Conformity Assessment: The European experience

May 2017

Zero Defect Zero Effect

Digital India
Power To Empower

Smart City
MISSION TRANSFORM-NATION

Make in India

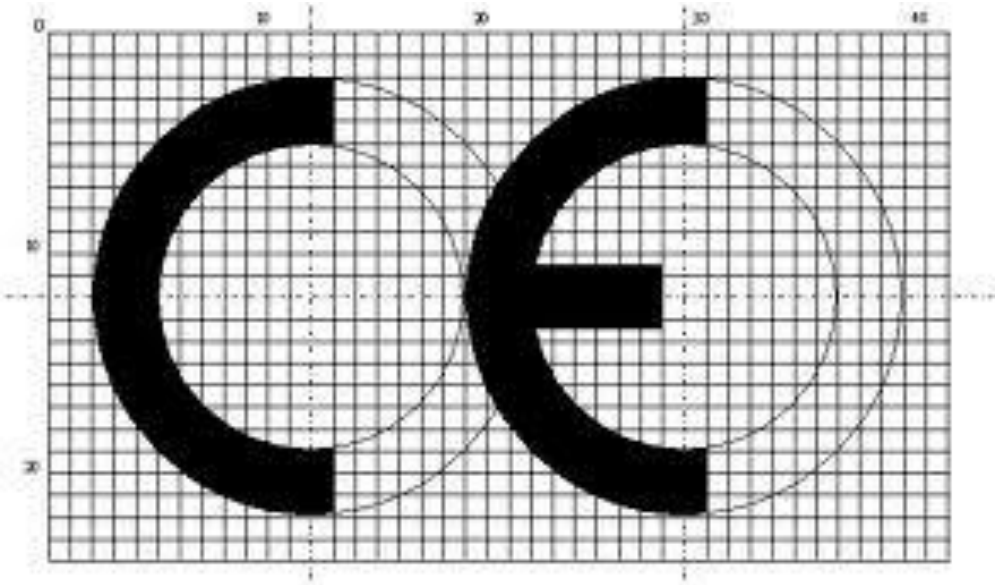
Now is the Time … (Can an efficient conformity assessment framework be a *pivotal* enabler of success?)

Retrospect:
Conformity Assessment in Europe pre 1990

Germany

Germany

1992



Goal: facilitation of trade

Requirements for the *correct* application of the CE Marking

- ✓ Design specifications
  - ➢ schematics,
  - ➢ list of critical components, materials,
  - ➢ photos, etc

- ✓ Evidence of evaluation and testing to all applicable EU Directives and/or Regulations (choice of applicable modules)
- ✓ List and addresses of all parties involved: Manufacturer, Brand owner, Importer, Distributor (as applicable)
- ✓ Declaration of Conformity

Market Surveillance

Two classic models:

- Pre-market testing/certification
  - Places responsibility on private sector
  - Finds problems before they reach consumer (Proactive)

- Post-Market Surveillance (EU Model)
  - Places responsibility (and cost) on government
  - Requires that safety incident occurs before action is taken
    - Unless regulator is checking products from open market

Relevance of Enforcement

Health and Safety

- Protection of Human Health and Safety
- Protection of Property
- Preservation of the Environment
- By ensuring products perform acceptably under:
  - Normal Use
  - Reasonable Foreseeable Misuse

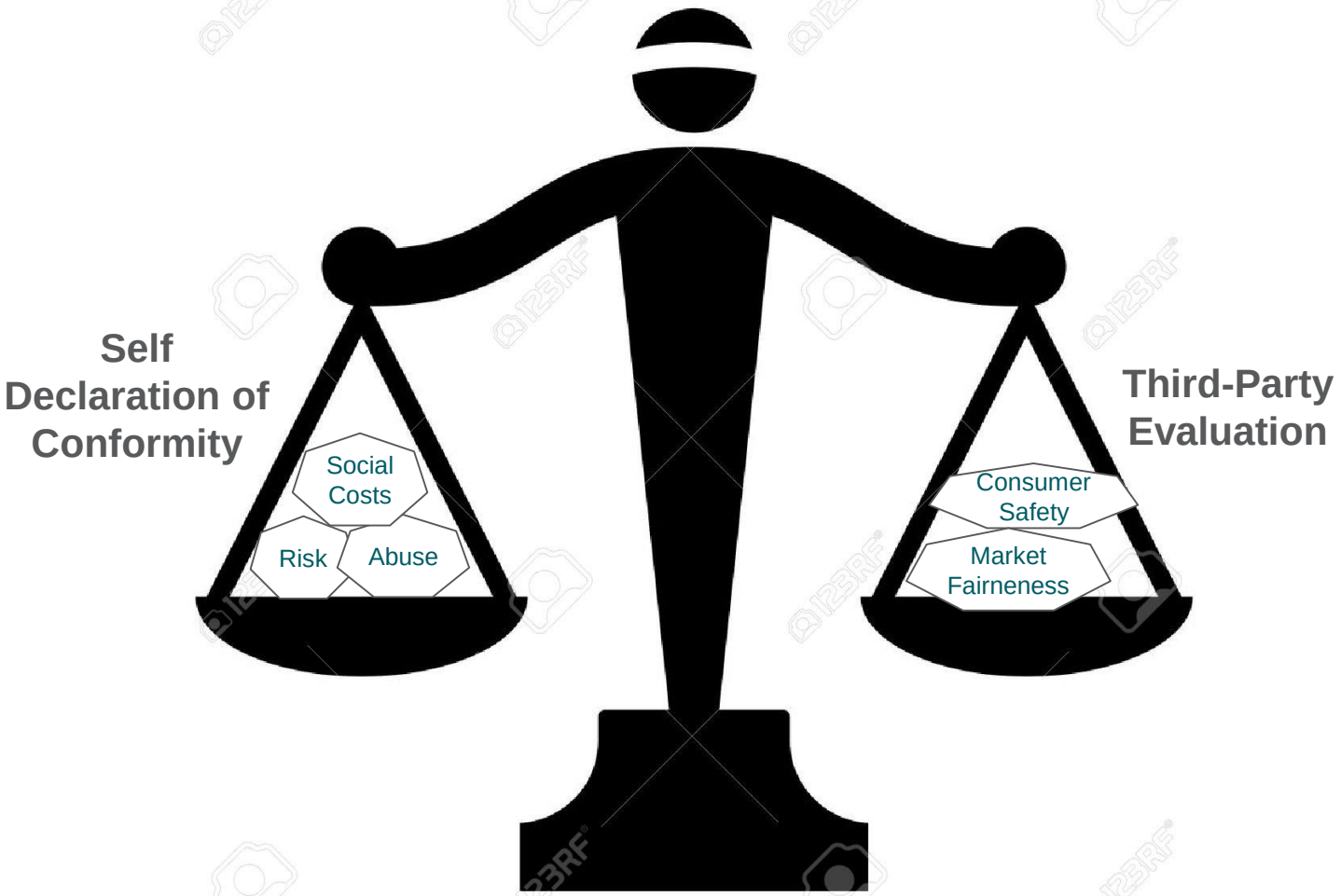
Fair Treatment

- Ensure that all manufacturers are meeting product safety regulations
- Ensure level playing field for all manufacturers of regulated products

Takeaways from the EU experience

- Framework started well, but it progressively deteriorated > now unbalanced and unstable
- Consumer safety and market fairness has been compromised
- Market Surveillance alone, as an enforcement model, is a very expensive, reactive proposition
- Pre-market *mandatory* testing is an option that receives mixed reviews
- New Regulations and Directives (RED, Eco-Design, eventually Cyber-Security) will only make matters more complicated

A complicated balancing act



Conclusions

- Partnerships that are based on public (design of proper framework, market oversight, enforcement) and private (pre-market testing and certifications) collaboration are, in modern times, a viable, balanced alternative

- Highest risk categories, particularly consumer products: best if they are identified early and regulated (India is a perfect example)

- Through time, continuous monitoring of both the regulated and the medium-risk, non-regulated categories

  >> maintain proper balance and credibility

  >> eye on new technologies and their impact/needs

- Penalty system is important: needs to be fair and dissuasive at the same time

- Injury database is an ambitious proposition, but very relevant to gauge future needs

- Government database of accidents and product recalls, for all MSAs to share

Thank you

Back up slides

Who Conducts Conformity Assessment?

First Party – Supplier of the product

Used when the risks associated with non-conformity are low to moderate and market and/or regulatory mechanisms are capable of adequately addressing non-conformities.

Second Party – Purchaser or user of product

(retailers or consumers; government, in cases involving technical regulations);

Third Party – an entity independent of the interests of First and Second parties

Used when the risks associated with non-conformity are moderate to high.

Conformity Assessment Mechanisms

Suppliers' Declaration of Conformity (SDoC) Compliance is self-declared by supplier of the product

Testing conduct specified tests and deliver test results and methods

Commercial Inspection and Testing purpose is to determine if products meet a customer's expectations; confidence needs of purchaser require inspection in addition to quality management systems

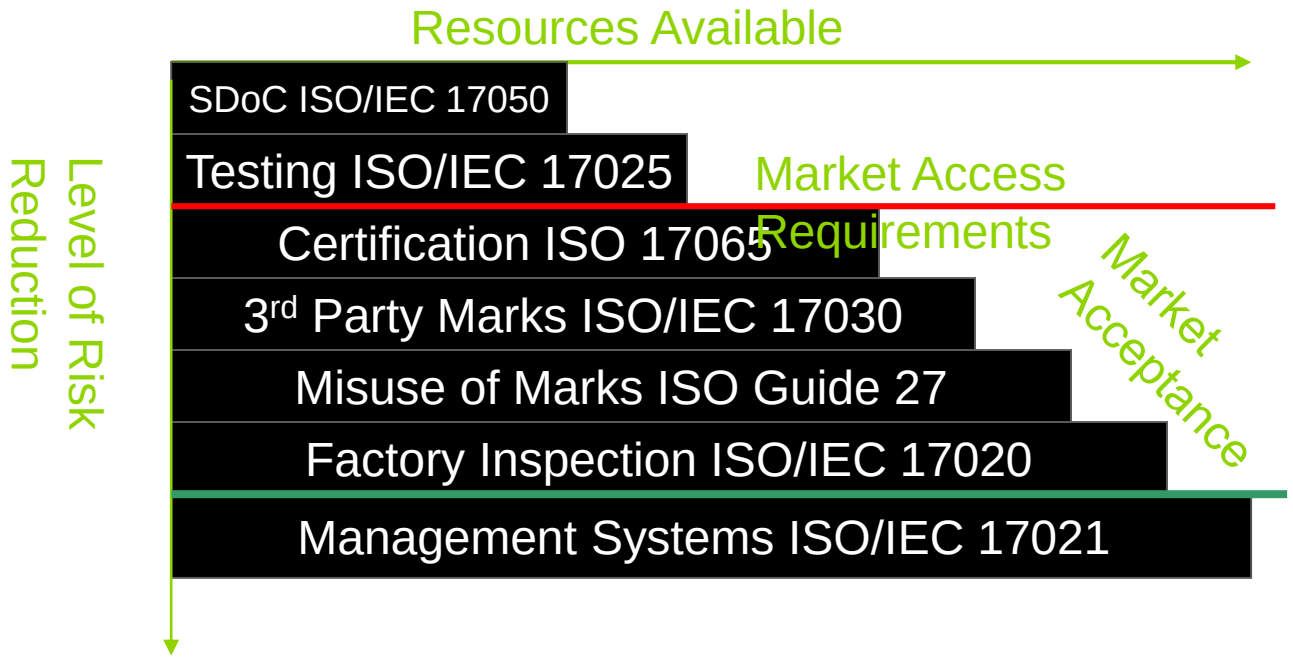
Product Certification basic components:

- investigation: includes testing, comparing to requirements, and determining compliance
- surveillance: includes among other things, unannounced and frequent product inspections, witnessing of production

Quality System Registration incorporates a review of the procedure, an on-site assessment of the implementation of the procedure, and audits to verify continued implementation and to identify areas that could be improved

Conformity Assessment Building Blocks

The system should reflect the product specific characteristics, the level of risk reduction sought, and the resources available for conformity assessment.



Elements of Product Certification System

There are certain functions and elements that need to be considered regardless of who carries out conformity assessment

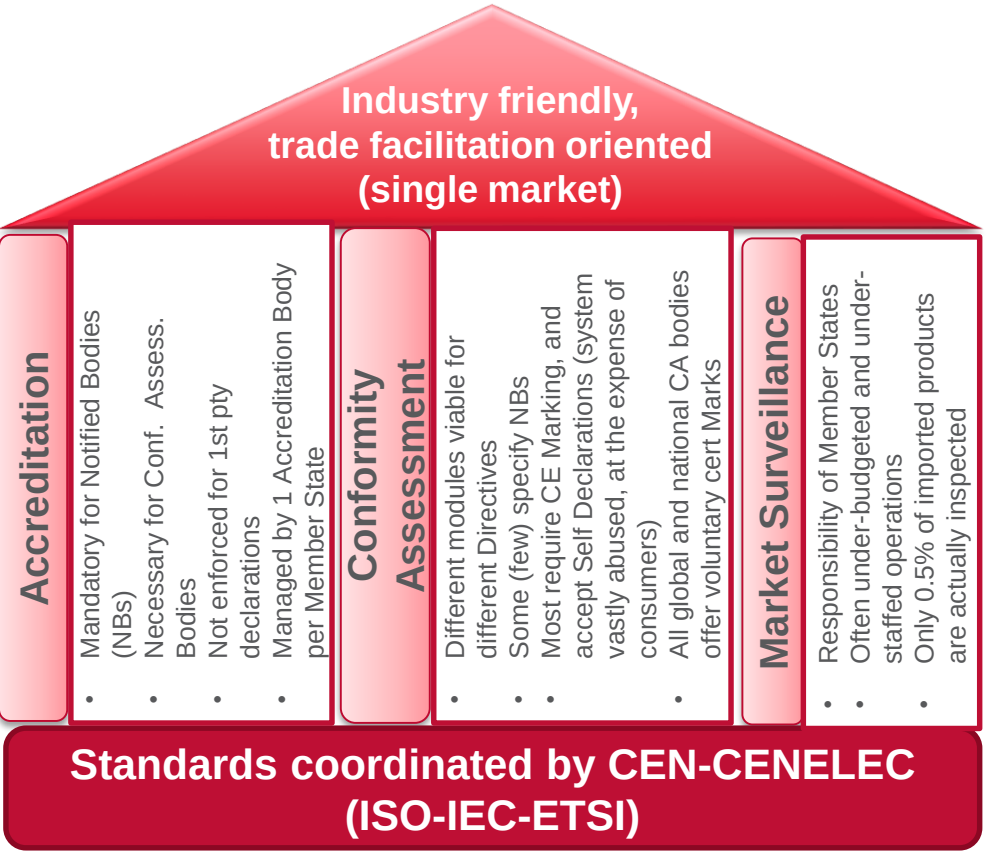
1. **Testing, evaluation, and documentation:** consideration must also be given to the need for accreditation of the laboratories conducting the testing. Accreditation can enhance the confidence in and consistency of test results.
2. **Certification:** authorization to use and apply the Mark.
3. **Factory inspection:** is a pre-market mechanism that more formally assures and enhances compliance of on-going production.
4. **Market surveillance and corrective action:** post-market function directed at validating the conformity of products that are available in the market. Tasks include testing and inspecting products obtained from the market to verify their compliance.

Certification Process

Type 5 Product Certification (ISO 17067)

1. Samples requested by the certification body
2. Determination of Characteristics
   - Evaluation of Product Construction
   - Testing of Product
3. Initial Assessment of the production process or quality system
4. Evaluation of the test and assessment reports
5. Certification Decision
6. License to use Mark of Conformity
7. Surveillance of the production process or quality system
8. Surveillance by testing or inspection of samples from the factory or the open market

EU Conformity Assessment Framework



Compliance with harmonized standards (EN versions) denotes presumption of conformity to applicable Directive or Regulation

- To comply Manufacturers/Importers must:
  - Produce a Technical File (with test reports demonstrating compliance to all applicable Directives)
  - Apply CE Marking (where viable)
  - Sign Declaration of Conformity
- Large number of non-conforming products on market (est. 18% with serious issues)
- Unfair market conditions for honest operators
- Surveillance and penalty system not evenly applied
- Currently under scrutiny

- CE Marking (not intended to be a consumer-facing symbol of safety)
- Many Directives/Regulations may apply to same product
- First-Party declarations rarely supported by legitimate 17025 laboratory reports
- Central database for reporting non-compliant products (RAPEX) inconsistently used
- Data from EU hospitals on injury types, causes not available

THANK YOU.