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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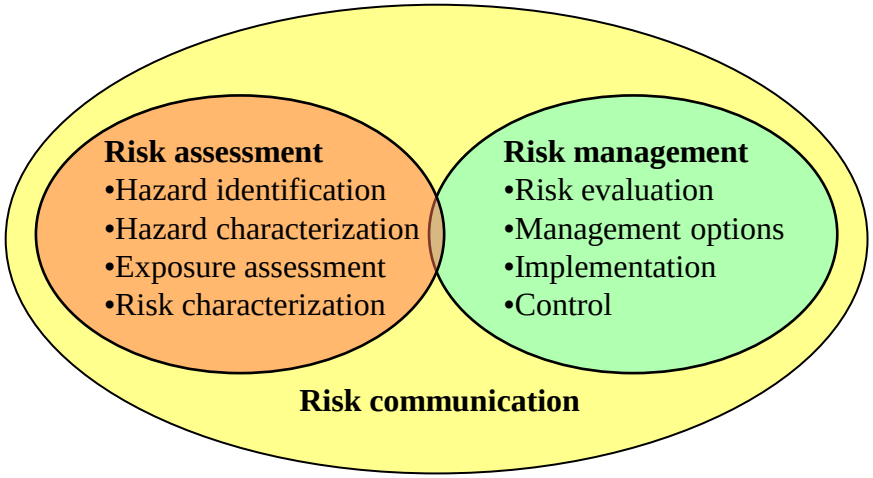
Semantics of risk



- 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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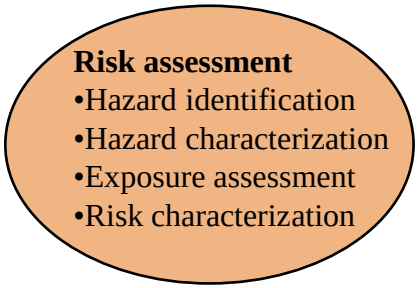
Available data determines type of method

- 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 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

Likelihood	Consequences				
	Insignificant	Minor	Moderate	Major	Severe
Almost certain	M	H	H	E	E
Likely	M	M	H	H	E
Possible	L	M	M	H	E
Unlikely	L	M	M	M	H
Rare	L	L	M	M	H

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
  - …

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

Data gaps	Chemical Risk Assessment	Qualitative Microbiol. Risk Assessment	Nutritional Risks ,DALY	MCDA	Risk Matrix	Expert Judgement
No human incidence data	Yes	**No**	**No**	Yes	Yes	Yes
No dose-response data	**No**	**No**	Yes	Yes	Yes	Yes
No occurrence data	**No**	**No**	Yes	Yes	Yes	Yes
No food consumption data	**No**	**No**	**No**	Yes	Yes	Yes
No growth models	N.A	**No**	Yes	**No**	**No**	**No**
No toxicological reference data	Yes	N. A	Yes	Yes	Yes	Yes

Adapted from Van der Fels-Klerx et al. EFSA supporting publication 2015:EN-710

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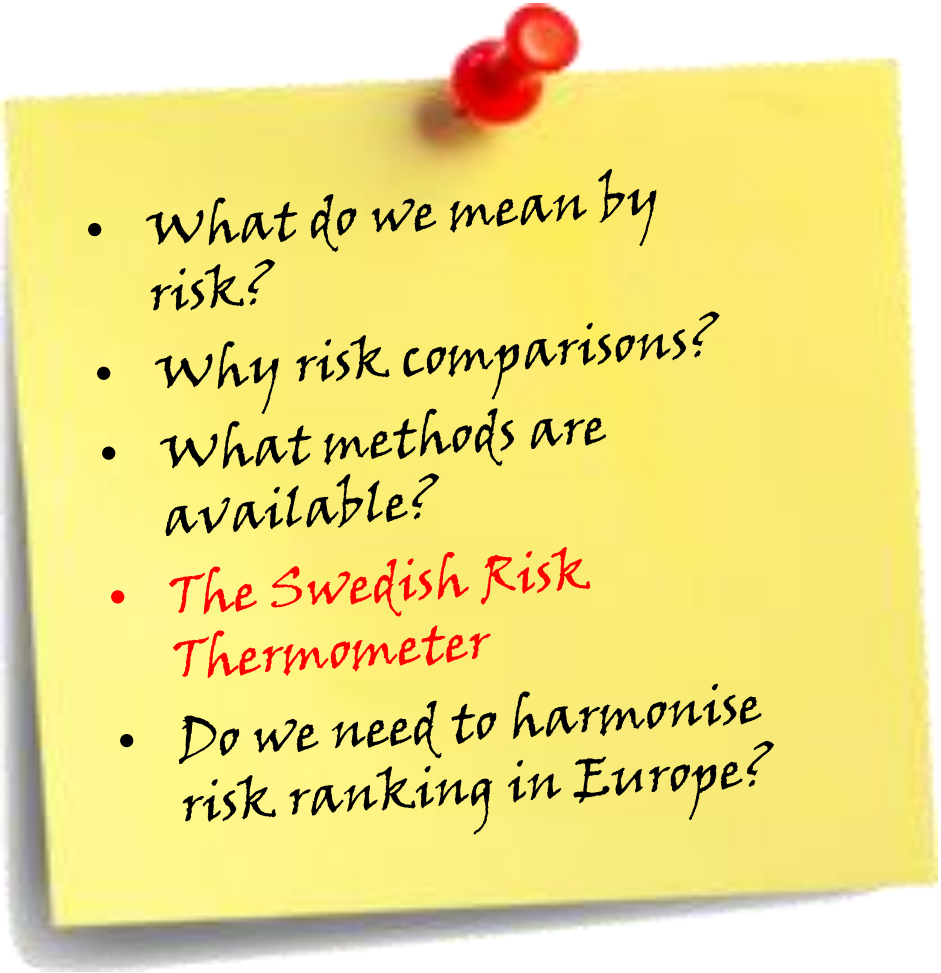

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The Risk Thermometer
(NFA 2015)

- A severity-adjusted margin of exposure approach - SAMOE
  - a generalization of the current framework for chemical risk assessment
  - $BMDL_{10}$, AFs, 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

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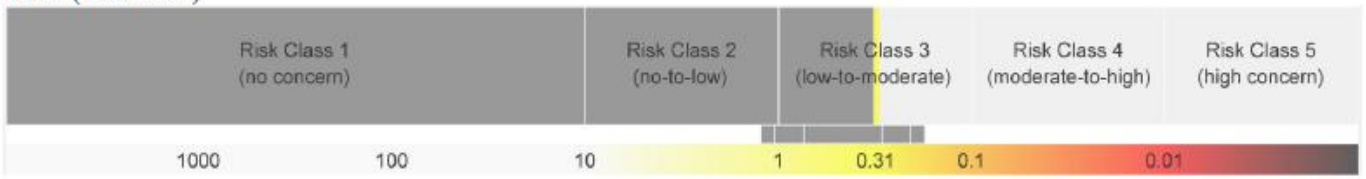
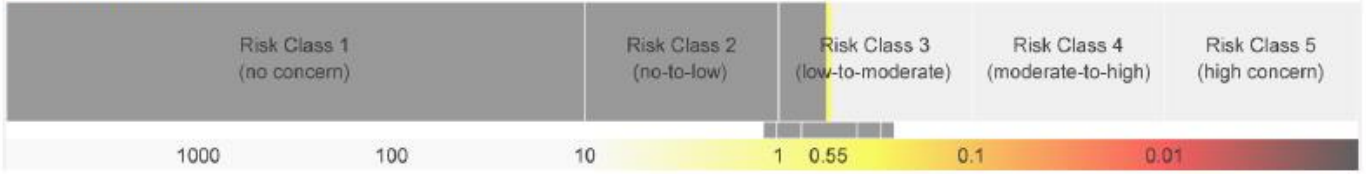
Tentative graphical illustration

Aimed at risk managers – level of concern - based on Swedish mean exposure

Lead (Table 6A)



Dioxin (Table 6B)



Cadmium (Table 6C)

Hexachlorobenzene (Table 6D)

Bisphenol A (Table 6E)

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

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

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

Van der Fels-Klerx et al. EFSA supporting publication 2015:EN-710

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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

		Disability weight (+ UI)		
		Mean	2.5%	97.5%
	Cancer			
Original	Cancer, diagnosis and primary therapy	0.265	0.222	0.303
Original	Cancer, metastatic	0.358	0.317	0.417
Original	Stoma	0.125	0.104	0.155
Original	Terminal phase, with medication (for cancers, end-stage kidney/liver disease)	0.515	0.459	0.572
Original	Terminal phase, without medication (for cancers, end-stage kidney/liver disease)	0.588	0.524	0.65
	Cardiovascular and circulatory disease			
Original	Acute myocardial infarction, days 3-28	0.098	0.08	0.121
Original	Angina pectoris, moderate	0.103	0.089	0.128
Original	Cardiac conduction disorders and cardiac dysrhythmias	0.295	0.258	0.343
Original	Heart failure, mild	0.052	0.041	0.063
Original	Heart failure, moderate	0.070	0.057	0.085
Original	Heart failure, severe	0.173	0.14	0.205
Original	Stroke, long-term consequences, moderate	0.075	0.059	0.093
Original	Stroke, long-term consequences, severe plus cognition problems	0.580	0.519	0.639

Haagsma *et al. Population Health Metrics* (2015) 13:10
DOI 10.1186/s12963-015-0042-4