"New Approach" legislation system

Parties involved, their responsibilities and interaction

Current challenges

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The pressure sector in a nutshell

- 65 billion € market in Europe
- Covering a wide variety of products
- Traditionally a heavily regulated area
- Developed at national level
- Dating back from the Industrial Revolution
- Deeply rooted national codes
- Related to worker and consumer safety
- A technically complex areas
- In which the recent European regulation seems to disturb a well-established order at global level…

A challenging environment, Stakeholders get apparently easily excited…..

- *"this document is inaccurate, bureaucratic and wholly unjustified….”*
- *“It makes an already difficult situation infinitely worse…”*
- *“it is the most blatant hijacking of the PED I have ever witnessed”*
- *“…the shining creations of the European Commission. This offshore body……”*
- *“The latest example of Euro-idiocy. It concerns the PED”*
- *“Proposed PED guideline change is ludicrous”*

Community Involvement in Pressure Equipment

- Common market regulatory framework, implemented through national administrations, based on the **New Approach**
- Trade issues
- Competitiveness of industry
- Research and Development

Basic Features of New Approach

- Definition of essential requirements, allowing for innovation and technological flexibility
- Access to Community market
- European standards giving presumption of conformity
- Conformity to be established with essential requirements
- Variety of conformity assessment procedures, related to risks involved
- Manufacturer responsible for placing on the market and CE marking of products
- Variety intervention mechanisms for authorities, who remain responsible for safety on the market

Why is the New Approach "New" ?

- Regulates risks, and not products: more risk related directives will apply to the same product
- Regulation based on risk management instead of technical solutions
- Regulation requires manufacturers to constantly improve products in order to reflect "state of the art"
- A stable regulatory environment with evolving compliance requirements
- Competitiveness is a specific objective of regulation
- Regulation introduces a wide flexibility for manufacturers, in choice of technological means and conformity assessment

Why is the New Approach "New" ?

- Use of European standards giving presumption of conformity; use of ENs is voluntary
- Authorities accept that conformity acceptance can be carried out on their behalf by independent bodies
- Conformity Assessment Procedures reflect risk categories
- Manufacturers can call upon any NB throughout the Union
- Conformity assessment covers always design and production
- Basic choice between product or quality assurance route
- Manufacturer takes full responsibility for affixing CE marking

The relation between Manufacturer and authorities

- The Directive leaves an important responsibility to manufacturers and Notified Bodies, in particular as there is no prior market approval mechanism
- At the same time, in order to allow Member States to assume their responsibility for public safety, it defines authorities' responsibilities and creates various intervention mechanisms

Who is, under the New Approach, the manufacture ?

- The person who is responsible for designing and manufacturing a product, with a view to placing it on the Community market, on his own behalf.
- He has an obligation to ensure that a product intended to be placed on the Community market is designed and manufactured, and its conformity assessed, to the essential requirements in accordance with the provisions of the applicable New Approach directives.
- He may use finished products, ready-made parts or components, or may subcontract these tasks. However, he must always retain the overall control and have the necessary competence to take the responsibility for the product

Who is the authorized representative ?

- Any natural or legal person appointed by the manufacturer to act on his behalf
- Must be established inside the Community.
- May be addressed by the authorities of the Member States instead of the manufacturer with regard to the latter's obligations under the New Approach directive in question.
- The manufacturer remains generally responsible for actions carried out by an authorised representative on his behalf.

"Intervention" mechanisms for authorities

- Overall responsibility for ensuring proper implementation
- Appointment and monitoring of notified bodies
- recognized third party organisation, user inspectorates
- Market surveillance; Verification of documents kept by the manufacturer
- Wrongly affixed CE marking
- Safeguard clause
- Formal objection to standards
- Reclassification
- EAM
- Requirement for national languages

Main challenges for the New Appraoch

- How to implement in a coherent way a common legal framework through 25 different national administrations ?
- How to ensure consistent safety levels between Member States ?
- How to ensure consistent conformity assessment and market surveillance ?
- How to build trust and confidence ?

Coherence in interpretation and implementation

- Standards
- Guidance documents developed by WGP
- Other technical documents, e.g. ASME
- Guidance of a general nature, such as Blue Guide
- Participation in Working Groups
- Notified Bodies Forum and NB Recommendations
- WGA: Working Group Administrative Cooperation

Conformity Assessment

- Coherent and consistent implementation of the modules
- Designation and monitoring of Notified Bodies
- Role of designation authorities
- Exchange of information between authorities and Notified Bodies at European level
- WGA: Working Group Administrative Cooperation
- Notified Bodies Forum

Market Surveillance

- Availability of sufficient human and financial resources at national level
- Data analysis and strategic market surveillance
- Proper enforcement policy
- Exchange of information and communication protocols
- Mutual assistance and cross border activities
- WGA: Working Group Administrative Cooperation

What is the role of the Commission if the Directive always refers to Member States:

- Member States shall take all appropriate measures….
- Member States shall not …….
- Member States shall regard…….
- Member States shall ensure……
- Where a Member State ascertains…
- ….The matter shall be referred to the competent authority……
- Member States shall inform ……
- Where a Member State considers…
- Member States may authorize…..
- Member States shall notify…..
- Member States may require……etc

Role of the Commission

- Ensure correct implementation

  e.g. organize coordination, guidance, infringement procedures, complaints handling
- Formulate recommendations and deliver opinions

  e.g. instruction of safeguard clause
- Power of decision and participate in shaping measures by Council and Parliament

  e.g. modifications of legal framework
- Exercise powers delegated by Council

  In PED, reclassification and report SPV-PED

Coordination

Various tools are available:

- WGP, WPG, WPM, MPG
- Guidelines, tutorials
- NB Forum and NB Recommendations
- WGA Working Group Administrative Cooperation
- PED website

Informal process and don't hesitate to

- contact the Commission
- call one of your colleagues in other countries
- raise issues in the various working groups

Control of proper implementation

- Verification of timely transposition
- Complaints and own Commission initiative
- Verification of the use of the safeguard clause
- Formal Communication on how we expect Directives to be applied
- Interface between Community and national legislation