EUROPEAN POLICIES ENCOURAGING REGULATORY USE OF VOLUNTARY STANDARDS AND CONFORMITY MECHANISMS

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POLITICAL AND LEGAL CONTEXT

Reliance on voluntary “private sector standards” in support of EU legislation has, since 1973 (adoption of the Low Voltage Directive), been part of EU policies.

Use of European standards to support:

= “New Approach” legislation and other legislation;

= European policies (e.g. e-inclusion, sustainable industrial policy);

= public procurement (Directive 2004/18/EC)

POLITICAL AND LEGAL CONTEXT

“NEW APPROACH” METHODOLOGY:

= concept elaborated in 1985 by the European Commission and endorsed by the Council and the European Parliament

= European legislation in given areas, whilst harmonising market access for the EU Internal Market, limits itself to essential protection requirements (health, safety, consumer protection, environment, interoperability);

= European voluntary standards provide for the technical expression of the legal requirements

POLITICAL AND LEGAL CONTEXT : REFORM OF THE NEW APPROACH (1)

The New Approach has been reformed by the recently adopted internal market Regulatory Package :

* **Decision 768/2008/EC** on a Common framework for the marketing of products (OJ L 218, ,13.8.2008, p. 82)

  = consolidated horizontal framework for the future and the updating of existing sectoral legislation

  = concept relating to the use of voluntary standards has been maintained and confirmed.

POLITICAL AND LEGAL CONTEXT : REFORM OF THE NEW APPROACH (2)

* **Regulation (EC) Nr. 765/2008** setting out the requirements for accreditation and market surveillance relating to the marketing of products.
(OJ L 218, 13.8.2008, p. 30).

ROLE OF EUROPEAN HARMONISED STANDARDS IN SUPPORT OF EU LEGISLATION (NEW APPROACH)

At present about 25 sectoral pieces of legislation provide for an explicit reference to and mechanisms for the use of European standards.

The use of “harmonised standards” remains entirely voluntary.

Manufacturers may deviate from “harmonised standards” and use other specifications, provided that other specifications are appropriate to establish compliance with the legal requirements.

ROLE OF EUROPEAN HARMONISED STANDARDS IN SUPPORT OF EU LEGISLATION (NEW APPROACH)

PRESUMPTION OF CONFORMITY

* Member States shall presume that products in conformity with harmonised standards are in conformity with relevant requirements set out in the legislation (see Article 3(2) of Decision 768/2008/EC)

Member State = national enforcement authorities, Notified Bodies

* The presumption of conformity facilitates the manufacturer's task of establishing compliance with the legislation. Compliance with standards, if applied, should be documented in the manufacturer's technical documentation.

WHICH STANDARDS MAY BE USED IN SUPPORT OF NEW APPROACH LEGISLATION?

Concept of “harmonised standards”

Legal definition in Decision 768/2008/EC (Annex I, Article R1(9)):

= standard to be adopted by CEN, CENELEC or ETSI

= adopted on the basis of a standardisation request (=mandate) from the Commission to CEN, CENELEC, ETSI

= references of adopted standards are published by the Commission in the Official Journal (see http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist.html)

WHICH STANDARDS MAY BE USED IN SUPPORT OF NEW APPROACH LEGISLATION?

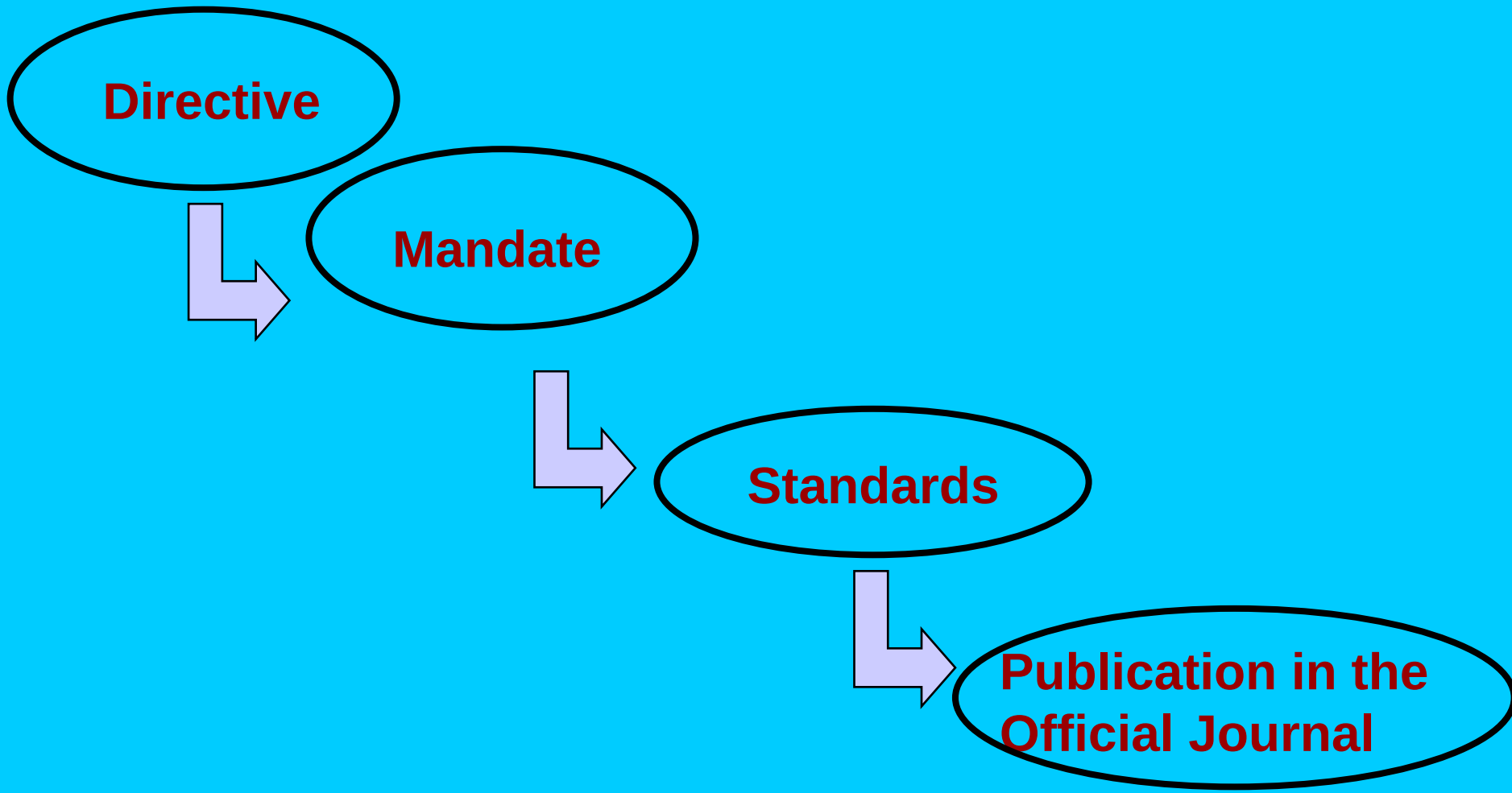
STANDARDISATION MANDATES

Invitation to CEN, CENELEC, ETSI and terms of reference for the elaboration of European standards. Mandates are available at:

http://ec.europa.eu/enterprise/standards_policy/mandates/index.htm

Except in the case of specific problems (rare!), the Commission does not interfere with the elaboration of technical solutions by the standards bodies

LEGISLATION AND NORMATIVE PROCESSES



WHICH STANDARDS MAY BE USED IN SUPPORT OF NEW APPROACH LEGISLTION?

European standardisation bodies – through an agreement between the Commission and EFTA – are committed to develop European standards in accordance with the standardisation principles:

= transparency,
= openness,
= impartiality,
= consensus,
= effectiveness,
= relevance,
= coherence.

Industrial sectors under the ‘New Approach’

	Harmonised standards
Low voltage electrical products	1099
Pressure vessels	255
Toys	20
Construction products	522
Machinery	817
Personal Protective Equipment	350
Medical devices	245
Gas appliances	154
Lifts	22
Cableway installations	25
Consumer products	43

WHICH STANDARDS MAY BE USED?

Use of mandated standards in support of other (than New Approach) legislation.

Examples:

= interoperability of railway systems,

= airworthiness,

= electronic communications,

= groundwater framework directive,

= biofuels,

= energy performance of buildings,

= general product safety directive (“consumer goods”)

For more information, please visit http://ec.europa.eu/enterprise/standards_policy/index_en.htm

In total, there are about 5000 European standards that can be used in support of European legislation.

RELIANCE ON INTERNATIONAL STANDARDS

EU is committed to make use, wherever possible, of international standards adopted by ISO, IEC, ITU to be uniformly transposed into European standards.

The Vienna Agreement (ISO-CEN) and the Dresden Agreement (IEC-CENELEC) have proven to be successful instruments to make increasing use of international standards.

The European standards bodies are encouraged to develop, wherever possible, relevant standards for regulatory needs at international level and to have them transposed as European standards in parallel.

RELEVANCE OF INTERNATIONAL STANDARDS

ILLUSTRATIVE CASE OF MEDICAL DEVICES (1)

* For electro-medical devices the IEC 601 standards have been used as the European harmonised standards from the outset of European medical devices legislation.

* In the non-electrical area, in addition to ISO activities, CEN has adopted a first set of mainly horizontal standards (risk assessment, quality systems, clinical evaluations).

RELEVANCE OF INTERNATIONAL STANDARDS

ILLUSTRATIVE CASE OF MEDICAL DEVICES (2)

* Thanks to the Vienna agreement, the second generation of these standards has been processed at ISO level.

Examples:

* quality systems : EN 46000 → EN ISO 13485, 13488
* risk analysis, management : EN 1441 → EN ISO 14971
* clinical investigations : EN 540 → ISO 14155
* sterile barriers : EN 868 → ISO 11607

ILLUSTRATIVE CASE OF MEDICAL DEVICES (3)

* The existence of an international regulatory cooperation at regulatory and private sector level (Global Harmonisation Task Force) and the involvement of ISO have been essential for the successful trend towards international harmonisation.

CONCLUSIONS (1)

* Thanks to a horizontal European standardisation policy committed on the use of standards in support of regulation, the implementation of this policy in numerous pieces of sectoral legislation has been successful.

* The role of regulators and standardisers and the mechanisms of interface between both are clearly defined. There is in general no confusion of responsibilities.

* Public interests (protection of health) can be well aligned with the private sector needs, whilst relying on voluntary standards.

CONCLUSIONS (2)

* Reliance on voluntary standards in support of legislation is instrumental in putting in place innovation-friendly regulation

* The approach is open to international harmonisation.

IMPORTANT INTERNET SITES TO REMEMBER

DG Enterprise	http://ec.europa.eu/enterprise/index_.en.htm
Harmonised standards	http://ec.europa.eu/enterprise/standards_policy/links/index.html
Medical devices	http://ec.europa.eu/enterprise/medical_devices/index_en.htm