Single Market, Conformity Assessment, Market Surveillance & Self Certification in EU

Agenda

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- Single Market
- Conformity Assessment
- Market Surveillance
- New Approach & Self Certification
- Conclusion

If time permits:

- IECEE: Conformity Assessment Scheme

Project is a permanent presence in India

SESEI (**S**econded **E**uropean **S**tandardization **E**xpert in **I**ndia) ***is a local face for the European standardization community in India: Dinesh Chand Sharma***

Why SESEI: India is a major trade partners for Europe, Increasing role of standards to gain market access and Evolving & complex nature of regulatory and standardization landscapes, Sharing best practices, work together

Sector: 1. ICT: M2M/IoT, Security, 5G, NFV/SDN, e-Accesibility, eHealth, eCALL… **2. Electrical equipment including Consumer Electronics**: Smart Grid, Smart Meter, LVDC, Micro- Grid, Lift Escalator… 3**. Automotive**: Connected Cars, ITS, e-Mobility… 4**. Smart Cities**: Mobility, Waste, Energy, ICT and other topics of mutual interests such as Machinery Safety, Cableways, Circular Economy, Railways etc.

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Single Market

Single market for goods

- EU single market for goods consists of 450 million consumers and 22.5 million small and medium-sized enterprises (SMEs).
- European Commission's main goal is to ensure the free movement of goods within the market, and to set high safety standards for consumers and the protection of the environment.
- **Building blocks of single market:**
  - **Conformity assessment**
  - **Market surveillance**
  - Information and Communication System on Market Surveillance (ICSMS)
  - Accreditation of conformity assessment bodies
  - Notified bodies
  - Legal metrology
- Conformity assessment is complementary to market surveillance. Both procedures help ensure the smooth functioning of the internal market.

Conformity Assessment

Conformity assessment

What conformity assessment is:

- The conformity of a product is assessed before it is placed on the market
- It needs to demonstrate that all legislative requirements are met
- It includes testing, inspection and certification
- The procedure for each product is specified in the applicable product legislation

How does it work in practice?

- Product legislation describes conformity assessment procedures for each product.
- Manufacturers may choose between different conformity assessment procedures, if applicable.
- Assessment is carried out by the manufacturer. If the applicable legislation requires it, a conformity assessment body is involved in the conformity assessment process
- EN ISO/IEC 17000 series of standards and accreditation are important instruments to help establish conformity with the requirements of applicable legislation.

Conformity assessment

What the notified bodies do:

Conformity assessment is a service to manufacturers in an area of public interest. It is the responsibility of the EU country to notify conformity assessment bodies within their jurisdiction according to principles laid down in Decision 768/2008/EC. Notified bodies:

- are free to offer their conformity assessment services to any economic operator inside or outside the EU
- may carry out these activities on the territory of other EU countries or non-EU countries
- must operate in a non-discriminatory, transparent, neutral, independent, and impartial manner
- must employ the necessary personnel, with sufficient knowledge and experience to carry out the conformity assessment in accordance with the law(s) in question
- must be adequately insured to cover their professional activities, unless liability is assured under the national legislation of the notifying EU country
- must provide information to their notifying authority, market surveillance authorities, and other notified bodies etc.

Manufacturers are free to choose any notified body that has been legally designated to carry out the conformity assessment procedure.

Market Surveillance

Market Surveillance

- Market surveillance involves checking whether products meet the applicable safety requirements. If they do not, it involves taking the necessary steps to ensure requirements are met, or imposing penalties.
- In the EU, market surveillance authorities (MSAs) in each country are responsible for controlling products and for taking the appropriate measures.
- MSAs cooperate closely with customs, which play a major role in protecting consumers from any imported unsafe products coming from outside the EU.
- European Commission finances coordinated activities between Member States MSAs to exchange best practices on market surveillance on the single market.
- Monitoring markets is not just crucial for protecting people from dangerous products but also for ensuring a level playing field for businesses."

Legislation in force

- Regulation (EC) 765/2008 sets out the requirements for accreditation and market surveillance relating to the marketing of products. The Regulation:
  - sets out clear obligations for EU countries to carry out market surveillance and to prohibit or restrict the marketing of dangerous or non-compliant products
  - provides MSAs the powers to obtain all necessary documentation from manufacturers to evaluate product conformity, to enter manufacturers' premises and take samples for testing, and in extreme cases to destroy products
  - Includes clear obligations for EU countries to ensure cooperation at national and international level.
- Decision 768/2008/EC on a common framework for the marketing of products contains provisions on market surveillance, obligations of businesses, traceability and safeguard mechanisms. These provisions are being incorporated in sector specific legislation.
- Directive 2001/95/EC (the General Product Safety Directive) contains additional market surveillance provisions, notably for non-harmonised consumer products.

New regulation on MS and compliance of products

- In June 2019 Regulation (EU) 2019/1020 on market surveillance and compliance of products was published, aiming at **improving** and **modernising market surveillance**.
- It will apply to 70 regulations and directives that harmonise at EU level requirements on non-food products to protect consumers, health and safety, the environment and other public interests
- It will replace Regulation (EC) 765/2008 as from 16 July 2021, and will improve them in particular by
  - preventing non-compliance by providing information to and joint activities with businesses
  - providing more effective enforcement tools to address online sales
  - improved cooperation: between EU countries, between market surveillance and customs authorities, and through an EU product compliance network

New approach & Self Certification

New Approach Directives

- Relationship b/w standardization and legislation at European level has been developed in accordance with the so-called 'New Approach' to technical harmonization and standards, which was introduced in 1985.
- **According to the New Approach:**
  - EU adopts legislation (EU Directives) that defines essential requirements (ERs) related to health, safety and environmental issues.
  - EC issues standardization requests (Mandates) to ESOs (CEN, CENELEC and ETSI), for preparing technical standards and specifications that facilitate compliance with these ERs;
  - Public authorities must recognize that all products manufactured (and services provided) in accordance with harmonized standards are presumed to conform to ERs as defined by the relevant EU legislation;
  - Standards remain voluntary and there is no legal obligation to apply them. Any producer (or service provider) who chooses not to follow a harmonized standard is obliged to prove that their products (or services) conform to ERs
  - When businesses make use of harmonized standards, they benefit from a 'presumption of conformity' with the requirements set out in the relevant European legislation. This means that they can sell their products or services throughout the Single Market – reaching a potential 600 million consumers in at least 34 countries.
  - Meanwhile, when European Standards are correctly applied, consumers benefit from safe and environmentally-friendly products and services.

Self certification

- Most products covered by New Approach Directives can be self-certified by the manufacturer and do not require the intervention of a Notified Body.
- To self-certify, the manufacturer must assess the conformity of products to the applicable directives, and to the standards if applied.
- Manufacturer may affix **CE marking** to products or equipment (and prepare and sign the Declaration of Conformity) as long as he/she can prove conformity to the applicable requirements. Proof is provided in the Technical File that the manufacturer must compile.
- Certain (high risk) products may not be self-certified, but must be subjected to an EC type-examination. This examination involves the inspection of a representative example by a Notified Body.

Conclusion

- Conformity assessment & Market Surveillance are essential building block of a single market in EU
- Assessment is carried out by the manufacturer only if the applicable legislation requires it, a conformity assessment body is involved in the conformity assessment process
- Manufacturers are free to choose any notified body that has been legally designated to carry out the conformity assessment procedure.
- New Regulation (EU) 2019/1020 on market surveillance will replace Regulation (EC) 765/2008 from 16 July 2021 and is aimed at improving and modernizing market surveillance
- Relationship b/w standardization and legislation at European level is carried out in accordance with 'New Approach Directive' for technical harmonization and standards
- As per new approach EU adopts legislation (Directives) that defines essential requirements (ERs) related to health, safety and environmental issues
- Most products covered by New Approach Directives can be self-certified by the manufacturer and do not require the intervention of a Notified Body.

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