OECD Workshop on Product Risk Assessment

Risk Assessment Approaches
Brazil Experience

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Brazil

Area: 8,52 million km²
Population: about 200 million
GNP: US$ 2,3 trillions
7th largest economy
Takes part of BRICs
Over 30 different regulatory agencies – Inmetro is one of them
INMETRO – Who We Are

- **National Institute of Metrology, Quality and Technology**
- **Created in 1973**
- **Under the Ministry of Development, Industry and Foreign Trade**
- **Support the competitiveness and the productivity of the national industry**
- **Protect safety and health of the consumer and the environmental**
Main Activities

• National Metrology Institute
• Enquiry Point of WTO’s Technical Barriers to Trade
• National Accreditation Body
• Regulator on Legal Metrology
• Regulator on Consumer Product Safety and Unfair Competition (“regulatory gap”)
• Coordinator of the Conformity Assessment Schemes implemented under the Brazilian Conformity Assessment System
• Coordinator of the Brazilian Legal Metrology and Quality Network (local inspectors) that is responsible for the inspections at the marketplace, industries and, more recently, at the borders, ports and airports
IMPLEMTATION CAP STEPS

1- Demands Identification and Prioritization
2- Regulatory Impact Analysis
3- Development
4- Implementation
5- Market Surveillance
6- Maintenance
7- Improvement
<table>
<thead>
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<th>Steps of the Regulatory Impact Analysis</th>
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<tr>
<td>Context</td>
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<tr>
<td>Legal Framework</td>
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<tr>
<td>Definition of the Alternatives</td>
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<td>Feasibility Analysis</td>
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<td>Impact Analysis</td>
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<td>Institutional Risk Analysis</td>
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<td>Comparison of the Alternatives’ Impacts</td>
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<td>Conclusions and Recommendations</td>
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Risk Assessment: Methodology and Data Base

- Probabilities are estimated from surveys and international injury data bases and stakeholders consultations

NEISS
RAPEX
Inmetro’s Injury Data Base
Health Data Base (DataSUS)
Brazilian Information System on Consumer Protection
Brazilian Recall Alert System
Manufacturers Associations
Consumer Protection NGO
Steps of the Regulatory Impact Analysis

Case study: Protection for stoves

1) Context: Suggestion to make mandatory sales of stove protectors together with stoves

2) Legal framework: “Joint sales” forbidden by Consumer’s law

3) Definition of alternatives:
   - make mandatory standards for stove protectors;
   - other measures
Risk Assessment: Methodology and Data Base

Case study: Protection for stoves

4) Feasibility analysis
   - Infrastructure to implement doesn’t exist

5) Impact analysis
   - Studies of Brazilian market (production / sales / costs)
   - About 54 brands of stoves
   - Costs of production and sales incomes are very close
   - Only 2 suppliers of protectors – low offer and low demand
   - High impact on prices to consumers
Risk Assessment: Methodology and Data Base

Case study: Protection for stoves

5) Impact analysis: Risk analysis of the product

Injury Data from DataSus:

- Injuries (burns) caused by contact with hot liquids, hot food, hot oil – about 1,009 accidents per year

- Injuries caused by contact with hot surfaces - about 124 accidents per year

- Population of children: about 34,000,000
Risk Assessment: Methodology and Data Base

- RAPEX RAG: http://europa.eu/sanco/rag/
Risk Assessment: Methodology and Data Base


### Product risks - Overview

**Scenario 1**: Low risk - Young children touching hot containers over a stove, liquid or other substances spills on the skin and causes scalds.

**Scenario 2**: Low risk - Young children touching hot containers over a stove, heating causes scalds.

**Scenario 3**: Low risk - A person near the flames may sustain burns, possibly after clothing catches fire.
Risk Assessment: Methodology and Data Base

- RAPEX RAG: http://europa.eu/sanco/rag/

**Scenario 1: Young children - Hot liquids**

**Product hazard**
- Hazard Group: Extreme temperatures
- Hazard Type: Hot liquids

**Consumer**
- Consumer Type: Young children - Older than 36 months and younger than 8 years (Vulnerable consumers)

**How the hazard causes an injury to the consumer**
- Injury scenario: Young children touching hot containers over a stove, liquid or other substances spills on the skin and causes scalds.
Risk Assessment: Methodology and Data Base

- RAPEX RAG: http://europa.eu/sanco/rag/

### Severity of Injury

<table>
<thead>
<tr>
<th>Injury:</th>
<th>Burn / Scald (by heat, cold, or chemical substance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level:</td>
<td>2 2º, 6-15% of body surface</td>
</tr>
</tbody>
</table>

### Probability of the steps to injury

<table>
<thead>
<tr>
<th>Step(s) to Injury</th>
<th>Probability</th>
</tr>
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<tbody>
<tr>
<td>Burn / Scald 2º X 10</td>
<td>0.000029</td>
</tr>
</tbody>
</table>

Calculated probability: 0.000029000
Overall probability: > 1/100,000
Risk of this scenario: Low risk
### Risk Assessment: Methodology and Data Base

- **RAPEX RAG:** [http://europa.eu/sanco/rag/](http://europa.eu/sanco/rag/)

<table>
<thead>
<tr>
<th>Probabilidad de lesión durante el ciclo de vida previsible del producto</th>
<th>Gravedad de la lesión</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevada</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 50%</td>
<td>H</td>
</tr>
<tr>
<td>&gt; 1/10</td>
<td>M</td>
</tr>
<tr>
<td>&gt; 1/100</td>
<td>M</td>
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<tr>
<td>&gt; 1/1 000</td>
<td>L</td>
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<td>&gt; 1/10 000</td>
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</tbody>
</table>

**S** - Riesgo grave  
**H** - Riesgo elevado  
**M** - Riesgo medio  
**L** - Riesgo bajo  

**Calculated probability:** 0.000029000  
**Overall probability:** > 1/100,000  
**Risk of this scenario:** Low risk
Risk Assessment: Methodology and Data Base

Case study: Protection for stoves

6) Institutional Risk Analysis
- it can harm competition
- it can harm liberty to choose, and increase prices
- it can’t conflict with consumer defense law

7) Conclusions and recommendations
- Don’t create a regulation for stove protectors
- Use campaigns to alert consumers related to domestic risks while using the stove
Product Risk Assessment is carried out in 2 different moments during the RIA:

**Pre-regulation**
- During the clarification of the “problem”
- To establish the risk level of the product

**Pos-regulation**
- To evaluate the technical regulation and, if it exists, its conformity assessment procedure
The Regulatory Impact Analysis is a very important tool for decision making.

Making Technical Regulation is increasingly an option to be analysed by the Brazilian government.

Data bases analysis and research are essential components to make Risk Assessment.

Brazilian Working Party on Consumer Safe and Health is trying to improve data collection of injuries in hospitals.

The Interamerican Recalls Rapid Alert System (SIAR) supported by Consumer Safety and Health Network will be also a data source for Risk Assessment for Brazil.
Workshop on Product Risk Assessment

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OBRIGADO!!!