



# EU Product Certification: Agricultural Equipment and Irrigation Technologies

**Louis W. Fredricks**  
**Commercial Assistant**  
**U.S. Mission to the European Union**  
**November 2, 2016**

# Commercial Service European Union (CSEU)

Provide U.S. business with counseling, advocacy and specialized research related to:

- EU technical and legal requirements
- Market access and compliance issues

Policy Hub for  
Commercial Service  
Europe

- Close coordination with colleagues in Washington D.C. and 23 European countries

# Outline



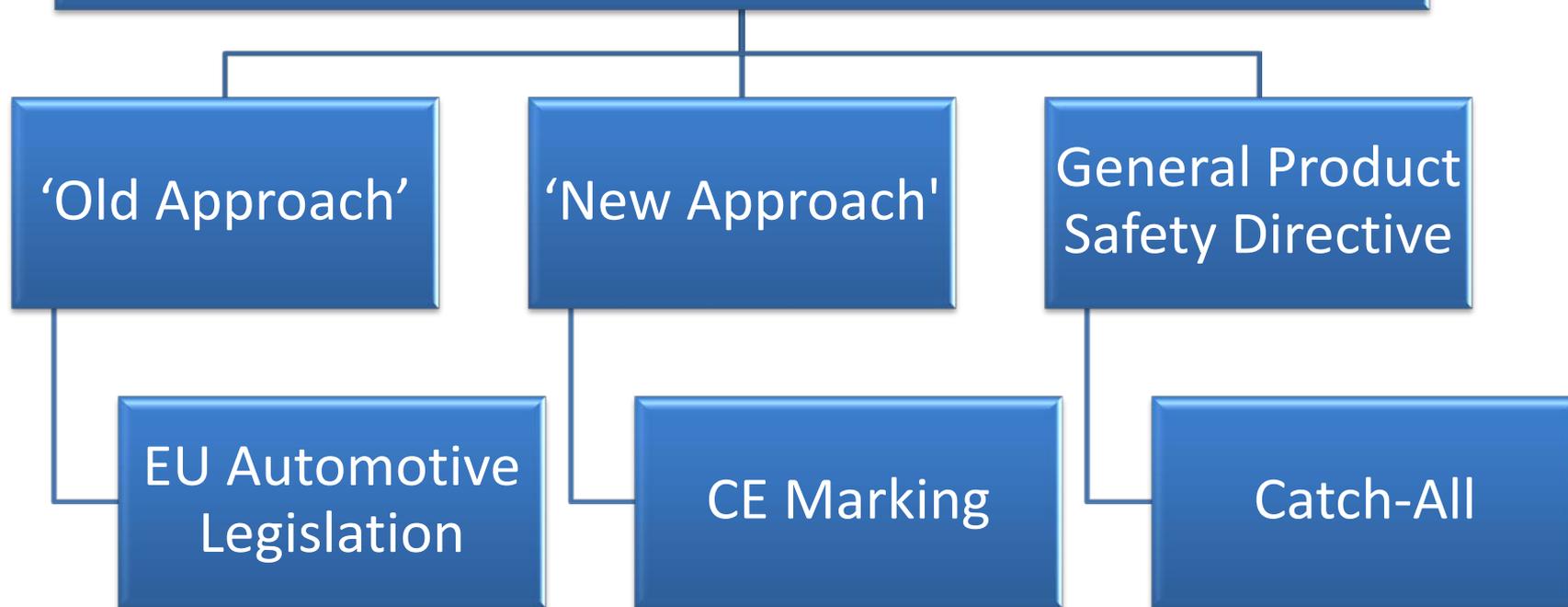
The EU's Regulatory Toolbox

EU Automotive Legislation

Overview of CE Marking

Useful Links

# EU Regulatory Toolbox



## You should know that ....

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



# Legislation in Key Sectors

- Consumer and product safety
  - 20+ CE marking laws
  - Many non-CE marking laws: food, nutritional supplements, cosmetics, tractors (and more)
  - Catch-all legislation: General Product Safety Legislation
- Environmental/energy requirements
  - RoHS, REACH, WEEE, packaging, energy efficiency

# EU Automotive Legislation

- Motor Vehicle Framework Directive (MVFD)
- EU Regulation on two- or three-wheel vehicles and quadricycles
- **Regulation 167/2013 on wheeled agricultural or forestry tractors**
  - Applies to tractors, trailers, and interchangeable towed equipment
  - Applicable as of January 1, 2016, replacing the existing regulation from 2003

# Type Approval Process

Prototype  
submitted for  
approval

Testing

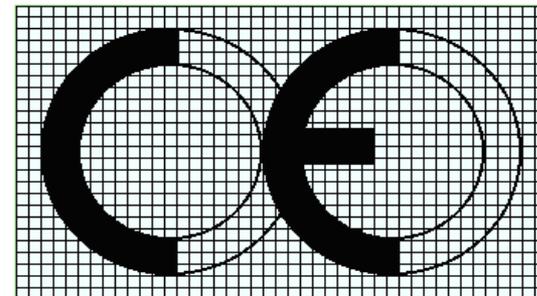
Production  
control

Type approval  
granted for  
placing on the  
market and  
use

Certificate of  
conformity for  
each vehicle  
placed on the  
market

# CE Marking: What does it mean?

- Required by EU law;
- CE originally meant “Conformité européenne”;
- It is a manufacturer’s statement of compliance with “essential requirements” related to safety, health, environment and/or energy efficiency;
- It is not a quality mark.



# Products Requiring CE Marking

- Low Voltage
  - Simple Pressure Vessels
  - Toys
  - **Construction Products**
  - Electromagnetic Compatibility
  - Personal Protective Equipment
  - Hot Water Boilers
  - Recreational Crafts
  - Marine Equipment
  - Lifts
  - Pressure Equipment
  - Measuring instruments
  - Non-automatic Weighing Scales
  - **Machinery**
  - Gas Appliances
  - Active Implantable Medical Devices, IVD, Medical Devices
  - Radio Equipment
  - Civil Explosives
  - Potential Explosive Atmospheres
- (not exhaustive!)

# Products not requiring CE Marking

- Chemicals
- Cosmetics
- Food/Food Contact Material
- Pharmaceuticals
- Cars and car components
- **Tractors**
- Biocides – pesticides
- Textiles
- ....
- General Product Safety Directive:
  - Furniture
  - Child care articles
  - Sports equipment
  - Non-electrical tools
  - Books
  - .....

# Is self-certification an option?

- This is about conformity assessment modules – which module is allowed? What are the choices for manufacturers?
- Rule of thumb:
  - Low risk – self certification
  - Higher risk products – mandatory involvement of notified body
- Modules such as quality system, type examination, etc. explained in
  - Annexes in the directives

# Who can handle testing?

- Depending on the type of product and what the directive stipulates:
  - The manufacturer
  - EU notified body
  - U.S. based subcontractors of EU based notified bodies (UL, ITS, DIN, BSI, ...)
  - Official conformity assessment bodies in the U.S. (few sectors)

# The Importance of Standards in Conformity Assessment

‘New Approach’: the unique link between European standards and product legislation:

- The development of European ‘harmonised standards’ (ENs) is ‘mandated’ or ‘requested’ by the European Commission to achieve its policy objectives.
- ENs are then developed by the CEN, Cenelec, and ETSI.
- The use of ENs provides ‘presumption of conformity’ with the essential health and safety requirements of relevant EU legislation (e.g. CE marking legislation).

# CE Marking in a nutshell:

- Mark of compliance with mandatory safety, environmental and/or energy efficiency requirements
- Manufacturers have a lot of choices and decisions to make – directive, standard, conformity assessment module
- May/may not need the services of an accredited test laboratory
- CE marking is about postmarket surveillance, not pre-market approval
- CE marking is not the alpha and omega – there could be other requirements (e.g. environmental requirements)

# Things to consider....

- 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

# Useful Links

## **USG websites:**

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

## **European Commission websites:**

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

### **CE Marking**

- [http://ec.europa.eu/growth/single-market/ce-marking/index\\_en.htm](http://ec.europa.eu/growth/single-market/ce-marking/index_en.htm)
- [http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index\\_en.htm](http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index_en.htm) (standards)
- [http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index\\_en.htm](http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm) (general guidance)

### **Type-Approval**

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

Thank you very much for your  
attention!

[Louis.Fredricks@trade.gov](mailto:Louis.Fredricks@trade.gov)