

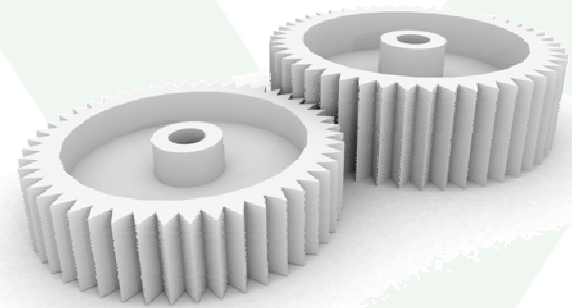


UNECE – WP6 Conference
“Traceability: a tool for managing risks”

Traceability requirements in EU regulations the industry perspective

31 October – 1st November 2011, Geneva

Philippe Portalier
Standardisation and Technical policy
Manager, Orgalime





Orgalime: 34 Member associations, 22 countries

Austria



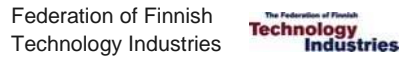
Belgium



Bulgaria



Finland



France



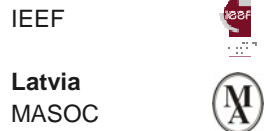
Germany



Great Britain



Ireland



Lithuania



Italy



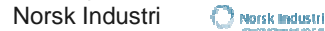
Luxembourg



The Netherlands



Norway



Poland



Portugal



Slovenia



Spain



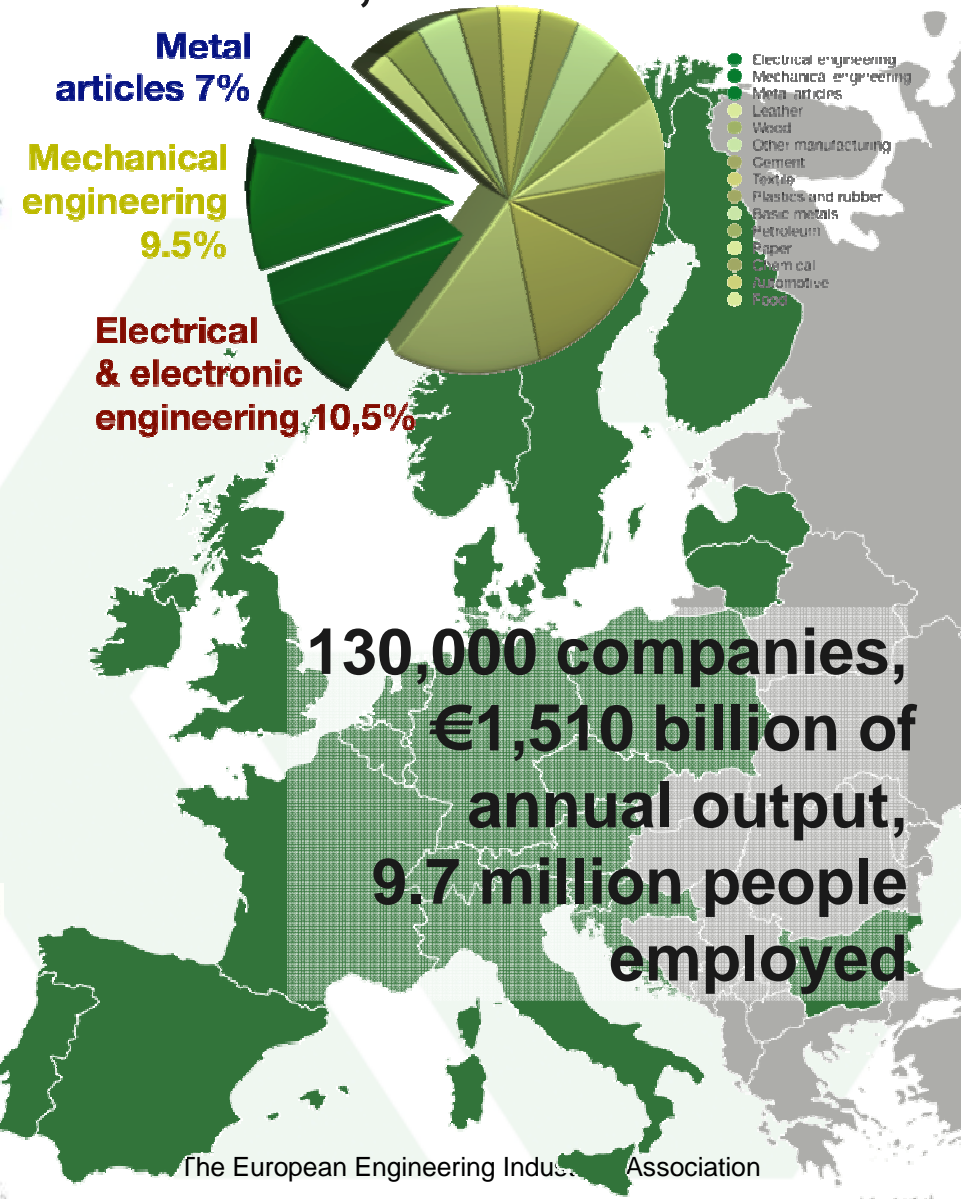
Switzerland



Sweden



Croatia





Orgalime industries

28% of the EU manufacturing output
= A link in industry value chains

- Our industry, mostly composed of SMEs, produces all sorts of electrical, mechanical and metallic products for professional users and consumers

For instance in:

- Buildings
- E-mobility
- Home appliances





Traceability in EU legislation for technical products:

- A **tool** for efficient market surveillance:
 - Feasible risk assessment
 - Proportionate risk management.



Legal framework:

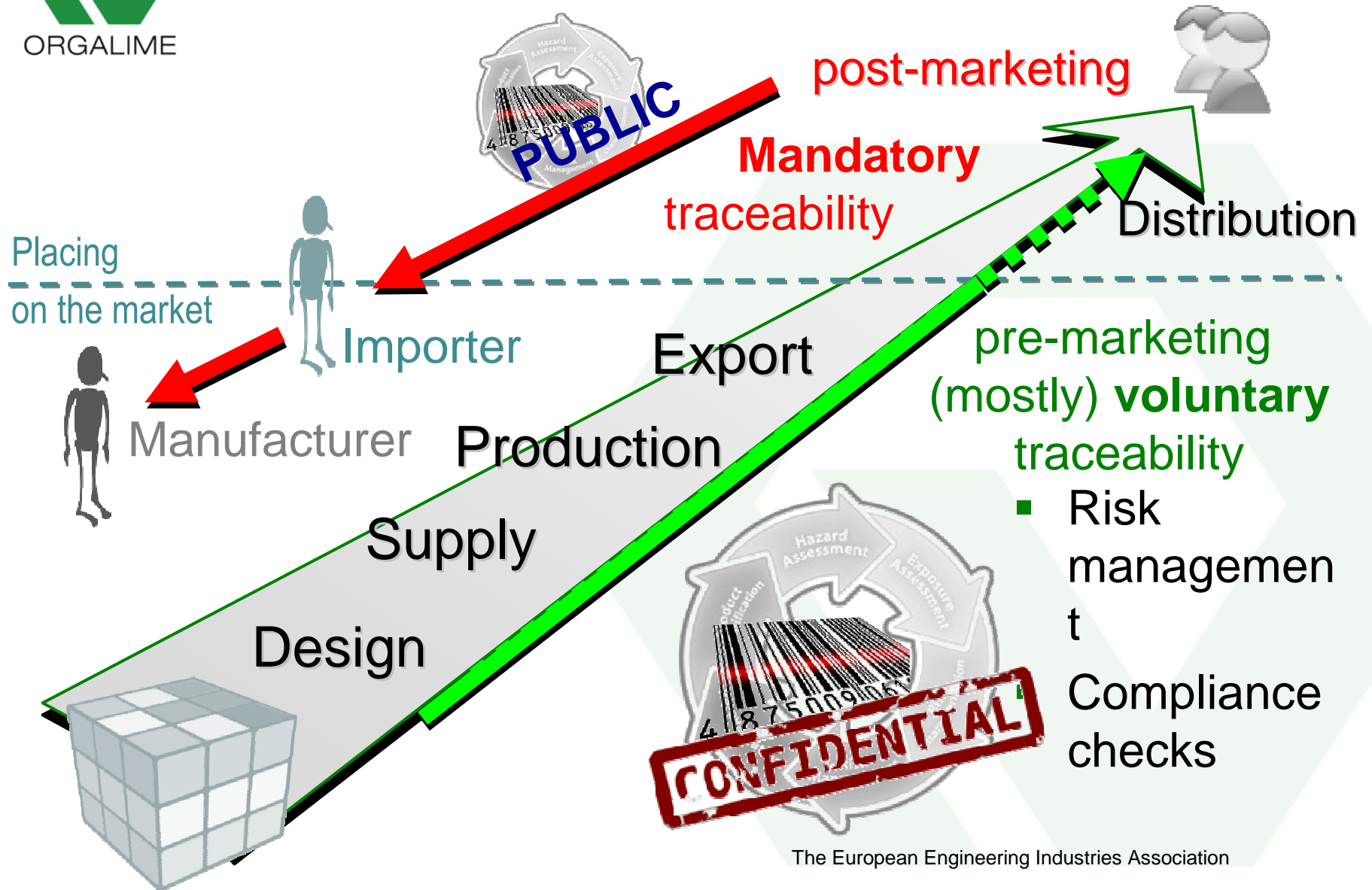
- Harmonised legislation
 - **Regulation 765/2008/EC**
+ **Dec. 768/2008/EC**
- + General product safety Directive



- Risk management
- Compliance checks



What traceability in EU legislation?





Traceability needs vary according to the product / business model



Industrial installation

High added value

On-demand production

Reduced supply chain*

Direct B2B relationship

Contractual management of postmarketing pbs

MSA & Labour inspection



Consumer good

Low added value

Mass production

Spread supply chain*

Multiple distrib. channels

Standard conditions
Consumer protection law

Market surveillance

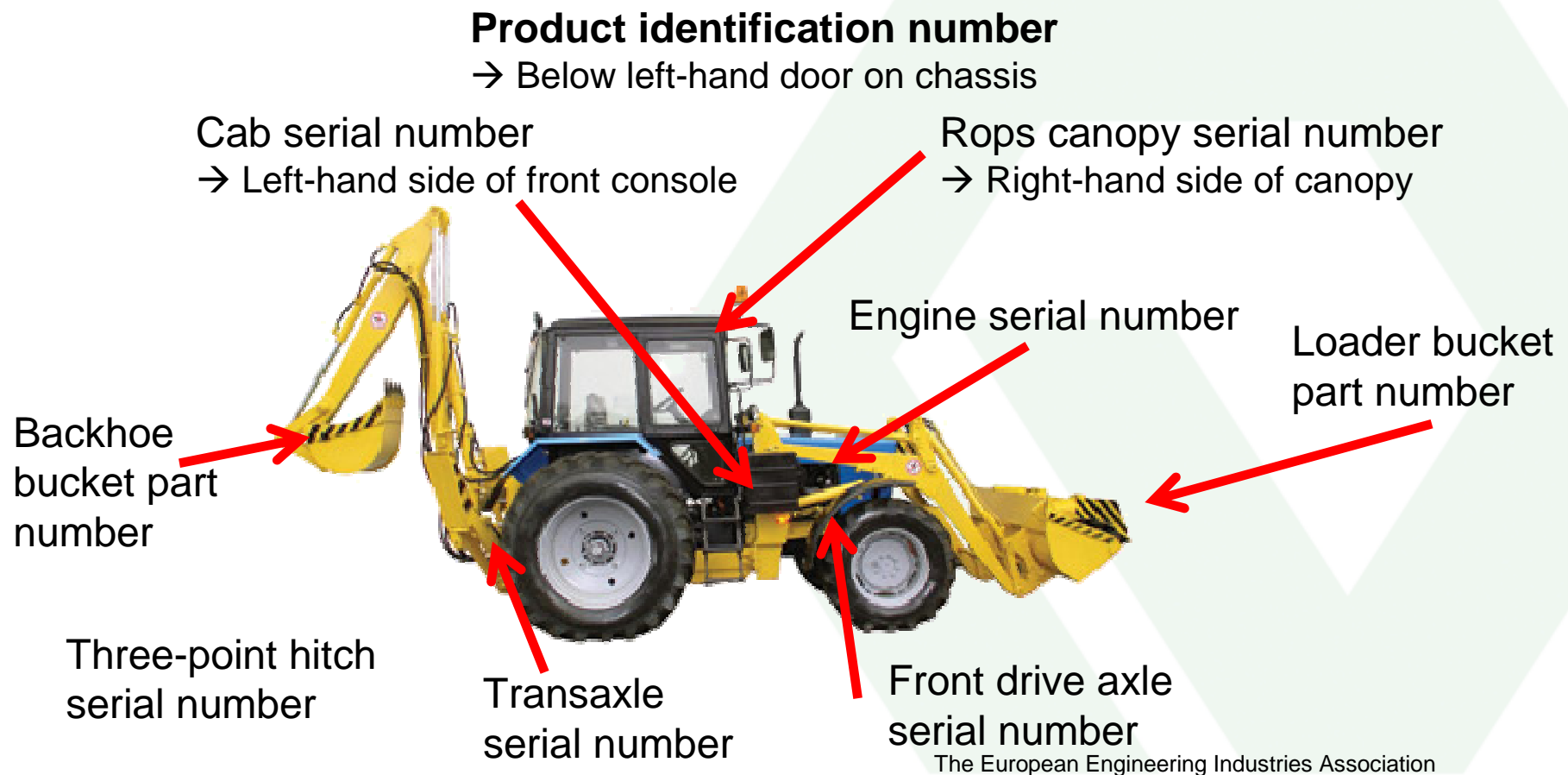
Placing on the market

* in majority of cases



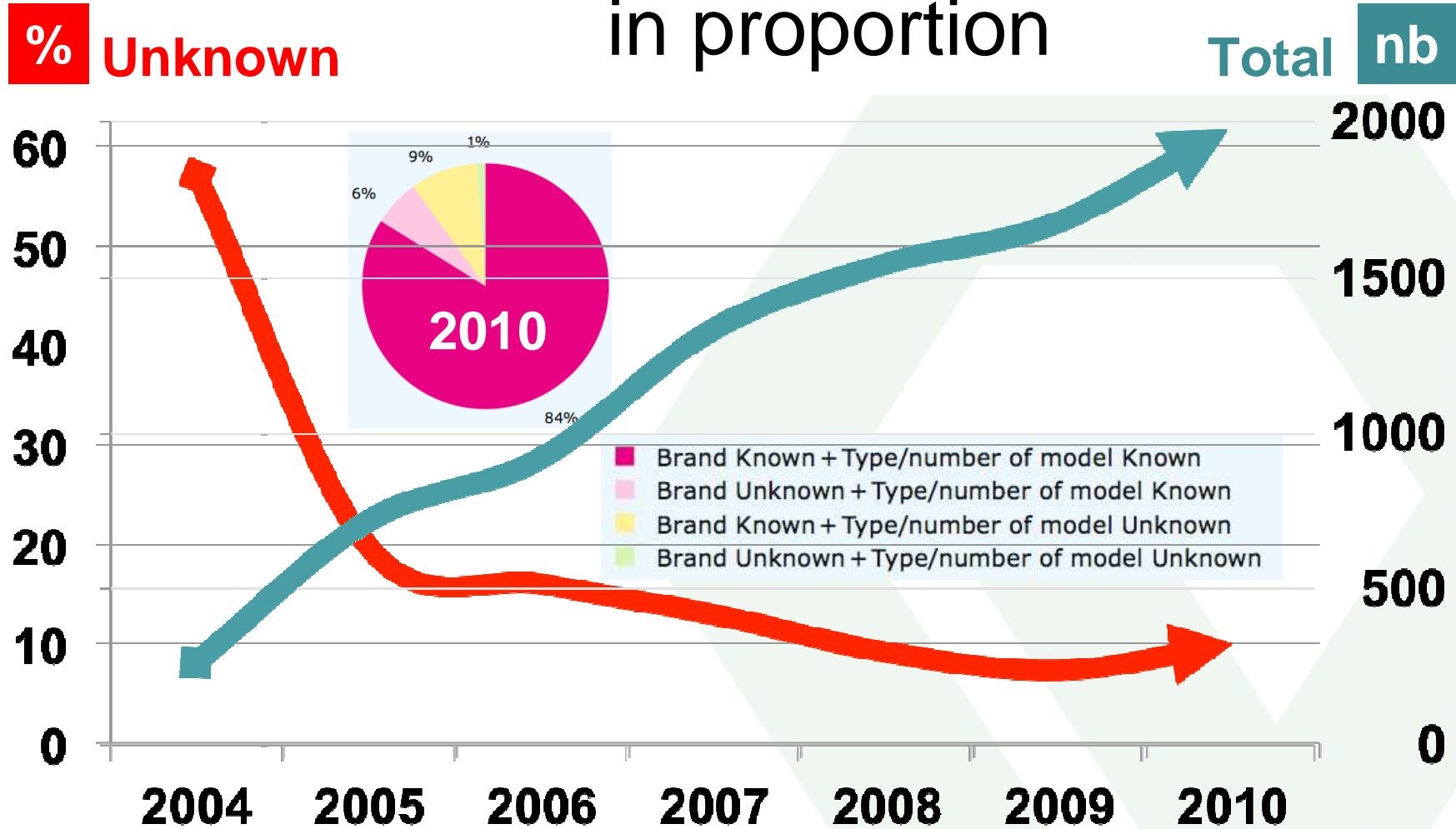
B2B and traceability an example: earth moving machinery

- product and parts are ID tagged





Dangerous consumer products of unknown origin are decreasing in proportion



Data from EC DG Sanco/Rapex

The European Engineering Industries Association



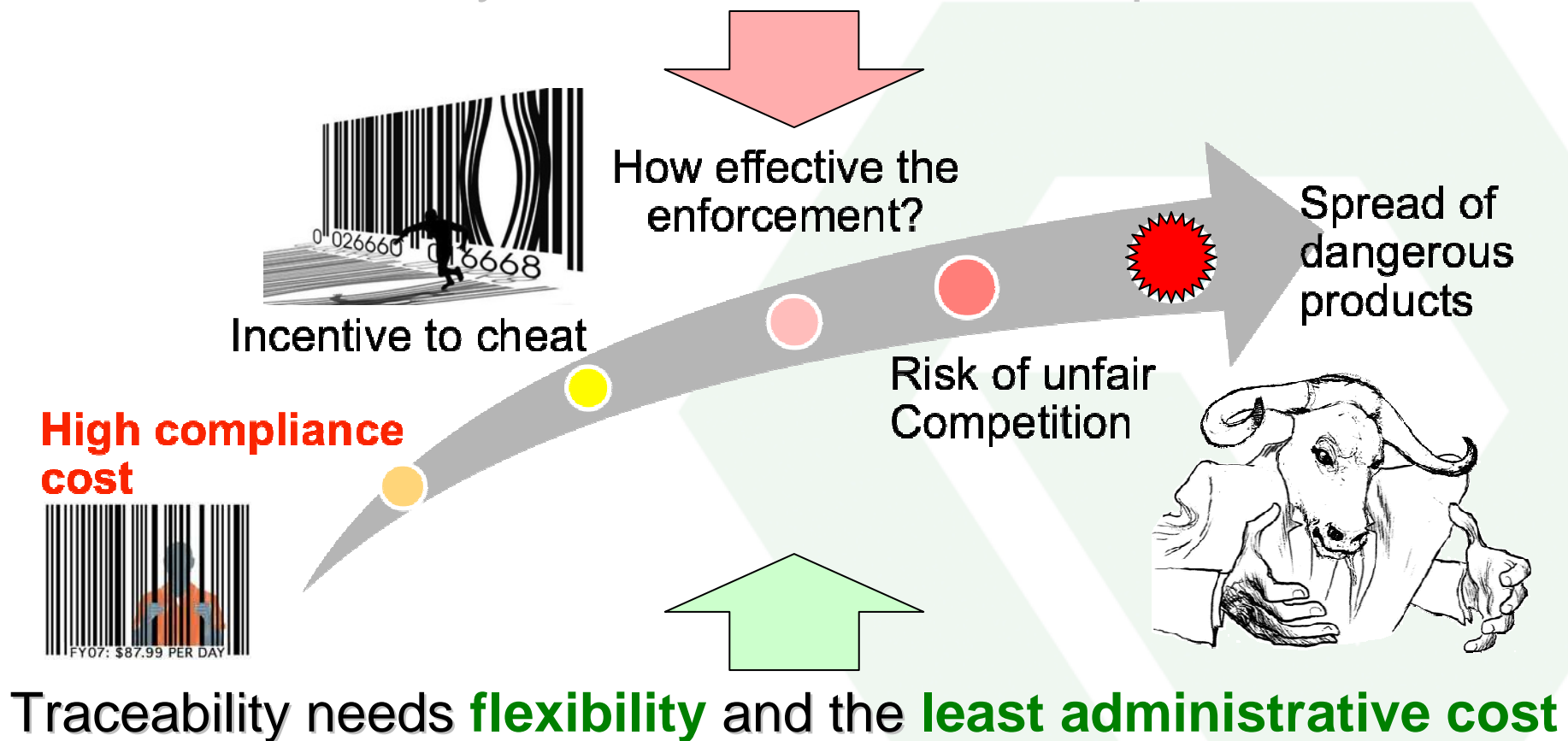
Consumers and traceability of “non-food” products

- Legitimate expectation of consumers with technical products:
 - That the product is **safe** (i.e. \neq CE \neq certified)
 - \neq food sector:
Traceability info about all components irrelevant
 - Indication of the country of origin \neq often irrelevant (too complex supply chain) → Brand matters more
 - That **recourse is possible** in case of problems (product liability laws) to get compensated



Challenges of an effective regulatory traceability

Traceability without **enforcement** is pointless





Challenges of an EU single market surveillance instrument

- Compliant producers are overwhelmed by legislative requirements
- Weak market surveillance and enforcement across the EU
 - Scarcity of resources but duplication of controls
 - Poor cooperation between Member States




Problems arise from weak enforcement,
not from lack of traceability


EU proposal of alignment of the GPSD with NLF should
not add more legal requirements to lawful
manufacturers



Solution 1: Unification of Traceability Requirements ?

- **All products to bear the same ID/traceability requirements**
 - Name and address of manufacturer, importer...
 - Declaration of Conformity + Customer/supplier registers
 - Technical file/evidence of Risk Assessment

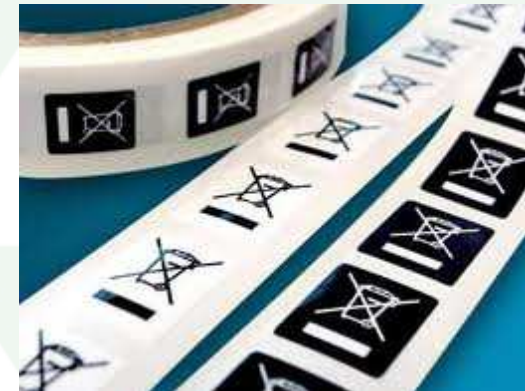
- **Consequences**
 - No proportionality between level of danger and level of traceability requirements
 - Unnecessary administrative burden for manufacturers
 - Consumer overwhelmed with unnecessary information

**Streamlining the requirements for all products
would ease the administrative burden,
unifying can be detrimental**



Solution 2: National Registers? The experience of WEEE Directive

- **Problematic for enforcement Authorities**
 - Difficulties to make use of national registers at EU level
 - High administrative and financial cost
- **Problematic for companies**
 - Legal uncertainty due to different requirements in each member state
 - Generates administrative burden: need to register in 27 countries
 - Fee imposed for registration in some Member States
- **Consumers**
 - Still need to bring back the waste at specific collection points (out of control of market operators)





Solution 2: an EU Register?

The experience of Reach

- **Facilitating to Market Surveillance Authorities**
 - Replacement of the different rules and regulations
 - More information is available
 - Volume of information registered created problems to IT tools

But...

- **Complex for companies**
 - Downstream users who have to contact suppliers and negotiate the right registration of a substance and its uses
- **Non transparent to consumers**
 - REACH heavily criticised by consumer organisations





Solution 2: an EU Register?

Review of the R&TTE Directive

- European Commission considers the possibility to introduce in the revision of the Directive a register of either
 - Producers or
 - Products
- **However:** such a register would
 - Not solve hard non-compliance issues: rogue economic operators will simply not register or forge the registration number
 - Add burden on lawful companies (encoding, additional IT...)
 - Remove authorities resources from focused surveillance actions in order to “administer” the register
 - Create legal uncertainty as to common requirements for the marketing of CE-marked products (Decision 768/2008/EC), which do not require a registration.





Conclusions: Recommendations to policy makers

1. Keep traceability requirements...

- Cost effective and flexible
 - Identification of the market operator could make use of modern means → Web address (url)
- Technology neutral – interoperability is key
- Affordable to economic operators esp. SMEs (no mandatory management system standards with third party conformity assessment)
- Proportionate to
 - The added-value of the product
 - The level of risk / severity of harm

2. ...combined with effective controls



Industry supports pro-active market surveillance

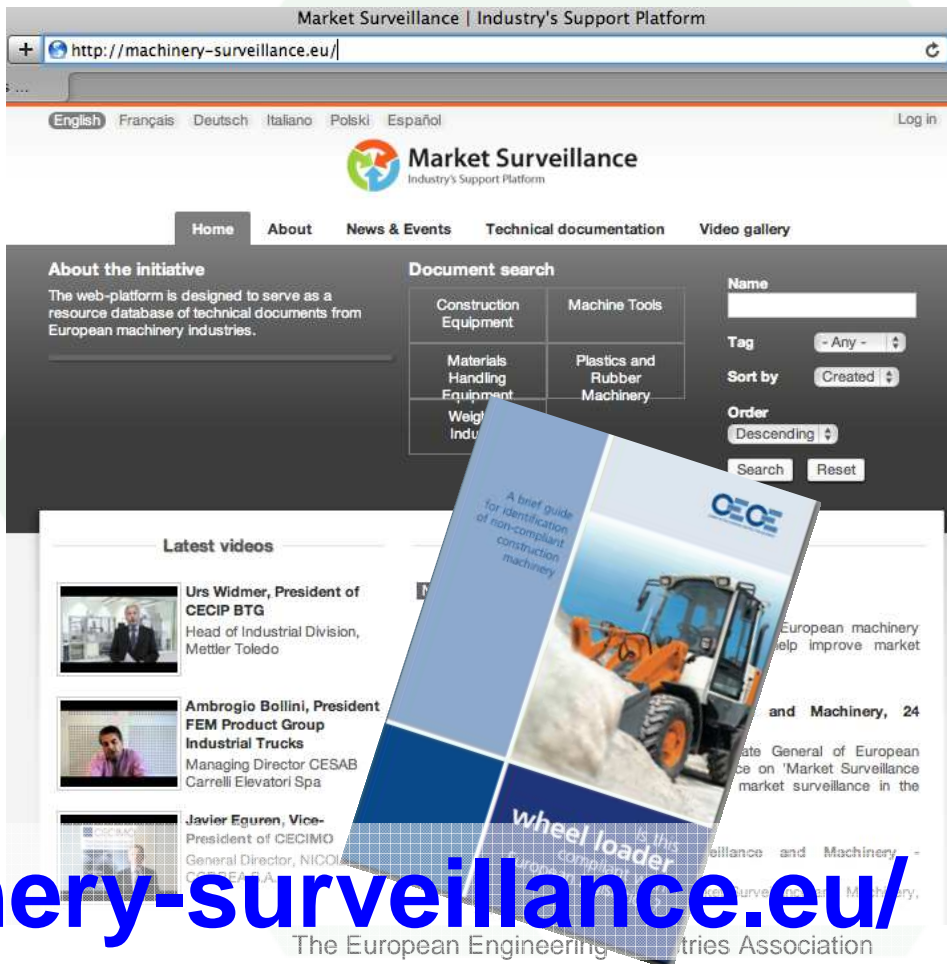
- Newly launched of a searchable Industry Support Platform

Sector organisations

 EUROMAP Europe's Association for plastics and rubber machinery manufacturers	 FEM European Materials Handling Federation
 cecimo European Association of the Machine Tool Industries	 CEMA European Agricultural Machinery
 CECE Committee for the European Construction Equipment	 CECIP European weighing industry

Coordinating organisation


ORGALIME
The European Engineering Industries Association



Market Surveillance | Industry's Support Platform

http://machinery-surveillance.eu/

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Thank you for your attention!



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