

The Yo-Yo ball

European experiences

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Science based decision making

**Risk assessment not a pure
mathematical science**

”Decision making process”

**From ”No problem” to the
precautionary principle**

”In particular the absence of accident history shall not be taken as an automatic presumption of a low level of risk” (EN 292:2 Machine safety)

What happened in the EU

French government decision to stop sale (and a voluntary withdrawal) RAPEX Notification 8019/03 (March 18)

NL investigation:

Average force for airway occlusion in children is 7.1 N.

Yo-Yo ball exceeds this with margin

Authority promotes voluntary sale stop

Cooperation with Custom Office

RAPEX responses from Member States

Similar actions as in the NL were taken in other EU countries.

Working procedures in Sweden

- Incidence reports from consumers, media
- Accident data checks (EHLASS –type)
- Technical analyses
- Risk assessment by experts
- Network intelligence (Prosafe, adco,s etc.)
- Decision making process

Harmonised risk assessment procedures in the EU

Risk Assessment of consumer products for the GPSD

This procedure is intended to help producers and distributors to decide if a risk from a consumer product is serious enough to require corrective action. The table is used to determine whether the overall risk is moderate, requiring some action, or serious, requiring rapid action.

Table A - Risk Estimation

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

Table B - Risk Evaluation

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

Example (with reference to the arrows)

Table A, If the severity of the possible injury is **Very Serious** and the probability is **Very Low**, the level of risk is **Low**.

Table B The acceptability of the risk depends on the type of user (e.g. normal adult) and, for normal adults, whether the product has adequate warnings and guards (**No**) and whether the hazard is obvious and necessary for the product to work (**No**).

Overall assessment From the above, the overall level of risk is **moderate**, and some action is required.

Assessing the level of risk can be difficult. It involves:

- Finding out exactly what the hazard is
- Assessing the likelihood that the hazard will lead to an injury
- Understanding how serious the injury might be
- Identifying the people who might be injured

Thank you