Criteria for the choice of conformity assessment procedures in a given risk-management context

WTO Committee on Technical Barriers to Trade
Geneva, 29 October 2013

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Outline

- Historical background
- The EU Conformity Assessment System
- Criteria for the design and choice of conformity assessment procedures in EU technical harmonization legislation
- Use of Supplier's Declaration of Conformity
- Conclusions – Lessons learned

A bit of history

on the development of an EU common conformity assessment policy

- June 1989 Commission Communication on a **Global Approach to certification and testing** (COM (89) 209 final)

- December 1989 Council Resolution on a **Global Approach to conformity assessment and testing**
  - Consistent approach to conformity assessment: modular approach for product certification and quality assurance; uniform selection criteria, introduction of the CE marking

A bit of history

on the development of an EU common conformity assessment policy

- **1993 Council « Modules » Decision (93/465/EEC, repealing and updating Council Decision 90/683/EEC)**
  - Implementation of the 1989 Council Resolution: detailed description of conformity assessment modules and guidelines for their choice + harmonised rules for the affixing and use of the CE marking (Global Approach)
- **New Approach**: performance-based essential requirements supported by harmonised voluntary standards + modular approach to conformity assessment + CE marking

A bit of history

on the development of an EU common conformity assessment policy

- July 2008: **New Legislative Framework**

  - **Regulation 765/2008:** common accreditation and market surveillance framework

  - **Decision 768/2008:** consolidates, completes and modernises basic New Approach concepts – Model for future legislation harmonising product-related requirements

Official Journal of the EU, L218, 13.08.08

New Legislative Framework

REGULATION

Accreditation

Market surveillance

- **internal**
- **imported products**

CE *general principles*

Financing elements

Applicable from 1 Jan 2010

Lex Specialis

sectorals/General Product Safety Directive

DECISION

Definitions / obligations

Notification (criteria / process / accreditation)

Conformity assessment procedures

Safeguard mechanisms (& market surveillance)

CE *marking*

Basis for future legislation

Regulation & Decision

REGULATION

Covers elements not included in sectoral legislation

Complementary to sectoral legislation

Applicable from 1 January 2010

Rights and obligations for Member States and individuals

DECISION

Covers elements already included in legislation

Sui Generis Decision

- **No direct effects for Member States or individuals**

Better Regulation tool: model Articles

- **“toolbox”**

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Decision 768/2008
Basis for future legislation - Scope

- **Common framework of general principles and reference provisions** for the drawing up of EU legislation harmonising product-related requirements

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Decision 768/2008
Basis for future legislation - Scope

- **However,** EU legislation may depart from such general principles and reference provisions if that is appropriate on account of the **specificities of the sector concerned**, especially if comprehensive legal systems are already in place
  - **Indicative list in recital 5 of the preamble to Decision 768/2008:**
    - **Recourse to other regulatory solutions**: feed and food, cosmetics, tobacco products, common market organisations for agricultural products, plant health and plant protection, human blood and tissues, medicinal products for human and veterinary use, chemicals
    - **Sectoral adaptations**: medical devices, construction products, marine equipment

Core WTO obligations on the design and choice of conformity assessment procedures

Art. 5.1.2 TBT Agreement

"*conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. […] [They] shall not be more strict than is necessary to give the importing Member adequate confidence that products conform with applicable technical regulations or standards, taking into account of the risks non-conformity would create*

Art. 5.4 TBT Agreement - *Use of relevant internatonal guides or recommendations*

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The EU conformity assessment system

Key features

- **Risk-based approach**
  - consideration of risks of products in relation to their intended use

- **Common selection criteria – One policy**
  - *Better consistency and coherence within a given sector* (e.g. SDoC for electro-technical products under different regulations – safey, EMC, radio and telecom equipment, RoHS)

The EU conformity assessment system

Key features

- **Modular approach fully transposing the ISO CASCO toolbox**
  - When third-party assessment is required, an alternative usually given between product verification and quality assurance modules
- **Preference to 1st party SDoC for low to medium risk products**
  - Free choice of laboratories (including in-house labs)

The EU conformity assessment system

Key features

- **Options for conformity assessment subject to full impact assessment**
  - ➢ Full application of Good Regulatory Practice principles
- **Clear separation of roles** between regulators, standardisers, accreditors, conformity assessment bodies and market surveillance authorities

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The EU conformity assessment system

Decision 768/2008

- **Modernise conformity assessment modules** initially set out in Council Decision 93/465/EEC, also in light of relevant ISO/IEC standards (17000 series) and guides
  - **Implement ISO CASCO Toolbox**

- **Choice of clear, transparent and coherent conformity assessment procedures, restricting the possible variants**

The EU conformity assessment system

Decision 768/2008

- **Menu of modules**, enabling the legislator to choose a procedure from the least to the most stringent, in **proportion to the level of risk involved and the level of safety required**

- **Avoid creating unnecessary burdens for economic operators**
  - ⇒ choice of appropriate conformity assessment procedure based on a regulatory impact assessment (=> more detailed and coherent selection criteria)
  - ⇒ special attention to SMEs' situation

Criteria for the choice of the most appropriate conformity assessment procedure

- **Type of product and economic infrastructure of sector**
  - Product characteristics and technology involved (mature vs new, simple vs complex design and technology, type and size of manufacturers, mass/serial production vs custom-made products)

- **Nature, type and degree of risk associated with the product**
  - ➢ in relation to the intended use of the product and the required level of protection of the relevant public interest (e.g. health, safety, environment, consumer protection)

Criteria for the choice of the most appropriate conformity assessment procedure

- **Where 3rd party assessment is mandatory**
  - Manufacturers should be given the choice, whenever possible, between product verification and quality assurance

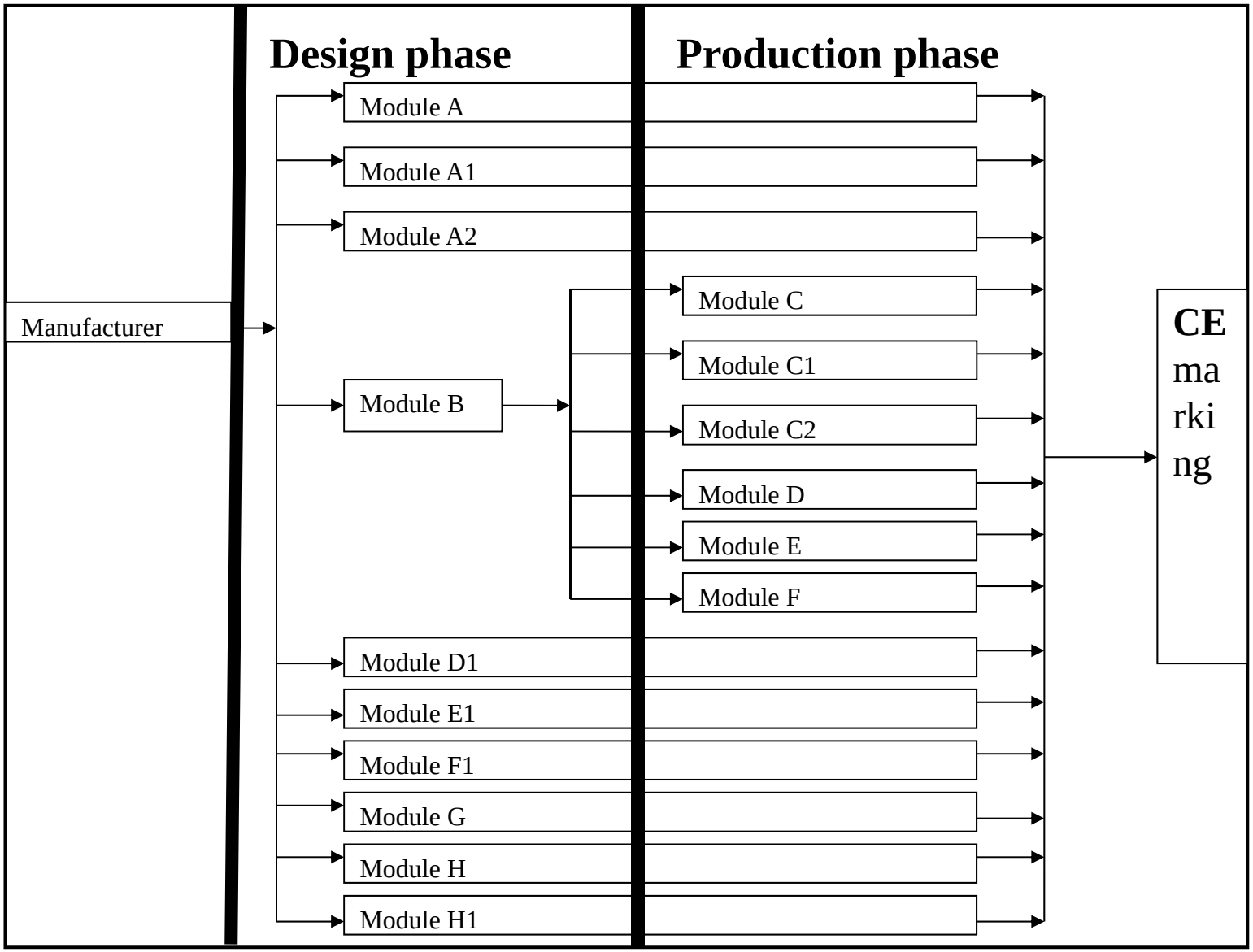
- **Principle of proprtionality - Avoid too burdensome modules in relation to the risks involved**

The basic Modules (the ISO CASCO toolbox)

- A Internal production control
- B EC type examination
- C Conformity to type
- D Production quality assurance
- E Product quality assurance
- F Product verification
- G Unit verification
- H Full quality assurance

The basic Modules (the ISO CASCO toolbox)

- **8 basic module**s (with some variants in some cases within a module)
- **Range of options** given to manufacturers **set in individual regulations**
- From a regulator's perspective, all procedures are deemed to lead to **equivalent results** in terms of product / system conformity


Design phase
Production phase
Manufacturer
Module A
Module A1
Module A2
Module B
Module C
Module C1
Module C2
Module D
Module E
Module F
Module D1
Module E1
Module F1
Module G
Module H
Module H1
CE marking

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Market Surveillance
Basic Principles

- **Responsibility of Members States**
- **Public authority activity**
- **Coordination role for the European Commission**

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Market Surveillance
Basic Principles

- **Objectives:**
  - **Ensure that only compliant products are on the market**
    - Even level of protection for consumers and users across the EU
    - Contribute to confidence in the market
  - **Guarantee a level-playing field for economic operators**

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SDoC – Selection criteria

- **Level of risk** (SdoC to be preferred for low risk products) **+ level of protection**
- **Known / unknown technology - Availability of standards**
- **Industrial infrastructure** (coherence within a sector (e.g. electro-technical sector) + SME friendly)

SDoC – Selection criteria

- **Availability of indipendent testing laboratories**
- **Effective enforcement** by public authorities (=> post-market surveillance), including **customs controls** on imported products
- **Adequate product liability regime**

SDoC – Examples of sectors

- Low voltage electrical / electronic products (safety)
- Radio and telecommunications (safety + EMC)
- Electromagnetic compatibility
- Electrical and electronic equipment subject to the RoHS (Restriction of Hazardous Substance Directive)
- Products subject to eco-design requirements
- Machinery (for certain types, only if harmonised standards are applied)
- Toys (if harmonised standards are applied)
- Recreational Craft (most categories)
- Medical devices (some categories)
- Personal Protective Equipment (some categories)
- Pressure equipment (some categories)

Overall assessment of SDoC

- **Satisfactory level of compliance** in sectors covered by SDoC in the EU
- Experience shows that **non-compliance tends to concentrate in relatively well-defined areas**
- Therefore, **market surveillance intensifies on some critical product families** of concern based on risk assessment techniques, including reinforced controls at the EU external border

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Overall assessment of SDoC

- **Effective post-market surveillance** acts as a deterrent, restores the level-laying field and rewards serious manufacturers
- **Efficient allocation of resources** between pre-market and post-market controls for optimal results in terms of enhanced product safety

Conclusions – Lessons learned

- EU experience shows that it is possible to attain a **high level of health, safety, environmental protection** whilst ensuring a **fair balance between pre-market and post-market controls**

- **Use Good Regulatory Practice principles and tools** (=> regulatory impact assessments) not only to determine the **need for regulation** but also in the **choice of conformity assessment procedures**

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Conclusions – Lessons learned

- Any type of conformity assessment procedure requires an **adequate level of post-market surveillance**

- Aim at an **efficient allocation of (private and public) resources** based on risk assessment and risk management considerations

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Links

- DG Enterprise Single Market for Goods
  - http://ec.europa.eu/enterprise/policies/single-market-goods/index_en.htm

- CE Marking
  - http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/