

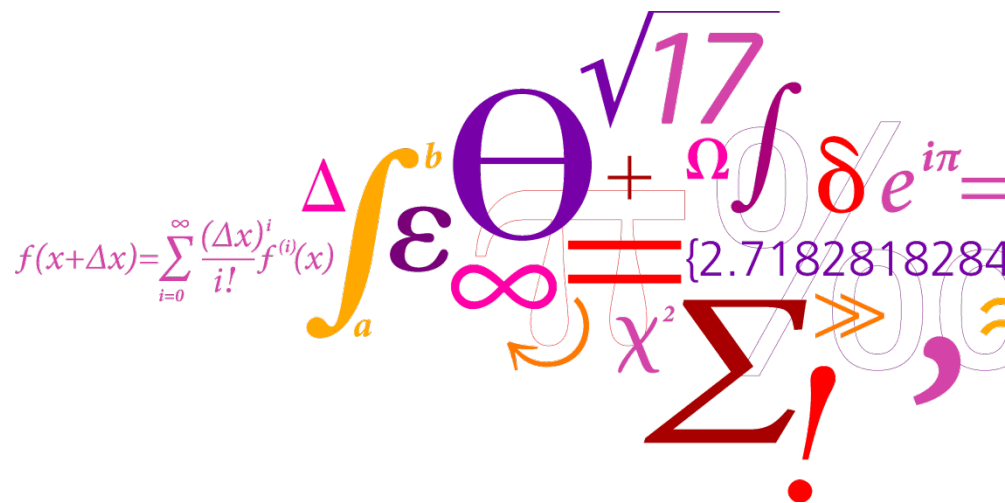
# How to compare risks and benefits of GMOs

## Risk-Benefit Assessment (RBA)

Morten Poulsen

DTU Food  
National Food Institute

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# Risk-Benefit Assessments (RBA)

- You can assess the risk and benefits of GMOs , and
- You can assess the risk-benefit of GMOs
  - **What is the difference?** (the first one is qualitatively and the second is quantitatively)

## Short definition of RBA

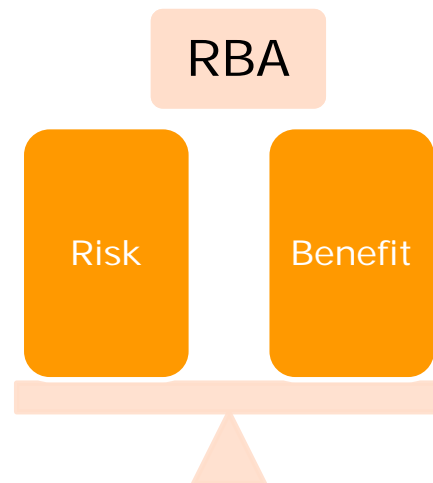
In an integrated risk-benefit analysis risks and benefits are identified, assessed and integrated for a specific food at a specific intake and for a specific group of people. Thereby it is possible to calculate the net health benefits of the selected food



Risk-benefit analysis is using existing data

# The concept of RBA

- The quantitatively RBA is a relatively new discipline
- Most of the RBA-research (2004- present) has been performed within EU-projects: NOFORISK, BENERIS, BRAFO, QALIBRA, SAFE FOODS, BEPRARIBEAN, PLANT LIBRA



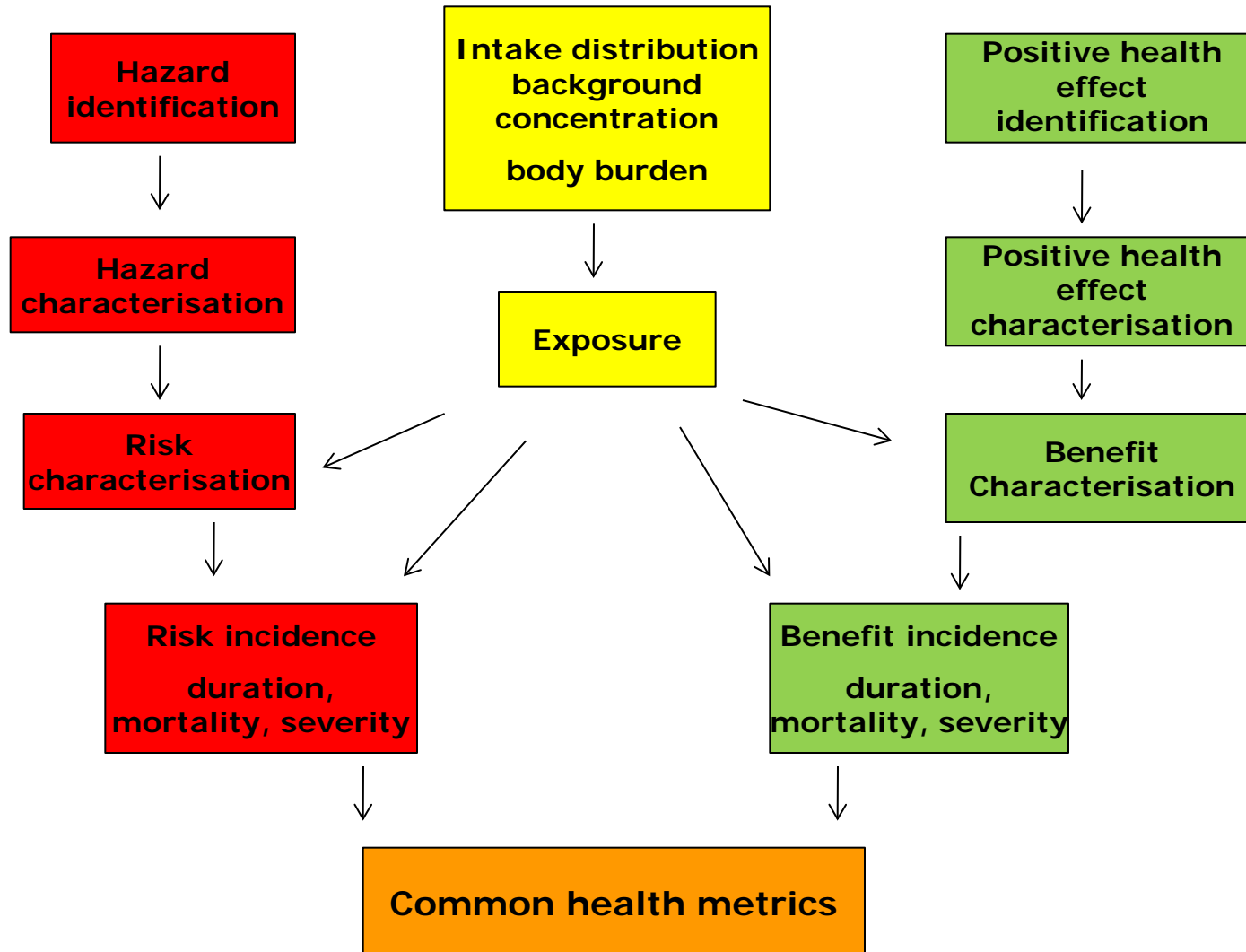
# RBA examples

Food	Benefits	Risks
Fish	Coronary heart diseases ↓	Neurological damage in the fetus / microbiological contamination
Fruits and vegetables	Cardiovascular diseases and cancer ↓	Pesticides
GM plants	Nutrition? Environment?	Health? Environment?

# RBA problems and when to perform a RBA

- Allow a food on the market
- Make a recommendation
- Fortify a food
- Change a production process
- Start an intervention
- Policy considerations

# The Risk-Benefit Analysis



# RBA problem formulation / preassessment

- Defining the risk-benefit question
- Set the scope and limitations of the assessment
- Describe reference (usually current diet) and alternative scenario
- Population to be considered
- Interaction with policy makers, risk assessors, other stakeholders



# RBA and net health gain or losses

Reference intake	Intake of interest
Health state	Health state



Decrease in health = risk

Increase in health = benefit



Net health

Does scenario "of interest" result in net health gains or losses compared with the reference scenario ?

# Measures of health impact

- Mortality (deaths)
- Morbidity (disease)
- Quality of life, functioning

# Net health impact measures

- Disability-adjusted life years (DALYs)
- Quality-adjusted life years (QALYs)
- Willingness to pay (WTP)

# DALY

DALYs take account of: number of people affected, severity of disease, duration of disease, years of life lost due to early mortality

Calculation of DALY:

Years lived with disease (YLD)

Severity of disease ( $w$ , 0-1)

Years of life lost (YLL)

$$\text{DALY} = \text{YLD} \times w + \text{YLL}$$

Sum up for all individuals in population

More DALYs bad, less  
DALYs good

# What do you need to perform a RBA

- A well-formulated problem
- Expertise (Toxicology, nutrition, modelling)
- Data (Exposure distributions/concentrations, dose-response, disease characteristics/incidences/weights/mortality)
- Common sense

# Interpretation of results

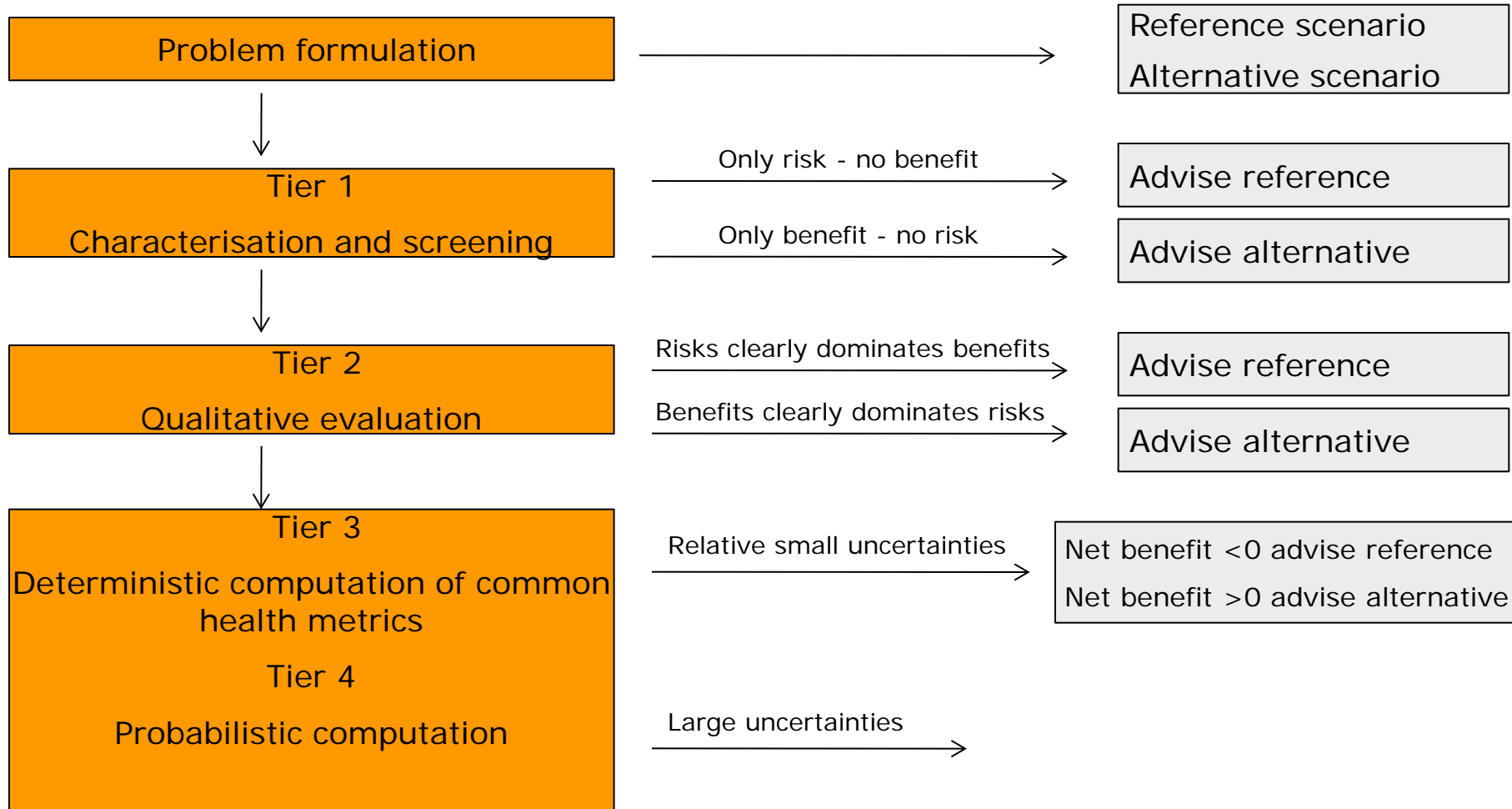
- Interpret with caution, take account of limitations
- Do not present results as "real" impacts
- Results are an indication of the potential average health impact of a long-term (steady-state) dietary change
- Characterise the associated uncertainties and communicate it to risk managers

# The tiered approach

- A full quantitatively RBA is very data demanding and involves large effort (time and money)
- Stop when you can answer the question
- How accurate needs the answer to be?
- What will be the case for GMOs?

# A proposal for a RBA procedure

## – the BRAFO approach





# RBA examples

Food	Benefits	Risks	Conclusion
Farmed salmon	Coronary heart diseases ↓↓	Contaminants / heavy metals ↑	Benefit dominates – stop at tier 2
Rice with lowered phytic acid	Increased mineral uptake ↑↑	Absorption of heavy metals →	Benefit dominates – stop at tier 2
Heat treatment of milk	Elimination of microorganisms	Change in taste	Benefit dominates – stop at tier 1
GM plants	?	?	?

Thank you  
Questions?