




Office for Product
Safety & Standards

PRISM – Product Safety RISk Methodology

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Why the need for PRISM?

- GB Risk Assessment Methodology needed post BREXIT
 - Opportunity to improve on the EU Safety Gate (RAPEX) risk assessment guidance and methodology
 - To promote the use of risk assessment
 - To improve outcomes
 - To resolve operational and practical matters
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Introduction to PRISM

Safety Gate (RAPEX) is at its heart

- if you know Safety Gate then PRISM will be very familiar

Structured in two parts

- Part 1: Fundamentals

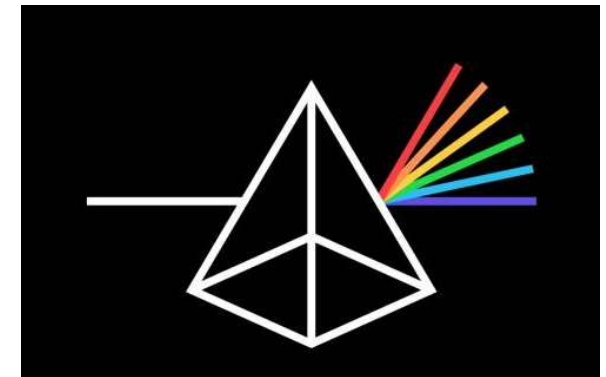
- Part 2: Additional guidance

Application (scope) is the same (as RAPEX), including exclusions

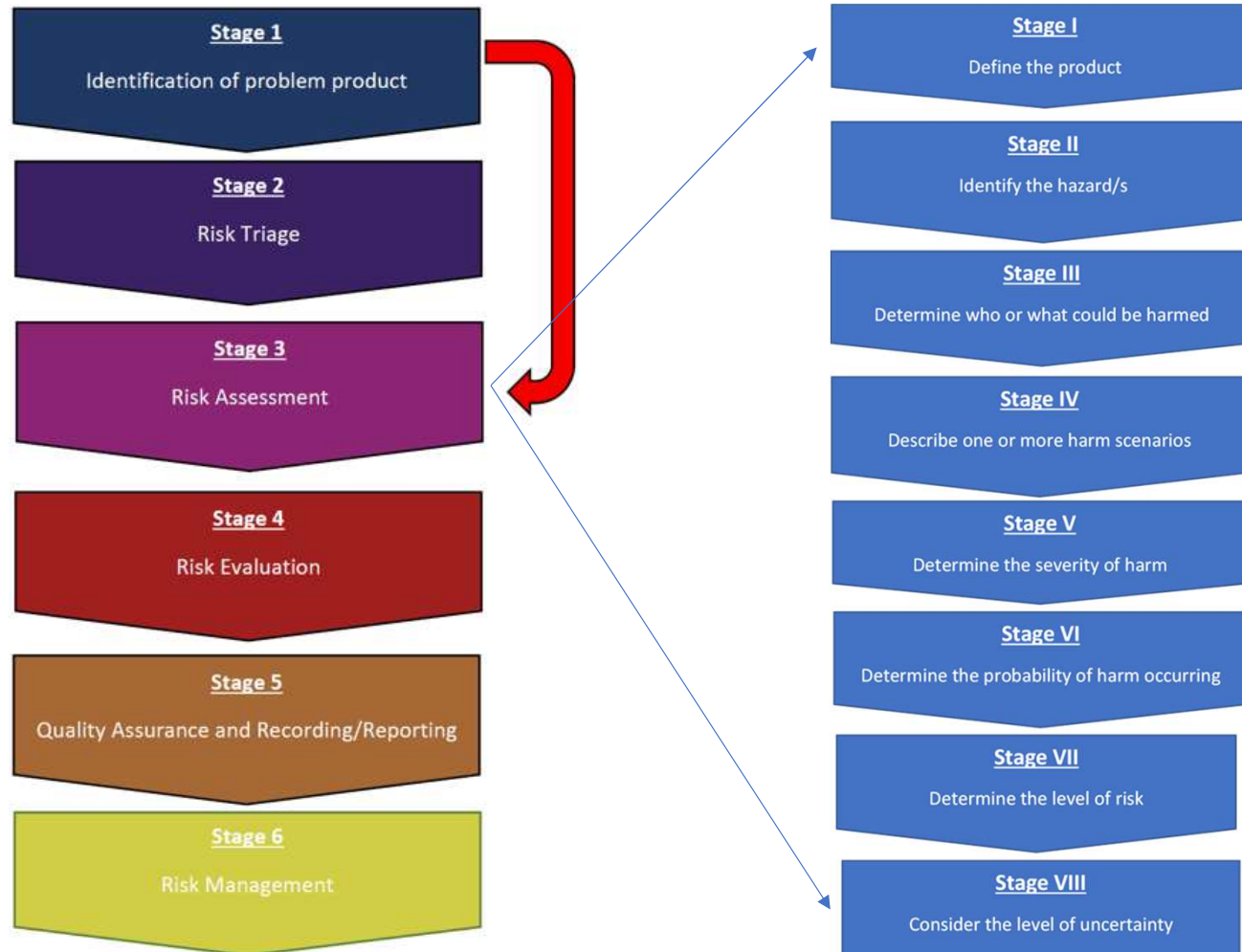
Methodology is inferential to infer future events

Takes account of data that MSAs have when determining risk

Provides transparent basis for determining action



Stages of PRISM



“Single item risk” and “all items risk”

Table 3: Level of risk (single item)				
Probability of harm over lifetime of product	Severity of harm			
	Level 1	Level 2	Level 3	Level 4
>50%	High risk	Serious risk	Serious risk	Serious risk
>1 in 10	Medium risk	Serious risk	Serious risk	Serious risk
>1 in 100	Medium risk	Serious risk	Serious risk	Serious risk
>1 in 1000	Low risk	High risk	Serious risk	Serious risk
>1 in 10,000	Low risk	Medium risk	High risk	Serious risk
>1 in 100,000	Low risk	Low risk	Medium risk	High risk
>1 in 1,000,000	Low risk	Low risk	Low risk	Medium risk
<1 in 1,000,000	Low risk	Low risk	Low risk	Low risk

Same as Safety Gate

Table 4: Level of Risk (all items)				
Estimated number of items in use	Risk associated with single item (derived from Table 3)			
	Low	Medium	High	Serious
>1m	High risk	Serious risk	Serious risk	Serious risk
500k – 1m	High risk	High risk	Serious risk	Serious risk
100k – 500k	Medium risk	High risk	High risk	Serious risk
50k – 100k	Medium risk	Medium risk	High risk	Serious risk
10k – 50k	Low risk	Medium risk	High risk	Serious risk
1k – 10k	Low risk	Medium risk	High risk	Serious risk
<1k	Low risk	Medium risk	High risk	Serious risk

New in PRISM!

Uncertainty and sensitivity analysis

PRISM departs from Safety Gate with an assessment of uncertainty:

- Low, medium and high uncertainty labels
 - Based on factors including product novelty and basis of evidence
- Uncertainty labels supported with a rationale

Sensitivity analysis – same as Safety Gate but supported by recognition of uncertainty

This is the end of the assessment stage, but not the end of PRISM.....!



Risk evaluation – a bridge between risk assessment and risk management

Two parts of risk evaluation:

1. Factors related to the nature of the risk
E.g., Subjects at risk, potential for psychological harm, prevalence forecast, potential for multiple casualties, people at increased risk, action taking place elsewhere
They are objective matters – ‘*the facts*’
2. Factors related to how the risk is being, or will be perceived
E.g., media influence, political interest, inability of user to control the risk
Subjective matters – ‘*tolerability*’ – Grenfell as an example)

Information for risk evaluation will have been collected during the risk assessment



Part two guidance – additional information and for more complex issues

- **Risk triage**
 - **Multiple hazards**
 - **People at increased risk**
 - The precautionary principle
 - Testing and product homogeneity
 - Use of data
 - Factors that influence how risk is perceived
 - **Relative risk**
 - **Risk differential**
 - Non-compliance deemed serious risk
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Risk triage

Formalises the process we regularly carry out, so our thinking and rationale is captured

Based on 5 “*risk predictor*” questions

For cases that fall between ‘*always needs a full risk assessment*’, and ‘*doesn’t need a risk assessment*’

E.g., the difference between labelling and serious failures

Tools is intentionally designed to be cautious



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Setting the scene

See Prism guidance [add gov.uk link] Part 2 (1) for guidance on carrying out a risk triage

Hazards identified:	Choking
Should the issue be referred to OPSS for	Yes - Novel – the risks of the usage of a product are unknown and unquantified
Are there other products of interest?	Yes, but unable to ascertain risk as outside of expertise. Follow up required.

Product Screening Assessment

Rationale for product selection:	Single consumer complaint - consumer is harmed
Likely maximum severity of harm (if more than one potential harm, the harm of most concern):	It is plausible this product could cause death
Estimate of probability of harm occurring (if more than one potential harm, the harm of most concern):	Common - a greater than even chance
Number of hazards	There seems to be multiple hazards that are of equal concern
Product availability and prevalence:	Widely available and many already sold

Indicative risk outcome based on estimations above

Estimated risk label	Serious risk
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Indicative risk with product availability / prevalence factored in

Risk weighted by availability	Serious risk
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Triage outcome

Should a full risk assessment be	Required
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Multiple hazards

Often the case with electrical products, e.g.,:

- Counterfeit mains plug
- Undersize conductors in mains cable
- Creepage and clearance issues

Individually, these may all be medium risk

Two methods to reflect multiple hazards in one product:

- Risk plus
- Combining

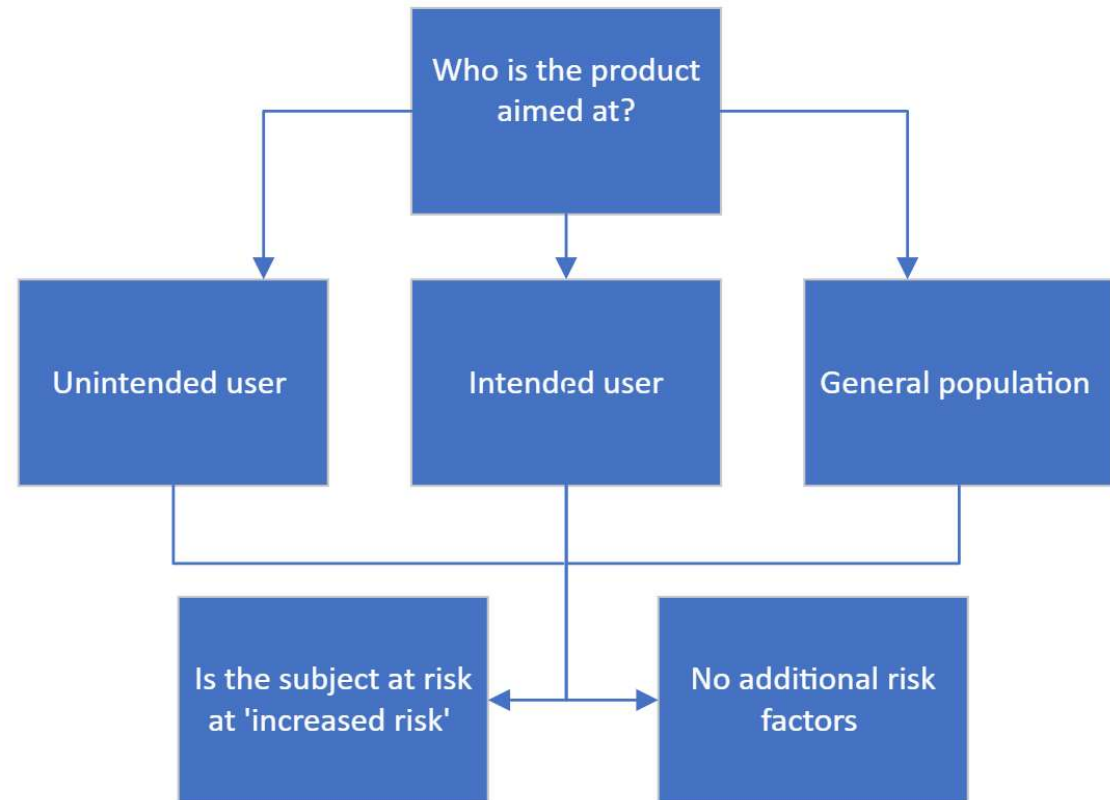


People at increased risk

Encourages broader thinking beyond traditional concepts, e.g., age

More than just perception of hazard considered

- Circumstances
- Characteristics



Risk differential and relative risk



Risk Differential:

Even compliant products can be risky!




Relative Risk:

Where do you start the harm scenario?



Reception and what's next...

- Its early days but so far PRISM has been well received and it has been well adopted
 - Training rolled out to users
 - Monitoring and review
 - Development of a digital tool (well underway) to replace the interim Excel tool
 - Development / adaptation to suit construction products
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Questions?