Methodology and uncertainty impact on risk ranking of microbiological hazards: present and future

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Outline

- Risk Ranking Background
- EFSA BioHaz Panel work on Risk Ranking
- Risk Ranking Methodology
- Uncertainty in Risk Ranking
- Risk Ranking tools
- Concluding remarks

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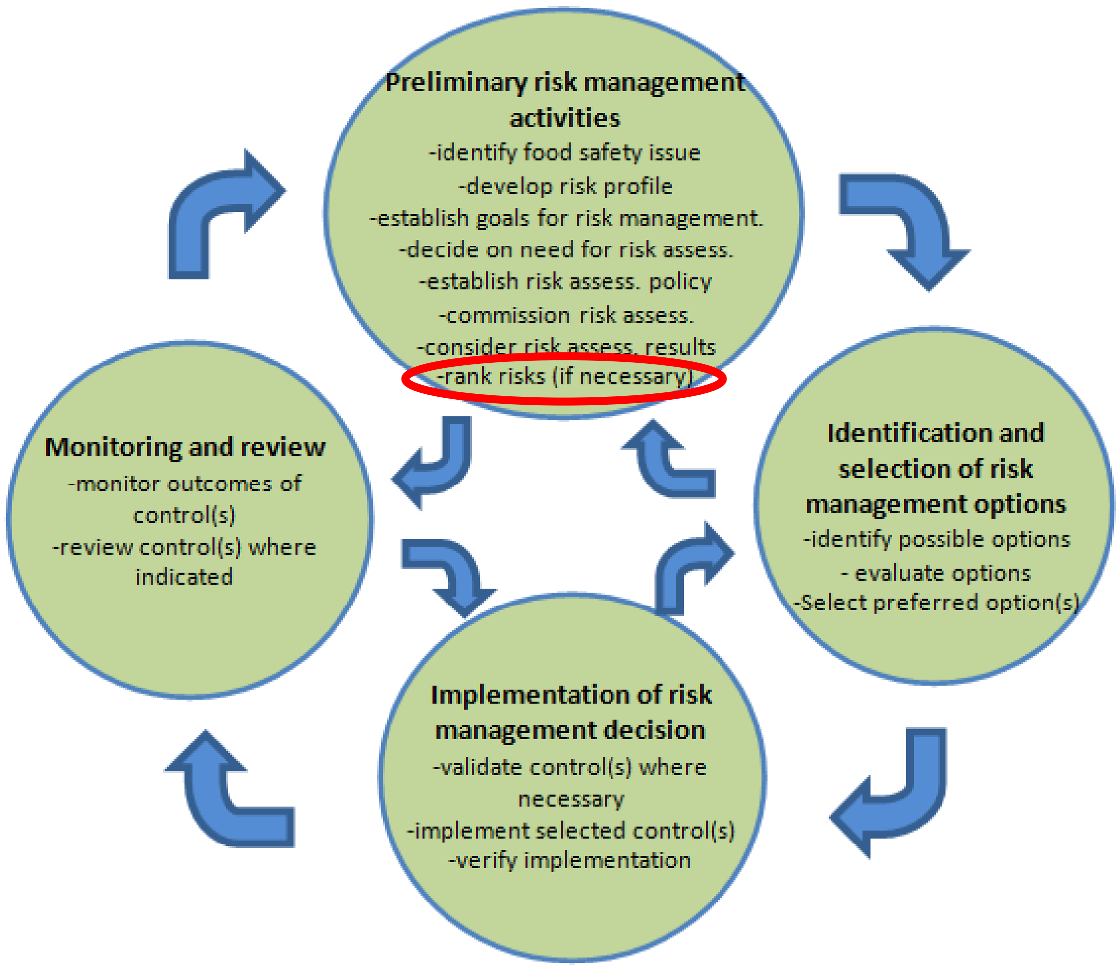
Risk Ranking Background



WHO Generic framework for Risk Management (WHO, 2006)

Risk Ranking Background

- In a science-based system, resources for food safety should be deployed in a manner that maximizes the public health benefit achieved through risk reduction.

- Risk ranking has been recognized as the proper starting point for risk-based priority setting and resource allocation

- Risk Ranking helps policymakers to focus attention on the most significant public health problems and develop strategies for addressing them

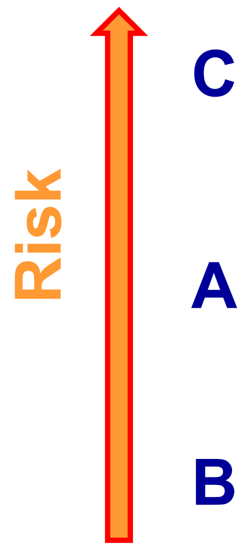
Risk Ranking Background

Risk Ranking can be considered as a type of Risk Assessment

But……

In Risk Ranking the objective is to evaluate the **"comparative risk"**

Example: Risk Ranking of Foods A, B, C



Risk Ranking Background

Risk Ranking can be considered as a type of Risk Assessment

But......

In Risk Ranking the objective is to evaluate the **"comparative risk"**

The above difference allows for application of alternative approaches that those used in Risk Assessment

Consistency | **Transparency**

Risk Ranking by EFSA

European Food Safety Authority

EFSA Journal 2012;10(6):2724

SCIENTIFIC OPINION

Scientific Opinion on the development of a risk ranking framework on biological hazards[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2 3]

European Food Safety Authority

EFSA Journal 2015;13(1):3939

SCIENTIFIC OPINION

Scientific Opinion on the development of a risk ranking toolbox for the EFSA BIOHAZ Panel[1]

EFSA Panel on Biological Hazards[2,3]

Risk Ranking Framework

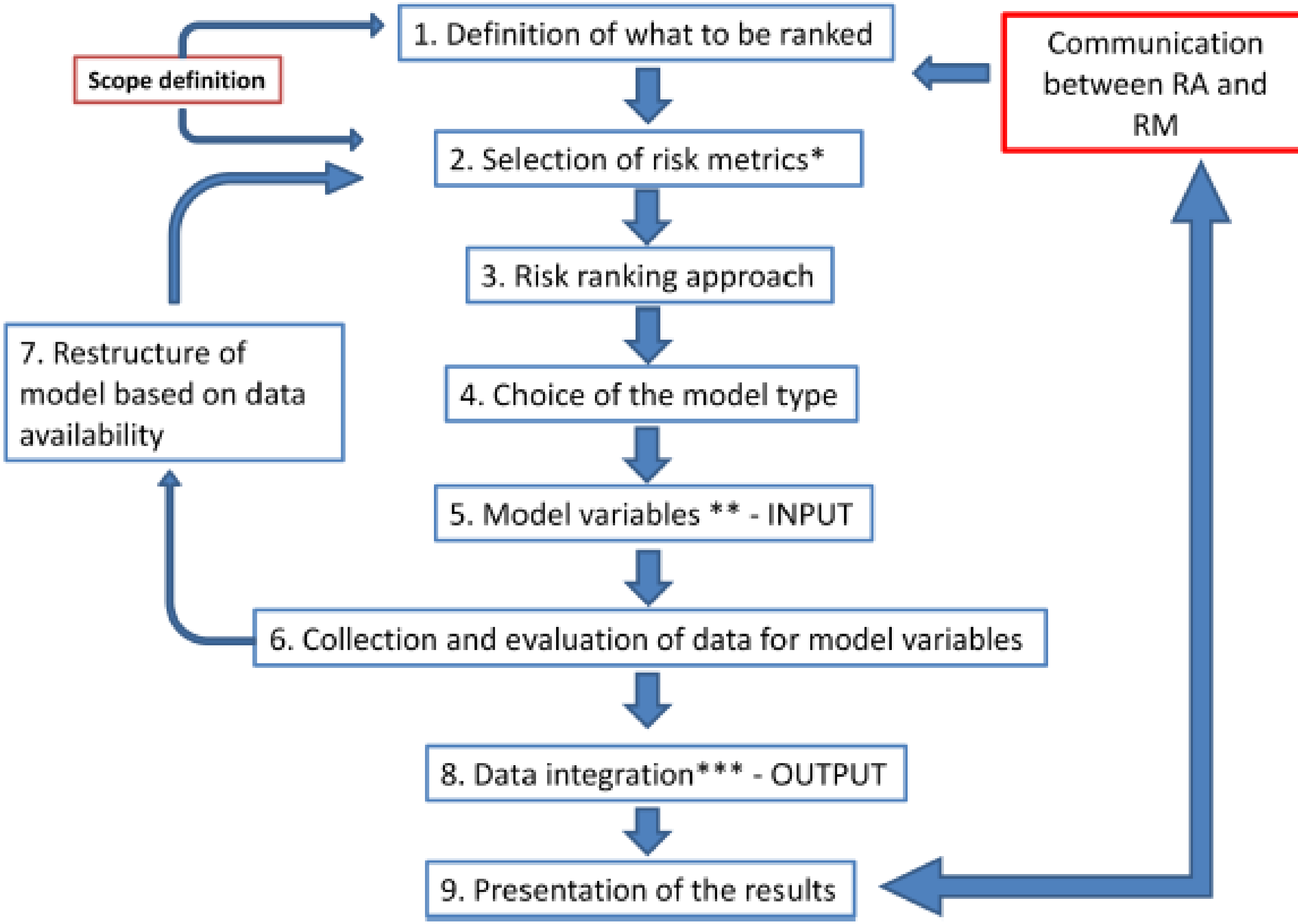


Figure 10: The proposed conceptual risk ranking framework for BIOHAZ Panel

Risk Ranking Methodology

Definition of what to be ranked

Three general levels on hazard-food combinations:

- **Level 1**: Single hazard in multiple food products (ranking of foods)
- **Level 2**: Multiple hazards in a single food product (ranking of hazards)
- **Level 3**: Multiple hazards in multiple food products (combined ranking of hazards and foods)
- Other (geographical, mitigation strategies, etc)

Risk Ranking Methodology

Selection of Risk Metrics

➢ **Different ways of expressing risk in a risk ranking process**

Simplest metric is number of adverse outcomes (e.g. illnesses, hospitalizations, and deaths)

Adverse outcome (illness) likelihood "per serving" the risk that individual consumers face when they eat a serving of a food

Adverse outcome (illness) "per annum"

measure of the risk faced by a certain population (e.g. a country)

Do not take into account severity and should be used only in the level of single pathogen in multiple foods

Risk Ranking Methodology

Selection of Risk Metrics

In case of **ranking multiple hazards**

Challenge: to find metrics to characterize the severity of the health outcomes and compare their overall *health and/or economic impact*.

Summary measures of public health

Disability adjusted life years (DALYs)
Quality-adjusted life years (QALYs)
Health-adjusted life years (HALYs)

Monetary risk metrics (cost of illness)

Risk Ranking Methodology

Selection of Risk Metrics

Can significantly affect risk ranking output

Product	Mean probability of illness per day per consumer of interest	Ranking
Smoked seafood	9.6E–08	2
Soft ripened cheese	2.1E–11	4
Pasteurised milk	2.7E–08	3
Frankfurters (reheated)	8.8E–12	5
Deli meats	1.1E–07	1

Product	Total predicted illnesses/annum in population of interest	Ranking
Smoked seafood	4	3
Soft ripened cheese	0.004	5
Pasteurised milk	500	1
Frankfurters (reheated)	0.005	4
Deli meats	307	2

Product	DALYs	Ranking
Smoked seafood	2.4	3
Soft ripened cheese	0.002	5
Pasteurised milk	300	1
Frankfurters (reheated)	0.003	4
Deli meats	184	2

Risk Ranking Methodology

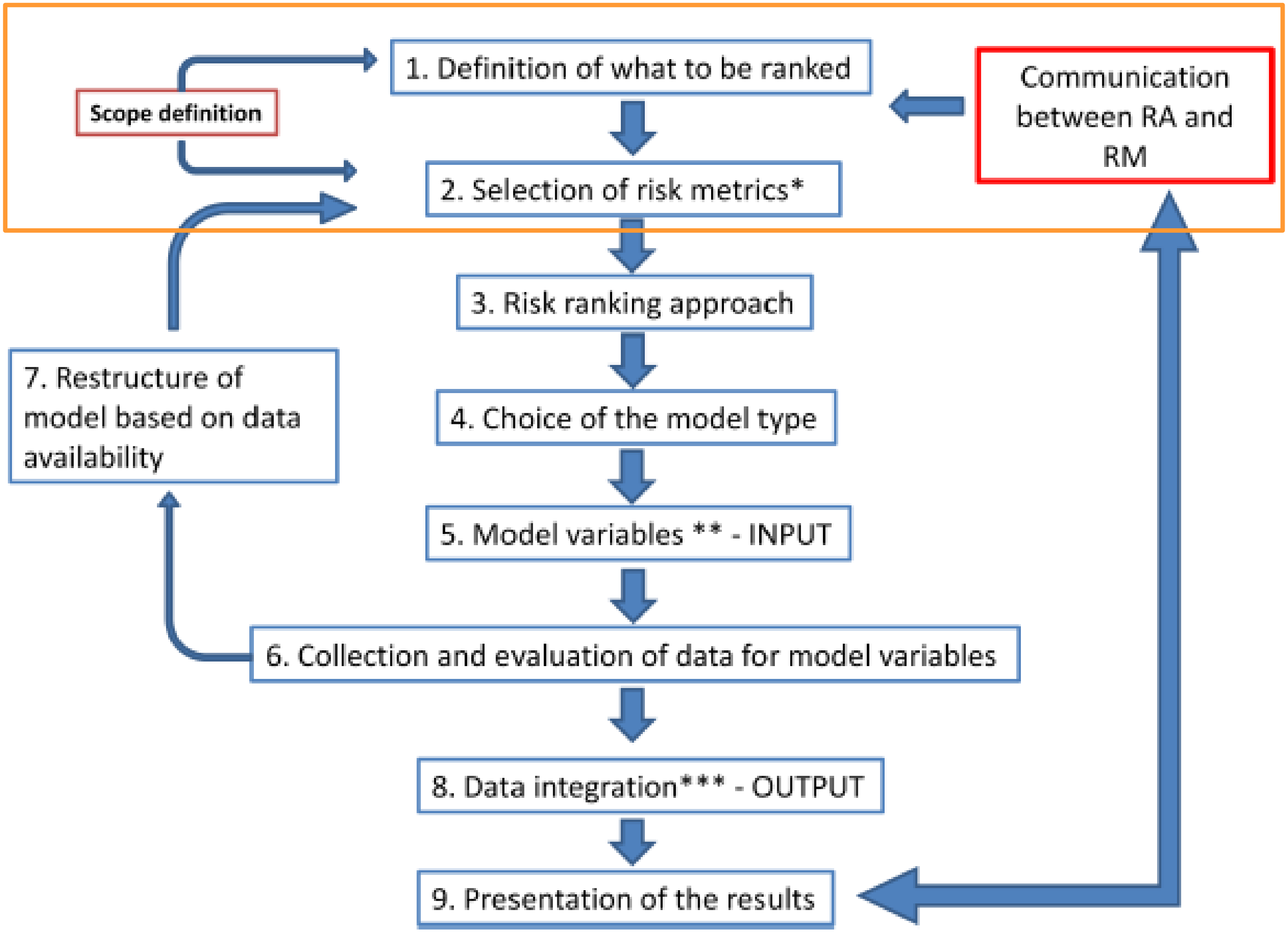


Figure 10: The proposed conceptual risk ranking framework for BIOHAZ Panel

Risk Ranking Approach

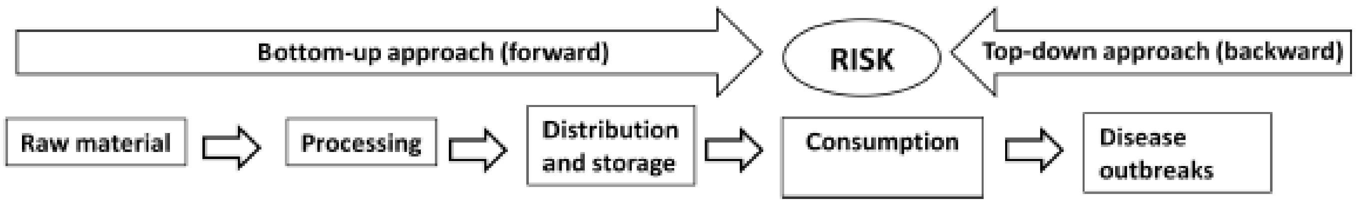


Figure 13: Possible combination of risk ranking approach (top-down and bottom-up) along the food chain.

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Trends in Food Science & Technology 33 (2013) 124–138

TRENDS IN FOOD SCIENCE & TECHNOLOGY

Viewpoint

Ranking the microbiological safety of foods: A new tool and its application to composite products

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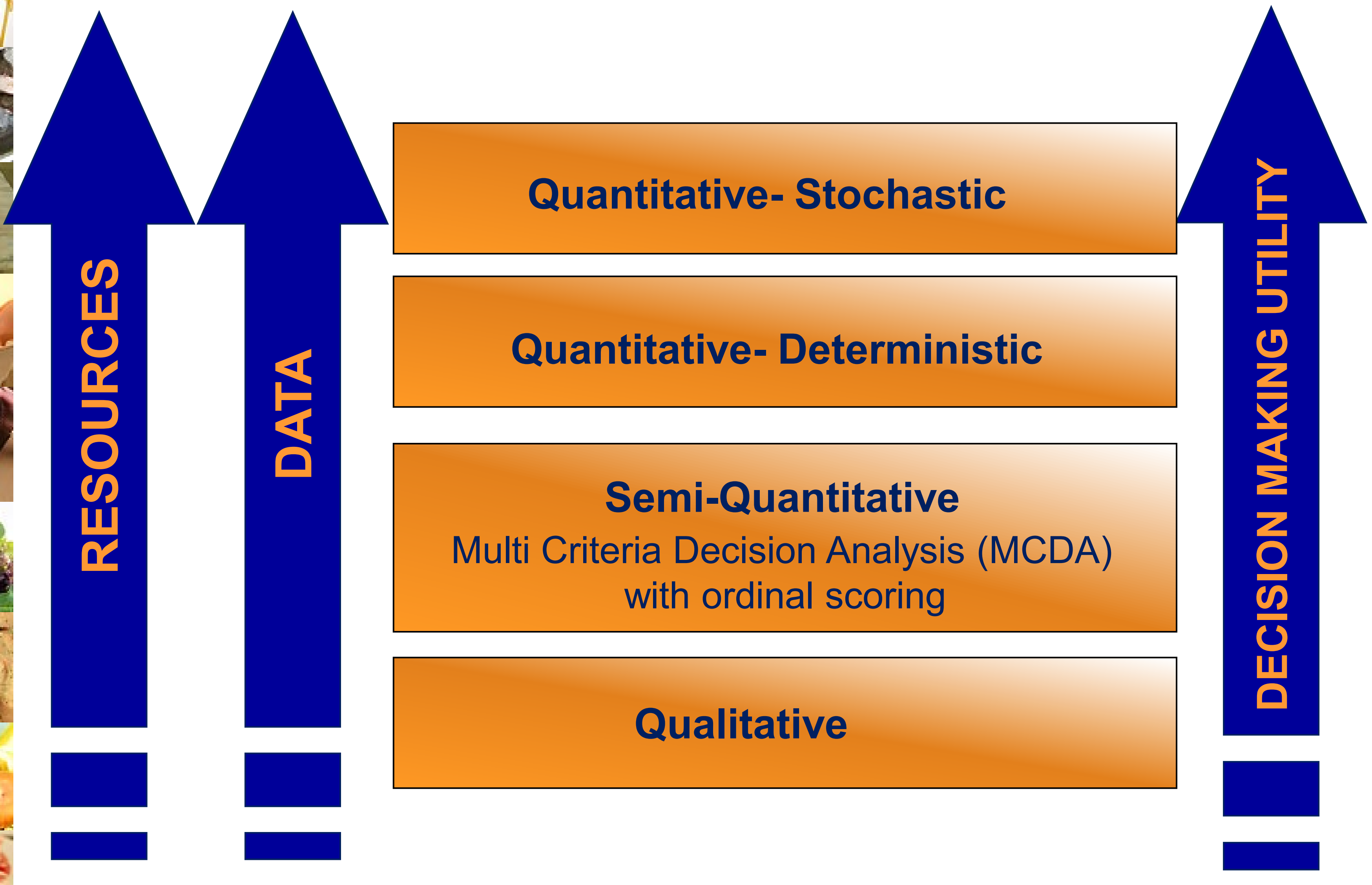
[h]Wageningen University, Laboratory of Food Microbiology, PO Box 17, 6700 AA Wageningen, The Netherlands (e-mail: marcel.zwietering@wur.nl)

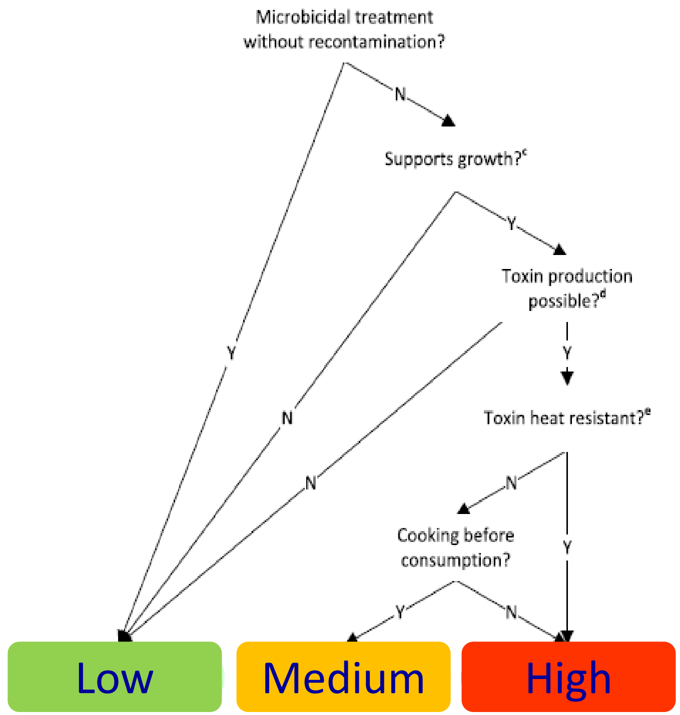
A methodology based on the combination of two comple-

Risk Ranking Model Type/Data integration



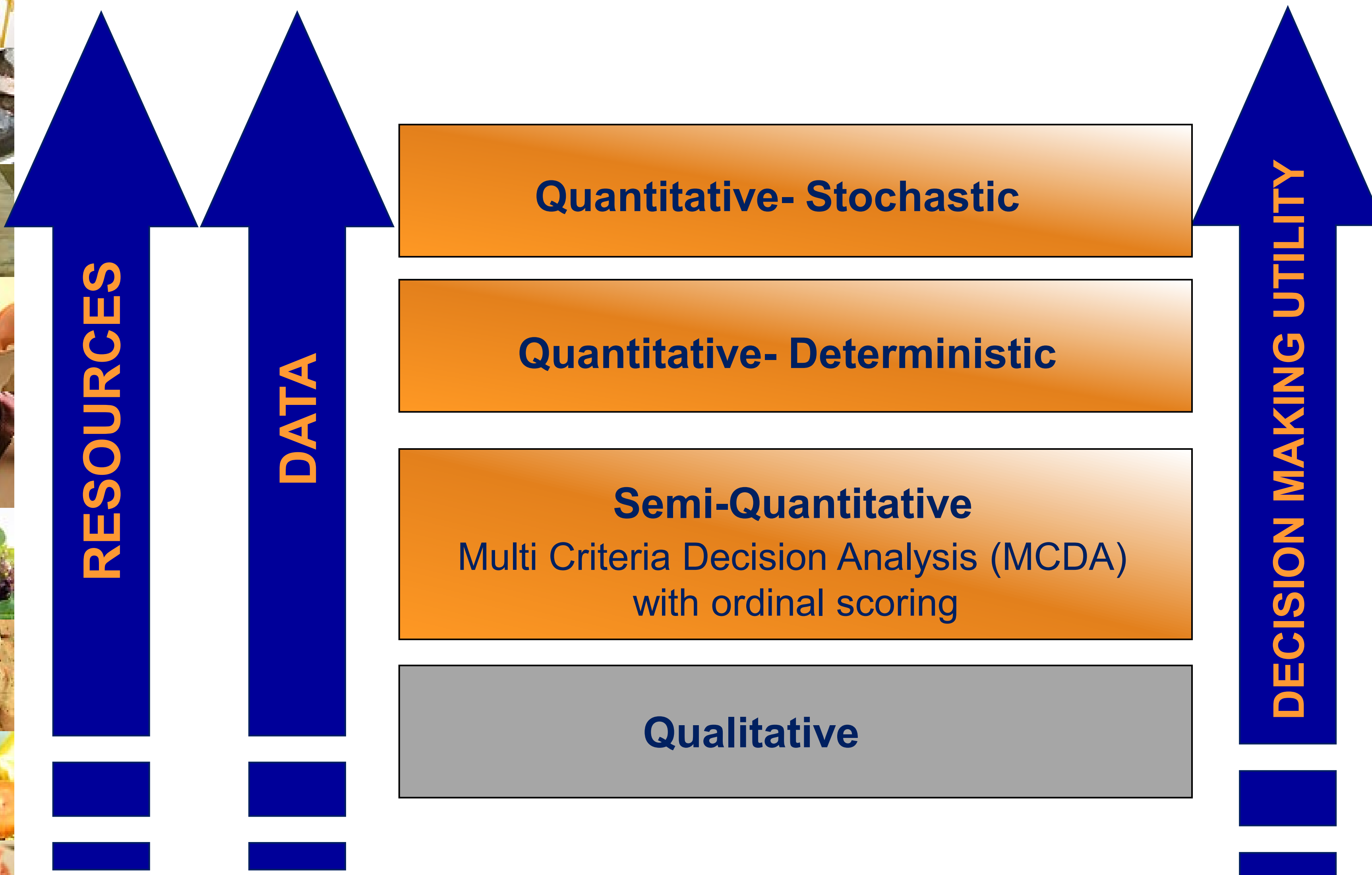
Risk Ranking Model Type/Data integration

Qualitative Model/Decision tree



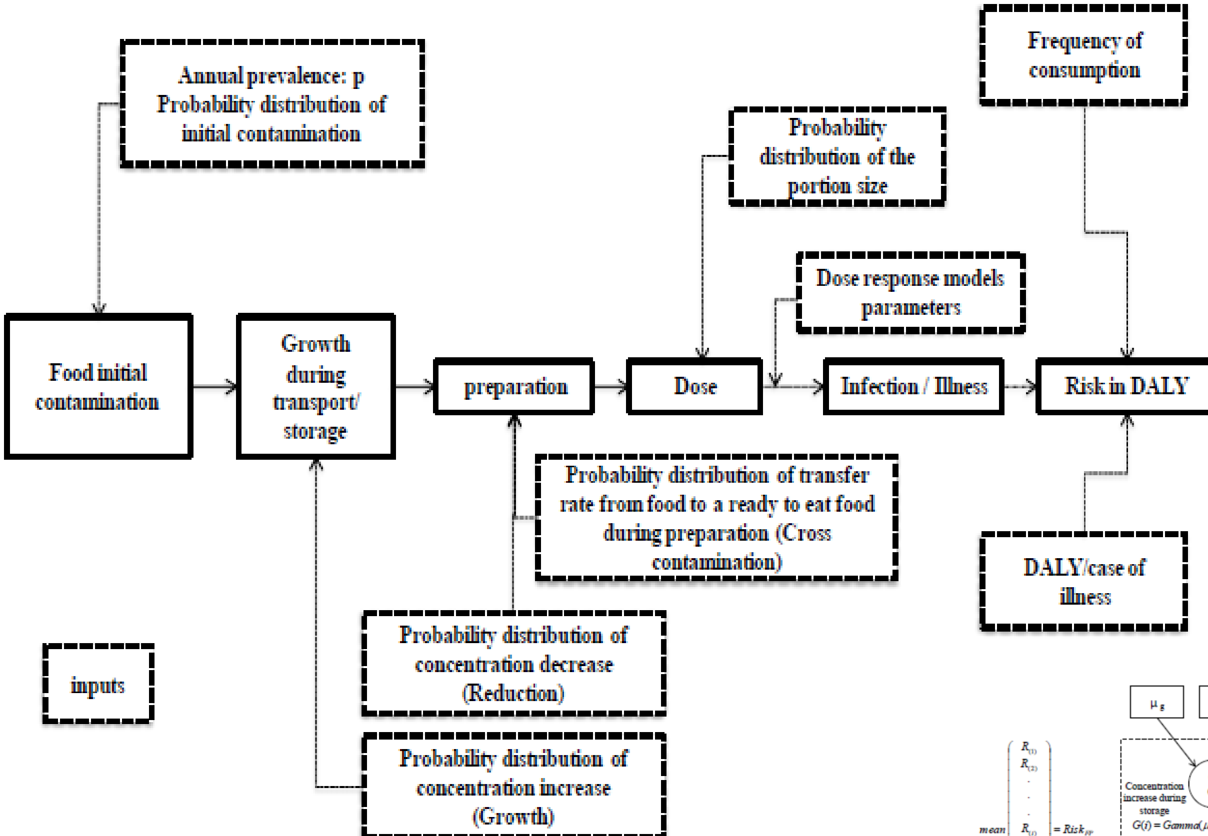
- **fewer data and time requirements**
- **very limited discrimination power for risk ranking**
- **arbitrary outcome is problematic**

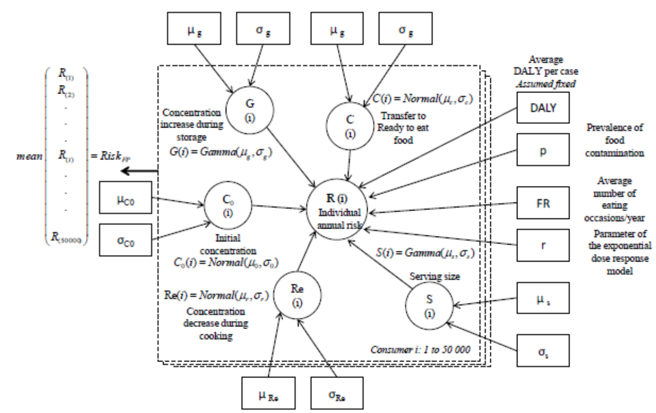
Risk Ranking Model Type/Data integration



Evaluation of Risk Ranking methodology

Generic Risk Assessement model





Evaluation of Risk Ranking methodology

We assumed all information about all parameters affecting risk *are perfectly known using virtual data*

Variables	Unit	Distribution/formula	Input parameters
Initial concentration (H_0)	Log_{10} CFU/g	Normal	μ_0 and σ_0
Portion size	g	Gamma (α,β)	$\mu_s = \alpha\beta$ $\sigma_s = \beta\sqrt{\alpha}$
Expected CFU per portion (E_0)	CFU/portion	$E_0 = S \times 10^{H_0}$	
Increase during storage (G)[(a)]	Log_{10}	Gamma (a,b)	$\mu_G = \alpha\beta$ $\sigma_G = \beta\sqrt{\alpha}$
Expected CFU per portion end of storage (E_S)	CFU/portion	$E_S = E_0 \times 10^G$	
CFU per portion end of storage (X_S)	CFU/portion	Poisson (E_s)	
Log_{10} probability of transfer to RTE (C)	Log_{10}	Normal	μ_c and σ_c
CFU transferred per portion (D_1)	CFU/portion	Binomial (X_s, 10^C)	
CFU remaining per portion (X_{nc})	CFU/portion	$X_{nc} = X_s - D_1$	
Log_{10} probability of survival during cooking	Log_{10}	Normal	μ_R and σ_R
CFU surviving cooking (D2)	CFU/portion	Binomial (X_s, 10^R)	
Probability of infection (PInf)		$PInf = 1 - (1 - r)^{(D1 + D2)}$	r
Probability of illness (PIll)		$PIll = PInf \times P(Ill \mid infection)$	$P(Ill \mid infection)$
Average probability of illness (APIll) per contaminated serving		Arithmetic mean of probability of illness (Monte Carlo simulation, 50 000 iterations)	
Annual probability of illness (API)		API = P × APIll × FR	FR: average number of eating occasion per year per person P: prevalence
Annual DALYs per 1E6 consumers		ADALY=API × DALY × 1E6 consumers	DALY per case

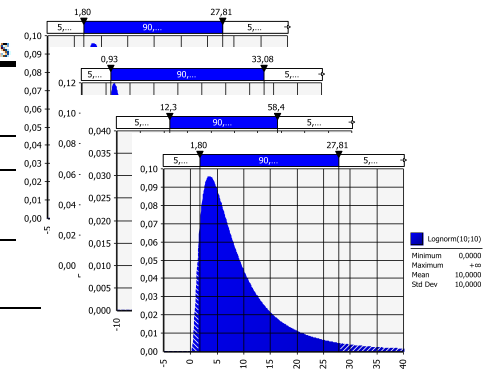
DALY: disability-adjusted life years.
(a): Based on relevant predictive modelling.

Evaluation of Risk Ranking methodology

Data Generator for food/hazard combinations

Variables	Unit	Parameters	Ranges of the parameters values
Initial concentration (H_0)	Log_{10} CFU/g	μ_0 σ_0	–3 to 3 0.1 to 1.5
Prevalence		P	10^{-4} to 1
Portion size	g	μ_s σ_s	10 to 500 0.1 to 1
Increase during storage (G)	Log_{10}	μ_g σ_g	0.3 to 3 0.1 to 1.5
Log_{10} probability of transfer to RTE (C)	Log_{10}	μ_c σ_c	–5 to –2 0.1 to 1.5
Log_{10} probability of survival during cooking	Log_{10}	μ_R σ_R	–6 to –3 0.1 to 1.5 If RTE product (50 % of the simulated scenario R = 0)
Probability of infection (PInf per CFU)		r	– 10 to – 2
Probability of illness (PIll)		PIll = PInf × P(Ill | infection)	1
Average number of eating occasions per year per person		FR	1 to 365
DALY per case	Year (log_{10})	DALY	–3 to 1

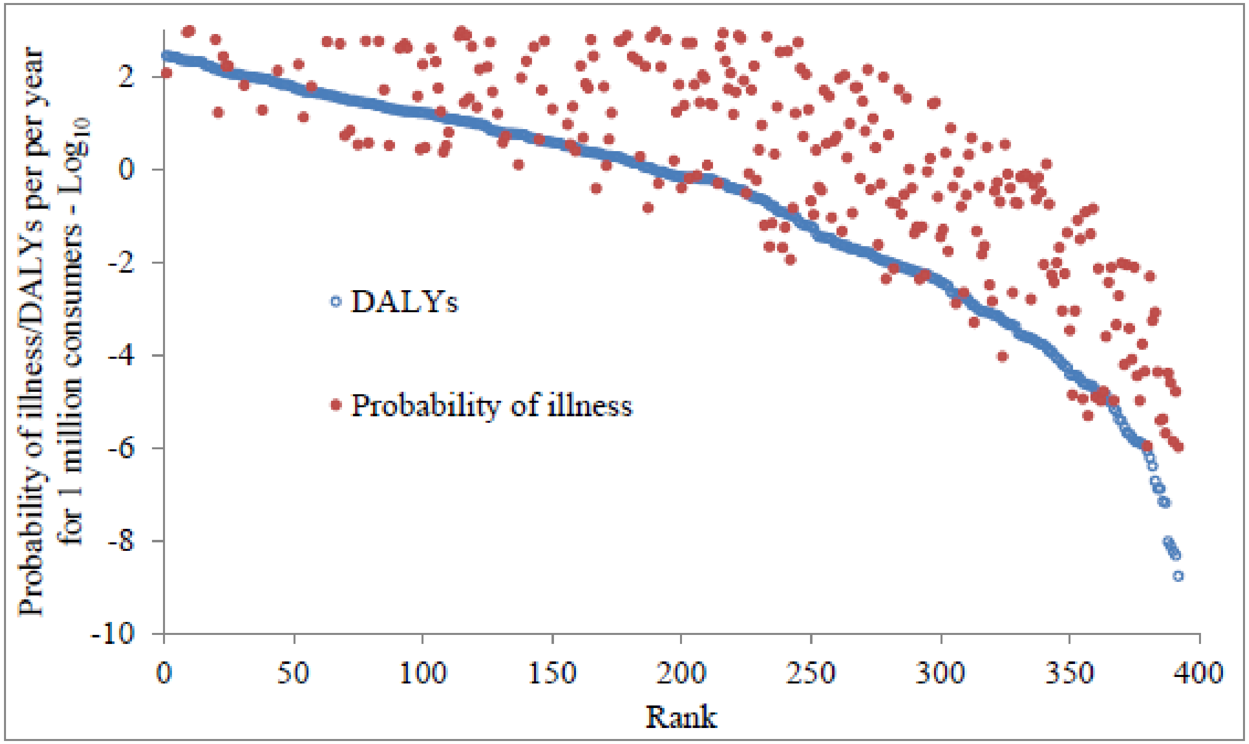
DALY: disability-adjusted life years.



400 selected food/hazard combinations

Evaluation of Risk Ranking methodology

The stochastic model used as reference



compared

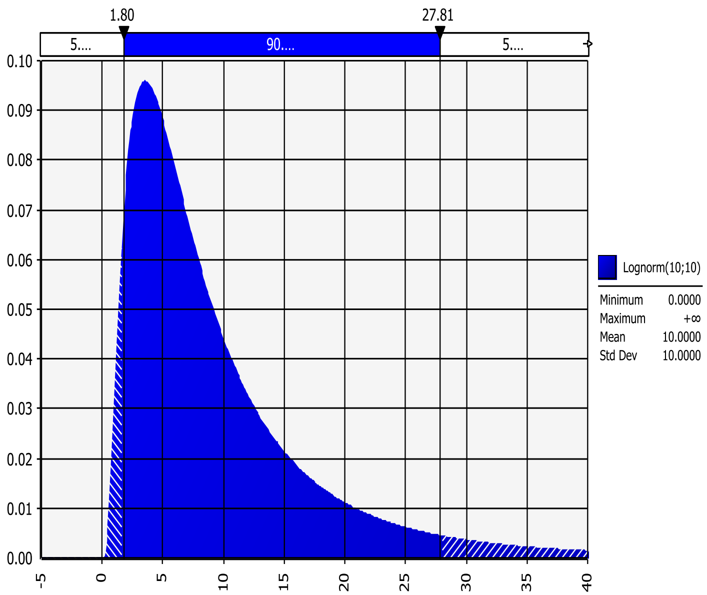
deterministic

(MCDA) Ordinal Scoring

Evaluation of Risk Ranking methodology

stochastic vs deterministic

Input Parameter
dataset (e.g concentration)

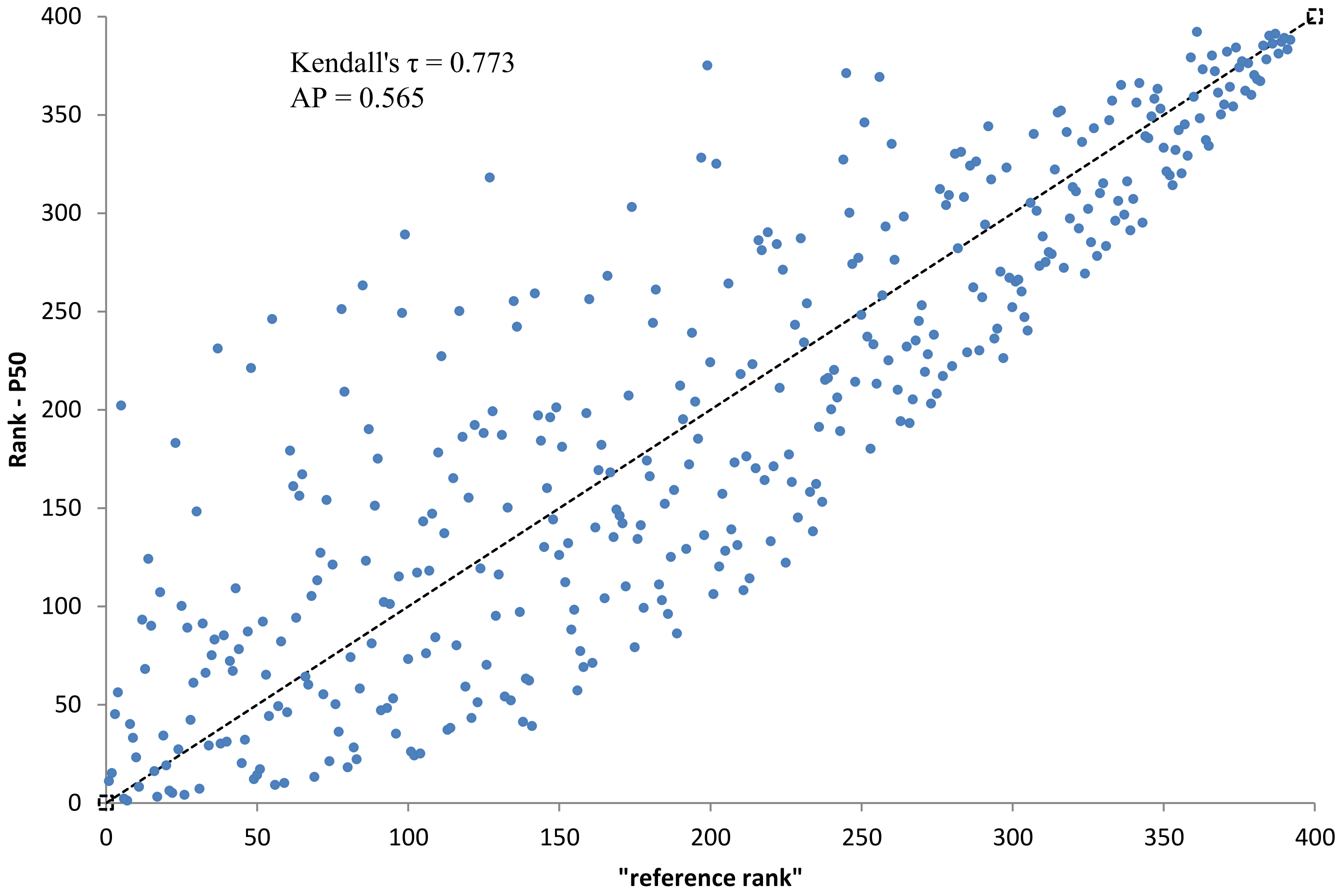


single value options

- arithmetic mean
- median,
- 75th percentile,
- 90th percentiles

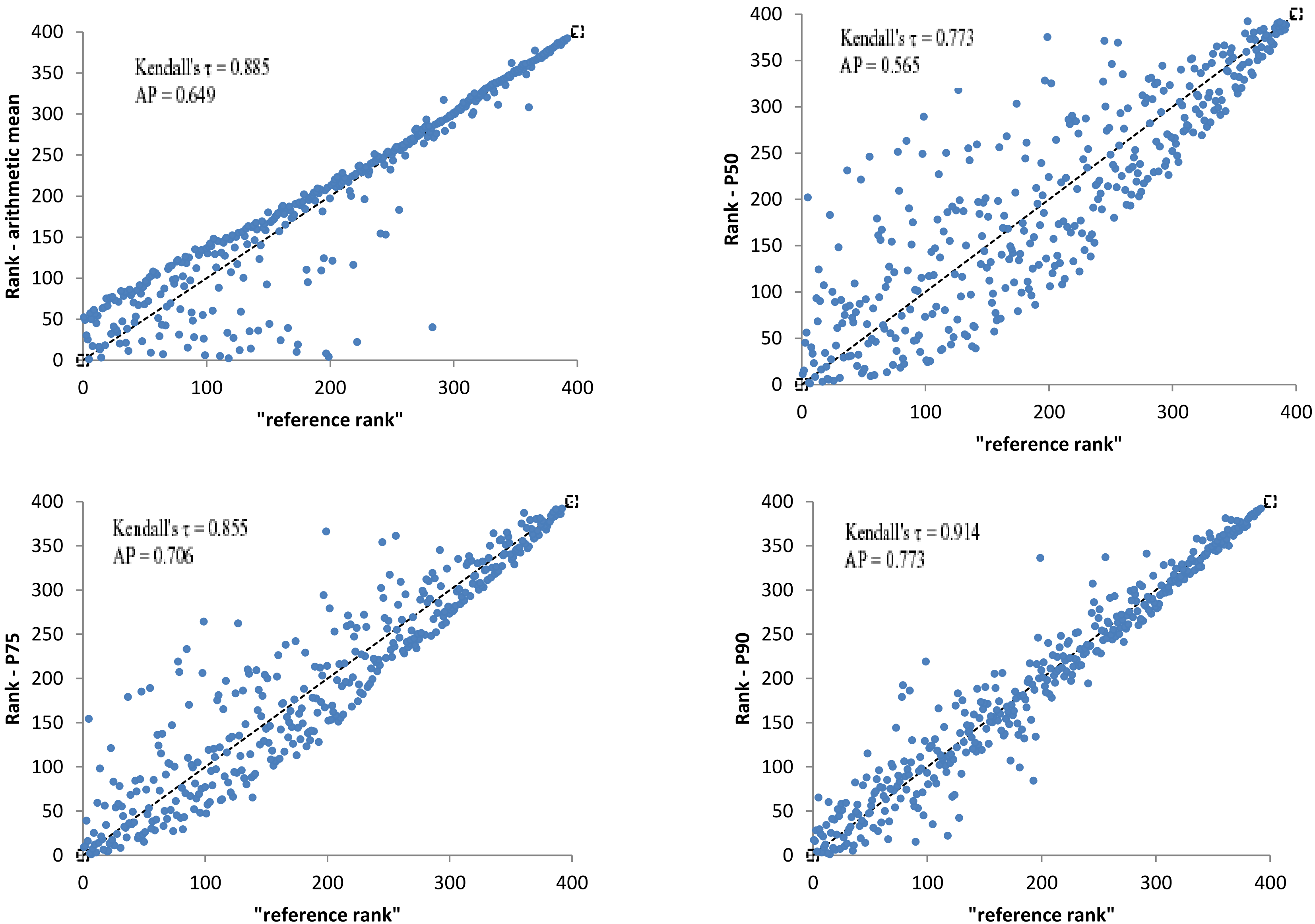
Evaluation of Risk Ranking methodology

stochastic vs deterministic



Evaluation of Risk Ranking methodology

stochastic vs deterministic

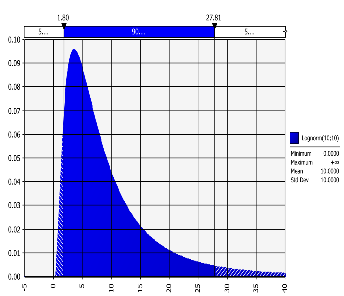


Evaluation of Risk Ranking methodology

stochastic vs MCDA ordinal scoring

Table 43: Categories and scores defined in the ordinal scoring approach

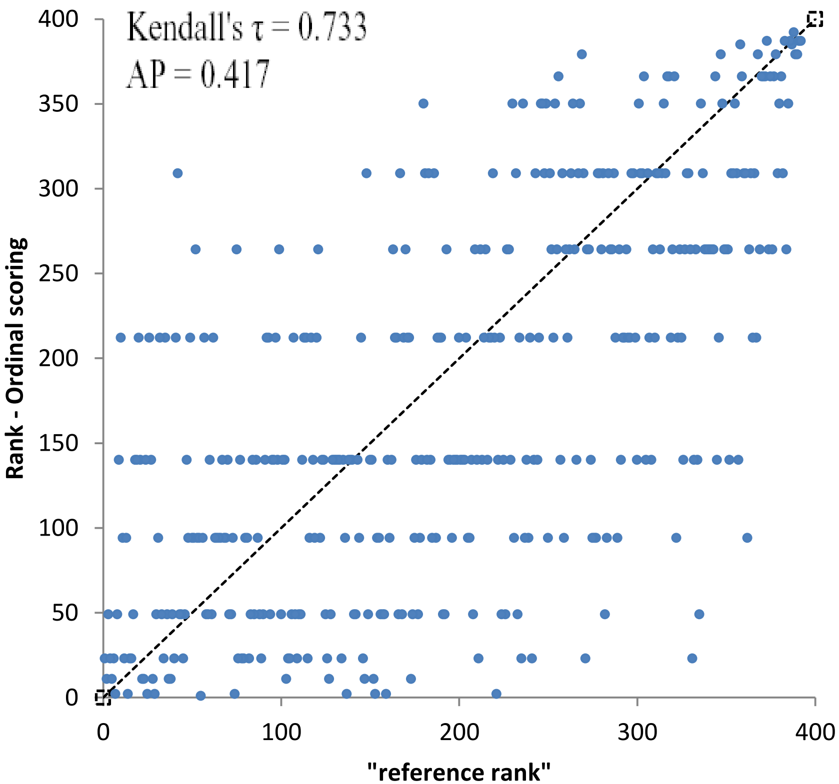
Inputs	Bins(x)	Ordinal score		Inputs	Bins(x)	Ordinal score	
		Linear	Log-scaled			Linear	Log-scaled
Initial concentration (H_0) in CFU/g	1.0E–03	1	0.000	Prevalence	1.0E–04	1	0.000
	1.0E–02	2	0.200		1.0E–03	2	0.250
	1.0E–01	3	0.400		1.0E–02	3	0.500
	1.0E+00	4	0.600		1.0E–01	4	0.750
	1.0E+01	5	0.800		3.0E–01	5	0.869
Portion size in grams	1.0E+01	1	0.000	Average number of eating occasions per year per person	1.0E+00	1	0.000
	3.0E+01	2	0.239		1.2E+01	2	0.421
	9.0E+01	3	0.477		5.2E+01	3	0.670
	2.7E+02	4	0.716		1.0E+02	4	0.787
	8.1E+02	5	0.954		2.1E+02	5	0.905
Increase during storage (G)	1.0E+00	1	0.000	Probability of transfer to RTE (C)	1.0E–05	1	0.000
	1.0E+01	2	0.200		1.0E–04	2	0.200
	1.0E+02	3	0.400		1.0E–03	3	0.400
	1.0E+03	4	0.600		1.0E–02	4	0.600
	1.0E+04	5	0.800		1.0E–01	5	0.800

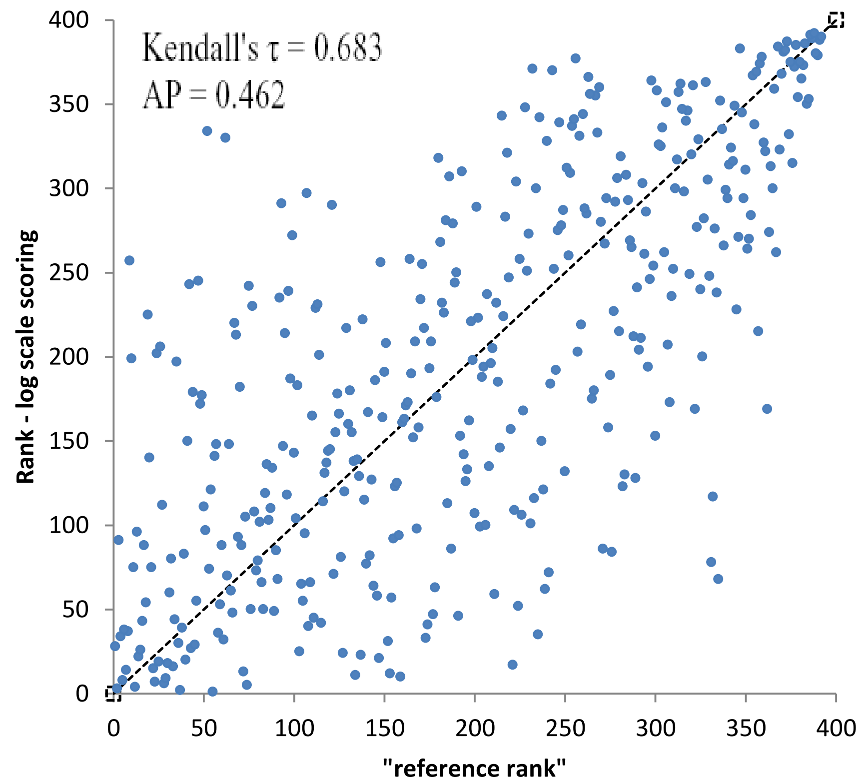


score

Evaluation of Risk Ranking methodology

stochastic vs MCDA ordinal scoring



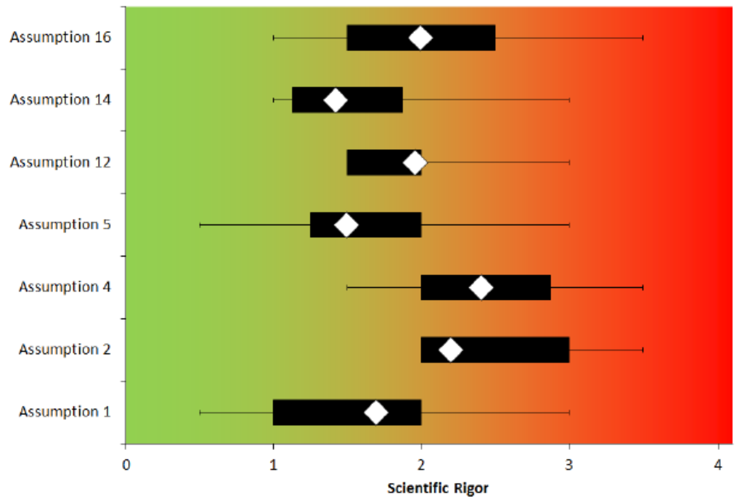


Uncertainty in Risk Ranking

Methodology

1. Identification/characterization of uncertainty sources

The NUSAP method



2. Selection of major uncertainty sources to be quantified

3. Quantifying uncertainty in risk ranking

Uncertainty in Risk Ranking

Quantifying uncertainty in risk ranking

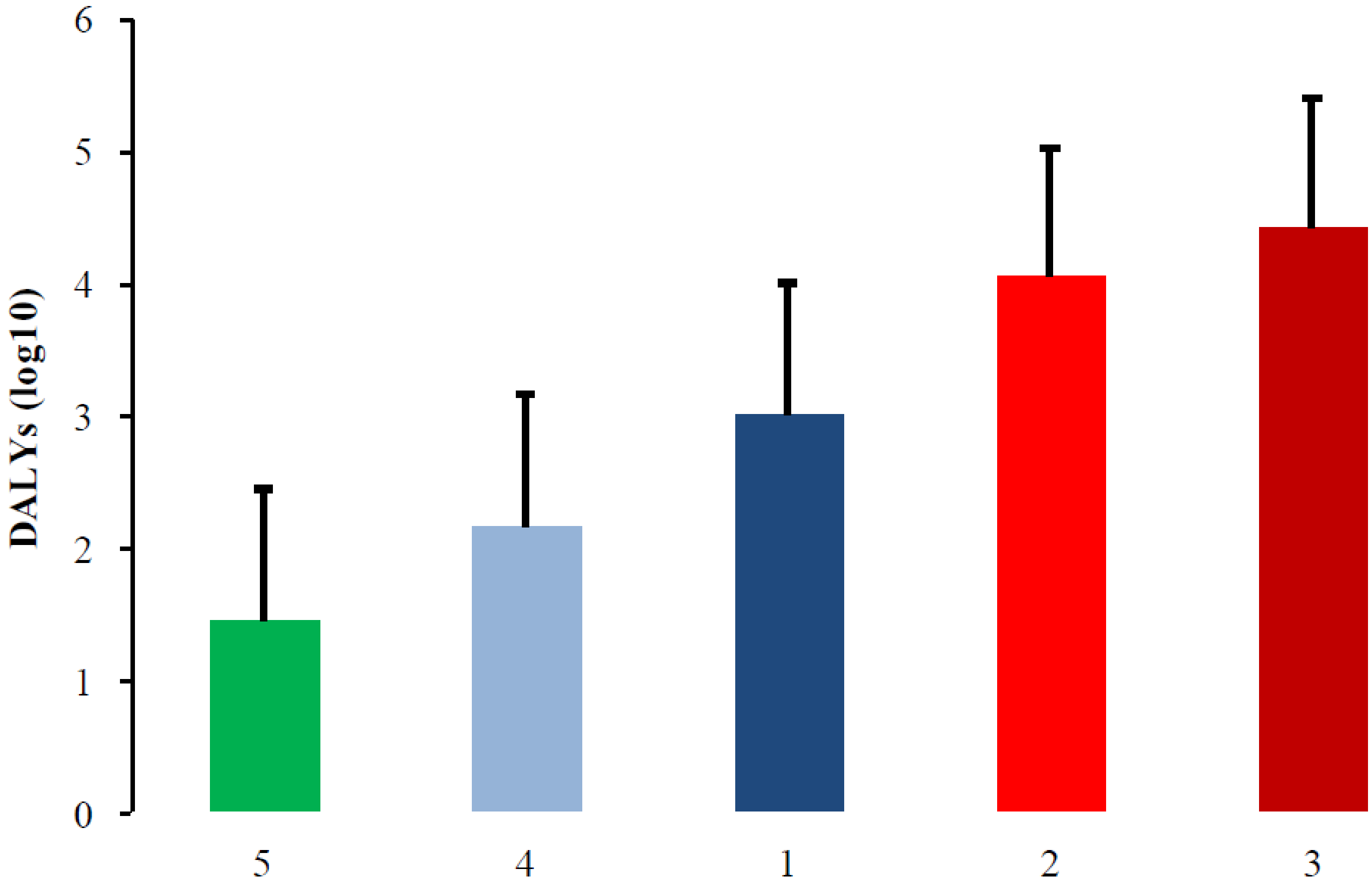
Model inputs	Parameters of the variability distribution	Variability distribution model (first order iteration in Figure 24)	Uncertainty distribution (second order iteration in Figure 24)
Prevalence	p	Bernoulli (p)	p ~ beta (a, b)
Initial concentration in $\log_{10}$ CFU/g	m_0 s_0	Normal (m_0,s_0)	M_0 ~ normal (x, y) S_0 ~ gamma (z, w)
Growth potential in $\log_{10}$	m_g s_g	Gamma (m_g, s_g)	m_g ~ normal (t, u) s_g ~ gamma (d, f)
Cross-contamination ($\log_{10}$ probability of transfer)	m_c s_c	Normal (m_c,s_c)	m_g ~ normal (q, s) s_g ~ gamma (g, h)
Portion size	m_s s_s	Gamma (m_s, s_s)	m_g ~ normal (k, l) s_g ~ gamma (n, r)
Potential reduction	m_r s_r	Normal (m_r,s_r)	m_g ~ normal (i, o) s_g ~ gamma (p, m)
Dose–response	r	No variability	p ~ beta (a', b')
DALY	DALY	No variability	DALY ~ gamma (v,e)
Frequency of consumption	FR	No variability	FR ~ normal (j,k')

DALY: disability-adjusted life years.

2D Monte Carlo Simulation

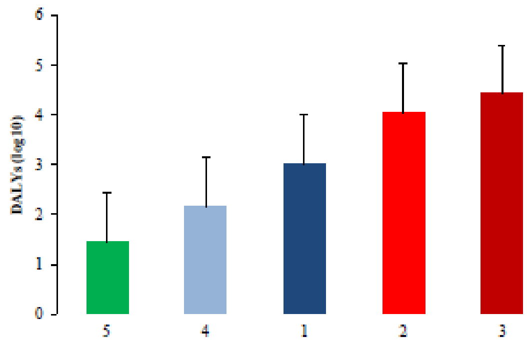
Uncertainty in Risk Ranking

Quantifying uncertainty in risk ranking

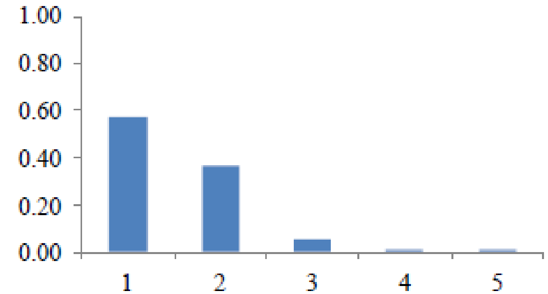


Uncertainty in Risk Ranking

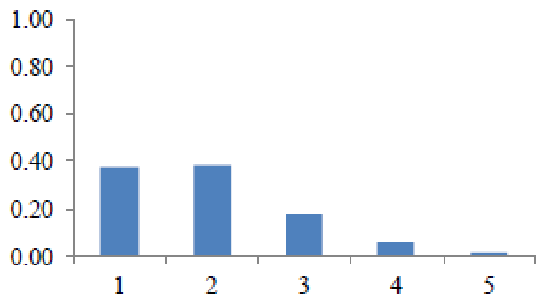
Quantifying uncertainty in risk ranking



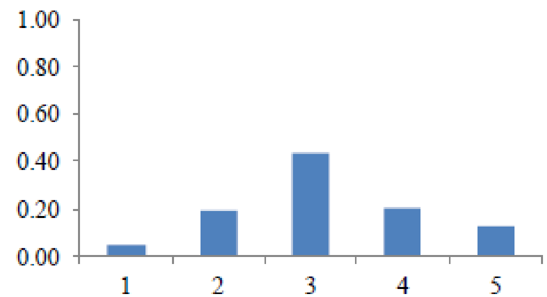
FP1



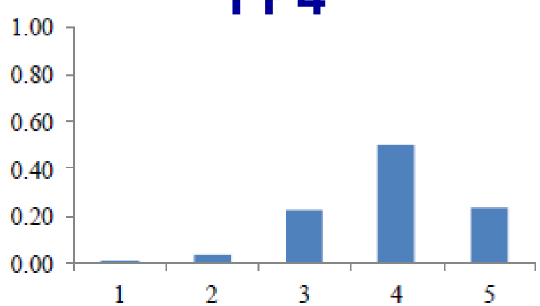
FP2



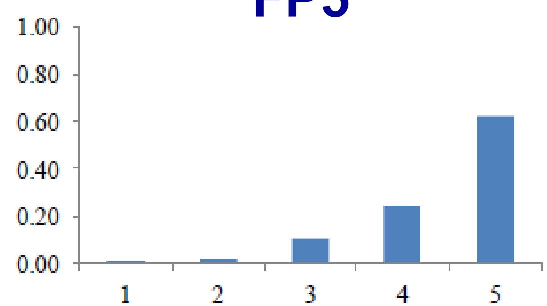
FP3



FP4

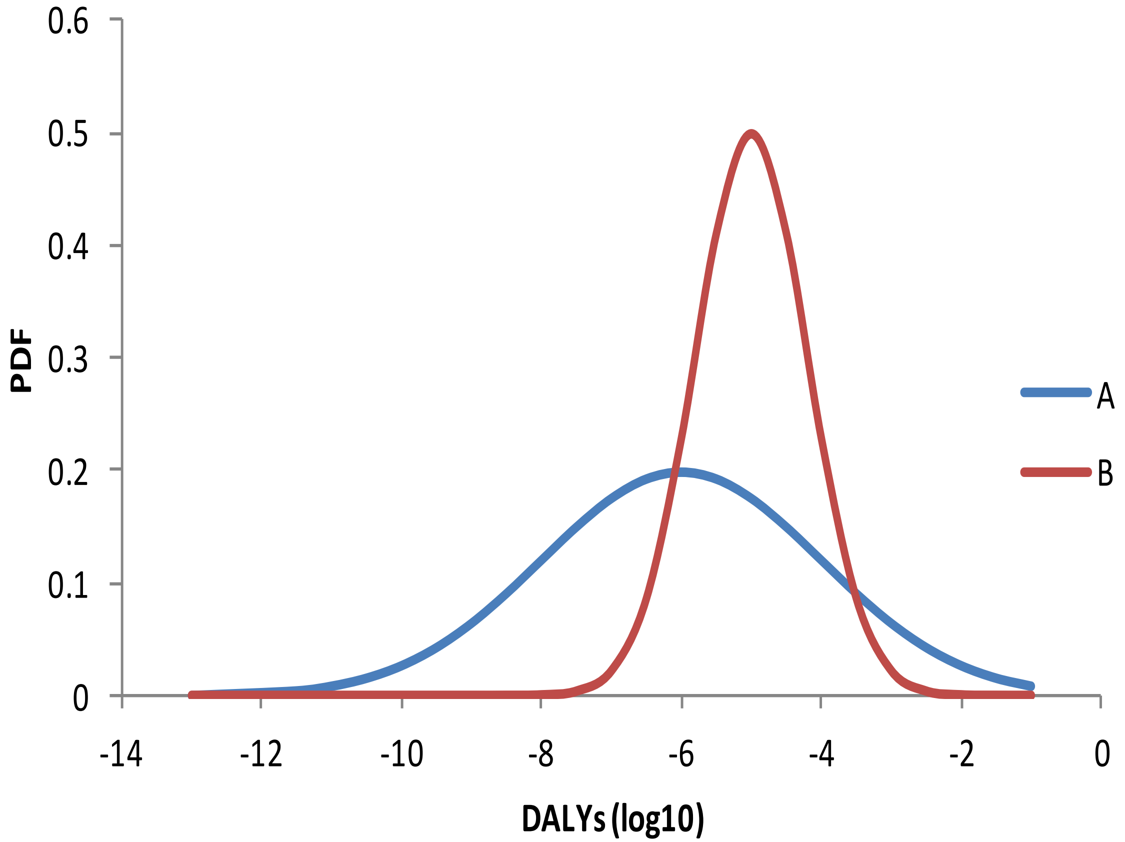


FP5



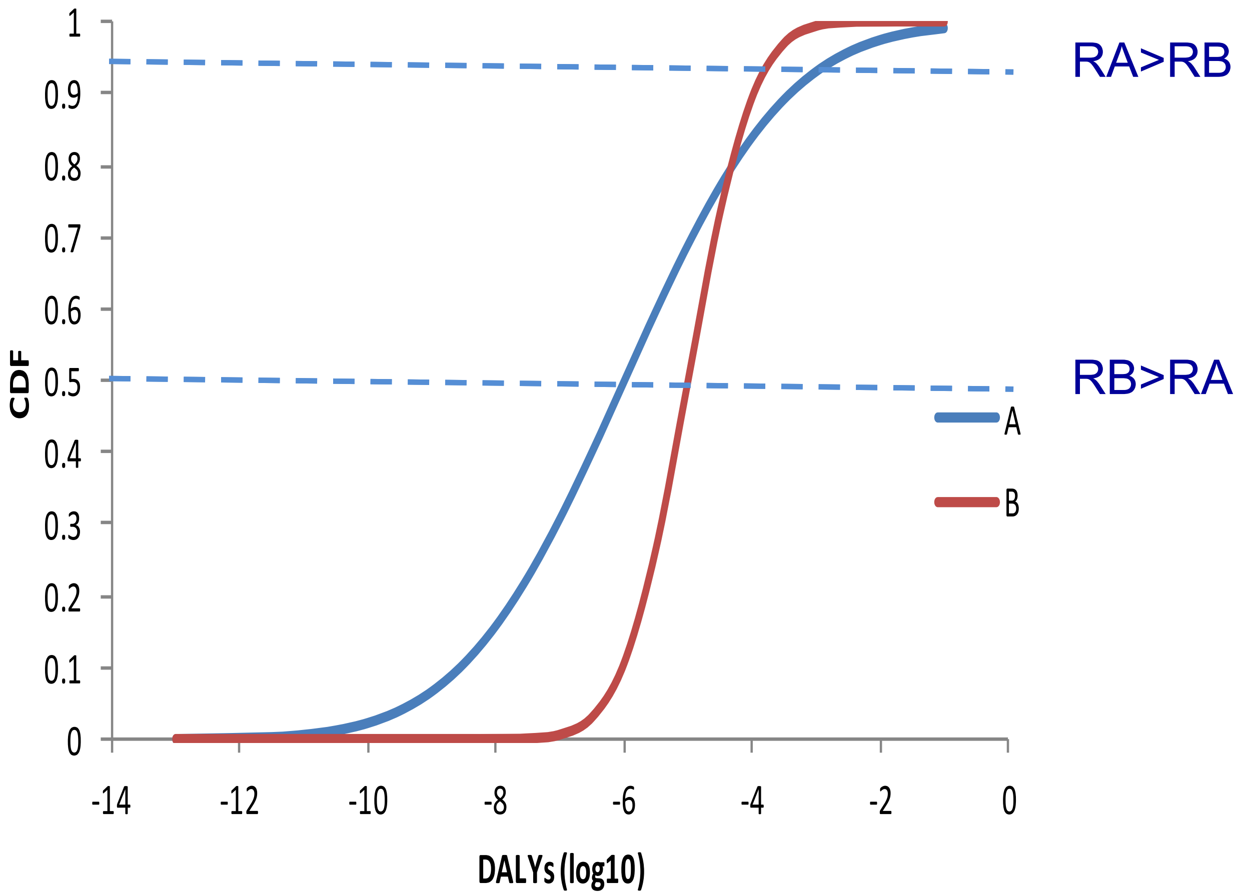
Uncertainty in Risk Ranking

Quantifying uncertainty in risk ranking



Uncertainty in Risk Ranking

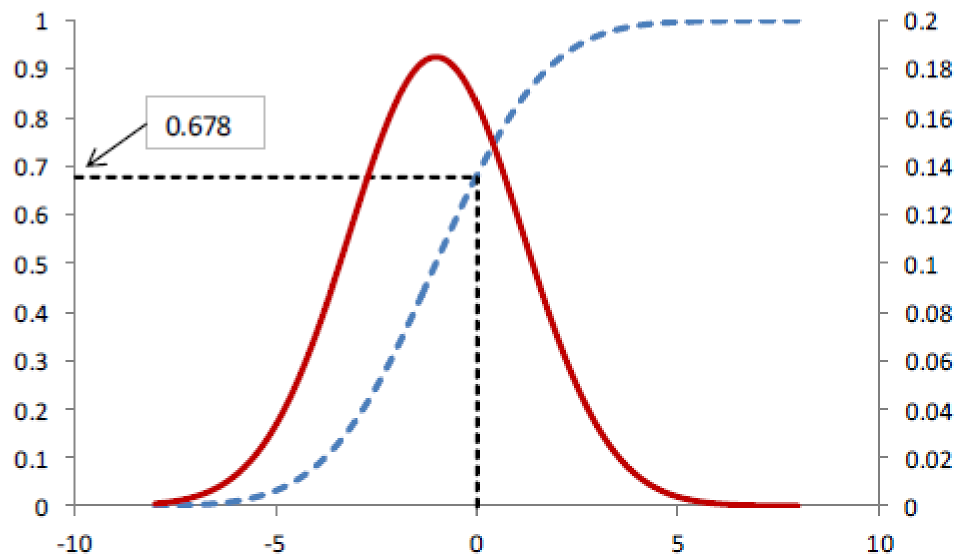
Quantifying uncertainty in risk ranking



Uncertainty in Risk Ranking

Quantifying uncertainty in risk ranking

PDF and CDF of the random variable (DA–DB). The probability of DA–DB < 0 is 0.678.



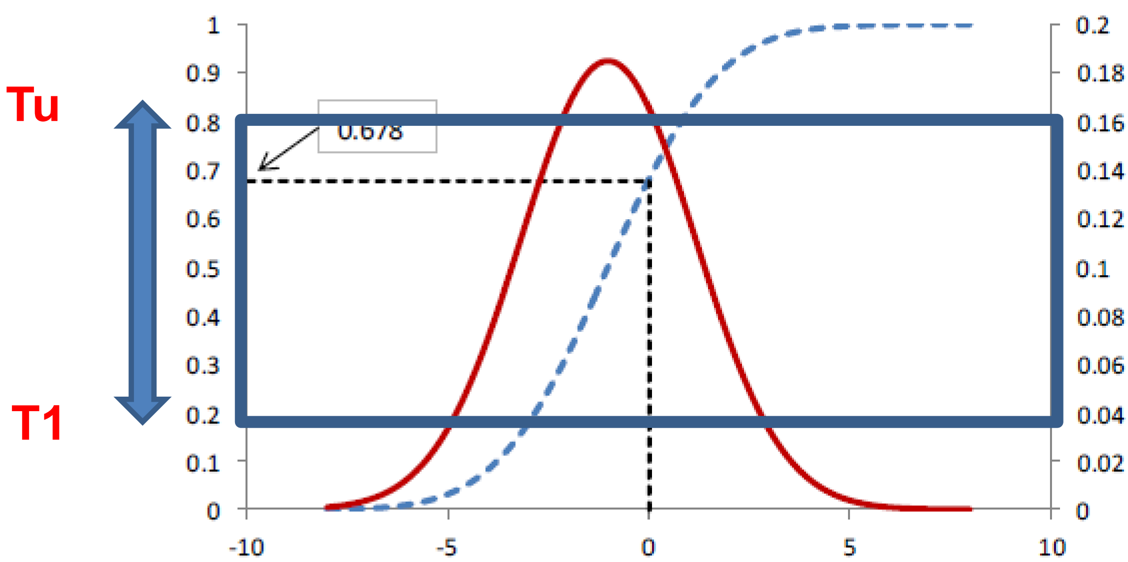
In the presence of Uncertainty

When risk-A different than risk-B?

Uncertainty in Risk Ranking

Quantifying uncertainty in risk ranking

Threshold probability range for ranking in the presence of uncertainty: A risk management decision



- if rAB > Tu, then A is more risky than B;
- if rAB < Tl, then B is more risky than A;
- if Tl < rAB < Tu, then A is equally risky to B.

Uncertainty in Risk Ranking

Quantifying uncertainty in risk ranking

Threshold probability range for ranking in the presence of uncertainty: A risk management decision

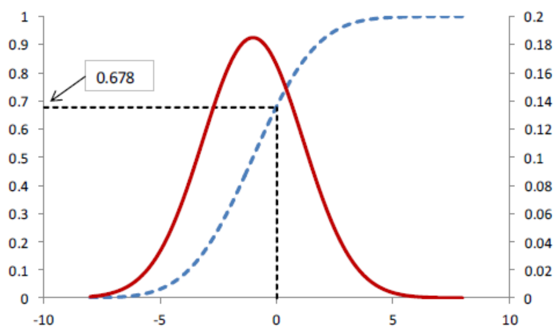
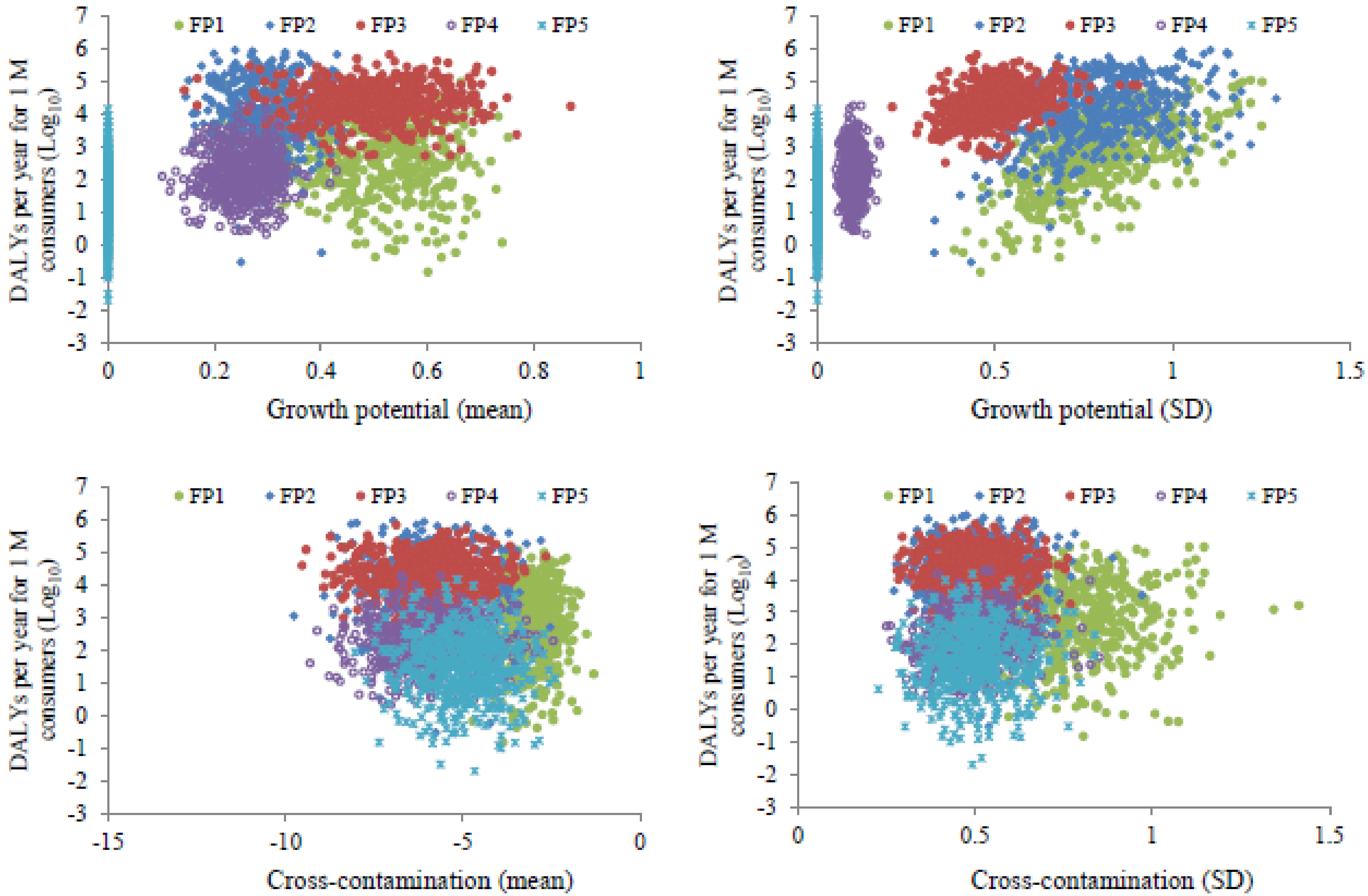


Table 49: Pairwise comparison using the probability of one food pathogen being ranked higher than the other food–pathogen pairs (rAB)

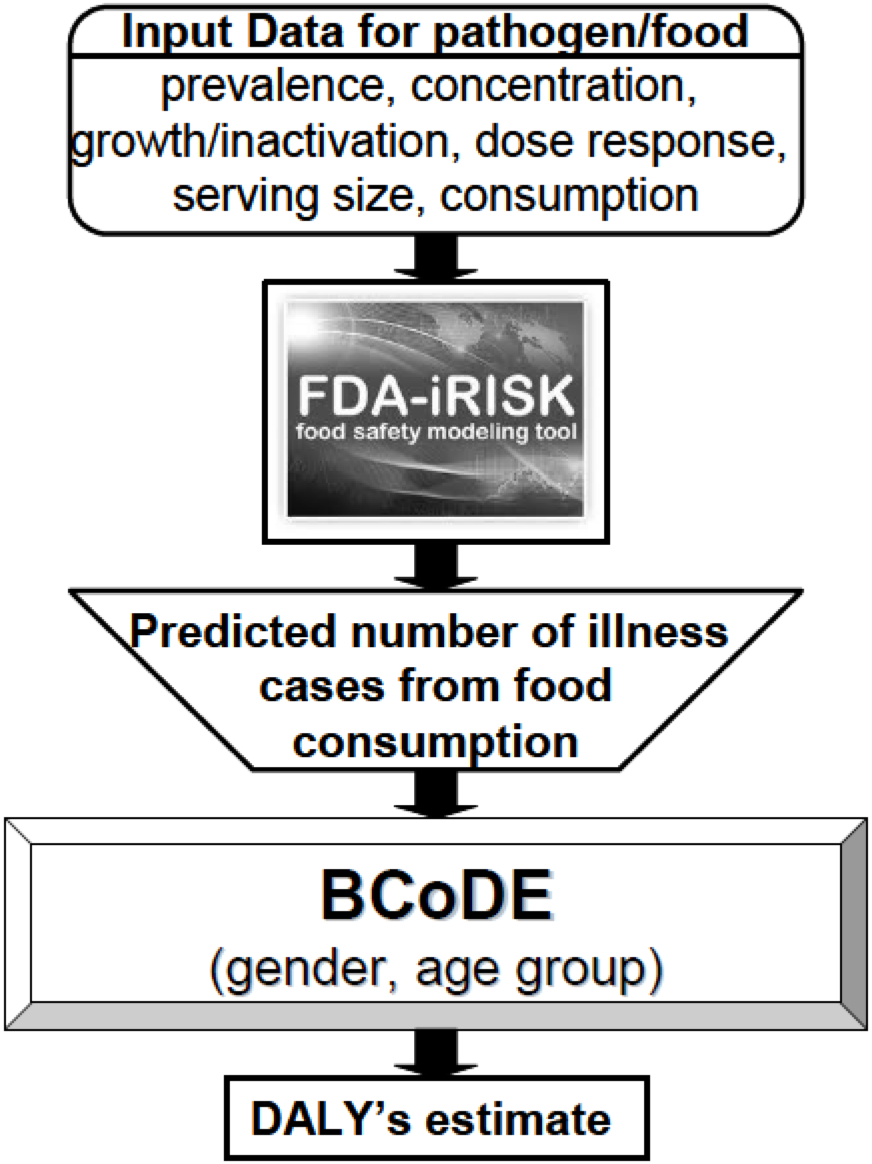
Rank orders without uncertainty	Median rank (2D Monte Carlo)	FP3	FP2	FP1	FP4	FP5	Final rank (2D Monte Carlo)
4	FP3	–	0.61	0.91	0.99	0.99	FP3, FP2 (1)
1	FP2		–	0.78	0.93	0.96	FP3, FP2 (1)
2	FP1			–	0.72	0.81	FP1 (3)
5	FP4				–	0.70	FP4, FP5 (4)
3	FP5					–	FP4, FP5 (4)

Uncertainty in Risk Ranking

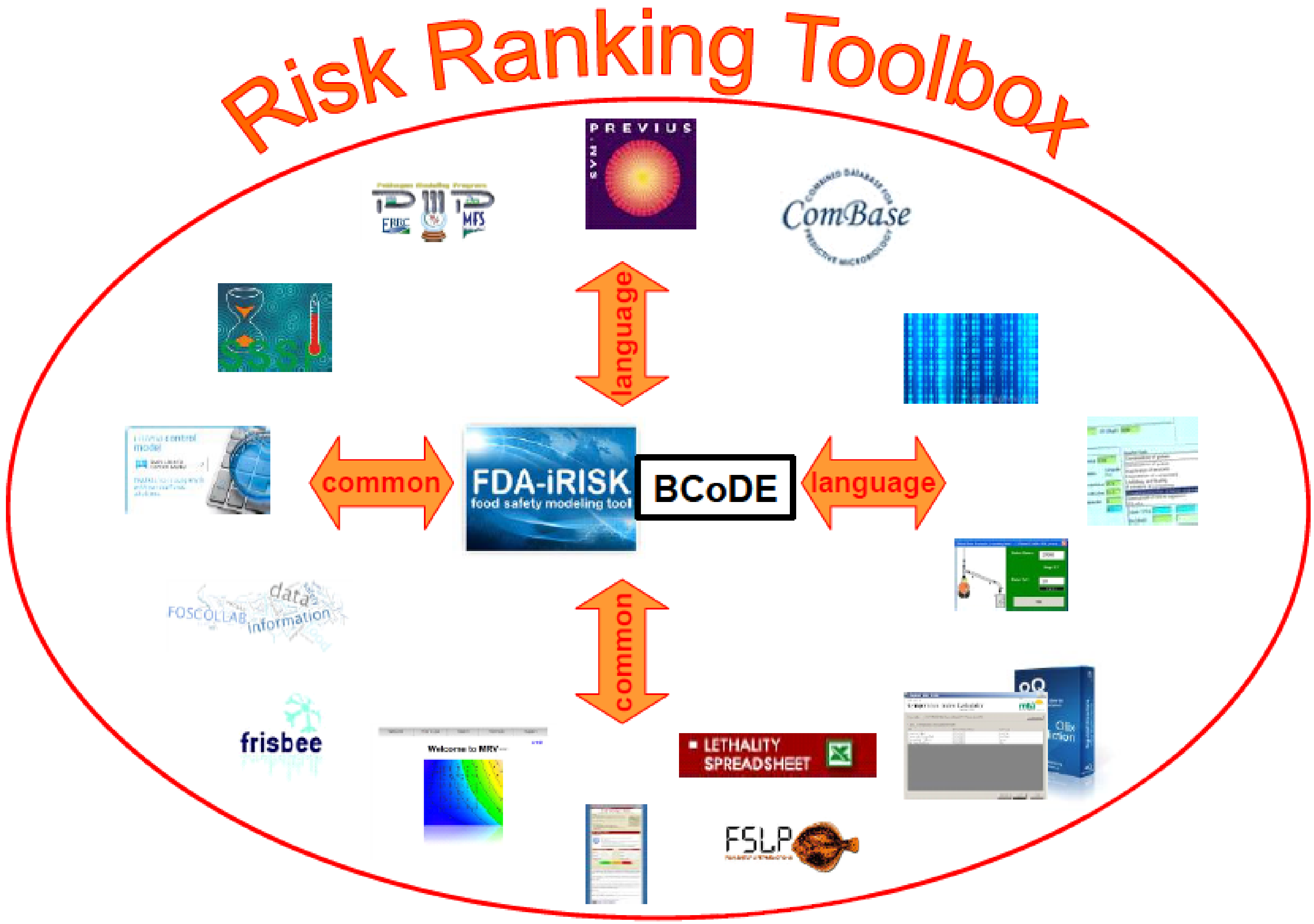
Quantifying uncertainty in risk ranking



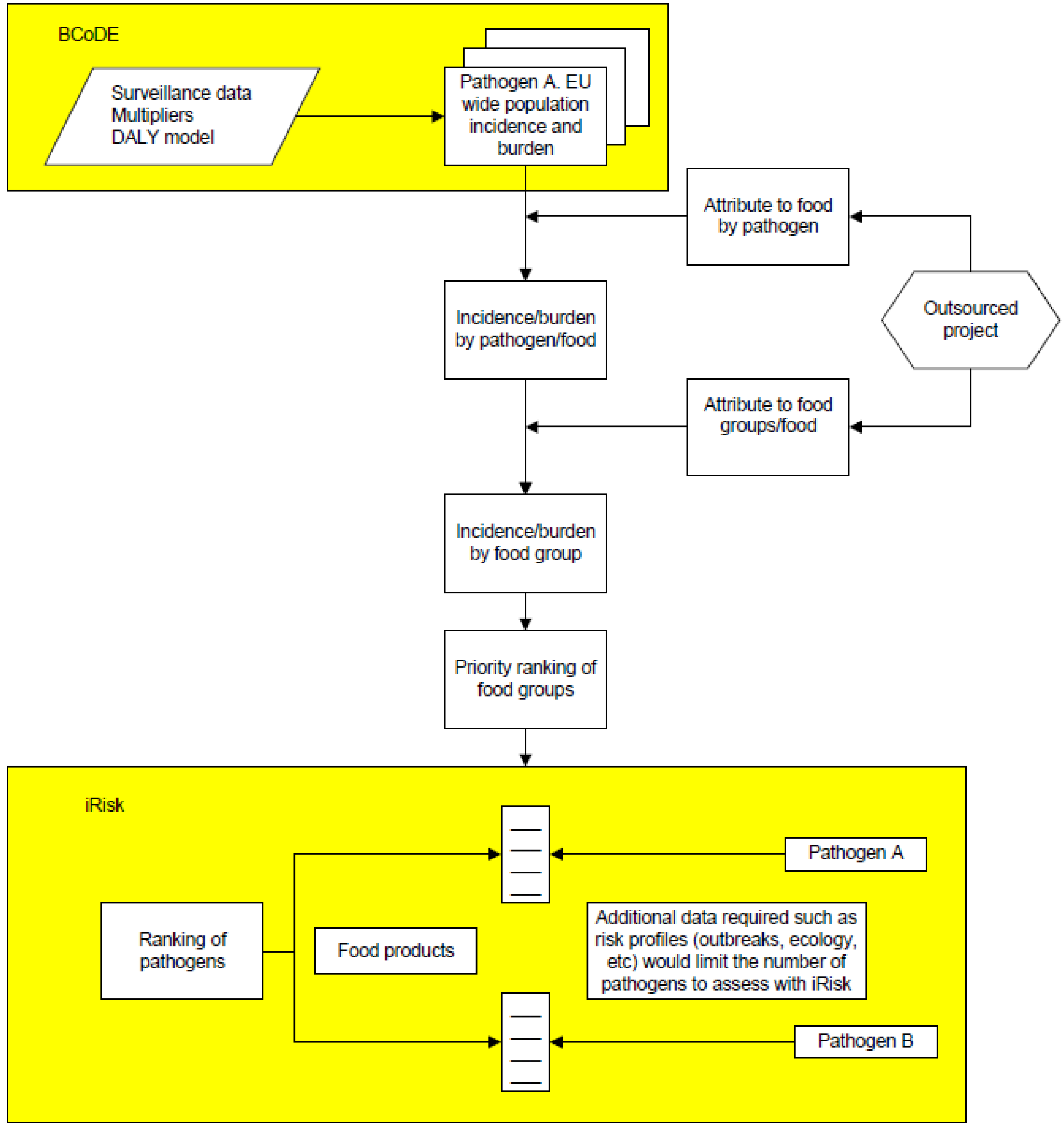
Evaluation of Risk Ranking software tools



Evaluation of Risk Ranking software tools



Evaluation of Risk Ranking software tools



Conclusions

- Fully quantitative stochastic models most reliable for risk ranking but need a good characterization of input parameters

- Deterministic models that ignore variability may result in risk ranking errors, which may be greater for the food–pathogen combinations with the highest risk

- In deterministic approaches, the selection of the point estimate used in the model can affect the risk ranking. Among different possible point estimates (arithmetic mean, median, 75th and 90th percentiles), the use of a high percentile provides, in general, ranking results which are most similar to a stochastic model

- Semi-quantitative models with ordinal scoring may lead to food–pathogen combinations classified into broad sets of categories with little discrimination. Considerable differences in risk ranking compared with a quantitative stochastic model. More errors than the deterministic approaches.

Conclusions

- Uncertainty in risk ranking needs to be carefully addressed and communicated to decision makers and stakeholders as one of the outcomes of the risk ranking process

- Uncertainty in rank orders cannot be formally quantified using qualitative or semi-quantitative ranking methods even though these are often applied in situations where data are limited.

- Expert elicitation procedures to incorporate diffuse information into the corresponding probability distributions may be adopted.

Acknowledgements

- Members of the BIOHAZ Panel
- Members of the working groups on risk ranking: Herbert Budka, Alessandro Cassini, Pablo S. Fernández Escámez, Tine Hald, Arie Havelaar, Kostas Koutsoumanis, Roland Lindqvist, Christine Müller-Graf, Moez Sanaa and Ivar Vågsholm
- EFSA Secretariat

Methodology and uncertainty impact on risk ranking of microbiological hazards: present and future

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Thank you