Approaches proposed by EFSA for Risk-Benefit Assessment

Opportunities and Challenges

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Disclosure statement

- I am a full-time employee of the Swedish Food Agency
- I am a member of the European Food Safety Authority Panel on Contaminants in the food chain (CONTAM-panel)
- I was a member of the EFSA working group that drafted the guidance on risk-benefit assessment of foods
- The views expressed in this presentation are those of myself and do not necessarily reflect the position the European Food Safety Authority

Introduction

The European Food Safety Authority, EFSA

- EFSA formed in 2002, and provides the scientific basis for laws and regulations to protect European consumers from food-related risks - from farm to fork
- Most of EFSA's work undertaken in response to requests from the European Commission (EC), the European Parliament and EU Member States
- EFSA scientific advice provided by its 11 Scientific Panels, dedicated to a different area of the food and feed chain, and the Scientific Committee (SC)
- EFSA also carry out scientific work on their own initiative, e.g., the recent update of the "Guidance on risk-benefit assessment of foods" by the Scientific Committee
  - Partly motivated due to that the European Commission will task EFSA with conducting a broader risk-benefit assessment on fish consumption

Introduction

Guidance on risk-benefit assessment of foods, EFSA 2024

- Guidance deals exclusively with health risks and benefits of foods
- Focuses on chemical hazards and nutrients
- Several approaches presented that can serve as a basis for supporting a diverse set of RBAs
  - Broadening the overall approach
  - Partly guided by Member State input that health impact metrics (like disability-adjusted life years) cannot always or easily be applied

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GUIDANCE

Guidance on risk–benefit assessment of foods

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Abstract
The EFSA Scientific Committee has updated its 2010 Guidance on risk–benefit assessment (RBA) of foods. The update addresses methodological developments and regulatory needs. While it retains the stepwise RBA approach, it provides additional methods for complex assessments, such as multiple chemical hazards and all relevant health effects impacting different population subgroups. The updated guidance includes approaches for systematic identification, prioritisation and selection of hazardous and beneficial food components. It also offers updates relevant to characterising adverse and beneficial effects, such as measures of effect size and dose–response modelling. The guidance expands options for characterising risks and benefits, incorporating variability, uncertainty, severity categorisation and ranking of different (beneficial or adverse) effects. The impact of different types of health effects is assessed qualitatively or quantitatively, depending on the problem formulation, scope of the RBA question and data availability. The integration of risks and benefits often involves value-based judgements and should ideally be performed with the risk–benefit manager. Metrics such as Disability-Adjusted Life Years (DALYs) and Quality-Adjusted Life Years (QALYs) can be used. Additional approaches are presented, such as probability of all relevant effects and/or effects of given severities and their integration using severity weight functions. The update includes practical guidance on reporting results, interpreting outcomes and communicating the outcome of an RBA, considering consumer perspectives and responses to advice.

KEYWORDS
benefit–risk, food safety, RBA, risk ranking, risk–benefit, risk–benefit assessment, risk–benefit communication

When is Risk-Benefit Assessment (RBA) relevant?

Relevant when both risks and benefits are clearly associated with consumption of foods

- Component: *Single food component with both positive and negative effects (e.g. vitamin A)*
- Food: *A specific food associated with both health risks and benefits (e.g. meat)*
- Component and food: *Risks from specific contaminant(s) weighted against benefits of the food*
- Diet: *A change of dietary patterns (e.g. increase in plant-based foods)*

RBAs differ depending on the level of complexity of the question in combination with the data and resources available

An opportunity, and/or need, to broaden the ways we assess the effects of chemicals and nutrients

- **RBA can support development or refinement of dietary advise**:
  - In SFA (2022) we assessed if our recommendations on whole grain needed revision if considering the increase in contaminant exposure besides the increase in beneficial effects
- **RBA generally conducted by evaluating scenarios**:
  - Difference between the present exposure situation and an alternative scenario/s

RBA vs risk assessment, and general challenges

- RBA may need to characterize several relevant effects over a range of potential intakes
  - The approach in risk assessment to identify the most sensitive/critical effect as a basis for establishment of health-based guidance values (e.g., RfDs) may not suffice
- Data on relevant risks and benefits may differ in nature, e.g., experimental vs. epidemiological data, and/or effect data for specific compounds (risk-side) vs. effect data related to foods/diets/change in consumption patterns (benefit-side)
- Negative and positive health effects need to be compared on a common scale to assess the overall tradeoff between risk and benefit
  - The following methodological part of this talk relate to this issue

Characterization and integration of risks and benefits

Summary of methods proposed in EFSA 2024 (Table 3 in report)

- Ranking approaches for initial prioritization of food components
  - Score-based ranking across toxicological, nutritional, and microbiological domains (Boué et al., 2022)
  - Severity-adjusted margin of exposure for chemical hazards (SFA, 2015)

- Exposure vs. health-based guidance values (HBGVs) or dietary reference values (DRVs)
  - Accounting for variability and/or uncertainty
  - Possibility to define HBGV/DRV using biologically-based benchmark response values

- Health impact metrics, e.g., disability-adjusted life years (DALYs)
  - Accounting for several dimension of a health effect (e.g., incidence, severity, duration)

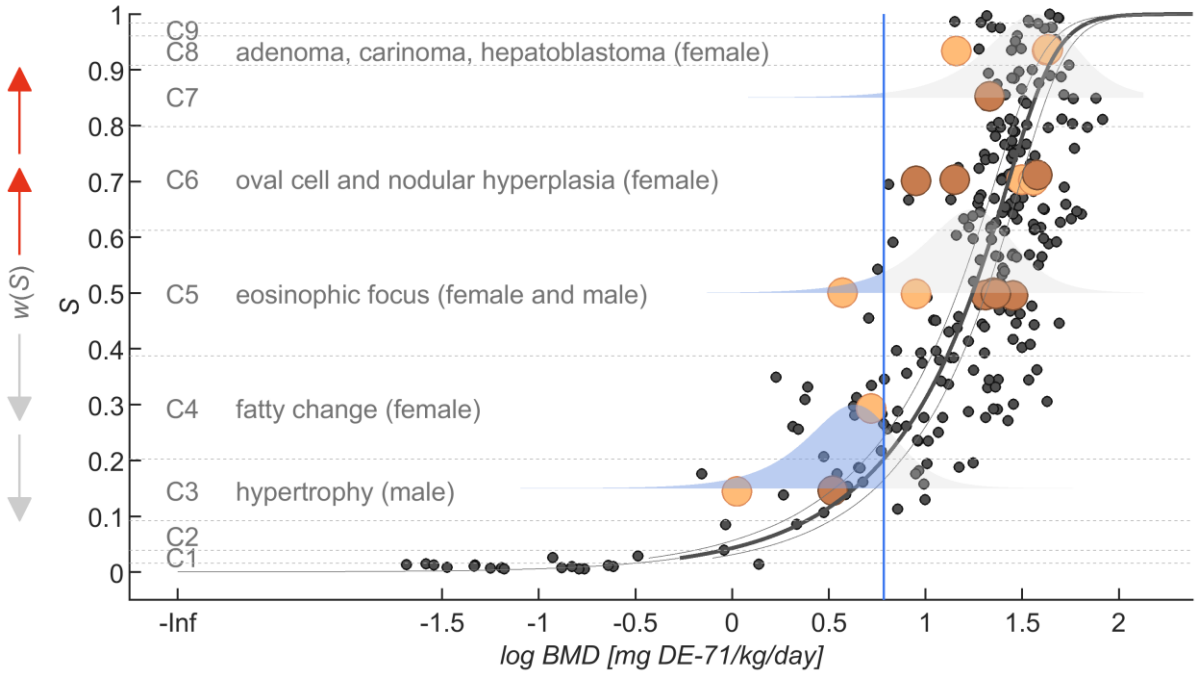
- Methods for joint assessment of multiple effects

- Decision analysis, e.g., multi-criteria decision analysis
  - E.g., when lacking a risk assessment-based rational for comparing/integrating health effects

Joint assessment of multiple effects

Characterization and integration of risk and benefits

- Health impact (e.g., DALYs) typically assessed with respect to specific diseases
- Categorical regression and methods in Sand et al., (2018/2022, Figure) used to combine data for a broad range of effects
- Methods include severity scoring system that places various health effects on a common scale (e.g., y-axis in the Figure)
- Proposed/applied for chemical hazards but may also assist RBA due to standardized effect/severity scoring system



Model for pentabromodiphenyl ether mixture (EFSA 2024)

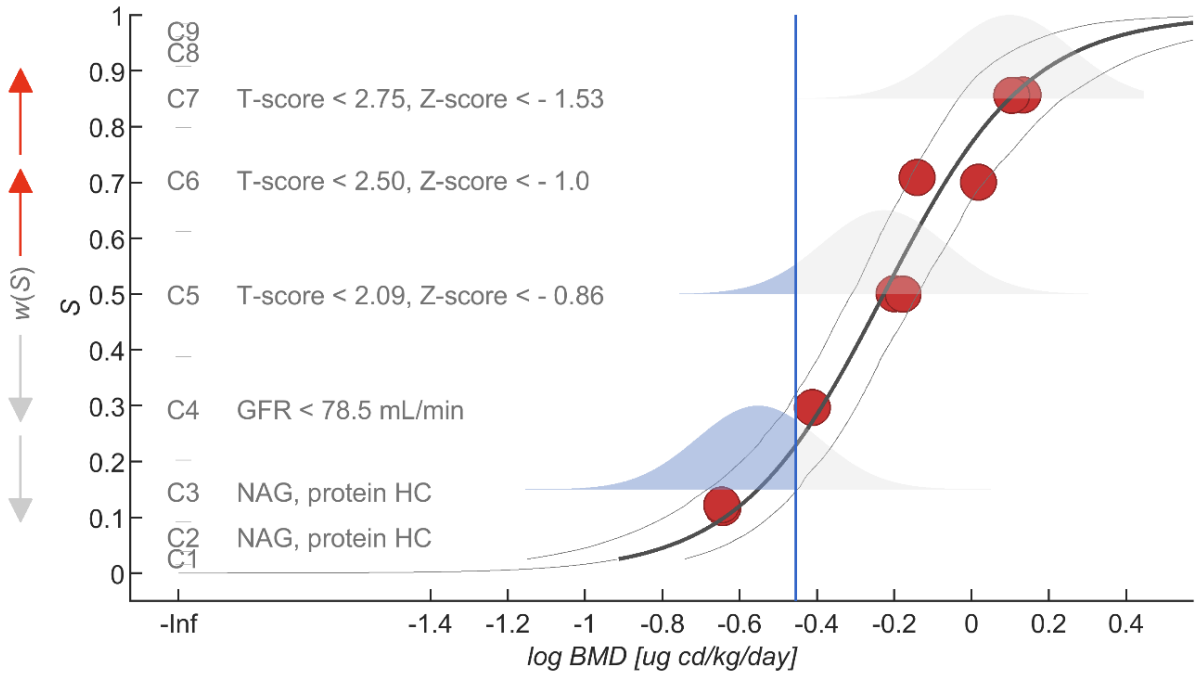
Large circles: BMDs based on 2-year study in rat (NTP 2016)

Small circles: BMDs from short term-study in same strain (Dunnick et al., 2018)

Joint assessment of multiple effects

Characterization and integration of risk and benefits

- Probability of a given severity category (e.g., C1 to C9 in Figure) can be estimated
- Weight function, *w*(*S*), facilitates effect integration - e.g., a weighted average of the probability of effect can be obtained
- A reduction in disease incidence (benefit) may be mapped in same system, and
  - Compared to the risk result for the same severity category, or
  - Weighted (S = 0 to 1) and compared to the integrated (weighted) risk result



Example of model for cadmium related kidney and bone effects (EFSA, 2024, Appendix D, Case study)

Concluding remarks and future work

- A fundamental challenge in RBA (and risk ranking) is balancing of various health effects
- EFSA RBA Guidance suggests that selection of weights/weighting approach is performed in consultation with the risk manager
- RBA traditionally assessed at the level of disease, but future of toxicology moves more towards collecting data in the other end (upstream from adverse apical response)
  - For example, can output from illustrated multiple-effect model be translated to health impact, e.g., from “integrated response” to disability-adjusted life years?
  - Can the model be applied to food components besides chemical hazards?
  - How important are selection of weights? Absolute results will change but a difference in results between two exposure scenarios (typical in RBA) may be less sensitive
  - More work on uncertainty analysis

Thank you!

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