



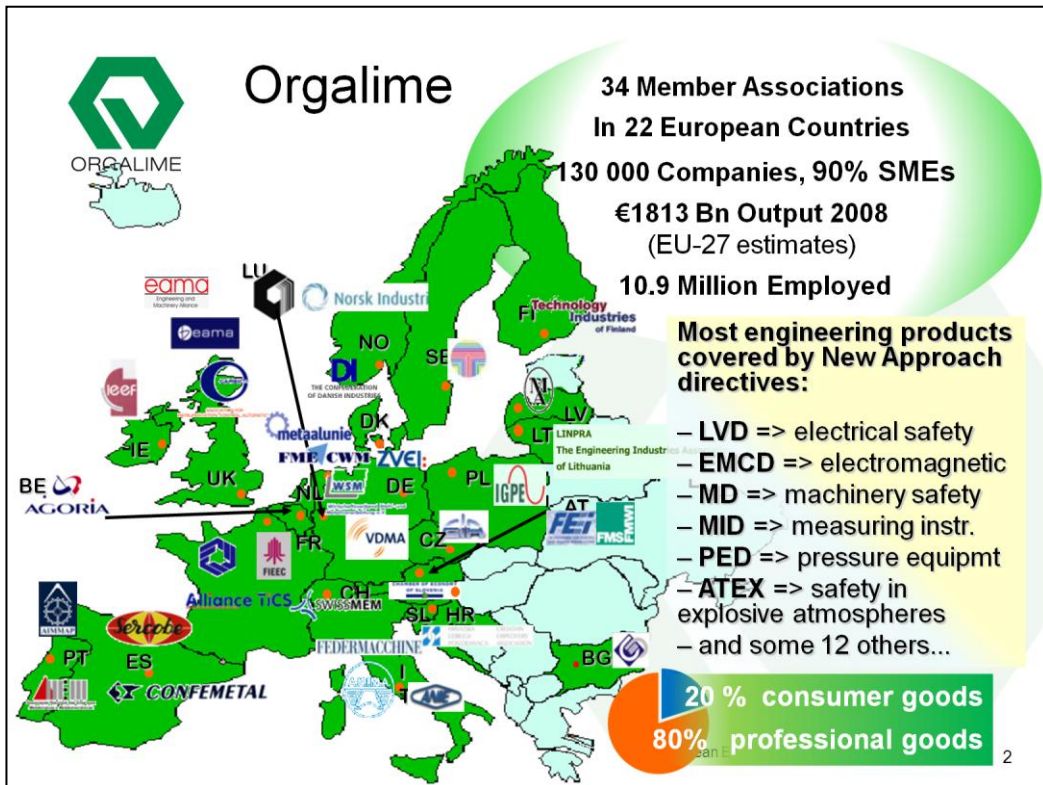
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*Effective market surveillance  
systems and risk management:  
a business perspective*

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The European Engineering Industries Association

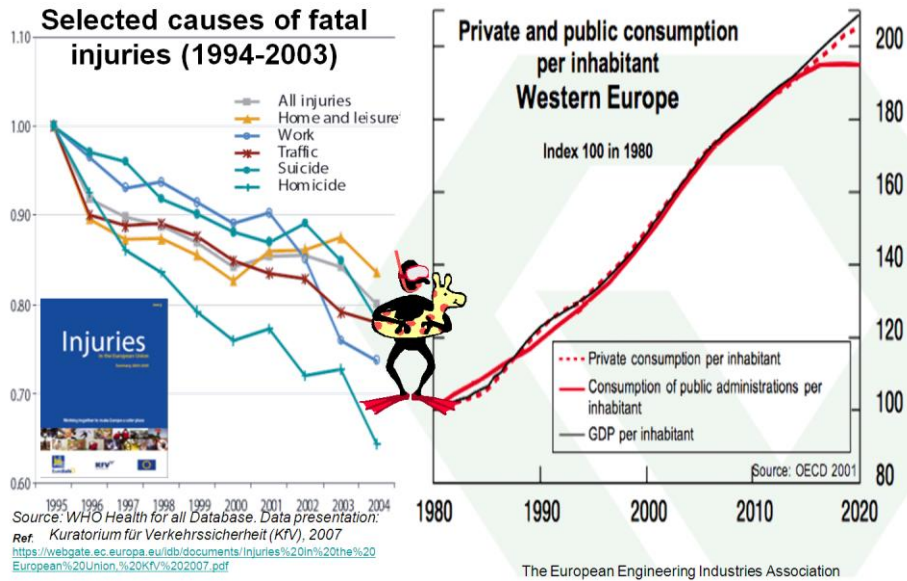


→ Orgalime is the European federation representing the interests at the level of the EU institutions of the European mechanical, electrical, electronic and metal articles industries as a whole.

→ Orgalime's member federations directly or indirectly represent some 130,000 companies of an industry which employs some 10.9 million people across 22 European countries, the overwhelming majority of them are small and medium sized enterprises (SMEs).



# Risk mitigation: Much has been achieved...



→ Much has been achieved to reduce the exposure of consumers and workers to risks arising from non-food manufactured products, mostly thanks to good engineering practices (as shown in the left-hand side): the various coloured lines show the index of fatal accidents of various causal origins: at school, at work, at home, on the roads... all of them are on a sharp and steady decline (here since 1994).

→ At the same time, according to an OECD figure (as shown on the right-hand side), private and public consumption per inhabitant in Western Europe has increased at a rapid pace during the same past decade, and this trend is likely to continue until 2020 at least: we use about 10 times more technical products in households than 10 years before, and yet the number of total injuries decreases.

→ This reminds us the compelling need to assess risks against reality, so as to minimise the risk perception bias in risk management decisions.



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## Risk mitigation = a complex mix of market and legal requirements

→ Legal

+ market requirements

Energy saving

Environmental

Social

Health & Safety

Etc...



→ Risk

assessment is documented in standards

**EU**  
**single market**

10 years

2 500 000 extra jobs

€ 877 000 000 000 in extra prosperity

<http://europa.eu.int/comm/10years>

*Legitimate, lawful business needs clear rules and legal stability in order to prosper*

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→ This presentation refers to the European Union context where the single market rules (mostly based on article 95 of the Treaty), have granted free circulation to products that meet a minimum set of common “essential requirements” in order to establish a “high level” of protection of various core policy interests: health and safety of consumers and workers, the environment, energy efficiency.

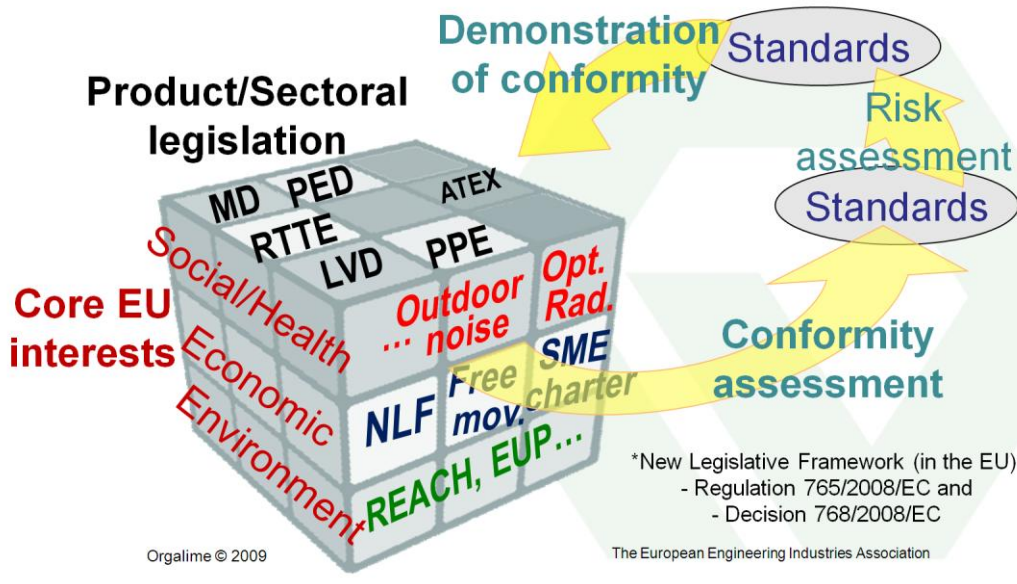
→ It is all about CONFIDENCE BUILDING: Risk mitigation is achieved throughout a complex mix of measurements, testing and compliance procedures in order to achieve the best balance between legal requirements and market needs.

→ For most electrical, mechanical and metallic products, risk assessment is documented in harmonised standards within the framework of applicable legislation.

→ It is important to underline that legitimate, lawful business needs clear rules and LEGAL STABILITY in order to prosper.



## NLF\* = towards a virtuous circle of compliance to EU laws?



→ The set of rules applicable to electrical/mechanical products is increasingly complex: over years, horizontal legislation dealing with social issues (e.g. The Outdoor Noise Directive, the Optical Radiation Directive), with economic issues (e.g. Marketing of Goods package, SME Charter...), or with the protection of the environment (REACH Regulation on chemicals, Ecodesign EUP Directive...), have added up to existing vertical product directives (such as the Machinery safety Directive, Pressure Equipment, Radio and telecommunication terminal equipment, Low Voltage, personal protective equipment, or for explosive atmospheres...).

→ For each policy of these vertical or horizontal policy requirement, there is a corresponding risk assessment procedure, which often adding up to the others, sometime in a conflicting way.

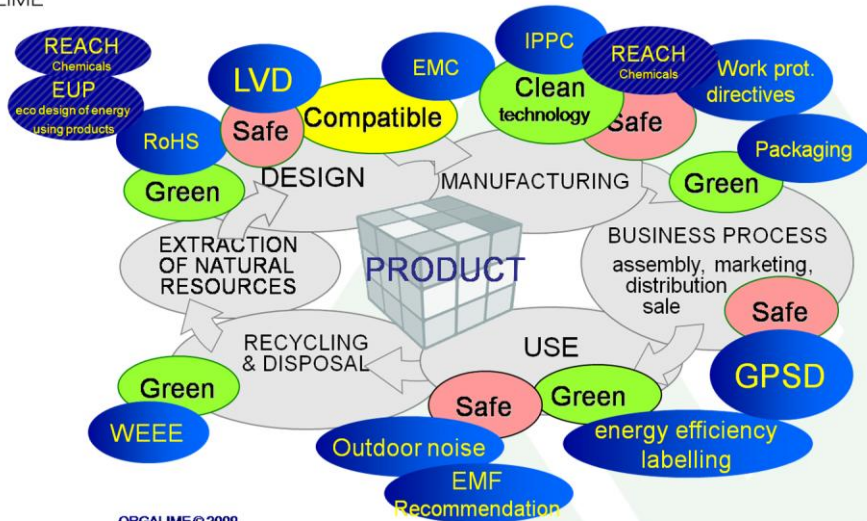
→ It is particularly relevant to avoid inconsistencies with regard to risk-assessment, which falls under the manufacturer's responsibility when he/she places professional equipment (e.g. a machine tool) on the market but falls under the employer's responsibility when the same equipment is used by the workforce.

→ The New Legislative Framework (NLF) provides the most cost-effective system to mitigate risks in human interaction with products and processes and Orgalime look forward to it being applied, in particular because it refers to harmonised standards in order to document the risk assessment and to facilitate the corresponding conformity assessment procedure.





## Dealing with risks is core of most EU laws, with different approaches



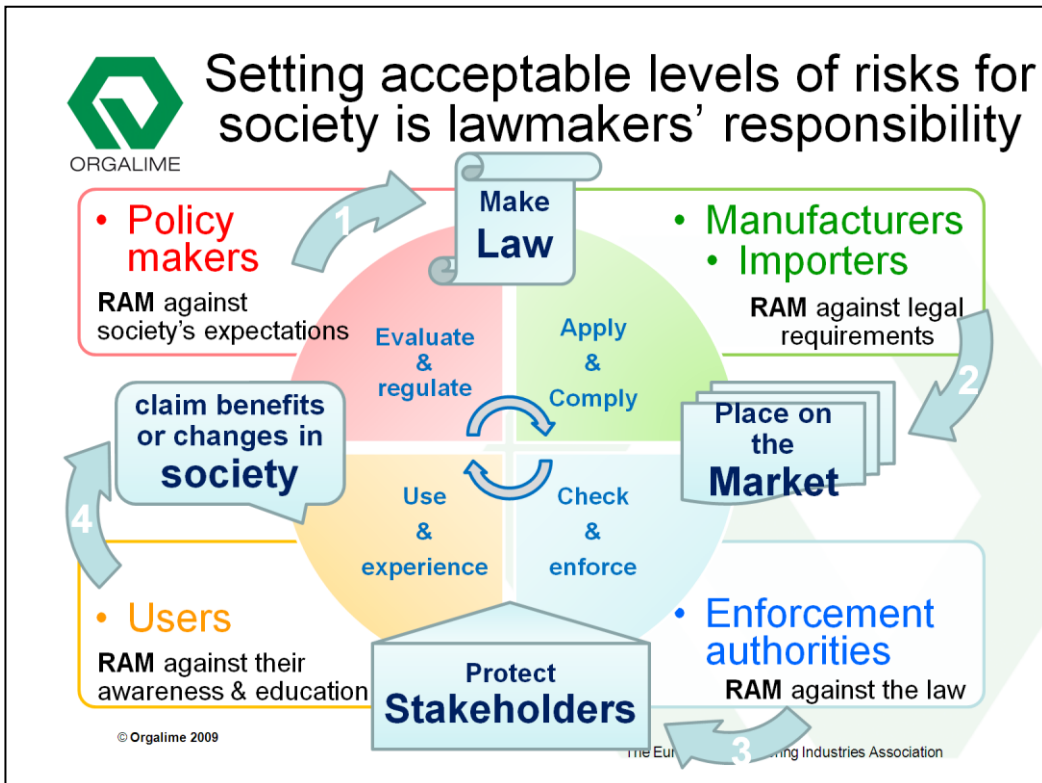
...but apply to the very same product!

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The concept of risk/hazard/safety is frequently the main objective of the law.

- It is the primary duty of policy makers;
- It requires boundaries, limits, thresholds to be of use to business and market surveillance authorities;
- It requires comprehensive technical knowledge to be translated into technical specifications for the design of products or the provision of services.

Application of risk assessment at company level including all tests and compliance procedures sums up to 15% to 20% of production costs.



This figure represents how the main stakeholders are involved in the mitigation of risks from all types or origin for society at large:

→ It starts obviously with policy makers: it is their very responsibility (under the democratic control of their respective institutions) to set the acceptable level of risks for society. Their decision could be based on a detailed risk assessment carried out by scientists. In case no scientific certainty is available, the legislator can make use of the precautionary principle with due consideration for the proportionality principle (as described in EC Communication 01/2000).

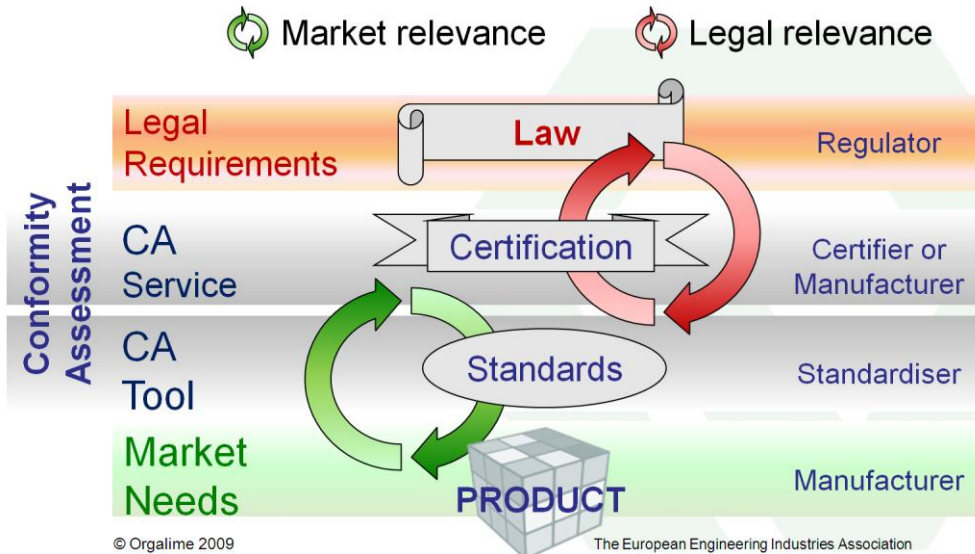
→ Manufacturers and other market operators should carry out a risk assessment for their product and services against the legal requirement. The use of harmonised standards could sometime provide them with the presumption of conformity to the legal requirements.

→ Inspection and market surveillance authorities are then assessing whether the product supplied to the market are in conformity with the requirements of the law, against the acceptable level set in the law. In some cases, where there is no applicable legislation, they have to assess the risk for the population they protect.

→ Eventually, users make their own risk assessment and management against their awareness and education bias, when they use and experience products and services supplied to them and reflect them further in polls and democratic consultations to policy makers.

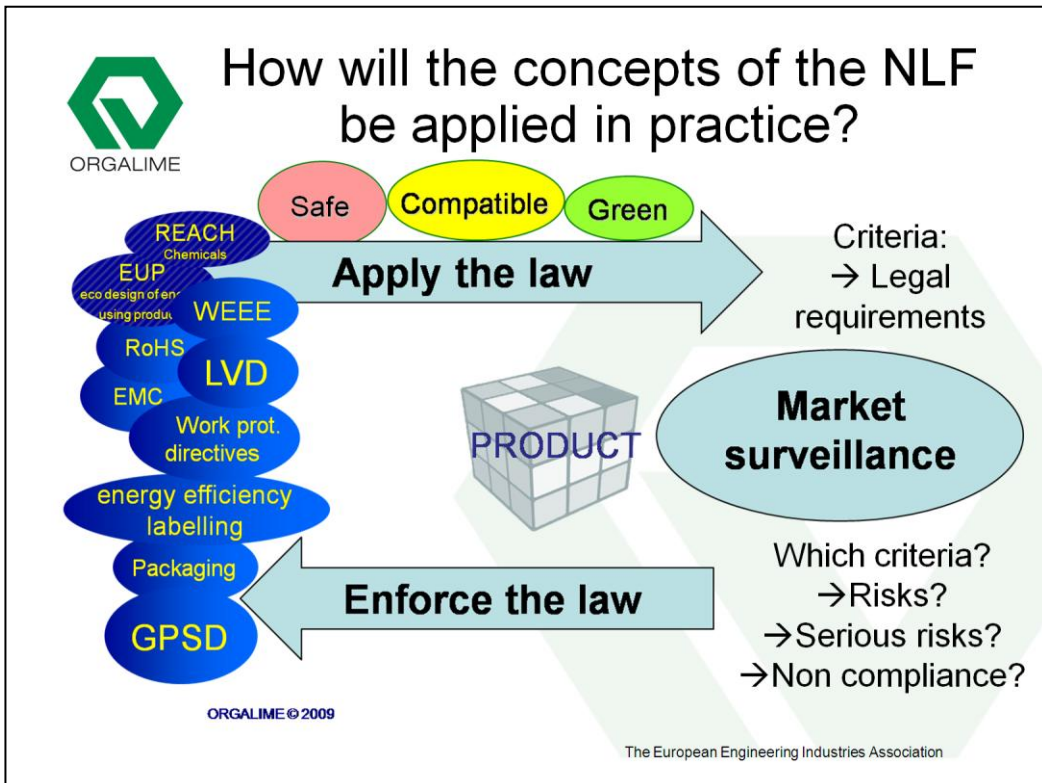


## Risk assessment is in standards for use as “better compliance” tools



- International / European standards are important tools to specify how manufacturers should assess the risk in the design of their products in their own specific technical environment / purpose of use;
- Standards are useful to check the conformity of products to all EU requirements for both manufacturers and authorities. In the European context, harmonised standards facilitate compliance and the placing on goods on the Community market... provided that they stay market relevant, i.e. fit for use by the company which will supply the product (or the service) to its own market.
- Certification is a business service to assist manufacturer or authorities in their tasks and duties. Enforcement should stay independent from commercial interests. Therefore, generalised and ‘de facto’ third-party certification is not appropriate to mitigate risks, because:
  - Member States control on accredited bodies operating abroad is loose.
  - Safety, just as any other legal requirement on energy efficiency or environment protection cannot be guaranteed by private marks or certification scheme.
  - Approval marks and certificates are forged as easily as the CE marking by counterfeiters and rogue traders.





→Manufacturers of engineering products (electrical/electronic, mechanical and metallic products) are used to the so-called “New Approach” whereby essential safety/etc.. requirements are set in the law and it is left up to manufacturers to demonstrate, mostly by using harmonised standards that they comply with the law.

→Since 2008, the New Approach is set in Decision 768/2008/EC as a model for future legislation. However the concept of “risk” and “serious risk” have been introduced too, which causes difficulties at the level of enforcement.

→The conditions for placing a product on the single EU market have been harmonised, but not their application and their enforcement, which depend from the market surveillance authorities of each Member State. Therefore the understanding of the concepts of “risk” and “serious risk” should be harmonised, as it may diverge from the well established concept of “non-conformity” to the requirements of the law (be it on safety, health, environment, climate...).



## Risk assessment under the GPSD (General Product Safety Directive)

**Risk Assessment Guidelines for the qualification of a rapid alert (RAPEX) determine the risk by combining Severity of harm and Probability of occurrence for each scenario.**

Probability of damage during the foreseeable lifetime of the product		Severity of Hazard			
		Very Serious	Serious	Moderate	Slight
Almost certain, might well be expected	> 50 %	S	S	S	S
Quite possible	> 1/10	S	S	S	S
Unusual but possible	> 1/100	S	S	S	S
Only remotely possible	> 1/1.000	S	S	M	A
Conceivable, but highly unlikely	> 1/10.000	S	L	L	A
Practically impossible	> 1/100.000	M	L	A	A
Impossible unless aided	> 1/1.000.000	L	A	A	A
(Virtually) Impossible	< 1/1.000.000	A	A	A	A

- Source: BE FPS Economy  
[ec.europa.eu/consumers/safety/committees/wks\\_pres2\\_11122007.pdf](http://ec.europa.eu/consumers/safety/committees/wks_pres2_11122007.pdf)

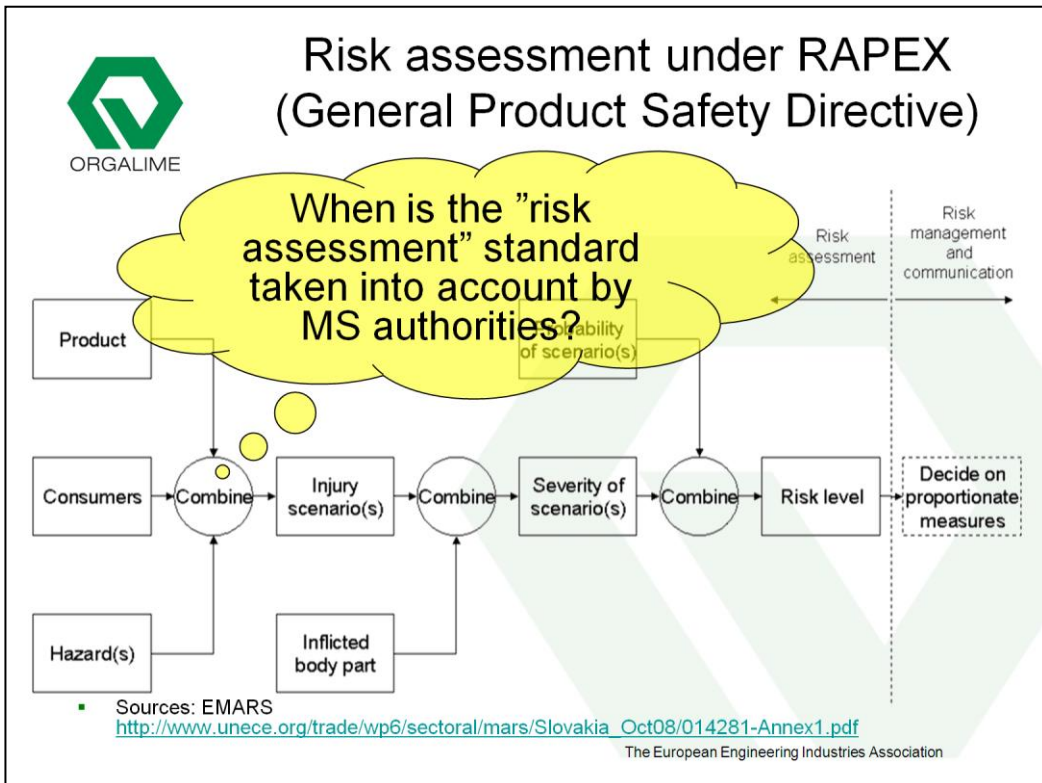
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→ The concept of “serious risk” which have been introduced in the 2008 New Legislative Framework comes from the 2001 General Product Safety Directive, where it serves as a criteria for national authorities to notify their colleagues within the rapid alert system (RAPEX).

→ It is used in an administrative procedure (article 12 of the GPSD). Yet, it logically requires authorities to act, should they discover the notified products on their market.

→ However, the risk assessment model, which is currently proposed is quite (too) simple as shown on the figure: it may be suitable for a hammer and other non-harmonised products, but is insufficient to assess risks for much more complex products (e.g. a lawnmower or a circular saw).

→ For instance, the new harmonised EN / ISO I3849-I standard is somehow much more detailed and fit for purpose for assessing risks arising from machinery safety-related control systems than the above model.



→ In the context of the application of the GPSD, risk assessment guidelines have been drafted to assist authorities in their decision. However these guidelines do not call for checking, as a first step, the risk assessment that should have been carried out by lawful manufacturers and which is often documented in standards (currently, 80% of products notified under RAPEX are covered by harmonised legislation!).

→ Risk assessment in product standards are helpful tools for those that use them. They are certainly better than a "best guess" according to the assessor's personal knowledge and cultural bias.

→ Product standards may have failures, but are open for revision on request by the European Commission (via standardisation mandate) and Member States authorities are welcome to send their experts in standardisation committees so as to improve them.



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## Business expects law enforcement not to give rise to varying interpretation



- Enforcement should be proportionate, i.e. :
  - technically reasonable
  - unambiguous for decision makers and authorities
  - fair : all to share risks and responsibilities
  - economically feasible
  - transparent and thus accountable for all
  
- Authorities should therefore make a wider use of standards, esp. when the law is unclear
  - To set measurement methods
  - As a reference to the state of the art and best engineering practices



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→ Because industry needs legal certainty, it expects the enforcement of the law not to give rise to varying interpretation from one to another Member State or from one to another administration.

→ Orgalime would like to see recourse to the precautionary principle by market surveillance authorities reduced to exceptional situations.

→ Consequently, enforcement should be proportionate, i.e.:

- technically reasonable
- unambiguous for decision makers and authorities
- fair : all to share risks and responsibilities
- economically feasible
- transparent and thus accountable for all

→ Uncertainty can often be bridged by use of standards in order to reduce the cases where authorities have to “guessimate” the risks for consumers, workers or the environment. Authorities should therefore make a wider use of standards, esp. when the law is unclear:

- to set measurement methods
- as a reference to the state of the art and best engineering practices



## What about managing societal risk of non-compliance?



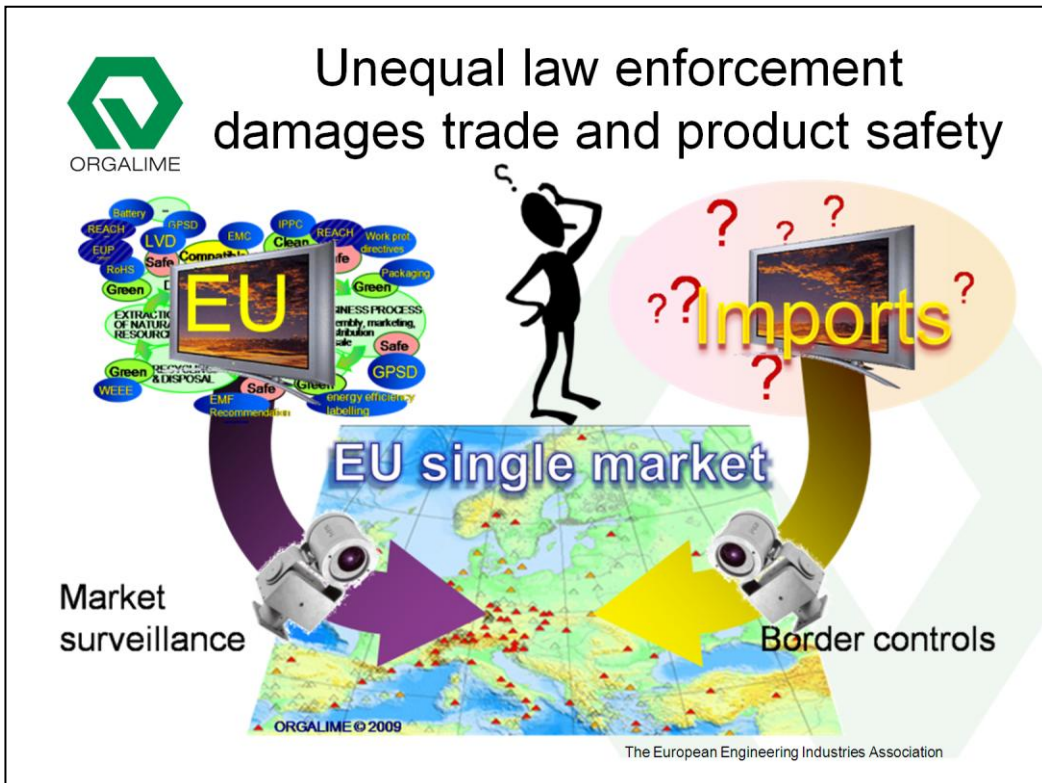
→ We live in a globalised world where it does not matter where products are manufactured. What matters is that all products meet the law of the country on the market of which they are placed.

→ Let us consider the trends and face reality: many professional products and even more consumer products (80% of toys) are imported into the EU from abroad. The figure shows the steady growth of international containerised trade in volume which was multiplied by 2 between 2002 and 2008 and is expected to double again before 2018.

→ Now the question is: have Member States doubled their control capacity in the same period?

Unfortunately not.





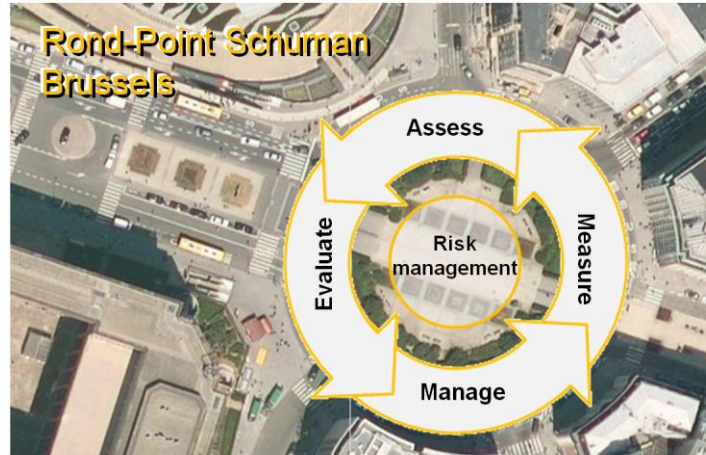
→ As mentioned earlier, meeting the high level of protection required for placing products on the internal market has a cost that could sum up to 15% of the manufacturing costs. Legitimate, lawful manufacturers expect their investment into compliance protected, as much as their intellectual property rights. European manufacturers hope for an equivalent level of surveillance, regardless of the origin of the product and the nature of risks:

- for health and safety of both consumers and workers
- for the environment and energy sustainability
- for growth and jobs in Europe

→ Whatever “good” or “better” the legislation, it is worth nothing without adequate enforcement and the situation, shall it not improve, may damage confidence in the internal market. It is why Orgalime has recently called on EU Member States to provide more means (staff + financing) in order to fulfill their duty of surveilling the market and controlling the borders up to a level which should be deterrent for most indelicate market operators.



## Efficient surveillance is about leaving all operators manage risks



- The “round-about approach”: enable risks to be taken with a reasonable level of control by all concerned

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→ What we need is a common approach to risk assessment, conformity assessment and enforcement.

→ This is the “roundabout approach”: introduced in the early Seventies, roundabouts are now common and frequent in our driver’s experience on European roads, because statistics show that they improve road safety. Why? Unlike mandatory “stop” signs or “red” crossroad lights that are not always observed and cause accidents, roundabouts oblige road users to manage risks for themselves: they learn to look ahead prior to insert into the traffic, at their speed, whatever their size and road user behaviour.

→ Likewise, efficient market surveillance is about entrusting all stakeholders manage risks at their level, leaving it up to them to evaluate risks according to their size, risk perception, culture and individual behaviour.

→ This is probably the most cost-efficient way to achieve the high protection levels that the EU is thriving for.



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**Efficient market surveillance =  
feasible risk assessment and  
proportionate risk management**



**Against the law, all the law, nothing else but the law**

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→ To conclude, efficient market surveillance and border controls are key to maintain confidence into the EU single market.

→ For this to be possible, we need a “smart grid” of communication across all stakeholders, member states and administrations so as to make the European system and its new legislative framework work.

→ It shall rely on a feasible risk assessment and a proportionate risk management against the law, all the law (not only consumer safety, but also worker safety, environment, climate change), nothing else but the law (without additional bureaucratic requirements).



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Thank you for your attention!

More on [www.orgalime.org](http://www.orgalime.org)



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References – Main Orgalime position papers related to the issue:

[22/4/2009 - Call for an effective pan-European market surveillance system](#)

[16/11/2007 - Product Safety and Consumer Confidence](#)

[29/6/2009 - Orgalime views for a cost-effective and market-relevant European standardisation system](#)

[23/6/2008 - Standardisation, innovation and the role of standards in support to EU legislation](#)

[16/11/2007 - Simpler Product Regulation](#)

[29/5/2007 - Market Relevance of Standards](#)