

How can you be better prepared for a product crisis?

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Before the product crisis: attempts to diminish its impact (I)

- Balancing commercial interest vs. risk
 - Design issues/manufacturing issues
- Understand your legal environment
 - precautionary principle
 - product recall legal mechanisms
 - collective redress mechanisms
 - criminal law

Before the product crisis: attempts to diminish its impact (II)

- Know your partners
 - official approval(s)
 - quality certification(s)
 - traceability of the product

- Contract
 - termination clauses (quality, traceability)
 - immediate compliance with recall orders/information request
 - “who’s who” provisions
 - procedure provisions

Before the product crisis: attempts to diminish its impact (III)

- Insurance policy
- Designing and setting-up your product crisis committee
 - design the group
 - appoint its members
 - divide-up duties and define procedures

Before the product crisis: attempts to diminish its impact (IV)


- Building up relationships
 - Government agencies
 - Consumers associations

Managing the product crisis

- 2.1. Internal organization
- 2.2. Relationship with the public authorities
- 2.3. Communication strategy

The day after

- 3.1. Situation A: The recall was necessary indeed:
 - a) Product liability cases
 - b) Director's liability

- 3.2. Situation B: The recall was not actually necessary
 -  Potential liability of the Government agency which ordered it?

- 3.3. Crisis management assessment

Product Liability, Product Safety Politics & the Law A European Approach

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Presentation Outline

- Political Implications
- Europe vs. US
- Handling differences between EU countries
- EU Product Liability Directive
- Exposure for Individuals
- Risk management tools
- *Limitation of liability*
contractual / other
Quality assurance agreements



**Meglena Kuneva,
European Consumer Commissioner**

Political Climate in Europe

- Consumerism (lead by EU Commission as watch dog for the unwary and unprotected)
- Unprecedented inventor of proposals for the benefit of consumers
 - ✓ Collective Redress (class actions!)
 - ✓ Car Advertising
 - ✓ Tobacco Warnings
- Attack on market economy
„Protect the stupid“ vs. right to contract

Issues

➤ Safety

- ✓ recall of „Starbuck“ Chinese made cups
- ✓ 73.000 coffee machines
- ✓ exploding batteries (mobile phones)

➤ Child Safety

- ✓ quality standards, test standards
- ✓ Mattel small magnetic parts (public apology, no „fault“ by Chinese supplier)

➤ Quality / Price vs. Safety !

2008 EU product ban





SAFE PRODUCTS, Europe vs. USA

EU

- Machinery Directive
- General Product Safety Directive
- National EU member states laws
- Tools: CE mark, Certificate of Conformity, GS sign, standards CEN, ISO 9000-EN 9000

USA

- Safe is a product that complies with all applicable standards, such as ASAE, SAE, ISO, *DIN*, *AFNOR*, *BSI*, CE etc. and does not pose an unreasonable hazard
- US „voluntary“ standards vs. EU uniform national policy

Defective vs. Unreasonably dangerous

- US procedural rules and substantive rules (precedents/case law) tend to favor plaintiff's position over strict EU statutory requirements.
- EU defect needed (?) EU/US failure sufficient ?
- Pre-trial procedures
 - Discovery, production of documents, incl electronic materials (litigation hold!), Interrogatory, Depositions
- Trial, procedure and substantive rules, jury decision what is unreasonably dangerous? facts vs. law
- Punitive damages
- Contingency fees

P.L. Claims Differences in success in EU countries (AMCHAM study 2006)

- **France:**
Generally more consumer oriented approach
- **France+Germany:**
apply res ipsa loquitur thereby „reversing“ the burden of proof
- **Italy:**
disproportionately high number of automobile cases
- **Ireland:**
amounts claimed+granted higher
- **UK:**
consumers most aware/knowledgeable

Spectrum Court decisions in EU

- France: explosion of furnace no need to prove exact cause!
 - Belgium: explosion of soft drink bottle, plaintiff not required to prove exact nature of defect
 - Germany: very similar case except seller rather than manufacturer as defendant, seller not liable!
 - UK: breakage of condoms, -breast implants
cause unknown
- Onus on plaintiff to prove the nature of the alleged defect, not merely that the product itself had failed.

ROME II, Conflict of Laws, European Approach

- aim = harmonization of conflict rules for non-contractual obligations (traffic accident) not directly related to Product Liability
- rule of thumb: lex loci delicti, except when same country residents involved
- EU proximity criterion – US close business contacts
- Art 5 Product Liability
criterion: product marketed in a given country (irrespective where purchased)

Sample Cases

- Purchase of pain reliever at airport pharmacy in Madrid (available also in Germany)
liability for side effects German Law!
Impact: Name ? Packaging ? Specifications ?
Manufacturer himself is liable even if not put into commerce by him here but by third party, except when not foreseeable !
- German by-stander injured by exploding bottle made in Egypt purchased in Tunisia,
Egyptian vs German Law
lex loci damni / law of residence of the manufacturer

2006 Commission Report on Member States p.l. activity General remarks

- 5 year status review, Art 21 85/374
- Reports by Lovells (2003) and Roselli (2004) keep development risk defense
- Court of Justice in re (France, Greece, Spain, Dk)

Specific Issues (no full harmonization)

- Burden of proof „substantiation defect and proving causation with damage in light of highly technical features of the products constitutes an unfair disadvantage“

Portugal, Austria presumption of fault (contract cases)

Directive (strict- but no absolute liability)

Qualifyers

- „defect“ art. 6(expectation test)
- € 500 threshold „deductible“ vs. minimal amount
- Defense of regulatory compliance (!)(?)
standards/homologation requirements
- „development risk defense“ art. 7 e option to
exclude (HIV blood)

„New“ approach: Safety vs. Liability

- Compliance with standards = no defence
- Non compliance = lost law suit
- Impact Intra-Company Manuals/Guidelines

Factors to be considered

- Operator / product behavior
- Foreseeability of events (even for unintended use)
modifications ! ?
- Warnings, Instructions
- Accident history
- Other product's design
- Competitors' products

EU Initiatives

- reports 40 fatalities and 1.500–1.900 injuries per year
- Preventive AND corrective action
recommended reading „Harmonization of Standards in the EU and impact on US business“
- **RAPEX**
EU rapid alert system for dangerous consumer products, exception food, pharmaceutical, medical devices. Rapid exchange of information between Member States and Commission, prevent/restrict marketing or use of products posing risk to the health and safety of consumers. Measures ordered by national authorities and measures taken voluntarily covered.

US measures

- CPSC (Consumer Product Safety Commission)
- NHTSA (National Highway Traffic Safety Administration)
(Ford Explorer / Firestone)
TREAD Act (Traffic Recall Enhancement Accountability+ Documentation)
- Federal vs. State action, separate set of rules, California !
- Sanctions:
monetary fines, imprisonment!

Legal exposure Germany, criminal law ! (selection of cases)

- Contergan (LG Aachen 1970)
- Lederspray (BGH July 1990)
- Holzschutzmittel (BGH August 1995)
- Eschede (LG Lüneburg 2003)
- Spielplatz- Decision (AG Siegburg 2006)
- Pflegebetten
- Lipobay

Risk Assessment tool

Table A - Risk Estimation

		Severity of Injury			Level of risk
		Slight	Serious	Very Serious	
Probability of injury	Very High		Very High	High	Very High
	High		High	Medium	High
	Medium		Medium	Low	Moderate
	Low		Low	Very Low	Low
	Very low		Very Low		Very low
					Extremely low
					Low

Table B - Risk Evaluation

Level of risk	Vulnerable people		Normal adults			
	Very vulnerable	Vulnerable	No	Yes	No	Yes
Very High	SERIOUS RISK - RAPID ACTION REQUIRED		Adequate warnings and guards? Obvious hazard?			
High	MODERATE RISK - SOME ACTION REQUIRED					
Moderate	LOW RISK - ACTION UNLIKELY					
Low						
Very low						
Extremely low						

Examples with reference to the general

Sample (Christmas Tree lights)

Table A Risk Estimation

- risk (electrocution)
very serious
- probability of failure
1 %, 2 %

Table B Risk Evaluation

- normal adults
- hazard not obvious
- Warning appropriate ? Yes/no?

Conclusion:

- Risk moderate, some action required
- Young children risk serious
Rapid action required