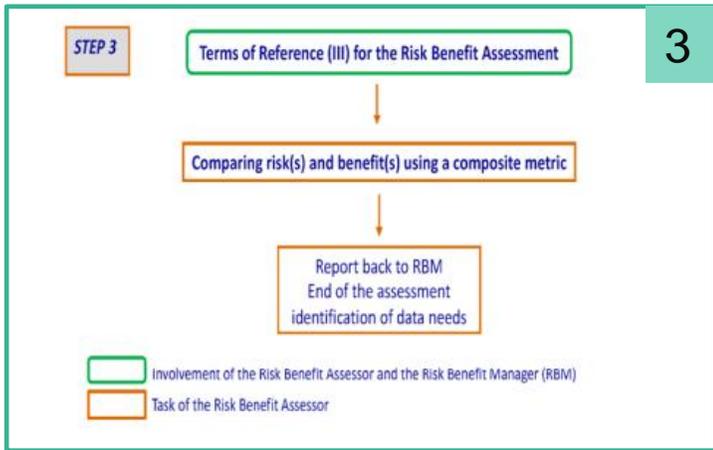
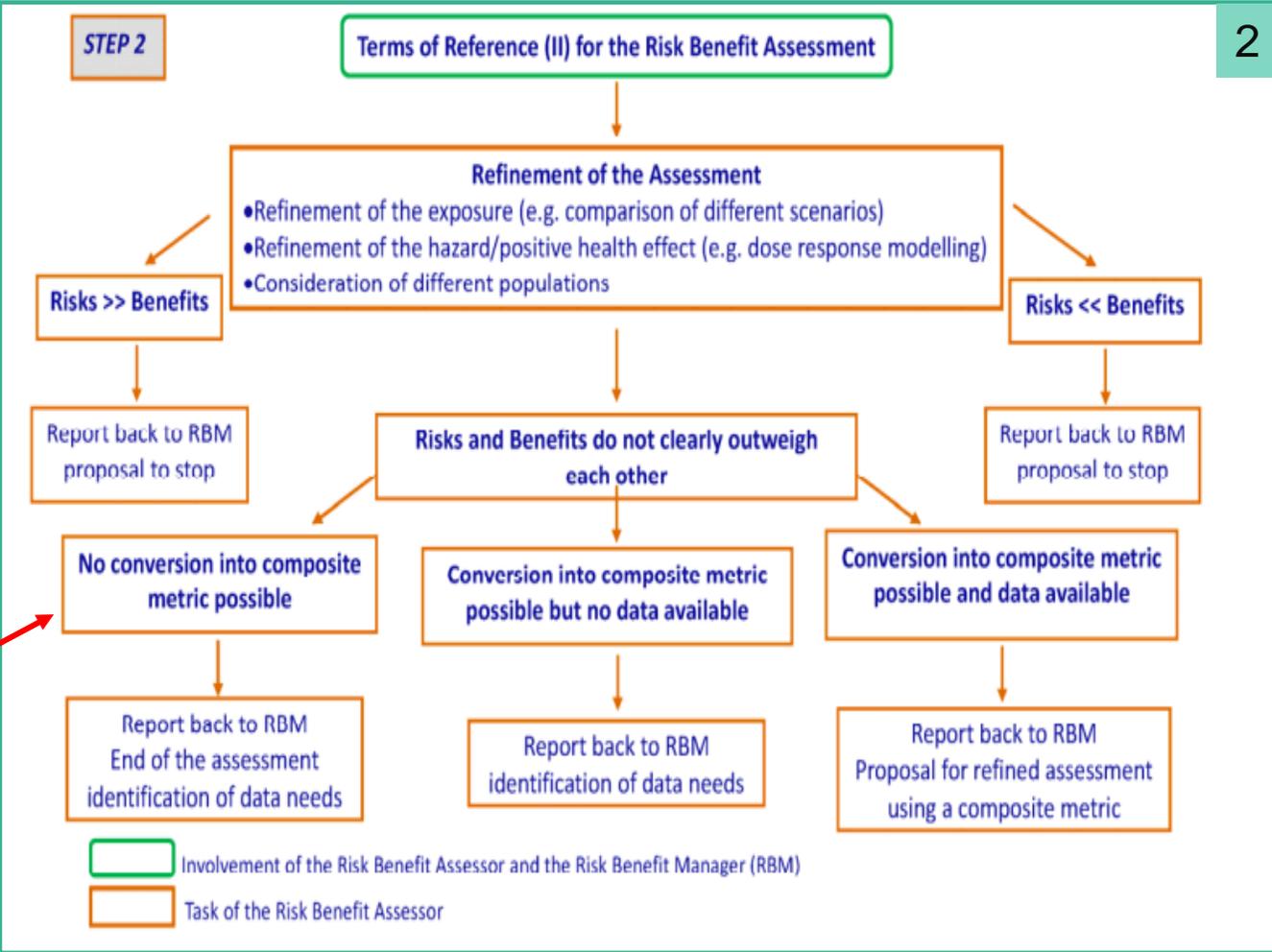
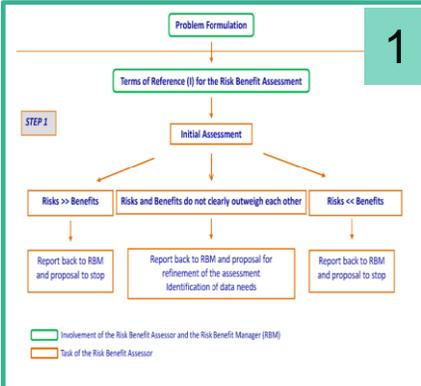


89th AF, 5th October 2023

EFSA RISK BENEFIT ASSESSMENT GUIDANCE UPDATE

Maria Bastaki
Methodology and Scientific Support Unit

EFSA 2010 RISK BENEFIT ASSESSMENT (RBA) GUIDANCE



FOUR LINES OF INPUT TO GUIDANCE UPDATE



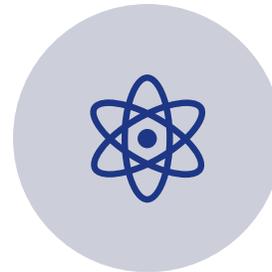
Feedback from EU
Member States (2021)



Limitations in RBA
identified in the 2010
Guidance



Developments in the
field since 2010



Output of the 26th
EFSA Scientific
Colloquium (2022)



SCOPE AND PURPOSE OF THE UPDATED GUIDANCE

"...lack of harmonization is still considered as one of the main challenges for RBA." Thomsen et al. 2021

Focus on chemical constituents

Acknowledge microbial and environmental; to be adapted in these areas

Multiple contaminants; dietary advice; exploration of healthy diet; scoping before new food/method/process; food replacement; intervention



TARGETS & KEY ELEMENTS OF THE RBA GUIDANCE



Consistency in
methodological
approach



Adaptation
to level of
complexity



Flexibility



Transparency

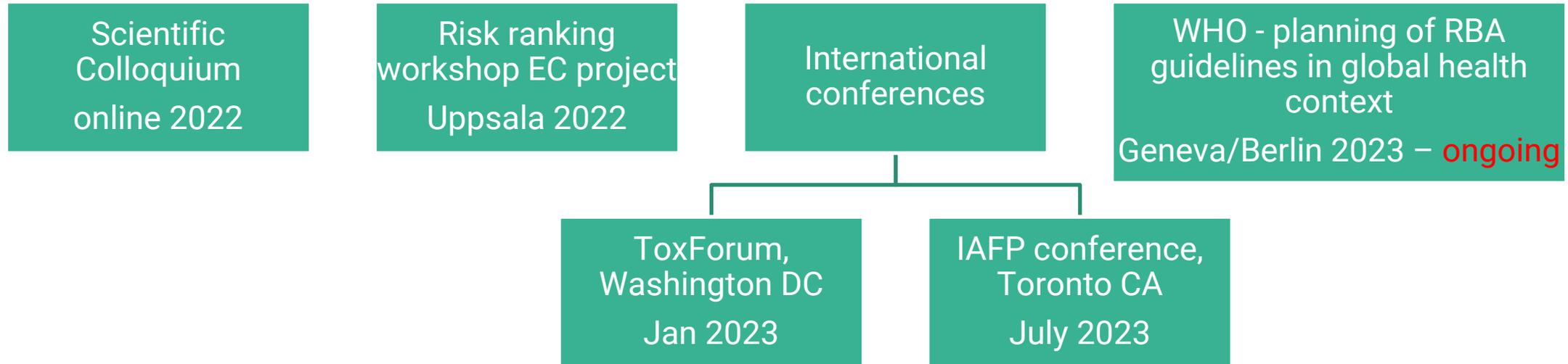


Harmonisation

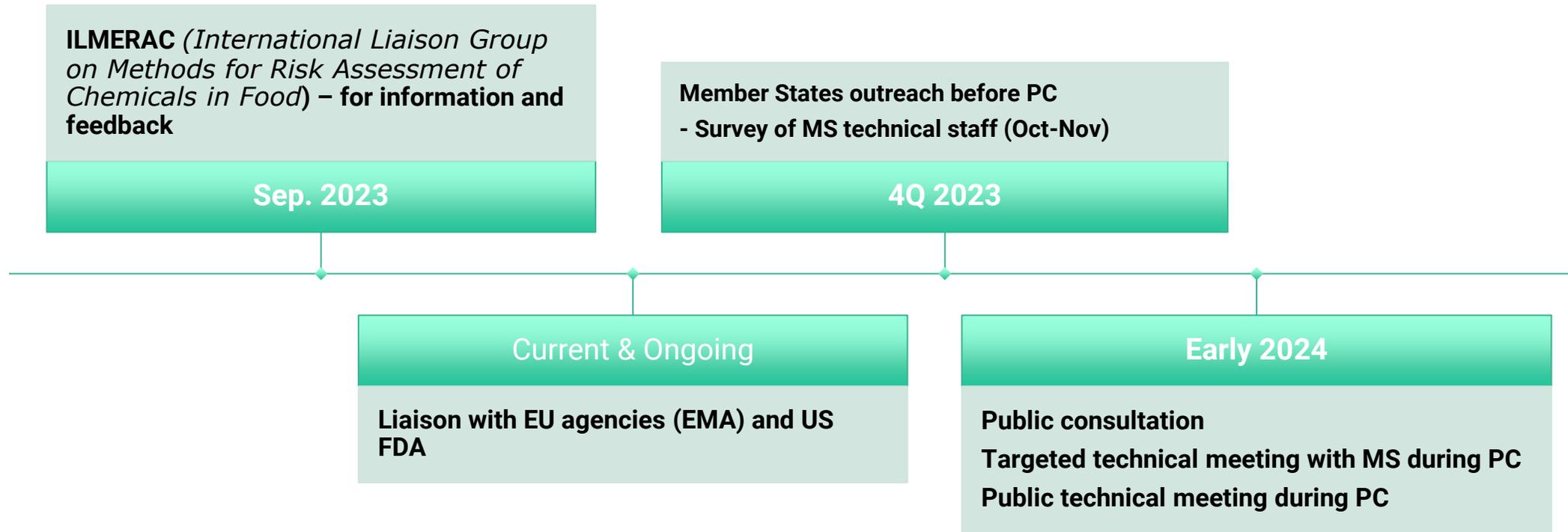
- **Methodological solutions to handle multiple risks and benefits beyond a single composite metric**
- **Justification and documentation of prioritisation of health endpoints and food constituents**
- Different selections, criteria, assumptions can lead to different RBA outcome
- Comprehensive vs. Feasible assessments
- Limited data reduce feasibility of comprehensive RBA and increase uncertainty in conclusion



INTERNATIONAL ENGAGEMENT



INTERNATIONAL ENGAGEMENT



#OpenEFSA

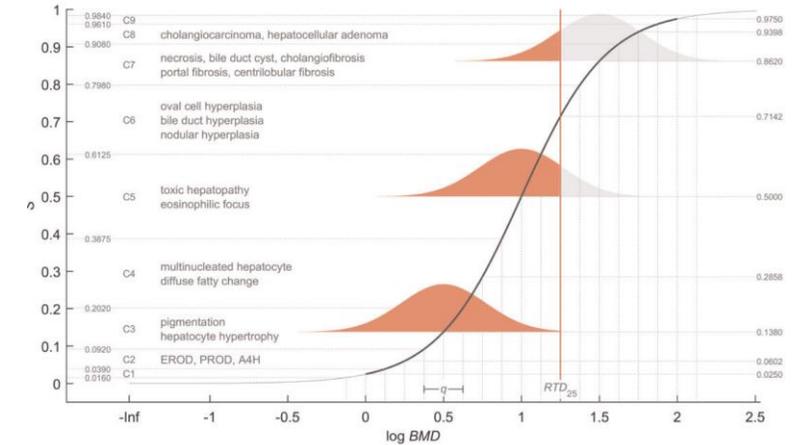


THANK YOU



UPDATE IN PRACTICE

- Elements retained from previous guidance
- Address needs previously identified
- Adapt to level of complexity:
 - multiple constituents
 - multiple health effects
 - different subpopulations
- Transparency of reasoning, assumptions and uncertainties



One metric does not fit all

ENDPOINT	Population	
	10 y old	50 y old
Fertility	RISK	
Cardiovascular		BENEFIT



REVISIONS AND ADDITIONS

Retained:

- Overall RBA framework
 - Tiered approach
-

To be done:

- Map stages of the RBA process with respective appropriate methods
- Refine templates
- Add examples or case studies (?)

Added:

- Approaches for selection and prioritisation of components and health effects
- Approaches for assessing multiple health effects
- Proposals for integrating risks and benefits while reflecting complexity
- Templates for reporting results
- Communication advice

Revised:

- Problem formulation considerations
- Account for severity but caution about weights based on value judgments
- Emphasis on transparency
- Distinction of variability and uncertainty