



## Supporting Transatlantic Trade

Standards and Conformance  
for Business and Regulators



# The value of standards and conformance to transatlantic trade: EU industry perspective

*Presented by*

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a conference organized by the American National Standards Institute  
in conjunction with the European Standards Organizations

# Overview

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## ■ Agenda

- Orgalime in brief, aims in trade
- Orgalime views on conformity assessment (e.g. policy conformance)
- Harmonised standards in the EU: A key tool to facilitate conformance:
- EU new legislative framework for the marketing of goods
- Our challenge ahead: cost-effective procedures, Making enforcement a reality, harmonise regional approaches to conformance
- Conclusion: Kiss & Tell...

# Orgalime in brief

Founded 1954

35 Member Associations

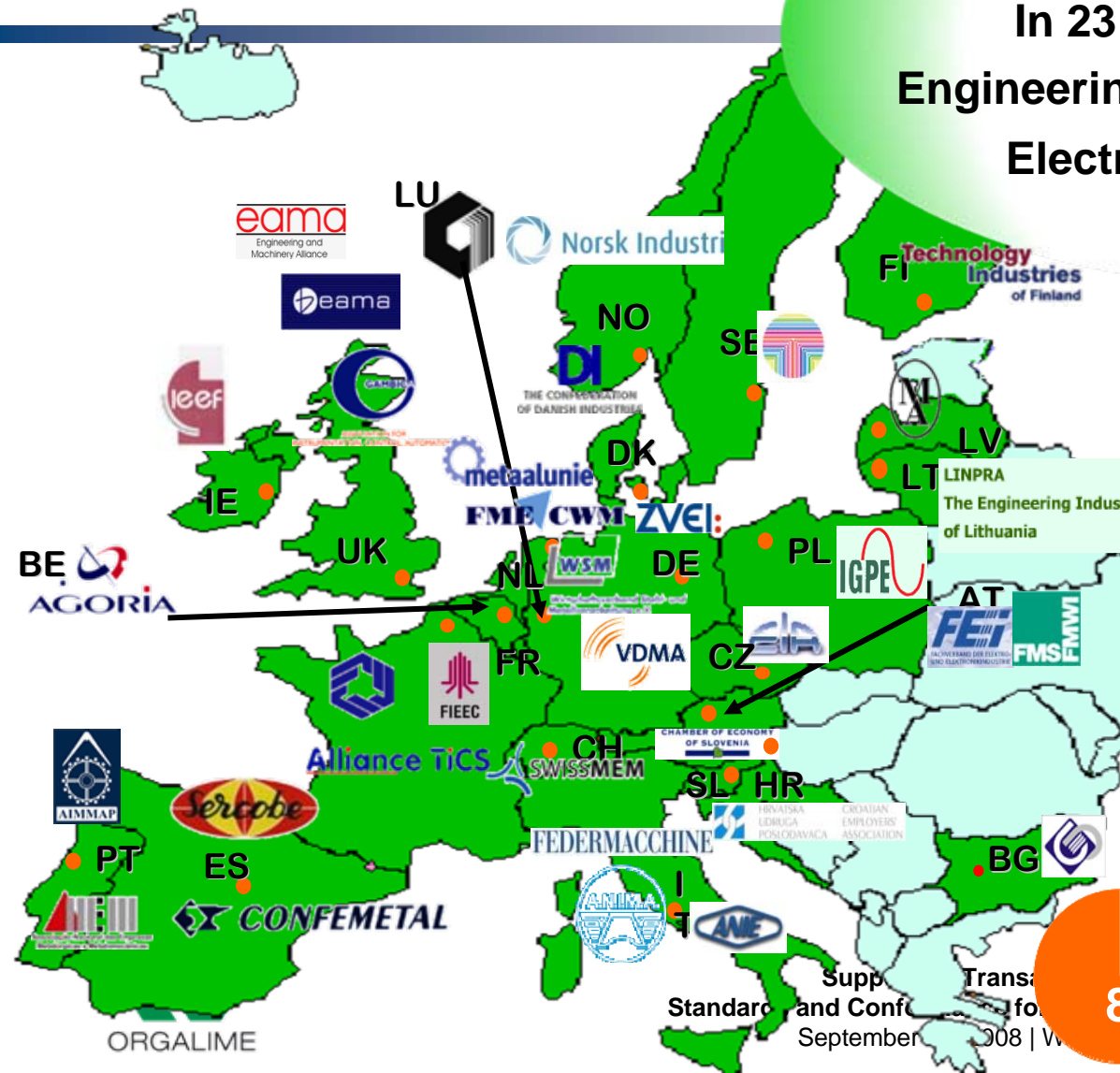
In 23 European Countries

Engineering industries : Mechanical  
Electrical - Electronic and  
Metalworking

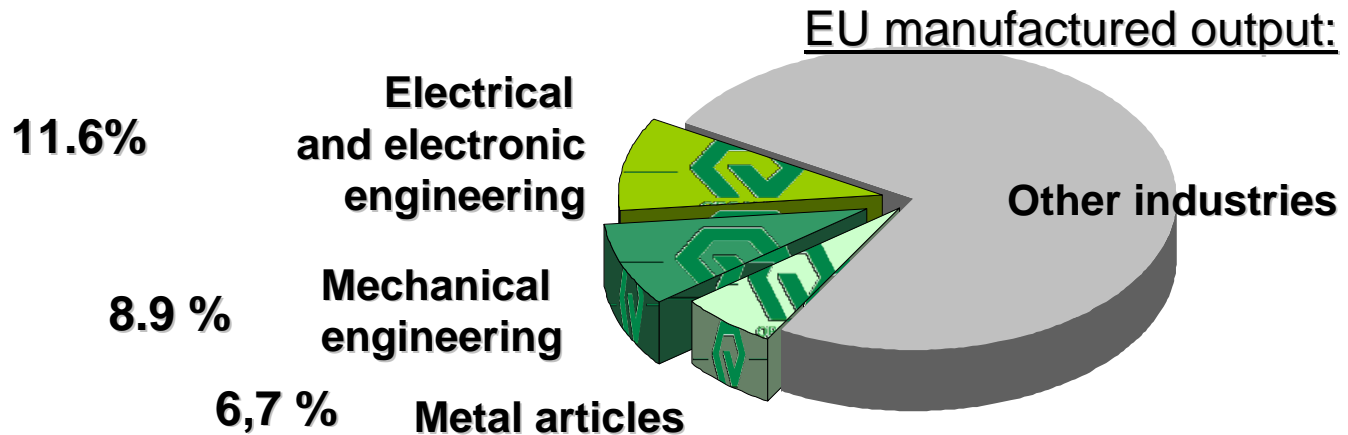
Most engineering products covered by New Approach directives:

- LVD => electrical safety
- EMCD => electromagnetic
- MD => machinery safety
- MID => measuring instr.
- PED => pressure equipmt
- ATEX => safety in explosive atmospheres
- and some 12 others...

20 % consumer goods  
80% professional goods



# Orgalime speaking for European engineering industries



- 130.000 Companies, 90% SMEs
- generating €1813 Bn Output 2007 (EU-27 est.)
- 27% of EU output of manufactured goods
- 33% of EU exports of manufactured goods
- Employing 10.9 million people

# Orgalime aims in general and in the area of trade

- N° 1 lobby of our industry on selected issues
- In the area of international trade:
  - Free and fair trade is central
  - Fair competition and anti-counterfeiting is a must
  - Push for open markets, including in the area of standardisation
  - Anti dumping should only be used for specific problems

# Orgalime views on conformity assessment

## - 1

- Conformity assessment is an essential element of the EU Internal Market, in both the regulatory and non-regulatory areas
- Industry has a vital interest in efficient conformity assessment
  - processes and infrastructures at the best performance to price ratio
  - In order to ensure a high level of safety and avoid the creation of barriers to trade

# Orgalime views on conformity assessment

## - 2

- Support global competitiveness of European engineering industry through:
  - Promoting harmonisation of conformity assessment, consistent with international standards & practice
  - Reducing need for multiple conformity assessment and striving for “one standard – one test – accepted everywhere”
  - Promoting mutual recognition agreements between 3rd party CABs and their integration in relevant international conformity assessment structures
  - Implementing policy based on 1st, 2nd and 3rd party conformity assessment

# Orgalime views on conformity assessment - 3

- Standards: an essential tool for European manufacturers
  - We are the primary stakeholders
  - We take responsibility for the work in the TCs (and most financing)
- Standards: a flexible tool to combine market needs with society expectations for safe, environment friendly products
  - Challenge 1: consistency with international standardisation and global needs
    - E.g. international safety standards to act against counterfeiting
  - Challenge 2: harmonised use of standards across the board by enforcement authorities



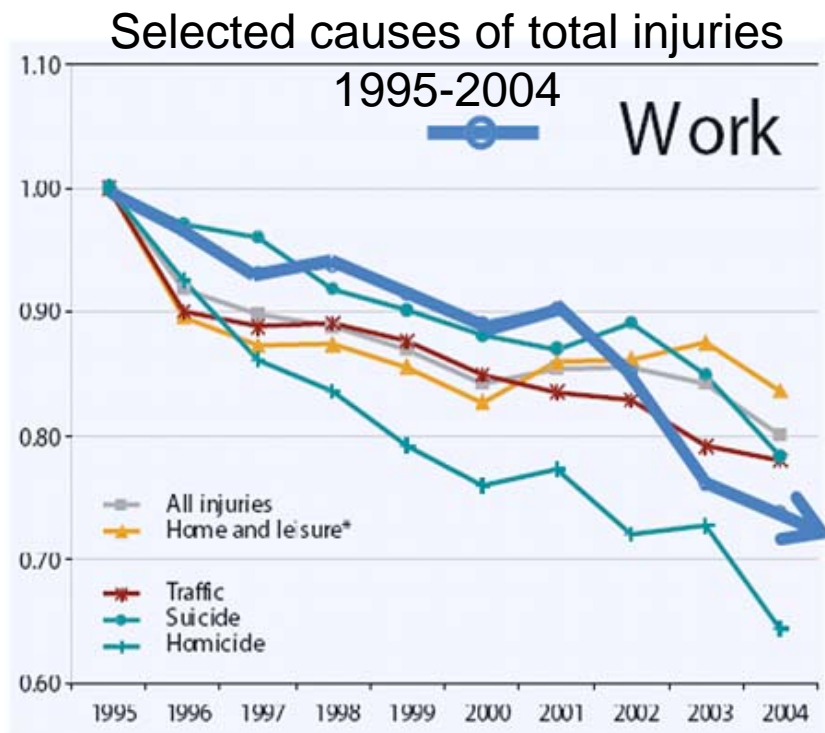
# EU New Legislative Framework: fostering standards and conformance

2 pieces of legislation for marketing products in the EU:

- [Regulation 765/2008/EC](#) of July 9th, 2008 on accreditation and market surveillance
  - setting up a unique accreditation system for both legal and market conformance
  - stronger requirements onto EU27 enforcement authorities
- [Decision 768/2008/EC](#) of July 9th, 2008 on a common framework for the marketing of goods:
  - Toolbox for the future
  - Includes the principles of the “New Approach” where use of EN standards facilitates demonstration of conformity to EU law

# Why the NLF is crucial for our industry?

Much has been achieved...



- NLF a step forward on the road to better regulation
- NLF establishes a shared responsibility among market operators
- NLF endorses the success of the New Approach for ensure safety
- NLF a great leap forward for product conformance?

# Our challenge ahead (1): cost-effective procedures

- Take full account of existing product legislation, harmonised standards and conformity assessment procedures
- 3rd party certification:
  - a useful tool to help manufacturers
  - Should be as far as possible a B2B tool
- Why? Simply because liability always remains with manufacturer or employer; not with the certifier!

# Our Challenge ahead (2): Making enforcement a reality

- From conformance to level-playing field: make enforcement deterrent to rogue market operators (the China syndrome)
- Bring more consistency in the enforcement chain
  - Clarify and harmonise concepts in risk assessment, evaluation and management
  - Use them across the enforcement chain
- Controlling the market is the business of enforcement authorities:
  - They must seek to remove products which do not comply with our laws
  - Trade, standardisation and certification have become global, but accreditation and controls must remain local

# Challenges ahead (3): harmonise regional approaches to conformance

- US « blame and shame if you fail » vs. EU catch-all precautionary approach.
  - Standards should remain a tool = reference for both manufacturers and enforcement authorities
  - Certification to remain a business service, not an obligation
- Need to harmonise key concepts such as “hazard”, “risk”, or “risk assessment” which are key for both placing product on the market and enforcing legislation
- Emerging risks:
  - clarify the legislative framework first
  - Set relevant standards according to technologies and products to match the required risk assessment

# Conclusion 1: Voluntary Standards have role to play in conformance mechanisms



# Conclusion 2: Kiss and Tell to facilitate transatlantic trade

- Keep It Simple Stupid!
  - Rules that are simple to understand and to apply are better followed
  - Rules that are supported by use of international standards facilitate conformance and transatlantic trade
  - Rules that are simple to apply are easier to enforce and are usually better enforced
- Truly Enforce the Law for all
  - Compliance to legislation impacting our products must improve for real => need for a level playing field on both sides of the Atlantic!
  - improved market surveillance is key to make a system of standards in support to legislation work.

# Conclusion 3: “one standard – one test – accepted everywhere”?

- Make your pick for the future of Transatlantic Trade:
  - ❑ “I had a dream...”
  - ❑ “Yes we can!”
  - ❑ “We care for own...”

Thank you for your attention!

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