



# An Update on EU Standards and Product Certification

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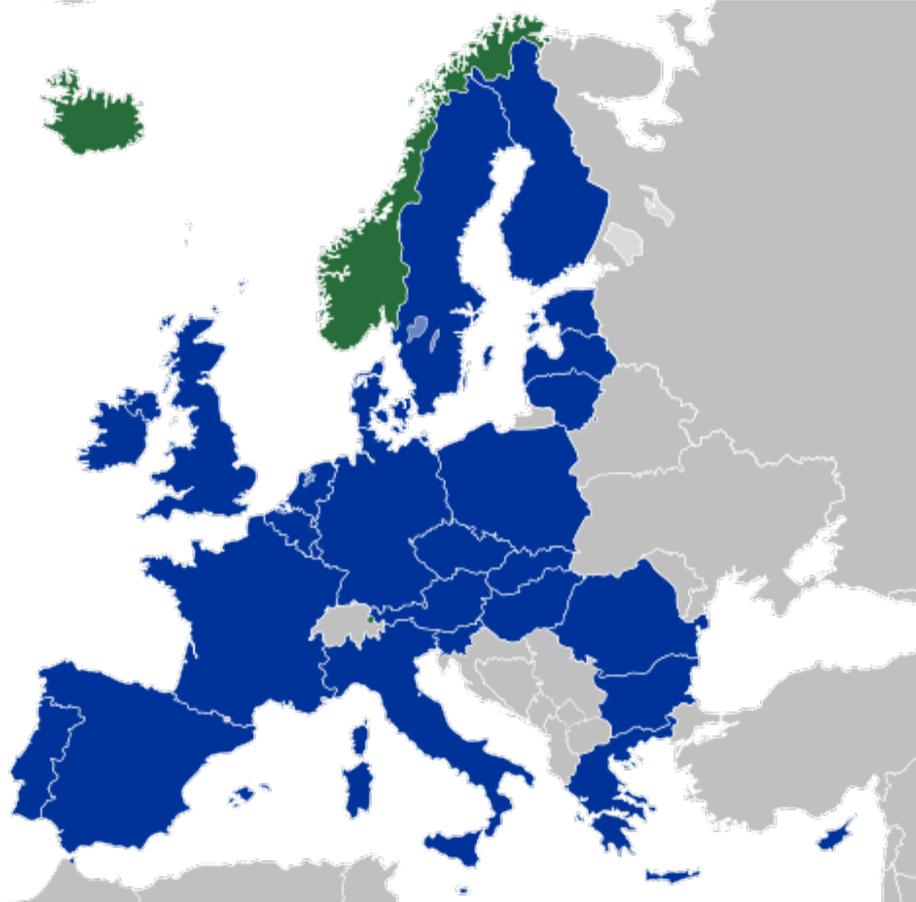


# Overview of Presentation

- 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

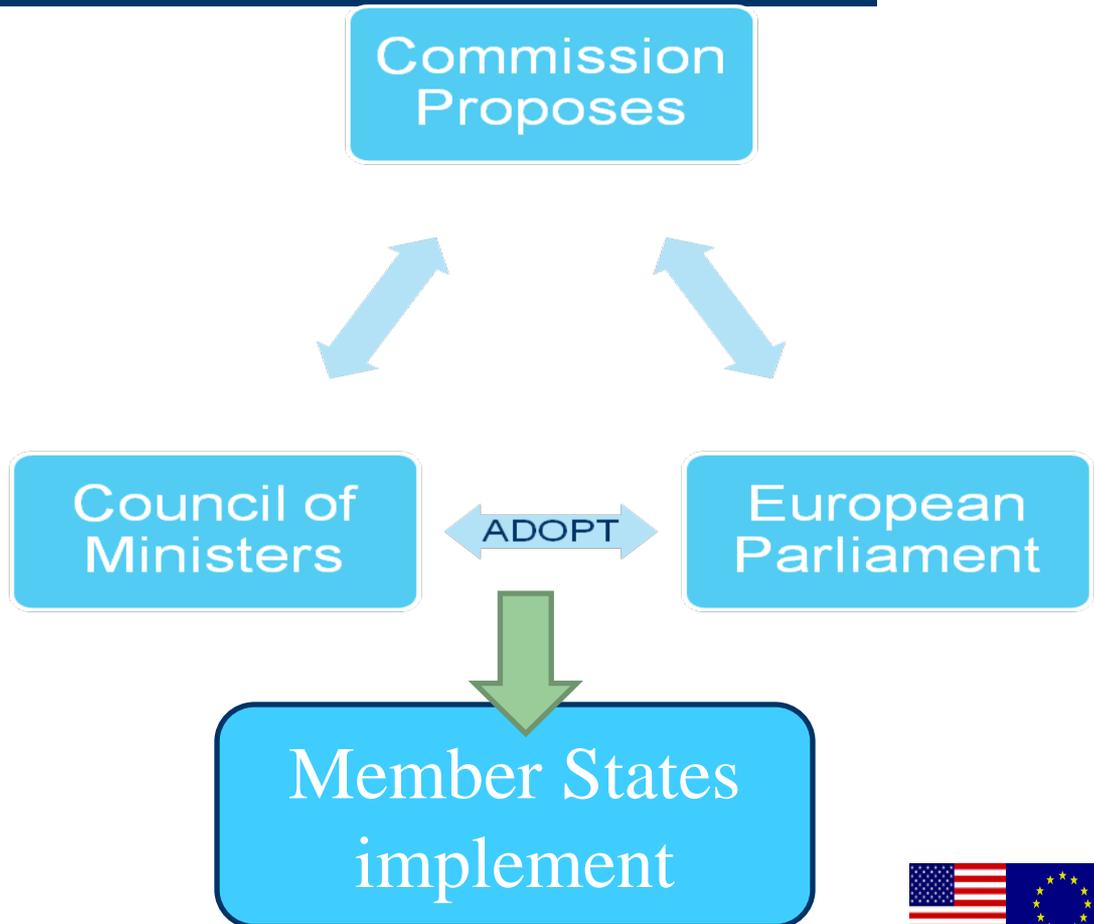
- First and foremost an economic, monetary and customs union
- Eurozone of 17 countries
- Expanding to include Croatia? Iceland? Turkey?
- Regulatory model promoted outside the EU (trade facilitation agreements)



# 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 3<sup>rd</sup> 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



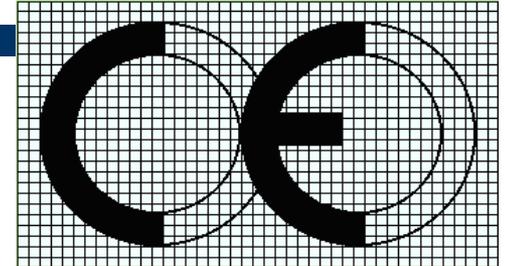
# Product Certification and Standards in Key Sectors

- 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:

<http://www.buyusa.gov/europeanunion/reach.html>



# 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](mailto:William.Thorn@trade.gov),  
[Sylvia.Mohr@trade.gov](mailto:Sylvia.Mohr@trade.gov)
- Market Access & Compliance  
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[susana.getman@trade.gov](mailto:susana.getman@trade.gov)
- REACH, RoHS, Environment, cosmetics, water  
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- Customs & Tariffs, WEEE  
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- Fisheries/NOAA  
[Stephane.vrignaud@trade.gov](mailto: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](http://www.buyusa.gov/europeanunion)

- See also:

[http://ec.europa.eu/enterprise/sectors/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/index_en.htm)

[http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index_en.htm)

<http://ec.europa.eu/enterprise/newapproach/nando/>

<http://www.export.gov/cemark/>





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Thank you for your attention!

