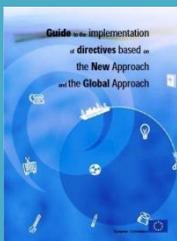
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MARKET SURVEILLANCE – national surveillance programmes

- ✓ National authorities are obliged by Article 18(5) of the Regulation (EC) No 765/2008 to establish, implement and periodically update and communicate their NMSP. Programmes may be general and/or sectoral in order to ensure that the overall EU market surveillance framework is respected..
- ✓ Programmes should take into consideration the balance between proactive and reactive control activities and any other factors which may influence enforcement priorities





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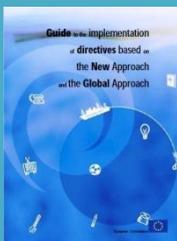
MARKET SURVEILLANCE – control of products from third countries by customs

Customs are they are the ideal place to stop unsafe and non-compliant products before they are released for free circulation and subsequently circulate freely within the European Union

Customs authorities have the following responsibilities

- ✓ to suspend the release of products when there is a suspicion that the products presents a serious risk to health, safety, environment or other public interest and/or do not fulfill documentation and marking requirements and/or the CE marking has been affixed in a false or misleading manner (*Article 27(3)*)
- ✓ not to authorise the release for free circulation for the reasons mentioned in Article 29
- ✓ to authorise the release for free circulation for any product in compliance with the relevant Union harmonisation legislation and/or nor presenting risks to any public interest;





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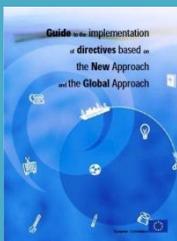
MARKET SURVEILLANCE – control of products from third countries by customs

Customs authorities have the following responsibilities (*continued*)

- ✓ Where the release for free circulation has been suspended, customs have to immediately notify the competent national market surveillance authority which is given three working days to perform a preliminary investigation of the products and to decide:
 - if they can be released since they do not present a serious risk to the health and safety or cannot be regarded as being in breach of Union harmonisation legislation
 - if they must be detained since further checks are necessary to ascertain their safety and conformity.

Customs authorities must notify their decisions to suspend release of a product to the market surveillance authorities, which in turn must be in a position to take appropriate action.





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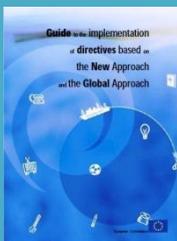


MARKET SURVEILLANCE – public information

The public should be aware of the existence, responsibilities and identity of national market surveillance authorities, and of how those authorities may be contacted.

National market surveillance programmes have to be made available to the public by way of electronic communication and, where appropriate, by other means.





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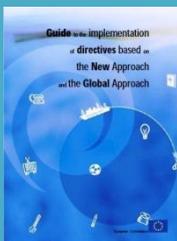


MARKET SURVEILLANCE – procedures

If a product is liable to compromise the health or safety of persons, market surveillance authorities must request without delay to relevant economic operators to:

- a) take corrective action (to bring the product into compliance with the applicable requirements laid down in the Union harmonisation legislation) and/or;
- b) withdraw the product and/or;
- c) recall the product and/or;
- d) stop or restrict supplying the product within a reasonable period.





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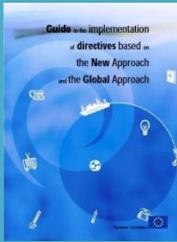


MARKET SURVEILLANCE – sanctions

The penalties provided for shall be effective, proportionate, and dissuasive and may be increased if the relevant economic operator has previously committed similar infringement.

- ✓ Sanctions are imposed by means of fines, whose sums vary from one Member State to the other.
- ✓ They may also include criminal sanctions for serious infringements.





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MARKET SURVEILLANCE – safeguard mechanisms for Member States

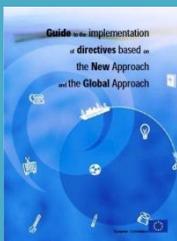
On one hand, the safeguard clause authorizes Member States to take restrictive measures in relation to products presenting a risk.

On the other hand, it ensures that all national market surveillance authorities are informed about dangerous products, and, accordingly, having the necessary restrictions extended to all Member States.

*It is a mechanism allowing all interested parties to be kept informed about **restrictive measures on the market.***

The safeguard procedure is distinct from the RAPEX procedure because of their different objectives, different notification criteria and different methods of application. Nevertheless, in some cases it may be possible to communicate information on national measures only once for the purposes of the two procedures





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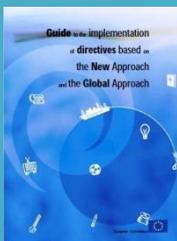
MARKET SURVEILLANCE – cooperation among Member States

The cooperation between national market surveillance authorities is indispensable for the success of the market surveillance policy of the Union as a whole.

The cooperation of Member States is facilitated by the European Commission.

- ✓ For the achievement of effective market surveillance in the Union, it is important that national surveillance authorities assist each other.
- ✓ To avoid duplication of product tests, or other investigations for market surveillance purposes, national authorities **should** exchange a summary report of these tests. This can be done by using the Information and Communication System for Market Surveillance ICSMS. National surveillance authorities should also consider whether or not there is a special need to carry out technical analyses or laboratory tests when another surveillance authority has already done so, and the results are available to those authorities or may at their request be placed at their disposal.





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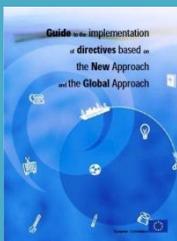
MARKET SURVEILLANCE – cooperation among Member States

***RAPEX** is EU's system for rapid exchange of information on dangers arising from the use of products.*

***ICSMS** (Information and Communication System for Market Surveillance) is an IT tool that provides for a comprehensive communication platform between all the market surveillance authorities.. ICSMS consists of an internal (accessible only to market surveillance authorities) and a public area.*

*A specific vigilance system applies in the case of **medical devices**.*





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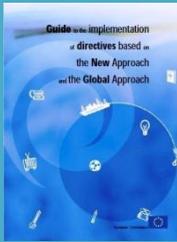
FREE MOVEMENT OF PRODUCTS WITHIN THE EU

Free movement clauses are provisions inserted in EU legislative acts which expressly prevent the Member States from taking more restrictive measures on a matter, if that matter fulfils the requirements of the law in question.

Therefore, Member States cannot impede the making available on the market of a product which complies with all the provisions of sectoral harmonisation legislation

A limitation to the free movement of product might be imposed in the case of **non-compliance** of a product with the essential or other legal requirements.





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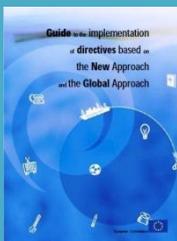
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INTERNATIONAL ASPECTS OF THE EU LEGISLATION ON PRODUCTS

- ✓ full integration of the EEA EFTA countries in the internal market by virtue of the EEA agreement
- ✓ alignment of the legislative system and infrastructure of the Candidate countries with those of the EU
- ✓ similar alignment by Neighbouring countries by conclusion of bilateral Agreements on conformity assessment and acceptance of industrial products (ACAAs),
- ✓ conclusion of bilateral (inter-governmental) Mutual Recognition Agreements (MRAs) for conformity assessment, certificates and marking, which are intended to reduce the costs of testing and certification in other markets,
- ✓ reliance on WTO Agreement on Technical Barriers to Trade





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Thank you !

Any questions?

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