EU regulation system for industrial products

by

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STRUCTURE OF THE PRESENTATION

1. Preliminary notions on the EU Technical Regulation System

2. Requirements for placing on the market industrial non-food products covered by the Association Agreement between EU and Ukraine

OBJECTIVES OF THE EU REGULATORY SYSTEM FOR PRODUCTS

- Safety objective: Ensure high level of product safety

- Internal Market objective*:* Eliminate technical barriers to trade

REGULATORY APPROXIMATION

The regulatory approximation, through a sector-specific legislation (EU Directives or Regulations) is a main tool to eliminate technical barriers to trade. Broad categories of products are:

- **Industrial non-food products**
- **Pharmaceuticals**
- **Chemicals (including fertilizers, paints, detergents)**
- **Tractors**
- **Energy (e.g. gas and electricity)**
- **Foodstuffs**
- **Cosmetics**
- **Motor vehicles**
- **Civil aviation aircrafts**
- **Other**

REGULATORY APPROXIMATION IN THE EU : TWO APPROACHES

The "Old Approach"

Legal technique that implies the detailed description of technical specifications of the products.

It is still used today for some product categories (e.g. foodstuff, pharmaceuticals, chemicals, motor-vehicles)

The New Approach

Legal technique since 1985 where legislative harmonisation is limited ***to essential safety requirements*** with which products must conform. Main legal instruments are Directives (the so-called New Approach Directives).

In 2008 the New Approach was revised by the "New Legislative framework" which established an overall coherence to the product safety legislation

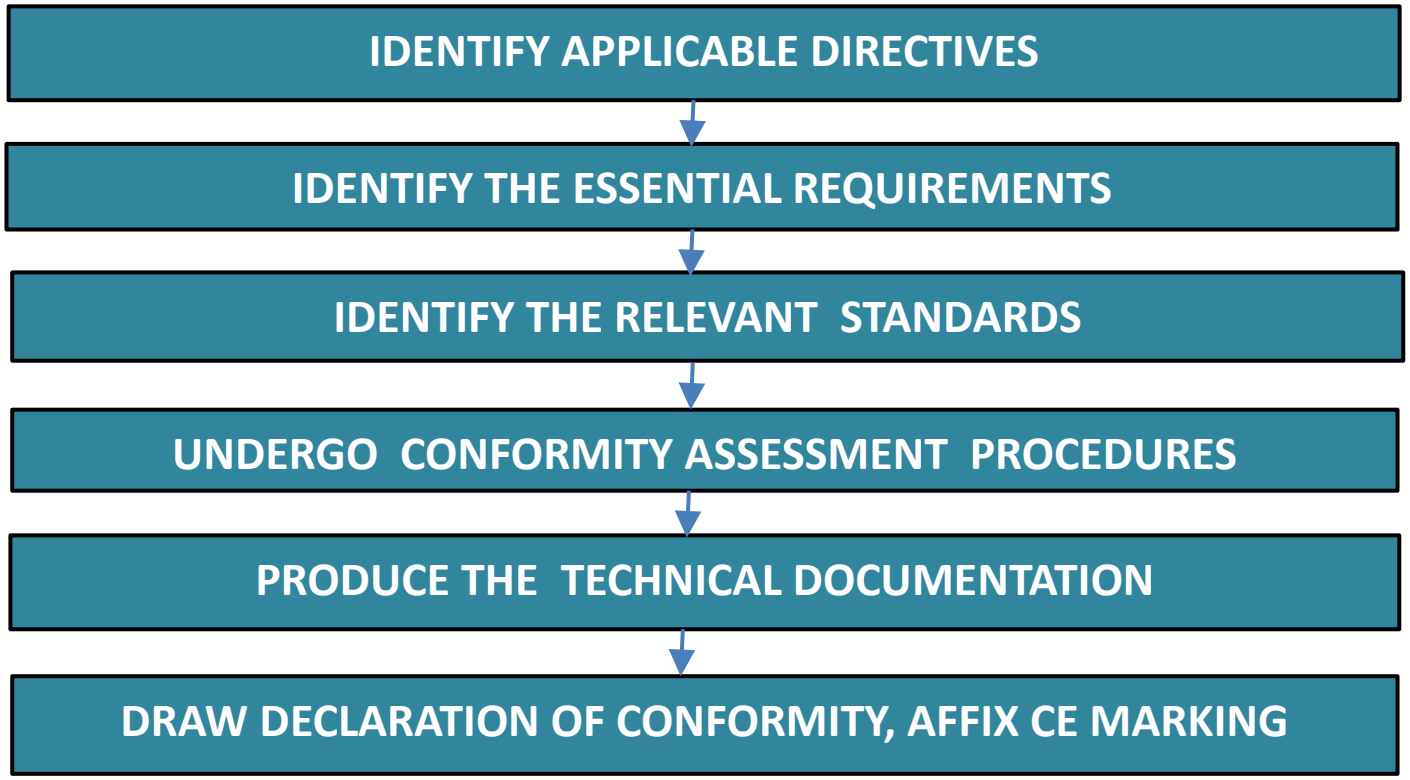
NEW APPROACH: FIELD OF APPLICATION

It applies to about 20 groups of NON-FOOD products, ranging from simple electric household appliances and going to sophisticated machinery, medical devices, etc.

These are predominantly the products covered by ***Annex III of the Association Agreement***

- **Low Voltage Equipment**
- **Toys**
- **Machinery**
- **Medical Devices**
- **Active Implantable Medical Devises**
- **In-vitro diagnostic medical devises**
- **Personal Protective Equipment**
- **Simple Pressure Vessels**
- **Pressure Equipment**
- **Electromagnetic Compatibility**
- **Gas Appliances**
- **Pyrotechnic Articles**
- **Civil Explosives**
- **Radio and Telecommunications**
- **Cableway Installations**
- **Lifts**
- **Construction Products**
- **Non-automatic weighing instruments**
- **Recreational Craft**
- **Equipment and protective systems for use in potentially explosive atmospheres**

HOW TO PREPARE FOR PLACING ON THE MARKET A PRODUCT COMPLIANT WITH THE EU REQUIREMENTS



PLACING ON THE MARKET COMPLIANT PRODUCTS

STEP 1: Identify the Applicable Directive(s)

Start by looking at the "Export Help-Desk Facility" of the web-site of the European Commission:

http://exporthelp.europa.eu/thdapp/index.htm

In the rubric "My Export» enter your product according to the specified nomenclature, the country of origin "Ukraine" and the EU countries of export destination and study the information

When New Approach Directive is involved, an overview is given on: http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm#h2-2

You have to look into the "scope" of the Directive in order to decide whether your product is covered by this Directive. It is possible that a product is covered by more than one Directive.

PLACING ON THE MARKET COMPLIANT PRODUCTS

Step 2: Identify the Applicable Essential Requirements

Essential requirements: These are the legally binding safety requirements that a product must respect, and are listed in the relevant Directive(s)

They define the safety performance of a product vis-à-vis the risks associated to its use.

The manufacturer should carry-out ***a risk assessment*** of his product to determine which essential requirements are applicable to his product

PLACING ON THE MARKET COMPLIANT PRODUCTS

Step 3: Identify the relevant Standards

Standards: Specifications (technical, process) that provide for technical solutions on how to meet the essential requirements. Standards are ***voluntary:***

- A product manufactured according to the European harmonised standards is assumed to comply with the legally binding essential requirements, imposed by the Directives.

Standards are not defined in the Directives.

A list with relevant standards by Directive, which is periodically updated can be visited in the internet via the following link:

http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index_en.htm

PLACING ON THE MARKET COMPLIANT PRODUCTS

Step 4: Undergo the Conformity Assessment Procedure

Conformity assessment: It concerns the verification of the compliance of the product with the essential requirements, during the design and the manufacturing stage.

- For low risk products conformity assessment procedures are simple and may be performed by the manufacturer (*self certification)*
- For high-risk products conformity assessment procedures are more complex and may require the intervention of external specialised organisations, the **Notified Bodies** (*third party certification*)

The applicable conformity assessment procedures and the involvement of a Notified Body are specified in the respective Directives.

If a Notified Body has to be involved, the manufacturer is free to choose one from any country in the EU.

The manufacturer can find a complete list of notified bodies as well as the product groups for which the bodies are competent on the NANDO web page from the European Commission:

http://ec.europa.eu/enterprise/newapproach/nando/

PLACING ON THE MARKET COMPLIANT PRODUCTS

Step 5: Produce the Technical Documentation

The manufacturer is obliged to prepare and keep the technical documentation of his product.

Detailed description on the contents of the technical documentation is usually given in specific articles or annexes to the Directive applicable to the product.

These documents are to be written at least in one of the official languages of the EU. Instructions for Users must be available in the official language/s of the country where the product is put on the market.

PLACING ON THE MARKET COMPLIANT PRODUCTS

Step 6: Draw the Declaration of Conformity and Affix the CE Marking

6.1. DECLARATION OF CONFORMITY

The EU Declaration of Conformity is a legal statement by the manufacturer or his authorised representative attesting that the product concerned complies with all of the relevant provisions of the Directive concerned.

The EU Declaration of Conformity must be drawn up by the manufacturer or by his authorised representative in the EU and must accompany the product until it reaches the user.

The EU Declaration of conformity must be drafted in one or more official EU languages.

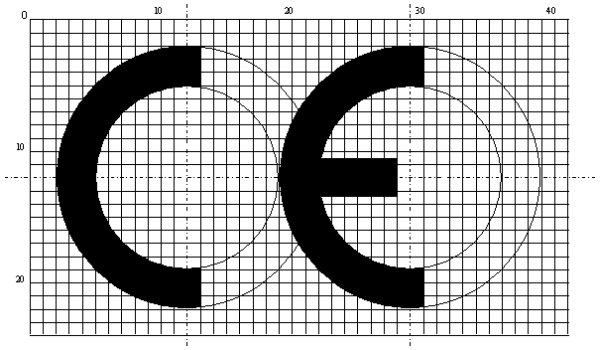
PLACING ON THE MARKET COMPLIANT PRODUCTS

STEP 6: DRAW THE DECLARATION OF CONFORMITY AND AFFIX THE CE MARKING

6.2. CE MARKING

The EU Directives require that the products, before putting them on the market are marked by the manufacturer with the **CE conformity marking**.

Dependent on the Directive, the CE conformity marking may contain also the identification number of the notified body, who e.g. was involved in the conformity assessment procedure



OBLIGATIONS OF THE MANUFACTURER AFTER PLACING THE PRODUCT ON THE MARKET

Satisfy traceability requirements:

- **Keep the technical documentation and EU Declaration of Conformity and making them available to the authorities upon request**
- **Indicate on the product and/or packaging and/or on the accompanying documentation: (1) the name; (2) the registered trade name; (3) a single contact postal address**
- **Identify to the market surveillance authorities any economic operator to whom he supplied the product**

Inform the national market surveillance authorities of any risk that the product presents after its placing on the market

ADDITIONAL SOURCES OF INFORMATION

Tutorial "Terms of exports to the EU. Database for free. "April 2013 g .:

http://exporthelp.europa.eu/thdapp/AR_RU_pdf/DGTrade_EH_main_document_RU.pdf

"Blue Guide" on the implementation of EU product rules 2014:

http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?item_id=7326

For a more extended version of the presentation, consult:

http://no-trade-barriers.com

THANK YOU!