T.C. ÇALIŞMA VE SOSYAL GÜVENLİK BAKANLIĞI
İŞ SAĞLIĞI VE GÜVENLİĞİ GENEL MÜDÜRLÜĞÜ

PRODUCT SAFETY MARKET SURVEILLANCE PERSONAL PROTECTIVE EQUIPMENT REGULATION

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- ROMA TREATY

  Establishment of a Single Market, with effect from 01.01.1993, was decided with Article 8A (amended with the European Single Act, dated 1985) of the Roma Treaty, dated 1957, which establishes the European Union.

- SINGLE MARKET

  This is the area within the European Union which is freed from internal borders and where **4 basic freedoms** of European Union, that is to say, **free circulation of goods, persons, services and capital** are ensured within the European Community. Thus, physical, financial and technical barriers should be removed.

FREE MOVEMENT OF GOODS

- Removal of customs duties and other taxes with similar effect
- Removal Quantity Restrictions (Quotas)
- Application of the Common Customs Tariff (CCT) for the Third countries
- Removal of Technical Barriers to Trade
  (Removal of non-Tariff Barriers)

FREE MOVEMENT OF GOODS

Technical Barriers (Non-Tariff Barriers);

- Different product standards
- Different technical specifications
- Conflicting commercial laws (such as health, security, compulsory standards, work, and consumer protection)

STANDARDIZATION IN THE EUROPEAN UNION

Even though the Member states' national legislations on health, security, compulsory standards, work, and consumer protection have similar purposes, the difficulties emerging from the differences among them used to bring about technical barriers.

Thus the European Standardization System was established. And within this system, a single European Standard has been regulated in many areas for producers, users and consumers. So, the same harmonized standards are applied all over the Community.

New Approach

EFFORTS FOR HARMONIZATION OF TECHNICAL LEGISLATION IN EUROPEAN UNION

- Old Approach - 1969
- New Approach - 1985
- Global Approach - 1989
- Modular Approach - 1990

New Approach

A new regulatory technique and strategy was laid down by the Council Resolution of 1985 on the New Approach to technical harmonisation and standardisation.

In general;

- Products are collected in a group of features in common,
- Minimum qualifications of the products required for placing on the market regarding the human safety, health and environmental terms "essential safety requirements" are defined,
- Member states have different technical regulations are required to harmonize their technical regulations.

New Approach

New Approach established the following principles;

- Legislative harmonisation is limited to essential requirements that products placed on the Community market must meet, if they are to benefit from free movement within the Community,
- The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonised standards,
- Application of harmonised or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements,
- Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding essential requirements.

New Approach

NEW APPROACH DIRECTIVES

The number of the new approach directives is 24. Only 3 of them does not include the obligation of attachment of the CE conformity marking to the product. For the other 21 directives, CE marking is obligatory.

CUSTOMS UNION AGREEMENT

- The Customs Union Agreement between Turkey and the EU was signed in 1995,
- Pursuant to the Decision No 1/95 of the EC-Turkey Association Council that establishes the customs union, Turkey became a participant of the free movement of goods which is one of the “four freedoms” that form the European single market,
- According to the agreement, Turkey’s customs legislation shall be treated in accordance with the applicable laws of the EU member countries.
- According to the agreement, Turkey adopted the EU's Common External Tariff in its trade with third countries.

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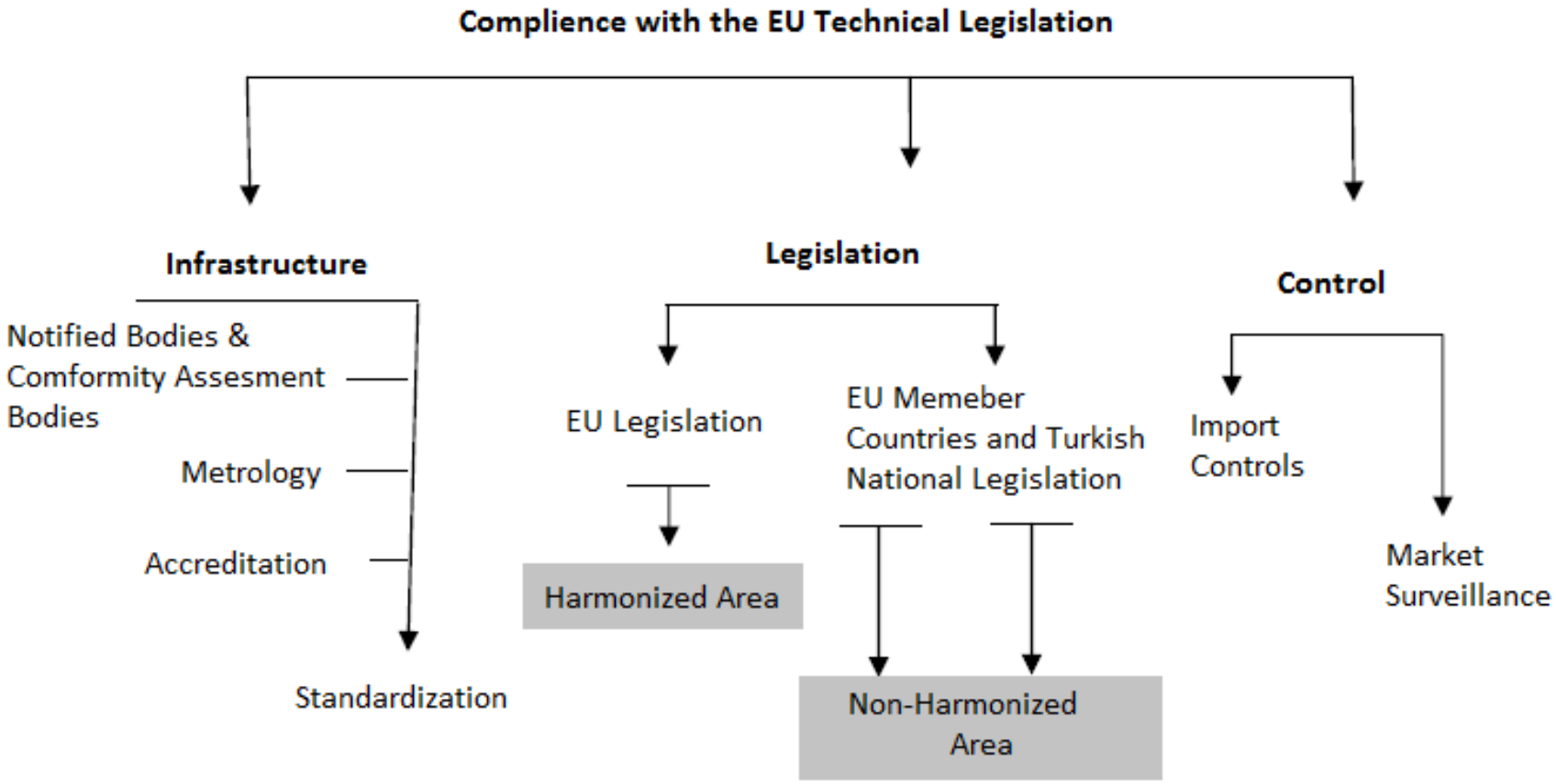
COMPLIENCE WITH THE EU TECHNICAL LEGISLATION

- According to the Decision No 2/97 of the EC-Turkey Association Council, the public institutions that will be harmonising the EU Legislation are determined by the Cabinet Decree No 97/9196 on "Determination of Institutions to Prepare Technical Legislation Regarding Increase of Export".

- According to the Cabinet Decree, the Ministry of Labour and Social Security are responsible for the implementation and harmonization of the regulations on Personal Protective Equipment.

- Ministry of Economy is the coordinator organization. Horizontal legislation (product safety regulatory framework) and regulations prepared by Ministry of Economy.

COMPLIENCE WITH THE EU TECHNICAL LEGISLATION



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New Approach Directive	Responsible Public Institution for Harmonization
Low voltage equipment (73/23/EEC;93/68/EEC)	Ministry of Science, Industry and Technology
Simple pressure vessels (87/404/EEC;90/488/EEC;93/68/EEC)	Ministry of Science, Industry and Technology
Toys (88/378/EEC;93/68/EEC)	Ministry of Health
Construction products (89/106/EEC;93/68/EEC)	Ministry of Environment and Urban Planning
Electromagnetic compatibility (89/336/EEC;92/31/EEC;93/68/EEC) (98/13/EEC)	Ministry of Science, Industry and Technology
Machinery (98/37/EC)	Ministry of Science, Industry and Technology
Personal protective equipment (89/686/EEC;93/68/EEC;93/95/EEC;96/58/EC	***Ministry of Labor and Social Security***
Non-automatic weighing instruments (90/384/EEC;93/68/EEC)	Ministry of Science, Industry and Technology
Active implantable medical devices (l90/385/EEC;93/42/EEC;93/68/EEC)	Ministry of Health
Gas appliances (90/396/EEC;93/68/EEC)	Ministry of Science, Industry and Technology
Hot water boilers (92/42/EEC;93/68/EEC)	Ministry of Science, Industry and Technology
Civil explosives (93/15/EEC)	Ministry of Science, Industry and Technology

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New Approach Directive	Responsible Public Institution for Harmonization
Medical devices (93/42/EEC;98/79/EC)	Ministry of Health
Equipment and protective systems intended for use in Potentially explosive atmospheres (94/9/EC)	Ministry of Science, Industry and Technology
Recreational craft (94/25/EC)	Ministry of Transport, Maritime Affairs and Communications
Lifts (95/16/EC)	Ministry of Science, Industry and Technology
Household electric refrigerators, freezers and combinations (96/57/EC)	Ministry of Science, Industry and Technology
Pressure equipment (97/23/EC)	Ministry of Science, Industry and Technology
Telecommunications terminal equipment (98/13/EC)	Information and Communication Technologies Authority
In vitro diagnostic medical devices 98/79/EC)	Ministry of Health
Energy efficiency requirements for ballast for fluorescent lighting (2000/55/EC)	Ministry of Science, Industry and Technology
Cableway installations designed to carry persons (2000/9/EC)	Ministry of Science, Industry and Technology
Radio and telecommunications terminal equipment (99/5/EC)	Information and Communication Technologies Authority
Medical devices (93/42/EEC;98/79/EC)	Ministry of Health

COMPLIENCE WITH THE EU TECHNICAL LEGISLATION

Legislation prepared by the Ministry of Economy :

- The Law on the Preparation and Implementation of Technical Legislation on Products (Law No. 4703)
- Regulation on Market Surveillance of the Goods,
- Regulation on Conformity Assessment Bodies and Notified Bodies,
- Regulation on CE Marking,
- Regulation on the Exchange of Information on Technical Legislation on Goods and Standards between Turkey and the European Union.
- Regulation on Mutual Recognition in the Non-Harmonised Area

FRAMEWORK LEGISLATION

- The Law on the Preparation and Implementation of Technical Legislation on Products (Law No. 4703) came into force on 11 January 2002

- The aim of the preperation of the law is to bring the necessary elements of the mechanism that's not available in Turkey regarding the " **EU's New Approach and Global Approach** " into our legal system.

- The main purpose of the law is to ensure placing only safe and compatible products with relevant the technical regulations on the market.

FRAMEWORK LEGISLATION

Law No. 4703 covers;

- Terms of placing on the market of the products,
- Obligations of producers and distributors
- Conformity Assesmet Bodies and Notified Bodies
- Market surveillance and inspection
- Prohibition of the placing on the market of the products, withdrawal and disposal of the marketed products
- Notifications

FRAMEWORK LEGISLATION

Products expected to be in complience with the relevant technical legislation due to the Law No. 4703 ;

- New products to be placed on the market,
- Used products that are reconditioned intended to be placed on the market.
- All kinds of old and used products imported from non-EU countries.

PRODUCT SAFETY

A product that;

- Conforms to its technical specifications,
- Conforms to the standards that refer to the new approach legislation that requires CE marking

is recognized as **SAFE**.

A product which does not bear the basic health and safety requirements specified in the relevant legislatıon is a **RISKY PRODUCT**.

PRODUCT SAFETY

In case there's no technical regulation exists, conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, where they exist:

- National and international standards,
- Product safety codes of good practice in force in the sector concerned
- The state of the art and technology
- Reasonable consumer expectations concerning safety

PRODUCT SAFETY

Safe product shall mean;

- Product which does not pose risk in normal period of use and under normal conditions, or
- That pose risk at an acceptable level, and
- That meets the basic health and safety requirements such as protecting public health and environmental, plant and animal existence.

PRODUCT SAFETY

- A non-comforming product may be requested to be transformed by the producer into a product that conforms to the relevant regulations,

  For an unsafe product;

- Placing on the market and importation of an unsafe product may be limited, prohibited,

- If it is already on the market, it may be withdrawn,

- If it cannot be rendered safe, it may be partially or totally eliminated according to the risk it poses.

PRODUCT SAFETY

However,

- Free movement of products is the fundamental principle,
- Limitation, restriction and withdrawal are exceptions,
- Exceptions are subject to rigid rules.

PRODUCT SAFETY

- Product safety is the key concept of the EU technical legislation,
- In EU countries, Directive 2001/95/EEC which revises the Directive 92/59/EEC regulates the product safety issues.
- The Law No.4703 was prepared based on the the EU Directive 92/59/EEC.

CE MARKING

- Existing in its present form since 1993, the CE marking is a key indicator of a product's compliance with EU legislation (New Approach Directives) and all appropriate conformity assessment procedures have been completed.

- CE marking enables the free movement of products within the European market.

- Member States may not restrict the placing on the market and entry into service of products bearing the CE marking, unless there is supporting evidence of the product’s non-conformity. The marking should be affixed prior to the product being placed on the European market and entering into service.

CE MARKING

- The European Commission refers to the CE Marking as a **"Passport"** which allows products to be freely circulated within the EU single market.

- Often, consumers will consider CE Marking on a product as an indication of conformance to laid down minimum standards, and therefore a minimum level of safety which other products may lack. CE Marking is thus for many consumers a **"Symbol of Safety“**.

IS NOT A QUALITY BUT SAFETY MARKING.

MARKET SURVEILLANCE

Market Surveillance are the activities carried out by public authorities to ensure that products comply with the requirements set out in the relevant legislation. These actions strengthen health, safety and other aspects of the public interest, like consumer protection and a level playing field for businesses.

In practice, market surveillance includes any necessary action (e.g. bans, withdrawals, recalls) to stop the circulation of products that do not comply with all the requirements set out in the relevant EU harmonisation legislation, to bring the products into compliance and to apply sanctions.

MARKET SURVEILLANCE

Market surveillance is vital to the smooth functioning of the Single Market. It is essential in protecting consumers and workers against risks presented by non-compliant products. In addition, market surveillance helps to protect responsible businesses from unfair competition by unscrupulous economic operators who ignore the rules or cut corners.

Standardization and conformity assessment are important elements of the market surveillance of technical products.

MARKET SURVEILLANCE

In brief the aims of the MS are;

- to ensure placing safe products on the market,
- Protection of consumers health,
- Prevention of unfair competition

MARKET SURVEILLANCE

Market surveillance authorities must have;

- Necessary power
- Resources
- Knowledge to properly perform their functions.

MARKET SURVEILLANCE

Market surveillance measures to be taken by the surveillance authorities;

- Organising random and spot checks;
- Obtaining all necessary documentation from manufacturer to evaluate product conformity;
- When justified, entering manufacturers' premises and taking samples for testing, and in extreme cases destroying products.
- If authorities find products presenting a risk, they must alert other potential users of those products to reduce the risk of further injury or harm.
- Products which present a serious risk, requiring rapid reaction, must be recalled from the market or measures must be taken in order to ensure that they do not reach the market.

MARKET SURVEILLANCE

Principles of MS;

- Visibility / deterrence,
- Compliance with the law
- impartiality,
- proportionality,
- Objective and consistency,
- All decisions should be based on proven grounds.,
- Adequate resources and capabilities,
- Effective co-operation with the EU.

MARKET SURVEILLANCE

Information exchange and effective cross-border co-operation between market surveillance authorities in different Member States is essential to ensure efficient, comprehensive and consistent market surveillance in the Single Market.

If a surveillance authority spots a product which presents a risk and could have an effect outside the territory of its Member State, the information is transmitted to all EU Member States using the Rapid Information System (RAPEX).

MARKET SURVEILLANCE

MS activities in Turkey;

- 10 different public institutions are responsible for performing MS for different product groups in Turkey.
- Ministry of Labour and Social Security are responsible for the market surveillance of Personal Protective Equipment.
- Ministry of Economy is the coordinator organization on MS activities.
- Import controls of PPE are carried out by the Ministry of Economy.
- The coordination between market surveillance authorities is handled by the Ministry of Economy throughout the Market Surveillance Coordination Board and the Market Surveillance and Product Safety Assessment Board.

Personal Protective Equipment Regulation

Definition of **PPE**:

PPE shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

- Respiratory protection,
- Eye protectors,
- Head protectors,
- Hearing protectors,
- Protection against falling,
- Foot and leg protectors,
- Protective clothing,
- Hand and arm protectors,
- Lifejackets.

Personal Protective Equipment Regulation

The Minimum Health And Safety Requirements For The Use By Workers Of Personal Protective Equipment At The Workplace (89/656/EEC)

Article 6-a

PPE Directive (89/686/EEC)

Personal Protective Equipment Regulation

- The PPE regulation was issued on the basis of article 4 of law no. 4703, dated 29.06.2001 and decision no 97/9196 of the Council of ministers, dated 15.01.1997. The main documents on the preparation of the Regulation is the EU Directive 89/686/EEC on Personal Protective Equipments.

- Personal Protective Equipment (ppe) regulation was published on the official journal, dated 9 February 2004, and entered into force on 9 February 2005.

- PPE Regulation was revised on 29.11.2006.

Personal Protective Equipment Regulation

Secondary Regulations And Communiques Prepared Within The Scope Of Personal Protective Equipment Regulation;

- Communique on the guideline on categorization of Personal Protective Equipment
- Communique on assignment of Notified Bodies in relation to Personal Protective Equipment
- Communique on harmonized national standards in relation to Personal Protective Equipment
- Regulation on procedures and principles in relation to Market Surveillance and Control

Personal Protective Equipment Regulation

Regulation covers;

- Principles of placing on the market,
- Obligations of producers and distributors,
- Responsibilities of Notified Bodies,
- Terms of Market Surveillance

Personal Protective Equipment Regulation

Manufacturer shall mean the natural or legal person, who:

- designs and/or manufactures a product covered by the Directive, or who has a PPE designed and/or manufactured with view to its placing on the market or for his own professional or private use, under his own name or trademark; or who:

- places a PPE on the market and/or puts it into service, under his own name or trademark.

Personal Protective Equipment Regulation

The manufacturer bears responsibility for;

- Undertaking an analysis to conclude if his product is subject to the PPE Directive and which requirements apply;
- Design and construction of the PPE in accordance with the Basic Health and Safety Requirements (BHSR) laid down in the Directive;
- Following the procedures for the assessment of the conformity of the product with the BHSR laid down in the Directive;
- providing marking and instructions for safe use, maintenance etc.

Personal Protective Equipment Regulation

Manufacturer is responsible for placing the safe and compatible product with the technical regulations on the market.

In case the manufacturer is not established in the country, authorized representative or importer is responsible.

Personal Protective Equipment Regulation

Distributor (definition mentioned in the Law No. 4703);

Any professional in the supply chain whose activity does not affect the safety properties of a product.

Obligations of the distributors;

Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with the requirements.

Personal Protective Equipment Regulation

General characteristics required in all PPEs (Basic issues related to the product safety “Basic Health and Safety Requirements” as mentioned in the Annex-II of the PPE Regulation):

- Should be ergonomic (Design Principle)
- Levels and classes of protection should be identified
- Should provide comfort and effectivity
- Should be light and durable
- Should contain information to be supplied by the manifacturer
- The PPE itself should not cause hazards

Personal Protective Equipment Regulation

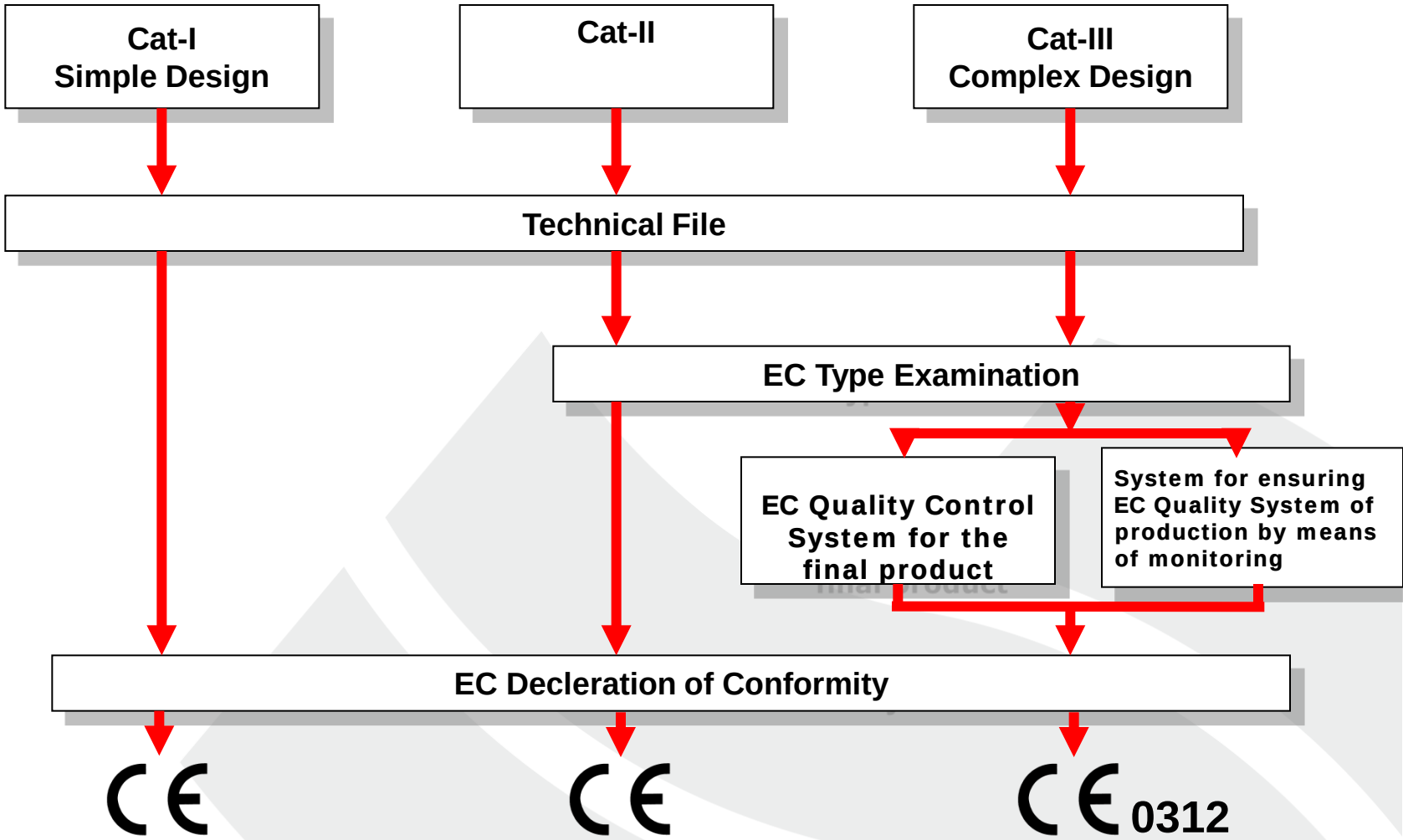
Communique on the guideline on categorization of Personal Protective Equipment;

The purpose of this Communiqué is to determine which category the PPEs are included in order to accomplish CE certification prodecures.

Personal Protective Equipment Regulation

- Category I: PPE of simple design (e.g. gardening gloves, footwear)
- Category II: PPE not falling into category I or III
- Category III: PPE of complex design (e.g. respiratory equipment, harnesses)

Personal Protective Equipment Regulation



Personal Protective Equipment Regulation

It is the manufacturer's responsibility to:

- carry out the conformity assessment
- set up the technical file
- issue the EC Declaration of Conformity (DoC)
- affix CE marking on a product

Personal Protective Equipment Regulation

Technical File

The documentations shall include:

- Comprehensive and detailed plans of PPE
- Calculation notes
- Prototype test results that confirm compliance with basic legal requirements
- Detailed list of basic requirements in Annex II of the PPE Regulation and harmonized standards or other technical specifications used
- Identification of control and test services used in conformity control of production
- Information for users

Personal Protective Equipment Regulation

Technical File

Continued…

- Photographs
- Illustrations including all the details such as postal codes, logos
- Definitions and bills of main materials for each model

Technical File shall be kept for 10 years after the PPE produced or imported by the manufacturer/importer.

Personal Protective Equipment Regulation

Notified Bodies carrying out the certification procedures related to PPE;

TSE

Foot, hand-arm, eye, head, face, body, hearing, respiratory protective equipment

Universal CERTIFICATION

UNIVERSAL CERTIFICATION NB 2163

Foot, hand-arm, eye, head protective equipment

THANK YOU FOR YOUR ATTENTION