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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:

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

HSE's Product Safety System



∅ **Split GB into 5 regions**

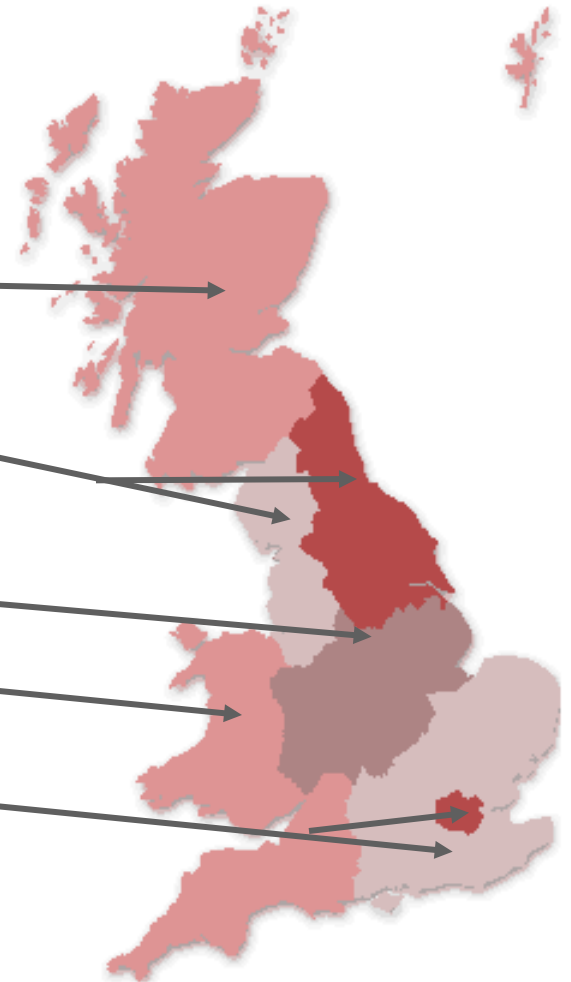
1. Scotland

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- **Set Essential Requirements (e.g. in the Machinery Directive) which don't get out of date**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**

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:

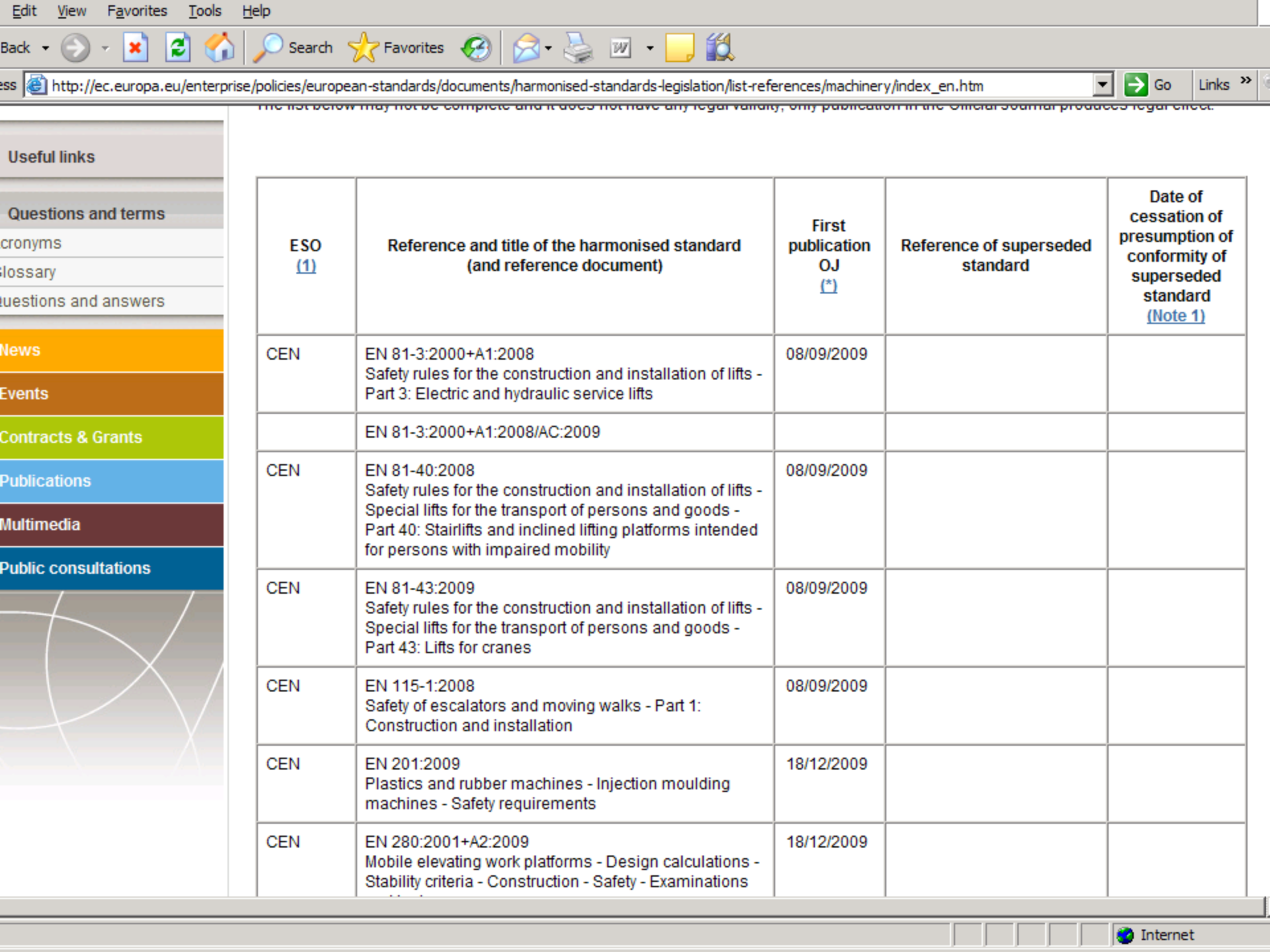
*The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account **the state of the art**, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of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

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**

<http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/>



The list below may not be complete and it does not have any legal validity, only publication in the Official Journal produces legal effect.

- Useful links
- Questions and terms
 - Acronyms
 - Glossary
 - Questions and answers
- News
- Events
- Contracts & Grants
- Publications
- Multimedia
- Public consultations

ESO (1)	Reference and title of the harmonised standard (and reference document)	First publication OJ (*)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN 81-3:2000+A1:2008 Safety rules for the construction and installation of lifts - Part 3: Electric and hydraulic service lifts	08/09/2009		
	EN 81-3:2000+A1:2008/AC:2009			
CEN	EN 81-40:2008 Safety rules for the construction and installation of lifts - Special lifts for the transport of persons and goods - Part 40: Stairlifts and inclined lifting platforms intended for persons with impaired mobility	08/09/2009		
CEN	EN 81-43:2009 Safety rules for the construction and installation of lifts - Special lifts for the transport of persons and goods - Part 43: Lifts for cranes	08/09/2009		
CEN	EN 115-1:2008 Safety of escalators and moving walks - Part 1: Construction and installation	08/09/2009		
CEN	EN 201:2009 Plastics and rubber machines - Injection moulding machines - Safety requirements	18/12/2009		
CEN	EN 280:2001+A2:2009 Mobile elevating work platforms - Design calculations - Stability criteria - Construction - Safety - Examinations	18/12/2009		

Use of Work Equipment Directive - 2009/104/EC

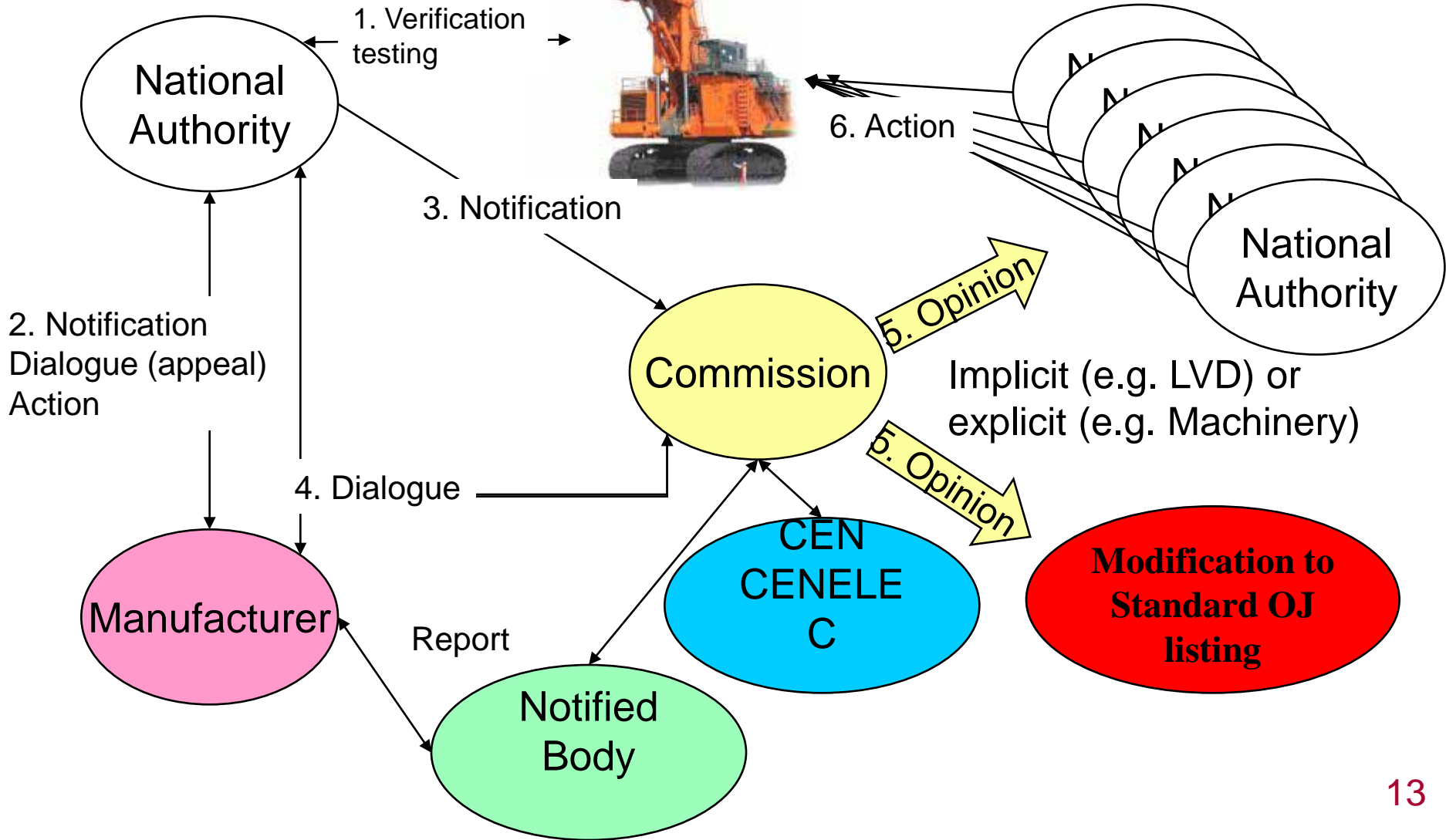


- Ø **Overlap with Machinery Directive (2006/42/EC)**
 - § **Article 4(1)a ... the employer shall obtain and use work equipment which ... complies with... the provisions of any relevant Community directive which is applicable;**
- Ø **This is also addressed in Machinery Directive Article 15:**
 - § **This 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.**
- Ø **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 Action₁**

Market Surveillance Implementation

- Ø **A CE marked product carries a “presumption of conformity” to all applicable Directives**
- Ø **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**
- Ø **If the Commission agree, all Member States are notified and are expected to take similar action to restrict the product**
- Ø **The Standard’s presumption of conformity will be withdrawn or limited**

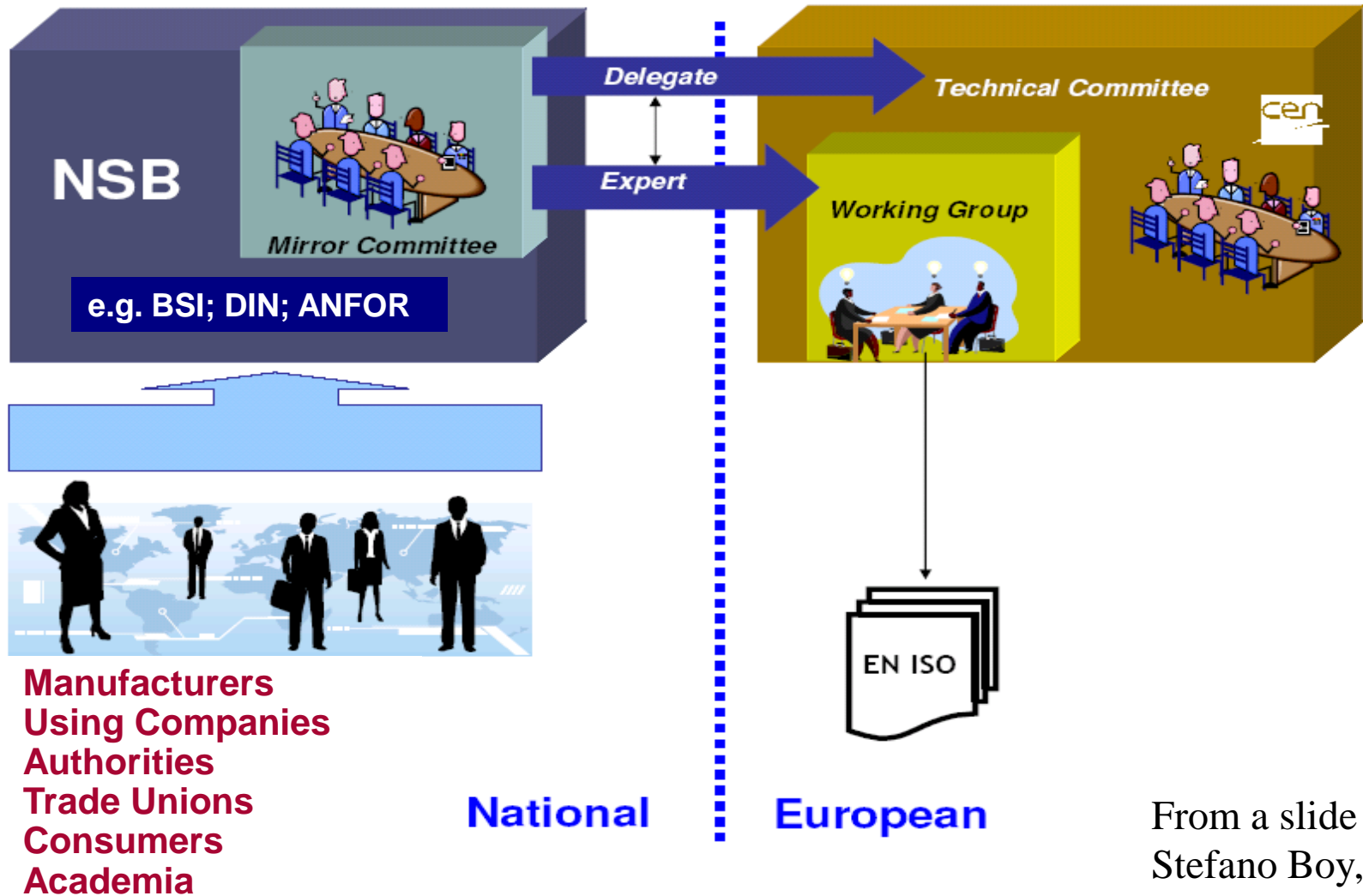
The EU “Safeguard Action” procedure



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

The EU Standardisation System

- ∅ **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

<http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/>

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 ?