An Update on EU Standards and Product Certification

Sylvia Mohr
Standards Specialist,
U.S. Mission to the EU

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Overview of Presentation

- The European Union today
- Market drivers/opportunities
- Product certification and use of standards in key sectors including example
- CS Services, resources and contacts
- Questions?
The European Union Today

- The European Economic Area:
  - The European Union: 27 Member States
  - Plus Norway, Liechtenstein and Iceland
  - Approx. 500 millions consumers
The European Union Today

- First and foremost an economic, monetary and customs union
- Eurozone of 17 countries
- Expanding to include Croatia? Iceland? Turkey?
- Regulatory model promoted outside the EU (trade facilitation agreements)
EU Legislative Process

**Directive**: adapted into national law and implemented by member states. Usually with a transition period.

**Regulation**: text implemented unchanged by member states. Entry into force usually immediate.
Market Drivers/Opportunities

- **Single Market** - comply once for all of the 27 EU markets
- The EU is promoting its **regulatory model** – with candidate countries and other 3rd country markets
- **Green technology** – strict environmental legislation creates market opportunities - energy efficiency, smart grids, e-mobility, green building
- **Public Procurement** – opportunities as a result of the Government Procurement Agreement
Product Certification and Standards in Key Sectors

- **Product safety / consumer protection**
  - 20+ CE marking directives
  - Pharmaceuticals, nutritional supplements, cosmetics

- **Environmental/energy requirements**
  - REACH & CLP, WEEE/RoHS, biocides, Energy Efficiency/ Green Building

- **Horizontal requirements**
  - Data Privacy, IPR, e-commerce, services, government procurement…
Product Safety Directives: CE Marking

- A mandatory label on the product and/or packaging
- A mark of compliance with safety requirements, not a quality mark
- Covering +/- 80% of products on the market
- An EU-wide “passport” for market access
Requiring CE Marking:

- Low Voltage
- Simple Pressure Vessels
- Toys
- Construction Products
- Electromagnetic compatibility
- Personal Protective Equipment

- Non-automatic weighing scales
- Machinery
- Gas appliances
- Medical Devices
- Telecom and radio Terminal Equipment
- Lifts
  - (list is not exhaustive)
REACH & CLP

- **REACH**: The Chemicals Regulation
  - Registration of chemicals with ECHA
  - Authorization and restriction for dangerous chemicals
  - New requirements for MSDS

- **CLP**: Regulation on the Classification, Labeling and Packaging of Chemicals

See our website:
WEEE and RoHS Directives - 1

- **WEEE (Waste Electrical and Electronic Equipment)** Directive aims to limit the amount of electrical waste in landfills.
  - Producers/exporters pay for collection and recycling

- **RoHS (Restriction of Hazardous Substances)** Directive aims to reduce environmental impact of Electrical and Electronic equipment
  - Some heavy metals & flame retardants banned in electrical and electronic equipment
WEEE and RoHS Directives - 2

- Revision of the ROHS directive
  - Successful outcome for US industry
- Revision of the WEEE directive
  - On going
- See our website:
  http://www.buyusa.gov/europeanunion/weee.html
Energy Efficiency and Labeling Directives

- Eco design and energy efficiency at the design stage
- Affects 35 energy using consumer products (dishwashers, chillers, DVD players, lights,....)
- Mostly about setting energy use limits
- Separate legislation for energy efficiency labeling of products and energy performance of buildings
Case Study: an AC Unit

- Low voltage, EMC: CE marking
- Self-certification
- Energy related requirements in the future
- Standards: EN 61000 (harmonics), EN 55014 (emission and immunity) among others
- Other requirements: WEEE and RoHS (depends on use), REACH (choice of refrigerant)

(not exhaustive)
Pharmaceuticals

- Centralized/decentralized market authorization procedures
- Pharmaceutical Legislative Package
  - combating counterfeiting
  - information to patients
  - pharmacovigilance
- Transparency Directive on pricing and reimbursement procedure
Cosmetics

- Directive 76/768 covers:
  - The procedure for placing cosmetics on the EU market
  - Safety requirements
  - Ingredients allowed/ banned
  - Labeling requirements
- New Regulation 1223/2009 (to replace the Directive):
  - Aims to cut red tape and strengthen product safety
  - Introduces a centralized EU notification system, clarifies safety requirements and responsibilities, introduces stricter rules on substances including on the use of nanomaterials in cosmetics
  - Most of the new requirements will apply from July 2013
Nutritional Supplements

- EU has a general law on nutritional substances that covers labeling and approved vitamins & minerals.
- Substances other than vitamins and minerals are still up to member states for approval.
- The Commission is developing limits on substances in nutritional supplements and expanding the scope of the law.
- European Food Safety Agency (EFSA) has key role in evaluating substances in nutritional substances.
Services Directive

- Represents 70% of EU GDP, 90% of all FDI into the EU, 9 out of 10 new jobs

- EU Services Directive:
  - Simplifies regulations
  - Abolishes discrimination based on nationality or residence
Unregulated? Not really ....

- The General Product Safety Directive is the catch-all directive
- Covers furniture, non-electrical sports equipment, child care articles, and more
- Importance of national legislation!
- Use of EN standards
Importance of Standards in EU

- Use of EU (EN) standards is voluntary
- Conformity assessment, or how a manufacturer meets the requirements in the directives, is mandatory
- Unique link between European Norms (EN) and legislation:
  - use of EN (harmonized) standards gives presumption of conformity to EU requirements
  - mandated by the European Commission
  - developed by 3 European Standards Organizations (ESOs) - CEN, CENELEC and ETSI
- UL and other US based standards do not necessarily meet these requirements
Post-Market Surveillance

- Inspection authorities need to have access to technical file (directly or through local representative)
- Penalties are in proportion to the violation
- Surveillance handled differently in different EU member states
- Role of importer /authorized representative strengthened
Success Stories
CSEU Services

- Market research reports
- Strategic advice for exporters
- CSEU Tenders Database support
- Advocacy
- Webinars
- Up-to-date information on our website including business service providers
Exporting to the EU: Be Prepared!

- Monitor what’s going on in the EU
- Pay attention to standards/regulatory requirements
- Participate in pre-legislative fora discussions
- Report trade barriers to U.S. Department of Commerce
- Seek help from Commercial Service
Commercial Service at USEU

- Standards, Conformity Assessment and Certification
  William.Thorn@trade.gov, Sylvia.Mohr@trade.gov

- Market Access & Compliance
  ashley.miller@trade.gov, susana.getman@trade.gov

- REACH, RoHS, Environment, cosmetics, water
  flavie.guerin@trade.gov

- Customs & Tariffs, WEEE
  john.fay@trade.gov

- Smart grid, e-vehicles
  Val.huston@trade.gov

- ICT, medical devices, privacy
  Lucie.Mattera@trade.gov

- Energy Efficiency, automotive, building products
  Sylvia.Mohr@trade.gov

- Government contracts; Defense contracts, EU funding
  Isabelle.maelcamp@trade.gov

- Pharmaceuticals, Nutritional Supplements, Services, Textiles, IPR
  susana.getman@trade.gov

- Fisheries/NOAA
  Stephane.vrignaud@trade.gov
Websites

- Contact the Commercial Service
  - in the US: http://www.buyusa.gov/home/export.html
  - In Brussels, Belgium: www.buyusa.gov/europeanunion

- See also:
  http://ec.europa.eu/enterprise/sectors/index_en.htm
  http://ec.europa.eu/enterprise/newapproach/nando/
  http://www.export.gov/cemark/
Thank you for your attention!