The role of Standards in EU supply legislation and practical ways they can support Current Best Practice at the Machinery Design Stage

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Session objectives

To cover as an overview:

- A little of how the HSE operate in the UK
- European New Approach legislation and the Machinery Directive
- What is meant by "state of the art"
- Role of harmonised standards and their limitations
- Interface with Use of Work Equipment Directive
- Answer (or try to!) any questions
Split GB into 5 regions

1. Scotland
2. Northern (NW + Y&NE)
3. Midlands
4. Wales and South West
5. Southern (London + E&SE)
Market Surveillance of industrial products in UK

- In UK Integrated with use and user inspection
  - they see lots of new and old equipment in use
  - defects can be hard to spot until seen in use
  - quick safety and CE check - speak to workforce
  - if problems are suggested a full investigation is made by the Product Safety Team

- Safety Unit have the operational policy lead on both product safety and the use of work equipment, we advise on the legislation application to inspectors and industry.

- Safety Unit, working with BIS, sit on the EU Machinery WG; ADCO; MACHEX Group
Basic Features of the New Approach to legislation

• Set Essential Requirements (e.g. in the Machinery Directive) which don’t get out of date

• Details of how to comply left to Harmonized standards that give a presumption of conformity

• Allow manufacturers to use their own approach, but it must reach the level of risk reduction in the Standard

• Government intervention limited to what is essential
AN IMPORTANT GOAL OF THE EU NEW APPROACH IS

An Internal Market with free movement of goods
The EU approach to setting up its market

Harmonized Standards instead of Authority Intervention

European Standards are adopted

• Voluntarily

• Covering a broad range of interests

• With a transparent consensus procedure

• Can be updated to the actual state of the art

• Listed in the OJ if they meet the EHSRs of the Directive concerned
“State of the ART”

- EHSRs as worded strictly, but are qualified by:

  The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.

- State of the art: best technology that can be economically applied in the industrial sector concerned

- Machinery may still be compliant if it does not fully meet all EHSRs, provided it is the current state of the art. This will be indicated in the harmonised Standard for that product
The EU approach to setting up its market

Presumption of Conformity of Standards

• Only Harmonised Standards that cover all the essential health and safety requirements can give a full presumption of conformity.

• You need to check Annex Zb of the Standard to check if some risks are not covered.

• They must be listed in the EU Official Journal.

<table>
<thead>
<tr>
<th>ESO</th>
<th>Reference and title of the harmonised standard (and reference document)</th>
<th>First publication OJ</th>
<th>Reference of superseded standard</th>
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<tbody>
<tr>
<td>CEN</td>
<td>EN 201:2009 Plastics and rubber machines - Injection moulding machines - Safety requirements</td>
<td>18/12/2009</td>
<td></td>
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Use of Work Equipment Directive - 2009/104/EC

- Overlap with Machinery Directive (2006/42/EC)
  - Article 4(1)a ... the employer shall obtain and use work equipment which ... complies with... the provisions of any relevant Community directive which is applicable;
  
- This is also addressed in Machinery Directive Article 15:
  - This Directive shall not affect Member States' entitlement to lay down ... requirements ... to ensure ... workers, are protected ... provided that this does not mean that such machinery is modified in a way not specified in this Directive.

- If a Standard is OJ listed there is a presumption that any machine built to the Standard is compliant. Therefore a National Authority cannot take action to require modification to the machine without a Safeguard Action
A CE marked product carries a “presumption of conformity” to all applicable Directives.

However - if an authority finds a product is non-compliant because of a defective harmonised standard, it can restrict or stop its sale, but must inform the EU Commission who will investigate.

If the Commission agree, all Member States are notified and are expected to take similar action to restrict the product.

The Standard’s presumption of conformity will be withdrawn of limited...
The EU “Safeguard Action” procedure

1. Verification testing
2. Notification Dialogue (appeal) Action
3. Notification
4. Dialogue
5. Opinion Implicit (e.g. LVD) or explicit (e.g. Machinery)
6. Action

- National Authority
- Commission
- CEN CENELEC
- Manufacturer
- Notified Body
- Modification to Standard OJ listing

Report
The EU Standardisation System

• **DIRECTIVE 98/34/EC – recital 24:**
  - the European standardisation system must be organised by and for the parties concerned, on a basis of coherence, transparency, openness, consensus, independence of special interests, efficiency and decision-making based on national representation

• So: manufacturers; using companies, workers (consumers) and enforcing authorities should be actively involved in the process

• Any imbalance may result in a poor or defective standard, e.g. if dominated by manufacturers

• Balance can be difficult under the Vienna agreement as Standards are negotiated in the ISO arena
The EU Standardisation System

From a slide by Stefano Boy, ETUI
Most Machinery Standards undergo a 5yr review cycle

If a significant limited update is needed a quick update can be made via the UAP – i.e. less than one yr (not often used)

If a “safeguard action” or objection is made successfully by an Authority there are two possibilities:

- Withdrawal of the listing in the OJ (standard then has no presumption of conformity)
- A modification to Annex Zb and a note placed in the OJ saying one or more of the EHSRs are not covered and so no “presumption of conformity” for these are given

For good standards it can be critical for the industry using the machinery (such as quarrying) to have a sustained input into the standard making process at both national and European levels

The Machinery ADCO is working on a system to get a coordinated input at the European level to present user and authority expertise
EU harmonised standards listed in OJ

EU Commission guidance on the Machinery Directive is on this page of Europa -
http://ec.europa.eu/enterprise/sectors/mechanical/machinery/index_en.htm

Questions ?