Risk assessment: What tools can market surveillance authorities’ use?

UN-ECE Conference on Risk Assessment and Management
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Danish Safety Technology Authority - in a nutshell

DIRECTIVES:
LVD - ATEX
GAD - MID
PYRO
GPSD - TOYS

95 Empl.
Ministry of Economic and Business Affairs
EMARS II Activities

A. Best Practice
B. Management and Planning of Future Joint Actions and Coordinated Market Surveillance Activities
C. Risk Assessment
D. Market Surveillance Guidance Material for External Stakeholders
E. Training
F. Continuous Improvement of National Market Surveillance Programmes
G. Standards Related Activities
H. Liaison with Notified Bodies
Why use risk assessment?

- Standards often gives the presumption of conformity with the safety requirements, but ...
- Non-compliance with standards is not equal to dangerous product!
- Lack of specific standards calls for risk assessment
- Risk assessment can answer the question: How dangerous is it? And it is a tool when a proportional reaction is calculated.
- Risk assessment is a good tool when you have to discuss with manufacturers – it helps to point out where you are in disagreement
Risk Assessment

Product

Consumers

Hazard(s)

Combine

Probability of scenario(s)

Injury scenario(s)

Inflicted body part

Severity of scenario(s)

Risk level

Combine

Risk assessment

Risk communication

Decide on proportionate measures
The tools... Old/Existing GPSPD

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### Table A - Risk Estimation

<table>
<thead>
<tr>
<th>Probability of Health/Safety Damage</th>
<th>Slight</th>
<th>Serious</th>
<th>Very Serious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>High</td>
<td>Medium</td>
<td>Low</td>
<td>Very Low</td>
</tr>
<tr>
<td>Medium</td>
<td>Low</td>
<td>Very Low</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severity of Health/Safety Damage</th>
<th>Overall Gravity of Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight</td>
<td>Very High</td>
</tr>
<tr>
<td>Serious</td>
<td>High</td>
</tr>
<tr>
<td>Very Serious</td>
<td>Moderate</td>
</tr>
<tr>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>Low</td>
<td>Very Low</td>
</tr>
</tbody>
</table>

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### Table B - Grading of Risk

#### Normal adults

<table>
<thead>
<tr>
<th>Vulnerable people</th>
<th>Normal adults</th>
<th>Adequate warnings and safeguards?</th>
<th>obvious hazard?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

#### Vulnerable people

<table>
<thead>
<tr>
<th>Moderate risk</th>
<th>Some action required</th>
<th>Low risk - Action unlikely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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SERIOUS RISK - RAPID ACTION REQUIRED

Moderate risk

Some action required

Low risk - Action unlikely
Nomogram - Lack of connection of safety earthing when a CEE-7 is used in Denmark

Worst case accident = Death

Probability = possible (legal to use)

Users opportunity to see the danger

Part result: significant presence of risk

A first assessment shows that it happens occasional

Final result = Significant problem
Nomogram - Information

Information campaign moves the curve

Situation today

Info - campaign
Nomogram – Mandatory RCCB

In order to have an accident you need to have a defect RCCB AND a defect apparatus.
The Nordic failure code list (LVD)

<table>
<thead>
<tr>
<th>Technical deficiencies</th>
<th>Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessible live part in normal use</td>
<td>3</td>
</tr>
<tr>
<td>Accessible basic insulated parts on class II products</td>
<td>2</td>
</tr>
<tr>
<td>Luminaries and domestic equipment of class 0</td>
<td>1</td>
</tr>
<tr>
<td>The creepage and clearance distance is less than 10% of the requirement in relevant standard</td>
<td>3</td>
</tr>
<tr>
<td>The creepage and clearance distance is more than 10% and less than 50% of the requirement in relevant standard</td>
<td>2</td>
</tr>
<tr>
<td>The creepage and clearance distance is more than 50% of the requirement in relevant standard</td>
<td>1</td>
</tr>
<tr>
<td>Cord extension set with class 0 plug and class 1 outlet</td>
<td>1</td>
</tr>
<tr>
<td>Cord extension set with class 1 plug and class 0 outlet</td>
<td>3</td>
</tr>
<tr>
<td>Cord extension set with class 2 plug and class 0 or 1 outlet</td>
<td>3</td>
</tr>
<tr>
<td>Class 1 plug on 2-conductor cable to class 0-device</td>
<td>3</td>
</tr>
<tr>
<td>Phase and earth mixed up in earthed coupling</td>
<td>3</td>
</tr>
<tr>
<td>The equipment lacks thermal cut-out and/or current cut-out</td>
<td>2</td>
</tr>
<tr>
<td>The rated current in the equipment is one step too high</td>
<td>1</td>
</tr>
<tr>
<td>The rated current in the equipment is more than one step too high</td>
<td>2</td>
</tr>
<tr>
<td>The rated current in equipment is so high that it is a fire hazard</td>
<td>3</td>
</tr>
<tr>
<td>The marking is incomplete or missing</td>
<td>2</td>
</tr>
</tbody>
</table>

Notes: (3) indicates a more severe code.
Final remarks

- New GPSD Guideline to be published in December – mandatory Risk Assessment for RAPEX
- We are still in the learning phase!
If time allows: An example of the steps in risk assessment

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Step 1, define the product
Step 1, define the product

RAPEX notification no. 0125/06
Cross pane hammer with metal handle and black plastic grip.
Step 2, identify the consumer
Step 2, identify the consumer

The product is normally used by adults.

Children may want to stand nearby to watch the adult working.
Step 3, identify the hazard(s)
Step 3, identify the hazard(s)

The plastic grip has insufficient mechanical strength and breaks when the user hits a hard surface.

(Only one hazard is considered in this example.)
Step 4, how does the hazard inflict on the consumer

- Product
- Consumers
- Hazard(s)
- Probability of scenario(s)
- Injury scenario(s)
- Severity of scenario(s)
- Inflicted body part
- Risk level

Decision:
- Risk assessment
- Risk communication

Proportionate measures
Step 4, how does the hazard inflict on the consumer

The upper part of the hammer bounces back and hits the user's arm. This causes bruising of the arm.

<table>
<thead>
<tr>
<th>Product hazards</th>
<th>Injury scenarios</th>
<th>Type of injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify all hazards that may lead to a consumer injury or health damage.</td>
<td>If you select a hazard from the Hazard List, a short scenario will be filled in here. <strong>Make this scenario more specific</strong> by describing at least: the exact hazard or defect in this product and the event that may result, the interaction of a person with the product during the intended and reasonably foreseeable use and the exposure to the hazard; the mechanism of injury.</td>
<td>For each hazard identified, describe the injury resulting from the injury scenario. If you select a hazard form the Hazard List, a typical injury(ies) will be filled in here. <strong>Make this more specific</strong> by describing both the injury and the body part. Click here to consult the Injury Scale.</td>
</tr>
<tr>
<td>low mechanical strength</td>
<td>Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm</td>
<td>Bruising of arm</td>
</tr>
</tbody>
</table>
Step 5, estimate severity of injury

- Product
- Consumers
- Hazard(s)
- Probability of scenario(s)
- Injury scenario(s)
- Inflicted body part
- Severity of scenario(s)
- Risk level

Risk assessment → Risk communication

Decide on proportionate measures
### Step 5, estimate severity of injury

<table>
<thead>
<tr>
<th>Type of injury</th>
<th>Slight</th>
<th>Moderate</th>
<th>Serious</th>
<th>Very serious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laceration, Cut</td>
<td>External (deep) (&gt;10 cm on body)</td>
<td>Optic nerve</td>
<td>Bronchial lobe</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(intra or into joint)</td>
<td>Throat gland</td>
<td>Desmophagus</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bladder</td>
<td>Aorta</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tendon or into joint</td>
<td>Nerve root cut</td>
<td>Spinal cord (low)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>White of eye</td>
<td>Brain</td>
<td>Deep lung laceration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Torque (deep)</td>
<td>Liver</td>
<td>Deep laceration of intestines, kidney, liver, spleen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Concre</td>
<td>Lung</td>
<td>Spleen, stomach, intestinal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Abdomen (deep but no organ damage)</td>
<td>Neck artery</td>
<td>Severed brain, high spinal cord</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Thoracic</td>
<td>Intestines</td>
<td>Completely severed aorta</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intestines</td>
<td>Kidney</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Liver</td>
<td>Brain</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spinal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lung (superficial)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Peril</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product hazards | Injury scenarios | Type of injuries | Severity of injuries | Probability of factors**

1. **Identify all hazards that may lead to a consumer injury or health damage.**
   - Consider all consumers, including the vulnerable.

2. **Product hazards**
   - Defect: handle grip breaks because shaft is too short. Top part of handle covers back and hits users arm.
   - Low mechanical strength

3. **Injury scenarios**
   - If you select a hazard from the Hazard List, a short scenario will be filled in here. Make this scenario more specific by describing at least:
     - The exact hazard or defect in this product and the event that may result:
     - The interaction of a person with the product during the intended and reasonably foreseeable use and the exposure to the hazard;
     - The mechanism of injury.

4. **Type of injuries**
   - For each hazard identified, describe the injury resulting from the injury scenario.
   - If you select a hazard from the Hazard List, a typical injury will be filled in here. Make this more specific by describing both the injury and the body part.

5. **Assign from the Injury Scale.**
   - Very serious to Slight.
   - Click into cell below.

6. **Severity of injuries**
   - Slight
   - Serious
   - Serious
   - Serious

7. **Select severity level from the scale**
Step 6, the probability of the injury scenario

- Product
- Consumers
- Hazard(s)
- Probability of scenario(s)
- Injury scenario(s)
- Inflicted body part
- Severity of scenario(s)
- Risk level
- Risk assessment
- Risk communication
- Decide on proportionate measures
Step 6, the probability of the injury scenario

Injury scenario is broken up in smaller steps.
Find probability of each step

1. Handle breaks (estimated probability 50%)
2. The upper parts hits the arm (estimated probability 20%)
Step 7, combine severity and probability

1. Product
2. Consumers
3. Hazard(s)
4. Probability of scenario(s)
5. Injury scenario(s)
6. Inflicted body part
7. Severity of scenario(s)
8. Risk level

Risk assessment
Risk communication

Decide on proportionate measures
Step 7, combine severity and probability

<table>
<thead>
<tr>
<th>Probability</th>
<th>Very Serious</th>
<th>Serious</th>
<th>Moderate</th>
<th>Slight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost certain, might well be $&gt;50%$</td>
<td>Serious risk</td>
<td>Serious risk</td>
<td>Serious risk</td>
<td>Moderate risk</td>
</tr>
<tr>
<td>Quite possible</td>
<td>$&gt;1/10$</td>
<td>Serious risk</td>
<td>Serious risk</td>
<td>Serious risk</td>
</tr>
<tr>
<td>Unusual but possible</td>
<td>$&gt;1/100$</td>
<td>Serious risk</td>
<td>Serious risk</td>
<td>Serious risk</td>
</tr>
<tr>
<td>Only remotely possible</td>
<td>$&gt;1/1000$</td>
<td>Serious risk</td>
<td>Serious risk</td>
<td>Moderate risk</td>
</tr>
<tr>
<td>Conceivable, but highly unlikely</td>
<td>$&gt;1/10.000$</td>
<td>Serious risk</td>
<td>Moderate risk</td>
<td>Low risk</td>
</tr>
<tr>
<td>Practically impossible</td>
<td>$&gt;1/100.000$</td>
<td>Moderate risk</td>
<td>Low risk</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Impossible unless aided</td>
<td>$&gt;1/1.000.000$</td>
<td>Low risk</td>
<td>Acceptable</td>
<td>Acceptable</td>
</tr>
<tr>
<td>(Virtual) Impossible</td>
<td>$&lt;1/1.000.000$</td>
<td>Acceptable</td>
<td>Acceptable</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
Step 8, report result
Step 8, report result

- Identification of product and case, description of the context
- Description of the hazards
- Description of injury scenarios and sensitivity

<table>
<thead>
<tr>
<th>Injury scenarios</th>
<th>Injury type and location</th>
<th>Severity of injuries</th>
<th>Probability of injuries</th>
<th>Resulting probability</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm</td>
<td>Bruising of arm</td>
<td>Slight</td>
<td>Handle breaking: 1/2, Hitting arm: 1/5</td>
<td>1/10</td>
<td>Low</td>
</tr>
</tbody>
</table>

- Conclusion
  (including reflections on the result.)