Risk Ranking Methodology

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Synopsis

- What do we mean by risk?
- Why risk comparisons?
- What methods are available?
- The Swedish Risk Thermometer
- Do we need to harmonise risk ranking in Europe?
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Semantics of risk

- Risk ≠ Hazard
  - Hazard = inherent property to cause damage
- Risk is
  - Probability of damage at a certain intake/exposure
  - Taking severity of damage into account?
  - Taking characteristics of affected population into account?
  - Taking uncertainties into account?
  - Taking risk perception into account?
- Should we rather talk about level of concern?
Hazard

Risk
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Purpose of the General Food Law
EG 178/2002

Among other things...

• **Protect consumers from negative health effects caused by food and feed**
  – By legally binding constraints and dietary advice
  – In cases of non-regulated agents
    • Need to prioritise based on risks due to limited resources
  – Non regulated risks get less resources

• **Reduce trade barriers – ensure free flow of food and feed**
  – Legally binding constraints
  – In case of regulated agents – sometimes less focus on level of risk. Could be important for rationalisation of decisions
  – Regulated risks get more resources
Equally important

• Vital to rank risks in communication with consumers
  – Distorted media debate causing unnecessary fears
    • Need for a simple, transparent adaptive system
    • Facilitate understanding of the scientific process
  – Increase public trust in authorities

• Ensure proportionality of risk management response from a health perspective
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Available data determines type of method

• Assessment of
  – nutritional and microbiological risks
    • almost always based on human data
  – chemical risks
    • seldom based on human data

• New developments in toxicology
  – Increased use of *in vitro* studies and *in silica* assessments

• Prioritising on “Other legitimate factors” OLFs
Risk ranking methods - I

- **Chemical Risk assessment**
  - Comparing Risk Characterisations
  - A harmonised wide spread methodology
  - Huge amounts of data – cumbersome
  - Restricted to natural science

- **Microbiological Risk Assessment**
  - Different combinations of
    - Deterministic, probabilistic, qualitative, semi-quantitative, quantitative modelling
  - EFSA QMRA-method
  - Lack of data is a constraint – uncertainty analysis important
  - QMRA could be one of the most efficient methods to estimate risk, including the relevant uncertainties
  - Complicated assessments – difficult for laymen

Risk assessment
- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization
Risk ranking methods – II

• **Risk ratio**
  – Ratio exposure/toxicological reference value
    • ADI, TDI, Benchmark dose (BD), RfD
  – Margin of Exposure – MOE – increased use
  – Can easily be applied if data are available
  – Restricted to natural science

• **Scoring methods**
  – Exposure multiplied by some effect characterisation
    • No consensus on what endpoints to include or how to set criteria
Risk ranking methods – III

• **Risk matrices**
  – Exposure and effect elements are depicted in a risk ranking matrix.
    • Effect on the one axis and exposure on the other.
    • Visualises both effect and exposure
    • Provides insights into the way these two elements contribute to the overall risk
    • Qualitative or semi quantitative, depend on expert input

![Risk Ranking Matrix](image-url)
Risk ranking methods – IV

• **Multi Criteria Decision Analysis - MCDA**
  – Typically used when multiple conflicting criteria are involved
  – Allows modelling with various weights for different input factors
    • E.g. health risk, life cycle environmental impact, financial cost, energy expenditure
  – Possible to consider inputs from stakeholder perception by assigning weights to the various criteria used
  – Allows inclusion of subjective elements that may be important for e.g. risk managers, depending on the aim of the ranking exercise.
  – Wide variety in modelling - difficult to communicate
  – Involves expert judgement – selection of experts very important
  – Covers more than natural science
  – Have been applied in cases where crucial information is missing, and yet a decision needs to be made
Risk ranking methods – V

• Flow charts/Decision Trees
  – A set of clearly defined questions/criteria
    • Specific for each type of problem
    • Yields, in most cases, qualitative indications of risk
  – Depends strongly on expert input
  – In some instances low transparency
    • Underlying reasons for classification unclear
Risk ranking methods - VI

• **Expert judgment**
  – Elicit rankings from experts, stakeholders, citizens
  – Often used when there are severe data gaps
  – Incorporate societal values
  – Performed at Workshops and by e.g. Delphi Surveys
  – Require careful design
    • Careful selection of participants
    • Proper framing

• **Disability Adjusted Life Years – DALY**
DALY

- DALY = YLL+YLD
- YLL
  - Number of years being prematurely dead
- YLD
  - Number of years as disabled
    - Corrected for severity of disability
- How to define severity
  - Death
  - Cancer
  - Malformations
  - Food poisoning
  - Liver damage
  - Sin rash
  - ...

National Food Agency
DALY

• Requires human disease data
  – Often restricted to nutrition and microbiology
• Modelling other types of data is difficult
• Once DALY has been calculated, comparisons are readily done
## Comparability between domains

<table>
<thead>
<tr>
<th>Data gaps</th>
<th>Chemical Risk Assessment</th>
<th>Qualitative Microbiol. Risk Assessment</th>
<th>Nutritional Risks, DALY</th>
<th>MCDA</th>
<th>Risk Matrix</th>
<th>Expert Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>No human incidence data</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No dose-response data</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No occurrence data</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No food consumption data</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No growth models</td>
<td>N.A</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>No toxicological reference data</td>
<td>Yes</td>
<td>N.A</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Adapted from Van der Fels-Klerx et al. EFSA supporting publication 2015:EN-710
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The Risk Thermometer (NFA 2015)

- A severity-adjusted margin of exposure approach - SAMOE
  - A generalization of the current framework for chemical risk assessment
  - \( \text{BMDL}_{10}, \text{AFs}, \text{severity factors (five options), exposure assessment} \)
  - Includes effects both with and without thresholds
- A model for *uncertainty* analysis
  - Semi quantitative analysis of SAMOE components
- A risk *classification* approach
  - Categorizes the SAMOE values in terms of five health concern levels
- A *graphical* illustration of the results - tailored for different users
Tentative graphical illustration
Aimed at risk managers – level of concern - based on Swedish mean exposure
Tentative graphical illustration
Aimed at the general public – based on mean exposure for all Swedes

No risk
Low risk
Possible risk
Risk
High risk
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Need for harmonisation?

• A rather complex multidisciplinary field
• Many studies have been performed in Europe using a wide variety of methods.
• Budgetary constraints, both nationally and on Community level necessitate risk based priority settings
• Legal demands on risk based food safety control
• **Definitively a need for cooperation and harmonisation on an EU level**
• Many thanks for your attention

• I wish HAH at least 10 more years as successful as the start!
EFSA funded assessment of available methods and their use 1993-2013

Table 2: Overview of method categories used for risk ranking of the various hazards

<table>
<thead>
<tr>
<th>Type of hazard</th>
<th>Risk assessment</th>
<th>Comparative risk assessment</th>
<th>Ratio</th>
<th>Scoring</th>
<th>Cost of illness</th>
<th>DALY/QALY</th>
<th>WTP</th>
<th>MCDA</th>
<th>Risk Matrix</th>
<th>Flow chart / Decision trees</th>
<th>Expert judgment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical</td>
<td>19</td>
<td>0</td>
<td>31(^3)</td>
<td>19(^3)</td>
<td>1(^2)</td>
<td>9(^3,4)</td>
<td>1(^2)</td>
<td>13</td>
<td>12</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Microbiological</td>
<td>72</td>
<td>0</td>
<td>6(^2)</td>
<td>5(^3)</td>
<td>9(^2)</td>
<td>19(^3)</td>
<td>6(^2)</td>
<td>4</td>
<td>4</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>Nutritional</td>
<td>4</td>
<td>2</td>
<td>1(^0)</td>
<td>0(^0)</td>
<td>0(^0)</td>
<td>1(^4)</td>
<td>0(^0)</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0(^0)</td>
<td>0(^0)</td>
<td>0(^0)</td>
<td>0(^0)</td>
<td>1(^1)</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Sum</td>
<td>95</td>
<td>2</td>
<td>38(^)</td>
<td>24(^)</td>
<td>10(^)</td>
<td>29(^)</td>
<td>8(^)</td>
<td>19(^)</td>
<td>16(^)</td>
<td>22(^)</td>
<td>15(^)</td>
</tr>
</tbody>
</table>

1WTP: Willingness to Pay; MCDA: Multi Criteria Decision Making; 2One reference describes both chemical and microbiological hazards; 3Three references describe both chemical and microbiological hazards. 4One reference describes both chemical and nutritional hazards.

Van der Fels-Klerx et al. EFSA supporting publication 2015:EN-710
Anticipated use can determine choice of method

• Risk of actual exposure to a defined agent
• Risk resulting from technical operators
  – Primary production
  – Food processing
  – Transports
  – Retailing
• The presentation will focus on the former use
# Disability factors - examples

<table>
<thead>
<tr>
<th>Condition</th>
<th>Disability weight (+ UI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cancer</strong></td>
<td></td>
</tr>
<tr>
<td>Original Cancer, diagnosis and primary therapy</td>
<td>0.265</td>
</tr>
<tr>
<td>Original Cancer, metastatic</td>
<td>0.358</td>
</tr>
<tr>
<td>Original Stoma</td>
<td>0.125</td>
</tr>
<tr>
<td>Original Terminal phase, with medication (for cancers, end-stage kidney/liver disease)</td>
<td>0.515</td>
</tr>
<tr>
<td>Original Terminal phase, without medication (for cancers, end-stage kidney/liver disease)</td>
<td>0.588</td>
</tr>
<tr>
<td><strong>Cardiovascular and circulatory disease</strong></td>
<td></td>
</tr>
<tr>
<td>Original Acute myocardial infarction, days 3-28</td>
<td>0.098</td>
</tr>
<tr>
<td>Original Angina pectoris, moderate</td>
<td>0.103</td>
</tr>
<tr>
<td>Original Cardiac conduction disorders and cardiac dysrhythmias</td>
<td>0.295</td>
</tr>
<tr>
<td>Original Heart failure, mild</td>
<td>0.052</td>
</tr>
<tr>
<td>Original Heart failure, moderate</td>
<td>0.070</td>
</tr>
<tr>
<td>Original Heart failure, severe</td>
<td>0.173</td>
</tr>
<tr>
<td>Original Stroke, long-term consequences, moderate</td>
<td>0.075</td>
</tr>
<tr>
<td>Original Stroke, long-term consequences, severe plus cognition problems</td>
<td>0.580</td>
</tr>
</tbody>
</table>

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