2nd LARAS
LATIN AMERICAN AND CARIBBEAN
RISK ASSESSMENT
SYMPOSIUM CHILE 2021

Development of a suitable approach for a risk benefit assessment (RBA) of nutrients and contaminants in fish

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Trusted science for safe food

efsa
European Food Safety Authority

Request of EC/SANTE (Aug 2020)

- To provide a risk-benefit assessment of fish consumption in relation to the presence of dioxins (PCDD/Fs) and dioxin-like PCBs, taking into account the estimated exposure to PCDD/Fs and DL-PCBs in relation with the established Tolerable Weekly Intake (TWI) of 2 pg TEQ/kg bw/week.
- In addition, to assess the influence of the presence of other contaminants in fish such as methylmercury, brominated flame retardants and perfluoroalkyl substances (PFAS) on the outcome of the risk-benefit assessment has to be provided.

Today's presentation

- **Interpreting the request** for scientific advice from the European Commission together with risk managers of the EC and EU Member States
- Translating risk management questions into **a workplan for EFSA** how to address the questions posed by the risk managers
- Developing **a multi-annual programme 2021-2025** for data collection, developing a risk-benefit assessment methodology for application to nutrients and contaminants in fish

Interpretation of the request from EC/SANTE

Scope of the assessment

- Which (other) contaminants and nutrients
- Update exposure assessments
- How to weigh health risks and health benefits?

Data collection and evaluation

- Updating occurrence data for contaminants and nutrients
- Different types of fish, geographical variation
- Estimates of % of HBGV and % of DRV for selected exposure scenarios

Formulating advice on risks and benefits

- Methods for (weighing) health risks and health benefits of contaminants and nutrients in fish
- Assess health outcomes of combined exposures?

Contaminants and nutrients in fish

NUTRIENTS

Long Chain Poly-Unsaturated Fatty Acids
Vitamins (e.g. Vitamin D)
Minerals *calcium, iodine, selenium, zinc)
…..

CONTAMINANTS

Dioxins (PCDDs, PCDFs and dioxin-like PCBs)
Methylmercury
Brominated flame retardants
PerFluoroAlkyl Substances (PFAS)
…..

(Groups of) substances with different health (positive/negative) effects, HBGVs and DRVs for different endpoints, differences in levels in various types of fish, with fish not always major source of dietary exposure

Exchange of views with EU risk managers

- EC and Member States need EFSA's advice that would support them in defining **dietary advice on consumption of fish**
- Several Member States considered an approach to estimate **% of HBGVs** and **% of DRVs** as not sufficient
- Member States need advice on **how to weigh risks and benefits of combined exposure** to contaminants and nutrients
- EFSA noted it needs an **update of the existing RBA guidance** to help risk managers to define (national) dietary advice

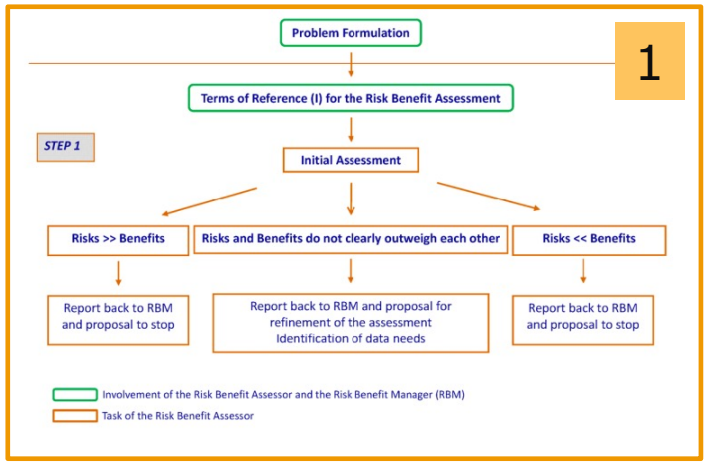
RBA GUIDANCE OF SC (2010)

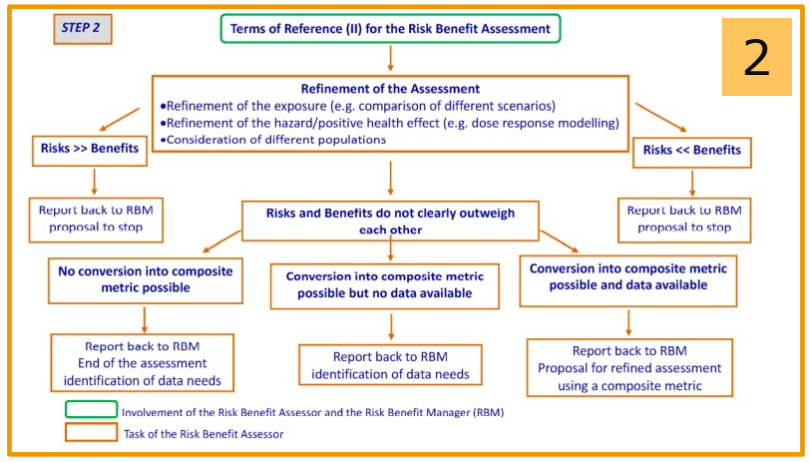
SCIENTIFIC OPINION

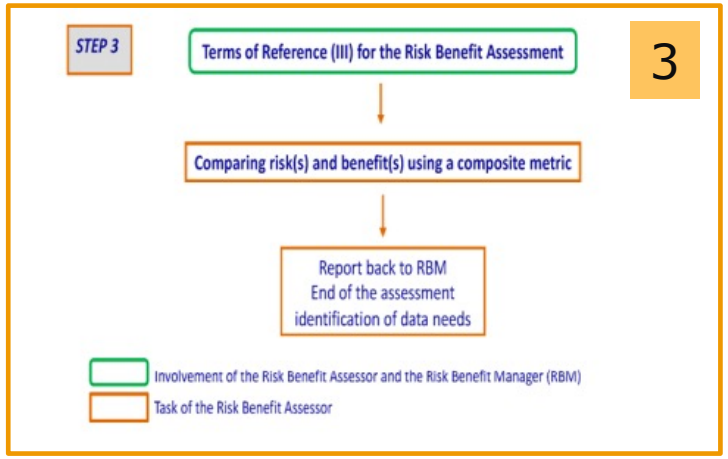
Guidance on human health risk-benefit assessment of foods[1]

EFSA Scientific Committee[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

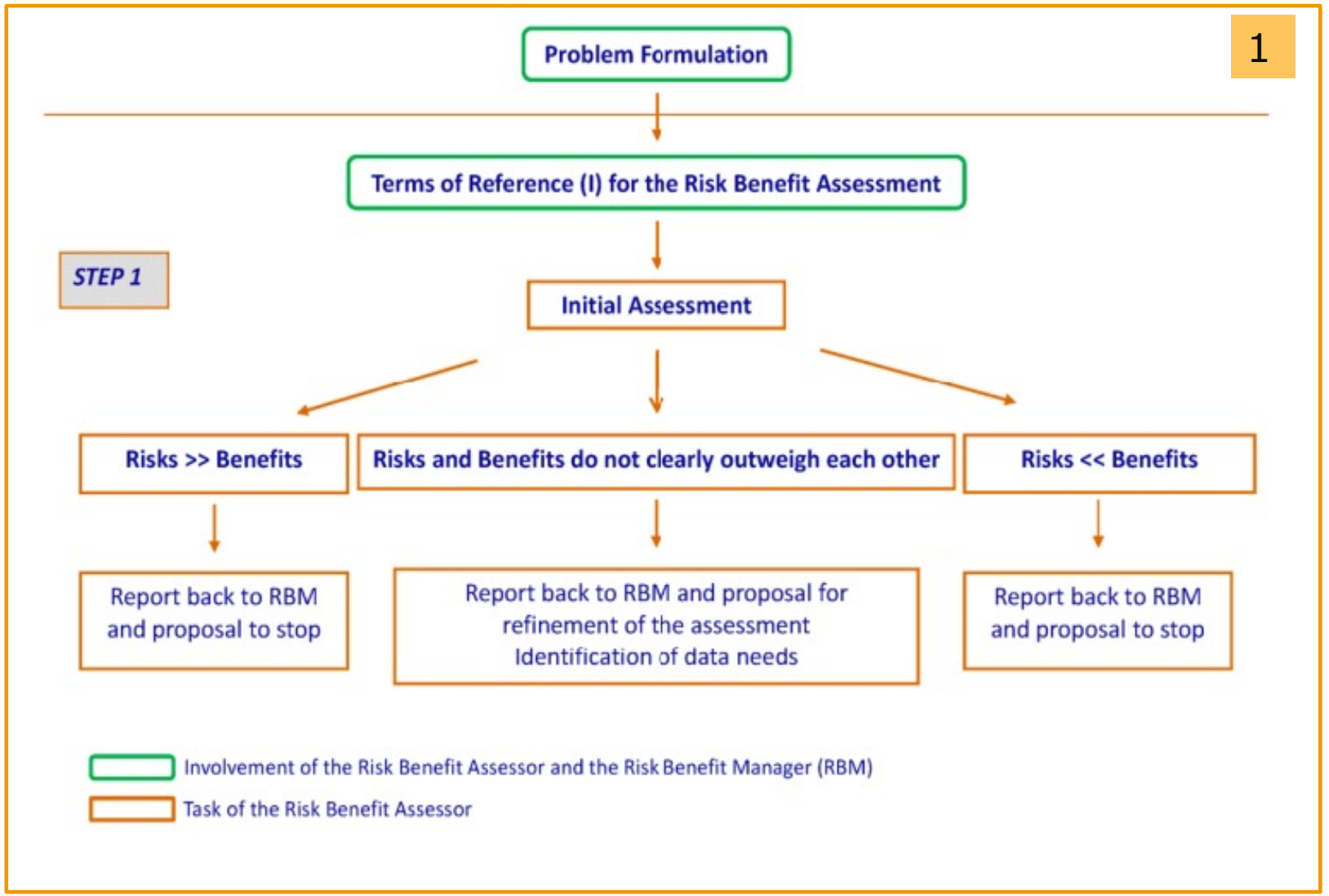


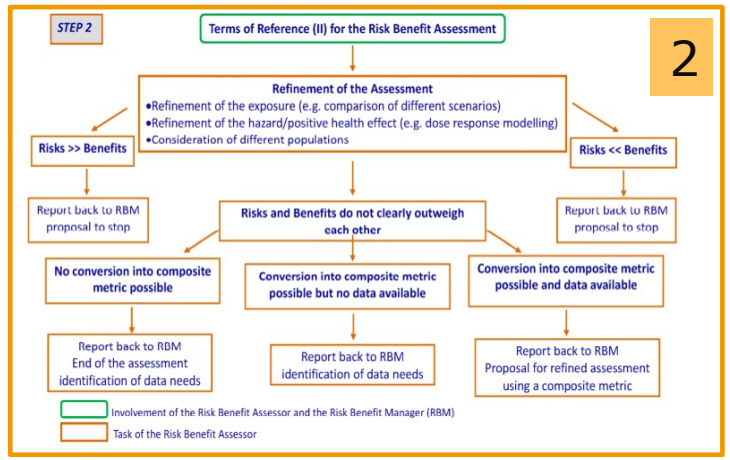


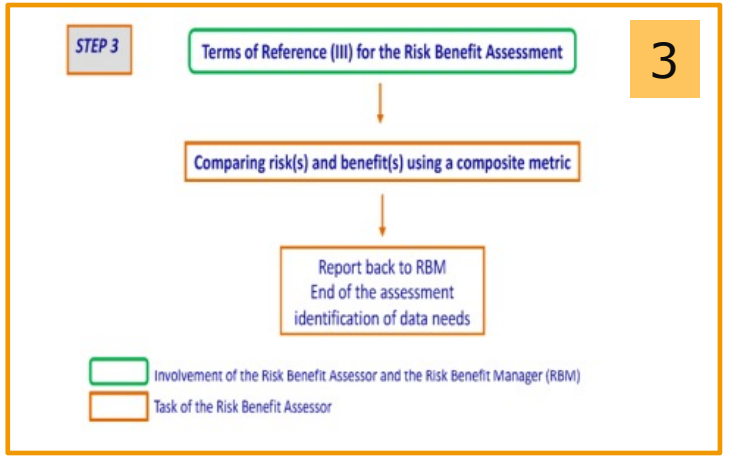


https://doi.org/10.2903/j.efsa.2010.1673

RBA GUIDANCE OF SC (2010)







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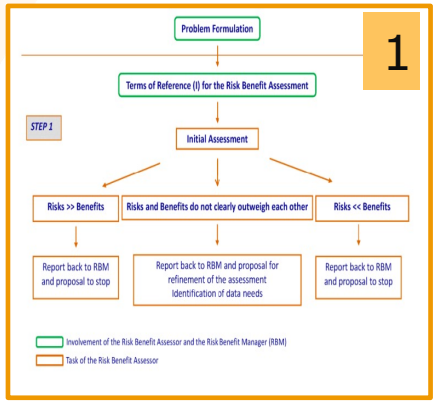

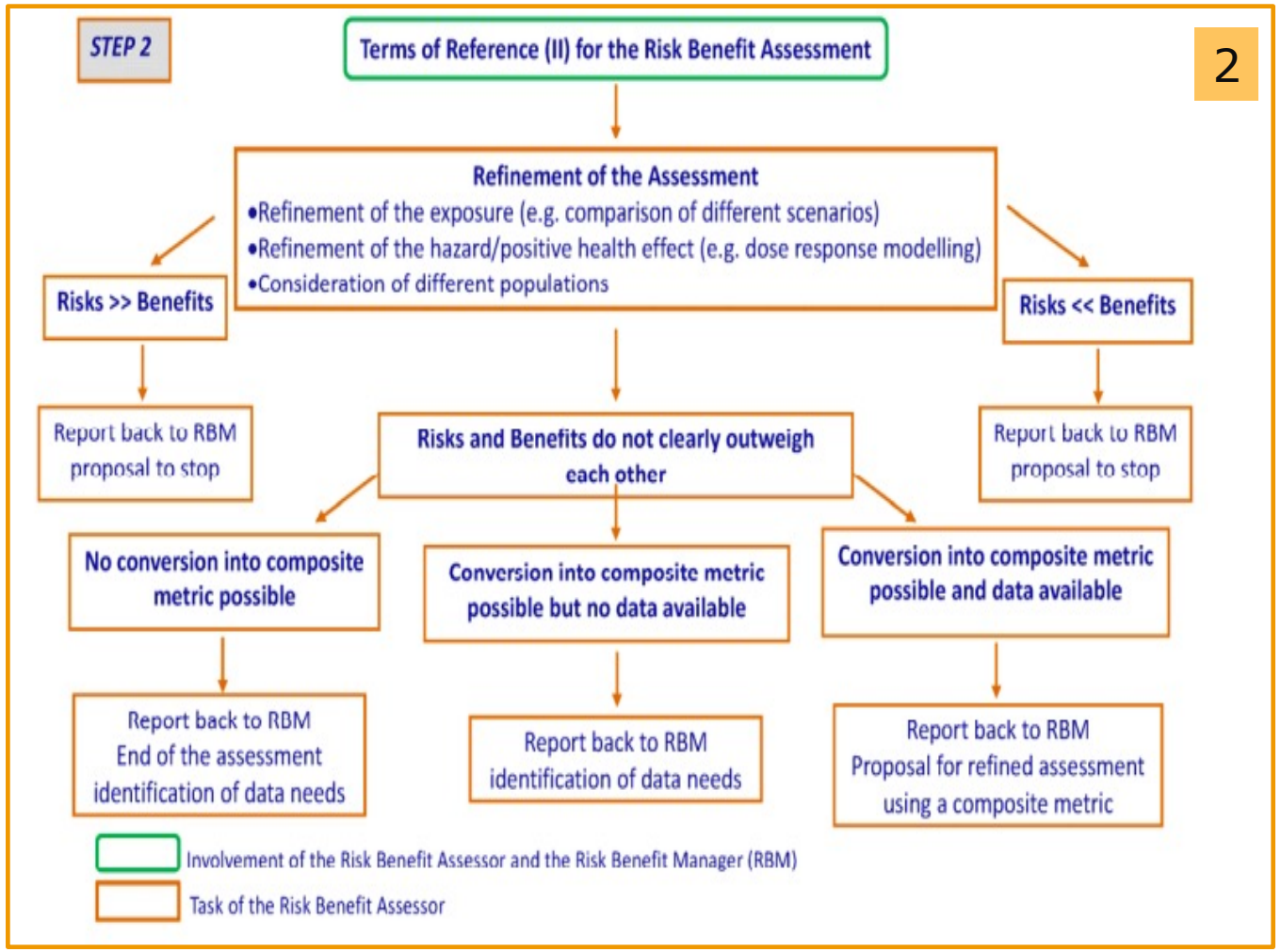

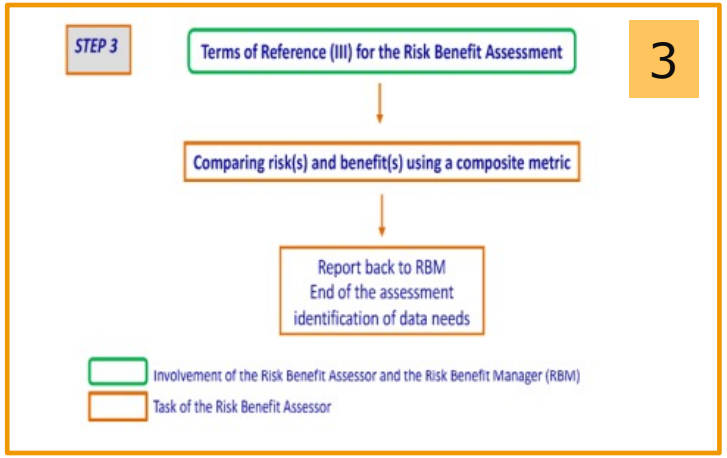

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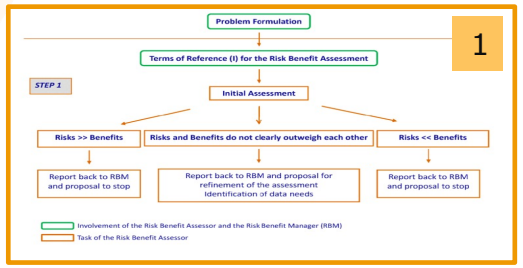

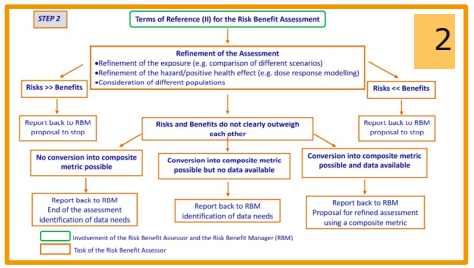

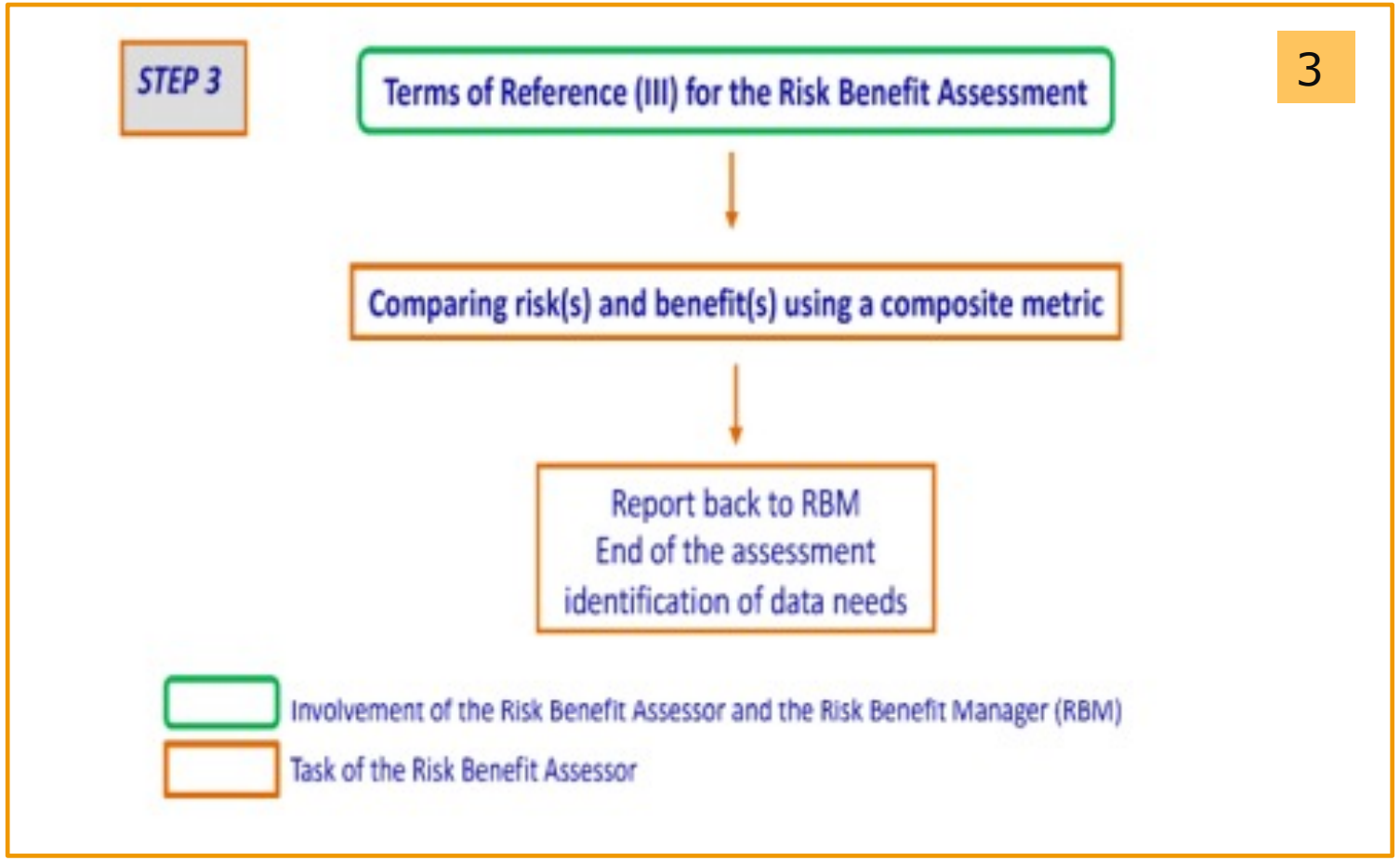

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Update of RBA Guidance is needed

- Possible outcome of applying EFSA's 2010 guidance*
  - When would fish consumption exceed HBGV for substance X
  - How much fish should be consumed to meet DRV for nutrient Y
  - Comparing risks and benefits using a composite metric (e.g. DALYs)

- Application of the 2010 Guidance will not provide:
  - Comprehensive assessment putting risks and benefits in **overall context**
  - Assessments translating fish consumption into **overall health outcomes**
  - **Characterising risks and benefits** by fish species, by types of fish (e.g. wild vs farmed), by population subgroup (for targeted dietary advice and consumption warnings)

*EFSA Scientific Committee statement on risks and benefits of fish consumption in relation to methylmercury (2015): how many servings of fish/seafood per week would population groups need to reach the TWI for methylmercury and the dietary reference value (DRV) for LCPUFAs. See: https://doi.org/10.2903/j.efsa.2015.3982

Proposed Work Plan

- To make use of recently released **opinions on contaminants**: dioxins, methylmercury, PFAS, brominated flame retardants, …
- To make use of existing opinions and ongoing EFSA work on **Dietary Reference Values** including **upper tolerable levels of vitamins and minerals**, main focus on LCPUFAs
- To consider the outcome of **recent EU and (inter)national projects** with a focus on risk-benefit assessment of consumption of fish
- To update **dietary exposure assessments** for EU Member States, where needed (e.g. dioxins using new WHO-TEFs of 2022)
- To **update the 2010 guidance** for RBA of foods of the EFSA Scientific Committee (also for future RBA requests)

PROPOSED PLANNING

Work packages	2021	2022	2023	2024	2025
WP1 Updated toxicological database for revision of TEFs for PCDD/Fs and DL-PCBs	**Contract** for updating TEF database (Aug)	**External Report** to WHO (April) **WHO Meeting** to revise TEFs (tbc)			
WP2 Updated dietary EA for PCDD/Fs and DL-PCBs using revised set of TEFs of WHO		**Technical Report** with updated dietary EA for dioxins using revised TEFs of WHO (Dec)			
WP3 Updating SC Guidance of 2010 for risk benefit assessment (RBA) of foods	Creation of **SC WG** for updating 2010 RBA Guidance of the SC (Nov)	**Scientific Colloquium** on possible RBA approaches (Feb)	**Draft guidance** for Public Consultation (April) Publication of **updated SC Guidance** (Aug)		
WP4 RBA of fish consumption in relation to presence of PCDD/Fs and DL-PCBs			Creation of a **SC WG** for RBA of Dioxins in Fish (Feb) **Draft Protocol** for public consultation (July)		**Draft opinion** for Public Consultation (July) Publication of **Scientific Opinion** (Dec)

Cooperation and Consultation are key

- **EFSA Scientific Committee**, Contaminants and Nutrition Panel, various EFSA units
- **Risk assessment agencies** at national, European and International level: EFSA Advisory Forum, IFCSLG and ILMERAC (incl. FAO, WHO & OECD)
- **Risk managers** in the European Commission and Member States – regular consultation of SANTE's working group on POPs
- **Scientific community, institutions and stakeholders** through events (e.g. Scientific Colloquium, Stakeholder Platform) and public consultations

Muchas gracias por su atención

Muito obrigado pela vossa atenção

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