31 March 2025
14:00-18:00
MINUTES - Agreed on 22 April 2025

Location:Teleconference

Attendees:

- Panel Members:
  Susanne HOUGAARD BENNEKOU, Ana ALLENDE, Angela BEARTH, Josep CASACUBERTA, Laurence CASTLE, Tamara COJA, Amélie CREPET, Thorhallur HALLDORSSON, Ron HOOGENBOOM, Helle KNUTSEN, Claude LAMBRÉ, Søren SAXMOSE NIELSEN, Dominique TURCK, Antonio VICENT CIVERA, Roberto VILLA, Holger ZORN
- European Commission and/or Member States representatives:
  Athanasios RAIKOS (Sante Unit E1), Silvia NICOLAU-SOLANO Silvia and Maria TABERNERO Sante Unit E4:Pesticides
- EFSA:
  Head of Risk Assessment Services Department (ENABLE): Nick Kriz

  Acting Head of Risk Assessment Production Department (ASSESS): Tobin Robinson

  Chief Scientist: Carlos das Neves

  Methodology and Scientific support Unit (MESE): Claudia Roncancio Pena, Daniela Maurici, Bruno Dujardin

  Chief Scientist office: Konstantinos PARASKEVOPOULOS

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declarations of Interest filled out by the Scientific Committee (SC) members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

4. Feedback from the Scientific Committee/ Scientific Panels/EFSA/ EC

4.1 Feedback from EFSA:

4.1.1 Proposals for future work in the area of Exposure – for information and discussion

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

EFSA presented the main priorities obtained from the Roadmaps for action on the risk assessment of combined exposure to multiple chemicals (RACEMiC, link here) and for advancing aggregate exposure to chemicals in the EU (ExpoAdvance, link here). Furthermore, additional priorities were collected from EFSA's Knowledge and Innovation Community (KIC) on Exposure.

The Scientific Committee (SC) was invited to provide feedback on the following priorities identified for future work in exposure science:

1. NAMs for grouping of chemicals (RACEMiC, priority high)
2. Methodologies for non-dietary Cumulative Risk Assessment (CRA) of pesticides (RACEMiC, on hold)
3. CRA strategies for chemical contaminants (RACEMiC, priority medium)
4. Pilot CRA for food additives and flavourings (RACEMiC, priority low)
5. EU framework on aggregate exposure assessment (ExposAdvance, priority high)
6. Use of human biomonitoring data (ExposAdvance, priority high)
7. Survey and label data for food supplements (KIC Exposure, priority high)
8. Pilot for feed consumption data collection (KIC Exposure, priority medium)

Overall, the priorities presented by EFSA were supported, taking note of the following discussion points.

General considerations

It was questioned how relevant is the risk assessment of combined exposure to multiple chemicals in the framework of regulated products, where products anyhow need to be assessed and approved one by one. While it was acknowledged that this may be more applicable to retrospective risk assessments, the prospective cumulative risk assessment is now also being implemented in the field of pesticides where the impact of a new authorization on cumulative risks also needs to be considered.

NAMs for grouping of chemicals

Scientific criteria for grouping of chemicals are already well established in a guidance document EFSA Journal, here). This project would mainly aim at exploring the different types of data and predictions that can be used for such grouping (e.g. PDF extraction, QSAR, Omics) and understanding how these different lines of evidence can be brought together in an automated and comprehensive manner (e.g. evidence maps). The SC recommended liaising with ECHA to possibly harmonize on this topic, noting however that the purpose of groupings chemicals in ECHA may be different.

Methodologies for non-dietary CRA of pesticides

While this activity was considered a high priority in the RACEMiC Roadmap and work was already planned for initiation in 2025, this is now on hold upon request of DG SANTE to mobilize resources on the implementation of the dietary CRA first. The SC expressed some doubt about this decision. The time needed to develop such methods and collect the data will be long, and EFSA should initiate this activity as soon as possible.

EU framework for aggregate exposure assessment

The development of an EU framework for aggregate exposure assessment is considered an important piece of work and it is recognised to be a real challenge in terms of time of resources. The SC therefore proposed to consider the option of outsourcing. A solid steering of this project will therefore be key and EFSA is currently discussing with the other agencies how to best involve them in this steering process. Furthermore, attention will be given to ongoing activities in PARC (link here), ensuring complementarity with this project.

Use of human biomonitoring data

While supported by the SC and DG SANTE, it was highlighted that a multitude PBK models is already available. EFSA and the SC agreed that this is an important point. This project should

investigate strengths and weaknesses of the different models and platforms that are already available and provide recommendations on the most appropriate models to be used for this purpose.

It was also noted that, with the draft "One Substance One Assessment (OSOA)" legal act requiring ECHA and EFSA to commission human biomonitoring surveys every 5 years, there may be the opportunity to perform joint dietary and human biomonitoring surveys in the future.

Survey and label data for food supplements

It was agreed that this activity would be crucial in several domains. Regarding the collection of label data (incl. proposed use levels), it was noted that this is a fast-changing market and collecting updated information from industry might not be feasible. This is why the project will explore options to actively pull information from the internet (e.g. scraping) rather than requesting data providers to submit the information.

Concerns were also expressed on the collection of survey data outside the usual dietary surveys as this information should be integrated there. It was noted that executing a dedicated survey on food supplements does not prevent EFSA in improving the reporting of food supplements in the 'usual' food consumption data collection. Considering the time needed for updating dietary surveys (about 10 years), a dedicated survey on food supplements may provide clarity on the shorter term.

Pilot for feed consumption data collection

The SC noted that this activity would probably be of low priority because the exposure models to be used for in the different domains have now been established.

4.1.2 Proposals for future work in the area of OMICS – for information and discussion

EFSA presented the outcome of the roadmap on action on the incorporation of Omics and bioinformatics in food/feed risk assessment (link here) focusing on the six recommendations for future actions which were the follwing:

1.Hybrid Sequencing Harmonisation: Developing standardized approaches for combining short-read and long-read sequencing

2.Public Omics Data Integration: Using machine learning to efficiently access and analyze public omics databases for chemical grouping

3.Metagenomics Implementation: Standardizing meta-omics approaches for analyzing complex microbial communities

4.GM Plant Assessment: Implementing omics methods for risk assessment of complex GM plants,

5.Allergenicity Assessment of novel foods: Improving allergenicity assessmenst for novel foods, particularly novel/innovative proteins

6.Bioinformatics Platform Development: Creating user-friendly tools accessible to non-specialists

Additionally, selected microbiome "roadmap" recommendations linked to Omics were presented such as the evaluation of the microbiome metabolic capacity of xenobiotics and the identification of biomarkers for understanding causality of microbiome effects on host health.

EFSA outlined the following recommendations that are proposed for prioritisation (following an internal prioritisation exercise that is still ongoing) to seek feedback from the SC.

- Proposal 2: Utilising public omics data for chemical grouping coupled with AI for direct data access and analysis resulting in more reliable predictions. This project would

complement the NAMs portfolio for the assessment of exposure ot multiple chemicals and is aligned with the overall EFSA strategic objective on advancing in this area.
- Proposal 3: Promoting the regulatory adoption of metagenomics approaches (limiting the scope to case study and focusing on the development of a standardised methodology for characterising complex microbial mixtures in regulated products.
- Proposal 5: Focusing on the development of advanced bioinformatics prediction tools (and excluding the proteomics part) to improve allergenicity assessments of innovative proteins addressing both cross-reactivity and de novo sensitisation aspects. In addition, the project would address other aspects such as establishing criteria for when/what experimental tests might be needed to validate the predictions. The expected results would be widely applicable to several areas of regulated products.
- Proposal 6: Building on an existing toolbox of analysis pipelines intended currently for use only by specialists, the project will develop a bioinformatics platform that would be highly accessible and user-friendly to a wider user base.
- Microbiome "roadmap": identifying fit for purpose microbiome biomarkers and/or investigating microbiome metabolic capacity to address some of the most critical needs identified in the gut microbiome report.

Two projects were suggested to be put on hold for the time being:

- Hybrid sequencing harmonisation
- Omics methods for GM plant safety assessments

Key Discussion Points

Proposal 5: allergenicity assessment for novel foods/innovative proteins

- The SC questioned whether the recommended actions under proposal 5 would offer a signficiant advantage for the allergenicity assessments. In addition, the possibility of facing considerable challenges was highlighted for example due to high complexity and individual immune variations
- EFSA clarified that the focus would be on improving in silico predictions beyond simple sequence homology using new information such as clinical relevance, exposure considerations and more comprehensive data on proteins such as information on 2D/3D protein structures and that the proteomics part was not indeed within the scope. In addition, it was noted that post-market monitoring falls outside EFSA's remit and that no monitoring systems are in place for allergenicity to provide usable data in the short/medium term.

Proposal 4: GM Plant Assessment

- It was argued that this proposal should not be put on hold highlighting that complex GMOs are already challenging existing assessment approaches and that legislative changes for plants developed by New Genomics Techniques (NGTs) might require new approaches (such as Omics) soon
- EFSA acknowledged that there are indeed significant upcoming challenges and clarified that it is keeping a close eye on the developments that might require shorter term actions.

Proposal 3: Microbiome Analysis

- It was highlighted that advancing on microbiome analysis methods is important for feed additives noting likely feasibility challenges on assessing microbiomes across many animal species and cost-effectiveness
- EFSA clarified that the initial focus would be on product characterisation

4.1.3 Way forward on structure of scientific opinions

EFSA has initiated a reflection on the length and readability of its scientific opinions and statements, which is part of a broader, ongoing evaluation of the speed and future direction of EFSA's risk assessments. This reflection is guided by three critical aspects that must be balanced when reporting EFSA's work: (1) minimising the resources spent on reporting (i.e., resource efficiency); (2) ensuring that the details are clear and open to examination (i.e., transparency and scrutiny); and (3) making information understandable and usable for both the public and risk managers (i.e., accessibility). Balancing these elements is essential to maintain the integrity and usefulness of EFSA's scientific work.

This activity aimed to investigate:

(1) Whether the current length and readability of EFSA's scientific opinions and statements are fit for purpose;

(2) Whether there is a need to reconsider them;

(3) How adjustments to the length and readability of EFSA's scientific opinions and statements could be best achieved.

The fitness for purpose of the length and readability of EFSA's scientific opinions and statements was explored, focusing on presentation formats, length, readability, data reusability, and the integration of digital tools. Guidance documents, pesticide peer review evaluations, reasoned opinions, scientific reports, and any supporting publications were excluded.

To address this issue, a Task Force (TF) was established that engaged with key stakeholders directly involved in producing the scientific opinions and statements, including representatives from the European Commission, EFSA's Panel coordinators, EFSA's Scientific Committee. The TF outlined intended outcomes and potential actions to be made to reach the goals. Actions were categorised into short-, medium- and long-term timeframes, progressing in three-year intervals.

This grouping aims to reflect realistic implementation periods, though in practice, their implementation is likely to be overlapping and cumulative. While specific actions are proposed, they will need to be prioritised and resourced as part of EFSA's work planning process in close articulation with the Scientific Committee and the different EFSA Panels. The list of proposed actions is intended to serve as a "catalogue" that can guide a discussion for selection and implementation according to specific needs.

Panel chairs were asked to discuss the list of possible actions with their respecitve panel members and come up with a selection of some actions to be piloted until spring next year. An overall discussion will take place at the July SC plenary where all panel chairs will illustrate which actions their respective panel have selected. In addition, by the end of the year, a follow up presentation will take place to touch ground on how this exercise is going and which benefits have the selected actions started to produce.

5. AoB

The SC was informed about the unexpected passing away of the dear colleague Konstantinos Koutsoumanis, vice chair of the EFSA SC, on 25th February. "Kostas" has been a vigorous champion of Europe's food safety system while serving as an EFSA expert for the last 18 years. He will be deeply missed.

6. Next meeting

The next SC plenary meeting will be held on 14-15 May 2025, as physical meeting in Parma, Italy.