

## Standards Notes Spring-Summer 2009

Dear Colleagues, SCE Team Leaders, ODO Team Leaders:

We're pleased to share the latest quarterly/periodic report from CSEU-Brussels on a broad range of standards-related and technical/regulatory developments, that we believe may be of interest to you and help you with your customer service.

In the future, we plan to offer more frequent and timely updates. We'll organize a survey in a couple of months to gather your input/feedback. In the meantime, I hope you find this overview of interest and useful. Feedback is welcome.

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!! Update your Post's Websites!! - Metrics

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### !! UPDATE YOUR WEBSITE!! - UNITS OF MEASUREMENT

The new EU directive was published in the Official Journal on May 7, 2009. The amendment indefinitely extends the use of supplementary units of measurement, such as pounds and inches. By granting this extension, the Commission, Council and European Parliament are effectively removing a barrier to trade which would have seriously hampered transatlantic trade as of January 1, 2010 when the units of measurement directive was supposed to enter into force.<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:114:0010:0013:EN:PDF>

### 1) MEDICAL

**Update on EU Medical Device Regulatory Issues:** The Commission announced that they are not going to work on a proposal recasting the regulatory framework for medical devices until next year. In the meantime, however, they are going to work on "implementing measures" addressing areas that need tightening such as Eudamed (the voluntary registration system), use of e-label, improved vigilance, among others. In addition, the Commission expressed an interest in working with the FDA on Unique Device Identifiers (similar to barcodes).

**Guidance on new directive 2007/47/EC:** the Commission issued an interpretative document clarifying - among others - the entry into force date of the new directive 2007/47/EC. After March 21, 2010, medical devices placed on the market or put into service must conform with the new requirements. Devices already on the market before that date only have to comply with the existing directive 93/42/EC. In addition, the new directive changes classification of some devices and limits the validity of certificates issued by notified bodies to five years. ([http://ec.europa.eu/enterprise/medical\\_devices/guide-stds-directives/transitionalperiod\\_2007-47-EC\\_guidance\\_final.pdf](http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/transitionalperiod_2007-47-EC_guidance_final.pdf))

### Updated lists of harmonized standards:

- Active implantable medical devices: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:041:0009:0012:EN:PDF>
- Medical devices: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:041:0013:0026:EN:PDF>

- In vitro diagnostics: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:041:0027:0029:EN:PDF>, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:095:0008:0012:EN:PDF>  
- Update on common technical specifications for in vitro diagnostics - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:039:0034:0049:EN:PDF>

## **2) AUTOMOTIVE**

- The European Parliament resolution on CARS21 "A competitive automotive regulatory framework" was released: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:041E:0001:0009:EN:PDF>  
- The UN/ECE Regulation #100 on batteries for electric cars was adopted as EU legislation: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:045:0017:0047:EN:PDF>  
- Adoption of regulation on type approval for hydrogen powered vehicles: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:035:0032:0046:EN:PDF>

## **3) CONSTRUCTION PRODUCTS DIRECTIVE ENERGY EFFICIENCY OF BUILDINGS**

The proposed directive amending the existing construction products directive passed the European Parliament. The EP proposed some changes - see website: <http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2008/0098>. The text is now in the Council.

The energy performance of buildings directive is undergoing review. According to the European Parliament, the Commission's target dates for implementation of the proposed new measures are not ambitious enough. The Council, on the other hand, is concerned about the proposed targets as well as the expansion of the scope. It appears unlikely that the text will be adopted in first reading as the Commission, EP and Council now plan to work on a compromise text. To be continued .... (<http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2008/0223>)

## **4) TOY SAFETY**

The new toy safety directive was published in the Official Journal- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:170:0001:0037:EN:PDF>  
The list of harmonized toy safety standards can be downloaded here: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:087:0002:0004:EN:PDF>

## **5) ENERGY USING PRODUCTS**

The document providing an overview of the ongoing work, available on our website, was updated to reflect the adoption of several implementing measures earlier this year (simple set-top boxes, external power supplies, office lighting, public lighting and domestic lighting). The Commission is already drafting guidance to interpret the implementing measures. Test methods will need to be developed by the European standards organizations in order to comply with the targets/limits set in the implementing measures.

[http://www.buyusa.gov/europeanunion/energy\\_using\\_products.html](http://www.buyusa.gov/europeanunion/energy_using_products.html)

## **6) MACHINE SAFETY**

**New requirement for U.S. exporters of Machines:** As of December 2009, when the new machine safety directive goes into force, U.S. exporters of machines will need to identify a person established in the European Union who is authorized to keep the manufacturer's technical file. The person should be no more than a letterbox, a point of contact for the authorities in case of questions about conformity of the machine or accidents. It could be the importer/distributor, a lawyer or any other person. The manufacturer remains responsible for compiling the technical file. The technical file does not have to be physically in the EU but should be rapidly accessible in case of need. We will be updating our existing market research report and provide a short list of representatives who are offering this new service.

List of standards: - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:074:0004:0060:EN:PDF>

## 7) ICT STANDARDIZATION

The Commission's white paper on use of standards in support of ICT was adopted beginning of July. Now it is for industry to respond to the Commission's consultation on the white paper. The deadline is September 15, 2009. The Commission expects that the impact assessment will be done in January 2010, paving the way for the introduction of a "legal package" by mid 2010. Some of the proposed actions are:

- establishment of multi-stakeholders ICT standardization platform
- direct referencing of specifications developed by fora and consortia
- promoting better co-operation between European standards organizations and fora/consortia

Consultation:

[http://ec.europa.eu/enterprise/newsroom/cf/itemlongdetail.cfm?item\\_id=3263&tpa\\_id=133&lang=en](http://ec.europa.eu/enterprise/newsroom/cf/itemlongdetail.cfm?item_id=3263&tpa_id=133&lang=en)

White paper: [http://ec.europa.eu/enterprise/ict/policy/standards/ict\\_index\\_en.htm](http://ec.europa.eu/enterprise/ict/policy/standards/ict_index_en.htm)

## 8) SERVICE STANDARDS

In 2005, the Commission issued a mandate for CEN to identify needs for service standards in support of the single market of services. On 1 July, 2009 CEN released its final report covering a series of feasibility studies (10 vertical, 1 horizontal). It concerns 10 feasibility studies assessing the needs and benefits of standardization in different service fields such as IT outsourcing, recruitment services, among others, as well as consumer related projects such as accessibility services in transport and tourism. The proposed deliverables can vary - CEN workshop agreements, EN or international standards. CEN's next step is the announcement of an action plan which will be made available on their website <http://www.cen.eu/cenorm/sectors/business+development/value/index.asp>.

Other links:

The final report:

<http://www.cen.eu/cenorm/sectors/business+development/value/executivesummaryapril2009.pdf>

Press release: <http://www.cen.eu/cenorm/news/pressreleases/sevicestandardization.asp>

## 9) ENLARGEMENT

According to Commission sources, Croatia - which is lining up to join the European Union - is making good progress with their adoption of EU legislation (the "acquis communautaire"). We also learned that the government of Croatia has made a formal request for an ACAA - an agreement allowing recognition and acceptance of conformity assessment in a number of sectors. It seems that other Balkan countries are considering to negotiate ACAAs. More details about the significance of ACAAs for U.S. exporters will be reported in the near future.

## 10) OTHER

- Amendment to marine equipment directive - <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2009:113:SOM:EN:HTML>
- Directive on non-automatic weighing scales - codified version: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:122:0006:0027:EN:PDF>
- Standard for personal music players: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:161:0038:0039:EN:PDF>
- Measuring instruments and methods of metrological control - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:106:0007:0024:EN:PDF>

Updated lists of harmonized standards:

- electromagnetic compatibility, low voltage, gaseous fuels and personal protective equipment: <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2009:126:SOM:EN:HTML>
- Pressure equipment <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:046:0011:0025:EN:PDF> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:081:0005:0022:EN:PDF>,
- Construction products: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:152:0009:0039:EN:PDF>
- Recreational craft: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:051:0012:0016:EN:PDF>

- Portable fire extinguisher standard: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:040:0033:0034:EN:PDF> and <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:048:0013:0015:EN:PDF>
- General Product Safety directive: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:038:0011:0014:EN:PDF>