



Traceability Requirements in the European Union

International Consumer Product Safety Caucus
ICPSC - Mini-Workshop

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Overview

- Role of Traceability
- Requirements under General Product Safety Directive 2001/95/EC
- Requirements under the Common Framework for Marketing of Products Decision 768/2008/EC
- Statistics
- Business survey
- Challenges and Way Forward



Role of Traceability

- **Upstream** traceability: identification of actors from whom a business/consumer has sourced products or components:
 - allows businesses to carry out safety assessment and ensure safety in the supply chain
 - allows authorities to ensure market surveillance and enforcement
 - allows consumers to contact business in case of safety problems
- **Downstream** traceability: identification of actors/consumers to whom a business has supplied their products:
 - allows businesses to take effective corrective action
 - allows market surveillance authorities to monitor and enforce corrective actions





Requirements under the General Product Safety Directive (Article 5)

■ Producers (manufacturers and importers)

“Producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to:

- (a) **be informed of risks** which these products might pose;
- (b) choose to **take appropriate action** including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers.

The measures referred to in the third subparagraph shall include, for example:

- (a) **an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified.**”

■ Distributors

“Distributors shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, **keeping and providing the documentation necessary for tracing the origin of products, and cooperating in the action** taken by producers and competent authorities to avoid the risks.”



Requirements under the GPSD in practice

- Producers must be informed of risks posed by their products → this is difficult if you do not know who is supplying you with products or individual components
- Producers must be able to take appropriate action to deal with unsafe products that they have supplied → this requires batch marking and the inclusion of producer contact details on packaging
- Distributors must keep and provide the documentation necessary for tracing the origin of products, and cooperate in corrective action

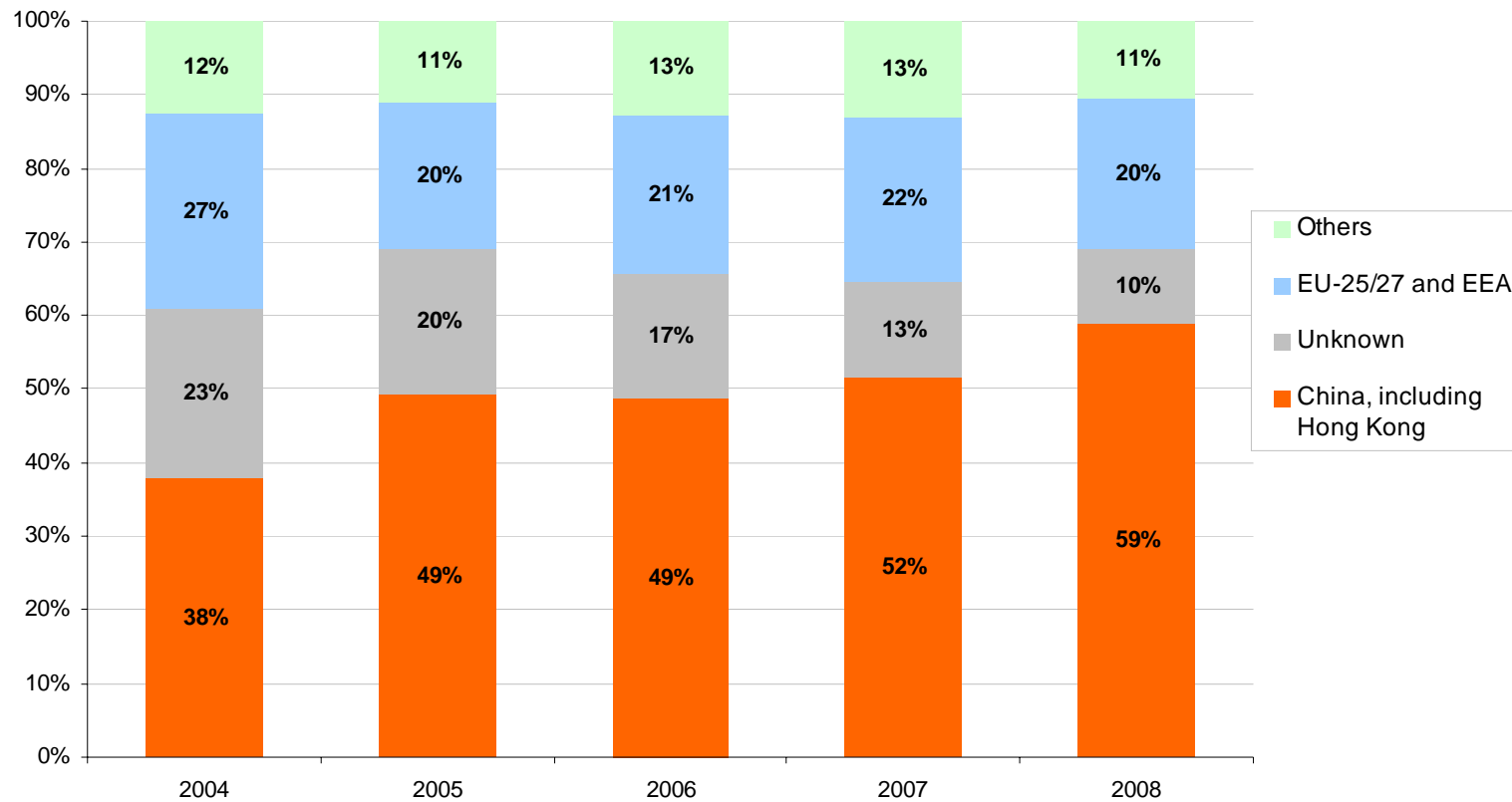


Requirements under the New Legislative Framework for products “harmonised” at the EU level

- Common framework for the marketing of “harmonised” products: Articles R2, R4, R5, R7
→ to be reflected in sectoral legislation
- Required information:
 - name, registered trade name or registered trade mark, address where the manufacturer/importer can be contacted,
 - type, batch or serial number or other element allowing product identification
- Distributors need to be able to identify suppliers one level upstream and downstream

RAPEX Statistics

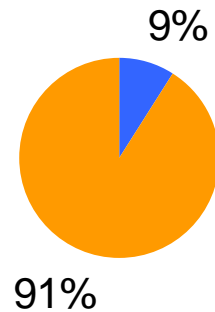
Notifications by country of origin (2004-2008)



RAPEX Statistics

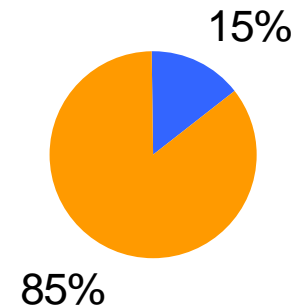
Indication of brand of dangerous product,
allowing identification and related traceability

2008



■ Brand unknown ■ Brand known

2007



■ Brand unknown ■ Brand known



European Business Survey 2008

- 35% of respondents would have trouble tracing products in the supply chain
- 15% identified as particular challenge in a product crisis identifying and communicating with customers and 24% getting the relevant product back from consumers or the supply chain or having it repaired *in situ*



Business Survey (continued)

- The vast majority of respondents are confident that their companies could in crisis:
 - quickly identify the supplier of any individual ingredient or component part in a particular batch of products (81%),
 - obtain necessary technical data about a product at short notice (80%) or
 - quickly and easily access copies of all relevant supply agreements (68%)

More information available at:

<http://www.freshfields.com/publications/pdfs/2008/mar10/21238.pdf>



Challenges in Ensuring Traceability

- Global sourcing and complex supply chains
- Volume of imports - limits of controls
- Limits of jurisdictions
 - at EU level, cross-border market surveillance and information exchange via RAPEX facilitate tracing
 - at international level, the RAPEX-China system allows AQSIO to tackle problems at the source
- Limitations of labelling
- Challenges of data management systems (scope, confidentiality, data protection)





Way forward

- In global markets, international cooperation and solutions are necessary to enhance traceability
- Global compatibility of solutions needed
 - Comments possible in WTO/TBT context
- Scope for global solutions explored
 - EU has in the recently adopted rules chosen to leave some flexibility to the economic operators as to how to fulfil the requirements in specific sectors/specific products
 - Discussions with other regulators



Thank you for your attention!

For more info, please see

<http://ec.europa.eu/rapex>

and

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

