Discussion document for EU standardization issues

1. Introduction

The harmonised standards[1] are key documents for the Market Surveillance authorities when carrying out MS activities since they give presumption of conformity.

The purpose of this document is to highlight the main challenges of access to documentation, access to process, and the key issues for market surveillance authorities.

2. Access to and availability of standardisation documents

The following issues of access to adopted standards need to be considered:

- **Awareness**

Through our MS activities we have seen that not all "economic operators" are satisfactorily aware of harmonised standards. There seems to be some basic confusion about the various standards e.g. what is an ISO standard vs. an EN- standard and non-harmonised EN-standard vs. a harmonised EN standard.

The use of a harmonised standard should be straightforward. A harmonised standard should clearly state which other standards are needed for the presumption of conformity.

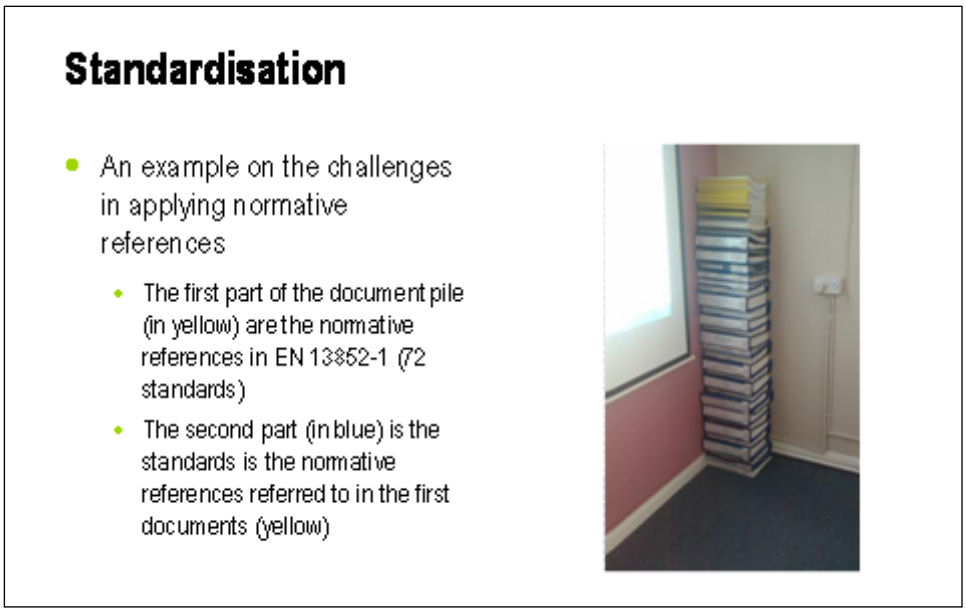
- **Quantity**

When applying a harmonised standard the manufacturer needs to apply a huge number of standards listed in the normative references.

For example one harmonised EN standard refers to many normative standards e.g. 485 references, see picture of the enormity of the task not only in terms of gathering the required information but also the fact of keeping all of the documents updated.

[1] A harmonized standard allows in our view for improved design and production which in turn:

- Presumption of conformity (when published in OJ)
- Facilitates enhanced safety through standard design
- Reduces need for country specific regulations and requirements
- Prevents dangerous / defective products entering the EU market
- Contributes to equal competitive conditions
- Improves transparency and consistency of cross border requirements
- Structured system for shortcomings and amendments (safeguard clause)



Greater clarity and conciseness is needed regarding the use of harmonised standards in order to comply with the basic safety requirements of the Machinery Directive. Hence to what degree can a manufacturer deviate from safety requirements in either the top level standard or cross-references normative standards and still be able to issue a declaration of conformity and attach the CE-marking to a machine?

- **Availability**

We are of the opinion that at least the MS authorities should have easy access to all essential harmonised standards. If we want the "economic operators" to use the EN standards, then they too should have access to them. As harmonised standards are referred to in national regulations, member states should at least evaluate a system to provide standards to the users, which do not cause a major financial burden if many normative standards are involved for safe design and manufacture of a product or machine.

Easy links to the relevant documents should be made available in the document itself.

- **Guidance**

When using the standard, guidance is needed in order to create more user-friendly documents.

For example when a harmonised standard makes reference to a huge number of normative documents the user needs instruction on how to use all the documents and what they relate to.

- **Cost**

Given the financial investment pulled into creating the standards, we have to ensure that they are used effectively and that that the desired outcome is achieved.

Updating all of these references is a cost issue.

As Market Surveillance is in high focus, the least the Market Surveillance authorities should have is easy and free access to all essential harmonised standards.

If we want the "economic operators" to use the EN standards, the member states should provide easy access to the standards without causing a major financial burden.

3. Access to process

Since the harmonised standard is a key document when carrying out Market Surveillance activities it is important that it covers the essential health and safety requirements in a sufficient manner.

From our point of view it is important to have various key players on board during a standardisation process in order to create a good set of standards. As far as we have noticed, the current situation is that the Market Surveillance Authorities are often absent during both the drafting process and during the feedback:

In our view also the regulatory authorities should be present and act their part on the standardisation scene. Being present means:

- Attending important /core CEN/CENELEC TC Committees
- Following up and contributing to as required and monitoring the drafting process
- Being on the standardisation scene in advance and not only when an incident has occurred
- Following up when standards are circulated for comments

In order to be able to participate on the standardisation scene the framework for standards work should be flexible and efficient in order to ease the partaking. For example the Petroleum Safety Authority has cooperated with our national standardisation organisation (Standard Norge) to request CEN to produce a harmonised standard for lifting equipment subject to the Machinery Directive. Through cooperation with our national standardisation organisations and other Market Surveillance authorities we have successfully managed to get CEN to adopt a work item to amend EN 13155 to include non-fixed lifting attachments in this harmonized standard.

However this process was in our view hindered by a criteria *set by CEN/CMC which states that at least 5 member states have to agree to actively participate in addition to more than 6 member states being in agreement to the proposal.*

Originally our proposal did not meet the first of these criteria because only 3 countries agreed to actively participate, see Resolution 231/2009.
However through good cooperation the criteria were met at the CEN TC meeting May 2010 and the work item was adopted, see Resolution 242/2010.

We question the need for 5 countries to take an active part in the drafting process. "Active part" could be redefined to allow for some of the 5 to have a monitoring function / agenda member.
It should be possible for member states / countries to share resources in the drafting process and cooperate in a rational way.

4. Important Issues for market surveillance authorities

4.1 **Template/ Cooperation in standards work**

Increased participation by the Market Surveillance Authorities might reduce the huge number of safeguard clauses and simplify the process and create safer standards. It is however not only a question of being part of the process, but it is also a question of having an effective template for being able to take part in standards work.

Key considerations are:

- The need to establish positive relations
- What kind of competence is needed where,
- Prioritizing and to what extent we can pool our resources.

In order to achieve rationalisation of our resources the various phases of standards work should be put into a template to include amongst others the following:

- Mandate to CEN/CENELEC
- The drafting process
- The national standardisation organisations ask for feedback
- The adopting process
- How to operate the adopted standards?
- Actions when shortcomings are registered?
- Safeguard Clause

Sharing views of focus and angle in the various phases of standards work, e.g. picking up standards of relevance for the offshore sector at the appropriate time, sharing country views on standards out for comments, focus on EU vs. US standards

Clarify cross border EU Harmonised Standardisation exploring the challenges of the use of non EU harmonised standards and create a model for cooperation in standards work

4.2 Lack of / lack of use of harmonised standards

The "new approach directives "do not oblige the manufacturers to use harmonised standards for the conception and the manufacture of products covered by the respective directives. This situation leads some manufacturers to use national or international codes and standards for example API (machinery) and ASME (pressure equipment) whether or not a harmonised standard actually exists.

It is a challenge for the MS authorities to see if the specifications chosen by the manufacturers meet the ESR of the new approach directives.

We need a model for how to carry out a gap analysis between the provisions of the chosen specifications- e.g. API, ASME and the ESR of the directives.

We might raise the focus of the advantages of the use of harmonised standards vs. American standards or other specifications.

Further enquires within areas of concern for example the Pressure equipment area might be useful to get an overview of the current status of the use of harmonised standards vs. other codes and standards.

There might also be a need for a greater number of harmonised standards e.g. where there is a tradition for use of American standards.