



Impact of Voluntary Standards in the European Union

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Standards in the European Union:

- Pre-1980 less than 2,000 European Standards
- Typical National Standards Development Organisation (SDO) produced 90-95% home-grown national standards
- Only 5-10% International or European Standards
- Today there are over 15,000 European Standards
- Only 5-10% of a typical National SDO's production is made up of home-grown national standards
- 90-95% are European or International standards
- European or International standards
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Legal Status of Standards

- New Approach – use of Harmonized European Standard confers a rebuttable presumption of conformity with legal requirements
- Harmonized European Standard must have reference published in Official Journal – around 30% of all European Standards are “harmonized”
- Same approach now adopted in General Product Safety Directive

How is the quality of Harmonised European standards controlled?

- Essential Safety Requirements
- Standardisation Mandates
- Horizontal and Risk-based Approaches
- Stakeholder Participation
- Safeguard Clause

Challenge for the Future – the international level

- Growing demand for international standards
- Co-operation agreements between European and International Bodies
- European standards work can be passed up to the international level
- 75% of European electro-technical standards are substantially the same as international standards and
- 40% of other European standards

Controlling the Quality of International Standards

- The same checks and balances are not in place at the international level
- There is less governmental involvement and influence
- A horizontal risk-based approach is not so well developed
- Some stakeholder groups are less well represented in the process
- Review by WTO in Dispute Panels trade-focussed

Conclusions

- Europe demonstrates harmonisation can take place without compromising safety
- Need checks and balances in the system
- Regulator has to be able to intervene as and when necessary - does NOT have to intervene systematically – “management by exception”
- Direct stakeholder involvement is very important and needs to be adequately resourced
- Horizontal risk-based approach is very important
- How to increase confidence in International standardisation is the next challenge