The different steps in risk-benefit assessment of foods

Parma Summer School 2019

Hanna Eneroth Nutritionist, PhD Department of risk- and benefit assessment





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





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

Step 2 Refined assessment



Livsmedelsverket

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

Step 3 Comparison of risks and benefits using a composite metric





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





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?





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





Health effect characterization

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





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





https://pixabay.com/images/

Exposure assessment

- Dietary intake data
- Food composition data
- Method according to type of exposure
- Acute exposure: calculate the probability of being exposed by a toxin or a microbiological hazard on a given day or per serving



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





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?





https://pixabay.com/images/

Other considerations in RBA

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



A closer look at step 2, Refined assessment



RBA of nuts

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





https://www.livsmedelsverket.se/globalassets/publikationsdata bas/rapporter/2014/2014_livsmedelsverket_16_risk_nyttovarde ring_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





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



Getting to know the stepwise approach





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.*







Thank you for your attention!