



voedsel en waren autoriteit

Roundtable

Risk analysis of Consumer Products

Roundtable ICPHSO 13th Annual Meeting and Training Symposium

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Risk assessment in the EU

'RAPEX' or 'serious risk' method in context of General Product Safety Directive

Factors: severity, probability, tolerability

Risk: low, moderate or serious

Included in:

- Guidelines to the management of RAPEX and Art. 11 Notifications
- Guide to Corrective Action including Recalls
- Guidelines for Notification of Dangerous Products

Experience with RAPEX method

Different numbers of notifications between EU Member States

Comparative trial by CSI (NL), 2004

- 15 products, >40 experts
- no product with full agreement on low, moderate or serious risk
- problems in applying method

Comparative inventory by RPA (UK), 2005

- alternatives: nomograph, risk matrix
- RAPEX methodology is 'risk averse' approach compared to alternatives



Ongoing work in risk assessment

EU WG Improvement of Risk Assessment Guidelines (IRAG)

EuroSafe WG Risk Assessment

Prosafe joint action project *Best Practice Market Surveillance*, Work package Risk assessment

ISO/COPOLCO WG Product Safety: proposal for guidance standard



EU WG IRAG

Initiative of EU Commission

Members nominated by EU member states

Step by step approach:

- identify difficulties, propose solutions
- practice test involving national authorities
- stakeholder consultation on draft improved document
- adoption of improved Guidelines 2007

RAPEX scheme for overall probability

Probability of health/safety damage from regular exposure to hazardous product	Probability of hazardous product		
	1%	10%	100% (All)
Hazard is always present and damage is likely to occur in foreseeable use	Medium	High	Very High
Hazard may occur under one improbable or two possible conditions	Low	Medium	High
Hazard only occurs if several improbable conditions are met	Very Low	Low	Medium



Difficulties in probability estimate

Two probability components: confusing

- 'hazard is always present' confused with '100% of products'

Probability of hazardous product not relevant for individual risk

Design flaw leads to at least 'medium' overall probability

'possible' or 'unlikely' conditions: difficult to identify / quantify

What is 'likely to occur in foreseeable use'?

RAPEX scheme for severity

Slight	Serious	Very serious
<2% incapacity usually reversible and not requiring hospital treatment.	2 – 15% incapacity usually irreversible requiring hospital treatment	>15% incapacity usually irreversible
Minor cuts Minor fractures Minor burns Sprains	Serious cuts Loss of finger or toe Damage to sight Damage to hearing Moderate burns	Death Loss of limbs Loss of sight Loss of hearing Serious burns (>25%)

RAPEX method Table A

		Severity of injury		
		Slight	Serious	Very Serious
Probability	Very High	Very High	High	
	High	High	Medium	
	Medium	Medium	Low	
	Low	Low	Very Low	
	Very High	Very High		
	High	High		

Overall gravity of outcome	
Very High	Very High
High	High
Moderate	Moderate
Low	Low
Very Low	Very Low

Diagram illustrating the RAPEX method Table A. The table shows the relationship between the Severity of injury (Slight, Serious, Very Serious) and the Overall gravity of outcome (Very High, High, Moderate, Low, Very Low) based on Probability (Very High, High, Medium, Low). Arrows indicate the mapping from the 'Very Serious' column of the first table to the 'High' row of the second table, and from the 'High' row of the first table to the 'High' row of the second table.

Source: RAPEX Guidelines

RAPEX method Table B

Overall gravity of outcome	Vulnerable people		Normal adults				warnings/guards? obvious hazard?
	Very Vulnerable	Vulnerable	no	yes	no	yes	
			no	no	yes	yes	
Very High	serious risk - rapid action required						
High							
Moderate							
Low							
Very Low							



Source: RAPEX Guidelines



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EuroSafe WG

ECOSA Conference Edinburgh April 2005 [www.ecosa.org]

Compared different sectors: food, workplace safety, chemical safety,...

Follow-up: EuroSafe WG on Risk Assessment

- scientific basis from existing sources
- definitions, parameters
- methods and data for quantitative risk assessment



Prosafe *joint action* project (2006 – 2008)

Project *Best Practice Market Surveillance*

Work Package Risk assessment

- apply methods to practical cases
- identify critical steps in risk assessment
- uniform reporting format



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Outlook

Synergy in ongoing initiatives – sharing of information

Find more objective parameters, in particular for probability

Explain how to use all data sources

Exchange information about practical cases of risk assessment

Improve method on basis of experience

Perform research to solve remaining problems