EU Regulatory Requirements and Standards

Sylvia Mohr/Louis Fredricks
Standards Team
U.S. Mission to the European Union
You should know that ....

- 80% of products are covered by mandatory EU legislation ....
- ... and it is not simple to figure out how products are regulated.
Overview of Presentation

- The EU Today
- Key Sectoral Legislation, Importance of Standards and Example
- Market Surveillance
- Do’s and Don’ts
- Trends
- CSEU: Service, Who is Who and Useful Links
The European Union Today

The European Economic Area:

- The European Union: 28 Member States
- Plus Norway, Liechtenstein and Iceland
- Over 500 million consumers
The European Union Today

- First and foremost an economic, monetary and customs union
- Eurozone of 18 countries
- EU expanding to include Serbia? Turkey?
- Regulatory model promoted outside the EU (trade facilitation agreements)
Legislation You Need to Know About

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

- **Environmental/energy requirements**
  - REACH & CLP, WEEE/RoHS, packaging, Energy Efficiency

- **Horizontal requirements**
  - Data Privacy, IPR, e-commerce, services, government procurement...
Importance of Standards in EU

- Compliance with EU legislation is mandatory, use of EU (EN) standards is voluntary

- 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
Example: Cosmetics

- EU Cosmetics law 1223/2009
- Good Manufacturing Practice (GMP) – voluntary standard EN 22716
- Notification by ‘responsible person’
- List of prohibited and restricted ingredients
- Environmental requirements for packaging
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
Do’s and Don’ts

- Be prepared before you go into a market
- Create a checklist: have I addressed safety? Packaging? Metric units?
- Simplify your task – is your supply chain familiar with EU legislation? Can your importer help?
- Verify regularly whether legislation and/or standards are undergoing review
- If in doubt about appropriate classification, don’t rely on one source only, check with others
- Don’t select a test lab until you have compared several quotes/services
- Look into certification while you’re talking to potential importers – don’t wait until the deal is done because certification takes time
Trends

- Energy Efficiency Implementing Measures
- 10 directives aligned with New Legislative Framework (NLF)
- Ongoing:
  - review of EN standards
  - review of medical device legislation
  - review of General Product Safety Directive
CSEU Services

- Market research reports
- Strategic advice for exporters
- Advocacy
- Webinars
- Up-to-date information on our website including business service providers
Who’s Who at USEU
Beryl Blecher, Minister Counselor

- SMEs
  - Patricia.Gonzalez@trade.gov

- IPR, ICT, data privacy
  - Michael.Rogers@trade.gov

- ICT, Data Privacy, WEEE
  - Isabelle.Roccia@trade.gov

- Export Controls/Customs & VAT, Renewable Energy/Government Procurement, Renewable energy and EU Funding
  - Ilona.Shtrom@trade.gov

- REACH, Environment, cosmetics
  - Matthew.Kopetski@trade.gov

- Standards Policy
  - Marianne.Drain@trade.gov

- Medical Devices, Building Products, Product Safety, Energy Efficiency, CE Mark
  - Sylvia.Mohr@trade.gov

- Automotive, CE Mark
  - Louis.Fredricks@trade.gov

- Pharmaceuticals, E-health, Services, Textiles, Nutritional Supplements
  - Susana.Getman@trade.gov

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

- **USG websites:**
  - http://www.export.gov/europeanunion/ and
  - http://www.export.gov/cemark/

- **Commission websites:**
  - http://ec.europa.eu/enterprise/newapproach/nando/ (laboratories)
Thank you for your attention!