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Workshop on Health Risk-Benefit Assessments: from science to decision-making

Deliverable 3.2

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Deliverable D3.2

D3.2

Approach to include risk-benefit assessment in regulatory decision-making

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0.1	10/07/23	Constanza De Matteu Monteiro, Sara Monteiro Pires, Sofie Theresa Thomsen, Morten Poulsen	Jeanne-Marie Membré	Editorials and amendments in section 4 and 5.
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Index of contents

Index of tables

Index of figures

1 Executive summary

The overall objective of HOLiFOOD is to improve the integrated food safety risk analysis framework in Europe to i) meet future challenges arising from Green Deal policy driven transitions in particular in relation to climate driven changes, ii) contribute to the UN's Sustainable Development Goals, and iii) support the realization of a truly secure and sustainable food production. HOLiFOOD applies a system approach, which takes into account the whole environment in which food is being produced, including economic, environmental, and social aspects.

Work Package 3 (WP3) of the HOLiFOOD Project, entitled "Holistic risk assessment for regulation", will develop methods and tools for a multi-domain framework that supports regulatory tasks in a changing global environment.

Risk-Benefit Assessment (RBA) of foods is an integrated assessment framework that estimates the public health impact of foods or diets by evaluating both beneficial and adverse health effects in different consumption scenarios. Due to the multidisciplinary nature of the RBA methods, the output of RBAs provides comparative information that can support the formulation of coherent food policies. Like the CODEX food safety risk analysis paradigm, RBA is based on close collaboration and interaction with risk-benefit management and communication.

As part of WP3 (Task 3.2), DTU hosted a virtual workshop with regulatory authorities with the overall aim to identify challenges and obstacles for using evidence generated through risk-benefit assessment of foods in decision-making. This report summarizes the main findings of the workshop and proposes approaches to include risk-benefit assessment in regulatory decision-making. Moreover, outputs of this deliverable (D3.2) will be used to guide following actions of the WP3 of the HOLiFOOD project.

The workshop was held on the 2nd of May 2023, and counted with the participation of representatives from national and international authorities with regulatory mandates within food safety and public health, and other stakeholders. The workshop included an opening keynote presentation, guided discussion sessions in working groups and plenary, and pre-workshop and during workshop surveys and quizzes. Thirty-seven participants from 19 different institutions across 13 European countries joined the workshop. The professional profile of participants varied, with a relatively good balance between risk assessors, risk managers and (some) risk communicators, and expertise in toxicology, microbiology, nutrition, or several. While participants had diverse views and identified a range of needs, collected input regarding opportunities and challenges for the increase in applications of RBAs to inform policymaking towards healthy and sustainable diets, was in general agreement. This suggests common directions for developments of RBAs, including in communication and knowledge translation.

2 Introduction

HOLiFOOD

The overall objective of HOLiFOOD is to improve the integrated food safety risk analysis (RA) framework in Europe to i) meet future challenges arising from Green Deal policy driven transitions in particular in relation to climate driven changes, ii) contribute to the UN's Sustainable Development Goals and iii) support the realization of a truly secure and sustainable food production. HOLiFOOD applies a systems' approach, which takes the whole environment into account in which food is being produced, including economic, environmental, and social aspects. Three supply chains are considered (i.e., cereals (maize), legumes (lentils) and poultry (chicken)). Artificial Intelligence (AI) and big data technologies will be used in the development of early warning and emerging risks prediction systems for known and unknown food safety hazards. In addition, tools, methods, and approaches will be developed for hazard detection – both targeted and non-targeted - and new holistic risk assessment methods will be developed in which food safety risk will be embedded in a comprehensive cost-benefit analysis of the food system including positive and negative health, environment, and economic dimensions. An effective impact pathway will be developed and implemented through integration of the HOLiFOOD outputs into the legal framework associated with the food risk analysis process. The impact pathway will be supported by an electronic data and knowledge sharing platform aiming at the full digitalization of food (safety) systems and supporting transparency and impact for all stakeholders. In order to align with stakeholder priorities, preferences and user requirements, the HOLiFOOD innovations will be designed and tested in a multi-actor approach (i.e., Living Lab) involving all stakeholders (e.g., authorities, food producers and citizens).

Introduction to this document

As part of WP3 of the HOLIFOOD Project (T3.2), DTU hosted an online workshop with regulatory authorities in May 2023. The overall aim of the workshop was to identify challenges and obstacles for using evidence generated through risk-benefit assessment of foods in decision-making. This report summarizes the main findings of the workshop and propose approaches to include risk-benefit assessment in regulatory decision-making. The outputs of this deliverable (D3.2) will be used to inform the next actions and tasks of the WP3 of the HOLIFOOD project.

3 Methodology

3.1 Aims of the workshop

Risk-Benefit Assessment (RBA) of foods is an integrated assessment framework that estimates the public health impact of foods or diets by evaluating both beneficial and adverse health effects in different consumption scenarios. Due to the multidisciplinary nature of the RBA methods, the output of RBAs provides comparative information that can support the formulation of coherent food policies. Like the classical risk analysis paradigm, RBA is based on close collaboration and interaction with risk-benefit management and communication.

The overall aim of the Risk-Benefit Assessment Stakeholder Workshop (T3.2) was to identify challenges and obstacles for using evidence generated through RBAs of foods in decision-making. To achieve this, the workshop was aimed at creating a space for dialogue and exchange of views among risk assessors, managers, and communicators. Specific objectives included:

- **Objective 1:** Investigate the type of evidence national and international regulatory authorities currently use to support regulatory tasks related to public health in food safety vs. nutrition.
- **Objective 2:** Identify challenges for using evidence generated through RBA in decision-making.
- **Objective 3:** Explore food regulators´ views regarding holistic assessments.

3.2 Selection of participants

A preliminary list of potential participants was created by the DTU team based on the network of DTU's Risk Benefit Research Group. The list was comprised of individuals within national and international authorities with regulatory mandates within food safety and public health. The list was complemented with additional contacts from other European countries that were missing representatives. These additional contacts were identified through a consultation with HOLiFOOD partners involved in WP3 and with selected members of the International Risk-Benefit Network (chaired by DTU). The target was to identify food regulators and other relevant actors either involved in risk management or with some experience in risk-benefit assessment. In total, 50 people were identified as potential candidates and were contacted to check their availability and interest in attending the workshop. Twenty-four contacts expressed interest in contributing to the workshop. Some contacts which could not be available on the proposed dates contributed by extending the invitation to other colleagues. Finally, in addition to the HOLiFOOD team, 26 participants from various backgrounds attended the meeting.

Participants were informed about how their personal data would be used and stored via written format (i.e., attached in the official invitation) and verbally before the workshop had started. The intended outputs of the workshop were also clarified. No objections were received. Participation was voluntary and attendees could leave the online meeting at any time during the workshop.

3.3 Workshop structure

The workshop was a virtual meeting held on the 2nd of May 2023 with a duration of 2 hours and 30 minutes.

To achieve the maximum number of participants, the date was defined according to the availability of most participants. The workshop was structured in three parts to address the objectives presented in section 3.1 (Table 1).

Table 1. Overall structure of the workshop

Topic	Time allocation
Welcome and introduction to the theme *(objective 1)*	25%
Discussion of main theme *(objective 2)*	60%
Wrap-up, exploration of remaining topics (*objective 3*), breaks between sessions	15%

Three different approaches to engaging with food regulators were implemented: pre-survey, discussions in plenary and breakout rooms, and interactive surveys during the workshop. Prior to the workshop, participants were invited to voluntarily contribute to an anonymous survey (Annex C). This survey aimed to tailor the workshop content by getting an overview of the participants' background and query about any potential expectations regarding the topics that should be discussed during the meeting. During the workshop, interactive surveys and group discussions were conducted. In the last session of the workshop, a plenary session discussed main points captured during the breakout rooms, identified transversal themes with related to challenges and opportunities to implementing RBA, and summarized the main outputs of the discussion.

The program of the workshop available in Annex A. The results of the survey are available in Annex D and E.

3.4 Workshop content

3.4.1 Opening presentation

A keynote speaker with a track-record of method development and implementation of case studies was invited to introduce RBA of foods. The talk presented the utility and applicability of RBA, an overview of the approach and available methods, current challenges with applying and using results of RBA, and perspectives for further developments in the area.

3.4.2 Themes proposed for discussion

To guide the discussion groups and address objective 2 of the workshop ("Identify challenges for using evidence generated through RBA in decision-making"), the organizers proposed three overall themes and sub-questions (see list below). These themes are related to one or more components of the risk-benefit analysis paradigm (Figure 1), as proposed by Nauta et al., 2018. Group moderators and rapporteurs were given templates to use in the discussions, which ensured consistency in the reporting of discussions. The moderators of each discussion group went

through the suggested topics, and the rapporteurs presented a summary of the group discussions in the plenary session that followed.

Overarching question: *Based on the information received at the workshop and your previous experiences, what are the challenges for using RBA results in policy making?*

- **Theme 1 (T1):** Challenges of using RBAs to inform policy making
  (*Sub-question: Could challenges be related to the structural organization of authorities?*)
- **Theme 2 (T2)**: Opportunities and needs of RBAs
  (*Sub-question: Are challenges related to the reliability of the RBAs methods?)*
- **Theme 3 (T3)**: Communication of RBAs
  (Sub-question: Are challenges related to how the results from RBAs are communicated?)

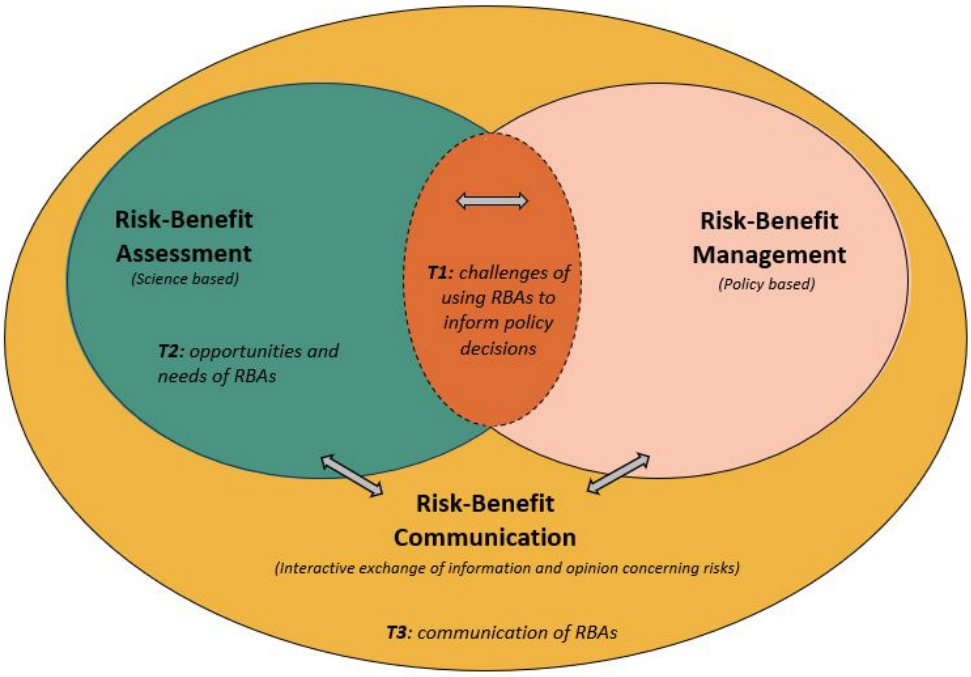


Figure 1. The risk-benefit analysis paradigm and overarching themes of discussion points of the HOLiFOOD stakeholder workshop. Adapted from FAO/WHO (2006) and Nauta et al., (2018).

4 Results

In total, 37 participants from 19 different institutions across 13 European countries joined the workshop (See Annex B). The professional profile of participants varied, with a relatively good balance between risk assessors, risk managers and (some) risk communicators, and expertise in toxicology, microbiology, nutrition, or several. In addition to national authorities' representatives, some participants represented international organizations: the European Food Safety Authority (EFSA), the World Health Organization (WHO), The Food and Agriculture Organization (FAO), and the European Commission (EC). Discussions were balanced and dynamic, with contributions from most participants in either plenary or breakout sessions.

Information collected through the surveys indicated that most of the participants had some prior knowledge of RBAs (self-stated as either "general knowledge" or "familiar with RBA methods") before attending the workshop (See Annex D and E). Although outputs from traditional risk assessment (e.g., focus on risks of a single domain) are still the most frequent type of evidence used by risk managers, there was a consensus on the great potential of RBA in generating evidence that can better inform policymaking.

The meeting allowed several participants with more experience in RBAs to share examples of relevant cases and describe lessons learned in their countries when communicating findings or using outputs from RBAs to support regulatory tasks. In addition to the example of the usefulness of RBAs to inform recommendations on fish consumption, other applications were discussed such as the risk-benefit case-study on nuts in the context of the Nordic countries. Nuts are one of the emerging food categories that may have increased relevance for the transition to sustainable diets, hence another pertinent example on the use of RBAs. RBAs were also recognized as a useful tool to generate tailored advice to vulnerable groups of the population, and as a more transparent approach for consumers to understand potential trade-offs among certain dietary choices.

These features contributed to the discussion about RBAs being the next step for improving the traditional risk analysis framework, as its multidisciplinary framework has the potential to accommodate a food system approach. There was a common consensus on the need for holistic approaches, as it is imperative that future risk assessments appropriately account for sustainability factors.

In general, groups held consistent views on the main challenges and opportunities for using RBA results to support policy decisions. In the next sections we present the main discussion points addressing objective 2 and 3 of the stakeholder workshop with a few sample quotes from the participants.

Main findings are presented in the next sections according to the themes previously introduced (see section 3.4.2). The actions listed were identified through the discussion of the themes and can be used to establish common directions. Furthermore, it will be useful to improve current processes for risk-benefit assessment and communication (see Figure 2). An overall mapping of the discussion points raised during the breakout rooms and plenary are presented in Annex F.

4.1 Challenges of using RBA to inform policy decisions

The discussion on the challenges of using RBA for policy decision was centered around two sub-themes: barriers related to the structural organization of authorities, and general challenges for moving toward holistic assessments. Most of the challenges identified in this theme are considered long-term.

"A fit assessment to be used in decision making should start by better formulating the decision-making problem. What is the problem and what are the alternatives?"

Barriers of structural organization of institutions

Participants recognized that, in countries across the EU, food safety and nutrition are separate disciplines, which is often reflected in the organizational structure of authorities. Consequently, this structural separation between nutrition and food safety departments and stakeholders reflects on the questions posed by policymakers to scientists, and in the request for evidence to

inform policies. This "dissociation" of problems causes, in practical terms, that the processes, priorities, and evidence used to inform decisions within each of those fields also result in separated actions. There was a general recognition that policies and requests for evidence formulated "in silos" may generate barriers to address problems in a multidisciplinary approach and integrate actions between food safety, nutrition, and possibly sustainability.

"Food safety and nutrition are separate domains not only in science but often structurally in institutions that need to be brought closer together. "

Furthermore, the challenge that some countries may not have all the data needed to carry out RBAs, nor the capacity to conduct such assessments was acknowledged. This also influences the adoption of RBA methods at international level.

Actions

- Break silos at risk management level. Promote opportunities for debates on improvements of risk analysis framework and processes for decision-making.
- Map country-specific data gaps and make it accessible; generate capacity for RBA.
- Facilitate processes for including both food safety and nutritional entities at the regulatory level in the interaction between risk-benefit assessor and risk manager and in the development of the problem formulation.

General challenges for moving toward holistic assessments:

The integration of other dimensions beyond health making RBA resemble a decision-making process, where separating the roles between risk assessors and managers is difficult, was also discussed. Furthermore, integrating other dimensions such as economic and environmental factors might make the assessment more complex and with more uncertainty, hence more difficult to communicate.

Actions

- For transparency reasons, it was suggested to run individual (i.e., single domain) assessments before integration into one metric/output. Policy makers should be able to identify the results of different domains in addition to an integrated output. This approach should also avoid potential loss of information.

4.2 Opportunities and needs of RBAs

Participants identified a variety of methodological, communication and awareness raising needs to enhance the use of RBA outputs for regulatory decisions. They have also acknowledged opportunities to address some of these needs.

"RBA is often presented as a complex, resource demanding and time-consuming modelling approach. The development of simpler RBA tools that can be applied efficiently will be useful."

Needs

- Simplified RBA approaches, which should be presented as a less complex, resource demanding and time-consuming modelling approach.
- Harmonized frameworks. Assessments considering different beneficial and adverse effects while responding to similar risk-benefit questions might generate different advice.

    - **Opportunities:** *Development of more RBA case-studies through tools research projects such as HOLiFOOD. Development of harmonized frameworks and methodologies for RBA that can be applied by national research institutions.*
- Transparency in communication of approaches, data used, model assumptions, and intermediate and final outputs of RBAs. Consumer´s trust might be impacted if advice from different assessments differ, and if transparent documentation and explanations are not provided.
- Objective and transparent framework on how the components to be included in the assessment are selected to ensure reproducibility.
- Harmonized processes to weigh the strength of available scientific evidence used to inform RBA (data) and select data based on established criteria.
    - **Opportunity:** *Accumulated experiences within RBA can support guidelines and ensure communication of methods, results and underlying uncertainties targeted to different stakeholders (scientist, risk managers, citizens, other stakeholders).*
- Better tools for data integration across domains.
- Increased number of case studies, tackling different foods, food components and diets, in different populations and countries
    - **Opportunity:** *Available training activities (such as EFSA training, regular annual PhD course at DTU) can increase capacity for RBA within national and international institutions. Engagement with stakeholders at national and international levels can increase the interest of risk managers to formulate risk-benefit questions and allocate resources for RBAs.*
- Enhance recognition of the utility and relevance of RBA by top agencies,
    - ***Opportunity:*** *Ongoing activities by the WHO/FAO and EFSA can promote engagement and active contribution of international agencies (WHO, FAO, EFSA) for the development and applications of RBA case studies.*

4.3 Communication of RBAs

In relation to the communication of RBAs, there was consensus about communicating both risk and benefits to citizens is important so trade-offs and recommendations can be better understood.

"Demonstrating to consumers that some risk may be tolerable to trade-off for benefits is needed. However, we need to remember that foods cannot and shall not be unsafe. If there is question of the safety of a food, an RBA should not be carried out - safety is imperative."

The following priorities to improve communication of RBA outputs were identified:

- Develop different communication materials and tools targeted to citizens and risk managers.
- Facilitate processes for internal communication between risk-benefit assessors and managers throughout the RBAs.
- In communication to citizens, clarify that food safety is never compromised. While food safety risks may be included in an RBA, consumers are always protected by regulatory frameworks that work towards ensuring the safety of foods available for consumption.
- In communication of the outputs of an RBA to citizens, it is important to communicate both the benefits and the risks to the public.
- Communication plans should consider consumers' perceptions around risks and benefits. Investing in dialogue with the public and involvement of social sciences is essential.
- As pointed out before (see section above: "Opportunities and needs"), communication of RBA needs to include main findings well as assumptions of the approach and uncertainties related to the lack or representativeness of data.

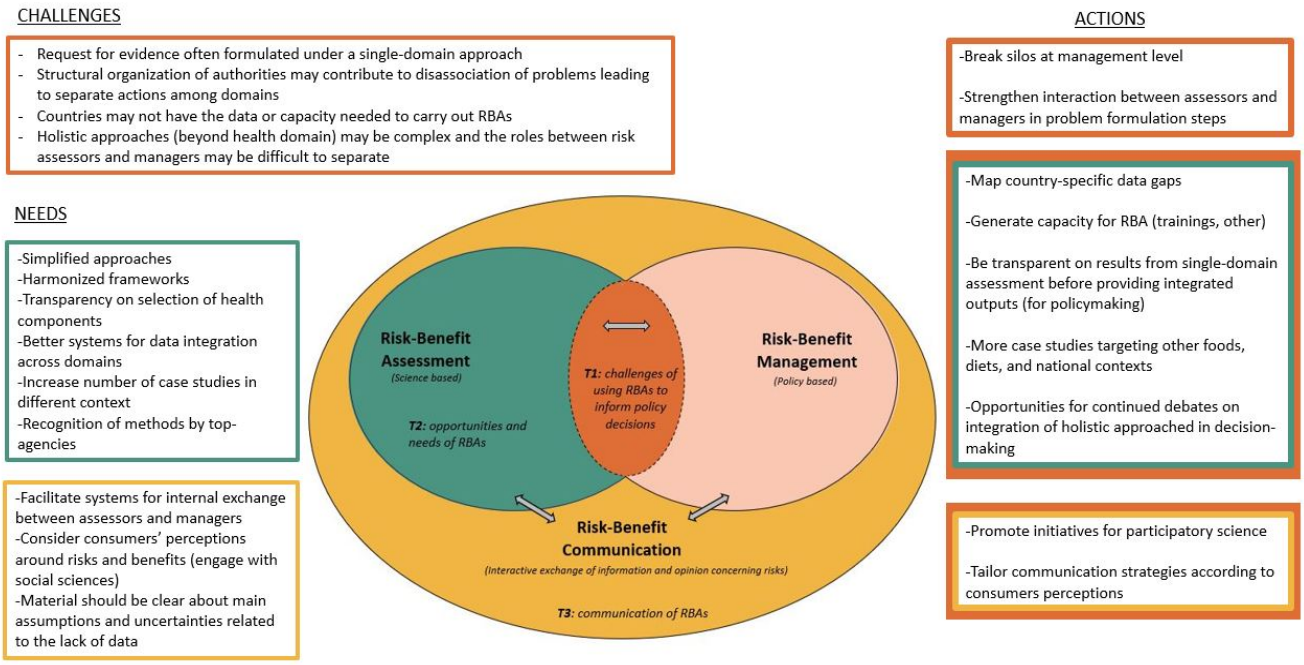


Figure 2. Challenges, needs, and actions to include risk-benefit assessment in decision-making. Key-discussion discussion points of the HOLiFOOD stakeholder workshop.

5 Discussion and future perspectives

The stakeholder workshop was successful, fulfilling the objectives set by its organizers. While participants had diverse views and identified a range of needs, opportunities, and challenges for the increase in applications of RBAs of food to inform policy decisions, collected input was in general aligned. In addition, a common direction for developments of RBAs, including in communication and knowledge translation was suggested.

For the development and increased use of RBAs, more case studies are needed targeting different food aggregation levels (e.g., application in new food categories, whole diets, or at food chain supply level) and in different contexts (e.g., across-countries, or even exploration of the feasibility to operationalize at global scale). The gained experience from additional case studies could be beneficial to tackle several obstacles identified in the workshop such as to demonstrate the flexibility and applicability of the RBA framework, identify data gaps, build capacity while increasing further partnerships, providing more information to base future discussions that aim at harmonizing frameworks at international level, and exploring (and improving) risk-benefit communication strategies.

Some of the challenges discussed in section 4.1 are linked to the structural organization of institutions, which may represent potential barriers and impact both current implementation of RBAs in decision-making and future challenges for moving towards holistic approaches. Solving these obstacles goes beyond the scope of the HOLiFOOD project as it would require structural reform of regulatory authorities. Several inputs collected during the stakeholder workshop are, however, helpful to guide the next actions of the HOLiFOOD project as highlighted below.

In addition to the action points highlighted in the above section, the following recommendations could serve as strategies to enhance the adoption of health RBAs in regulatory decision-making; First, it is suggested to continue promoting spaces for close dialogue with risk-benefit managers, and other participatory science initiatives. This will help to set up a well-defined scope for the study and refine the risk-benefit question. Secondly, risk-benefit assessors should provide a transparent approach for justifying the selection of the health components that shall be included in the assessment. Recent methodological improvements have been proposed to address this challenge in a more transparent and harmonized way (Boué et al., 2022). Thirdly, improvements could be implemented to the risk-benefit communication strategy. Although the elaboration of a tangible communication strategy is still a future endeavor of the HOLiFOOD project, it is possible to identify a few important elements from this early stage. For example, better understanding the consumers' perceptions around risks and benefits in relation to the selected food supply chains might be beneficial to tailor future communication strategies that is suitable for the countries in which the case studies will be applied. The involvement of experts from social sciences could be essential for the development of the right communication strategy. In addition, future approaches should address the challenges in communicating not only main findings but also in expressing underlying assumptions and uncertainties.

Lastly, when considering holistic approaches, it is suggested to conduct individual (domain-specific) assessments before integrating the outputs into one metric. For transparency reasons, it is recommended that policymakers should be able to identify results of the different domains in addition to the integrated output. This approach should avoid potential loss of information when using summary measured of population health.

6 Knowledge dissemination plan

The main findings of this deliverable are foreseen to be disseminated through the format of a scientific publication. Potential journals will be identified and discussed with the WP3 leader and relevant partners involved in T3.2 after approval of this deliverable. In addition to the forthcoming scientific article and the HOLiFOOD website, the overall results will be presented in the format of a poster and pitch presentation at the 16th European Public Health Conference, which will be held in November 2023 in Dublin, Ireland.

7 References

Boué, G., Ververis, E., Niforou, A., Federighi, M., Pires, S. M., Poulsen, M., Thomsen, S. T., & Naska, A. (2022). Risk–Benefit assessment of foods: Development of a methodological framework for the harmonized selection of nutritional, microbiological, and toxicological components. *Frontiers in Nutrition*, *9*. https://doi.org/10.3389/fnut.2022.951369

FAO/WHO. (2006). *Food safety risk analysis. A guide for national food safety authorities*. https://www.fao.org/3/a0822e/a0822e.pdf

Nauta, M. J., Andersen, R., Pilegaard, K., Pires, S. M., Ravn-Haren, G., Tetens, I., & Poulsen, M. (2018). Meeting the challenges in the development of risk-benefit assessment of foods. In *Trends in Food Science and Technology* (Vol. 76, pp. 90–100). Elsevier Ltd. https://doi.org/10.1016/j.tifs.2018.04.004

8 Annex A

Workshop Program

Time	Topic	Location
10:00	Welcome and introduction	Constanza De Matteu, DTU
10:20	Opening presentation: Introduction to risk-benefit assessment of foods	Sofie Theresa Thomsen, DTU
10:40	Break	
10:45	Breakout out session - Three parallel discussion groups	*Group moderators*: Jeanne-Marie Membré, INRAE Morten Poulsen, DTU Sofie Theresa Thomsen, DTU *+ rapporteurs*
11:25	*Break*	
11:30	Plenary – Reporting of the points discussed in the discussion groups	*Moderator:* Sara Monteiro Pires, DTU *+ rapporteurs*
11:45	Plenary discussion	*Moderator:* Sara Monteiro Pires
12:25	Wrap-up and concluding remarks	Sara Monteiro Pires
12:30	*End of the workshop*	

9 Annex B

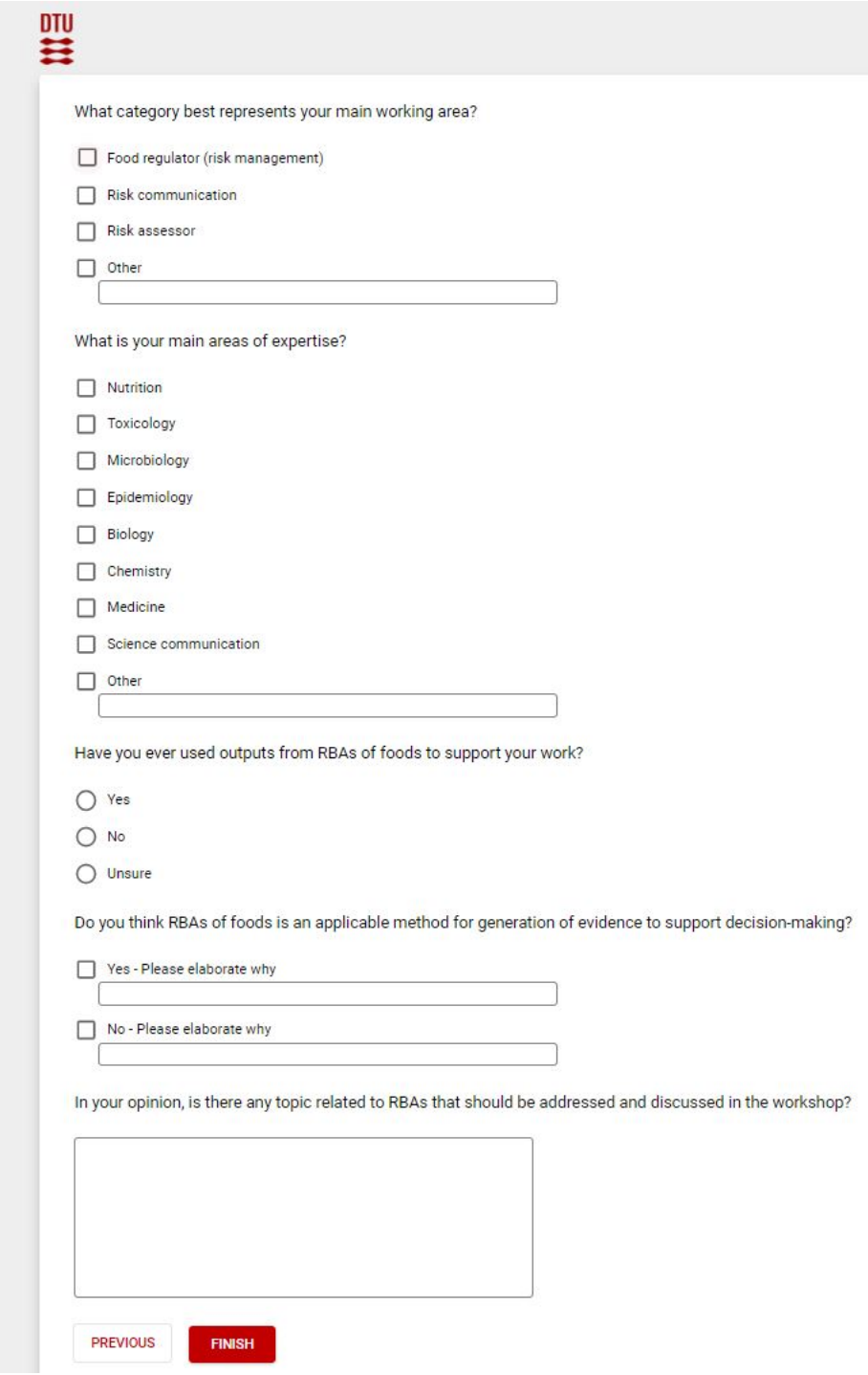
List of organisations contributing to the workshop

Name of organisation

ANSES - French Agency for Food, Environmental and Occupational Health & Safety
ASAE – Portuguese Economic and Food Safety Authority
BfR - German Federal Institute for Risk Assessment
DTU - Technical University of Denmark
EC – European Commission (DG SANTE)
EFET - Hellenic Food Authority
EFSA - European Food Safety Authority
FAO – Food and Agricultural Organization of the United Nations
FCNAUP - Faculty of Nutrition and Food Sciences from University of Porto
FVST – Danish Veterinary and Food Administration
Hungarian Ministry of Agriculture
INRAE - French National Research Institute for Agriculture, Food and Environment
NVWA - Netherlands Food and Consumer Product Safety Authority
Norwegian Food Safety Authority
SLV – Swedish Food Agency
The Dutch Ministry of Health, Welfare and Sport
UVMB - University of Veterinary Medicine Budapest
UNEW – Newcastle University
WHO – World Health Organization

10 Annex C

Outline of the preworkshop survey



DTU

What category best represents your main working area?

- [ ] Food regulator (risk management)
- [ ] Risk communication
- [ ] Risk assessor
- [ ] Other

What is your main areas of expertise?

- [ ] Nutrition
- [ ] Toxicology
- [ ] Microbiology
- [ ] Epidemiology
- [ ] Biology
- [ ] Chemistry
- [ ] Medicine
- [ ] Science communication
- [ ] Other

Have you ever used outputs from RBAs of foods to support your work?

- ( ) Yes
- ( ) No
- ( ) Unsure

Do you think RBAs of foods is an applicable method for generation of evidence to support decision-making?

- [ ] Yes - Please elaborate why
- [ ] No - Please elaborate why

In your opinion, is there any topic related to RBAs that should be addressed and discussed in the workshop?

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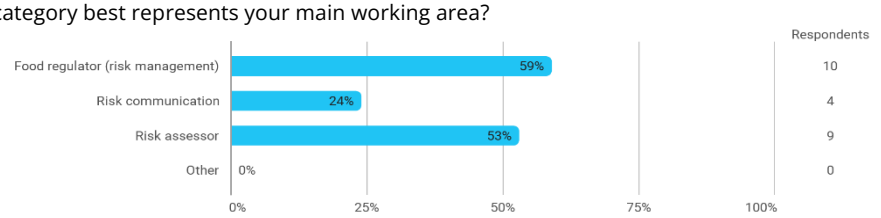
Survey suported by survey-xact.dk

11 Annex D

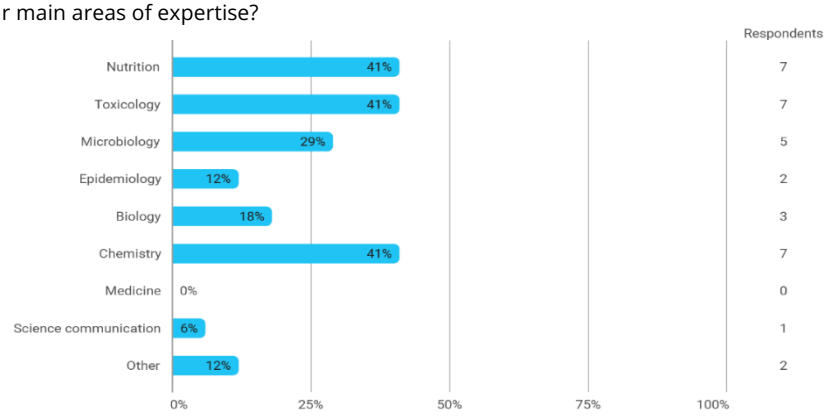
Results of the preworkshop survey

Total number of respondents: 17

1. What category best represents your main working area?

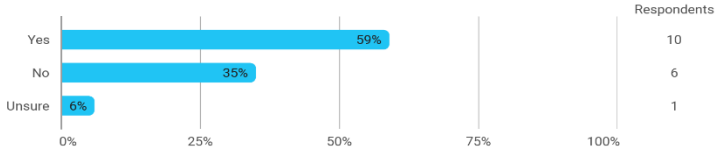


2. What are your main areas of expertise?

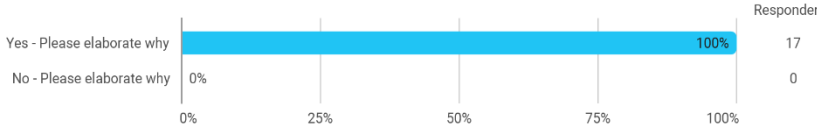


Other: public health; regulation on contaminats

3. Have you ever used outputs from RBAs of foods to support your work?



4.Do you think RBAs of foods is an applicable method for generation of evidence to support decision-making?



Respondent answers:

- To be able to consider the pro's and contras of a food product
- In the field of nutrition (and in particular for the development of food-based dietary guidelines), evaluating both risks and benefits of foods is required. Determining the optimal amounts that can be recommended for the general population or specific segments of the population must take into consideration both the presence and amounts of beneficial essential and non-essential nutrients as well as the presence of other substances (e.g. potential contaminants or substances that have ADIs etc.)
- Transparency in decision making
- Because its value is intuitively important for citizens
- It provides information about health aspects of diets
- In order to make a decision, prioritize actions or choose between different measures, the manager needs to evaluate the benefits associated with these measures in relation to the level of risk to the consumer
- RBA is unavoidable with a growing knowledge of risks and when realising zero risk does not exist.
- The risk-benefit assessment is the complete tool for making informed decisions, which shows both sides of the equation and enables better and more sustained decisions to be made.
- Because it combines all the available information
- many uncertainties but at present bst tool to give balanced dietary advice
- Specially to provide recommendations for fish consumption
- It provides a more complete picture of the evidence
- Yes, especially for healthy foods e.g. fish which contain both essential nutrients and several contaminants. The risks vs benefits need to be weighed for different groups. For some gruops e.g. middle aged men the benefits might be weighted higher than the risks. Whereas, the risks weigh more in sensitive gruops like pregnants.
- Trends to derive lower Health based guidance values and to develop more sensitive analytical methods result in more and more risk assessments ending up with the conclusion of "concerns for consumer health"
- To support a risk manager in decision-making
- An RBA is necessary to tolerate levels of contaminants in food which are according to risk assessments not (fully) safe but the food in which these contaminants occur contain ingredients that are beneficial for health and therefore might outweigh the risks related to contaminants. health benewhich
- I think it is necessary to make a realistic more informed decision

5. In your opinion, is there any topic related to RBAs that should be addressed and discussed in the workshop?

Respondent answers:

- As I do not have hands-on-experience with RBA,
  1. What type of data are required? (minimum requirements)
  2. Which are the preferred models to use (particularly if more than 1 risks are included)?
- Shortcomings of the models, which are only as good as the data that is put into them. Also - how to communicate and quantify risk ranking - between lowered IQ, short and non-fatal diarrhea, severe disease or cancer risk.
- Ways of communicating the results of the survey to the public
- How to compare different risks or benefits? Which scale or metric?
  microbiological or chemical risks vs. nutritional benefits
  microbiological or chemical risks vs. environmental/sustainability benefits and vise-versa
- Real-life examples of how risk-benefit studies have managed to reach policymakers.
- Socio-economical issues
- How should be selected the list of chemical contaminants and of nutriments to be included in the RBA analysis? Apart in the context of fish consumption advice, for which other food categories would RBA be useful?
- Perhaps a couple of thoughts:
  a) including systematic measures for the strength of evidence and uncertainties in the outcome of RBA, especially when data sources are poor.
  b) whether RBA can be more informative to risk managers if it is not exclusively centered on human-health but considers also animal health and welfare as well as environmental sustainability issues.
- We are waiting for Efsa to finalize their risk benefit assessment for fish before we change our advice for fish. It would be interesting to elaborate around fish and to get an update from Efsa about their time plans. The last information we got was that it will be finalized in 2025.
- 1) Uncertainties in RBA
  2) Who is responsible to perform RBA? Is it more a matter of risk assessment or risk management?
- Until now we have mainly seen RBAs which address one contaminant in a food, e.g. dioxins and PCBs in fish, mercury in fish but it is important to have RBAs which look at all contaminants present in a food., i.e. a comprehensive risk benefit analysis related to the consumption of a food.

Note: Some respondents did not reply to this question.

12 Annex E

Results of the interactive survey

Round 1

Question: How would you describe your current knowledge on risk-benefit assessment?	*Number of answers*
Limited to none. I am looking forward to learning more today.	6
I have some general knowledge on RBAs	7
I am familiar with the RBA methods	10
Question: what category best represents your main working area?	*Number of answers*
Risk assessor	14
Risk manager	7
Risk communicator	1
Other	7
Question: Have you ever used results from RBAs of foods to support your work?	
Not sure	1
No	9
Yes	16

Round 2

Question: Are you familiar with other holistic assessment methodologies? If yes, which?	*Number of answers*
No	14
Comments: No, but interested in methods that included sustainability in the RBA	
Yes	6
Comments: Cost-benefit DALY MCDA One Health	

13 Annex F

Overall mapping of discussion points

Theme 1: Challenges of using RBAs to inform policy making	Sub-question	Comments
T1.1: Food safety (toxicology; microbiology) and nutrition are often structurally divided into different departments within institutions. This might pose a challenge to integrate domains (and assessments).	Structural organization	Both successful and challenging examples at national level were reported regarding communication across departments or institutions.
T1.2: Breaking silos at management level for better problem formulation might help overcome challenges related to structural organization (e.g., departmental fragmentation).	Structural organization	Outputs are dependent on the problem formulation and the risk-benefit question being commissioned. A different type of question (more holistic) will lead to a different approach to assess risk.
T1.3: Collaboration of a one department with the industry could result in challenges to other departments as benefits might be more often emphasized than risks.	Structural organization	
T1.4: Integrating other dimensions beyond health makes the RBA look like a decision-making process, where separating the roles between risk-benefit assessors and managers will be difficult	Holist approaches	If holistic approaches are the next step for more transparency in decision-making, it may require reforms in how policymaking is currently being done. Linked to key-point T1.2
T1.5: It is suggested to run domain-specific assessments before integration of results into one metric. Policy makers should be able to identify the results of different domains in addition to the integrated output. It avoids loss of information and increase transparency.	Holistic approaches	Start assessment without the involvement of risk managers, add other layers of complexity (integration of domains) in a later stage.
T1.6: The assessment output needs to be applicable for decision-making, and the complexity of the assessment depends on the problem formulation and possible alternatives.		Assessment does not always need to be complex or require complex data. Link to key-point T1.2
T1.7: Some countries still lack data and capacity to conduct RBAs which raise challenges to authorities		
Theme 2: Opportunities and needs of RBAs	**Sub-question**	**Comments**

T2.1: Need for harmonization of frameworks. Assessments considering different beneficial and detrimental effects might generate different advice.	Reliability of methods	Sometimes a simple RA can reach different conclusions. Consumer´s trust might be impacted if advice from different assessment differ, and objective explanations are not provided. However, different populations and contexts calls for different decisions.
T2.2: RBA not yet fully recognized by top agencies	Reliability of methods	Harmonization of frameworks could lead to recognition in top agencies. Link to key-point T2.1
T2.3: Use of one single population summary metric is challenging as certain metrics only be applied to certain conditions.	Reliability of methods	
T2.4: Can risk assessors introduce bias as components to be included in the assessment and weighing comes down to a value of judgment that might differ depending on the assessment panel?	Reliability of methods	
T2.5: Lack of data availability to characterize both risks and benefits may lead to incomplete assessments	Reliability of methods	Lack of data is also a general problem in risk assessment. More case studies can help identify data gaps that is specific to RBAs.
Theme 3: Communication of RBAs	**Sub-question**	**Comments**
T3.1: Need to consider consumers perceptions around risks and benefits when formulating a communication plan. Dialogue with the public and involvement of social sciences is essential.	Communication of RBAs	Discrepancy how consumers perceive risk and benefit vs scientists or risk managers. Public might give more importance to a certain risk (e.g., pesticides) than other (e.g., aflatoxins) Risk acceptability in the population might differ based on the food item
T3.2: Communication of main findings only is not enough. Important to communicate on assumptions behind the conclusions and uncertainties related to lack of data	Communication of RBAs	Example on risk-benefit case-study on nuts
T3.3: Integrating other dimensions such as economic and environmental factors might make the assessment more complex, hence more difficult to communicate	Holistic approaches	
Other discussion points	**Sub-question**	**Comments**

#1: Use of different sources of data pertinent of each domain: How to integrate these data and make sure they are correctly interpreted, combined, and communicated?	Reliability of methods; Communication of RBAs	Epidemiological studies to characterize health effects; use of animal data to assess toxicological parameters
#2: Benefits in general are well stablished and static but as for risks, more and more contaminants need to be considered in assessments. How to generate one piece of advice?		
#3: Conduct more case-studies targeting different food categories and contexts.	Future perspectives	Demonstrate that is feasible in different contexts (including in developing countries), gain more experience on different cases outside the RBAs on fish consumption
#4: Potentially, stronger case studies could be performed in low-resource settings	Future perspectives	Demonstrate that benefits could outweigh risks, while exploring context of countries with issues regarding vitamin deficiency Link to key-point #3
#5: Global RBAs could be beneficial for general issues but more valuable/informative if focused on a specific region	Future perspectives	
#6: RBAs on fish could be expanded to account for PFAs	Future perspectives	
#7: Holistic approaches are needed for a food systems approach and accounting for sustainability	Holistic approaches	
#8: Policy should allow risks to be present, if there is also a (assumed, higher) benefit		There is no scenario with no risks. Trade-offs are always present.

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