

98th AF, 3-4 December 2025

EFSA RISK BENEFIT ASSESSMENT GUIDANCE



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RISK BENEFIT ASSESSMENT (RBA) GUIDANCE FOLLOW UP



EC mandate to EFSA for RBA of fish - in dialog process



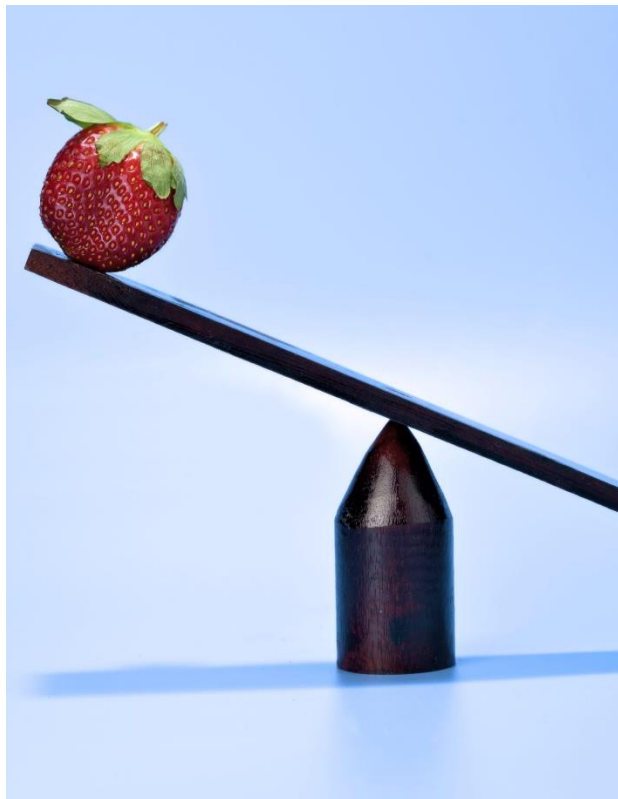
Trainings



Implementation of guidance



EC MANDATE FOR RISK-BENEFIT ASSESSMENT OF FISH



TERMS OF REFERENCE

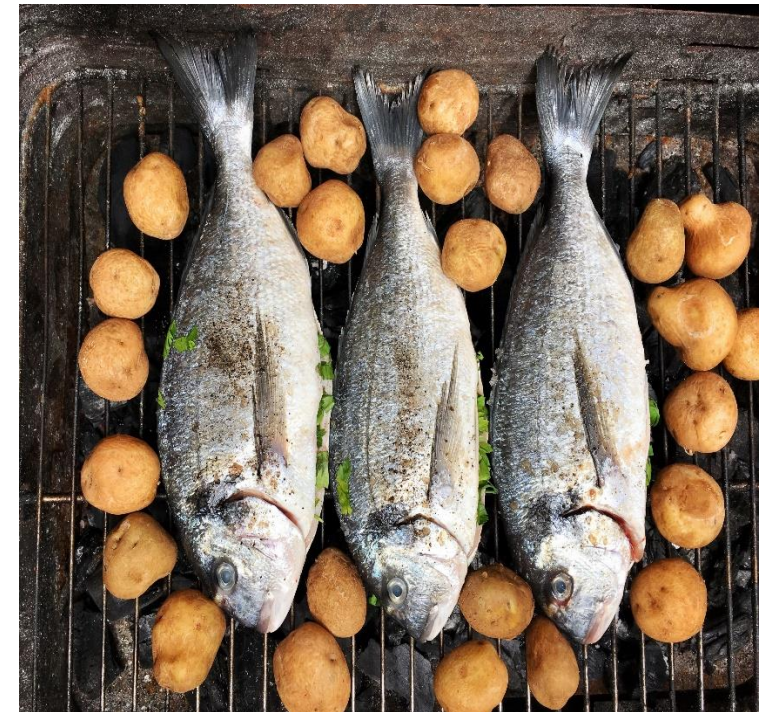
- 'In accordance with Art. 29 (1) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a risk-benefit assessment of **finfish consumption** by fish species and type (for example but not limited to fatty/lean, predatory/non-predatory, wild-caught/farmed) in relation to the **combined presence** of dioxins (PCDD/Fs) and dioxin-like PCBs, perfluoroalkyl substances (PFAS), polybrominated diphenyl ethers (PBDEs), inorganic arsenic, dimethylarsinic acid(DMA), inorganic mercury and methylmercury in fish.'



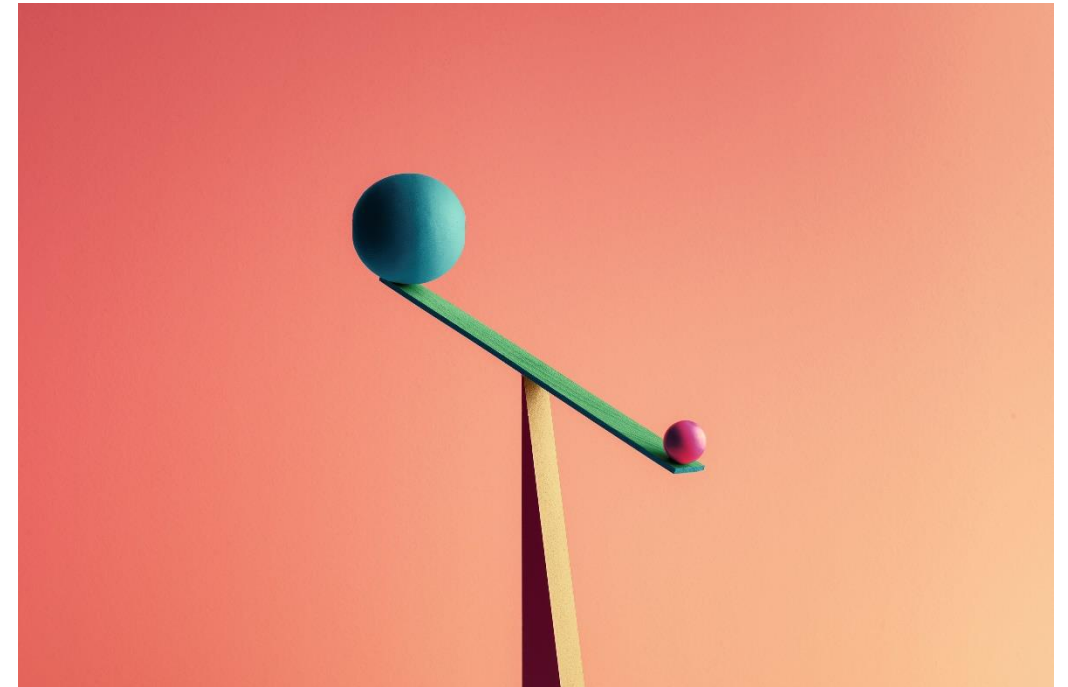
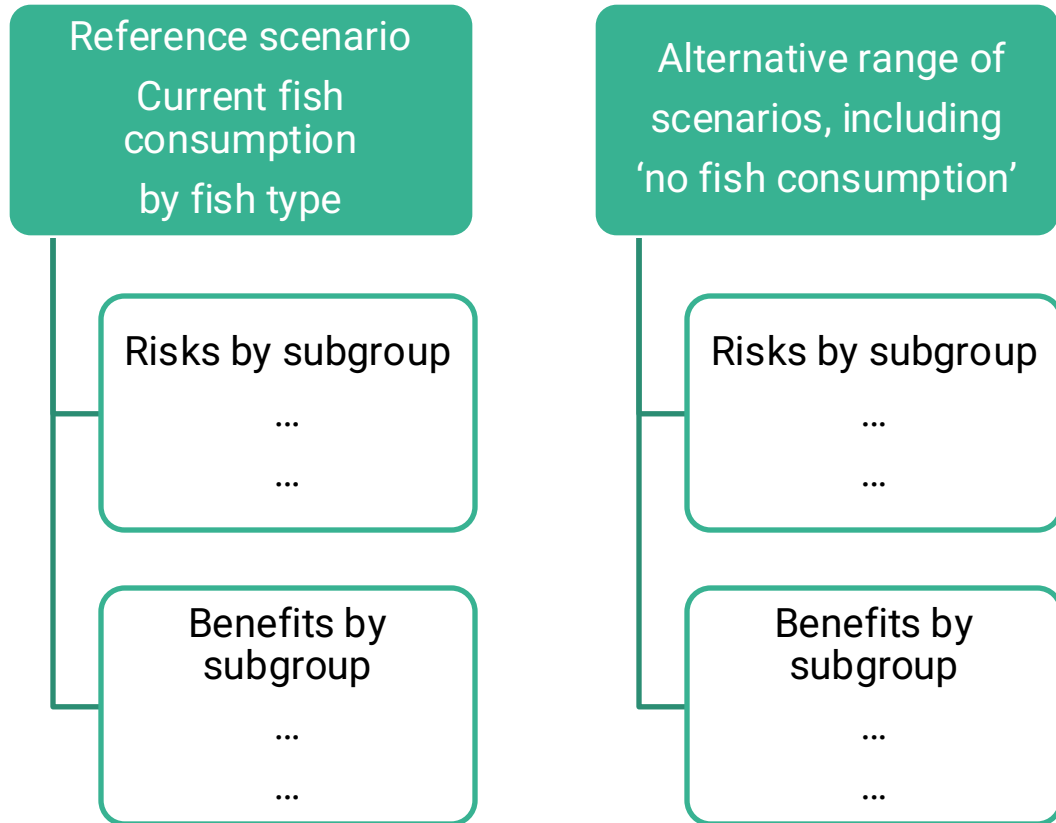
PURPOSE OF REQUEST

To produce a risk-benefit assessment that can be used by other competent authorities as input when developing Food-Based Dietary Guidelines.

Aim to give advice on recommended amount of fish consumption depending on level of contamination.



RBA DESIGN – REFERENCE SCENARIO VS ALTERNATIVES



ITERATIVE PROCESS OF PROBLEM FORMULATION, TOR, RBA

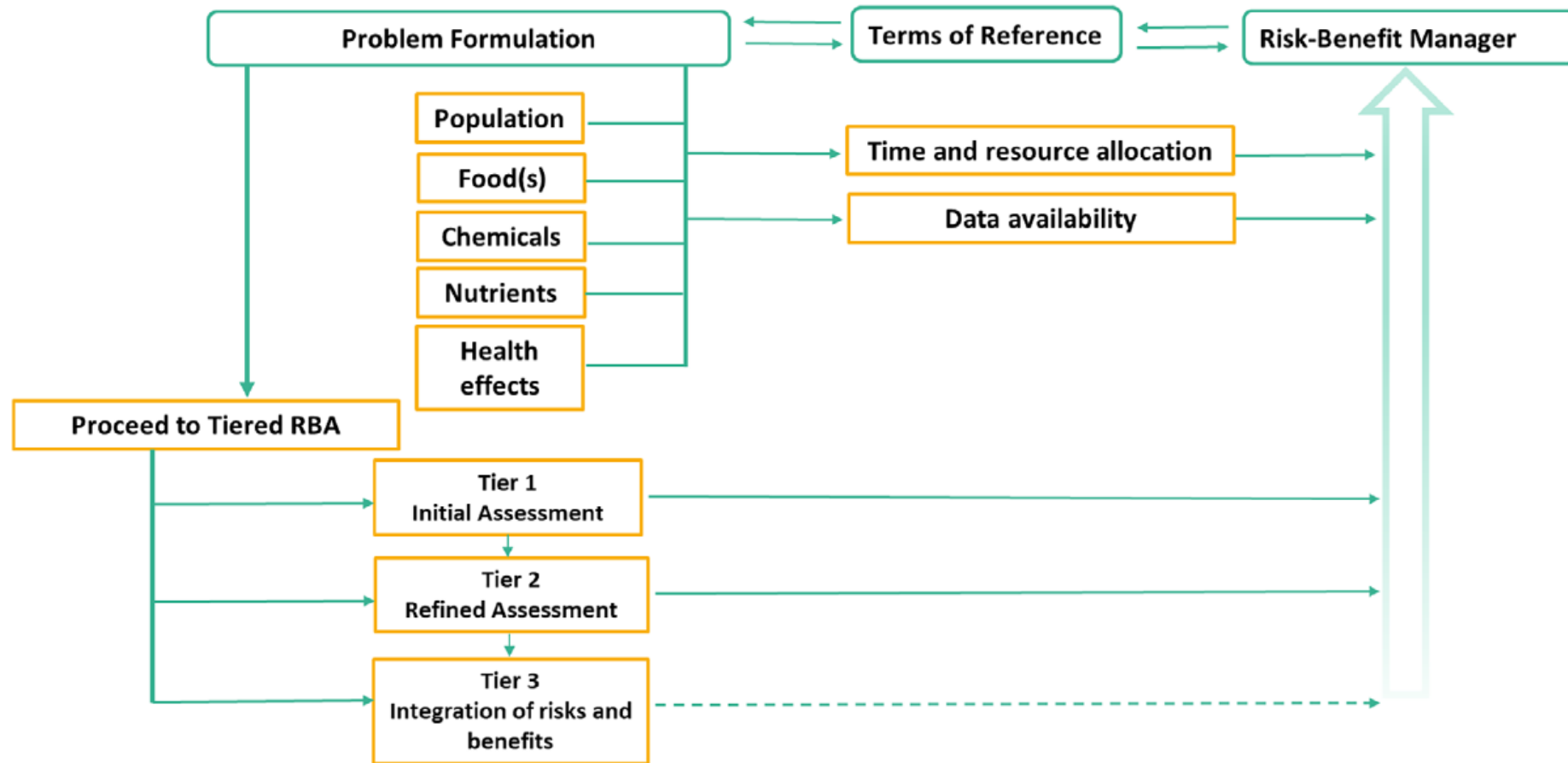
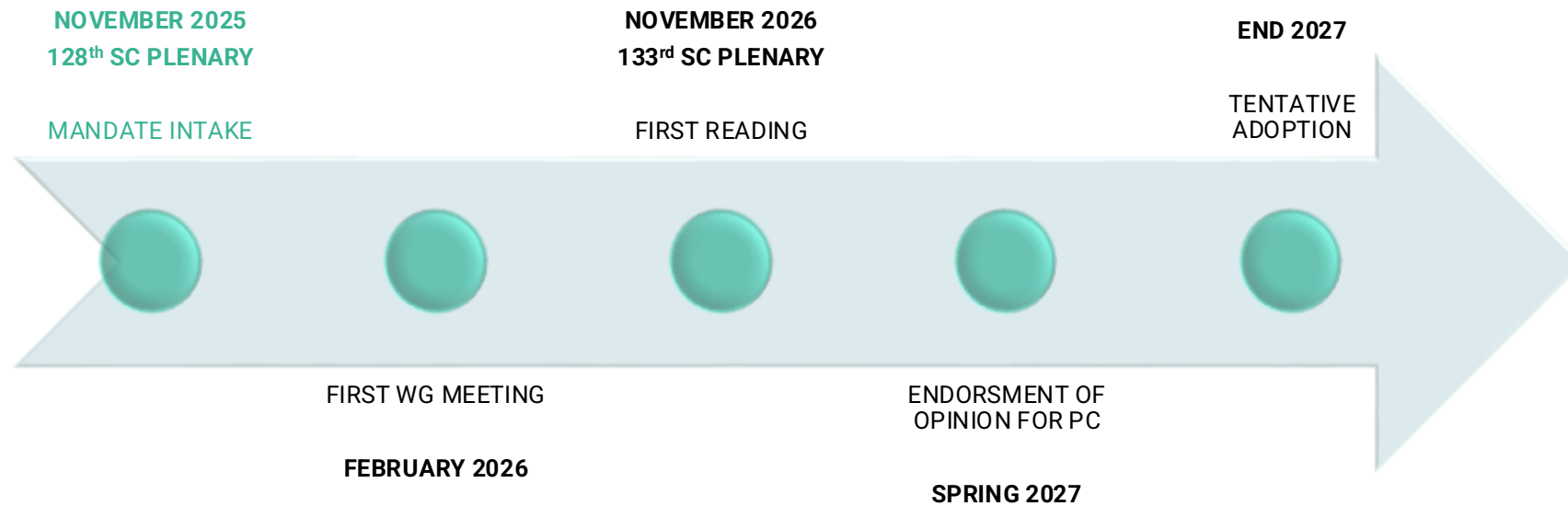


FIGURE 1 Iterative process of problem formulation in consultation with the risk-benefit manager in preparation for conducting an RBA.



ANTICIPATED TIMELINE



TRAININGS

- Introductory RBA training in place offered via the EFSA Academy
- More advanced training with experts of all RBA methodologies can be developed following the first implementation of the guidance in the RBA of fish.



IMPLEMENTATION OF THE RBA GUIDANCE

- MS are invited to implement the guidance in house on topics of interest and return feedback on the experience



RESULTS OF MS SURVEY - 14 MS RESPONDED (NOVEMBER 2023)



6 MS conduct RBA in-house: **source of expertise for EFSA**

Denmark, France, Germany have their own methods or guidance

Latvia, Norway, Sweden consult EFSA guidance



8 MS interested in co-developing case studies: **source of expertise for EFSA**

Cyprus, Denmark, Estonia, France, Germany, Greece, Norway, Poland



10 MS do not conduct RBA in house and/or are interested in EFSA training on the updated guidance: **audience for capacity building**



ACTIVITIES AND FEEDBACK

- 8 MS are engaged in national or international collaborative activities
(Cyprus, Denmark, France, Germany, Greece, Latvia, Norway, Sweden)
- 5 MS suggested the following aspects be included to the updated guidance to better help them with conducting a Risk Benefit Assessment:
 - ✓ harmonized methods (DTU, ANSES, KUA, SFA)
 - ✓ inclusion of alternative metrics to DALYs
 - ✓ quality assessment of publications; weight of evidence
 - ✓ guidance about outcomes – marker vs hard endpoints
 - ✓ “measurable” outputs for better interpretation
 - ✓ examples; case studies
 - ✓ “visual” outputs, such as charts & graphs, in addition to numerical/tabular and decision-trees
 - ✓ short and visual guidance; easily understood and applicable



ongoing work for new guidance on
biomarkers of effect
M-2025-00074





THANK YOU

#OpenEFSA



RELATED ASSESSMENTS



EFSA assessments

- 2005 CONTAM wild-farmed fish
- 2012 RA Methylmercury (MeHg)
- 2014 Benefits seafood + RA MeHg
- 2015 RBA MeHg-fish
- **2020 RA PFAS's**
- **2024 RA Inorganic As**
- **2024 RA Small organic As**
- **2024 RA PBDEs**
- **2026 RA UPDATE PCDD/Fs + DL-PCBs**

External assessments

- 2022 VKM RA PCDD/Fs and DL-PCBs
- 2022 VKM RBA of fish
- 2024 FAO/WHO RBA of fish
- 2024 ATSDR Mercury Tox Profile
- 2024 ATSDR DRAFT PCDD/F Tox Profile



PUBLIC CONSULTATION



**TARGETED MEETING ONLY WITH
MS AT THE BEGINNING OF THE
PUBLIC CONSULTATION: 3**



**NO NEED FOR TARGETED
MEETING WITH MS (WRITTEN
COMMENTS SUFFICIENT): 6**



**ONLY ONE PUBLIC
MEETING WITH ALL
STAKEHOLDERS: 8**



RBA CAPACITY AMONG MS AND USE OF EFSA GUIDANCE

		CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FRANCE	GERMANY	GREECE	LATVIA	MALTA	NORWAY	POLAND	ROMANIA	SPAIN	SWEDEN
PART I – CONDUCTING RISK BENEFIT ASSESSMENTS															
1	Do you or your office conduct Risk Benefit Assessments of foods?	NO	NO	YES	NO (REM, TAI) NO	YES	YES	NO	YES	NO	YES	NO	NO	NO	YES
2	If yes, do you have expertise in-house for this purpose?	N/A	N/A	YES	N/A	YES	YES	N/A	YES	N/A	YES	N/A	N/A	N/A	YES
3	If yes, do you consult the EFSA Guidance for this purpose?	N/A	N/A	NO	YES, if we would	NO	NO	N/A	YES	N/A	YES	N/A	N/A	N/A	YES
3a	If no in Q3, which Guidance do you consult for conducting Risk Benefit Assessments?	N/A	N/A	While the risk-benefit framework	Each Risk Benefit Assessment	The BfR guidance	N/A	N/A	N/A	N/A	Also consulting Hoekstra 2012	N/A	N/A	N/A	
3b	If yes in Q3, what do you find challenging in applying the EFSA Guidance?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Use of guidance	N/A	Hoekstra, 2012 is N/G	N/A	N/A	N/A	
4	What national or international activities/initiatives on Risk Benefit Assessments are you involved in?	Participation in the EFSA Risk Benefit Assessment	NONE	National: development of a risk-benefit framework	No involvement in EFSA activities	We are currently developing a risk-benefit framework	A workshop on RBA was held in 2018	The Dept. of Hygiene and Food Safety	We were involved in the EFSA Risk Benefit Assessment	NO ANSWER	International Risk Benefit Assessment	N/A	Our institution is not involved in EFSA activities	We are not aware of any EFSA activities	A representative of the EFSA
5	What additional aspects do you think should be included in an updated EFSA Guidance?	The updated EFSA Guidance	N/A	Case studies	Not enough expertise	Short and visual	N/A	NO ANSWER	There are no comments	NO ANSWER	Quality assessment	N/A	Not applicable	NO ANSWER	The inclusion of a representative of the EFSA
PART II – CONSULTING AND APPLYING PUBLISHED RISK BENEFIT ASSESSMENTS IN DECISION MAKING															
6	Do you or your office use Risk Benefit Assessments published by EFSA?	NO	YES	NO	YES	NO	YES	NO	NO		NO	NO	NO	YES	YES
7	If yes, what do you find challenging in (or missing from) the output of the EFSA Guidance?	N/A	NO ANSWER	N/A	NO ANSWER	N/A	N/A (from response)	N/A	N/A			N/A	N/A	We found difficulties	The opinions are not clear
8	What type of output (e.g. numerical, tabular, visual, etc) would you prefer for the EFSA Guidance?	1. Visual 2. Tabular 3. A simplified graphic	NO ANSWER	Visual additional	Visuals would be helpful	Visuals would be helpful	Not applicable for visual output	Charts (example shown in survey); Raw data/tables	N/A		N/A		It would be helpful	The use of decision support tools	It would be helpful
PART III. CONSULTATION AND FOLLOW UP PHASES															
9	Do you have any preference for the public consultation:						Since the remit of the BfR lies within the area of risk assessment, not management, this question does not fully apply. (It appears plausible, however, that								
	Targeted meeting only with MS at the beginning of the Public Consultation	YES	NO	YES		YES			NO			NO	NO		NO
	No need for targeted meeting with MS (written comments sufficient)	NO	YES	NO					YES			NO	YES	YES	YES
	Only one public meeting with all stakeholders:	YES	YES	NO	YES			YES	YES			YES	NO		YES
	Other proposals? (e.g., physical or virtual?)	Physical						hybrid meeting							
10	Would you be interested in engaging with EFSA in developing case studies?	YES	NO	YES	YES (TAI); NO (REM)	YES	The BfR has indicated	YES	YES/MAYBE		YES	YES	NO	NO	NO
11	Would you be interested in receiving training on using the updated EFSA Guidance?	YES	NO	NO	YES (REM, LABRI)	YES	YES	YES	YES		YES	YES	YES	NO	YES
12	Any other comments/suggestions		RBA is not applied in the Czech Republic.											We have answered “no” because	

