

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



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Risk Assessment – GPSD-requirements:

GPSD, Article 2 b)

„‘safe product’ shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, ...“

Risk Assessment – GPSD-requirements Article 2 b) cont.:

... taking into account the following points in particular:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- the categories of consumers at risk when using the product, in particular children and the elderly."

„Serious Risk“

Precondition for RAPEX-notifications based on:

■ **Art. 12 GPSD:**

“Where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products **by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX...**”

■ **Art 2 (d) GPSD:**

“‘serious risk’ shall mean any **serious risk**, including those the effects of which are not immediate, **requiring rapid intervention by the public authorities;**”

GPSD Risk Assessment - Procedure

Risk Assessment of consumer products for the GPSD

This procedure is proposed to assist enforcement officers when deciding whether a specific hazardous situation caused by a consumer product is intolerable and constitutes a serious risk under the General Product Safety Directive.

Table A - Risk Estimation

		Severity of Health/Safety Damage			Overall Gravity of Outcome
		Slight	Serious	Very Serious	
Probability of Health/Safety Damage	Very High		Very High	High	Very High
	High	Very High	High	Medium	High
	Medium	High	Medium	Low	Moderate
	Low	Medium	Low	Very Low	Low
	Very Low	Low	Very Low		Very low

Table B - Grading of Risk

		Vulnerable people		Normal adults		Adequate warnings and safeguards? obvious hazard?	
		Very vulnerable	Vulnerable	No	Yes		No
Overall Gravity of Outcome	Very High	SERIOUS RISK - RAPID ACTION REQUIRED					
	High	Moderate risk		Some action required			
Moderate				Low risk - Action unlikely			
Low							
Very low							

Table available:

- **RAPEX Guidelines: serious risks**
- **Recall Guide: « Product Safety in Europe: risk requiring notification by business »**

http://ec.europa.eu/comm/dgs/health_consumer/dyna/rapex/rapex_en.cfm

THE PRECAUTIONARY PRINCIPLE (1)

The General Product Safety Directive (art 8 p 2)

When Member States take measures they shall act in accordance with the Treaty (in particular with the free movement of goods requirements) in a “*manner proportional to the seriousness of the risk, and taking due account of the precautionary principle*”.

THE PRECAUTIONARY PRINCIPLE (2)

Commission communication

- Potentially dangerous effects
- Scientific evaluation does not allow the risk to be determined with sufficient data
- Clear conditions for its application confirmed by the European Court of Justice

Communication on precautionary principle available on:

<http://ec.europa.eu/scadplus/leg/en/lvb/l32042.htm>

