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
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

Stage 1
Identification of problem product

Stage 2
Risk Triage

Stage 3
Risk Assessment

Stage 4
Risk Evaluation

Stage 5
Quality Assurance and Recording/Reporting

Stage 6
Risk Management

Stage I
Define the product

Stage II
Identify the hazard/s

Stage III
Determine who or what could be harmed

Stage IV
Describe one or more harm scenarios

Stage V
Determine the severity of harm

Stage VI
Determine the probability of harm occurring

Stage VII
Determine the level of risk

Stage VIII
Consider the level of uncertainty
### “Single item risk” and “all items risk”

#### Table 3: Level of risk (single item)

<table>
<thead>
<tr>
<th>Probability of harm over lifetime of product</th>
<th>Severity of harm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 1</td>
</tr>
<tr>
<td>&gt;50%</td>
<td>High risk</td>
</tr>
<tr>
<td>&gt;1 in 10</td>
<td>Medium risk</td>
</tr>
<tr>
<td>&gt;1 in 100</td>
<td>Medium risk</td>
</tr>
<tr>
<td>&gt;1 in 1000</td>
<td>Low risk</td>
</tr>
<tr>
<td>&gt;1 in 10,000</td>
<td>Low risk</td>
</tr>
<tr>
<td>&gt;1 in 100,000</td>
<td>Low risk</td>
</tr>
<tr>
<td>&gt;1 in 1,000,000</td>
<td>Low risk</td>
</tr>
<tr>
<td>&lt;1 in 1,000,000</td>
<td>Low risk</td>
</tr>
</tbody>
</table>

#### Table 4: Level of Risk (all items)

<table>
<thead>
<tr>
<th>Estimated number of items in use</th>
<th>Risk associated with single item (derived from Table 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>&gt;1m</td>
<td>High risk</td>
</tr>
<tr>
<td>500k – 1m</td>
<td>High risk</td>
</tr>
<tr>
<td>100k – 500k</td>
<td>Medium risk</td>
</tr>
<tr>
<td>50k – 100k</td>
<td>Medium risk</td>
</tr>
<tr>
<td>10k – 50k</td>
<td>Low risk</td>
</tr>
<tr>
<td>1k – 10k</td>
<td>Low risk</td>
</tr>
<tr>
<td>&lt;1k</td>
<td>Low risk</td>
</tr>
</tbody>
</table>

Same as Safety Gate

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
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
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

Diagram:
- Who is the product aimed at?
  - Unintended user
  - Intended user
  - General population

Is the subject at risk at ‘increased risk’

No additional risk factors
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
Questions?