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# Basic principles in risk assessment

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“Joint Actions & Best Practice”  
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*Dr. Matthias Honnacker*  
*Risk Assessment activity*  
*under Joint Action 2011*

# Content

**RAPEX Risk Assessment is the European method to conduct an investigation on products.**

- How does it compare to other methods touching
  - other product fields,
  - other protection targets?
- What are its limits and how might they be solved?
  - Proposal for a structured technique to improve uncertain factors.

# Basic principle of risk assessment

## •Determination

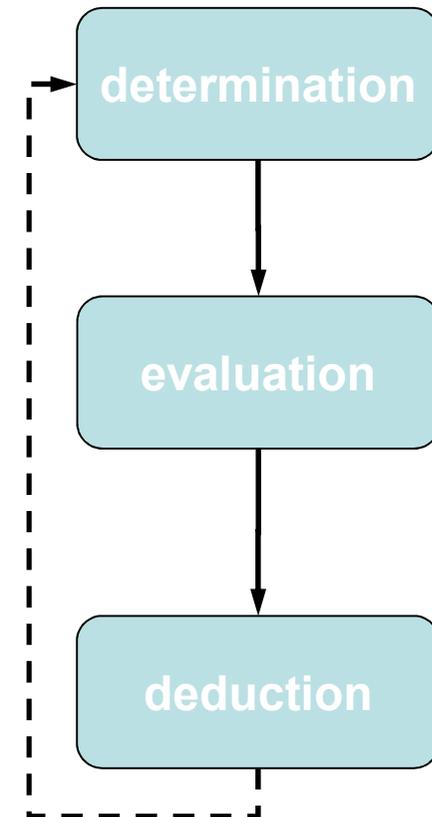
- Identification, description, circumstances of contact, possible consequences
- Factors: physical, chemical, biological, ergonomic, psychological, organizational, etc.

## •Evaluation

- Value categories, criteria for determining the need for action
- RAPEX methode, risk graph, nomograph, FMEA, etc.

## •Deduction

- Identification / selection of measures
- Reduction of risk, damage prevention
- Implementation, evaluation
- in a given context, e.g. market surveillance, safety, reliability



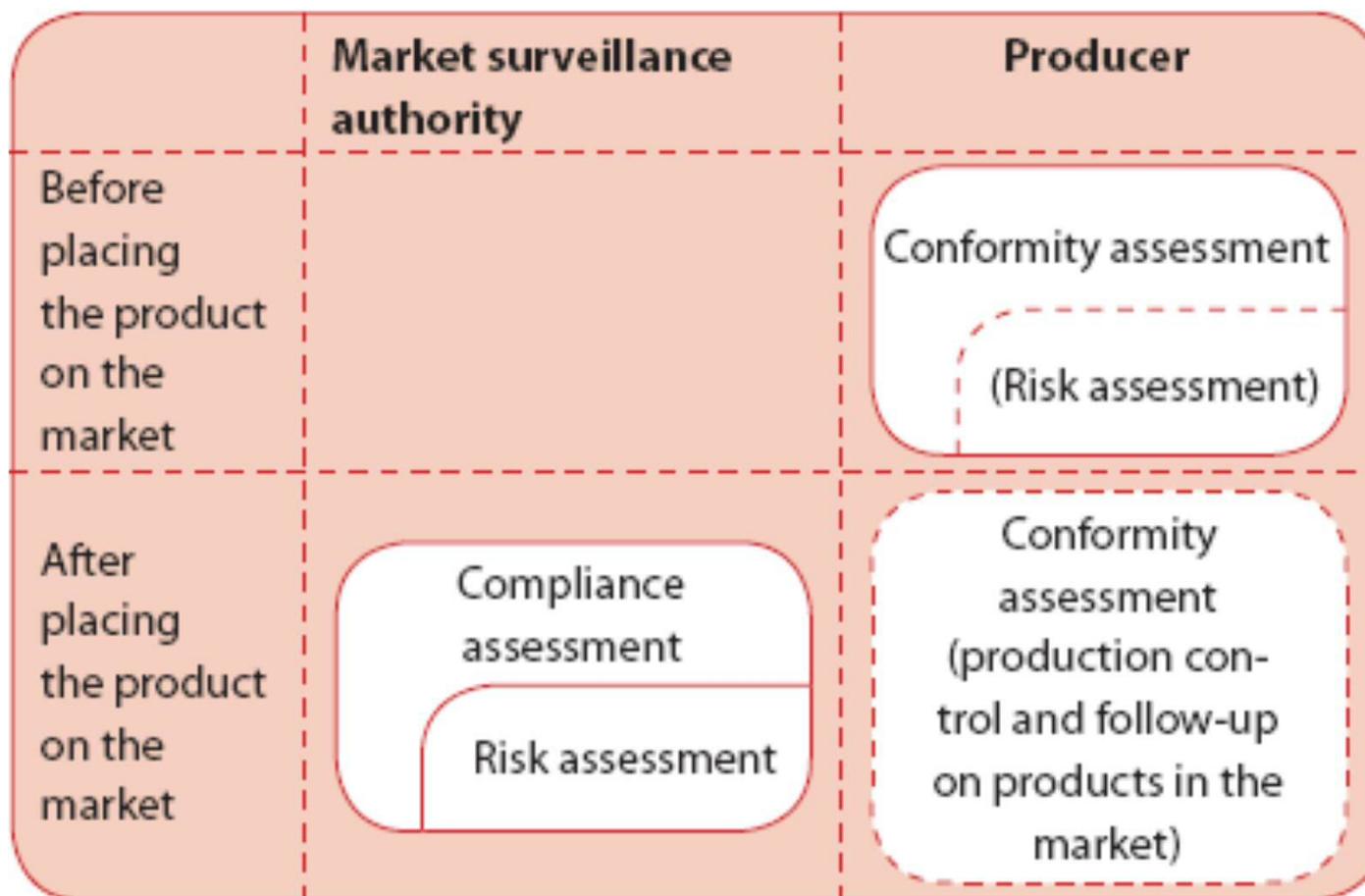
# Common elements

## Risk Assessment comprises

- risk analysis, comprising
  1. determination of the limits,
  2. hazard identification,
  3. risk estimation, and
- risk evaluation.

(EN ISO 12100 Safety of machinery – General principles for design – Risk assessment and risk reduction)

## Protection from unsafe products



## Economic operator's view

### Risk Assessment

- makes internal (!) **decision support** more objective
- objectifies decisions
- makes results plausible
- makes results **communicable to the outside (!)**
- also against casualties, insurance and prosecutors...  
and market surveillance authorities

## Enforcement's view

### Risk Assessment

- makes internal (!) **decision support** more objective
- objectifies decisions
- makes results plausible
- makes results **communicable to the outside (!)**
- also against casualties, insurance and prosecutors...  
and economic operators.

## Enforcement's view

- In conformity or not?
- Risk Level?
- Which procedure? RAPEX or not?
- Justification of the corrective measures.

## Proceeding in RAPEX Risk Assessment

### Criteria for the evaluation of risk level

**Table 1:** Vulnerable consumers

**Table 2:** Hazards, typical injury scenario and typical injury

**Table 3:** Severity of injury

**Table 4:** Probability of injury

**Table 5:** Risk level from the combination of the severity of injury  
and the probability

RAPEX-Guidelines (COM-Decision 2010/15/EU)

## Different worlds?

- The general approach is common to risk assessment procedures in all sectors
  - food, feed,
  - Medical Devices,
  - motor vehicles, ...
- and covers all kinds of hazards
  - physical, chemical, nuclear, biological factors,
  - acute or long-term effects, ...
- and every protection target
  - human beings,
  - animals and environment,
  - property and critical infrastructure, ...

## Uncertainties and weaknesses

- How likely is it that a certain chemical causes cancer?
  - Estimation - based on animal testing.
- How likely is it that a pram collapses in such a way that a child's finger is cut off?
  - Estimation - based on intuition.

*Is the one better than the other?*

## Uncertainties and weaknesses

Any operational risk assessment suffers from

- lack of field data
- time-consuming process
- subjectivity
- uncertain probability factors

## First Conclusion

- The RAPEX Risk Assessment follows common principles and is as good or as bad as any other method!

## What is feasible in Market Surveillance?

### On Site

- Visual inspection
- Obvious violations of law
- Formal requirements (labeling, documentation ...)
- Obvious safety issues (sharp edges, small parts, instability ...)
- Easy standard requirements and simple test (eg dimensions, small parts, laser)
- Possibly investigation after accident ...

### In addition (usually no more on-site)

- Data Research (eg ICSMS, RAPEX, IDB, PROSAFE, standards ...)
- Other simple tests (eg surface temperature ...)
- To some extent "disassemble" ...
- Laboratory test.

## Reminder

How likely is it that a pram collapses in such a way that a child's finger is cut off?

- Estimation - based on intuition.

Any operational risk assessment suffers from

- lack of field data
- time-consuming process
- subjectivity
- uncertain probability factors

## Proposal for a solution

- The RAPEX guidelines advises to discuss with colleagues - a good proposal.
- My proposal is to do this in a systematic way using an approach inspired by the **DELPHI method**
  - This is a structured communication technique, originally developed as a systematic, interactive forecasting method which relies on a panel of experts.

## Delphi method for Market Surveillance

- Delphi is based on the principle that forecasts (or decisions) from a structured group of individuals are more accurate than those from unstructured groups.
- Experts answer questionnaires in two or more rounds.
- After each round, a facilitator provides an anonymous summary of the experts' forecasts from the previous round as well as the reasons they provided for their judgments.

## Delphi method for Market Surveillance

- Thus, experts are encouraged to revise their earlier answers in light of the replies of other members of their panel.
- It is believed that during this process the range of the answers will decrease and the group will converge towards the "correct" answer.
  - Example / experiment will follow during the Risk Assessment Market Place

## Decision based on intuition

- Gerd Gigerenzer, a director at the Max Planck Institute for Human Development, is researching the science of good decision making.
- The trick is not to amass information, but to discard it: to know intuitively what one doesn't need to know.
- He suggests that we hone the cognitive, emotional, and social repertoire we've evolved over the millenia.

## Gut feelings and intuition

- What lies behind our moral behavior if not reflection and reasoning?
- How Simple "rules of thumb" can help amateurs beat the stock market, outfielders catch a fly ball, parents choose a school, or lovers a mate?
- How can market surveillance officers estimate the probability of certain steps leading to an accident?

## Gut feelings and intuition

- The repertoire consists of rules of thumb that, unlike the rules of theoretical logic, have evolved expressly to cope with the human experience.
- Social intelligence, for example, relies on powerful intuitive tools including trust, deception, identification, rumor, wishful thinking, and cooperation.

# Gut feelings and intuition

- Social and political change, good or bad, often originates from these factors rather than from lucid reasoning.
- What looks like a reasoning error from a purely logical perspective can be a highly intelligent social judgement in our fiendishly complex lives.

## Scientific background and source

- Gigerenzer, G., & Engel, C. (Eds.). (2006). *Heuristics and the law*. Cambridge, MA: The MIT Press in cooperation with Dahlem University Press.
- Gigerenzer, G. (2007). *Gut Feelings. The intelligence of the unconscious*. New York: Viking.

## First Conclusion

- The RAPEX Risk Assessment follows common principles and is as good or as bad as any other method!

## Second Conclusion

- Uncertainties can not be solved but there are approaches to deal with that problem - science based and easy to handle !



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- Thank you for your attention!
- Have fun with Delphi...

## Example / Experiment

- Let's do the Delphi...
- Based on RAPEX  
0812/11
- Pushchair/pram  
notified by Slovakia



## Example / Experiment



- In the access zones of a child on the side construction there are accessible gaps, where the fingers of a child can be entrapped.
- The pushchair is equipped only with one folding device on rear bottom part.
- It may result in the vehicle folding and in an entrapment of a child in the vehicle by incidental manipulation with the pushchair.

## Procedure

- Please take the Risk Assessment sheets and estimate the probabilities for the given steps.
- Where possible try to explain your reason for your choice.
- We collect the sheets and prepare a summery.
- With the knowledge about the summery we start a second round and compare with the first.