The different steps in risk-benefit assessment of foods

Parma Summer School 2019

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Outline

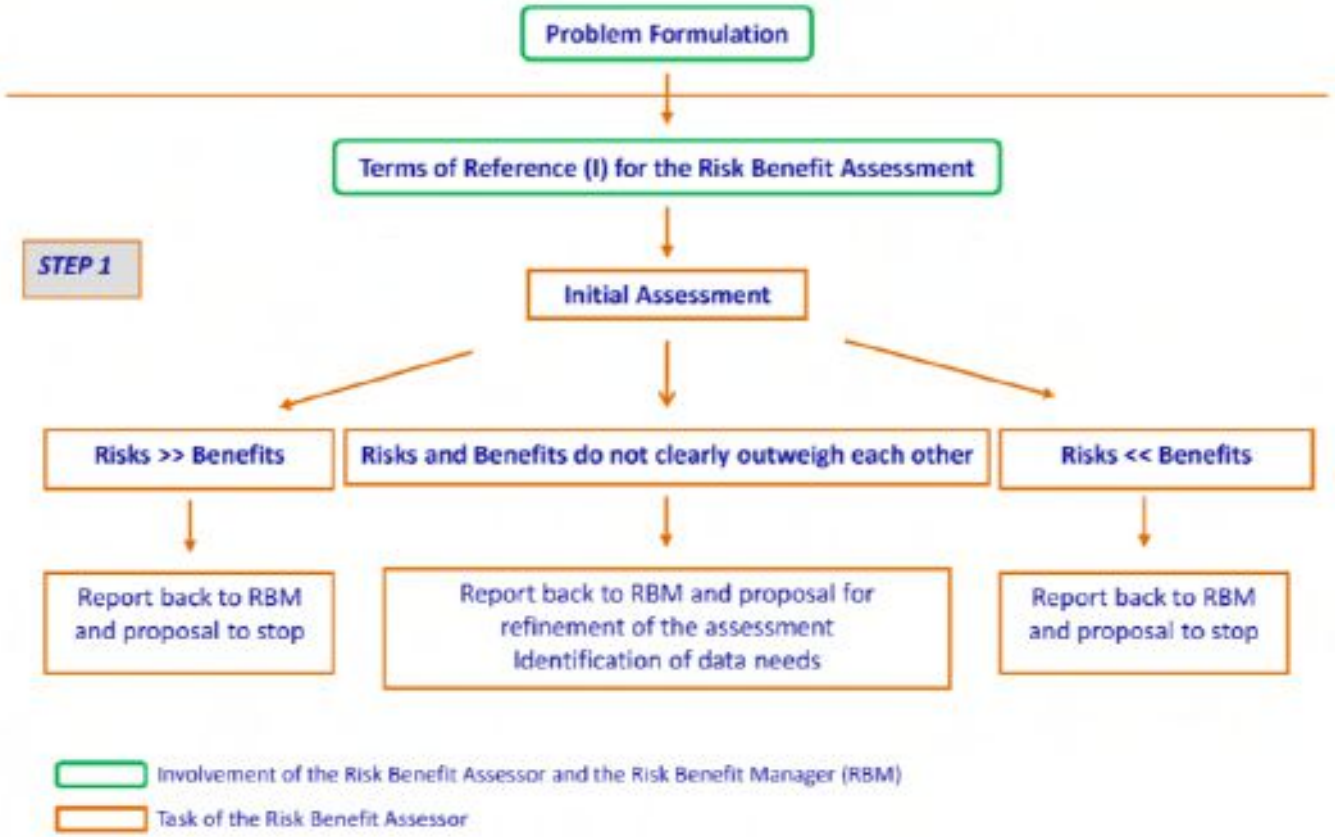
- Introduction to EFSA:s three step approach
- The risk-benefit asessment (RBA) process
- A closer look at EFSA:s step 2
- Examples of government agency work with RBA

Human risk benefit of foods, Efsa 2010

- Defines risks and benefits
- Acknowledges the work in ongoing projects
- Acknowledges the need for RBA on different levels

A three step approach

Step 1 Initial assessment



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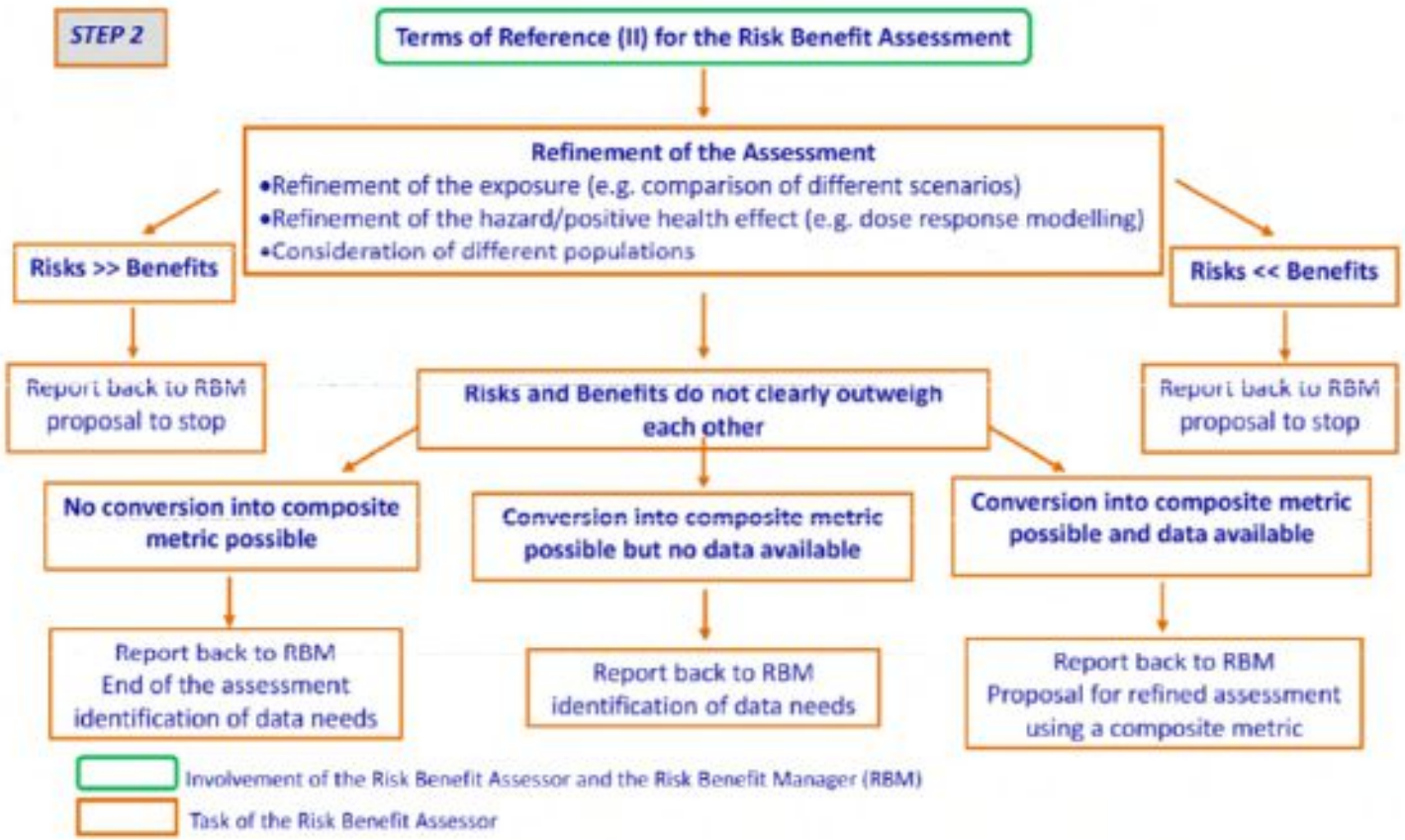
Human risk benefit assessment of foods, EFSA Journal 2010; 8(7):1673

Step 2 Refined assessment



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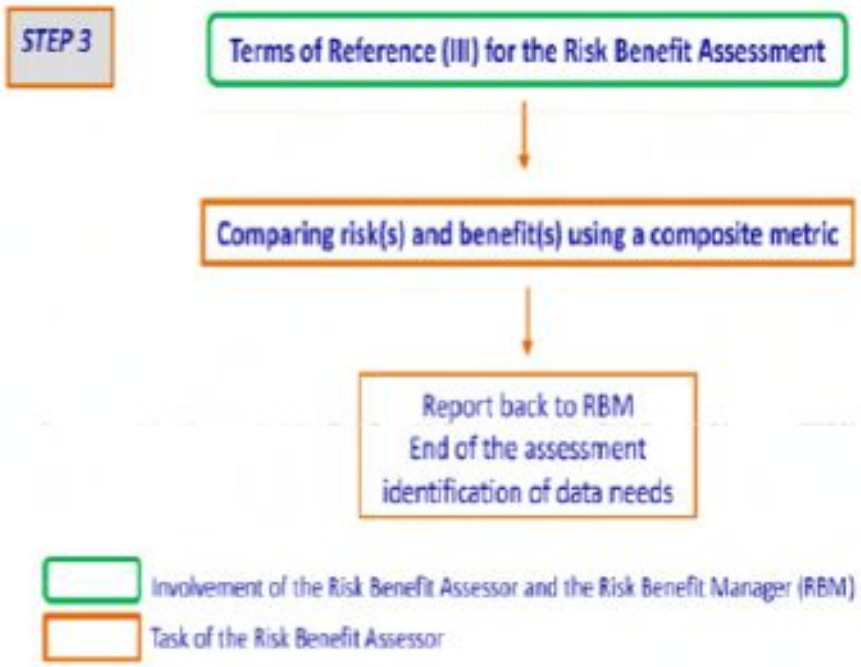
Step 3 Comparison of risks and benefits using a composite metric



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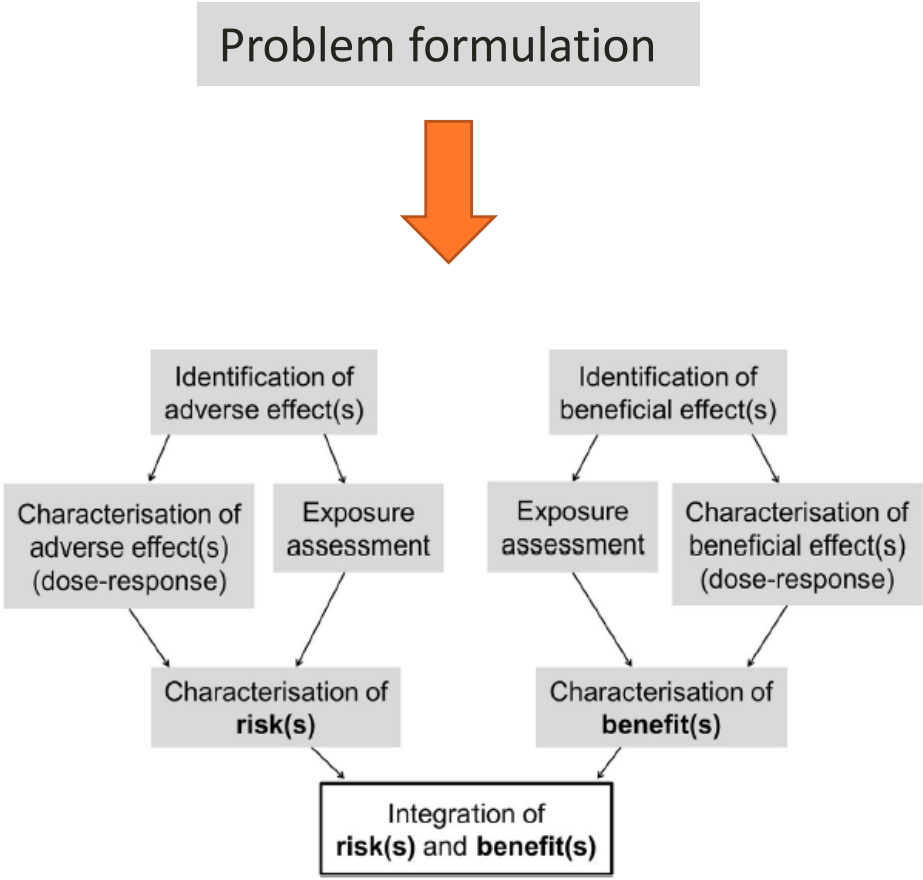
Human risk benefit assessment of foods, EFSA Journal 2010; 8(7):1673

The RBA process

1. Problem formulation
2. Health effect identification
3. Health effect characterization
4. Exposure assessment
5. Risk- and benefit characterization



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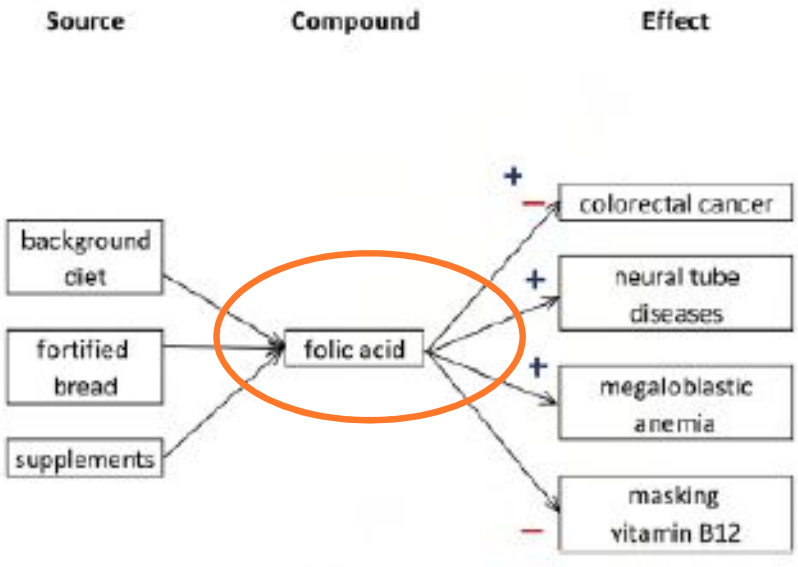
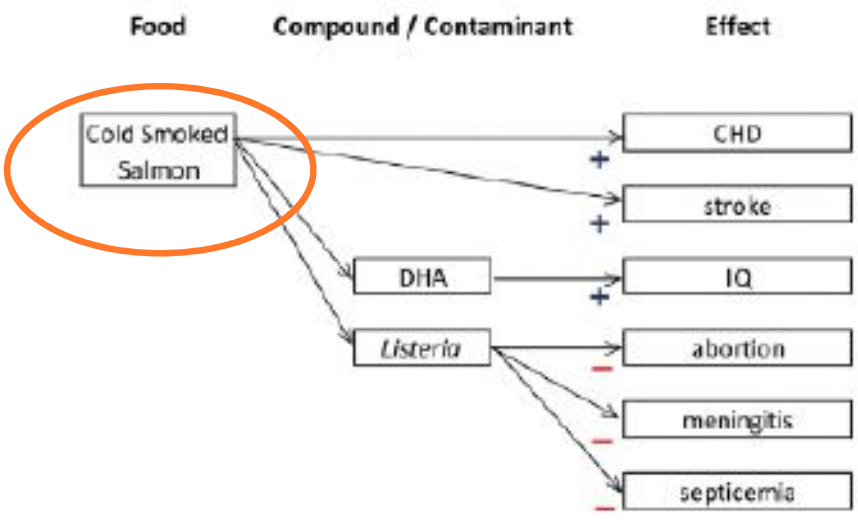
Pires et al, Risk benefit assessment of foods: Key findings from an international workshop, *Food Res Intern 2019 (116) 859-869.* Adapted from Tijhuis et al., 2012.

Problem formulation

- Level of aggregation (see next slide)
- Target population
- Scenarios, you need at least two scenarios to compare
- Importance of framing to decide on exclusion and inclusion criteria. What is your time frame? What kind of resources do you need?

Substance, food or whole diet?





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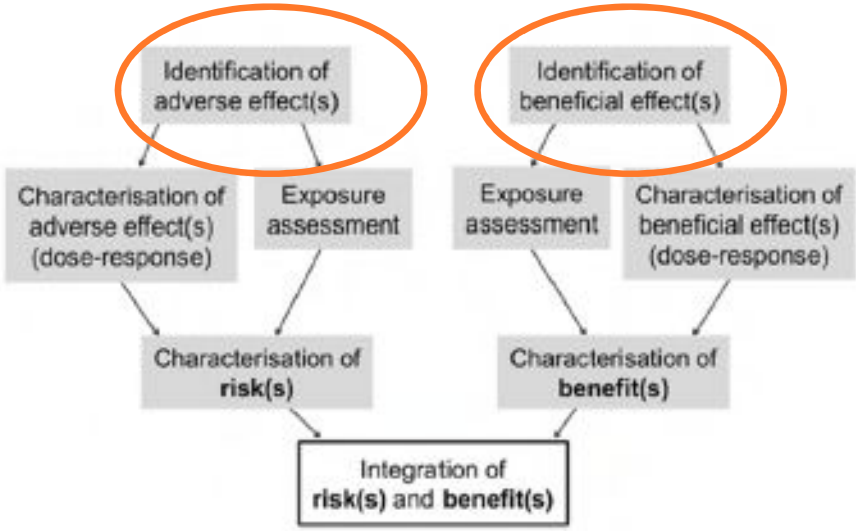
Nauta, et al. Meeting the challenges in the development of risk-benefit assessment of foods. *Trends in Food Science and Technology 2018. June (76)90-100.*

Health effect identification

- Literature review to identify relevant adverse and beneficial effects
- Assess the quality of identified literature (there are tools for this)
- Assess the level of evidence based on the available literature



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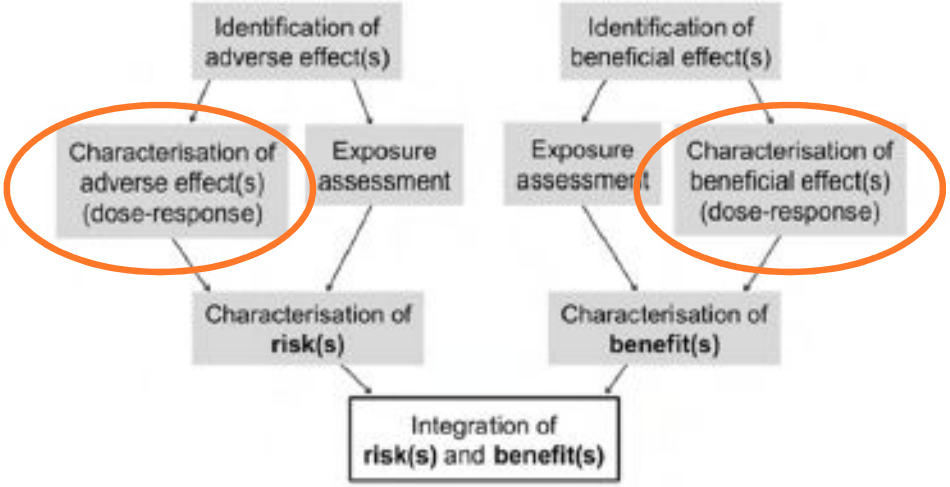
Health effect characterization

- Different outcomes:

1. Continuous,
2. Categorical (comparison with a health-based value) or
3. Quantal (probability of an effect)



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You need a multidisciplinary team!

You may end up with:

- Data from human observational studies expressed as relative risks of disease
- Data from animal models showing a change in expressed hormone levels
- A survey of occurence of contaminated sprouts at restaurants

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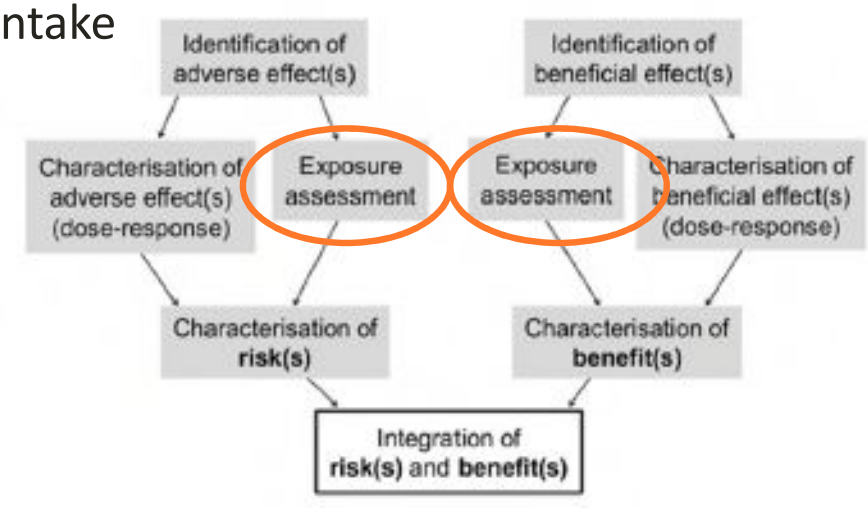
Exposure assessment

- Dietary intake data
- Food composition data
- Method according to type of exposure

1. Acute exposure: calculate the probability of being exposed by a toxin or a microbiological hazard on a given day or per serving
2. Chronic exposure: estimate the long-term average intake



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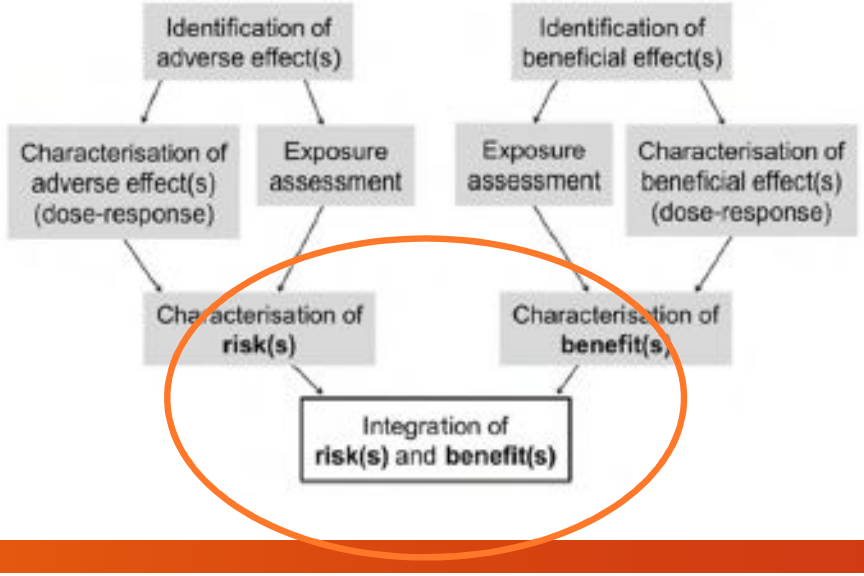
Risk and benefit characterization

- Qualitative: Compare exposure to health based guidance values
- Quantitative RBA: Same for both risk and benefit side e.g. mortality
- Composite metrics (integrated measures) e.g. DALYs, QUALYs, Cost of Illness



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A moment to reflect….

- Were the concepts of RBA familiar to you?
- Did the RBA process differ from the way you usually work with these concepts?
- Do you have any questions?

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Other considerations in RBA

- Uncertainty
- Data availability
- Variability, heterogeneity
- Substitution (explicit or unknown)

A closer look at step 2, Refined assessment

1. Problem formulation

2. Health effect identification

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4. Exposure assessment

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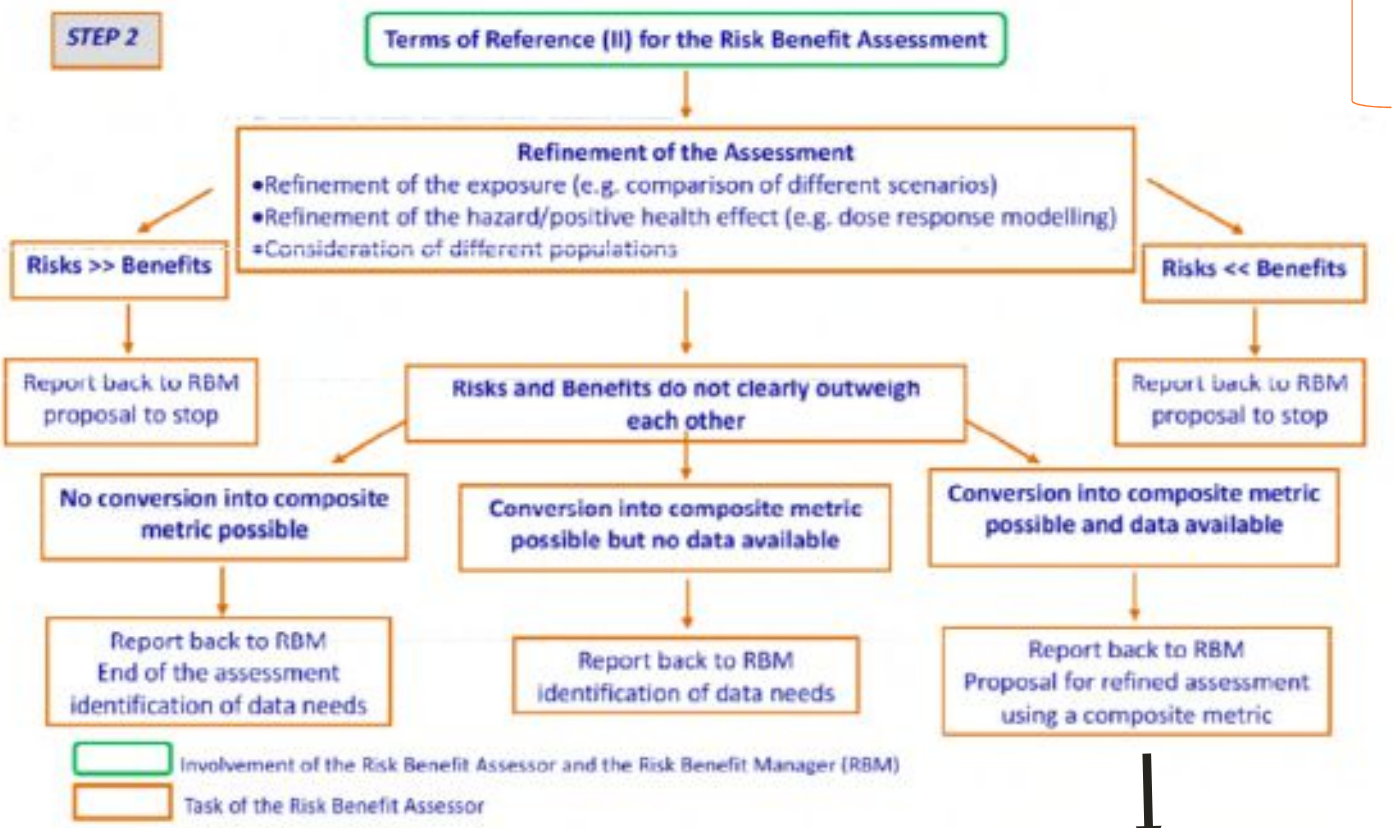

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Step 3, Comparison of risks and benefits using a composite metric

Human risk benefit assessment of foods, EFSA Journal 2010; 8(7):1673

RBA of nuts

- Should we include nuts in food based dietary guidelines?
- Conclusions from assessment with a qualitative approach was vague


Rapport 16 – 2014

Risk- och nyttovärdering av nötter

– sammanställning av hälsoeffekter av nötkonsumtion

av John Bylund Hanna Enemoth, Sina Wallin och Lilianne Abramson-Zetterberg

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https://www.livsmedelsverket.se/globalassets/publikationsdatabas/rapporter/2014/2014_livsmedelsverket_16_risk_nyttovardering_notter.pdf

RBA of nuts, step 3

- With a quantitative approach, using DALY:s (EFSA:s step 3) we came to another conclusion
- Cardiovascular benefits clearly outweighs the risks associated with aflatoxin exposure

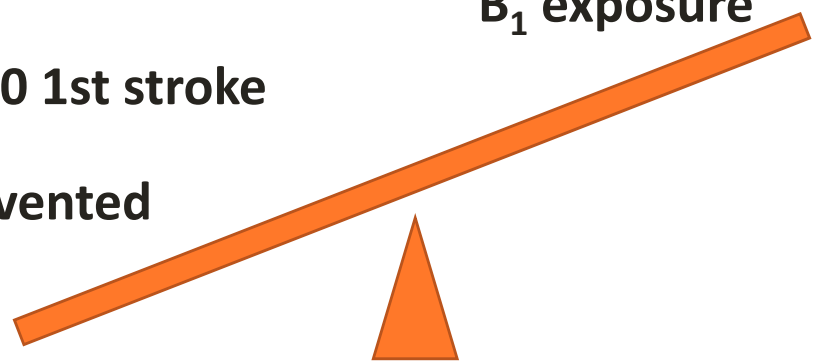
Scenario: Increased consumption of nuts to 30 g per day in Swedish population aged 18-79

3715 1st MI

5390 1st stroke

prevented

0-3 cases of liver cancer due to aflatoxin B_1 exposure



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Eneroth et al, Risks and benefits of increased nut consumption: cardiovascular health benefits outweigh the burden of carcinogenic effects attributed to aflatoxin B_1 exposure. *Nutrients 2017 Dec 13;9(12).*

Why should a government agency work with RBA?

RBA may provide the best evidence concerning

- The contamination of otherwise healthy foods
- Different level of risk in different strata of the population
- Inconclusive research on food and health

The aim of a RBA is to support decision making

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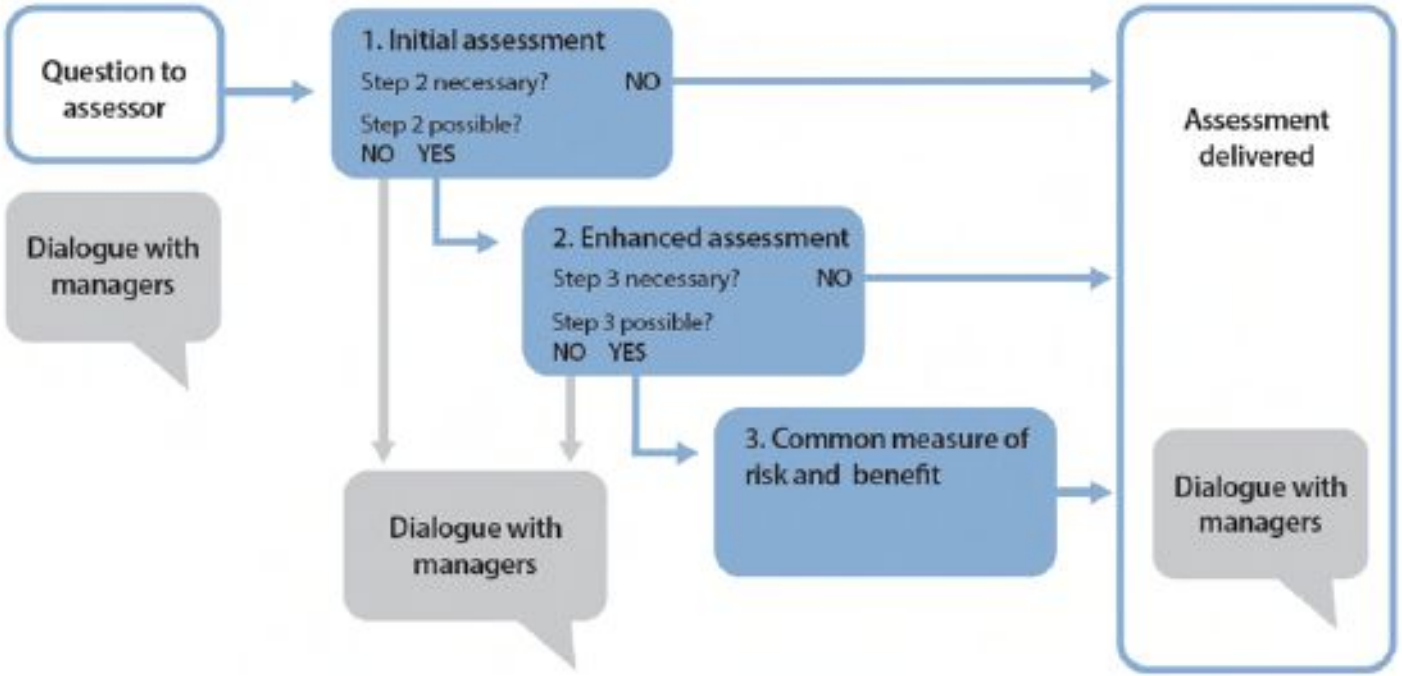
Getting to know the stepwise approach



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Eneroth, et al. Risk-benefit assessment of foods in Sweden - developing a working procedure. *European Journal of Nutrition & Food Safety 2016*, *6*(2), 75-78.

Conclusions from work at NFA

- It is valuable to clarify what the different steps in a RBA mean for a particular organization
- It is challenging to work in multi-disciplinary teams
- We generally don´t have the capacity of doing full RBAs
- It is useful to identify risks and benefits in all projects

Summary of the lecture

- EFSA provides guidance on the depth of a risk-benefit assessment
- The process of RBA is similar to that of a risk assessment, but characterizes risks *and* benefits in the final step
- Method has to be tailored to the particular RBA-question in focus after careful problem formulation

Suggested readings

- Risk-benefit assessment of food substitutions. Sofie Theresa Thomsen, PhD Thesis DTU 2019.
- Pires et al, Risk benefit assessment of foods: Key findings from an international workshop, *Food Res Intern 2019 (116) 859-869.*
- Boobis et al, Critical appraisal of the assessment of benefit and risks for foods, BRAFO consensus working group. *Food Chem Tox. 2013 May (55) 659-675.*
- Tijhuis et al, State of the art in benefit-risk analysis: food and nutrition. *Food Chem Tox. 2012 Jan (50) 5-25.*

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Thank you for your attention!