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Horizon scanning exercise on preparedness for future risk assessment requirements and possible challenges in regulatory science

Tea Paulović[1], Olivier Chartier[1], Maria Chiara Zingaretti[1], Daniele Bertolozzi[1], Giulia Martino[1], Thomas Krüger[1], Florent Pelsy[2], Linus Sioland[2], Lise Oulès[2], Antonia Custance Baker[3], Elise Hoek[4], Fabrice Nesslany[5], Lynn Frewer[6], Peter Rakers[7], Remco Schrijver[8], Steffen Foss Hansen[9], Steven Libbrecht[10]

[1] Ecorys, [2] Milieu Law and Policy Consulting, [3] Individual expert, [4] Wageningen University & Research, [5] Institut Pasteur de Lille, [6] Newcastle University, [7] Blue Ocean Views, [8] VetEffecT, [9] Technical University of Denmark, [10] Esset Engage

FINAL REPORT

Abstract

The horizon scanning exercise aimed to support EFSA's preparedness for future risk assessment requirements and challenges in regulatory science and communication in scientific thematic areas for which knowledge gaps might exist. Six areas of common interest (i.e. thematic areas) were explored through the horizon scan: (i) animal welfare and safety of the food chain, (ii) exposure science in risk assessment, (iii) nutrition and healthy diets from sustainable food systems, (iv) safety assessment of innovative products, (v) sustainable food systems and food safety, and (vi) evidence-based risk communication in the EU Food Safety System. By applying a horizon scanning methodology and a comprehensive mapping exercise, this project delivered an overview of emerging and upcoming (scientific) developments in these six thematic areas, to enable the anticipation of future work and expertise requirements. A modified Delphi method was used to collect the necessary information from (regulatory) scientists and other EU and international stakeholders. Moreover, the mapping exercise provided an understanding of ongoing and planned research activities being undertaken by relevant scientific actors, thus identifying potential opportunities for cooperation. The horizon scan resulted in a set of recommended actions for the six thematic areas that could contribute in EFSA's preparedness and in preventing challenges and potential divergences from materialising. With all necessary prudence, the report can conclude that while significant research is undertaken, the connection to EFSA's strategy is not yet fully clear to all relevant stakeholders, emphasising the need for cooperation between EFSA and its stakeholders. The findings of this horizon scanning exercise should not be considered as an indication of the direction that ongoing EU policy initiatives in the food system may take. In order to address future regulatory science and policy needs, EFSA should work jointly with other EU agencies and policy makers towards identifying solutions.

Key words: horizon scanning, animal welfare, exposure science, nutrition, innovative products, sustainable food systems, risk communication

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Correspondence: SPIDO@efsa.europa.eu

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Summary

With the adoption of the "Transparency Regulation" (Regulation (EU) 2019/1381)[1] in 2019, the European Food Safety Authority (EFSA) acquired new competencies related to the verification of evidence used in the risk assessment process. According to Article 32d of this Regulation, the European Commission may "*in exceptional circumstances of serious controversies or conflicting results, request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned ("verification studies") may have a wider scope than the evidence subject to verification".* Following this requirement, EFSA is working on strengthening the identification and prioritisation of scientific thematic areas for which scientific studies are required to address critical data gaps and develop roadmaps for action to address these gaps and minimise the need for possible verifications studies. The horizon scanning exercise on preparedness for future risk assessment requirements and possible challenges in regulatory science is a project that aims to support EFSA in reaching this goal.

The general objective of the project was to solicit feedback on preparedness from relevant actors for future risk assessment requirements, and possible challenges in regulatory science and communication that bear the risk of scientific divergence in work areas of common interest. EFSA contributes to the safety of the European Union (EU) food chain by providing scientific advice to risk managers by communicating risks to the public and cooperating with member states.[2] In this context, another aim of this project was to identify the potential for collaboration in areas of common interest, to help strengthen cooperation between EFSA and other EU/national institutions through building and fostering strong partnerships.

The project focussed on six areas of common interest (referred to as thematic areas):

1. Animal welfare and safety of the food chain.
2. Exposure science in risk assessment.
3. Nutrition and healthy diets from sustainable food systems.
4. Safety assessment of innovative products.
5. Sustainable food systems and food safety.
6. Evidence-based risk communication in the EU Food Safety System.

Through the use of a horizon scanning methodology and a comprehensive mapping exercise, this project has delivered an overview of emerging and upcoming (scientific) developments in the six thematic areas, enabling the anticipation of future work and expertise requirements. Furthermore, it provided an understanding of what relevant scientific actors are doing to identify potential opportunities for cooperation or spillover effects, and to identify organisations for upcoming work.

[1] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

[2] EFSA Strategy 2027, https://www.efsa.europa.eu/sites/default/files/2021-07/efsa-strategy-2027.pdf

Horizon scanning is the **systematic examination** of relevant potential future developments, by considering forces active in the broader context. These forces are referred to as **driving forces** and are the factors that will shape the future context. They include relevant scientific and technological developments, socioeconomic developments, political and legislative developments, and ecological developments. These refer both to forces that have an outcome that can be reasonably predicted (so-called **"trends"**) and to forces that will generate an outcome that is essentially uncertain (so-called **"uncertainties"**). For EFSA, horizon scanning fits within the objective of preparedness for future risk assessment requirements. Consequently, the horizon scanning for this project looked for forces and future developments relevant to risks related to food.

The horizon scanning exercise involved three feedback cycles. Each feedback cycle included a workshop with expert groups covering the six thematic areas identified as areas of common interest. Additionally, a mapping exercise was performed to map ongoing and planned research activities as well as interest for collaboration. The mapping of research activities was initiated during the second feedback cycle, following the second workshop. It consisted of desk research on the mapping of research activities, which was followed by the survey launch. Launching the survey after the second workshop enabled the project team to adjust the survey to the outcomes of the second workshop, taking into account the preliminary findings on challenges and potential scientific divergences.

In a first step, it was necessary to **develop the structure of the horizon scanning**, before the horizon scanning was then implemented. This project relied on a **modified Delphi method** to collect the information necessary for the individual steps of the horizon scanning. For this, (regulatory) scientists and other stakeholders from across the EU and internationally were invited to a series of virtual workshops. For each of the six thematic areas, between 14 and 24 experts were invited to participate in **Technical Expert Groups** (TEG).

The thematic area of animal welfare explored topics related to **animal welfare on farms, during transport and at slaughter**, as well as **animal welfare labelling** and **risk assessment of animal welfare**. Animal welfare during transportation was found to be the least researched work area. However, potential divergences linked to this work area as identified by the panel indicate a possibility for the potential divergences to materialise and a strong need for research in the field. Mobilising the research community should not present a challenge as there was plenty of interest for collaboration on this research topic.

Thematic Area 2 explored **aggregated exposure science, EFSA's framework, guidance and tools for exposure reconstruction to chemicals via (forward and reverse) dosimetry,** and **development of standards for the integration of EFSA Open Access Tools for the collection of dietary data in new exposome/Human Biomonitoring (HBM) studies**. Most of the research on exposure science in risk assessment relates to aggregate exposure assessments, covering two identified potential divergences which the Delphi panel deemed as highly urgent to address and as having a potentially high impact on EFSA's preparedness. On the other hand, a potential divergence between EFSA and other risk assessment bodies or agencies (*e.g.* ECHA) regarding forward and reverse dosimetry might have higher chances of materialising given that there is a lower level of ongoing research related to this topic. There still appears to be a need for further research on biomonitoring

data, in particular in relation to the lack of internal reference values and kinetic data to interpret human biomonitoring data.

Thematic Area 3 explored topics such as **nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems, science-based dietary guidelines in relation to sustainable food systems and environmental impact, relationship between foods and chronic metabolic diseases**, and **possible food safety issues related to a sustainable healthy diet**. Evaluating the nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems is an outstanding topic that was found to be highly researched and debated among the research community. It should be mentioned that the gut microbiome was considered as part of Thematic Area 4 as well, specifically within the context of understanding the influence of microbiota modifications on human health. As there seems to be no consensus on the definition of a healthy or unhealthy microbiome, the issue needs to be formulated precisely. A starting definition should be made, followed by scoping and a systematic review by EFSA. Otherwise, the impact of ultra-processing on metabolic diseases was seen as an area where potential divergences could materialise. The mapping exercise showed that this is currently the least researched topic within this thematic area, however many research groups indicated interest for future collaboration.

Thematic Area 4 discussions evolved around **innovative (and sustainable) food and feed products** and **related technologies/resources**, as well as **innovative production approaches**. It also included the identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification, including the understanding of the influence of microbiota modifications on human health. Risk assessment and characterisation of complex/non-conventional foods was found to be a research field where potential divergences could emerge, yet there was only limited ongoing research on this topic, revealing a potential gap in this area. Similarly, as for Thematic Area 3, characterisation of a healthy microbiota stood out as a popular research topic. This presents a positive development as the Delphi panel identified potential divergences which may arise regarding definitions, including the definitions of a healthy microbiome and related dysbiosis, the standards that define a "healthy" microbiota, and what could cause adverse effects on the latter.

Thematic Area 5 explored topics related to sustainable food systems and food safety. These included discussing **sustainable food production, stimulation of sustainable food processing and distribution, promotion of sustainable food consumption,** and **new dietary guidelines (including methodological aspects for developing them) to accompany a shift to more sustainable diets**. Sustainable food systems and food safety encompass a variety of research topics, which (as the mapping found) were relatively well researched. Potential challenges and divergences that stood out were linked to environmental and health risks associated with the reuse of wastewater for irrigation and to risk assessments of food potentially contaminated with soil pollutants. While there was already ongoing research related to these topics, these appeared amongst the most popular topics when it comes to future interest in collaboration. However, the most pertinent issues identified for this thematic area were related to risk assessments of organic fertilisers and the ways in which infectious agents and toxic chemicals can be introduced to and subsequently impact the food chain. The mapping showed that this was the most researched among the explored topics, but there is still a lack of data to adequately assess the risk that infectious agents such as bacteria, virus and fungi pose to the food chain, and so several actions were thus recommended.

Thematic Area 6 reflected on the **development and implementation of an integrated risk communication framework, the identification of research needs that are considered crucial to further inform appropriate RC in the EU, potential differences between different target audiences and risk communication contexts**, and the **relevance of messaging to consumer priorities, preferences and understanding**. A challenge considered as a key priority by the Delphi panel relates to institutions having sufficient capacity to adapt their risk communications in light of digitalisation and rapid technological change. Closely linked to this is the need to ensure that enough research is performed to "update" risk communications in the digital age. While social media analysis and differences in consumers access to digital platforms are among the research areas which drew most interest from research groups, both in terms of current and future research, foresight about additional digital communication needs are only researched to a limited extent.

A need to develop interdisciplinary approaches, for alignment, and for collaboration with other agencies and institutions were frequent remarks during the thematic expert group discussions. The synthesis indicated that several identified potential divergences were considered as being urgent and as having a high impact on EFSA's preparedness. These were, however, already explored by a number of research groups active in the respective research areas. With all necessary prudence, the report can conclude that **a lot of relevant research is being done but the connection with EFSA's strategy is not yet fully clear**. The respective research centres and institutions conducting such studies are not aware of the relevance for EFSA, and vice versa. Strengthening the cooperation between EFSA and such stakeholders through building and fostering strong partnerships could help to overcome this issue. Cooperation could contribute to limiting the number of blind spots – *i.e.* challenges and potential divergences of high importance but with low levels of ongoing research – identified in the horizon scan, which could be tackled via the Horizon Europe working program or other channels publishing calls for proposals in the upcoming years.

Overall, the horizon scanning exercise on preparedness for future risk assessment requirements and possible challenges in regulatory science determined several work areas for each of the six thematic areas as well as a list of possible challenges and potential divergences. In doing so, the horizon scan contributed to the development of scientific themes, which EFSA will take forward by investing in leading the creation of roadmaps for action. While new concepts such as healthy diets from sustainable food systems, sustainability scores in food systems, and the nutritional impact of the microbiome have sparked interest among research communities, their impact for regulatory science is not yet fully understood. Nevertheless, the horizon scan allowed for the formation of recommended actions that should prevent challenges and potential divergences from materialising. It must be stressed that the findings of this horizon scanning exercise should not be considered as an indication of the direction that ongoing EU policy initiatives in the food system may take. In order to address future regulatory science and policy needs, EFSA should work jointly with other EU agencies and policy makers towards identifying solutions.

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1. Introduction

With the adoption of the "Transparency Regulation" (Regulation (EU) 2019/1381)[3] in 2019, the European Food Safety Authority (EFSA) acquired new competencies related to the verification of evidence used in the risk assessment process. According to Article 32d of this Regulation, the European Commission may "*in exceptional circumstances of serious controversies or conflicting results, request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process*. *The studies commissioned ("verification studies") may have a wider scope than the evidence subject to verification"*. Following this requirement, EFSA is working on strengthening the identification and prioritisation of scientific thematic areas for which scientific studies are required to address critical data gaps and developing roadmaps for action to address these gaps and minimise the need for possible verifications studies. The horizon scanning exercise on preparedness for future risk assessment requirements and possible challenges in regulatory science is a project that aims to support EFSA in reaching this goal.

This final report provides an overview of the project methodology as well as the results obtained from the project tasks. The general objective of the project was to solicit feedback on preparedness from relevant actors for future risk assessment requirements, and possible challenges in regulatory science and communication which bear the risk of scientific divergence in work areas of common interest. EFSA contributes to the safety of the European Union (EU) food chain by providing scientific advice to risk managers, by communicating risks to the public and by cooperating with member states.[4] In this context, another aim of this project was to identify the potential for collaboration in areas of common interest, to help strengthen cooperation between EFSA and other EU/national institutions, through building and fostering strong partnerships.

The project focussed on six areas of common interest (referred to as thematic areas):

7. Animal welfare and safety of the food chain.
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12. Evidence-based risk communication in the EU Food Safety System.

Through the use of a horizon scanning methodology and a comprehensive mapping exercise, this project has delivered an overview of emerging and upcoming (scientific) developments in the six thematic areas, to enable the anticipation of future work and expertise requirements. Furthermore, it provided an understanding of what relevant scientific actors are doing to identify potential opportunities for cooperation or spillover effects, and to identify organisations for upcoming work. It is noted that the exercise and its findings are not to be considered as an indication of the direction that ongoing EU policy initiatives in the food system may take.

[3] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

[4] EFSA Strategy 2027, https://www.efsa.europa.eu/sites/default/files/2021-07/efsa-strategy-2027.pdf

2. Methodology

This section presents the methodology of the horizon scanning exercise on preparedness for future risk assessment requirements and possible challenges in regulatory science. The first sections define the problem formulation of the project and the overall approach to the problem. It is followed by two sections describing the main tasks implemented to reach the project objectives – the horizon scanning exercise and the mapping of ongoing and planned research activities.

2.1. Problem formulation

Set up in the early 2000s, the European Food Safety Authority (EFSA) is the body of the European Union that provides scientific advice to the EU on food safety-related issues. EFSA offers opinions, scientific advice, and assesses risks on a wide array of food-related topics, including plant protection, contaminants, additives or novel foods[5].

In its work, EFSA cooperates closely with and complements the national food safety bodies of the 27 EU Member States. In their work, EFSA and national food safety bodies often work on similar topics and scientific challenges regarding food safety. Ideally, risk assessments by national bodies and EFSA should be aligned to ensure the harmonised protection of public health. Yet, in regulatory science governing food and feed risk assessment (including those based on the legislative framework), potential serious scientific controversies or divergences could on occasion be unavoidable.

The nature of these divergences can be broad, but is often linked to different opinions and approaches on how to carry out risk assessment, different data sets used and most importantly differences in expert judgement which is an essential component of the risk assessment process. In its own guidelines on divergences, EFSA notes that *"diverging scientific opinions can arise at any stage of development of a scientific output prepared by EFSA and a national body in parallel. In addition, there is the possibility that either EFSA or the national body will commence work on developing a new opinion relating to an issue where there is already a published opinion"*[6].

The mandate of EFSA acknowledges this, as according to Article 30 of the EU Food Safety Regulation[7], EFSA should identify any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks. Article 32d of the same Regulation[8] further stipulates that the European Commission can, in exceptional circumstances that could result in serious controversy or conflicting results to Commission studies, ask EFSA to verify the evidence used in risk assessment processes.

To ensure that EFSA is prepared for future challenges and to minimis the potential for possible divergences, and associated requests from the European Commission to issue scientific opinions, the agency needs to anticipate potential work areas where these challenges and divergences can emerge

[5] https://www.efsa.europa.eu/en/aboutefsa.
[6] https://www.efsa.europa.eu/sites/default/files/event/150611a/af150611a-ax13.pdf.
[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.
[8] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. OJ L 231, 6.9.2019, p. 1-28.

and what form these might take. Providing this foresight and insight on future needs and challenges is therefore the core aim of this study.

2.2. Overall approach

The methodology for this project was defined by taking into account the seven specific objectives laid out in the tender specifications, ranging from a refined problem definition and identification of relevant stakeholders to stakeholder recommendations on what (if any) additional themes EFSA should consider in its future planning. **Table 1** provides an overview outlining how our proposed approach addressed each of these specific objectives.

Table 1: Specific objectives and methodological approach to address them

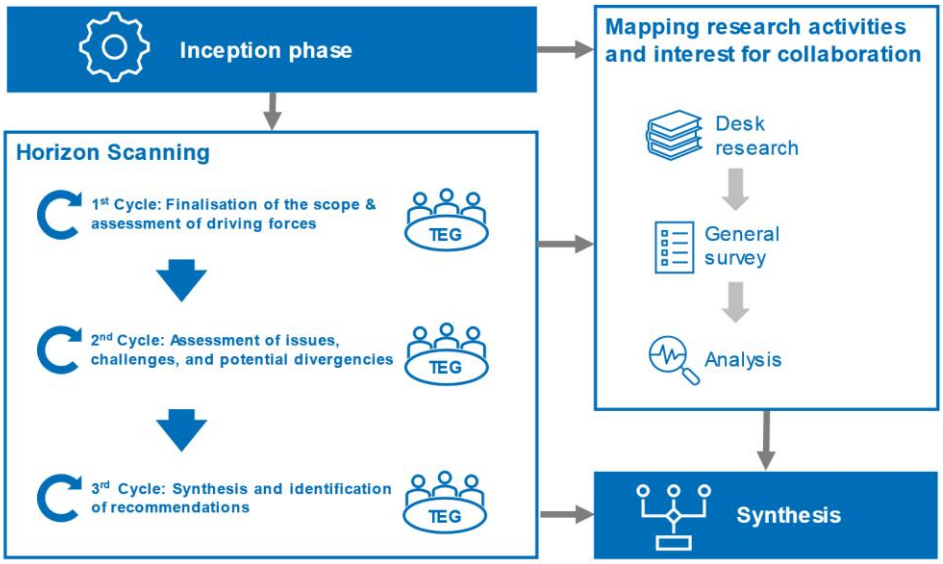
Specific objective	Definition as provided by the Terms of Reference (ToR)	Element of our approach addressing the specified objective
Objective 1 – Refining the problem formulation proposed in the offer	To provide a fine-tuned problem formulation to address the overall objective (as described above), including a workplan describing and potentially fine-tuning the details of the methodology proposed in the offer and that will be used to address all subsequent objectives (2-7).	Our methodological approach addresses all specific objectives through four tasks: 1) the inception phase, 2) the horizon scanning exercise, 3) the mapping of research activities, and 4) the reporting phase. All refinements to the methodology were presented in all previous reports delivered to EFSA throughout the implementation of the project, including the revised descriptions of the thematic areas.
Objective 2 – Identification of the actors relevant for each proposed theme	To carry out a comprehensive mapping of EFSA's partners and other actors that have relevant activities within each of the proposed scientific themes, as listed above and design appropriate questions for soliciting feedback and collecting the required information to address objectives 3-7.	Relevant actors were identified during Task 1 (inception phase) in collaboration with EFSA. The interactive background document that was shared with the participants before the first workshop included information on the scope of the exercise and questions that served as a basis for soliciting stakeholder feedback.
Objective 3 – Feedback from the identified actors on the proposed themes	To collect, analyse and synthesise the views of the actors identified under objective 2 on each of the proposed themes when identified as relevant to their work and activities, taking into account the factors/criteria described, so that the development of these themes would effectively cover future regulatory needs in the food and feed risk assessment, and hence could prevent serious scientific divergences/ controversies possibly leading to verification study requests under Article 32d of Regulation (EU) 2019/1381.	Feedback on the proposed themes was collected during the first cycle of the horizon scanning exercise (Task 2). Workshop 1 explored the work areas within each thematic area (including thoughts from participants on missing ones) as well as the driving forces.
Objective 4 – Feedback from the identified actors on the specific work areas to focus	To collect, analyse and synthesise the views of the actors identified under objective 2 on what work areas within the proposed themes should be	Feedback on specific work areas was collected during the first cycle (*i.e.* first workshop) of the horizon scanning exercise (Task 2). A prioritisation of

Specific objective	Definition as provided by the Terms of Reference (ToR)	Element of our approach addressing the specified objective
	prioritised, *e.g.* based on policy implementations, new guidance development, or relevant work programmes.	driving forces for each work area was carried out, resulting in a clustering of driving forces to inform the prioritisation of work areas.
Objective 5 – Feedback from the identified actors on issues/challenges in food and feed regulatory science	To collect, analyse and synthesise the views of the actors identified under objective 2 on any issues/challenges in areas of regulatory science of the food and feed risk assessment area (including those sourcing from the legislative framework) that have the potential to lead in serious scientific divergences/ controversies which might trigger verification study requests. Possible divergences both within the proposed themes identified by EFSA or within any other scientific topics relevant within EFSA's work areas should be considered.	Feedback on the issues and challenges in food and feed regulatory science were collected during the second cycle (*i.e.* second workshop) of the horizon scanning exercise (Task 2).
Objective 6 – Overview of relevant ongoing and planned activities of the identified actors	To acquire, analyse and synthesise information from the actors identified under objective 2 to obtain an overview of their ongoing and planned activities (if any) in research projects at national, European and international level, related to the proposed themes (or any similar ones) and solicit feedback on the potential for cooperation/collaboration in any specific areas within these themes.	An overview of ongoing and planned activities is obtained through the mapping of research activities (Task 3). The mapping was conducted by screening relevant databases and is complemented by a survey targeting food safety authorities and relevant research institutions.
Objective 7 – Information on the identified actors' recommendations for additional themes	To acquire, analyse and synthesise information from the actors identified under objective 2 on any justified recommendations for additional themes that should be prioritised by EFSA in order to ensure that the objectives of Regulation (EU) 2019/1381 on transparency, sustainability, preparedness and robustness are met.	Information on recommendations for additional themes was collected during the third cycle of the horizon scanning exercise (Task 2).

Our overall approach to tackling the seven objectives listed above is captured in **Figure 1** below. Firstly, a **horizon scanning exercise** involving three feedback cycles was implemented. Each feedback cycle included a workshop with expert groups covering the six thematic areas identified as areas of common interest. Secondly, a **mapping exercise** was performed to map ongoing and planned research activities as well as interest for collaboration. The mapping of research activities was initiated during the second feedback cycle, following the second workshop. It consisted of desk research on mapping of research activities, which was followed by the survey launch. Launching the survey after the second workshop enabled the project team to adjust the survey to the outcomes of the second workshop, taking into account the preliminary findings on challenges and potential scientific divergences (more information

on the mapping of research activities can be found in section 2.4). The findings from both exercises, the horizon scanning and the mapping, are synthesised in this final report.

Figure 1: Overall approach to the project



Source: Own elaboration

2.3. The horizon scanning exercise

Horizon scanning is the **systematic examination** of relevant potential future developments, by considering forces active in the broader context. These forces are referred to as **driving forces** and are the factors that will shape the future context – typically relevant scientific and technological developments, socioeconomic developments, political and legislative developments and ecological developments. These refer both to forces that have an outcome that can be reasonably predicted (so-called **"trends"**) and to forces that will generate an outcome that is essentially uncertain (so-called **"uncertainties"**). For EFSA, horizon scanning fits within the objective of preparedness for future risk assessment requirements. Consequently, the horizon scanning for this project looked for forces and future developments relevant to risks related to food.

In a first step, it was necessary to **develop the structure of the horizon scanning**. Following this, the horizon scanning was then implemented. This project relied on a **modified Delphi method** to collect the information necessary for the individual steps of the horizon scanning. For this, the project team reached out to and convened (regulatory) scientists and other stakeholders from across the EU and internationally and invited them to discuss the issues at hand in a series of virtual workshops. The next section (2.3.1) provides an overview of the individual steps of the horizon scanning. The section thereafter (2.3.2) introduces the modified Delphi methodology employed for its implementation.

2.3.1. Steps of the horizon scanning exercise on preparedness for future risk assessment requirements and possible challenges in regulatory science

To operationalise the horizon scanning for this project, a series of eight distinct steps were developed that provided structure to the exercise. These steps lead logically from the definition of the scope towards the identification and assessment of driving forces, challenges, and divergences. The final step consisted of the development of recommendations to EFSA. The table below provides an overview of the individual steps of the horizon scanning and their respective purpose and focus.

Table 2: Overview of individual steps of the horizon scanning for EFSA

Step	Explanation
Step 1: Scope definition	This step includes a clear definition of the key questions that are at the core of the horizon scan and which guide the decision as to whether a development or force is considered relevant. For this assignment, the key questions are related to the thematic areas. This step also provided the opportunity to validate the selection of six thematic areas.
Step 2: Identification of relevant driving forces	The identification of driving forces was a steppingstone in this horizon scanning exercise, as it helped to identify trends, uncertainties which have the potential to affect EFSA's work in general, and specific thematic areas. Driving forces were thus listed for each of the six thematic areas.
Step 3: Mapping of the driving forces (per thematic area)	The resulting list of relevant driving forces was then positioned on an impact-likelihood map, in order to differentiate between forces that are considered particularly impactful (with respect to food risks) and those which will have a more limited impact, as well as to assess the level of uncertainty with respect to the outcome of the driving force.
Step 4: Analysis of the driving forces (per thematic area)	Subsequently, the driving forces – especially those which are of high impact – were further analysed to better understand the outcome of these forces by the time horizon. In the case of trends, the analysis of the outcome of the force is often backed by readily available scientific data (reports, databases, publications, etc). Where there are uncertainties, the analysis of the outcome of the force involved the identification of the range or spectrum of potential outcomes, highlighting the most extreme possible outcomes.
Step 5: Identification of issues and challenges (per thematic area)	Once the relevant driving forces were well understood, the focus shifted to identification of challenges and potential scientific divergences associated with these driving forces (or combinations of driving forces), considering the spectrum of potential outcomes. As an output of this step, a list of challenges and potential scientific divergences was created.
Step 6: Mapping of issues and challenges (per thematic area)	Following the creation of this list, challenges and potential divergences were positioned on a likelihood-time horizon map, in order to reflect the likelihood that a particular challenge or divergence will occur, and the timing of its possible occurrence.
Step 7: Identification of potential divergences	The resulting impact-probability map served as a basis to identify potential divergences. Some divergences might be listed even if they are not linked to the challenges. Divergences associated with "high likelihood – short time horizon" issues would require a specific and more immediate course of action such as mitigation plans. Divergences associated with "low likelihood – long time horizon" issues would require monitoring, rather than immediate action.

Step	Explanation
Step 8: Identification of recommendations	The identified potential divergences were rated on three dimensions: the impact on EFSA's preparedness strategy, the urgency and scientific complexity. These three dimensions were summarised to obtain an overall score of the subjective importance of the divergence. The bridge between the divergences and actions recommended to address the divergences is the readiness level scale and each divergence is assessed on a scale from 1 to 3. The first readiness level refers to an issue that is still at conceptual level and there is little knowledge on it. The second readiness level indicates that there is a certain degree of knowledge on a topic (*e.g.* on definitions, tools, methods) but gaps remain. The third readiness level describes a situation where there is extensive knowledge on an issue but no consensus. Finally, based on the outcome of the previous steps, recommendations are formulated in the form of possible actions to take.

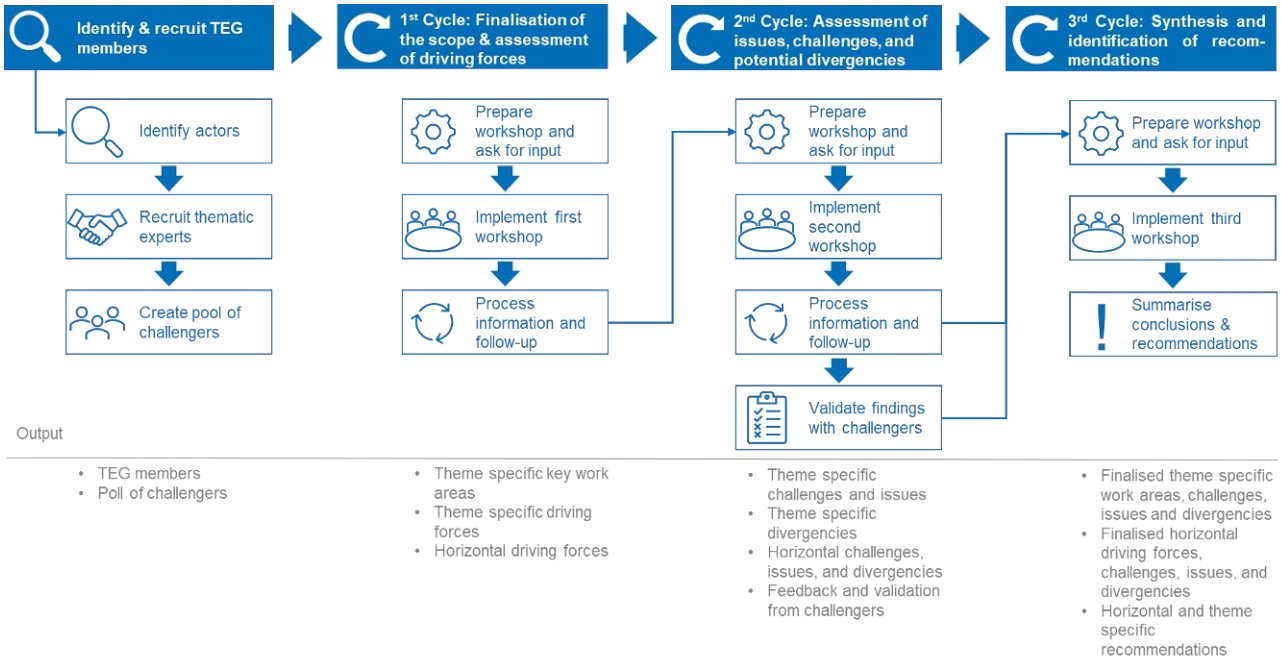
2.3.2. Horizon scanning implementation: modified Delphi methodology

The Delphi methodology is a structured communication approach. It usually builds on the insights from thematic experts who exchange views/information on complex topics across several iterations anonymously. Experts provide input and ideas, which are collected and subsequently shared with all other experts for feedback and revision. This feedback is collected again and builds the basis for the following iteration cycle. The Delphi methodology is used for many purposes. According to Linstone and Turoff (2002), Among its core uses is foresight, since the set-up allows for the collaborative discussion and development of ideas on complex topics. A usual Delphi runs through four phases: exploration, reaching of a common understanding, exploration of disagreement, and final evaluation[9].

In line with the principles of the Delphi methodology, a series of information and feedback collection cycles was implemented. For this project, the project team opted for three cycles and direct exchange among experts, rather than an anonymous exchange via repeated questionnaires. For each of the six thematic areas, between 14 and 24 experts were invited to participate in **Technical Expert Groups** (TEG), which met repeatedly in all three workshops to discuss their thematic area of expertise. The project team was there to support and maintain this **interactive and iterative exchange** among experts. While the team facilitated the workshop sessions, team members did not participate actively in the discussions themselves, to avoid any bias of the results. The figure below visualises the objectives and content of the three cycles, as well as the preparatory step and the identification and recruitment of TEG members. In the following figure, the recruitment of experts and implementation of the horizon scanning are explained in greater detail.

[9] Linstone, H., Turoff, M. (2002), The Delphi Method: techniques and Applications, available here: https://web.njit.edu/~turoff/pubs/delphibook/delphibook.pdf.

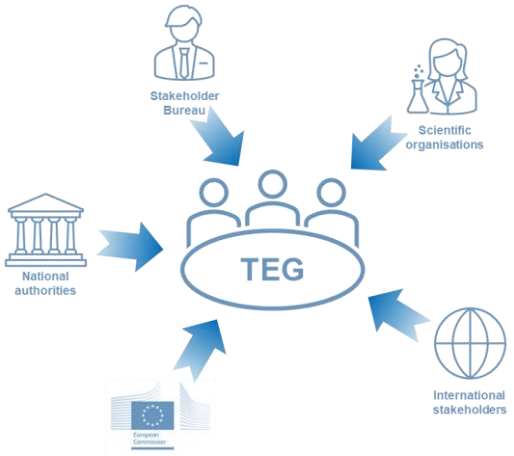
Figure 2: Logic of the cyclical approach to the horizon scanning



2.3.2.1. Recruitment of TEG members

Before the implementation of the workshops, TEG members had to be recruited. Based on input from EFSA and a mapping of relevant stakeholders via desk research, individuals and institutions were contacted and invited to participate in the horizon scanning exercise. For each TEG, the aim was to convene between eight and twelve experts from the scientific community, national competent authorities and food safety agencies, members of the Stakeholder Bureau, as well as members of international organisations and relevant EU bodies (including EFSA, ECHA, and the European Commission). An important pre-condition for the participation in the TEGs was the willingness of stakeholders to **contribute actively** to the discussions and to **attend all three workshops**.

Figure 3: Composition of thematic expert groups



In addition to Article 36 organisations[10], other EU agencies and international organisations that were contacted by EFSA, the project team also invited experts from other research institutions to participate in the exercise. The selection of experts and their allocation within the six TEGs was based on their expressed interest in the thematic areas and in close collaboration with EFSA. As the TEG sessions were organised in parallel, each expert could only be a member of one TEG.

To enhance the validity of the results of the horizon scanning, experts who indicated interest to contribute in the horizon scanning exercise but did not participate in the workshops were included in a pool of challengers. This pool of challengers was invited to provide their feedback and thoughts via a questionnaire reporting on the preliminary results of the exercise after the second workshop (see section 2.3.2.2). A detailed overview of the TEG members for the six topics is presented in Appendix A.1.[11]

2.3.2.2. Workshop implementation and follow up

Following the recruitment of the TEG members, the three workshops were organised over a period of 3 months. Each workshop for the individual TEGs combined plenary and breakout sessions in which all experts took part. In each breakout session, a facilitator and a co-facilitator from the project team were present to structure and drive the discussion forward. Another member of the project team was present in each breakout session to take notes of the discussions and their outcome. Plenary sessions towards the end of each workshop provided experts with an opportunity to present their findings and learn about the progress made by other TEGs.

Jointly, the three workshops covered the eight steps of the horizon scanning (see **Table 2**). The table below (**Table 3**) provides an overview of the steps each workshop addressed.

Table 3: An overview of the steps addressed in each workshop

Workshop	Steps covered
Workshop 1: identification, mapping, and analysis of driving forces	Step 1: Scope definition Step 2: Identification of relevant driving forces Step 3: Mapping of the driving forces Step 4: Analysis of the driving forces
Workshop 2: identification and assessment of issues, challenges, and potential divergences	Step 5: Identification of issues and challenges Step 6: Mapping of issues and challenges Step 7: Identification of potential divergences
Workshop 3: synthesis and identification of recommendations	Step 8: Validation of potential divergences and challenges Step 9: Identification of recommendations

[10] https://efsa.force.com/competentorganisations/s/

[11] Appendices can be found in the online version of this output (in the "Supporting information" section)

The first workshop on the identification, mapping, and analysis of driving forces

The first workshop aimed to identify, map and prioritise driving forces relative to each thematic area. The plenary session began with a formal opening, and a presentation on the scope, objectives, process, and timing of the total project. The facilitators and co-facilitators guided the discussion to explore the driving forces that could influence the risk assessment requirements and challenges in food safety-related regulatory science, per thematic area. The workshop was structured into morning and afternoon sessions, each including a breakout session where experts discussed work areas and driving forces per thematic group. The first breakout session aimed to explore whether work areas had been left out. It also explored the driving forces of proposed thematic areas. In the second breakout session, the mapping and analysis of driving forces was conducted.

The second workshop on the identification and assessment of issues, challenges and potential divergences

The second workshop focussed on the identification, mapping, and prioritisation of potential challenges and divergences related to each thematic area. The second workshop followed the structure of the first and consisted of a morning and afternoon breakout session, where experts discussed issues within their thematic groups. The second workshop explored the following points:

- State-of-the-art science in food safety for that specific thematic area.
- Identification of present and future challenges in food safety policies.
- Risk assessment regarding potential divergences.
- Mapping and ranking of the divergences per consequence/impact.

The third workshop on synthesis and identification of recommendations

The third and final workshop aimed to rank the potential divergences and challenges in food safety-related regulatory science and to provide recommendations with respect to the divergences and challenges that have been identified, including with respect to the use of horizon scanning for future risk assessment. Several sessions were held, interchanging between plenary and breakout sessions. This workshop entailed a final review of the findings per thematic area, with prioritised/clustered divergences, and inputs coming from the challengers (for an explanation of the role of "challengers", see section 2.3.2.3 – Validation by challengers). After a plenary revision of "where we stand" in the horizon exercise, TEG members began the breakout sessions with the discussion on the challengers" feedback and finalisation of the list of challenges and divergences. After reaching a consensus on the list of divergences, participants ranked the divergences according to three criteria: (i) impact for EFSA (preparedness), (ii) sense of urgency (occurrence), and (iii) scientific complexity (complexity). This was followed by a second plenary session in which the co-facilitator of each group presented the TEG top divergence during the plenary. The participants of the plenary had the chance to rank the top six divergences.

Across the implementation, experts contributed actively. Attendance for the individual workshops and breakout sessions was high. **Table 4** below reports the number of participants per workshop, as well as per TEG compared to the number of experts recruited.

Table 4: The number of participants per workshop/TEG compared to the number of experts recruited

	Recruited	Present at workshop 1	Present at workshop 2	Present at workshop 3
TEG 1 - Animal welfare and safety	16	12	9	6
TEG 2 - Exposure science in risk assessment	22	18	13	11
TEG 3 - Nutrition & healthy diets	22	17	15	13
TEG 4 - Safety assessment of innovative products	22	23	23	16
TEG 5 - Sustainable food systems & safety	24	21	16	12
TEG 6 - Evidence-based risk communication	14	11	11	10

To ensure that the results of each workshop were summarised and distributed among participants and shared with EFSA, the project team followed up with a presentation paper after the first and final workshop. The presentation paper was the key document that linked the results of one workshop to the preparations for the next, and it was amended over the course of the three feedback cycles to account for new inputs from the TEGs and from EFSA. The full presentation paper can be found in Appendix A.8[11].

2.3.2.3. Validation by challengers

In order to challenge the views expressed by TEG members, the approach included a validation element by so-called "challengers". Relevant experts who indicated interest in the horizon scanning exercise but did not participate in the workshops were asked to participate in the exercise as challengers. After the second workshop, an interactive background document containing the main outcomes of workshops 1 and 2 was **shared solely with the challengers**. The document was shared via EU survey in the form of a questionnaire, to make gathering feedback as easy and straightforward as possible. The survey link was shared with the selected **55 challengers** via email. The challengers were given one week to provide their feedback on the identified driving forces, potential scientific divergences, and challenges of a thematic area. It was possible for each challenger to provide feedback on more than one thematic area. In total, 24 challengers provided their contributions. The feedback was used as an input for the third workshop and discussed within the TEGs.

2.4. Mapping of ongoing/planned activities and collaboration interests

The main objective of this task was to provide a comprehensive overview of the ongoing and planned activities undertaken by different actors in research projects falling under the remit of EFSA. The mapping was intended to classify activities along different dimensions, allowing for a clear identification of their relevance within each potential scientific theme and work area investigated throughout the horizon scanning. This task resulted in a comprehensive overview of the activities carried out by different stakeholders engaged within the context of the horizon scanning exercise and to solicit feedback on the potential for collaboration in each thematic area that was identified throughout the horizon scanning implementation. The results of this task have been combined with the outcomes of the horizon scanning exercise in the analysis and synthesis of findings.

The implementation of this task relied on two different activities running in parallel:

- Desk research
- Survey

2.4.1. Desk research

Desk research aimed to identify available information on research projects, while paying specific attention to ongoing and planned activities carried out at national and EU levels in relation to the challenges and potential scientific divergences identified. Considering the heterogeneity of publicly available information, the desk research was done following a structured methodology, based on a Boolean operator[12] developed per thematic area and based on a set of keywords used for screening research projects (see Appendix A.5[11]). The desk research was implemented following the steps described below.

Step 1: Identification of data sources

As a first step, at the inception stage potential data sources for the screening were identified. Given the variety of information available, multiple data sources were identified to ensure a wide coverage across different types of projects. Appendix A.4[11] provides an overview of the databases consulted at the inception stage.

Step 2: Preliminary screening of projects and assessment of data sources

After identifying the potential data sources, a first screening of the available information was implemented, relying on a series of preliminary keywords based on the definition of each thematic area. The aim of this exercise was to test the feasibility of the proposed methodology and to identify the most appropriate databases for screening. In particular, we assessed whether the databases contained all the information we aimed to collect for each project while ensuring that any duplicates were excluded from our collection.

At the end of the screening, we concluded that CORDIS represents the most relevant database as it is the primary source of results from the projects funded by the EU's framework programmes and contains extensive information about projects.

[12] For definition of Boolean operator please see https://library.alliant.edu/screens/boolean.pdf

All other data sources were excluded as they did provide the project information needed or were built on CORDIS (making the search redundant). In particular, the H2020 database, EFSA database, the ERA-LEARN database and the TIM database rely on CORDIS. As such, they do not seem to add to the original source. In the CHAFEA Health Programmes Database, the advanced search does not work with Boolean operators and keywords are predefined by the platform. Hence, the set of keywords identified is not applicable. The same issue is identified for the FAO database, which works with predefined keywords not suitable for our approach. Use of the Basic search tool was considered, but, in any case, the database does not allow downloadable lists. Similarly, the advance search option of the LIFE Programme Database provides only predefined keywords, making the set of keywords identified unusable. Moreover, the content and topics of this database do not appear adequate for the scope of our search. For the ERA-LEARN database, basic search tools different from Boolean operators are available, but the output lists appear limited in the number of projects yielded per thematic area.

Step 3: Screening of projects

In the third step of the desk research, a thorough screening of ongoing research projects in CORDIS was carried out. To perform this step, six operating Booleans were developed, one per each thematic area, based on a set of keywords (see Appendix A.5[11]). The latter were defined building on the results of the second workshop. In particular, challenges and scientific divergences identified were translated in research topics and used as keywords to carry out the research activities. An overview of the results of the desk research is presented in Appendix A.5[11].

After the screening of projects, evidence collected from CORDIS was cross-checked to avoid replication and to filter out redundant information. The relevance of each identified research project was assessed based on the informed opinion of the co-facilitators, who also used the results from the workshop discussions to further screen the information collected via desk research.

With regard to international research projects, the analysis relied on the information obtained via the survey (see section below). Stakeholders from identified international organisations were included in the sample and asked to reply to the online questionnaire to ensure that international research projects are also considered.

In addition, we used the same Boolean operators used for the screening in CORDIS to search for research papers in Web of Science. The key objective of this additional exercise was to identify key stakeholders in the six thematic areas that could be engaged for the survey. For each thematic area, we ranked the ten researchers and organisations with the highest number of publications and also disseminated the survey to those researchers/organisations.

2.4.2. Survey

The second activity of the "mapping of ongoing/planned activities and collaboration interests" consisted of a survey targeting experts. The aim of the survey was twofold:

- **Complement the desk research** by gathering information on the activities related to research projects undertaken by research institutions identified during the inception phase.
- **Collect stakeholder feedback** on the potential for establishing collaboration across different scientific thematic areas.

The survey was launched via the online tool EU Survey on the 25th October 2021 and remained open for three weeks (until the 12th of November). The survey was initially shared with a list of 146 stakeholders, agreed and validated by EFSA, belonging to:

- EU agencies and bodies providing scientific assessment on topics related to one or more of the scientific thematic areas.
- Scientific research institutes.
- International organisations responsible for research projects whose scope falls under the remit of the horizon scanning.

To ensure that international research projects were included, a particular effort was made into reaching out to international organisations. This helped enhance the scope of the "mapping of ongoing/planned activities and collaboration interests", also covering third country projects.

As mentioned above, the survey was also disseminated to 60 other key stakeholders identified as a result of the screening carried out in Web of Science (see section above). The list of organisations/research groups that were contacted to respond to the survey is presented in Appendix A.2[11].

The survey questionnaire was developed building on the inputs collected during the first two workshops and the research topics were formulated based on challenges and potential scientific divergences. It consisted of a combination of open and closed questions, with the following objectives:

- Collect general information about the respondents (*i.e.* name, name of organisation, country, etc.) and the thematic areas within which their organisation/research groups are involved.
- Collect information on ongoing and/or planned research projects implemented by the stakeholders for selected research topic(s).
- Investigate stakeholder levels of interest in setting up collaborations in the six thematic areas covered by the study.

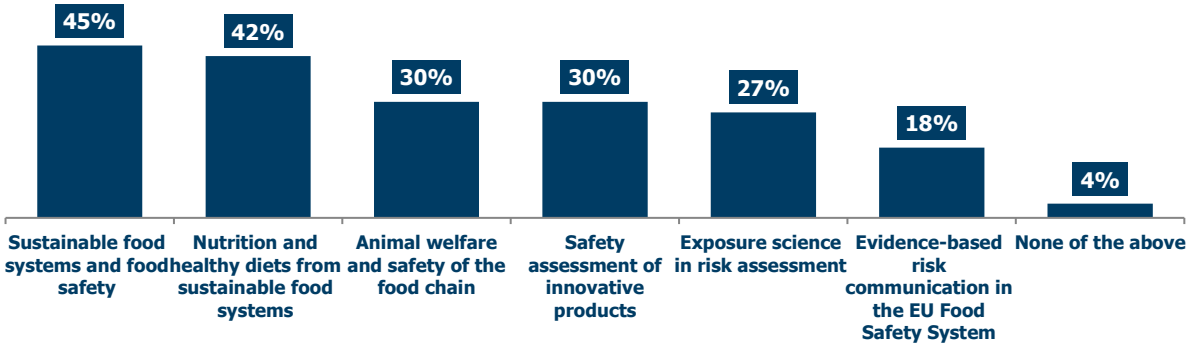
The structure of the questionnaire is provided in Appendix A.6[11].

Overall, among the 206 stakeholders contacted, 110 responded to the survey, of which 76% (84) responded on behalf of a research group and 24% (26) on behalf of the organisation they work for.

In terms of geographical coverage, the respondents come from 24 countries: 18 Member States and 5 non EU countries (Australia, China, Japan, United Kingdom and United States). As noted, the survey questionnaire was structured around the six thematic areas covered by the study. The distribution across them is presented in **Figure 4** below.

Figure 4: Distribution of respondents across thematic areas[13]

[13] Please note that the option "None of the above" corresponds to responses provided from additional stakeholders that were identified from the desk research (see section 2.4.1) and who were not involved in the horizon scanning exercise.



2.5. Synthesis

The synthesis and accompanying recommendations built on the results of the horizon scanning exercise, and the mapping of research activities, providing insight on the state of play of ongoing research and its coverage of potential divergences and challenges in each thematic area. The horizon scanning resulted in an assessment of all potential divergences across three parameters: i) impact for EFSA and on its preparedness strategy, ii) sense of urgency, and iii) scientific complexity, while challenges were assessed on a likelihood – time horizon scale. The aim of such a benchmarking exercise was to indicate divergences and challenges that stood out as being potentially more impactful and would thus require immediate action. Additionally, each potential divergence was categorised against a readiness level. Categorising the potential divergences helped the panel construct recommended actions. Three categories of readiness were defined for the exercise:

1. Concept level
2. Already established/developed tools, methods, or data
3. Extensive knowledge is present but no consensus (yet)

The first, conceptual readiness level, presented a problem where we only have a basic understanding of the issue. Potential actions linked to preventing such issues from materialising include research projects (coming from EFSA or other sources such as Horizon Europe). The second category describes a situation where there are certain established or developed tools, methods and data, however, there are still knowledge gaps or lack of agreement amongst the research community. Potential actions to address issues categorised at this level include research geared towards regulatory science but also other initiatives such as those available at member state level. On EFSA's side this can include issuing guidance (e.g. via formation of working groups) or conducting case studies to prove validity of research. The third category entails a state where there is extensive knowledge on an issue but no consensus on specific aspects related to it (*e.g.* agreement on datasets required). If there is no consensus, EFSA can foster dialogue and eventually may publish opinion(s) on the issue.

The recommended actions are presented per identified potential divergence and are dependent on the readiness level of each divergence. The synthesis reflects on any potential blind spots in any of the thematic areas by reflecting on the overall rating of a divergence (*i.e.* the sum of the urgency, complexity and level of (regulatory) preparedness assigned to the divergence by the Delphi panel) and the level of ongoing research on the related topic.

3. Results per thematic area

This section presents the findings of the project. For each thematic area the findings of the horizon scanning exercise are first presented, as gathered in the workshops, followed by the results of the mapping of research activities. The findings were synthesised for each thematic area and are accompanied by recommended actions.

3.1. Thematic area 1: Animal welfare and safety of the food chain

The thematic area of animal welfare and safety of the food chain focused on five work areas.

Work area 1 concerns **animal welfare on farm**, which considers how animal welfare can be affected on farm. Animal, environment, and farm management and practices, such as housing systems used and farming practices (*e.g.* mutilations), fall under this work area.

Work area 2 refers to **animal welfare during transport** and considers how animal welfare can be affected during transport. Several factors related to animals (such as body condition, age and fitness for transport), micro climatic and environmental factors (such as temperature and humidity) as well as other factors (such as loading density, transport route, resting, watering, and feeding) were raised during the workshop discussions. The fitness of animals for transport is an issue that falls under this work area, as well as the issue of transport of "end of career animals". Long duration transport are those which have the potential to mostly impair animal welfare. This relates to intra- or inter-country transport or export to third countries (by road, boat or even airplane) of free moving animals such as cattle, veal calves, slaughter pigs, sheep and goats, etc. Issues involving watering, feeding and the availability and suitability of resting areas fall under this work area. In addition, challenges relating to hot weather and its effect on animal welfare are also covered by this work area.

Work area 3 considers the **welfare of animals at slaughter.** Animal, environment, and management factors during the lairage, pre-stunning, stunning (by penetrating bolt, by electrical device, or by CO_2, etc.) and bleeding phase, as well as ritual slaughter, were raised for further discussion.

Work area 4 considers the **animal welfare labelling and certification.** A label is any claim made on a product, but such a claim may or may not be regulated by a public or private agency. A certification, however, refers to a label where specific standards have been adhered to. Organisations which issue such certificates to producers are controlled by an accreditation or governing body if the certification scheme meets these standards. In some countries the government may approve private certificates which may result in reduced inspection frequencies.

Work area 5 refers to **risk assessment (including exposure science) of animal welfare**. It considers how risk assessment of animal welfare contributes to animal welfare and which driving forces and scientific divergences are at stake.

3.1.1. Results of the horizon scanning

The horizon scanning exercise resulted in 11 potential divergences and 10 challenges for thematic area 1 on animal welfare and safety of the food chain. These are listed in **Table 5** below.

Table 5: Potential divergences and challenges on animal welfare and safety of the food chain identified by the Delphi panel

Potential divergence	Challenge
Work Area 1: Welfare of animals on farm	
1. Establishing scientific criteria for reduction of use of antimicrobials before animal health and welfare is compromised.	1. How can animal welfare benefits be balanced with other public values such as food safety, biodiversity, animal health, or climate and environment.
2. Need for transformation from simple indicators towards more benchmarking indicators on trends over time and for different production systems.	2. One welfare concept – not yet a mature field, so concept and analyses are unclear.
3. Quantification of animal welfare criteria and weighing animal welfare versus animal health/climate/environment, etc: multicriteria analysis	3. How to assess benefits of investments in housing and other facilities for better welfare of animals
4. How to balance the way that alternatives for climate and environment protection may affect animal welfare	
Work Area 2: Animal welfare during transport	
5. Scientific agreements on maximum transport distances and durations for transport of live animals	4. Where to locate animal production given fewer slaughterhouses, which may lead to more concentration of animal farming near slaughterhouses when transport is restricted but has as the co-effect of requiring longer and more costly transport to distribution/processing centres
	5. How a disease outbreak should affect transport of live animals
6. Which data are meaningful to monitor animal welfare related to transport by car, ship or plane	6. How to balance climate change and animal welfare risks with risk of harming the EU economy
	7. Contribution of live animals for land preservation in specific territories
	8. Difficulties in weighing need for animal transport by ship or plane due to lack of data
Work Area 3: Welfare of animals at slaughter	
7. How to balance meat and carcass quality and food safety with animal welfare on scientific criteria	9. What are requirements that should be asked from people performing ritual slaughter
8. To what extent animal welfare data should be collected, which data to collect, how to collect data and the standardisation of data; and data availability	
Work Area 4: Animal welfare labelling (and certification)	
9. Which are crucial indicators to be used for what to put on labels on animal welfare	10. Which information would be required on animal welfare labels and what can be put on the label for consumers to understand

Potential divergence	Challenge
	11. How to weight animal welfare against climate/sustainability/other issues in labels
Work Area 5: Risk assessment (incl. exposure science) of animal welfare	
10. Which (field)data to collect; which indicators, standardisation, approach to measurement (how to quantify)	12. How to balance animal welfare with climate and efficient management of resources, and biodiversity
11. How to develop animal welfare methodology (risk benefit analysis) and how to develop methodology in a way that the risk managers (*i.e.* Competent Authorities, Commission) can establish thresholds, benchmark options	

Work Area 1: Welfare of animals on farm

A potential divergence could be linked to **establishing acceptable levels of reduction in the use of antimicrobials before animal health and welfare is compromised** due to lack of sufficient medicines, or that the creation of an acceptable minimal usage (in and of itself) would decrease the incentive to seek or develop alternatives for antimicrobials. This means certain antibiotics may be excluded from animal use, hence risking inability for proper treatment, which could lead to animal welfare issues. In this context, creating a maximum percentage of antimicrobial usage reduction was not supported as an indicator because (high) antimicrobial usage reduction can still mean high usage in practice. Therefore, the actual antimicrobial usage in quantity (as daily dose or equivalent absolute indicator) was considered to be a better indicator.

Other potential divergences identified refer to the use of data. In particular, a **potential divergence is linked to the need for a transformation from a variety of available indicators for single welfare topics towards more integrated benchmarking indicators on trends over time and for different production systems.** It is important to consider this over a longer time horizon. Furthermore, the creation of meaningful data versus mere data creation without established benchmarking and monitoring based on a limited dataset was debated as a task for science and policymakers to address.

Another potential divergence links to data usage, specifically the question **how to weigh animal welfare versus other public values such as animal health, climate and environment – this will require a multicriteria analysis.** The weighing of multiple public values will become increasingly important but it is very difficult to address, and will most likely cause scientific and public debate. As such, it falls under the domain of risk management. Nevertheless, the political debate could be eased if supported by scientific assessment regarding maximum risk reduction when considering combining such values.

Another potential divergence refers to climate and environment, in particular **how to balance the ways that alternatives for climate and environment protection may affect animal welfare.** Namely, scientific debate will be needed to indicate possible gains and benefits of current practices and how these could be balanced against alternatives (illustrating consequences of different scenarios).

While balancing gains and benefits against alternatives in itself is a matter of political debate, science can provide data that can feed into the political decision process.

In addition to the potential divergences described above, several challenges were also identified under this work area. One of them emerged out of the **One Welfare concept**, which is still not well developed. It sometimes also contains the environmental element which is not yet a mature field. Another topic of discussion was related to how welfare pressure might positively impact farmers' welfare (following the positive impact of seeing animals in better shape), but may also negatively impact farmers when investments for better animal welfare are not paid back to farmers and instead end up mostly in the downstream supply chain (retail, internet, shops). Thus, science-based information could help with ensuring transparency on required return on investment at farm level bearing in mind different public values.

Moreover, one of the challenges links to whether and **how animal welfare benefits can be balanced against other public values such as biodiversity, animal health, climate and environmental health**. For example, outdoor farming claims land from nature, with possible negative consequences for biodiversity (biodiversity risk); outdoor poultry may contract avian influenza from migratory birds or outdoor pigs may contract African Swine Fever from wild boars (animal health risks); and outdoor farming raises the carbon footprint (climate risk). It was argued that contagious disease outbreaks also occur in highly bio secure indoor animal production systems.

Finally, another challenge relates the question of **assessing the benefits of investments in housing and other facilities for better welfare**. This may also hamper innovation and progress in practice because farmers hesitate to change, not knowing which investments are optimal.

Work Area 2: Animal welfare during transport

Under this work area, a potential divergence relates to the economic viability of the reduction in transport of live animals. In particular, it links to **scientific agreements on maximum transport duration for live animals**, especially when slaughter plants are also present "nearby" (~5 hours). The second potential divergence refers to data needs and concerns regarding **which data are meaningful to monitor animal welfare related to transport by car, ship or plane.** The background of this point is the assumption that reduced transport options would drive geographical concentration of animal production sites and slaughtering plants to ultimately possible integration.

In addition, several challenges were discussed by the Delphi panel. Most of them refer to economic viability of the driving force to limit live animal transport. One challenge arises from the **risk of concentrating animal farming closer to slaughterhouses. This reduces the time required for animal transport but at the same time consistently increases the time and costs for transport to distribution/processing centres**. The driving force may lead to more concentration of animal farming near slaughterhouses. It might also induce longer transport of meat from slaughtering plants to processing plants. This could initiate a trend for more smaller scale (even mobile) slaughterhouses near areas with animal production. But the challenge might arise around the extent to which this is advisable, because smaller slaughterhouses might be less reliable in maintaining high levels of food safety and animal welfare.

Another challenge can come from the question of **how to balance climate change and animal welfare risks with the risk of harming the EU economy**. There is the risk that the demand for live animal transport to third countries (mostly to Islamic North-African/ Middle Eastern countries) is replaced by import from outside EU (*e.g.* South-America, Australia) with serious climate change and animal welfare risks. Experts argued that the market demand would simply be replaced with animals from outside the EU. Finally, a challenge refers to the **need to transport live animals to islands** where animals have an explicit role in territorial preservation (*e.g.* pigs/cattle on the Canary Islands).

Work Area 3: Welfare of animals at slaughter

A potential divergence relates to the question of **how to balance sometimes conflicting meat and carcass quality and food safety benefits with animal welfare consequences on scientific criteria**. An example of this is the gas stunning of pigs. CO_2 may be considered a good stunning method from the slaughterhouse (food business operator) viewpoint but not from the pig's welfare viewpoint. Electric stunning may be better for the animals, but there are technical issues and meat quality may be affected. This requires balancing pros and cons for creating food waste against possible animal welfare benefits. The second identified potential divergence links to data on animal welfare. More specifically, to **what extent animal welfare data should be collected, which data should be collected, how to collect data and the standardisation of data, and data availability.**

Only one challenge was discussed under this work area. It links to the question of **what requirements should be set for workers performing ritual slaughter.** Some experts claimed that it is not clear which requirements should be placed on those working in slaughterhouses. This would be particularly important for people performing slaughtering without stunning as killing without stunning causes serious welfare consequences. However, other experts argued that sufficient documentation is available on how to perform ritual slaughter.

Work Area 4: Animal welfare labelling (and certification)

Only one potential divergence was identified under this work area. It is linked to determining the **crucial indicators to be used for what to put on labels on animal welfare** and the practicality of providing such information on the label.

In addition to the divergence, a challenge is related to **which information would be required on animal welfare labels.** The question is whether labels should also be able to contain indicators on slaughter data (*i.e.* stunning – in appropriate way rather than yes/no; or for ritual slaughter: yes/no), transport, etc. Another challenge could emerge from the question of **how to weigh animal welfare against climate, sustainability or other issues in labels.**

Work Area 5: Risk assessment (incl. exposure science) of animal welfare

A potential divergence links to the question of **which (field)data to collect and which indicators, methods of standardisation, means of measurement (how to quantify) and quality of thresholds (good/bad/acceptable/other) to use**. This is applicable to all production phases (on farm, transport, and slaughter). Science should offer clarity and validate essential data on animal welfare.

The need for thresholds for animal, environmental and management indicators on fitness for travel was strongly highlighted. Although this is a risk management rather than a risk assessment element, it was considered important to mention as it is seen as a crucial element for animal welfare improvement. Risk assessment studies should contain indicators with defined thresholds in order to be useful in practice, since much debate arises when no threshold is defined (including court cases instigated by inspectors against the private sector). The Transport Regulation uses open norms for many requirements (*e.g.* "adequate", "sufficient"). Interpretation of these open norms can differ among member states and between them and NGOs.[14]

Another potential divergence was identified regarding **how to adapt the animal welfare methodology (risk benefit analysis) to system approach/exposure science** and **how to develop the methodology in such a way that the risk managers (*i.e.* Competent Authorities, Commission) can establish thresholds and benchmark options.**

The challenge identified under this work area refers to the question of how to balance considerations not only for animal welfare but also for climate and efficient management of resources, as well as biodiversity (multicriteria analysis system approach/exposure science).

3.1.2. Results of the mapping exercise

The mapping of research activities on animal welfare and safety of the food chain combined responses from the survey targeting research groups across the world and the screening of ongoing relevant research projects. Based on the potential divergences and challenges described in the section above, the survey questioned participants on several research topics. **Table 6** below shows the correspondence between potential divergences, challenges and research topics.

Table 6: Research topics linked to potential divergences and challenges in animal welfare and safety of the food chain

Research topic	Potential divergence	Challenge
Work Area 1: Welfare of animals on farm		
1. Effect of the reduction of uses of antimicrobials in animal husbandry	1. Establishing scientific criteria for reduction of use of antimicrobials before animal health and welfare is compromised.	NA
2. Identification of animal welfare indicators for benchmarking	2. Need for transformation from simple indicators towards more benchmarking indicators on trends over time and for different production systems.	NA
3. One welfare concept	NA	1. One welfare concept – not yet a mature field, so concept and analyses are unclear.

[14] For more details see https://www.europarl.europa.eu/RegData/etudes/STUD/2018/621853/EPRS_STU(2018)621853_EN.pdf

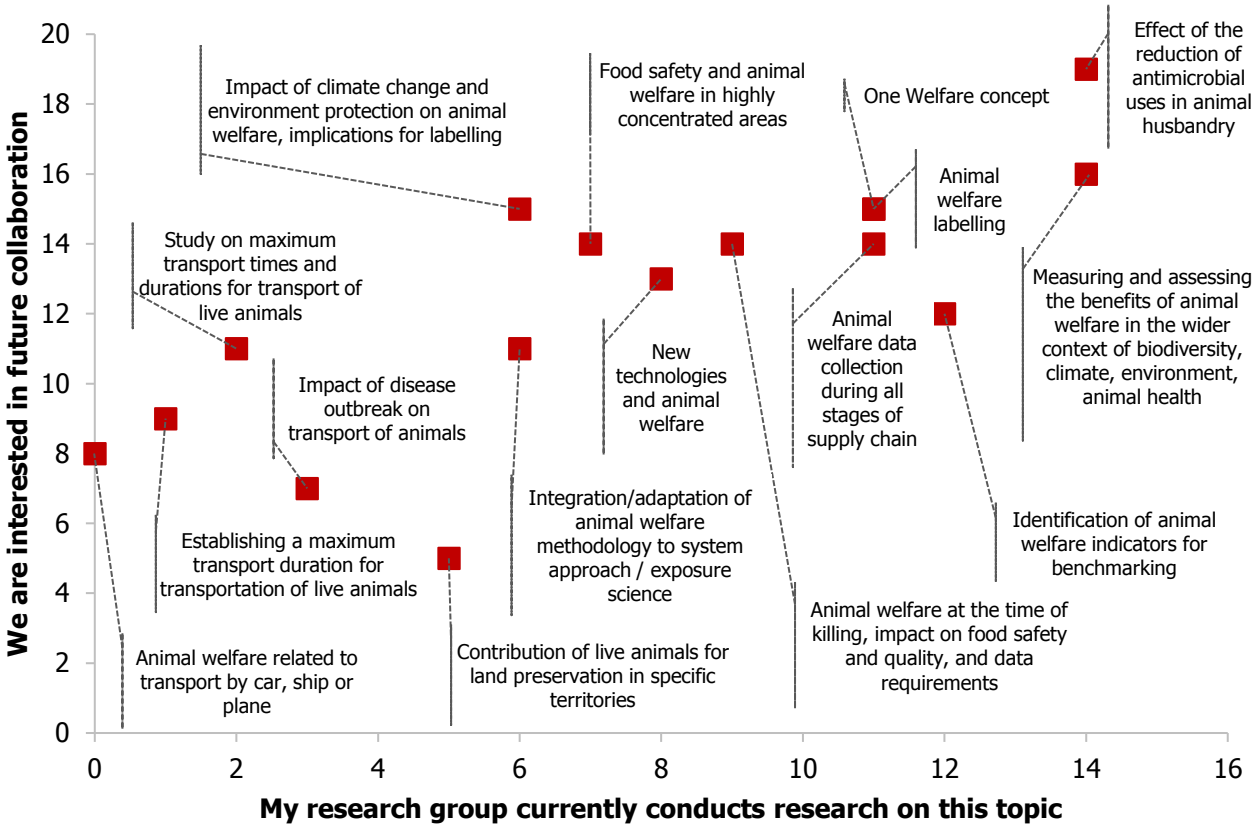
Research topic	Potential divergence	Challenge
4.Measuring and assessing the benefits of animal welfare in the wider context of biodiversity, climate, environment, animal health	3. Quantification of animal welfare criteria and weighing animal welfare versus animal health/climate/environment etc: multicriteria analysis	2. How can animal welfare benefits be balanced with other public values such as food safety, biodiversity, animal health, or climate and environment.
5. Impact of climate change and environment protection on animal welfare, implications for labelling	4. How to balance the way that alternatives for climate and environment protection may affect animal welfare	
6. New technologies and animal welfare	NA	3. How to assess benefits of investments in housing and other facilities for better welfare of animals
Work Area 2: Animal welfare during transport		
7. Establishing a maximum transport duration for transportation of live animals	5. Scientific agreements on maximum transport distances and durations for transport of live animals	4. How to balance climate change and animal welfare risks with risk of harming the EU economy
8. Study on maximum transport times and durations for transport of live animals		
9. Food safety and animal welfare in highly concentrated areas	NA	5. Where to locate animal production given fewer slaughterhouses, which may lead to more concentration of animal farming near slaughterhouses when transport is restricted but has as the co-effect of requiring longer and more costly transport to distribution/processing centres
10. Impact of disease outbreak on transport of animals	NA	6. How a disease outbreak should affect transport of live animals
11. How to best generate meaningful data for animal welfare related to transport by car, ship or plane	6. Which data are meaningful to monitor animal welfare related to transport by car, ship or plane	7. Difficulties in weighing need for animal transport by ship or plane due to lack of data
12. Contribution of live animals for land preservation in specific territories	NA	8. Contribution of live animals for land preservation in specific territories
Work Area 3: Welfare of animals at slaughter		
13. Animal welfare at the time of killing (including ritual slaughter), impact on food safety and quality, and data requirements	7. How to balance meat and carcass quality and food safety with animal welfare on scientific criteria	9. What are requirements that should be asked from people performing ritual slaughter
	8. To what extent animal welfare data should be collected, which data to collect, how to collect data and the	

Research topic	Potential divergence	Challenge
	standardisation of data; and data availability	
Work Area 4: Animal welfare labelling (and certification)		
14. Animal welfare labelling: indicators, data requirements	9. Which are crucial indicators to be used for what to put on labels on animal welfare	10. Which information would be required on animal welfare labels and what can be put on the label for consumers to understand
		11. How to weight animal welfare against climate/sustainability/other issues in labels
Work Area 5: Risk assessment (incl. exposure science) of animal welfare		
15. Animal welfare data collection during all stages of supply chain (indicators, standardisation, threshold)	10. Which (field)data to collect; which indicators, standardisation, approach to measurement (how to quantify)	12. How to balance animal welfare with climate and efficient management of resources, and biodiversity
16. Integration/adaptation of animal welfare methodology (risk benefit analysis) to system approach / exposure science	11. How to develop animal welfare methodology (risk benefit analysis) and how to develop methodology in a way that the risk managers (*i.e.* Competent Authorities, Commission) can establish thresholds, benchmark options	

Results of the survey on research activities and interest in collaboration

The survey collected information on ongoing and planned research activities related to animal welfare and the safety of the food chain from 33 research groups/organisations covering 11 countries. **Figure 5** shows that most of the research on animal welfare and the safety of food chains relates to "**establishing scientific criteria for reduction of use of antimicrobials**" and "**quantification of animal welfare criteria and weighing animal welfare**". The latter also represents the divergence considered the most pertinent by the Delphi panel as it was placed in the lowest readiness level (*i.e.* conceptual stage) and as having a high impact on EFSA preparedness. Overall, research groups from several different countries indicated they were conducting research on an array of topics related to animal welfare. Nevertheless, two research topics have not yet received much attention in the research community: "establishment of a maximum transportation time for transportation of live animals" and "how to best generate meaningful data for animal welfare related to transport".

Figure 5: Overview of research groups conducting research and expressing interest in TEG 1 research topics



Source: Survey on mapping of research activities and collaboration interest

As mentioned above, **quantification of animal welfare criteria and weighing animal welfare versus animal health/climate/environment** (divergence 3) was considered as one of the two most pertinent divergences by the Delphi panel. The importance and interest for the related research topic "**measuring and assessing the benefits of animal welfare in the wider context of biodiversity, climate, environment, animal health**" was confirmed by the survey results, which showed that it was the most popular research topic by number of research groups currently working on it (14 research groups). In addition, more than half of the research groups working on this thematic area are interested in collaborating. This research topic is also related to two challenges. The first, how to balance animal welfare benefits against other public values such as food safety, biodiversity, animal health, or climate and environment" (challenge 2), and the second, how to balance animal welfare with climate and efficient management of resources, and biodiversity" (challenge 12).

The divergence related to the **development of animal welfare methodology** (divergence 11) was also considered as having a high impact on EFSA's preparedness strategy by the Delphi panel. However, the ongoing and planned research on the related research topic "integration/adaptation of animal welfare methodology (risk benefit analysis) to system approach / exposure science" is limited, with six of research groups from two different countries indicating they were conducting research on this topic.

Nevertheless, the interest for future collaboration is considerable, with 11 research groups (representing 30% of respondents) indicating they would cooperate on this topic.

As mentioned, the potential divergence **establishing scientific criteria for reduction of use of antimicrobials before animal health and welfare might be compromised** (divergence 1) is the second most researched topic within the thematic area, with 14 research groups currently conducting research and nine research groups planning to do so in the future. In addition, this research topic was indicated as interesting for future collaboration by 19 research groups, more than 50%[15] of respondents to the survey.

The Delphi panel stressed the need to determine **which (field)data to collect, which indicators to use, as well as standardisation and approach to measurement** (divergence 10), implying the need to define clear guidance to establish a common approach. The Delphi panel considered this as the divergence having the highest impact on EFSA preparedness. The survey showed that 14 research groups indicated interest in future collaboration in addition to the ongoing and planned research on the topic, as indicated by 11 and seven research groups, respectively.

The least researched topic in the thematic area on animal welfare and safety of food chains is related to **meaningful data to monitor animal welfare related to transport by car, ship or plane** (divergence 6)**.** None of the research groups that took part to the survey have ongoing or planned research related to this topic. However, a considerable number of respondents reported interest for future collaboration. A similar situation is shown for the potential divergence arising from the need for **scientific agreements on maximum transport times, distances and durations for transport of live animals** (divergence 5). As for the potential divergence above, only one research group indicated ongoing and planned activities but the interest for future collaboration is relatively higher (nine research groups). For both divergences, this element seems to indicate a possibility for the divergence to materialise and a strong need for research on the field.

The potential divergence **need for transformation from simple indicators towards more benchmarking indicators on trends over time and for different production systems** (divergence 2) showed a relatively high number of research groups (12) conducting research in the field and interested in future collaboration on the topic.

Finally, the least urgent potential divergence as assessed by the Delphi panel was **"how to balance meat and carcass quality and food safety with animal welfare on scientific criteria"** (divergence 7)**.** According to the survey, nine research groups are currently conducting research "animal welfare at the time of killing and impact on food safety and quality", four research groups from five different countries are planning to do it in the future and 14 research groups are interested in collaborating on this topic.

Ongoing EU-funded research projects related to animal welfare in risk assessment

The mapping of multi partner large scale EU ongoing research activities showed that there are two ongoing projects related to animal welfare (see **Table 7**). The full project descriptions and links are available in Appendix A.5 [11].

[15] The percentage indicates the share of research groups out of total responses for thematic area exposure science in risk assessment.

Table 7: List of identified projects related to animal welfare and safety of the food chain

Topic	Project name	Project description
Animal welfare labelling	MEAT-QUALITY	The project aims to provide consumers with quality pork and broiler meat, by developing novel solutions that address societal demands, environmental concerns and economic needs on farm and in the chain. Animal welfare is addressed in the third step of the project, that will check the novel farming practices against sustainability aspects: animal welfare, environmental impact and economic viability. It relates indirectly to the identified divergence on animal welfare labelling, where new farming practices need to be communicated to the consumer, by branding, labelling and so forth.
Animal welfare in highly concentrated areas	CHICKENSTRESS EUROPEAN TRAINING NETWORK	It aims to study factors responsible for hens" stress and what makes them stress resistant. While not directly linked to a divergence, it relates to research on "animal welfare in highly concentrated areas.

3.1.3. Recommended actions

Recommended actions were discussed by the Delphi panel for the two potential divergences identified as key priorities based on the readiness categorisation under the thematic area animal welfare and safety of food chain:

- "How to develop animal welfare methodology (risk benefit analysis)" and "How to develop methodology in a way that the risk managers (*i.e.* Competent Authorities, Commission) can establish thresholds".
- Which crucial indicators should be put on labels to convey information about animal welfare?

Divergence 11 (Work Area 5): "How to develop animal welfare methodology (risk benefit analysis)" and "How to develop methodology in a way that the risk managers (*i.e.* Competent Authorities, Commission) can establish thresholds"

As mentioned above, the Delphi panel considered the potential divergence "how to develop animal welfare methodology (risk benefit analysis)" and "how to develop methodology in a way that the risk managers (*i.e.* Competent Authorities, Commission) can establish thresholds" as a key priority. The main action discussed was the need for a research project in the field, involving social/environmental scientists, to cover issues related to other public values such as climate and environment. Since this is not considered a new area of research, another action suggested was the creation of a (possibly self-mandated) working group to address aspects related to the lack of consensus on what are meaningful animal welfare data. Alternatively, EFSA could consider addressing the issue within an existing working group.

	Actions recommended
1	Research project focusing on the topic, involving social/environmental scientists, to cover issues related to other public values related to climate and environment (possibly under Horizon Europe).

	Actions recommended
2	Inclusion within an existing working group or creation of a (possibly self-mandated) working group to define indicators for data collection on animal welfare in animal production chain, and to relate values of such indicators to levels of risk mitigation, to facilitate risk managers to define thresholds for animal welfare indicators.

Divergence 9 (Work Area 4): "Which are crucial indicators to be put on labels for animal welfare?"

The main potential action identified for this potential divergence is to establish a working group. Tools and methods for identifying animal welfare consequences, are currently available but are too complicated to be put on a label. Some indicators might be difficult to interpret for consumers, such as housing dimensions, transport conditions, or dust and/or ammonia levels in pig housing. Development of different labelling scenarios was named as one of the possible activities, using images such as a happy cow or traffic lights, aggregate names (*i.e.* meadow milk, rooting pig), or housing details, to study the consequences of different labelling scenario's on economics, to elaborate on wider implications, to consider societal aspects and to study consumer attitudes related to different labelling scenarios on animal welfare.

	Actions recommended
1	Establish a working group (possibly self-mandated).

3.2. Thematic area 2: Exposure science in risk assessment

The thematic area of exposure science in risk assessment focused on three work areas.

Work area 1 focused on the **move from a single-route exposure assessment to an aggregate exposure assessment**, which would consider multiple exposure sources (*e.g.* diet, environment, workplace, etc.) and exposure routes (oral, dermal and via inhalation). Currently, EFSA opinions focus on diet as part of its primary remit of the chemical exposure assessment. More holistic assessments are also called for in other areas. For instance, by the new EU chemical strategy for sustainability, where an alignment on the "One-substance-one-assessment" approach might push towards more aggregate assessments and allow ultimately the prioritisation of routes and sources of exposure for risk management activities.

Work area 2 considers how to **develop EFSA's framework, guidance and tools for exposure reconstruction to chemicals via (forward and reverse) dosimetry**, as EFSA currently does not have a guidance document on harmonised methods for aggregate exposure assessment to address exposure to chemicals from different routes and sources. With the trend of moving towards more aggregated exposure assessments, there is a need to develop respective guidance and tools. Forward and reverse dosimetry are useful for the calibration and validation of aggregate exposure assessments (useful to remedy the lack of information in dietary sources/intakes).

Work area 3 considers **how to develop standards for the integration of EFSA Open Access Tools for the collection of dietary data in new exposome/Human Biomonitoring (HBM) studies**. This work area is linked to the increasing availability of personal data (use of consumer products, air

pollution, physical activity, biomarkers of exposure, etc.) that might be relevant to assess chemical exposure from multiple sources. However, such data are not currently collected with a view of integrating them with EFSA exposure assessment/risk assessment workflow, and there is no clear framework for the correct integration and interpretation of such data and related uncertainties.

Beyond the work areas mentioned, more general issues linked to exposure assessment could be considered as part of this thematic area, such as the choice of population on which the risk assessment is based (consideration of local exposure vs general / average exposure).[16]

3.2.1. Results of the horizon scanning

The horizon scanning exercise resulted in a list of six potential divergencies and six challenges on the thematic area of exposure science in risk assessment, as shown in **Table 8**.

Table 8: Potential divergences and challenges on exposure science in risk assessment identified by the Delphi panel

Potential divergence	Challenge
Work Area 1: From single-route exposure assessment to an aggregate exposure assessment	
1. Use of different estimates to combine routes / make different assumptions / different decisions on how conservative the assessment should be	1. Data more likely to be missing in aggregated exposure assessments because greater numbers of routes assessed lead to higher levels of uncertainty, and varying levels of uncertainty across datasets.
2. Use of different approaches as to when and how aggregated exposure assessments should be done	2. Level of risk may differ across different routes of exposure, making aggregated exposure assessments more complex.
3. Use of different datasets leading to divergence (hotspots, route of exposure, point of entry, inhalation, etc.)	3. EU legislation requiring single-route exposure assessment in many cases. As a result, regulations may push in different directions: push for "One substance, one assessment" and aggregated exposure assessments versus sectoral regulation pushing for single-exposure assessment.
Work Area 2: Developing EFSA's framework, guidance and tools for exposure reconstruction to chemicals via (forward and reverse) dosimetry	
4. Potential divergence between EFSA guidance and other risk assessment bodies or agencies (*e.g.* ECHA) regarding forward and reverse dosimetry	4. The development of a common denominator for internal exposure will be challenging.
5. Different observations based on the biomonitoring data available	5. Lack of internal reference values and kinetic data to interpret human biomonitoring data.
Work Area 3: EFSA Open Access Tools for collection of dietary data in new exposome/HBM Studies	
6. Methodology to use and integrate open dietary data in new exposome/HBS	6. Challenges in using open data (*e.g.* integrating them in the assessments, assessing the level of acceptable uncertainty).

[16] These issues were not further elaborated during this horizon scanning exercise.

Work Area 1: From single-route exposure assessment to an aggregate exposure assessment

Aggregated exposure assessments are more complex overall than single route assessments, as they require data from many different sources and via several routes thereby increasing the likelihood that key input data and information will be missing for some of the exposure routes. Aggregate exposure assessments may also require more assumptions to be made about exposure scenarios and decisions about the optimal level of conservativism to be applied when judging and interpreting the available data. This might lead to divergences in the aggregated exposure assessment stemming from different judgements, decisions and interpretations from different risk assessment bodies.

Potential divergences may be generated as a result of differences in assessment outcomes coming from different assumptions and the interpretations regarding the same data, as well as differences in outcomes stemming from variable scope assessments (*e.g.* looking at different routes or using different datasets). It is therefore possible that **different risk assessment bodies (*i.e.* agencies) use different datasets in risk assessment leading to divergence (hotspots, route of exposure, point of entry, inhalation, etc) or they might take different approaches as to when and how aggregated exposure assessments are done.**

It is unlikely that potential divergences will be completely phased out by the development of guidance and harmonisation in the future. **Developing guidance and harmonisation on aggregated exposure assessment** can stir up controversies while the guidance is being developed, whereas the continued dialogue between EFSA and stakeholders about the guidance can help reduce divergences progressively - but probably not fully resolve them. Thus, another challenge relates to the harmonisation in assessments, which could be difficult due to different information and interpretations with regard to aim, data collection, etc. This could lead to challenges in the process of developing a harmonised approach.

Theoretically, aggregated exposure assessments should enable better prioritisation for risk management (as they would allow the identification of main sources and routes), but this might be more complex as considering more exposure routes and sources would likely lead to more uncertainty and divergences in interpretation. This in turn could impede prioritisation. Furthermore, there might be a disparity between existing regulations that require the single route assessment of a given substance and the use of aggregated exposure assessment.

Additionally, **several challenges emerge in relation to aggregated exposure assessments**[17]. The first challenge links to data that is more likely to be missing in aggregated rather than single route exposure assessments, because greater numbers of routes assessed lead to higher and varying levels of uncertainty across datasets. The second challenging aspect links to determining the level of risk stemming from differences in the hazard profile of a given chemical as a function of its exposure route (*e.g.* inhalation versus oral or dermal) or differences across exposure routes, making aggregated exposure assessments more complex. Finally, EU legislation requires single route exposure assessment in many cases. As a result, a regulatory push at EU level for more aggregated assessments, coming in particular from the Chemicals Strategy for Sustainability and the aim to have "One-substance-one-assessment", might distort the creation of a harmonised approach. On the one hand, there can be a

[17] All challenges are listed in the presentation paper, which is annexed to this report (see Appendix A.8[11])

push for having "One substance-one assessment" and aggregated exposure assessments, while on the other hand there is sectoral regulation pushing for single-exposure assessment.

A challenge specifically pointed out is the **interpretation of biomonitoring data**. Although this facilitates the accumulation of useful knowledge concerning total exposure to a chemical, it is very difficult to discern individual sources of exposure and individual routes to enter the body. Thus, biomonitoring data are useful for understanding total exposure to contaminants, but its value in tracing back individual exposure routes is limited thereby limiting its utility in single source exposure assessments.

Work Area 2: Developing EFSA's framework, guidance and tools for exposure reconstruction to chemicals via (forward and reverse) dosimetry

According to the Delphi panel, there should ideally be only one European guidance on exposure reconstruction to chemicals by (forward and reverse) dosimetry. Discussions between risk assessment bodies are required and there may be a **divergence between EFSA guidance and other agencies (*e.g.* ECHA) regarding aim, scope and method**. In that regard, there is a challenge of developing a common denominator for internal exposure. Other potential divergences link to the **differences in opinion on what is being observed based on the biomonitoring data available**. The lack of internal reference values and kinetic data to interpret human biomonitoring data pose a challenge in this field.

Work Area 3: EFSA Open Access Tools for collection of dietary data in new exposome/HBM Studies

The greater availability of open data, including data collected by stakeholders and individuals, raises issues related to **how such data should be integrated into exposure assessments** (as they are not always systematically collected). This might lead to potential divergences, as different bodies could adopt different approaches towards integrating and interpreting such data. Thus, the potential divergence identified relates to the use of EFSA Open Access Tools when integrating open dietary data in new exposome and human biomonitoring studies, including the level of confidence that should be placed in the data collected by individuals.

A challenge relating to this potential divergence poses the question of how open data should be used (*e.g.* integrating them in the assessments, assessing the level of acceptable uncertainty) and the issues linked to the level of confidence that can be granted to data collected by individuals. In this case, addressing this challenge would prevent the divergence from occurring.

Other challenges in this work area include: (i) the misuse by individuals making use of their "own dietary data" to develop their own scenarios (*e.g.* maximising all potential dietary inputs), (ii) lack of harmonisation in sharing biomonitoring data at EU level,[18] and (iii) finding a balance between having transparency and individual protection in open data and data protection policies as transparency can help reduce divergence and increase common understanding.

3.2.2. Results of the mapping exercise

[18] Where projects like HBM4EU struggled with this, while PARC does not have an agreement yet.

The mapping of research activities on exposure science in risk assessment combined responses from the survey targeting research groups across the world and the screening of ongoing relevant research projects. Based on the potential divergences and challenges identified through the horizon scan, the survey questioned participants on several research topics. **Table 9** shows the correspondence between potential divergencies, challenges and research topics that cover the field of the identified divergence.

Table 9: Research topics linked to potential divergences and challenges in exposure science in risk assessment

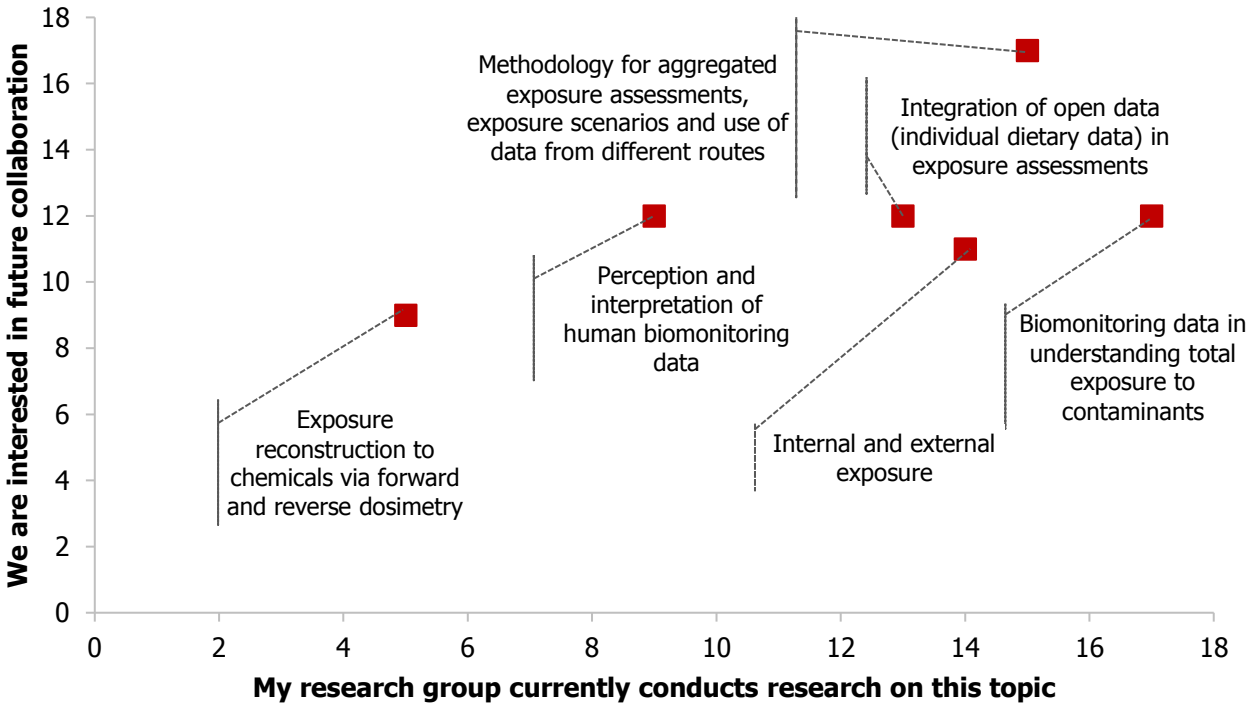
Research topic	Potential divergence	Challenge
Work Area 1: From single-route exposure assessment to an aggregate exposure assessment		
1. Biomonitoring data in understanding total exposure to contaminants	1. Use of different estimates for combining routes / make different assumptions / different decisions on how conservative the assessment should be	1. Data more likely to be missing in aggregated exposure assessments because greater numbers of routes assessed lead to higher levels of uncertainty, and varying levels of uncertainty across datasets.
2. Methodology for aggregated exposure assessments, exposure scenarios and use of data from different routes	2. Use of different approaches as to when and how doing aggregated exposure assessments	2. Level of risk may differ across different routes of exposure, making aggregated exposure assessments more complex.
3. Integration of open data (individual dietary data) in exposure assessments	3. Use of different datasets leading to divergence (hotspots, route of exposure, point of entry, inhalation, etc.)	3. EU legislation requiring single-route exposure assessment in many cases. As a result, regulations may push in different directions: push for "One substance, one assessment" and aggregated exposure assessments versus sectoral regulation pushing for single-exposure assessment.
Work Area 2: Developing EFSA's framework, guidance and tools for exposure reconstruction to chemicals via (forward and reverse) dosimetry		
4. Internal and external exposure	4. Potential divergence between EFSA guidance and other agencies (*e.g.* ECHA) regarding forward and reverse dosimetry	4. The development of a common denominator for internal exposure will be challenging.
Work Area 3: EFSA Open Access Tools for collection of dietary data in new exposome/HBM Studies		
5. Perception and interpretation of human biomonitoring data	5. Methodology to use and integrate open dietary data in new exposome/HBS	5. Challenges in using open data (*e.g.* integrating them in the assessments, assessing the level of acceptable uncertainty).
6. Exposure reconstruction to chemicals via forward and reverse dosimetry	6. Different observations based on the biomonitoring data available	6. Lack of internal reference values and kinetic data to interpret human biomonitoring data.

Results of the survey on research activities and interest in collaboration

The survey collected information on ongoing and planned research activities related to specific research topics in exposure science in risk assessment, which included responses from 30 research groups covering 15 countries (see Appendix A.7[11]). An overview of ongoing research on the highest ranked

divergences points towards potential blind spots in research and could provide an indication on how to calibrate future research activities. **Figure 6** shows that most of the research on exposure science in risk assessment relates to **aggregate exposure assessments**, covering two divergences (divergence 1 and 2) which the Delphi panel deemed as highly urgent to address and having a potentially high impact on EFSA's preparedness. On the other hand, a potential divergence between EFSA and other risk assessment bodies or agencies (*e.g.* ECHA) regarding forward and reverse dosimetry might have higher chances of materialising given that there is a lower level of ongoing research related to this topic.

Figure 6: Overview of research groups conducting research and expressing interest in TEG 2 research topics



Source: Survey on mapping of research activities and collaboration interest

The research topic on aggregate exposure assessment titled "**methodology for aggregated exposure assessments, exposure scenarios and use of data from different routes**" was the most popular research topic in the thematic area, with 15 research groups (50%[19]) from 12 different countries stating they are currently conducting research on it. Given the high ranking of divergences related to aggregate exposure assessment (divergence 1 and 2), it is not surprising that ten research groups indicated they would conduct research on this topic in the future. More than half of the research groups working on exposure science in risk assessment are interested in collaboration, which points to a solid base of researchers interested in exploring this field further.

[19] The percentage indicates the share of research groups out of total responses for thematic area exposure science in risk assessment.

The challenge of **biomonitoring data and its usefulness for understanding total exposure to contaminants** (challenge 6) appeared as the most researched field within the thematic area exposure science in risk assessment. The research topic "biomonitoring data in understanding total exposure to contaminants" was the most frequently chosen topic amongst the survey respondents, with 17 research groups indicating they were currently working on it. Given that the horizon scanning stressed the challenge of using biomonitoring data in tracing back individual routes, the ongoing or planned research could possibly provide more insight to the reliable and robust interpretation of biomonitoring data.

There still appears to be a need for further **research on biomonitoring data**, in particular relating to the lack of internal reference values and kinetic data to interpret human biomonitoring data. The survey shows ongoing and planned research in the field and, importantly, a relatively high interest in future collaboration, with 40% of surveyed research groups working in exposure science having expressed their interest in collaboration.

The potential **divergence between (methodological) EFSA and other agencies (*e.g.* ECHA) guidance regarding forward and reverse dosimetry** (divergence 4) emerged as the third highest ranked divergence in the horizon scanning, implying the need for a uniform methodological approach towards forward and reverse dosimetry. According to the survey, five research groups from four countries are currently conducting research on the topic. The survey indicated that "exposure reconstruction to chemicals via forward and reverse dosimetry" was the least researched topic amongst the six presented in this thematic area, which points towards a potential research gap. Nine research groups (30% of TEG 2 respondents) indicated they would be interested in collaboration on this research topic, which provides an opportunity to address the gap.

Internal and external exposure assessment is broadly covered by ongoing research as almost 50% of research groups working within the area of exposure science in risk assessment indicated they are currently conducting research on this topic. This is of importance, as the development of a common denominator for internal exposure (challenge 4) was identified as a challenge through the horizon scanning.

Lastly, several challenges relating to the use of open dietary data, the potential misuse individual dietary data, and the **integration of such data in new exposome/HBM** studies appeared to be a popular research topic, with 13 research groups currently conducting research on "integration of open data (individual dietary data) in exposure assessments" and 40% of the research groups indicating interest in future collaboration on the topic.

Ongoing EU-funded research projects related to exposure science in risk assessment

At EU level, 8 ongoing projects related to exposure science in risk assessment have been identified. The mapping showed that there are ongoing projects in the field of "methodology for aggregated exposure assessments, exposure scenarios and use of data from different routes", while several projects build on biomonitoring data. The list of ongoing multi partner large scale EU-funded projects includes (*inter alia*):

1. PANORAMIX – Providing risk assessments of complex real-life mixtures for the protection of Europe's citizens and the environment
2. CHEMO-RISK – Chemometers for in situ risk assessment of mixtures of pollutants

3. RISK-HUNT3R – RISK assessment of chemicals integrating HUman centric Next generation Testing strategies promoting the 3Rs
4. ATHLETE – Advancing Tools for Human Early Lifecourse Exposome Research and Translation
5. PlasticsFatE – Plastics fate and effects in the human body
6. NanoSolveIT – Innovative Nanoinformatics models and tools: towards a Solid, verified and Integrated Approach to Predictive (eco)Toxicology (NanoSolveIT)
7. EU-ToxRisk – An Integrated European "Flagship" Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century
8. European partnership for the assessment of risks from chemicals (PARC)

When it comes to **aggregate exposure assessments**, scientific uncertainty remains on the validity of the dose addition principle for complex mixtures of large numbers of chemicals at low concentrations as they occur in our bodies. Precisely this is the challenge that the PANORAMIX project seeks to address by showcasing a novel experimental path based on whole mixture assessments for identifying and quantifying the risk of chemical mixtures extracted from real-life samples representing environment and food as well as humans. As a result, the PANORAMIX project hopes to provide ready-to-use and practical tools for mixture risk assessment of several chemicals with a diverse range of adverse health outcomes.

Other projects focus on developing chemical risk assessment methodologies. For instance, CHEMO-RISK aims for a novel scientifically sound chemical **risk assessment paradigm** that integrates exposure and effect assessment of a broad range of chemicals into a single procedure and provides information relevant to ecosystem and human health. This will hopefully enable a unified risk assessment paradigm with risk-based trigger values that distinguish between acceptable from unacceptable effects.

Whereas the CHEMO-RISK project focusses on ecosystem and human health, the RISK-HUNT3R project is a complete **human-centric risk assessment strategy**, including the establishment, optimisation and assembling of all essential safety testing elements: exposure assessment, information on chemical distribution in the body, hazard characterisation, adverse outcome prediction and determination of actual risk in defined scenarios. Human (disease) genetics and exposome data will ensure anchoring of test results to the human situation. The project hopes to ensure regulatory relevance by testing the applicability of the critical test systems integrated in the next generation risk assessment strategy. According to the RISK-HUNT3R project, the final deliverable will be a comprehensive computational framework for the prediction of human adverse outcomes, and a set of stringently evaluated assays to feed the required data into this framework.

The project ATHLETE aims to develop a toolbox of advanced, next-generation, **exposome tools** and a prospective exposome cohort, which will be used to systematically quantify the effects of a wide range of community-level and individual-level environmental risk factors on mental, cardiometabolic, and respiratory health outcomes and associated biological pathways during the first 2 decades of life, to implement acceptable and feasible exposome interventions, and to translate the resulting evidence to policy recommendations and prevention strategies.

Finally, the project PlasticsFate aims to assess the impact of micro- and nano-plastics (MP/NP) and associated additives/adsorbed contaminants (A/C) in the human body. The project focuses on developing innovative approaches that can be integrated into a **novel risk assessment strategy** specifically designed for MP/NP to provide the policy relevant and scientifically sound data needed to support the health-relevant aims of European strategies for plastics.

3.2.3. Recommended actions

Work Area 1: From single-route exposure assessment to an aggregate exposure assessment

Divergence 1 (Work Area 1): Different agencies may use different estimates for combining routes / making different assumptions / different decisions on how conservative the assessment should be leading to divergent views

The first divergence might be caused by the use of different methodologies by different institutions for the same exposure route and for combining exposure routes in an aggregated exposure assessment. There are, however, already existing guidance documents for some exposure routes and for combining routes (readiness level 2).

The state of the art should be evaluated in terms of methodology and guidance across institutions, to identify whether the approach(es) taken by different institutions for the same exposure route or for combining exposure route differ, and whether guidance is missing for certain exposure routes (in which case assessing whether there are enough case studies available to develop a guidance would be useful). This action is divided into several steps as outlined in the table below. Actions 1, 2, and 3 describe the state-of-the-art review; action 4 proposes the creation, if deemed necessary, after the first three steps, of an interagency working group for eventually developing common approaches and guidance.

	Actions recommended
1	Intra-agency EFSA evaluation of state-of-the-art, "lessons learned from case studies (*e.g.* BPA, phthalates)"; need for more case studies or assess if already enough are available to develop guidance. Possibility to include at least some of the 15 research groups already conducting research on methodologies for aggregate exposure assessment through the formation of a working group.
2	Compare interagency exposure assessment methodologies and possibilities for combining different approaches into an aggregation assessment (regulatory requirements, data available, conservatism). The projects PANORAMIX and CHEMO-MIX could be ongoing projects of interest.
3	Outreach to EU Member States Competent Authorities, scientific experts, etc. with regard to aggregation assessment (already in place for many other issues).
4	Interagency working group for developing guidance, pilot studies, case studies, etc. focussed on aggregation assessment and collaboration between *e.g.* EFSA and ECHA (already in place for many other issues).

Divergence 2 (Work Area 1): Different agencies may use different datasets (hotspots, route of exposure, point of entry, inhalation, etc)

The second divergence might be caused by the use of different datasets leading to different conclusions. This second divergence is strongly linked to the first one. As methodologies and guidance already exist, the proposed action to be taken is similar to the second one on the first divergence (and the same action can actually address both divergences) – assessing the state of the art in terms of methodology and guidance across institutions to identify points of divergence in exposure route assessment and exposure routes combination in aggregated exposure assessments, and harmonising where relevant.

	Actions recommended
1	Compare interagency exposure assessment methodologies and possibilities for combining different approaches into an aggregation assessment (as already described in the context of Divergence 1).

Divergence 3 (Work Area 1): Different bodies might take different approaches as to when and how aggregated exposure assessments should be done

The third divergence in Work Area 1 might come from the fact that, although there is a strong regulatory push at EU level for aggregated exposure assessment (one substance – one assessment approach), EU legislation requires single-exposure assessment in many cases, which might lead to different approaches as to how aggregated exposure assessment is integrated in agencies" work.

The proposed action to be taken is similar to the actions proposed for the first two divergences (and the same action could address all of them at the same time). That is assessing the state of the art in terms of methodology and guidance across institutions to identify points of divergence in exposure route assessment and exposure routes combination in aggregated exposure assessments and harmonising where relevant.

	Actions recommended
1	Compare interagency exposure assessment methodologies and possibilities for combining different approaches into an aggregation assessment (as already described in the context of Divergence 1).

Work Area 2: Developing EFSA's framework, guidance and tools for exposure reconstruction to chemicals via (forward and reverse) dosimetry

Divergence 4 (Work Area 2): Potential divergence between EFSA guidance and other agencies (*e.g.* ECHA) regarding forward and reverse dosimetry, methodologically speaking

The first divergence of Work Area 2 relates to the potential divergences between guidance from different agencies on using forward and reverse dosimetry. Notably, guidance and methodologies do already exist. Proposed actions relate to comparing methodologies and guidance and discussing possible harmonisation in an existing EFSA working group. Based on these discussions, an EFSA opinion could establish a common approach.

	Actions recommended
1	EFSA working group for developing guidance, pilot studies, case studies, etc. Important to include ECHA although, it is already happening to some extent.
2	EFSA opinion.

Divergence 5 (Work Area 2): Differences in opinion on what is being observed based on the biomonitoring data available – different stakeholders might see differences leading to divergence

The second divergence of Work Area 2 might be caused by different and possibly conflicting interpretations of biomonitoring data available. There are past and ongoing EU research projects (such

as PARC), but guidance and models to use biomonitoring data have not yet been established and there are different points of view on how to use the data. This divergence is thus considered to be at conceptual level. The action proposed is to continue and strengthen research and inter-agency dialogue on the topic and at a later stage, when there is sufficient research to establish guidance with the support of an EFSA working group.

	Actions recommended
1	Research projects (define how to use biomonitoring data, perception of the use of biomonitoring data by different stakeholders, continue ongoing stakeholder dialogue (*e.g.* PARC) about how to characterise the selected exposure population, personal exposure data and position biomonitoring data in the risk assessment).
2	EFSA working group for developing guidance, pilot studies, case studies, etc.

Work Area 3: EFSA Open Access Tools for collection of dietary data in new exposome/HBM Studies

Divergence 6 (Work Area 3): Methodology to use and integrate open dietary data in new exposome/ human biomonitoring studies, including level of confidence in data collected by individuals

The only divergence in Work Area 3 relates to approaches on the use of open dietary data in new exposome/ human biomonitoring studies. There is still significant uncertainty on which data can be collected, how to use them and the level of confidence that can be placed on data collected by individuals (concept level). Actions proposed therefore include research projects and validation studies.

	Actions recommended
1	Research projects (How to make use of dietary apps; comparative data from dietary apps vs. surveys, 24 h recalls; Validation study/-ies on the level of confidence that risk assessors can put into data collected by individuals; how to deal with confidentiality in general, for individuals, etc.)

3.3. Thematic area 3: Nutrition and healthy diets from sustainable food systems

Nutrition and healthy diets within the context of sustainable food systems is a main research area and an emerging priority at the EU level. Four key work areas (WA) have been identified within this thematic area.

Work Area 1 refers to evaluating the **nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems**. The influence of the microbiome on human health is an important topic, as highlighted by EFSA's editorials on the need to include microbiomes into EFSA's scientific assessments[20]. This topic was also explored within thematic area 4 (safety assessment of innovative products) within the work area on the identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification, including the understanding of the influence of microbiota modifications on human health.

Work Area 2 focuses on developing **science-based dietary guidelines in relation to sustainable food systems and environmental impact,** which could be a point of reference for relevant bodies

[20] EFSA Journal 2020;18(6):e18061, DOI:https://doi.org/10.2903/j.efsa.2020.e18061

to develop their own tailored-made (e.g. regional, national, local). The adoption of several actions to promote sustainable food consumption, and to facilitate the shift toward healthy sustainable diets, is planned. Therefore, there could be a need to complement current dietary guidelines with science-based information on sustainability (including for example environmental impact or food waste aspects).

Work Area 3 explores the **relationship between foods and chronic metabolic diseases and the environmental impact of food to enable consumers to choose a healthy and sustainable diet**. This work area is focussed on the possible relationship between sustainable foods and metabolic diseases, and how this could support consumers in choosing healthy and sustainable food products.

Work Area 4 reflects on **possible food safety issues related to a sustainable healthy diet**. Other and new food safety hazards could occur in the supply chain of sustainable products, for example due to new products or during processing and storage. These potential hazards could be chemical or microbiological and should be carefully considered.

3.3.1. Results of the horizon scanning

The horizon scanning exercise resulted in a list of five potential divergencies and three challenges on the thematic area of nutrition and healthy diets from sustainable food systems as shown in **Table 10**.

Table 10: Potential divergences and challenges on nutrition and healthy diets from sustainable food systems identified by the Delphi panel

Potential divergence	Challenge
Work Area 1: Evaluating the nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems	
1. No consensus on the definition of a reference healthy or unhealthy microbiome.	NA
Work Area 2: Developing science-based dietary guidelines in relation to sustainable food systems and environmental impact (complementing existing and developing new guidelines)	
2. The evaluation of the impact of dietary patterns will be different depending on what aspect we are looking at (gas emissions, water usage, usage of local resources, transport used to bring the food etc).	1. When developing science-based dietary guidelines different disciplines should contribute to the process. Actors have different types of expertise (health, economic and environmental), and data are spread over different databases. Therefore, there is a need for modelling expertise to link knowledge from different databases managed by different actors and authorities.
Work Area 3: Exploring the relationship between foods and chronic metabolic diseases and the environmental impact of food to enable consumers to choose a healthy and sustainable diet	
3. There is a need for a definition of ultra-processed food (nutrients, additives, and way of processing).	NA
4. Potential divergences on the impact of different diets might occur (in transition to more sustainable diets), and the question of how to replace important nutrients could arise as the evidence around some issues can be differently evaluated by different organisations. Therefore, uncertainty in science could lead to varying analyses by various authority	

Potential divergence	Challenge
organisations regarding the evidence and different conclusions across member states.	
5. Methods, data, and omics needed to study the relationship between diets and metabolic diseases will become more pronounced in the future and with it the evaluation of the impact of dietary patterns on metabolic diseases, which might be different depending on what aspect we are looking at (gas emissions, water usage, usage of local resources, transport used to bring the food etc) possibly leading to different conclusions.	
Work Area 4: Possible food safety issues related to sustainable healthy diets	
NA	2. Lack of methods and data to properly monitor and conduct research on specific contaminants in sustainable food products. Methods are difficult to develop and the process takes several years.
	3. Lack of testing methods for non-intentionally added or unknown substances (for example photoinduced substances which can be formed due to sunlight).

Work Area 1: Evaluating the nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems

There is no scientific consensus on the **definition of a healthy microbiome**. The gut microbiome is characterised by a large degree of inter-individual variation which has led to the emergence to the phenomenon of responders and non-responders to gut-directed foods and other interventions. Furthermore, there is no holistic view on the co-presence of different species on the microbiome and long-term effects are often not known. Food intake and diets vary within a day and across individuals, which also affect the microbiome composition and activity. Adding complexity is the lack of a standard approach in assessing the impact on the microbiome.

On the other hand, there seems to be some consensus on the profile of an unhealthy microbiome which can be seen in a wide variety of intestinal and extra-intestinal diseases. Defining an unhealthy microbiome is important and maybe easier than defining a healthy microbiome, however limiting research to what is unhealthy (as a reference) will not provide the complete picture. Therefore, a reference point is needed on what we define as a healthy and unhealthy microbiome.

Work Area 2: Developing science-based dietary guidelines in relation to sustainable food systems and environmental impact (complementing existing and developing new guidelines)

When it comes to dietary guidelines in relation to sustainable food systems and environmental impact, EFSA could evaluate health effects to support member states in drafting dietary guidelines and it is important to know what aspect of environmental impact is being scrutinised. There are many ways to **interpret the environmental impact of food, which entails different ways of assessing dietary patterns (*e.g.* gas emissions, land use, water usage, usage of locally produced products, local varieties, transport used to bring the food, etc.)**. Guidelines on one aspect of

environmental impact may affect other aspects and risks managers should be aware of these different aspects and should take different aspects into account. As there is no standard method in assessing the evidence for sustainability and the environmental impact, divergent opinions might occur (*i.e.* different organisations using different methods leading to a divergence of findings).

The **development of science-based dietary guidelines will be challenging**, as different disciplines should be involved in the making of such guidelines. Data are scattered across different actors and different databases. Food consumption surveys and health data are collected separately. Similarly, data on the cost of food (economic aspects) and environmental impact are collected by different actors and stored in different places. The challenge is therefore to involve all relevant actors that hold the necessary expertise (health, economic and environmental). There is a need for modelling expertise to link and combine knowledge from these different disciplines managed by different actors and authorities.

Work Area 3 - Exploring the relationship between foods and chronic metabolic diseases and the environmental impact of food to enable consumers to choose a healthy and sustainable diet

(Ultra) processing can have both positive and negative impacts on metabolic diseases. It is therefore not clear how ultra-processed food should be classified given the current knowledge on processing and health. Several studies show that, over time, the consumption of more processed food items is related to the increased incidence of metabolic disease. It is a mix between processing steps and including additives and nutrients such as salt/sugar/fat. The usage of the term "ultra-processed food" today is more a proxy for foods high in sugar/fat/salt. The assessment of what type of process is bad for health is often not properly considered in current classifications of "ultra-processed food". To avoid potential divergences there is a **need for a definition of ultra-processing of food** on two different layers. Firstly, there is a need to look at processed foods themselves, and secondly, the way these ultra-processed foods are processed. This divergence was considered the most pertinent divergence in this work area by the Delphi panel.

The need to ensure that malnutrition is not increased due to the change to more sustainable diets is a driving force which is anticipated to materialise in the future. Thus, there is a need to look at the shift towards more sustainable diets on health – in particular, the policy shift from meat-based diets to plant-based diets. This creates a potential challenge in ensuring a balanced intake of nutrients and vitamins. EFSA could be asked to evaluate the health effect of a specific shift in diets. Potential divergences on the impact of different diets might occur, and the question of how to replace important nutrients could arise as the evidence around some issues can be evaluated differently by different organisations (*e.g.* on the discussion around the maximum sugar intake and health). EFSA's role is different from those of other expert organisations (US Food and Drug Administration and WHO). EFSA has a strictly science-based advisory function towards risk managers, while these other organisations are responsible for both risk assessment and risk management/policy setting. When science does not give a clear answer on an issue, this could lead to uncertainty across member states, with different states emphasising different research findings. **Therefore, uncertainty in science could lead to varying analyses by various authority organisations regarding the evidence and different conclusions across member states. In the transition to more plant-based diets, there is a need to consider the impact on dietary balance. If the dietary balance changes, the effects on health should be better understood.**

Lastly, the same potential divergence was identified in this work area as for Work Area 2 related to different methods resulting in different findings and conclusions on the relation between sustainable diets and metabolic diseases. One of the driving forces expected to materialise in the future relates to methods and data (*e.g.* omics) needed to study the relationship between diets and metabolic diseases. For instance, there are many ways to look at the environmental impact. **The evaluation of the impact of dietary patterns on metabolic diseases will be different, depending on the aspect being examined (*e.g.* gas emissions, water usage, usage of local resources, methods used to transport food, etc.).** The data are scattered among different actors and databases, which makes it tricky to analyse the evidence on the impact of dietary patterns on the environment.

Work area 4 – Possible food safety issues related to sustainable healthy diets

Two challenges were identified related to sustainable healthy diets. The first is linked to the need for risk-based monitoring and risk-benefit assessment, which emerges because of the introduction of new or other contaminants and allergens in sustainable food products. The challenge is that there is a **lack of methods and data to properly monitor and conduct research on specific contaminants**. Thus, food analysis and the collection of concentration data of different substances to which people are exposed (*e.g.* contaminants and allergens) is expensive and difficult. Robust methodologies which can be used to assess other substances such as microplastics, specific toxins, and BPA are lacking. Where methods are developed, they first need to be validated – a process which can take several years. The funding of research related to adverse substances as present in our food and related to biomonitoring is limited and hard to obtain. There is a need for a central database and the right tools to be able to use the existing biomonitoring data in risk assessment. Data are currently scattered between member states with different reporting systems.

The second challenge relates to the safety assessment of sustainable packaging and edible coatings. In particular, there is a **lack of testing methods for measuring non-intentionally added or unknown substances**, which can have negative health effects.

3.3.2. Results of the mapping exercise

The mapping of research activities on nutrition and healthy diets from sustainable food systems combined responses from the survey targeting research groups across the world and the screening of ongoing relevant research projects. Based on the potential divergences and challenges identified through the horizon scan, the survey questioned participants on several research topics. **Table 11** shows the correspondence between potential divergencies, challenges and research topics that cover the field of the identified divergence.

Table 11: Research topics linked to potential divergences and challenges in nutrition and healthy diets from sustainable food systems

Research topic	Potential divergence	Challenge
Work Area 1: Evaluating the nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems		

Research topic	Potential divergence	Challenge
1. Knowledge of gut microbiome in relation to human health, including the definition of microbiome/dysbiosis and research on potential adverse effects of microbiota.	1. No consensus on the definition of a reference healthy or unhealthy microbiome.	NA
Work Area 2: Developing science-based dietary guidelines in relation to sustainable food systems and environmental impact (complementing existing and developing new guidelines)		
2. New paradigm for the development of science-based dietary guidelines taking into account both dietary pattern and environmental impact.	2. The assessment of the impact of dietary patterns being different depending on the aspects (*e.g.* gas emissions, water usage, usage of local resources, transport used to bring the food etc) being considered.	NA
3. Modelling and data integration (of different expertise on health, economy and environment) for the development of integrated science-based dietary guidelines.	NA	1. When developing science-based dietary guidelines, different disciplines should contribute to the process. Actors have different types of expertise (health, economic and environmental), and data are spread over different databases. Therefore, there is a need for modelling expertise to link knowledge from different databases managed by different actors and authorities.
Work Area 3: Exploring the relationship between foods and chronic metabolic diseases and the environmental impact of food to enable consumers to choose a healthy and sustainable diet		
4. Impact of ultra-processing on metabolic diseases	3. There is a need for a definition of ultra-processed food (nutrients, additives, and way of processing).	NA
5. The transition to more plant-based diets and its impact on dietary balance.[21]	4.Potential divergences on the impact of different diets might occur (in transition to more sustainable diets), and the question of how to replace important nutrients could arise as the evidence around some issues can be differently evaluated by different organisations. Therefore, uncertainty in science could lead to varying analyses by various authority organisations regarding the evidence and different conclusions across member states.	NA
6. Same as research topic #2 above	5. Methods, data, and omics needed to study the relationship between diets and metabolic diseases will become more pronounced in the	NA

[21] While the Delphi panel agreed to change the terminology of the related potential divergence (and driving force) by changing 'plant-based' to 'sustainable' diet, we have kept the original title of the research topic as it appeared in the survey.

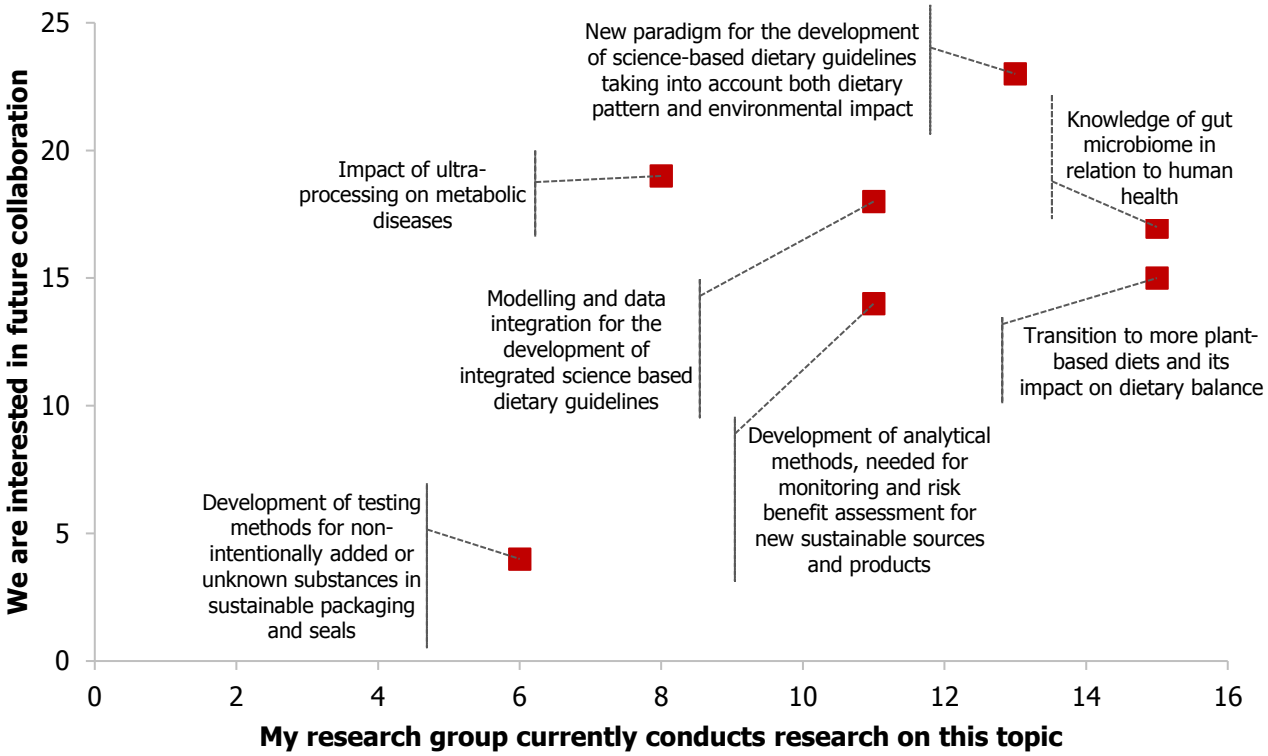
Research topic	Potential divergence	Challenge
	future and with it the evaluation of the impact of dietary patterns on metabolic diseases, which might be different depending on what aspect we are considering (gas emissions, water usage, usage of local resources, transport used to bring the food etc), possibly leading to different conclusions.	
Work Area 4: Possible food safety issues related to sustainable healthy diets		
7. Development of analytical methods, needed monitoring and risk benefit assessment for new sustainable sources and products.	NA	2. Lack of methods and data to properly monitor and conduct research on specific contaminants in sustainable food products. Methods are difficult to develop, and the process takes several years.
8. Development of testing methods for unintentionally added or unknown substances in sustainable packaging and seals	NA	3. Lack of testing methods for unintentionally added or unknown substances (for example photoinduced substances which can be formed due to sunlight).

Results of the survey on research activities and interest in collaboration

The survey collected information on ongoing and planned research activities related to nutrition and healthy diets from sustainable food systems covering **46 research groups from 12 countries**. Additionally, the survey provided information on plans for future research and interest in collaboration for the 7 mentioned research topics.

Figure 7 shows the number of research groups currently conducting research on a given topic and the interest for doing future research. Overall, most research is currently being conducted on the gut microbiome, with 15 research groups indicating they are working on research related to the **"gut microbiome in relation to human health, including the definition of microbiome/dysbiosis and research on potential adverse effects of microbiota**". Similarly, the "**transition to more plant-based diets and its impact on dietary balance**" appeared to be an equally popular research topic (15 research groups currently conducting research). On the other hand, only six research groups were working on the "development of testing methods for non-intentionally added or unknown substances in sustainable packaging and seals".

Figure 7: Overview of research groups conducting research and expressing interest in TEG 3 research topics



Source: Survey on mapping of research activities and collaboration interest

As previously mentioned, research on the **gut microbiome** seems to be the amongst the more interesting research topics, with several research groups indicating interested in future collaboration on this topic. The highest interest for future collaboration has been expressed for the topics "impact of ultra-processing on metabolic diseases", "modelling and data integration for the development of integrated science based dietary guidelines" and "new paradigm for the development of science-based dietary guidelines taking into account both dietary pattern and environmental impact". However, research on "**impact of ultra-processing on metabolic diseases**" is currently only being conducted by eight research groups from two different countries. The lowest interest for collaboration (research groups from three countries) was expressed for the "development of testing methods for non-intentionally added or unknown substances in sustainable packaging and seals", which is currently being researched by six research groups in five different countries.

In conclusion, two of the most researched topics related to the 1) **microbiome** and 2) **developing science-based dietary guidelines in relation to sustainable food systems and environmental impact.** These link to the potential divergences that were not assessed as the most urgent ones by the Delphi panel. The potential divergence that was considered as most urgent and as having a high impact on EFSA's preparedness (*i.e.* "The assessment of the impact of dietary patterns being different depending on the aspects (*e.g.* gas emissions, water usage, usage of local resources, transport used to bring the food etc) being considered") was amongst the most researched ones, implying that there is an alignment in terms of the sense of importance and state of the art of research. There are different

degrees of coverage in terms of ongoing research linked to the potential divergences and challenges, with each research topic having several research groups currently working on it.

Ongoing EU-funded research projects related to Nutrition and healthy diets from sustainable food systems

At EU level six multi partner large scale ongoing projects related to nutrition and healthy diets from sustainable food systems have been identified (**Table 12**). The mapping showed that there are ongoing projects in the field of "**healthy microbiome**" and in the field of "**sustainable diets**". Interestingly, two projects (SymbNET and NextGenProteins) are relevant for TEG 4 (see section 3.4.2) as they cover the gut microbiome and its adverse effects, which was an overarching topic. The full project descriptions and links can be found in Appendix A.5[11].

Table 12: List of ongoing EU funded projects on nutrition and healthy diets from sustainable food systems

#	Topic	Project name	Project description
1	Healthy microbiome	SymbNET Genomics and Metabolomics in a Host-Microbe Symbiosis Network	SymbNET brings together world-leading research institutions with expertise in host-microbe symbiosis under a joint European network. The project will promote the transfer of knowledge, collaborative projects and staff exchange visits among the participating institutions.
2	Healthy microbiome	EPYC – Evolution of pro- and eukaryotic commensals within the human gut	The EPYC project will give insights in microbial evolution in the human gut. The project will characterise the evolution of long-term human-associated eukaryotes and prokaryotes, using colonisation patterns in 3 human generations.
3	Healthy microbiome	ExpoBiome – Gut microbiome molecular complex in human health and disease	By providing mechanistic insights into the molecular basis of human-microbiome interactions, the project will generate essential new knowledge about causal relationships between the gut microbiome and the immune system in health and disease.
4	Aspects influencing sustainability in healthy diets and transition to more sustainable diets	Diverfarming Crop diversification and low-input farming across Europe: from practitioners engagement and ecosystems services to increased revenues and chain organisation	Sustainability is investigated specifically for diversified cropping systems in the project Diverfarming by developing innovative farming and agribusiness strategies, including more rational use of farmland and farming inputs (water, energy, machinery, fertilisers, pesticides), improved delivery of ecosystem services, and proper organisation of downstream value chains adapted to the new diversified cropping systems with decreased use of energy.
5	Aspects influencing sustainability in healthy diets and transition to more sustainable diets	ProFuture - microalgae protein ingredients for the food and feed of the future	ProFuture aim to set the basis for market uptake of innovative, healthy and sustainable food and feed products, reformulated with protein-rich ingredients from microalgae for food and feed.

#	Topic	Project name	Project description
6	Aspects influencing sustainability in healthy diets and transition to more sustainable diets	NextGenProteins Bioconversion of underutilised resources into next generation proteins for food and feed	NextGenProteins focuses on microalgae, single cell proteins and insects as three promising sources of alternative proteins, that can be produced sustainably by using waste streams. The project aims to demonstrate the suitability and economic viability of the alternative proteins in food and feed value chains and explore their market opportunities with the industry, stakeholders, policymakers and consumers.

3.3.3. Recommended actions

Work Area 1: Evaluating the nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems

Divergence 1. (Work Area 1): No consensus on the definition of a reference healthy or unhealthy microbiome.

There is no consensus on the definition of a reference healthy or unhealthy microbiome. Thus, as a starting point, the problem needs to be formulated precisely. A starting definition should be made, followed by scoping and a systematic review by EFSA. Here, EFSA could reflect on results of ongoing EU funded projects such as the EPYC and SymbNET.

	Actions recommended
1.	Provide guidance to define healthy or unhealthy microbiome by starting with a problem formulation

Work Area 2: Developing science-based dietary guidelines in relation to sustainable food systems and environmental impact (complementing existing and developing new guidelines)

Divergence 2. (Work Area 2): The evaluation of the impact of dietary patterns will be different depending on what aspect we are looking at (gas emissions, water usage, usage of local resources, transport used to bring the food etc).

As described above, the evaluation of the environmental impact of dietary patterns will be different, depending on the aspect considered (gas emissions, water usage, usage of local resources, transport used to bring the food etc) and this could lead to different conclusions and decisions. When it comes to actions to address the potential divergence, the Delphi panel referred to available tools and best practices needing to be mapped (*e.g.* European Union Food System Sustainability Compass[22] and a tool from FAO) as a starting point. Additionally, EFSA could help in defining healthy and sustainable diets. In addition, a nutrition score and eco-score (including emissions, local productions, etc.) could be developed to be put on food packaging. While this is outside EFSA's remit, EFSA could provide scientific advice or support at the request of the EC.

[22] https://ec.europa.eu/jrc/en/science-update/food-system-sustainability-compass

	Actions recommended
1	Mapping available tools and best practices. Reflect on research currently being conducted on this topic (13 research groups).
2	Defining healthy and sustainable diets – possibly reflect on ongoing EU projects.
3	Support risk managers in the development of eco-score on food products.

Work Area 3 - Exploring the relationship between foods and chronic metabolic diseases and the environmental impact of food to enable consumers to choose a healthy and sustainable diet

Divergence 3. (Work Area 3): There is a need for a definition of ultra-processed food (nutrients, additives and methods of processing).

Possible actions relate to guidance that should be provided in order to define ultra-processed food (including nutrient profiling, degrees of processing, product categories, etc.). EFSA could provide scientific advice or support at the request of the EC. However, the definition should not only be based on science, but also on other practical factors that play a role, such as food policy (which is outside EFSAs mandate and up to the risk managers).

	Actions recommended
1.	Provide guidance to define ultra-processed food

Divergence 4. (Work Area 3): Potential divergences on the impact of different diets might occur (in transition to more sustainable diets), and the question of how to replace important nutrients could arise as the evidence around some issues can be differently evaluated by different organisations.

Uncertainty in science could lead to different analyses of the evidence by different authority organisations and different conclusions across member states. In the transition to more sustainable diets, we need to consider the impact on dietary balance. If the dietary balance changes, what will be the effect on health and what is considered healthy? While the panel considered that there is already existing knowledge on the topic, no consensus has been reached.

EFSA could help member states by providing tools or methodologies to assess these issues systematically. EFSA should model potential consequences of different diets and different intake scenarios (for example a diet with or without meat or fish) could be included in such a model.

	Actions recommended
1.	Collect and map available tools and methodologies, followed by identification of gaps.
2.	Provide tools or methodologies to predict consequence of changes towards sustainable diets.

Divergence 5. (Work Area 3): Methods, data, and omics needed to study the relationship between diets and metabolic diseases will become more pronounced in the future and with it the evaluation of the impact of dietary patterns on metabolic diseases.

The evaluation of the impact of dietary patterns on metabolic diseases will be different depending on the aspect(s) examined (gas emissions, water usage, usage of local resources, transport used to bring the food etc). This could lead to different conclusions and decisions. This divergence is comparable to Divergence 1, and thus the actions are comparable as well. Criteria could be different for different countries, depending on local resources. The Delphi panel questioned if this divergence was up to EFSA or risk managers. Specifically, metabolic diseases is also the expertise of other international agencies. Therefore, no other concrete actions were defined for this divergence.

3.4. Thematic area 4: Safety assessment of innovative products

Thematic area 4 initially entailed four working areas. However, the Delphi panel suggested including the fourth work area (understanding of the influence of microbiota modifications on human health) as part of the third work area (identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification).

Work Area 1 dealt with **innovative (and sustainable) food and feed products and related technologies/resources** (*e.g.* novel whole foods/feeds and food/feed ingredients such as algae and insect-derived, and *in vitro* meat). The main issue explored in this working area is the assessment of new hazards in such innovative products (*e.g.* for *in vitro* meat due to the presence of growth factors, or serum from animals-synthetic culture media).

Work Area 2 also focused on **innovative (and sustainable) food and feed products,** yet with particular attention on the **innovative production approaches** (*i.e.* using new technologies to produce innovative foods and feeds, such as new genomic techniques (NGT) and synthetic biology approaches).

Work Area 3 was related to **the identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification, including the understanding of the influence of microbiota modifications on human health**. Research in this area is needed given that the evolution in (re)sources of protein implies new challenges in risk assessment, such as the assessment of allergenicity or the safety assessment of new-to-nature components (*e.g.* novel/new nucleic acids, proteins) and organisms (xenobionts). This work area also covers how innovative foods should be assessed in terms of effects on the gut barrier function and related effects on the immune function (*e.g.* by investigating whether it is necessary to consider any significant modifications of gut microbiota (dysbiosis) in the risk assessment process).

3.4.1. Results of the horizon scanning

The horizon scanning exercise resulted in a list of five potential divergencies and ten challenges on the thematic area of safety assessment of innovative products as shown in **Table 13**.

Table 13: Potential divergences and challenges on safety assessment of innovative products identified by the Delphi panel

Potential divergence	Challenge
Work Area 1: Innovative (and sustainable) food and feed products – technologies/resources	

Potential divergence	Challenge
1. Raising consumer demand for healthier and/or innovative foods with less negative environmental impact could lead to potential divergences due to both the complexity and diversity of food, as well as to the variability of the new technologies involved in the production of such products.	1. Considering higher environmental sustainability and new protein sources can be challenging due to the complexity and variability of new technologies, as well as the characterisation of new hazards which might be linked with such innovative products and technologies.
	2. Consumer choices and ethical concerns, and the acceptance by the public of innovative foods/food products pose the challenge of how to incorporate environmental risks and considerations on animal welfare into risk assessment, as well as providing appropriate/tailored communication to the public.
	3. The identification of new biological and chemical contaminants and additives poses the challenge of identifying needs for systematic screening of emerging hazards.
	4. The increased degree of innovation and investment (more new producers/new food technology) in the current food system may lead to different approaches vis-a-vis applicants and a rising need for harmonisation.
Work Area 2: Innovative (and sustainable) food and feed products – innovative production approaches	
2. Some products may have apparent similar (or dissimilar) food safety characteristics to food historically consumed leading to potential divergences on data requirements for risk assessment of innovative food and feed products from innovative production approaches (incl. data waiving).	5. Defining risk to benefit assessment in a more holistic approach (which includes risks/benefits to both humans and to the environment). Additionally, how to prioritise the benefits and which are the trade-offs as well as how to measure trade-off between environment and health.
	6. Analytical methods to distinguish between conventional and innovative (*e.g.* NGTs) products.
	7. Harmonisation of data requirements/guidelines. Chemical Strategy for sustainability is a very good example of where inter-agencies (*e.g.* EFSA and EMA) alignment of assessment guidelines will be needed and where the problem formulation needs to be clearly defined.
	8. Harmonisation of data requirements/guidelines for substances and technologies of emerging hazards (such as new biological and chemical contaminants).
	9. Characterisation of new hazards, availability of analytical methods and integration of the benefit to risk analysis.
Work Area 3: Identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification, including the understanding of the influence of microbiota modifications on human health	
3. The definitions of microbiome /dysbiosis, the characterisation of a healthy microbiota (setting standards)	

Potential divergence	Challenge
and the recognition of what is an adverse effect on microbiota.	10. Need for a monitoring system to identify food allergy trends or to detect new allergens.
4. The overall strategy for protein safety assessment needs clarification (*i.e.* agreement on the validation process, clarity on concepts of dose-response relationships)	
5. Dataset requirements for assessment of complex foods (characterisation of composition; knowledge of main individual substances and/or data needed for the whole product). Potential of divergences also regarding the needs for pre-clinical data (battery of tests to define).	

Work Area 1: Innovative (and sustainable) food and feed products – technologies/resources

For Work Area 1, one potential divergence has been identified, linked to rising consumer demand for healthier and/or innovative foods with less negative environmental impact and positive impact on human health, in particular on microbiota. This potential divergence might arise due to both the **complexity and diversity of food**, as well as to the **variability of the new technologies** involved in the production of such products. Moreover, the characterisation of the biological safety of such products is also perceived as a potential divergence in this context.

The Delphi panel additionally highlighted four challenges within this work area. With respect to the broader political context pushing towards higher environmental sustainability of the food chain, the **complexity and variability of new technologies** appears as a challenge, together with the characterisation of new hazards which might be linked with such innovative products and technologies.

Consumer choices and ethical concerns (*e.g.* the desired reduction of the number of farmed animals) and the acceptance by the public of innovative foods/food products poses the challenge of how to **incorporate environmental risks and considerations on animal welfare into risk assessment**, as well as providing appropriate/tailored communication to the public.

The emerging safety concerns linked to the identification of new biological and chemical contaminants, additives and matrices brings challenges that are inherently linked to the emerging nature of such hazards (*i.e.* the lack of knowledge and understanding). This results in the **need for systematic screening of such emerging hazards**.

Finally, the **increased degree of innovation and investment** (more new producers/new food technology) in the current food system, may lead to different approaches vis-à-vis applicants (submission of such dossiers with a lower quality). Such new "players" should be educated accordingly, to indirectly facilitate the risk assessment which can be perceived as a challenge.

Work Area 2: Innovative (and sustainable) food and feed products – innovative production approaches

For Work Area 2, one potential divergence and four key challenges have been identified. The potential divergence is related to **data requirements for risk assessment for innovative foods,** stemming from the fact that some products may have apparent similar (or dissimilar) food safety characteristics to food which has been historically consumed.

Several challenges were identified by the Delphi panel in relation to innovative and sustainable food and feed products. Firstly, there is a need to establish a **more holistic approach for risk assessment**, considering **impacts on health and on the environment** (*i.e.* how to prioritise the benefits and how to measure the trade-off between environment and health benefits), which derives from the opportunity to have a more sustainable food chain. Secondly, an emerging interest on different sectors (*e.g.* organic/GM-free sector vs NGTs) brings the challenge of **developing analytical methods or, alternatively, dedicated procedures to reveal any qualitative differences** (new hazards) **between conventional and innovative products** from those obtained by NGTs or those derived from synthetic biology/biotechnology. Thirdly, the challenge of **harmonisation of data requirements/guidelines** for substances and technologies of emerging hazards (such as new biological and chemical contaminants) has been highlighted. In the context of this harmonisation, the panel also stressed the importance of inter-agency cooperation (*e.g.* EFSA and EMA). The last challenge arises from the consumers demand for novel food combined with organisms and components which are new-to-nature (e.g. Synthetic biology products);[23] namely, the **characterisation of new hazards and related availability of analytical methods** or, alternatively, dedicated procedures, alongside the feasibility of adapting existing risk assessment approaches.

Work Area 3: Identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification, including the understanding of the influence of microbiota modifications on human health

For Work Area 3, three potential divergences have been identified, along with one challenge.

Alongside the recent **increase in scientific knowledge on gut microbiome and its relationship with human health**, potential divergences may arise regarding definitions, including the definitions of healthy microbiome itself and related dysbiosis, the standards that define a "healthy" microbiota, and what could cause the adverse effects on the latter.

The diversification of protein sources together with a shift towards more plant/insects/microbial derived protein may also lead to divergences in the short term, as the overall **strategy for protein safety assessment requires clarification/revision**. A potential divergence is linked to adverse immune reactions that might arise from the consumption of such protein products, and/or due to the lack of clarity on what characterises a protein as an allergen as well as the poor understanding of the dose-response concepts. Moreover, there is a lack of validated and predictive models to properly assess all potential adverse effects of proteins, mainly in terms of allergenicity but also toxicity (combination of *in silico*, *in vitro, in vivo* data/methods in a weight of evidence approach). The Delphi panel identified one challenge that is linked to this potential divergence – the **need for a monitoring system to identify food allergy trends** or to detect new allergens.

With respect to multi-ingredient food or composite food mixtures (defined as complex/non-conventional food), potential divergences may arise from **requirements regarding datasets needed to perform the assessments of such complex food** (*e.g.* data on characterisation of composition, knowledge

[23] Synthetic Biology (SynBio) is an interdisciplinary field at the interface of engineering and biology aiming to develop new biological systems and impart new functions to living cells with potential applications in the food and feed system. It is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organism. For more information refer to EFSA Journal 2021;19(2):6301, 21 pp.

of main individual substances and/or data needed for the whole product, definition of reference products and harmonised reference values for the baseline of risk assessment). Another potential divergence is perceived in the need for pre-clinical data, where the appropriate battery of tests is yet to be defined.

3.4.2. Results of the mapping exercise

The mapping of research activities on the safety assessment of innovative products combines responses from the survey targeting research groups across the world and the screening of ongoing relevant research projects. Based on the potential divergences and challenges identified through the horizon scan, the survey questioned participants on several research topics. **Table 14** shows the correspondence between potential divergencies, challenges and research topics that cover the field of the identified divergence.

Table 14: Research topics linked to potential divergences and challenges in safety assessment of innovative products

Research topic	Potential divergence	Challenge
Work Area 1: Innovative (and sustainable) food and feed products – technologies/resources		
1. Characterisation of new contaminants coming from new sources (valorisation of food waste and new sources of proteins)	1. Raising consumer demand for healthier and/or innovative foods with less negative environmental impact could lead to potential divergences due to both the complexity and diversity of food, as well as to the variability of the new technologies involved in the production of such products.	1. Considering higher environmental sustainability and new protein sources can be challenging due to the complexity and variability of new technologies, as well as the characterisation of new hazards which might be linked with such innovative products and technologies.
2. Characterisation of biological safety in novel/healthy food products processed with new techniques (*e.g.* high power process, low heat treatment).		
3. Environmental impact of production of in vitro cultured meat		2. Consumer choices and ethical concerns, and the acceptance by the public of innovative foods/food products pose the challenge of how to incorporate environmental risks and considerations on animal welfare into risk assessment, as well as providing appropriate/tailored communication to the public.
4. Systematic screening of emerging hazards and use of NAM (new approach methodologies) for risk assessment		3. The identification of new biological and chemical contaminants and additives poses the challenge of identifying needs for systematic screening of emerging hazards.
		4. The increased degree of innovation and investment (more new producers/new food technology) in the current food system may lead to different approaches vis-à-vis applicants and a rising need for harmonisation.

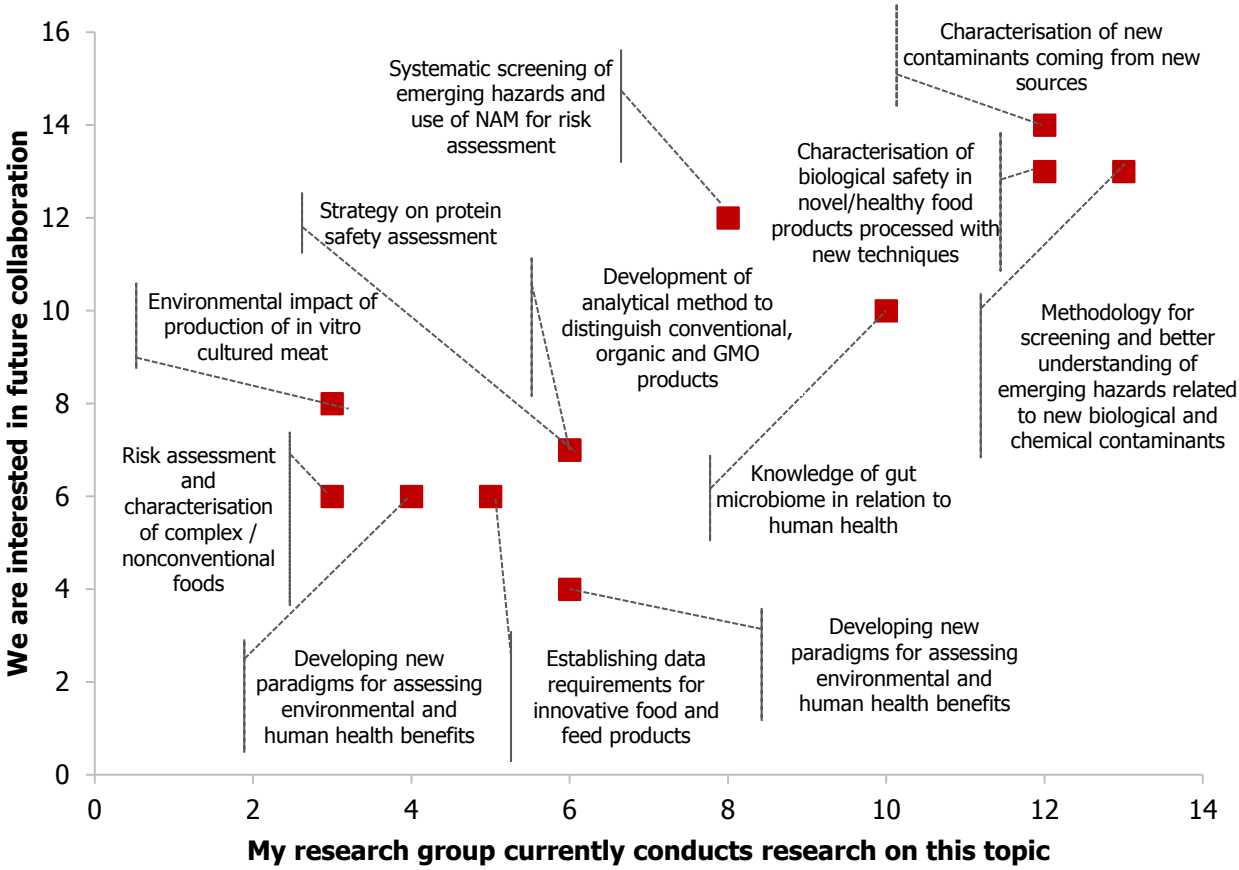
Research topic	Potential divergence	Challenge
Work Area 2: Innovative (and sustainable) food and feed products – innovative production approaches		
5. Establishing data requirements for innovative food and feed products	2. Some products may have apparent similar (or dissimilar) food safety characteristics to food historically consumed leading to potential divergences on data requirements for risk assessment of innovative food and feed products from innovative production approaches (incl. data waiving).	5. Defining risk to benefit assessment in a more holistic approach (which includes risks/benefits to both humans and to the environment). Additionally, how to prioritise the benefits and which are the trade-offs as well as how to measure trade-off between environment and health.
6. Developing new paradigms for assessing environmental and human health benefits		
7. Analytical methods to distinguish between conventional and GMO NGTs and their products.		6. Analytical methods to distinguish between conventional and innovative (*e.g.* NGTs) products.
8. Same as research topic #3 above		7. Harmonisation of data requirements/guidelines, Chemical Strategy for sustainability is a very good example where inter-agencies (*e.g.* EFSA and EMA) alignment of assessment guidelines will be needed; and the problem formulation needs to be clearly defined.
		8. Harmonisation of data requirements/guidelines for substances and technologies of emerging hazards (such as new biological and chemical contaminants).
9. Integration of health benefits to the risk analysis of novel/healthier food		9. Characterisation of new hazards, availability of analytical methods and integration of the benefit to risk analysis.
Work Area 3: Identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification, including the understanding of the influence of microbiota modifications on human health		
10. Knowledge of gut microbiome in relation to human health, including the definition of microbiome/dysbiosis, research on potential adverse effects of microbiota and development of models/protocols allowing the assessment of the actual adverse effects on microbiota.	3. The definitions of microbiome /dysbiosis, the characterisation of a healthy microbiota (setting standards) and the recognition of what is an adverse effect on microbiota.	10. Need for a monitoring system to identify food allergy trends, or to detect new allergens.
11. Strategy on protein safety assessment, including general toxicology (particularly knowledge on dose-response relationships) and potential adverse immune reactions	4. The overall strategy for protein safety assessment needs clarification (*i.e.* agreement on the validation process, clarity on concepts of dose-response relationships).	
12. Risk assessment and characterisation of complex/non-	5. Dataset requirements for assessment of complex foods (characterisation of	

Research topic	Potential divergence	Challenge
conventional foods (multi-ingredient, composite).	composition, knowledge of main individual substances and/or data needed for the whole product). Potential of divergences also regarding the needs for pre-clinical data (battery of tests to define).	

Results of the survey on research activities and interest in collaboration

A total of 33 research groups from 22 countries indicated their current and planned research activities on the topic of the safety assessment of innovative products. Overall, there seems to be a balanced representation of research topics related to safety assessment of innovative products. **Figure 8** shows that there is ongoing research covering several research topics. The safety assessment of innovative and sustainable food/feed products, and the associated new technologies, appear as a very popular research area among respondents. In fact, both the topics of "**characterisation of new contaminants coming from new sources (valorisation of food waste and new sources of proteins)**" and "**characterisation of biological safety in novel/healthy food products processed with new techniques** (e.g. high power process, low heat treatment)" show a relative high number of research groups involved in research on this topic (12 groups in both areas) as well as an interest to work on such areas in the future (14 and 13 research groups planning activities in such topics respectively).

Figure 8: Overview of research groups conducting research and expressing interest in TEG 4 research topics



Source: Survey on mapping of research activities and collaboration interest

The potential divergence focusing on the "**characterisation of a healthy microbiota**" (divergence 3) also appears as a popular topic among the research community, with one third of the research groups (10) currently conducting research in this area. "**Environmental impact of production of in vitro cultured meat**" seemed to be less interesting for the research community, where three research groups (covering six different countries) were currently exploring this topic in their research and eight indicating interest in future collaboration. "Risk assessment and characterisation of complex/non-conventional foods" was researched by three research groups in only one country, with six research groups indicating they would be interested in collaborating on this topic in the future.

The risk of adverse immune reactions that could potentially be associated with (new) proteins is not extensively researched, with 20% of respondents conducting research on topics such as general toxicology of proteins, dose-response relationships, and potential adverse immune reactions. Notably, the same research topics also shed light on another potential divergence (divergence 4) related to this area, namely the "**revision on the general strategy for protein safety assessment**", which was considered slightly less urgent by the Delphi panel compared to the divergence on adverse immune reaction linked to proteins.

The potential divergences on datasets required to perform the assessment of complex non-conventional food (*e.g,* characterisation of composition, knowledge of main individual substances and/or data needed for the whole product) (divergence 5) and the needs for pre-clinical data (challenge 3) are both explored within the research topic of "**risk assessment and characterisation of complex/non-conventional foods**". However, this study topic is not currently being investigated by a high number of research groups (three research groups out of 33), revealing a potential gap in this area. Finally, the potential divergence related to the **data requirements for risk assessment of innovative food and feed products produced from innovative production approaches** (divergence 2) was amongst the least researched topics (five out of 33). Likewise, it was considered as comparatively less urgent by the Delphi panel.

Ongoing EU-funded research projects related to Safety assessment of innovative products

The mapping of European research projects allowed the identification of nine ongoing projects in the field of safety assessment of innovative products. The list of multi partner large scale ongoing EU-funded projects includes (inter alia):

1. NextGenProteins – Bioconversion of underutilised resources into next generation proteins for food and feed
2. FARMYNG – Flagship demonstration of industrial scale production of nutrient Resources from Mealworms to develop a bioeconomY New Generation
3. PLENITUDE – First-of-its-kind, large-scale, lowest-cost, zero-waste biorefinery for the production of proteins for food and feed application from low cost sustainable feedstocks
4. Prolific – Integrated cascades of PROcesses for the extraction and valorisation of proteins and bioactive molecules from Legumes, Fungi and Coffee agro-industrial side streams
5. Meat4All – Industrialisation and commercialisation of a competitive, sustainable and consumer oriented alternative animal protein source
6. AquaIMPACT - Genomic and nutritional innovations for genetically superior farmed fish to improve efficiency in European aquaculture
7. AQUABIOPROFIT – AQUAculture and Agriculture BIOmass side stream PROteins and bioactives for Feed, FITness and health promoting nutritional supplements
8. INVADERS – Mucus-Penetrating Microbiota: Characterisation, Mechanism and Therapeutic in Metabolic Disease
9. SymbNET – Genomics and Metabolomics in a Host-Microbe Symbiosis Network
10. Homo.symbiosus – Assessing, preserving and restoring man-microbes symbiosis

The NextGenProteins project focuses on **novel sources of proteins**. NextGenProteins will investigate the EU regulatory framework for the production and use of alternative proteins in food and feed. Regulatory aspects will also be explored in the FARMYNG project, which seeks to transform insects for the production of animal nutrition, while considering the safety of the end-products in full conformity with EU regulations.

Two projects (*i.e.* Meat4All and PLENTITUDE) focus on the **development of cultured meat**. Both projects will up-scale cultured meat production technology, hence contributing to the divergence related

to the "Characterisation of biological safety in novel/healthy food products processed with new techniques". The AquaIMPACT project aims to promote the efficient utilisation of European aquaculture by developing products and services based on genomic selection for breeding industry, while AQUABIOPROFIT seeks to develop side stream biomass processing technologies to up-concentrate nutrients and bioactives.

Finally, three projects that focus on **gut microbiome** have been identified (*i.e.* INVADERs, SymbNET and Homo.symbiosus). INVADERs and Homo.symbiosus will contribute to improving the knowledge of gut microbiome in relation to human health. SymbNET aims to establish a European network for host-microbe symbiosis research.

3.4.3. Recommended actions

Work Area 1: Innovative (and sustainable) food and feed products – technologies/resources

Divergence 1 (Work Area 1): Complexity and diversity of food and characterisation of biological and chemical safety of new contaminants

This divergence was assessed to be at conceptual level, and it entails two elements, which require a different set of actions, as detailed below.

The component of "Characterisation of biological and chemical safety" appears as a key priority in the view of consumer demand for innovative (and healthier) food, which are characterised by new processing techniques of high diversity and complexity, as well as new components influencing microbiota. The actions recommended to tackle this divergence revolve around establishing criteria to assess such new chemical and biological components, as detailed in the table below.

	Actions recommended
1	Research to map all key questions is needed (*i.e.* which information is needed in relation to technologies and type of food).
2	Research to map new chemical or biological molecules/hazards requiring new characterisation methods (or use of existing methods looking at new end points) would be necessary, as well as the assessment of fit-for purpose of existing characterisations methods to identify new chemical or biological molecules. If gaps are identified, the development of new analytical methods should be initiated to assess all potential new substances.
3	Rethink new concept for safety characterisation of micro-organisms (extension of the Qualified Presumption of Safety (QPS) system adapted to new products).
4	Establish more detailed risk assessment criteria for cellular agriculture.

The actions proposed to tackle the second component of Divergence 1, related to the complexity and diversity of food, can be summarised as follows:

	Actions recommended
1	A survey of technologies (to identify technologies to identify critical points regarding safety and what is known and not known).
2	A research project or case study to map the complexity and identify the factors influencing risk assessment.

	Actions recommended
3	An EFSA working group on innovative foods with a mandate on key factors influencing the modulation of risk assessment in regards of food technologies.

Work Area 2: Innovative (and sustainable) food and feed products – innovative production approaches

Divergence 2 (Work Area 2): Data requirements for risk assessment of innovative food and feed products from innovative production approaches

The actions recommended to tackle Divergence 2 from Work Area 2 revolve around strategies to meet the data requirements for the assessment of innovative food and feed products, as detailed in the table below:

	Actions recommended
1	To create an EFSA working group for establishing data requirements for innovative foods (working on definition, benchmarks, specific guidance, how to incorporate new findings in assessments etc.).
2	To rethink new concept for safety characterisation of micro-organism (extension of the QPS system adapted to new products such as for example synthetic micro-organism).
3	To establish more detailed risk assessment criteria for cellular agriculture.

Work Area 3: Identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification, including the understanding of the influence of microbiota modifications on human health

Divergence 3 (Work Area 3): definitions of microbiome/dysbiosis, characterisation of a healthy microbiota (setting standards) and definition of adverse effect of a microbiota

Actions proposed for the **divergences linked to the microbiome** were the following:

	Actions recommended
1	Set up a working group on microbiota with a mandate to provide a definition of microbiome/dysbiosis, on the characterisation of a healthy microbiota and on how to assess adverse effects induced on microbiota or by microbiota dysregulation.
2	Fact finding project to review state of knowledge on microbiota (survey, review of literature etc.)
3	Research project on the correlation between dysregulation of the microbiota and adverse effects.
4	Research on most relevant experimental tools (*in vitro* and *in vivo* models) to characterise microbiota and to assess adverse effects.
5	Large scale population-based project to characterise healthy microbiota (possibly Horizon Europe project).

Divergence 4 (Work Area 3): Need for clarification/revisitation on the overall strategy for protein safety assessment needs, agreement on validation processes and possible adverse immune reactions

This divergence, related to the overarching topic of new protein sources and protein diversification, entails three different aspects that can be tackled via set of different actions, as described below. The divergence was deemed to be at second readiness level with some already established tools and methods.

The actions proposed to address the **overall strategy for the assessment of protein safety** were the following:

	Actions recommended
1	Establish a working group on the overall strategy for protein assessment, including the effect on the immune system, including allergenicity, adequacy of standard toxicology studies/paradigm for protein.
2	Establish benchmark for risk assessment principles for cellular agriculture versus conventional agriculture.
3	Research project on adaptation of existing approaches and development of new ones (for example the use of omics, *in silico* and *in vitro* assays in safety assessment of protein – to avoid animal tests).
4	Case study or Pilot study on allergenicity, improve tools and develop new approaches to predict allergenicity of protein.
5	How to define reference points and/or health-based guidance values for new protein.
6	Research on methodology and tools to assess the relevance of individual immune response.
7	Research project (*e.g.* Horizon Europe research) in for establishing a post-market monitoring assessment system for novel proteins (create a decision tree, risk management and risk assessment).

Still linked to the same area of proteins, actions have been proposed also for the component of the divergence related to **the need of an agreement on validation processes**, as detailed below:

	Actions recommended
1	Working group to harmonise requirements for describing the whole processes of production of innovative foods.
2	A mechanism to incorporate conclusions from assessing bodies and institutes from the member states.

Finally, the actions proposed for the components of the divergence related to the possible **adverse immune reactions** stemming from this protein sources, **dataset requirements for complex food** and **needs for pre-clinical data** include the following:

	Actions recommended
1	Basic research is needed on immune reaction particularly regarding allergic reaction (issue of individual susceptibility).
2	Research on concepts of dose-response relationships related to general toxicology.
3	Establish benchmark risk assessment opinions on key components of tissue cultured media.
4	Implement a systematic literature review and data collection on the key components of the culture media used for synthetic meat.
5	Research project to fill knowledge gap on stacked GMO and synthetic biology.

3.5. Thematic area 5: Sustainable food systems and food safety

The term "food system" describes the whole food chain and includes production, processing, distribution consumption and disposal of food[24]. Although there is no standard definition of a sustainable food system, the Group of Chief Scientific Advisors to the European Commission refers to the definition provided by the FAO in 2014 that *"a sustainable food system delivers food security and nutrition for all in such a way that the economic, social and environmental bases to generate food security and nutrition for future generations are not compromised. A sustainable food system should thus ensure and contribute to all elements of environmental, social and economic sustainability"[25].* The EU legal and policy framework contributing to a sustainable food system is therefore wide and diverse and encompasses, beyond the Common Agriculture Policy (CAP) and the Common Fisheries Policy (CFP), policy areas such as environment, climate and biodiversity conservation policies, health and food safety, research and innovation, single market and competition, trade and development policies. The key flagship of the European Green Deal fostering the transition to sustainable food systems is the Farm to Fork Strategy[26] for a fair, healthy and environmentally friendly food system adopted in 2020, which sets (inter alia) actions to:

- Ensure sustainable food production, including aspirational targets on pesticide and fertiliser use reduction, antimicrobial use reduction for farmed animals, and increase in surface of land dedicated to organic farming.
- Ensuring food security.
- Ensure sustainable food processing, wholesale, retail, hospitality and food services practices.
- Promote sustainable food consumption and facilitating the shift to healthy, sustainable diets.
- Reduce food loss and waste.
- Combating food fraud along the food supply chain.

Considering these definitions and the EU policy framework described above, four work areas were developed under this theme.

Work area 1 focused on the impacts of the circular economy in the **emergence of potential food safety issues**, linked to the re-use of inputs/products transferred from one productive process to another. It also covered the potential food safety risks linked to the replacement of chemical fertilisers by organic amendments which could introduce contaminants into food and feedstocks, such as antimicrobials from manure, pesticides from compost, or heavy metals from sewage sludge. It identified the potential emerging risks linked to the use of "biological pesticides" as an alternative to chemical pesticides (*e.g.* the introduction of foreign species in the environment for pest control). Concerns were

[24] FAO, Sustainable food systems Concept and framework (2018) available at: https://www.fao.org/3/ca2079en/CA2079EN.pdf

[25] European Commission, Directorate-General for Research and Innovation, Group of Chief Scientific Advisors, Towards a sustainable food system : moving from food as a commodity to food as more of a common good : independent expert report, Publications Office, 2020, https://data.europa.eu/doi/10.2777/37244

[26] European Commission, 2020. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system: https://ec.europa.eu/info/sites/info/files/communication-annex-farm-fork-green-deal_en.pdf.

raised about the impact of extreme weather patterns linked to climate change such as flooding leading to potential pollution of food and feedstocks and of surface water used for drinking and agricultural purposes. Climate change impacts were also mentioned leading to increased exposure to natural toxins. Finally, the use of alternative protein sources and how to address their safety and sustainable aspects was discussed.

Work area 2 focused on the **reduction of food transport and the shift towards shorter/local food chains** as a key component of sustainable food processing and distribution, on the reduction of food waste, on new sustainable food processes potentially leading to new emerging foodborne hazards.

Work area 3 focused on the consequences of increased **consumption of alternative forms of protein**, of the development of sustainable food packaging and its reduction and on the development of food labelling covering sustainability aspects.

Work area 4 focused on **changes in dietary choices toward more sustainable diets** and on the inclusion of sustainability in dietary science-based guidelines.

3.5.1. Results of the horizon scanning

The horizon scanning exercise resulted in a list of eight potential divergencies and 22 challenges on the thematic area of sustainable food systems and food safety as shown in **Table 15**.

Table 15: Potential divergences and challenges on sustainable food systems and food safety identified by the Delphi panel

Potential divergence	Challenge
Work Area 1: Sustainable food production	
1. Risk assessment of organic fertilisers and on how infectious agents and toxic chemicals, in particular antimicrobials can be introduced and impact the subsequent food chain.	1. Coping with the increasing use of organic fertilisers potentially leading to unforeseen risks linked to such increase (*e.g.* increased exposure to contaminants) and the chemical complexity of such fertilisers. Ensuring that contaminants do not end up in the food chain.
	2. Lack of data to quantify the hazards of antibiotic resistance genes in food (*e.g.* linked to re-use of wastewater).
	3. Development of chemicals that can be recycled with low energy use.
2. Assessing risks from biological pesticides when limited data is available and determining which data is needed to carry out such assessment.	4. Developing an adequate method to assess risks from biological pesticides and assess the availability of data needed to carry out risk assessments.
	5. Ensuring that new products do not get "orphaned" as there is not enough data generated to support their use (*e.g.* because the private sector does not have sufficient incentive to provide the research and data collection).
	6. Conducting risk assessment on pollutants in soil linked to flooding.

Potential divergence	Challenge
	7. Need to reassess the biodegradability of compounds (pesticides/fertilisers) in soil and water due to changes in moisture levels and temperature. Studying and assessing exposure and hazards from natural toxins linked to climate change.
3. Risk assessment of wastewater to be re-used for agricultural purposes and on how infectious agents and toxic chemicals, in particular antibiotics can be introduced and impact the subsequent food chain.	8. Conducting risk assessment of wastewater to be reused for agricultural purposes to ensure that there are no food safety risks linked to contaminants such as residuals of medicinal products.
4. Different approach to the risk assessment of alternatives to animal protein sources that is based on limited data (*e.g.* some public bodies may be comfortable accepting a certain type/amount of data as sufficient, some may not).	9. Lack of harmonisation of the way new alternative protein sources are assessed leading to the need to develop a harmonised risk assessment framework. Lack of data and different ways of measuring the impacts of cultivated meat as well as data on new alternative proteins.
5. Addressing the sustainability aspects of artificial meat (*e.g.*, at present EFSA does not look at the broader environmental such as carbon elements of food - but they may be required to do so in future as part of sustainability).	10. Nutritional issues linked to non-animal protein sources that are not equivalent to animal proteins.
	11. High potential for fraud since it is difficult to identify whether it is lab grown meat or not.
Work Area 2: Stimulation of sustainable food processing and distribution	
NA	12. Exposure to contaminants (PM10, PM2.5[27]) in urban areas and the promotion of soilless systems (mostly organic substrates issued from recycled residues) could bring new risks.
	13. On whether the decarbonisation of transport of food should be prioritised over the decarbonisation of food production.
	14. Developing food packaging that reduces spoilage and waste as well as plastics that can be recycled with low energy demands.
6. Sustainable food processes leading to potential emerging foodborne hazards.	15. Lack of data to assess novel food processes/technologies to preserve food without refrigeration, as well as reduction in use of preservatives or sterilising methods in food.
	16. Communication challenges on the risks and benefit of technological innovation and ensuring that food safety is not impaired because of environmental considerations.
Work Area 3: Promotion of sustainable food consumption	
7. On the food safety aspects linked to a plant-based diet.	17. Lack of scientific data and consumption data to substantiate advice given by food safety authorities.
	18. More alternative packaging materials emerging affecting shelf life of food or potentially hazardous a challenge for food safety risk assessments due to data availability.

[27] For more information, please refer to https://www.epa.gov/pm-pollution/particulate-matter-pm-basics

Potential divergence	Challenge
	19. The trade-off of reducing food packaging versus the potential expansion of the use of refrigerants/refrigeration and food spoiling.
8. Creation of a scientific basis for the development of sustainable food labelling	20. Increase of fraud and food crimes linked to the development of sustainable food marking systems.
Work Area 4: New dietary guidelines (including methodological aspects for developing them) to accompany a shift to more sustainable diets	
NA	21. Difficulties to develop standardised methodology for dietary guidelines when including sustainability aspects.
	22. Collecting data on more natural toxins that might occur as a result of climate changes.

Work area 1: Sustainable food production

One scientific divergence linked to the development of circular economy emerged and it concerns **the risk assessment of organic fertilisers and on how infectious agents and toxic chemicals, in particular antimicrobials can be introduced and impact the subsequent food chain** (divergence 1). One scientific divergence emerged in relation to the regulatory/policy changes that encourage the reduction of particular fertilisers and pesticides, concerning **the way biological pesticides should be assessed when limited data are available and which data are needed to carry out such assessment in such case** (divergence 2). Looking at water management and the reuse of wastewater for agricultural purposes, the risk assessment of wastewater to be re-used for agricultural purposes emerges as a potential divergence. Specifically, **on how infectious agents and toxic chemicals such as antimicrobials could be introduced and impact the subsequent food chain** (divergence 3). Two potential scientific divergences emerged linked to the increased production of alternative protein sources. The first potential divergence concerned **the approach to the risk assessment of alternatives to animal protein sources due to limited data** (divergence 4), while the second related to the **manner in which the sustainability aspects of cultured meat would have to be addressed** (*e.g.* carbon elements of food) (divergence 5).

The **implementation of a circular economy** might lead to a series of challenges. Firstly, the difficulty to cope with the increasing use of organic fertilisers potentially leading to unforeseen risks as well as their chemical complexity (*e.g.* compost, manure, wastewater treatment plants, farm residues). Likewise, it will be challenging to ensure that contaminants do not end up in these fertilisers and are removed where feasible so as to not end up in the food chain (challenge 1). The Delphi panel pointed towards the challenge of addressing the lack of data to quantify the risks linked to antimicrobial resistance genes as a potential contaminant in food stemming from organic fertilisers (challenge 2). On the energy aspects of the circular economy, the development of chemicals that can be recycled with low energy use was considered a challenge (challenge 3).

Regulatory/policy changes which encourage the reduction of fertiliser and pesticides use could potentially lead to challenges linked to biological pesticides, such as the development of an adequate method to assess risks from these pesticides, as well as the availability of data impacting the possibility to carry out risk assessments (challenge 4). Another challenge might be the availability of new alternative products, such as "orphaned products", if there is not enough data generated to support

their use since the private sector does not have sufficient incentive to carry out research and data collection (challenge 5).

Extreme weather patterns from climate change (such as flooding), which could lead to potential pollution of soils for growing food and of surface water used for drinking and agricultural purposes could result in the difficulty to conduct risk assessment of pollutants in soil because of flash flooding (challenge 6). Another challenge linked to climate change, is its impact on the biodegradability of compounds and on increased exposure to natural toxins for food consumers. This may entail, respectively, the need to reassess the biodegradability of compounds (pesticides/fertilisers) in soil and water due to changes in moisture levels and temperature, and to study and assess risks from natural toxins linked to climate change (challenge 7). One last important aspect of climate change is the increase in the reuse of wastewater for agricultural purposes, leading to challenges in conducting the risk assessment of wastewater to be reused for agricultural purposes, to ensure that there are no food safety risks linked to contaminants such as residues of medicinal products (challenge 8).

The **increase in the production of alternative protein sources** could lead to challenges, such as the need to develop an adequate risk assessment framework for methodologies to generate data and indicators needed to measure the impacts of cultured meat, to generate data on new alternative sources of proteins (*e.g.* insects) and to address potential food safety issues in the European population which is not exposed to such proteins (challenge 9). Another challenge identified is to ensure that there are no nutritional issues linked to non-animal protein sources that are not equivalent to animal proteins (challenge 10). Finally, the increased production of such proteins may create high potential for fraud, such as the difficulty in assessing whether meat is lab-grown or not (challenge 11).

Work area 2: Stimulation of sustainable food processing and distribution

One scientific divergence emerged within the context of increasing foodborne hazards due to the development of sustainable food processes, namely the **assessment of such foodborne hazards** (divergence 6).

The reduction of food transport and the promotion of shorter/local food chains could lead to several challenges such as the development of new food safety risks linked to the development of urban agriculture. This includes exposure to contaminants (PM10, PM2.5) in urban areas and use of soilless systems with organic substrates issued from recycled residues with pathogens (challenge 12). The Delphi panel stressed another challenge with defining the priorities for decarbonisation, namely the transport of food versus food production (challenge 13).

When considering **the reduction of food waste,** developing food packaging that reduces spoilage and waste and uses plastics that can be more easily recycled with low energy demand was considered challenging (challenge 14). Lastly, several challenges were identified related to **the development of sustainable food processes leading to new emerging foodborne hazards.** These include the lack of data to assess novel food processes/technologies to preserve food without refrigeration, the risks of bacterial infections linked to the reduction in the use of preservatives or sterilisation methods in food, and lack of data for the risk assessments of novel food processes/technologies to preserve food without refrigeration (challenge 15). Related to these are the challenges of communicating the risks and benefits of technological innovation and ensuring that food safety is not impaired because of environmental considerations linked to the processing and distribution of food (challenge 16).

Work area 3: Promotion of sustainable food consumption

The Delphi panel identified two potential divergences linked to the promotion of sustainable food consumption. Related to the development of alternative forms of protein, the panel stressed potential divergences emerging on **the food safety aspects linked to a plant-based diet** (divergence 7). The second divergence is linked to the development of food labelling systems on sustainability aspects and concerns around **the creation of a scientific basis for the development of sustainable food marking systems** (*i.e.* labelling) (divergence 8), which is an ultimate risk management consideration.

The panel further identified several challenges related to the promotion of sustainable food consumption. One concerns the **development of alternative forms of protein** and the need to develop scientific data and consumption data (*e.g.* surveys do not provide robust data on novel food consumption) to substantiate the advice given by food safety authorities (challenge 17).

The **development of sustainable packaging or removal of packaging** was seen as potentially fuelling several related challenges such as the need to assess and ensure that alternative packaging materials do not affect the shelf life of food and are safe (*e.g.* potential hazards of alternatives to BPA, new plasticisers and microplastic residues) (challenge 18). The trade-off between reducing food packaging versus the expanded use of refrigerants/refrigeration was outlined as a challenge (challenge 19). Lastly, **the development of a food labelling system on sustainability aspects** can lead to increased fraud and food crimes (challenge 20).

Work area 4: New dietary guidelines (including methodological aspects for developing them) to accompany a shift to more sustainable diets

Challenges were identified regarding the **guidelines for sustainable diets,** but there no scientific divergences were identified by the Delphi panel. The first set of challenges relates to changes in dietary choices, including sustainability aspects, which can make the development of EU portion size guidance challenging as well as the guidance around diet recommendations for different regions, which should take into account differences such as climate, availability of food products, and existing diet trends (challenge 21). The set of challenges concerns the need to include sustainability aspects in dietary guidelines, which could prove difficult since there would be a need to develop a related standardised methodology to collect data on the increase of natural toxins that might occur as a result of climate change (challenge 22).

3.5.2. Results of the mapping exercise

The mapping of research activities on sustainable food systems and food safety combined responses from the survey targeting research groups across the world and the screening of ongoing relevant research projects. Based on the potential divergences and challenges identified through the horizon scan, the survey questioned participants on several research topics. **Table 16** shows the correspondence between potential divergencies, challenges and research topics that cover the field of the identified divergence.

Table 16: Research topics linked to potential divergences and challenges in sustainable food systems and food safety

Research topic	Potential divergence	Challenge
Work Area 1: Sustainable food production		
1. Risks related to pathogens, hazardous chemicals, antibiotics residues in organic fertilisers transferring to food	1. Risk assessment of organic fertilisers and on how infectious agents and toxic chemicals, in particular antibiotics, can be introduced and subsequently impact the food chain.	1. Coping with the increasing use of organic fertilisers, potentially leading to unforeseen risks linked to such increases (*e.g.* increased exposure to contaminants) and the chemical complexity of such fertilisers. Ensuring that contaminants do not end up in the food chain.
		2. Lack of data to quantify the hazards of antibiotic resistance genes in food (*e.g.* linked to re-use of wastewater).
		3. Development of chemicals that can be recycled with low energy use.
2. Methodology for assessing the risk from biological pesticides	2. Assessing risks from biological pesticides when limited data is available and determining which data is needed to carry out such assessment.	4. Developing an adequate method to assess risks from biological pesticides and assess the availability of data needed to carry out risk assessments.
3. Comparison between biopesticides and synthetic conventional pesticides		5. Ensuring that new products do not get "orphaned" as there is not enough data generated to support their use (*e.g.* because the private sector does not have sufficient incentive to provide the research and data collection).
4. Risk assessment of food potentially contaminated with soil pollutants (*e.g.* following extreme events, such as flooding)		6. Conducting risk assessment on pollutants in soil linked to flooding.
NA		7. Need to reassess the biodegradability of compounds (pesticides/fertilisers) in soil and water due to changes in moisture levels and temperature. Studying and assessing exposure and hazards from natural toxins linked to climate change.
5. Environmental and health risks associated with reuse of wastewater for irrigation	3. Risk assessment of wastewater to be re-used for agricultural purposes and on how infectious agents and toxic chemicals, in particular antibiotics, can be introduced and impact the subsequent food chain.	8. Conducting risk assessment of wastewater to be reused for agricultural purposes to ensure that there are no food safety risks linked to contaminants such as residuals of medicinal products.
6. Risk assessment of alternatives to animal protein sources (*e.g.* insects)	4. Different approach to the risk assessment of alternatives to animal protein sources that is based on limited data (*e.g.* some public bodies may be comfortable accepting a certain type/amount of data as sufficient, some may not).	9. Lack of harmonisation of the way new alternative protein sources are assessed leading to the need to develop harmonised risk assessment framework. Lack of data and different ways of measuring the impacts of cultivated meat as well as data on new alternative proteins.

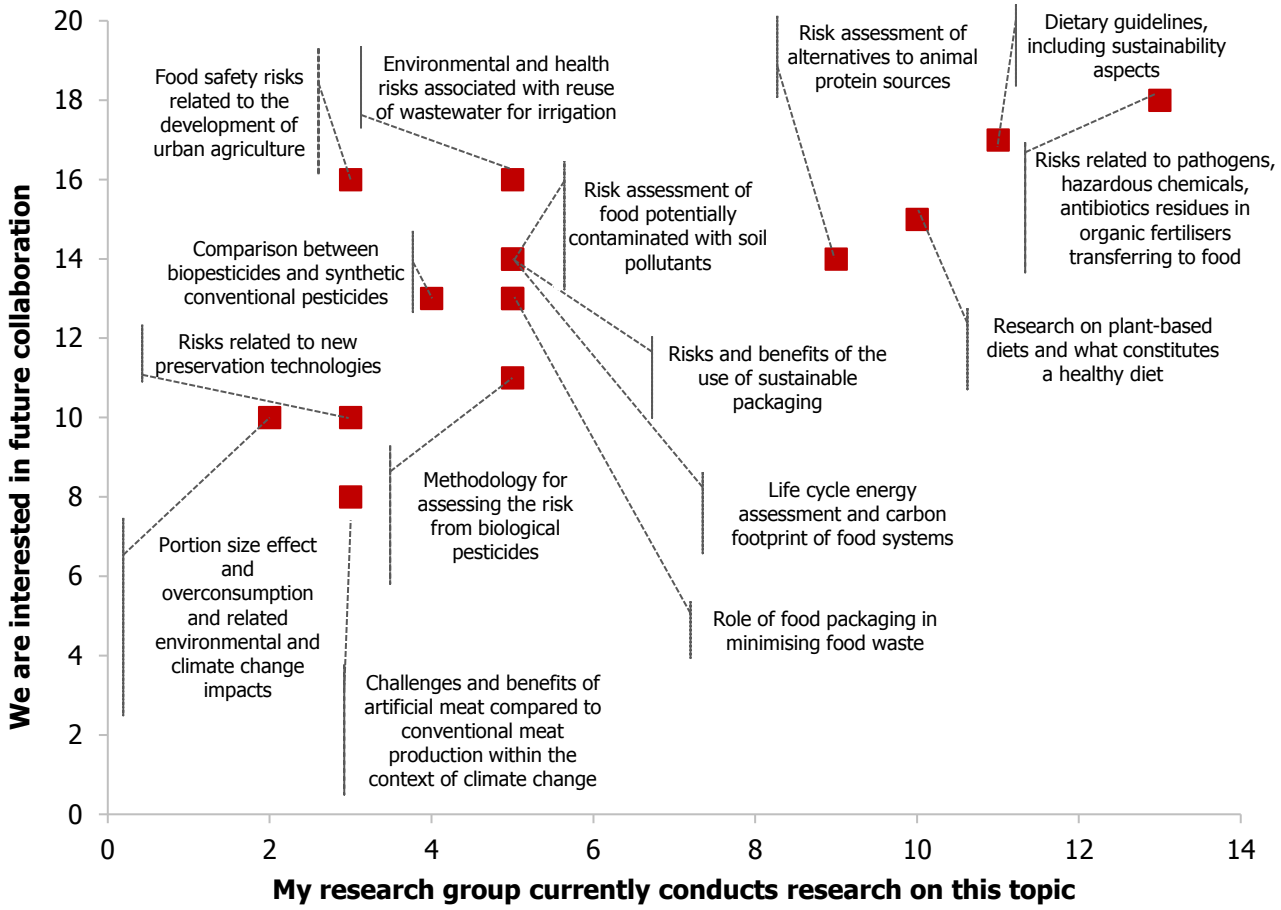
Research topic	Potential divergence	Challenge
7. Challenges and benefits of artificial meat compared to conventional meat production within the context of climate change (CO2 lifecycle emission of the two types of production)	5. Addressing the sustainability aspects of artificial meat.	10. Nutritional issues linked to non-animal protein sources that are not equivalent to animal proteins.
		11. High potential for fraud since it is difficult to identify whether it is lab grown meat or not.
Work Area 2: Stimulation of sustainable food processing and distribution		
8. Life cycle energy assessment and carbon footprint of food systems	NA	12. Exposure to contaminants (PM10, PM2.5) in urban areas and the promotion of soilless systems (mostly organic substrates issued from recycled residues) could bring new risks.
9. Food safety risks related to the development of urban agriculture.		13. On whether the decarbonisation of transport of food should be prioritised over the decarbonisation of food production.
10. Role of food packaging in minimising food waste.		14. Developing food packaging that reduces spoilage and waste as well as plastics that can be recycled with low energy demands.
11. Risks related to new preservation technologies.	6. Sustainable food processes leading to potential emerging foodborne hazards.	15. Lack of data to assess novel food processes/technologies to preserve food without refrigeration, as well as reduction in use of preservatives or sterilising methods in food.
		16. Communication challenges on the risks and benefit of technological innovation and ensuring that food safety is not impaired due to environmental considerations.
Work Area 3: Promotion of sustainable food consumption		
12. Research on plant-based diets and what constitutes a healthy diet.	7. On the food safety aspects linked to a plant-based diet.	17. Lack of scientific data and consumption data to substantiate advice given by food safety authorities.
13. Risks and benefits of the use of sustainable packaging.		18. More alternative packaging materials emerging affecting shelf life of food or potentially hazardous a challenge for food safety risk assessments due to data availability.
		19. The trade-off of reducing food packaging versus the potential expansion of the use of refrigerants/refrigeration and food spoiling.

Research topic	Potential divergence	Challenge
	8. Creation of a scientific basis for the development of sustainable food labelling.	20. Increase of fraud and food crimes linked to the development of sustainable food marking systems.
Work Area 4: New dietary guidelines (including methodological aspects for developing them) to accompany a shift to more sustainable diets		
14. Portion size effect and overconsumption and related environmental and climate change impacts.	NA	21. Difficulties to develop standardised methodology for dietary guidelines when including sustainability aspects.
15. Dietary guidelines, including sustainability aspects.	NA	22. Collecting data on more natural toxins that might occur as a result of climate change.

Results of the survey on research activities and interest in collaboration

The survey collected information on ongoing and planned research activities related to sustainable food systems and food safety from 49 research groups covering 15 countries. The surveyed research groups indicated current research, plans for future research and interest in collaboration for 15 research topics. **Figure 9** shows the number of research groups that indicated they were conducting research and were interested in collaboration research topics. "**Risks related to pathogens, hazardous chemicals, antimicrobial residues in organic fertilisers transferring to food**" is the research topic with the highest number of research groups currently conducting research (13) and expressing interest in future collaboration (18), suggesting room for further developments in this direction. By contrast, "**portion size effect and overconsumption and related environmental and climate change impacts**" was the least researched topic (2), with less interest in being expressed for future collaboration (10) than for most other TEG 5 topics. High interest in future collaboration was expressed for "**environmental and health risks associated with reuse of wastewater for irrigation**", "**dietary guidelines including sustainability aspects**", and "**food safety risks related to the development of urban agriculture**".

Figure 9: Overview of research groups conducting research and expressing interest in TEG 5 research topics



Source: Survey on mapping of research activities and collaboration interest

Overall, most of the research topics in sustainable food systems and food safety were relatively well researched. Nevertheless, interest in future collaboration was high for most topics. When looking at the number of research groups working on TEG 5 research topics, most research is related to Work Area 1 on "sustainable food production". Of these, the potential divergence on **how to assess risks from biological pesticides when limited data are available** (divergence 2) stood out as having the highest impact according to the Delphi panel. The survey showed that only five research groups from four different countries were currently conducting research on methodologies for assessing risks from biological pesticides. Given the high importance attributed to this potential divergence by the panel, this research field might be of specific interest for risk assessors.

The potential divergence **on the risk assessment of organic fertilisers** (divergence 1) was considered highly relevant by the Delphi panel but found to be in its early development stages (*i.e.* still at the concept level). It is therefore not surprising that 13 research groups across 8 different countries are conducting research on the associated research topic of "**risks related to pathogens, hazardous chemicals, antibiotic residues in organic fertilisers**", with nine research groups expressing an interest in collaborating on this topic.

The Delphi panel suggested that there was an existing level of knowledge on the potential divergence related to **the risk assessment of wastewater to be re-used for agricultural purposes** (divergence 3). While five research groups from four different countries indicated they were currently working on "**environmental and health risks associated with reuse of wastewater for irrigation**", there is a high level of interest for future collaboration in this field. 8 countries are conducting research on the challenges and benefits of artificial meat and 7 on the risk assessment of alternatives to animal protein source.

The only identified divergence in Work Area 2 on **new sustainable food processes leading to potential new emerging foodborne hazards** (divergence 6) was found to be covered by ongoing research, with 4 research groups from 8 different countries conducting research on **"risks and benefits of the use of sustainable packaging"**.

Other potential divergences related to Work Area 3 **on food safety aspects linked to a plant-based diet** (divergence 7) and the **scientific basis for the development of sustainable food labelling** (divergence 8) were rated by the Delphi panel as having a comparatively low impact on EFSA's preparedness. This might be related to the fact that ten research groups are currently conducting research on **plant-based diets and what constitutes a healthy diet** (albeit, clustered in 3 different countries).

Ongoing EU-funded research projects related to sustainable food systems and food safety

At EU level there are 30 multi partner large scale ongoing projects related to sustainable food systems (see **Table 17** below). The descriptions of all the projects listed in Table 17 can be found in Appendix A.5[11].

Table 17: List of ongoing EU funded projects on sustainable food systems and food safety

#	Project name
General research on sustainable food systems	
1	SUSFOOD2: Sustainable production and consumption
Sustainable food production	
Alternatives to chemical pesticides	
2	Use of microRNAs to combat plant pathogens
3	ECOBREED Increasing the efficiency and competitiveness of organic crop breeding
4	Diverfarming – Crop diversification and low-input farming across Europe: from practitioners' engagement and ecosystem services to increased revenues and chain organisation
Use of organic fertilisers and re-use of wastewater in the circular economy context	
5	RUN4LIFe – Recovery and Utilisation of Nutrients 4 Low Impact Fertiliser
6	NextGen – Towards a next generation of water systems and services for the circular economy
7	PROMISCES – Preventing Recalcitrant Organic Mobile Industrial chemicals for Circular Economy in the Soil-sediment-water system

#	Project name
8	SPRING – Strategic Planning for Water Resources and Implementation of Novel Biotechnical Treatment Solution and Good Practices
9	WATER-MINING – Next generation water smart management systems: large scale demonstrations for a circular economy
10	HYDROUSA – Demonstration of water loops with innovative regenerative business models for the Mediterranean region
11	Promoting One Health in Europe through joint actions on foodborne zoonoses, antimicrobial resistance and emerging microbiological hazards
12	Circular agronomics – efficient carbon, nitrogen and phosphorus cycling in the European Agri-food system and related up- and down-stream processes to mitigate emission
13	ORGANIC-PLUS Pathways to phase-out contentious inputs from organic agriculture in Europe
Production of alternative sources of proteins	
15	PLENITUDE – First-of-its-kind, large-scale, lowest-cost, zero-waste biorefinery for the production of proteins for food and feed application from low-cost sustainable feedstocks
16	ProFuture (microalgae protein ingredients for the food and feed of the future)
17	Meat4All (Industrialisation and commercialisation of a competitive, sustainable and consumer oriented alternative animal protein source)
18	CCMeat (Barley Biofarmed Growth Factors to Make Cell Cultured Meat an Affordable Reality)
19	PEPPER (Industrial-scale plant-based protein production in a cell-free platform)
Sustainable food processing	
Reduction of food transport and the promotion of shorter/local food chains	
20	FoodE – Promoting urban-rural governance to transform food systems
21	CITIES2030 - Co-creating resIlient and susTaInable food systEms towardS FOOD2030
Reduction of food waste and food packaging	
22	FOODRUS – An Innovative Collaborative Circular Food System to Reduce Food Waste and Losses in the Agri-Food Chain
23	A natural solution for post-harvest protection of fruits and vegetables"
24	GLOPACK – Granting society with Low environmental impact innovative PACKaging
25	SCALIBUR – Scalable technologies for Bio-Urban waste recovery
26.	Agro2Circular – Territorial circular systemic solution for the upcycling of residues from the agri-food sector
Promotion of sustainable food consumption	
27	Strength2Food – Strengthening European Food Chain Sustainability by Quality and Procurement Policy
28	SafeConsumE – Safer food through changed consumer behaviour: Effective tools and products, communication strategies, education and a food safety policy reducing health burden from foodborne illnesses
29	FoodTraNet – Advanced research and Training Network in Food quality, safety and security including research on traceability
Guidelines for sustainable diets	
30	Data Science and AI assisted holistic software to digitally design optimised high quality and safe food products with minor environmental impact

3.5.3. Recommended actions

Work area 1: Sustainable food production

Divergence 1 (Work Area 1) on the risk assessment of organic fertilisers and on how infectious agents and toxic chemicals, in particular antimicrobials, can be introduced and impact the subsequent food chain (debate between chemists and toxicologists)

This divergence is still at concept level. There is a lack of data to adequately assess the risks of infectious agents such as bacteria, virus and fungi impacting the food chain. There is also missing data on the risks linked to the use of soilless systems (*e.g.* hydroponics and urban agriculture) where pollutants can be highly concentrated compared to "traditional" soil cropping. The following actions were recommended.

	Actions recommended
1	Tools to develop a holistic assessment. Streamline data and certain areas data are missing (*e.g.* pharmaceuticals and microplastics).
2	More research on uptake of pollutants in foodstuffs (how those hazards get to food).
3	More research on impacts of antimicrobials (*i.e.* measuring background levels).
4	More research to check the capacity of antimicrobial resistance genes and bacteria, viruses and fungi from food to colonise the gut.
5	More research on risks linked to the potential high concentration of pollutants in soilless systems (hydroponic, urban agriculture).

Divergence 2 (Work Area 1): How to assess risks from biological pesticides when limited data are available and in such case which data are needed to carry out such assessment

Some tools and methods are established to assess these risks but there is a lack of consensus on how such risk assessment should be carried out considering the lack of data and the fact that compared to (natural/synthetic) substances, species can be invasive in an appropriate context and any living agents may colonise the environment. The following actions were recommended.

	Actions recommended
1	More research on the use of biological pesticides (*e.g.* risks linked to living agents such as species that can be invasive in a specific context).
2	Guidelines on how to do risk assessment on biological pesticides among member states.
3	Guidelines on data requirements for applicants seeking an authorisation of new biological agents.

Divergence 3 (Work Area 1): On the risk assessment of wastewater to be re-used for agricultural purposes and on how infectious agents and toxic chemicals, in particular antimicrobials, can be introduced and impact the subsequent food chain

There is extensive knowledge and research carried out on the risks linked to the re-use of water for agricultural purposes but there is still a lack of consensus on how to assess this risk. There is a wide variability regarding the types of wastewater, so it was necessary to characterise and monitor different scenarios (*e.g.* large treatment plants from large cities, to smaller scale scenarios). The following actions were recommended.

	Actions recommended
1	Research on characterisation of different scenarios (large treatment plants from large cities, to smaller scale) monitoring is necessary.
2	International colloquium on wastewater risks when re-used for agricultural purposes and an EFSA panel under risk assessment.

Divergence 4 (Work Area 1): Food safety risk assessment of new alternatives to animal protein sources

On this divergence the co-operation between industry and academia as well as additional research should be considered. The divergence was assessed as being at the second level of readiness (meaning there are already established tools and methods). The following actions were recommended.

	Actions recommended
1	Data gaps to be addressed even for more classic alternative sources of proteins (*e.g.* what are the positive impacts on sustainability) by research projects.
2	Research required on hazards associated with lab grown meat, if any.
3	More cooperation between industry and science.
4	Data gaps on hazards and level of exposure.
5	Alternative protein hazards linked to processing.

Divergence 5 (Work Area 1): On how to address the sustainability aspects of artificial meat (*e.g.* at present EFSA does not look at the broader environmental (*e.g.* carbon) elements of food, but they may be required to do so in future as part of sustainability).

This divergence is at the concept stage and interdisciplinary research is necessary. The following actions were recommended.

	Actions Recommended
1	Interdisciplinary research to be fostered.
2	Research on life cycle assessment of artificial meat.

3	Research on impacts of ingredients (*e.g.* use of antimicrobials, animal foetal calf sera) to grow the cells used to produce artificial meat.
4	Agreements on metrics needed to measure the sustainability impacts of artificial meat.

Work area 2: Stimulating sustainable food processing and distribution

Divergence 1 (Work Area 2): New sustainable food processes leading to new potential foodborne hazards

There are established tools and methodologies, and extensive knowledge, but no consensus in place. The following actions were recommended.

	Actions recommended
1	More research on emerging risks from the EWRS in EFSA (early signals).
2	Discussion at stakeholder meetings with industry.
3	Article 36 of the food safety Regulation on actions on trends in new sustainable food processing and production (*e.g.* reduce food packaging materials such as plastic, underwater farming, urban agriculture and the exposition of food systems to pollutants from urban areas).

Work area 3: Promotion of sustainable food consumption

Divergence 1 (Work Area 3): On whether a plant-based diet is a healthy diet (*e.g.* iron) as part of the broader lack of consensus on what constitutes a healthy diet.

There is extensive knowledge in this area, but no consensus. The following actions were recommended.

	Actions recommended	
1	For developing a consensus on what constitutes a healthy diet:	
	a. What is it what we need to make progress on defining what is a healthy diet within the concept of sustainability.	b. Research on what could be a healthy diet within the sustainability framework
2	We need to make progress on defining a healthy diet within the concept of sustainability.	
3	Research on what could be a healthy diet within the sustainability framework.	

Divergence 2 (Work Area 3): scientific basis for the development of sustainable food labelling

There are some established tools and methodologies for the development of sustainable food labelling but the open question of EFSA's role in food labelling (which is primarily considered as a risk

management issue) remains. The following actions were recommended despite the unclarity of the future role of EFSA will have on the development of criteria to define what sustainable food is.

	Actions recommended
1	EFSA to develop tools and methods once the role of EFSA on sustainability consideration if any has been clarified by mid-end 2022.

3.6. Thematic area 6: Evidence-based risk communication in the EU Food Safety System

Evidence-based risk communication in the EU food safety system focused on four work areas.

Work area 1 concerned on the development and implementation of an **integrated risk communication (RC) framework**, which would consider how to link risk assessment to effective RC, which in turn would respond to the communication needs of different target audiences. This would include integration and harmonisation of RC across different European and national institutions where this was appropriate according to local regulatory structure.

Work area 2 addressed the **identification of research needs** that are considered crucial to further inform appropriate RC in the EU**.**

Work area 3focused on **potential differences between different target audiences, and between risk communication contexts**, including the social, cultural and technological factors affecting the information needs of target audiences**.**

Work area 4, alignment of labelling with consumer priorities, preferences and understanding, was reformulated to "**Relevance of messaging to consumer priorities, preferences and understanding**", as labelling was considered more of a risk management activity than one of **RC**.

In all of the work areas, the emphasis was understanding challenges and how to respond to these rather than on identification of divergences as such, as scientific divergences would not occur in relation to risk communication strategies.

The following areas are also of concern: (i) RC in relation to social platforms, (ii) RC in "peacetime" as opposed to during active crises, and (iii) there are competing models of RC in the literature, given that some approaches may work better than others according to context and target audiences. These were adequately integrated into the four pre-defined key work areas.

3.6.1. Results of the horizon scanning

The horizon scanning exercise resulted in a list of 17 challenges on the thematic area of evidence-based risk communication in the EU Food Safety System, as shown in **Table 18**.

Table 18: Challenges on evidence-based risk communication in the EU Food Safety System identified by the Delphi panel

#	Challenge
Work Area 1: Integrated risk communications	
1	Having the institutional capacity to adapt RC *e.g.* in light of digitalisation and rapid technological change.
2	Maintaining a stable and predictable information flow, where there are now increasingly multiple channels, platforms and tools.
3	Being able to pre-emptively communicate what is being done to protect the public.
4	Ensuring that consumer information is disseminated based on their actual needs, and how these differ between groups with "shared values", rather than the "classical" demographic delineation (*e.g.* changing target groups for different cuisines).
5	Ensuring that required knowledge of "who needs what" is available and up-to-date for decision-makers and practitioners.
6	Interdependency between experts working in different agencies or sectors in the eyes of the public – statements and actions from other experts and institutions can affect public trust in others as well.
7	How to effectively communicate risk when the specifics of the risk are uncertain or contested, or rapidly changing (*e.g.* in the case of an emerging risk).
Work Area 2: Research needs that are considered crucial to further inform appropriate risk communication in the EU	
8	Ensuring that sufficient research is done to "update" RCs in the digital age, in a continually changing socio-technical environment.
9	How RCs within the wider food system (including *e.g.* producers) can be harmonised and knowledge exchanged effectively between all stakeholders and actors.
10	Knowledge of behavioural research on how consumers information preferences and evaluation of information sources develop, whether there are "trigger events" which influence trust, and how to address this effectively.
11	Having access to research that assesses changes in risk and benefit perceptions continually, so that changes over time can be recorded.
Work Area 3: Social, cultural and technological factors affecting the information needs of target audiences	
12	Individual differences in people's skills and motivations to use new digital tools – There is a need to ensure that people are not excluded or left behind in transition.
13	There is a need to ensure that the voices of all stakeholders are heard in the changing food landscape, including in relation to changing consumer concerns (*e.g.* higher emphasis from citizens on sustainability).
14	Multiple channels are required to reach different audiences with different needs – these must also be coordinated within and across institutions.
15	Trust in different sources may vary culturally, and different demographic groups, or groups of people with "shared values" will not react uniformly to incidences or events.
Work Area 4: Relevance of messaging to consumer priorities, preferences and understanding	
16	Ensuring that changes in consumer priorities and expectations are understood and taken into account.

#	Challenge
17	There is a need to react promptly in relation to events or incidences that need to be communicated to the public.

Work Area 1: An integrated RC framework

Various challenges were related to this work area. The digitisation of risk communication (RC) (and alternative information sources accessed by the public and other stakeholders, and the speed at which these platforms were evolving) is an important RC issue, including in relation to "not leaving some groups of consumers behind". Other challenges included the need to develop effective RC in "peacetime", and to harmonise RC across the EU, within EU member states, and internationally. Increased distrust in institutions and experts is an important challenge. This includes variation in trust across different groups of people in society, linked to the need to monitor changing perceptions of risk in time and between differing geographical regions and/or social groups with "shared values". A key concern is to ensure that there is **institutional capacity**, in terms of both institutional resources and "soft" resources, such as trained staff that can use new digital tools and communication channels.

In response to the changing preferences, capacities and attitudes of target audiences, it is important to **know and understand target audiences** and to use this information to tailor communication channels to their needs. This will require understanding what those needs are *a priori*. This is necessary to ensure that important information reaches all audiences, regardless of their circumstances. In this context, there is value in **pre-emptive communication** conveying what is being done to protect the public, particularly when this prevents or mitigates a food safety issue arising, in order to increase trust.

Finally, trust in institutions is contingent not only on their own actions, but also those of adjunct experts and institutions – **the actions of one actor can have implications on trust in other actors or institutions**. For example, communication by a public health agency can influence trust in a food safety agency.

Work Area 2: Research needs that are considered crucial to further inform appropriate RC in the EU

There are areas relevant to effective RC which may be identified as important, but where there is research already occurring. Particular research needs were linked to increased digitalisation, the interconnectedness of food systems, the issue of growing societal distrust and how to manage this in RC, and the ongoing issue of change in public perceptions and how this influences the content of RC messaging.

The main discussion points in this work area concerned the **up-to-date mapping of public opinions and attitudes** (*e.g.* regarding what is expected from safe food, how different demographic groups use different communications channels, and how views of risk and benefit change over time). Ensuring that this is considered in real time means that early shifts in attitudes and consumption habits can be identified and acted upon pre-emptively, rather than retroactively. It is also important to understand how "shared values across participants on social media platforms differ from standard demographic differentiation of perceptions and attitudes". Research is also needed into the communication of uncertainties in relation to changing risk, for example in the context of emerging risk issues.

Work Area 3: Social, cultural and technological factors affecting the information needs of target audiences

Challenges were again linked to responding to the rapid changes occurring in digital environments, and how to respond to these changes. In addition, changes in societal concerns – for example, in relation to the environment and sustainability of food production – need to be addressed in research. Public response to emerging or new risks may differ from established risks (*e.g.* they may be viewed as more severe or threatening) and this needs to be considered in the RC process.

The most significant point of discussion in this work area again concerned how **different audiences have different communication needs**. Here, a point was raised specifically in relation to the need to ensure that specific groups of consumers are not "left behind" in the transition to new digital tools and communication channels. For example, older people and disadvantaged populations may not always be reached digitally, either due to different media consumption habits or due to lack of access to the required tools. The need for **multiple channels, including traditional media,** in communicating to the public was therefore emphasised.

An additional issue of discussion was how **trust varies between demographic groups and can change for different reasons**. In an EU context, the public of some member states may *a priori* have a higher trust in public institutions, and therefore be more likely to respond positively to their recommendations. Within member states, different groups within the public will place different levels of trust in different actors. Risk communicators should be aware that events or incidents can affect trust differently within these groups.

Finally, consumer perceptions (for example in relation to concerns on environmental health) may influence the way risk messages need to be crafted, combined with the nature of scientific evidence required to address consumer concerns.

The challenges linked to digitalisation and the interconnectedness of the food system were identified, but it was also recognised that technological solutions, such as integrating communication into QR codes or using block chain technologies to enable rapid responses to food risks and food recalls, linked to RC, could be exploited. Key points here focussed on **how consumer priorities and attitudes change over time**, so that communication strategies can be adapted accordingly. There was also an emphasis on the need to **act fast to change information in case of incidences or emergencies** to ensure that a proactive approach is taken and is appreciated by the public. There was some discussion about the role of labelling, and whether this should be used as a "digital" RC tool given that traceability systems are becoming more precise and robust– in the context of risk communication activities falling under the risk management purview.

3.6.2. Results of the mapping exercise

The mapping exercise on evidence-based risk communication in the EU Food Safety System combined responses from the survey and the screening of ongoing relevant research projects. Based on the challenges identified through the horizon scan, the survey questioned participants on several research topics. **Table 19** below shows the correspondence between challenges and research topics.

Table 19: Research topics linked to potential divergences and challenges in exposure science in risk assessment

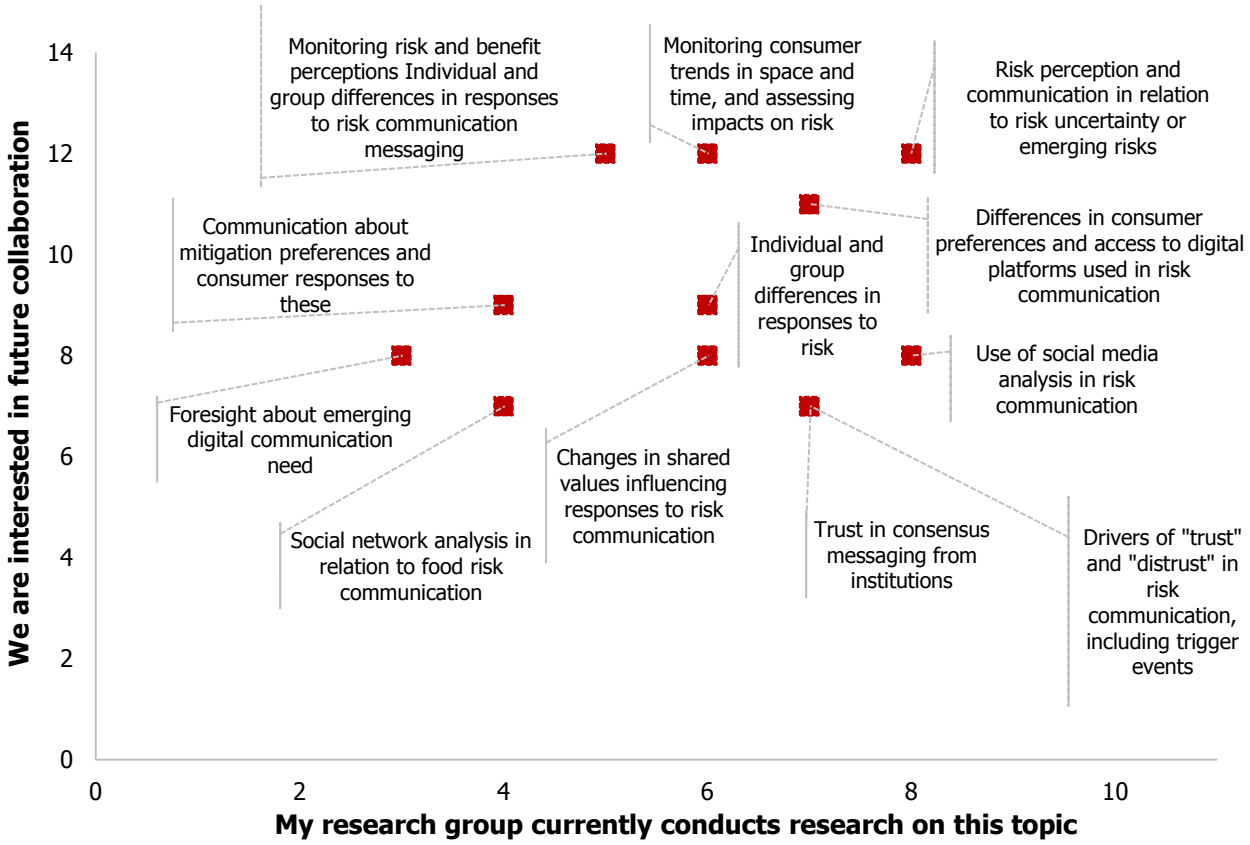
Research topic	Challenge
Work Area 1: Integrated risk communications	
NA	1. Having the institutional capacity to adapt RC *e.g.* in light of digitalisation and rapid technological change.
1. Differences in consumer preferences and access to digital platforms used in risk communication	2. Maintaining a stable and predictable information flow, where there are now increasingly multiple channels, platforms and tools.
2. Communication about mitigation preferences and consumer responses to these	3. Being able to pre-emptively communicate what is being done to protect the public.
3. Use of social media analysis in risk communication	4. Ensuring that consumer information is disseminated based on their actual needs, and how these differ between groups with "shared values", rather than the "classical" demographic delineation (*e.g.* changing target groups for different cuisines).
	5. Ensuring that required knowledge of "who needs what" is available and up-to-date for decision-makers and practitioners.
4. Trust in consensus messaging from institutions	6. Interdependency between experts working in different agencies or sectors in the eyes of the public – statements and actions from other experts and institutions can affect public trust in others as well.
5. Risk perception and communication in relation to risk uncertainty or emerging risks	7. How to effectively communicate risk when the specifics of the risk are uncertain or contested, or rapidly changing (*e.g.* in the case of an emerging risk).
Work Area 2: Research needs that are considered crucial to further inform appropriate risk communication in the EU	
6. Foresight about emerging digital communication needs	8. Ensuring that sufficient research is done to "update" RCs in the digital age, in a continually changing socio-technical environment.
7. Social network analysis in relation to food risk communication	9. How RCs within the wider food system (including *e.g.* producers) can be harmonised and knowledge exchanged effectively between all stakeholders and actors.
8. Drivers of "trust" and "distrust" in risk communication, including trigger events	10. Knowledge of behavioural research on how consumers information preferences and evaluation of information sources develop, whether there are "trigger events" which influence trust, and how to address this effectively.
9. Monitoring risk and benefit perceptions and individual and group differences in responses to risk communication messaging	11. Having access to research that assesses changes in risk and benefit perceptions continually, so that changes over time can be recorded.
Work Area 3: Social, cultural and technological factors affecting the information needs of target audiences	

Research topic	Challenge
10. Individual and group differences in responses to risk communication messaging	12. Individual differences in people's skills and motivations to use new digital tools – There is a need to ensure that people are not excluded or left behind in transition.
	13. Multiple channels are required to reach different audiences with different needs – these must also be coordinated within and across institutions.
11. Monitoring consumer trends in space and time, and assessing impacts on risk perceptions	14. There is a need to ensure that the voices of all stakeholders are heard in the changing food landscape including in relation to changing consumer concerns (*e.g.* higher emphasis from citizens on sustainability).
12. Changes in shared values influencing responses to risk communication	15. Trust in different sources may vary culturally, and different demographic groups, or groups of people with "shared values" will not react uniformly to incidences or events.
Work Area 4: Relevance of messaging to consumer priorities, preferences and understanding	
13. Same as #2	16. Ensuring that changes in consumer priorities and expectations are understood and taken into account.
	17. There is a need to react promptly in relation to events or incidences that need to be communicated to the public.

Results of the survey on research activities and interest in collaboration

Overall, the challenges identified by the Delphi panel are already explored within research conducted in several countries. The survey collected information from 20 research groups across 11 countries. **Figure 10** shows the research topics associated to challenges, most of which were generally found in Work Area 1. While research was conducted on all TEG 6 research topics, some stood out as being less explored within the research community such as "**communication about mitigation preferences and consumer responses to these**" and "**foresight about emerging digital communication need**".

Figure 10: Overview of research groups conducting research and expressing interest in TEG 6 research topics



Source: Survey on mapping of research activities and collaboration interest

Interestingly, more than half of the respondents (12 research groups out of 20) expressed interest for possible future collaboration in the field of **"risk perception and communication in relation to risk uncertainty or emerging risks"**, which is a topic which is already highly researched. This topic also seems to have a wide potential for collaboration in terms of geographical scope. The most popular research topic is related to how to **effectively communicate risk when the specifics of risk are uncertain, contested or rapidly changing** (challenge 7). The urgency of ensuring that citizens are kept informed even in volatile situations is reflected by the results of the mapping exercise, which indicates that eight out of 20 research groups are conducting research, and 12 would be interested in future collaboration on the topic.

Another challenge considered as key priority by the Delphi panel relates to **institutions having sufficient capacity to adapt their risk communications in light of digitalisation and rapid technological change** (challenge 1). Closely linked to this is the need to **ensure that enough research is performed to "update" risk communications in the digital age** (challenge 8). While social media analysis and differences in consumers access to digital platforms are among the research areas which draw most interest from research groups both in terms of current and future research,

foresight about additional digital communications needs is only researched by three of the surveyed institutions, while eight others would be interested in future collaboration. The ongoing research on social media and digital platforms can help inform the ongoing adaptation to the digital transformation, but additional focus on future needs can help anticipate future requirements as well.

Another challenge considered highly pertinent related to **ensuring that consumer information is disseminated based on their actual needs as a group** (challenge 4). This is one of a few challenges linked to the diversity of citizens, both in terms of attitudes, values and habits. These other challenges include **knowledge of how consumer information preferences and risk-benefit perceptions develop over time** (challenges 10 and 11), **individual differences in people's skills and motivations to use digital tools** (challenge 12), **coordination is required between multiple communications channels aimed at different groups of people with different needs** (challenge 14), and the **variation in trust in different sources of information between cultural and demographic groups** (challenge 15).

These are among the more researched topics: six institutions are currently researching consumer trends in space and time (including changing risk perceptions) and individual and group responses to risks. Both challenges also showed high interest for future collaboration, indicated by nine and 12 research groups, respectively. Differences in risk perception are researched by an additional seven and 11 research groups indicated interest for future collaboration. The number of linked research topics under this broader challenge ensures that the challenge is looked at from a broad set of perspectives. Additional exercises may work to synthesise the findings of the linked research topics for broader insights.

A final set of challenges relate to how public institutions like EFSA can ensure continued trust in their communications. Fulfilment of the challenges discussed above will go some way towards ensuring this goal by ensuring that citizens' needs and expectations in terms of risk communication are being met through appropriate platforms. Additional actions which can reinforce and build trust is to **promptly react to events or incidences affecting the public** (challenge 17) and to **pre-emptively communicate what is being done to protect the public outside of active crisis situations** (challenge 3). According to the mapping exercise, both challenges showed a strong interest in future collaboration that was indicated by seven and eight research groups, respectively.

Linked to these is the challenge of **perceived interdependency among institutions** (challenge 6), whereby the public may perceive different experts as "linked" by the fact that they are public figures, even if they derive from different institutions. Whether this perception is correct or not, an impression that experts are giving conflicting advice can have a negative effect on trust towards institutions in some demographic groups. This is reflected by it being one of the more-researched areas among surveyed institutions, with seven research groups working on the topic, 3 research groups planning to conduct research on the topic and eight research groups interested in future collaboration.

Ongoing EU-funded research projects related to evidence-based risk communication

The mapping of multi partner large scale ongoing research projects resulted in a list of eight EU-funded projects relating to evidence-based risk communication. The list of ongoing EU-funded projects includes (*inter alia*):

1. INEXTVIR – Innovative Network for Next Generation Training and Sequencing of Virome

2. SWEET
3. Foodsafety4EU
4. SafeConsumE – Safer food through changed consumer behaviour
5. Trust and Transparency for the Food Supply Chain
6. InnoFoodAfrica
7. Food Systems in European Cities
8. Food Stuff Information: Reality and Illusions

INEXTVIR (Innovative Network for Next Generation Training and Sequencing of Virome) seeks to generate a better understanding of **viral communities and their role in agricultural ecosystems** by using the latest advances in high throughput sequencing (HTS) technologies coupled with modern big data analytical approaches and socioeconomic analysis. The research is relevant to challenge 7, how to effectively communicate risk when the specifics of the risk are uncertain or contested, or rapidly changing (*e.g.* in the case of an emerging risk), as there is a dedicated research activity focused on risk and benefit perception and communication associated with the plant virome in agriculture.

SWEET will develop and review evidence on long term **benefits and potential risks involved in switching over to sweeteners and sweetness enhancers** (S&SEs) in the context of public health and safety, obesity, and sustainability. The research is directly relevant to challenge 5, ensuring that required knowledge of "who needs what" is available and up-to-date for decision-makers and practitioners, and to Challenge 11, having access to research that assesses changes in risk and benefit perceptions continually, so that changes over time can be recorded. A dedicated work package assesses the risk and benefit perceptions associated with natural and artificial sweeteners and applies this to the development of effective risk communication strategies. Social media analysis has been conducted to assess discussion of risks and benefits of both types of sweeteners across several social media platforms, as well as the traditional media.

Foodsafety4EU is a collaborative action to support the European Commission (EC) in shaping the **food safety system of the future**. The objective is to design, develop and release a multi-stakeholder platform and innovative digital tools to help citizens, scientists, companies, EC, EFSA, and Food Safety Authorities co-design and shape together the future Food Safety System in Europe. It has relevance to all aspects of TEG 6, including challenges linked to communication within the food system, as it will design, develop and release a multi-stakeholder platform to help citizens, and other food chain actors, to shape together the future Food Safety System in Europe. Risk communication and knowledge exchange are integral to its activities.

The overall goal of the project SafeConsumE is to provide effective, **science-based and sustainable strategies** for food authorities, market actors and the research community to help consumers mitigate risk, thus reducing the health burden from food-borne illness in Europe. The research is central to Work Area 1 (an integrated risk communication framework) as the overall aims of the project to support food safety authorities in the improvement of their risk communication practices.

Trust and Transparency for the Food Supply Chain aims to optimise the information on expiration date stated on the label. The FreshIndex was created to provide all parties information on exact and true freshness of the food. It is a platform for the exchange of data on food quality and safety. The FreshIndex is the exact expiry date which will replace the current sub-optimal solution and contribute

to reduction of costs and food waste. The research allows consumers to use their mobile phones to scan the product barcodes and get detailed information on the product production, its path to the consumer and the remaining shelf-life, and so is of relevance to Work Area 4, relevance of information/messaging to consumer priorities, preferences and understanding.

The project Food Systems in European Cities aims to accelerate the growth of CRFS by bringing together local initiatives across Europe and co-developing and disseminating new tools to promote and bolster **citizen-driven food systems**. The project will encourage local communities to work in line with the EU sustainable development goals. It will define the operational methodology for the assessment of CRFS and promote cooperation between European CRFS. The research is of direct relevance to Work Area 3, the social, cultural and technological factors affecting the information needs of target audiences, as communication and knowledge exchange between the public and other stakeholders is embedded in the research activities. The strategic goal of the project "Food Stuff Information: Illusions And Reality" is to investigate channels of information about food products in the chains "producer - consumer", "producer - mediator - consumer", "producer - producer" from a linguistic point of view and to research how effectively they affect the addressee.

3.6.3. Recommended actions

Various recommendations and actions were identified in relation to the challenges of thematic area 6. It should be noted that some of these spanned, and were common to, several work areas. This section summarises for each challenge how advanced the conceptualisation of the challenge is, actions which have been proposed, and the level of ongoing research based on the survey.

Work Area 1: An integrated RC framework

Challenge 1 (Work Area 1): Having the institutional capacity to adapt RC (*e.g.* considering digitalisation and rapid technological change)

A challenge is to ensure that requisite institutional capacity is in place to meet the challenges of digitalisation and rapid technological change. A consensus action to address this was to leverage existing social media expertise within the organisation (or, if it is not in place, recruit to fill this gap) to develop training programmes for risk assessors and risk managers.

This challenge is somewhere between concept level and a medium readiness level with established tools and methods. The gravity of the challenge is reflected by the results of the mapping exercise: social media analysis in relation to risk communication and differences in how consumers access digital platforms are common research areas (8 and 7 institutions researching these, respectively). However, foresight activities of future digital communications needs are less researched and may benefit from additional attention.

	Actions recommended
1	Allocate or assign staff (including specialists in social media) to **develop relevant training programmes for risk assessors and risk managers**. If they are not already present in the

	organisation, there is a need to ensure that staff with such skills or expertise can be recruited to ensure internal capacity.

Challenge 2 (Work Area 1): Maintaining a stable and predictable information flow, where there are now increasingly multiple channels, platforms, and tools

In a complex communications landscape where information is disseminated both through traditional media channels and digital channels, the maintenance of a stable information flow presents challenges for public-facing organisations. An inventory or mapping of the current risk communications information flows was recommended to identify bottle necks (*e.g.* whether the information reaches the target audience, or whether situation updates are given as much visibility as initial statements and communications). The currently available tools and metrics should be taken into consideration when evaluating the efficiency of different tools and channels.

Different ways of using social media – including analysis of social media metrics, differences in access to digital platforms, and social network analysis – are to different extents being researched by the institutions surveyed in the mapping exercise, indicating that research attention is being paid to the theme.

	Actions recommended
1	**Mapping the information flow of RC** through existing channels (including through usage and reach metrics) in order to **identify and address bottle necks** within this process.
2	**Ensuring that available tools and metrics are used** in order to monitor responses to messages in real-time and to adapt strategy as required. It may be relevant to conduct pilot research, as case study or natural experiment to address this issue.

Challenge 3 (Work Area 1): Being able to pre-emptively communicate what is being done to protect the public

Pre-emptive communications of EFSA's activities and what is being done in "peacetime" activities is an effective way of increasing trust in communications. This would ensure that EFSA is not only visible in crisis situations, but can also show ongoing work, thus giving a sense of continuity in its activities.

Three actions may be required. First, a behavioural research project funded through the Horizon programme or in collaboration with the JRC could contribute to knowledge of how such communications are received and whether pre-emptive communications are indeed effective as a trust-building tool. Second, it is important to continue already ongoing proactive communications campaigns (of which EUChooseSafeFood was cited as an example of good practice). Third, communications should, to a greater extent than is currently practiced, include information on how the food system is structured and what is EFSA's role within it, to increase public knowledge about the activities within EFSA. Comparatively few of the institutions surveyed in the mapping exercise are investigating this issue, with 4 researching communication on mitigation preferences and consumer responses to them.

	Actions recommended
1	Develop a **behavioural research project** funded through, for example, the Horizon programme or in collaboration with the JRC.
2	**Additional proactive communications campaigns** which can communicate ongoing activities – the EUChooseSafeFood campaign was mentioned as an example of good practice in this area. Similar activities should continue to be rolled-out, informed by associated activities based on, for example, Eurobarometer trust results.
3	To improve the public understanding of the EU food system, campaigns should also **integrate messaging on how the broader food safety ecosystem is structured and EFSA's role within it**.

Challenge 4 (Work Area 1): Ensuring that consumer information is disseminated based on their actual needs, and how these differ between groups with "shared values", rather than the "classical" demographic delineation (*e.g.* changing target groups for different cuisines)

With changing demographics and food habits, the target groups in different crisis situations may also have changed. A given example of this was that foods which are traditionally associated with specific communities are now enjoyed also beyond these communities (for instance, sushi is consumed far beyond the Japanese community in many European countries). Being aware of how consumer patterns have changed can aid the effective targeting of crisis communications. Changes in shared values is researched by 6 out of the surveyed institutions in the mapping exercise, placing it in the middle of the themes in terms of research coverage, which is in line with the fact that the panel concluded there were established tools and methods in relation to this challenge.

	Actions recommended
1	A **research project which can assess changing values**, how these link to diets and habits, as well as the drivers of these changes. The focus is current, developing and future values and food choices and habits. This could likely occur within the scope of the Horizon programme.

Challenge 5 (Work Area 1): Ensuring that required knowledge of "who needs what" is available and up to date for decision makers and practitioners

Decision makers and practitioners must have the information and resources they need to make informed decisions. This requires continued collaboration over and across institutions, similar to the work of the One Health framework. Additionally, monitoring of information needs is required to assess public opinion. While this is already conducted within annual Eurobarometer surveys, additional information may be acquired through, for example, smaller *ad hoc* surveys or social media analysis.

	Actions recommended
1	**Continued development of a knowledge network** is needed to synthesise existing research and knowledge in collaboration with other EU institutions. The One Health framework was mentioned by the Delphi panel as an example of good practice in inter-institutional cooperation.

2	**Monitoring of information needs of various audiences** in real time at an institutional level, as a more regular complement to annual Eurobarometer surveys. This can be conducted through, for example, smaller ad hoc surveys or social media listening.

Challenge 6 (Work Area 1): Interdependency between experts working in different agencies or sectors in the eyes of the public – statements and actions from other experts and institutions can affect public trust in others as well

One challenge raised in the workshop was that the public may conflate the statements and actions of officials from different institutions and agencies. Incorrect, inconsistent or unclear communications from one public institution therefore risks damaging the trust in other institutions. An example of this was the COVID-19 pandemic, where the public experienced communications from health authorities both nationally, on an EU level, and from other countries, via news media, at times with conflicting messages. An assessment of current coordination between different institutional actors is therefore necessary. The majority opinion was that there is extensive knowledge but no consensus on this challenge. Consumer trust in consensus messaging from institutions is also one of the most-researched areas among surveyed institutions in the mapping exercise (7).

	Actions recommended
1	**Institutionally assess coordination between different actors** (especially institutions and agencies), and how this is operationalised.

Challenge 7 (Work Area 1): How to effectively communicate risk when the specifics of the risk are uncertain or contested, or rapidly changing (*e.g.* in the case of an emerging risk)

An ongoing, changing situation complicates risk communication, especially where not all variables are known. This can partially be addressed by promoting – and where required, developing and evaluating – the efficacy of EFSA's existing guidelines on crisis communications. Separated communications channels for ongoing and rapidly changing situations are needed, to differentiate them from routine day-to-day communications. This challenge has a medium readiness level with established tools and methods. It is also one of the two most-researched topics among the research groups surveyed in the mapping exercise, with 8 surveyed institutions indicating that they are researching risk perception in relating to risk uncertainty.

	Actions recommended
1	Use, promote and develop and evaluate the efficacy of **existing EFSA crisis communications** guidelines (*e.g.* the RC Handbook, crisis communications guidelines, uncertainty communications guidance). Continued development can include testing the utility of the application or translating into use cases to ensure that all materials and translational activities are up to date.
2	**Develop separate communications channels** based on the need to rapidly communicate uncertainty and what is being done about it, separately to routine day-to-day communication.

Work Area 2: Research needs that are considered crucial to further inform appropriate RC in the EU

Challenge 8 (Work Area 2): Ensuring that sufficient research is done to "update" RC in the digital age, in a continually changing socio-technical environment.

This challenge links to challenge 1 but takes a wider view to ensure that research is being done elsewhere on how to update risk communications in the digital age. The recommendation to start developing risk communications via digital platforms and social media analysis was covered by a number of the institutions surveyed in the mapping exercise (7 and 8 research groups, respectively), indicating that knowledge in the area is developing.

	Actions recommended
1	Begin with an **initial development of a research agenda focusing on risk communication needs within the digital ecosystem**, and how to adapt to technological changes. This could be a Horizon-funded project.

Challenge 9 (Work Area 2): How RC within the wider food system (including *e.g.* producers) can be harmonised and knowledge exchanged effectively between all stakeholders and actors

Globalisation and the integration of transnational markets have led to more complex food systems and interdependencies between actors within it. It is therefore important to investigate how risk communications can be harmonised between different actors, while also ensuring that all parts of the food system are involved and can be reached by communication efforts.

EFSA's mapping of actors in the food system should be extended, with complementary information on subnational actors and a clear segmentation between primary producers and secondary actors. A separate research project could investigate the public trust and transparency impression towards different categories of food system stakeholders (*i.e.* between producers, distributors, institutional actors, etc.). Trust in consensus messaging is one of the research areas which most surveyed institutions (7) in the mapping exercise) are researching. Given the impression of the Delphi panel that the topic is relatively under-researched (*i.e.* concept level), there may be cause for additional research.

	Actions recommended
1	Conduct a **research project to map actors in the food system**, together with their influence and role, and their relationships to each other within the food system and to EFSA. This is to some extent done already but can be complemented by increased information on subnational actors and a segmentation between primary producers and secondary actors.
2	An additional research project could complement this work by investigating **trust and transparency among and towards different categories of food system stakeholders.**

Challenge 10 (Work Area 2): Knowledge of behavioural research on how consumers information preferences and evaluation of information sources develop, whether there are "trigger events" which influence trust, and how to address this effectively.

A consequence of the increased individuation of media channels and habits is that consumers not only use different channels, but also receive information in different ways. For instance, "trigger events" which have a significant effect on public trust in an institution can vary strongly between older and younger consumers or members of different cultural groups. Behavioural research and a continuation of current social media analysis activities can strengthen knowledge in the area, enable communications to be addressed to the needs of different socio-demographic groups accordingly (and possibly in different ways depending on the media channel and the main demographics using it). The area appears well-researched based on the mapping exercise, with 7 institutions researching drivers of trust and distrust.

	Actions recommended
1	**Mapping and synthesis of existing activities**, possibly complemented by a **behavioural research project** either funded by Horizon or in collaboration with JRC.

Challenge 11 (Work Area 2): Having access to research that assesses changes in risk and benefit perceptions continually, so that changes over time can be recorded.

Changes over time in risk and benefit perceptions need to be recorded, so that institutions can respond to these changes in a timely manner. EFSA currently carry this out to some extent, and so a mapping and synthesis of existing activities across European institutions was recommended.

The six institutions surveyed in the mapping exercise are currently monitoring consumer trends in real time, and five are monitoring changing risk and benefit perceptions. The challenge therefore appears sufficiently covered by existing EFSA activities and research bring conducted outside of EFSA.

	Actions recommended
1	Map and synthesise existing activities.

Work Area 3: Social, cultural and technological factors affecting the information needs of target audiences

Challenge 12 (Work Area 3): Taking into account individual differences in people's skills and motivations to use new digital tools, to ensure that people are not excluded or left behind in the transition

While digital tools including social media are widely used and have increasingly large user bases among older age groups, some demographics have lower take-up rates than others. This should be borne in mind in the transition toward more digital tools and channels (challenges 1 and 8): an active effort must be made to ensure that certain demographic groups are not "left behind". Based on the mapping exercise, there are multiple projects in force which consider either the use of social media analysis (8) or differences in access to platforms (7).

	Actions recommended
1	Commission an **internal institutional evaluation of the communication channels in use** (which, how many, and for what distinct purposes), and if they respond to the needs of audiences.

Challenge 13 (Work Area 3): There is a need to ensure that the voices of all stakeholders are heard in the changing food landscape including in relation to changing consumer concerns

Citizens' preferences in relation to their food are in constant change through changes in food availability and evolving political priorities. Notably, increased emphasis on environmental sustainability means that the information citizens require regarding their food may be more extensive than previously. Recommended actions are to continue to monitor the changing attitudes and habits of consumers – for example, as an extension of existing Eurobarometer work – and to have more stakeholder forums on a European level to give food system actors an opportunity to share their thoughts.

	Actions recommended
1	**Pan-European monitoring of changing attitudes and habits** of consumers, potentially as an extension of ongoing Eurobarometer work (or increasing the frequency of Eurobarometer surveys). Some EU Member States have regular exercises to this effect. It may also be possible to formalise and synthesize national research results to further inform EFSA actions.
2	**Sectoral stakeholder forums or frameworks at the European level to** enable feedback from different sector stakeholders. Although some are already in place, these could be expanded to be more inclusive of the food sector overall.

Challenge 14 (Work Area 3): Multiple channels are required to reach different audiences with different needs – these must also be coordinated within and across institutions.

This links with challenge 12, in relation to people's differing fluency in digital tools. Similarly, important scientific communications may not reach all desired audiences if not sufficiently targeted and adapted to their level of existing knowledge. Also, there are several ongoing research projects occurring in relation to social media use and risk communication.

	Actions recommended
1	**Institutional coordination** to adapt the level of detail in scientific communication to the needs of different audiences, which will depend on their level of previous knowledge. This is to ensure that communications are accessible to all audiences.
2	A possible **research project on how actors on different levels can cooperate and coordinate**, illustrated and informed by realistic situations or mechanisms.

Challenge 15 (Work Area 3): Trust in different sources may vary culturally, and different demographic groups, or groups of people with "shared values" will not react uniformly to incidences or events

Linked to challenge 10, how "trigger events" of declining trust can vary between different demographic groups, trust in certain information sources also vary. For example, this can be seen in the differing levels of trust in public institutions in the EU Member States. Ongoing work to monitor the level of trust in information sources, and mapping changes over time, should be continued.

The challenge relates to a number of the research themes and research is currently being conducted: 7 research institutions indicated that they are researching drivers of trust and distrust, 6 are researching changes in shared values, and 6 are investigating individual and group responses in relation to RC messaging.

	Actions recommended
1	**Continue ongoing institutional work to monitor the level of trust** in different information sources, continue to map changes over time, and identify causes of change.

Challenge 16 (Work Area 4): Ensuring that changes in consumer priorities and expectations are understood and taken into account

As consumers' priorities and expectations of transparency change, it is important that EFSA remain informed on the timing and nature of the changes. Such work is underway, and the recommendation is that this is to be continued through the mapping and synthesis of existing activities. As indicated in the mapping exercise, several research projects are considering changing priorities and expectations. There appears to be little additional action required to overcome the challenge.

	Actions recommended
1	Map and synthesise existing activities.

Challenge 17 (Work Area 4): There is a need to react promptly in relation to events or incidences that need to be communicated to the public

In rapidly developing situations (see also challenge 7), it is important that institutions such as EFSA are able to react promptly and communicate the necessary information to the public. Challenge 1 indicated that there is a need to ensure that appropriate capacities and institutional knowledge are in place and this is also relevant here. Additionally, while there is a crisis plan on the EU level, additional coordination could occur to ensure that national plans and activities have coordination mechanisms where, for example, an event occurs in a border region and requires collaboration between different member states. According to the mapping exercise, risk perceptions in relation to uncertain or emerging situations is one of the themes in which most surveyed institutions are researching (8).

	Actions recommended
1	**Ensuring that appropriate capacity and institutional knowledge is in place** (cf. Challenge 1, Work Area 1, which also seeks to ensure this).
2	While a crisis plan is available at EU level, national-level plans may vary in their prescribed actions. **Coordination between national plans and activities** can therefore be strengthened.

4. Conclusions

The aim of the horizon scanning exercise was to gather the views of EFSA stakeholders on preparedness for future risk assessment requirements and possible challenges in regulatory science in six thematic areas. Performing a horizon scan is by default a divergent exercise, where participants need to deal with a significant level of uncertainty. Single point forecasts on how the world will evolve are no longer valid in this era of digitalisation and globalisation. One of the most relevant uncertainties could be the potential (expanding) discrepancy between scientific challenges and societal challenges in the near future, an issue that clearly emerged during the ongoing COVID-19 pandemic. This has emphasised the need for evidence-based risk communication more than ever before.

To identify and assess the issues potentially affecting regulatory preparedness and regulatory science, two research paths were followed - the horizon scan exercise and the mapping of research activities. The horizon scanning relied on a modified Delphi panel, which allowed thematic experts to contribute to the exercise through three workshops. The mapping exercise consisted of a scanning of ongoing EU funded research project and an online survey. The scanning resulted in a list of relevant projects for the six thematic areas, while the survey collected data on the level of ongoing research on topics related to the thematic areas as well as interest in future collaboration. The synthesis of both research paths contributed to recommended actions related to identified challenges and potential divergences in the six thematic areas.

Thematic area 1 on animal welfare explored topics related to **animal welfare on farms, during transport, at slaughter**, as well as **animal welfare labelling** and **risk assessment of animal welfare**. Animal welfare during transportation was found to be the least researched work area. However, two potential divergences linked to this work area as identified by the panel indicate a possibility for the potential divergences to materialise and a strong need for research in the field. Mobilising the research community should not present a challenge as there was plenty of interest for collaboration on this research topic.

Thematic area 2 explored **aggregated exposure science, EFSA's framework, guidance and tools for exposure reconstruction to chemicals via (forward and reverse) dosimetry,** and **development of standards for the integration of EFSA Open Access Tools for the collection of dietary data in new exposome/Human Biomonitoring (HBM) studies**. Most of the research on exposure science in risk assessment relates to aggregate exposure assessments, covering two identified potential divergences which the Delphi panel deemed as highly urgent to address and having a potentially high impact on EFSA's preparedness. On the other hand, a potential divergence between EFSA and other risk assessment bodies or agencies (e.g. ECHA) regarding forward and reverse dosimetry might have higher chances of materialising given that there is a lower level of ongoing research related to this topic. There still appears to be a need for further research on biomonitoring data, in particular relating to the lack of internal reference values and kinetic data to interpret human biomonitoring data.

Thematic area 3 explored topics such as **nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems, science-based dietary guidelines in relation to sustainable food systems and environmental impact, relationship between foods and chronic metabolic diseases**, and **possible food safety issues related to a sustainable healthy diet**. Evaluating the nutritional impact on gut microbiome (microbiota) modulation in relation to sustainable food systems is an outstanding topic that was found to be highly researched and debated

among the research community. It should be mentioned that the gut microbiome was considered as part of thematic area 4 as well, specifically within the context of understanding of the influence of microbiota modifications on human health. As there seems to be no consensus on the definition of a healthy or unhealthy microbiome the issue needs to be formulated precisely. A starting definition should be made, followed by scoping and a systematic review by EFSA. Otherwise, the impact of ultra-processing on metabolic diseases was seen as an area where potential divergences could materialise. The mapping exercise showed that this is currently the least researched topic within this thematic area, however, many research groups indicated interest for future collaboration.

Thematic area 4 discussions evolved around **innovative (and sustainable) food and feed products** and **related technologies/resources** as well as **innovative production approaches**. It also included the identification of new tools and methodologies in risk assessment needed to improve "new" hazard identification, including the understanding of the influence of microbiota modifications on human health. Risk assessment and characterisation of complex/non-conventional foods was found to be a research field where potential divergences could emerge yet there was only limited ongoing research on this topic, revealing a potential gap in this area. Similarly, as for thematic area 3, characterisation of a healthy microbiota stood out as a popular research topic. This presents a positive development as the Delphi panel identified potential divergences which may arise regarding definitions, including the definitions of healthy microbiome itself and related dysbiosis, the standards that define a "healthy" microbiota, and what could cause the adverse effects on the latter.

Thematic area 5 explored topics relates to sustainable food systems and food safety. These included discussing **sustainable food production, stimulation of sustainable food processing and distribution, promotion of sustainable food consumption,** and **new dietary guidelines (including methodological aspects for developing them) to accompany a shift to more sustainable diets**. Sustainable food systems and food safety encompass a variety of research topics, which (as the mapping found) were relatively well researched. Potential challenges and divergences that stood out were linked to environmental and health risks associated with reuse of wastewater for irrigation and risk assessment of food potentially contaminated with soil pollutants. While there was already ongoing research related to these topics, these appeared amongst the most popular topics when it comes to future interest in collaboration. However, the most pertinent issues identified for this thematic area were related to risk assessments of organic fertilisers and the ways in which infectious agents and toxic chemical can be introduced and subsequently impact the food chain. The mapping showed that this was the most researched among the explored topics, but there is still a lack of data to adequately assess the risks of infectious agents such as bacteria, virus and fungi impacting the food chain and thus several actions were recommended.

Thematic area 6 reflected on the **development and implementation of an integrated risk communication framework, the identification of research needs that are considered crucial to further inform appropriate RC in the EU, potential differences between different target audiences, and between risk communication contexts**, and **relevance of messaging to consumer priorities, preferences and understanding**. A challenge considered as key priority by the Delphi panel relates to institutions having sufficient capacity to adapt their risk communications in light of digitalisation and rapid technological change. Closely linked to this is the need to ensure that enough research is performed to "update" risk communications in the digital age. While social media analysis and differences in consumers access to digital platforms are among the research areas which

drew most interest from research groups both in terms of current and future research, foresight about additional digital communications needs is researched only to a limited extent.

A need for developing interdisciplinary approaches, alignment and the need for collaboration with other agencies and institutions were frequent remarks during the thematic expert group discussions. The synthesis indicated that several identified potential divergences were considered as being urgent and having a high impact on EFSA's preparedness. These were however already explored by a number of research groups active in the respective research areas. With all necessary prudence, the report can conclude that **a lot of relevant research is being done but the connection with EFSA's work needs to be enhanced.** The respective research centres and institutions conducting such studies are not aware of the relevance for EFSA, and vice versa. Strengthening the cooperation between EFSA and such stakeholders through building and fostering strong partnerships could help overcome this issue. Cooperation could contribute to limiting the number of blind spots – *i.e.* challenges and potential divergences of high importance but with low number of ongoing research – identified in the horizon scan, which could be tackled via the Horizon Europe working program or other channels publishing calls for proposals in the upcoming years.

Overall, the horizon scanning exercise on preparedness for future risk assessment requirements and possible challenges in regulatory science determined several work areas for each of the six thematic areas as well as a list of possible challenges and potential divergences. In doing so, the horizon scan contributed to the development of scientific themes, which EFSA will take forward by investing in developing roadmaps for action. While new concepts such as healthy diets from sustainable food systems, sustainability scores in food systems and the nutritional impact of the microbiome have sparked interest among the research communities, their impact for regulatory science is not yet fully understood. Nevertheless, the horizon scan allowed for the construction of recommended actions that could prevent challenges and potential divergences from materialising. It has to be stressed that the findings of this horizon scanning exercise should not be considered as an indication of the direction that ongoing EU policy initiatives in the food system may take. In order to address future regulatory science and policy needs, EFSA jointly with other EU agencies and policy makers should work towards identifying solutions.

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Abbreviations

AHAW	Animal Health and Welfare
BPA	Bisphenol A
CAP	Common Agriculture Policy
CEF	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CFP	Common Fisheries Policy
CHAFEA	Consumers, Health, Agriculture and Food Executive Agency
CORDIS	The Community Research and Development Information Service
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and
GEF	Global Environment Facility
GMO	Genetically Modified Organism
GPRC	General Plan for Risk Communication
JRC	Joint Research Centre
MS	Member State
NATO	North Atlantic Treaty Organisation
NGT	New Genomic Techniques
OECD	Organisation for Economic Co-operation and Development
RARA	Risk Assessment Research Assembly
SC	Scientific Committee
TEG	Thematic Expert Group
TIM	Tools for Innovation Monitoring
US FDA	U.S. Food and Drug Administration
WHO	World Health Organisation
WS	Workshop