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EDITORIAL

Advancing EFSA's regulatory science: Updated research and innovation needs

Abstract

This editorial provides an update on research & innovation (R&I) needs that can support EFSA's regulatory science in the coming years. The paper presents research needs for EFSA's work in a number of domains: omics technologies; gut microbiome; new approach methodologies (NAMs); allergenicity risk assessment; aggregate exposure assessment and environmental risk assessment (ERA). In briefly describing R&I needs, the document also addresses emerging challenges and opportunities. The authors acknowledge that this overview is not exhaustive and refer to earlier publications for additional R&I needs, as well as to the roadmaps for a more in-depth presentation. Finally, the document calls for transdisciplinary research, reflecting on the interdependencies between human, animal, plant and environmental health. This editorial will be valuable to stakeholders, research agenda setters and funders, both public and private, in formulating calls for research and project funding related to food safety.

1 | INTRODUCTION

Climate change, public health crises and digital transformation clearly go beyond national boundaries and need a critical mass of efforts to be handled effectively and consistently.[1] Today's health threats, environmental challenges and societal issues demand ambitious investments in research and innovation (R&I).

EU agencies have a deep understanding of existing research knowledge and the data gaps that limit the quality of scientific advice in public health, environmental protection, food safety and nutrition.[2] These agencies help directing R&I efforts, bridging the science-policy gap and supporting the European research agenda, both individually and collectively. Their involvement in the programming of the EU Research Framework programmes is beneficial, because of their regulatory science perspective, their expertise and current or future tasks on research topics.[3] Research not only generates scientific knowledge but also builds current and future risk assessment (RA) capacity.

In 2019, EFSA published 'Food Safety Regulatory Research Needs for 2030' which consolidated key research needs and priorities for food safety RA.[4] These needs informed the development of EFSA's Strategy 2027 and the 'pathways for action' in the Food 2030 R&I policy framework.

In 2022, EFSA organised the 'ONE – Health, Environment & Society – Conference 2022' to explore how scientific advice on food safety and nutrition should evolve to meet new policy targets and societal demands for safe, nutritious and sustainable food. The conference highlighted institutional needs for the provision of transdisciplinary scientific advice on

[1]European Commission: Directorate-General for Research and Innovation, Mitra, A., Canton, E., Ravet, J., & Steeman, J.-T. The added value of European investments in research and innovation, Publications Office of the European Union, 2024. https://data.europa.eu/doi/10.2777/682623.

[2]European Food Safety Authority, EU-ANSA agencies' engagement in the EU research knowledge cycle – An overview, Publications Office of the European Union, 2018. https://data.europa.eu/doi/10.2805/32422.

[3]Stef Bronzwaer, Mike Catchpole, Wim de Coen, Zoe Dingwall, Karen Fabbri, Clémence Foltz, Catherine Ganzleben, Robert van Gorcom, Anthony Humphreys, Pikka Jokelainen, Ernesto Liebana, Valentina Rizzi, Bernhard Url, One Health collaboration with and among EU Agencies – Bridging research and policy, One Health, 15, 2022, https://doi.org/10.1016/j.onehlt.2022.100464.

[4]EFSA (European Food Safety Authority). (2019). Editorial on food Safety Regulatory Research Needs 2030. EFSA Journal, 17(7), e170622. https://doi.org/10.2903/j.efsa.2019.e170622.

The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

public health, environmental protection, food safety and nutrition, to enhance the institutional preparedness for the challenges of a rapidly changing world. The main research needs identified at the conference were reported by Devos et al.[5]

Since the ONE conference, EFSA has issued several scientific theme papers and commissioned the development of roadmaps that provide recommendations on the actions and steps needed to achieve EFSA's strategic goals and ensure preparedness for RA opportunities and challenges.[6] These documents aim to translate research findings into regulatory science, harmonise methodologies to reduce divergencies, and address critical knowledge gaps in fields such as omics technologies, the gut microbiome, new approach methodologies (NAMs), allergenicity RA, aggregate exposure to chemicals, environmental risk assessment (ERA) and risk communication.[7]

Building on these developments and the roadmap recommendations, it is timely to provide an update on the latest R&I needs, focusing on areas where scientific advances have created new opportunities for regulatory application, methodological limitations hinder comprehensive RA, international harmonisation efforts yield global benefits and investments deliver maximum impact.[8]

2 | ADVANCING FOOD SAFETY RA WITH OMICS DATA

Advances in omics technologies offer an opportunity to enhance RA capacities across human, animal and environmental health domains for biologicals and chemicals, including those within EFSA's remit, as indicated in the recent roadmap for action on the application of omics.[9] Adopting omics approaches can provide deeper insights into mechanisms of action, improve hazard identification and characterisation, and enable more precise and quantitative RAs.

While EFSA has made progress in integrating specific omics approaches, such as genomics through whole genome sequencing, the broader adoption of other omics technologies (e.g. transcriptomics, metabolomics) into RA remains limited. Challenges that hinder implementation include: (1) lack of standardisation and validation frameworks; (2) difficulties in data integration and interpretation due to the lack of analytical approaches capable of handling large and complex datasets; and (3) scarcity of case studies that demonstrate regulatory applicability across different RA domains.

R&I will be needed to:

- Develop robust approaches for integrating transcriptomic, metabolomic and proteomic data, along with in vitro to in vivo extrapolation, to gain mechanistic insights and derive multi-omics-based points of departure (PoD) for chemicals. These approaches should support both untargeted screening approaches for comprehensive hazard identification and targeted, risk hypothesis-driven analyses that focus on specific modes of action or adverse outcome pathways (AOPs) of regulatory concern.
- Adopt metagenomics in biological RA by developing standardised methods and approaches for metagenomics data generation and analysis. This includes for instance, microbiome investigation and more comprehensive detection and characterisation of foodborne pathogens.
- Develop proof-of-concept case studies, demonstrating the integration of omics technologies in diverse RA domains, including the safety assessment of genetically modified foods and allergenicity evaluation for novel foods.

3 | ADVANCING FOOD SAFETY RA WITH GUT MICROBIOME DATA

The human gut microbiome plays a crucial role in maintaining health. There is considerable evidence showing that dietary components (xenobiotics), including food additives and contaminants, adversely affect the gut microbiome, potentially leading to metabolic or inflammatory disorders. However, substantial data and methodology gaps hinder the development of RA approaches to evaluate the impact of food-related compounds on gut microbiota and their subsequent effects on human health (Garrido-Romero et al., 2024).[10]

Three critical gaps requiring attention are: (1) understanding how chemicals interact with the gut microbiome and influence host health, including causal relationships between chemical exposures, microbiome changes and metabolic/

[5]Yann Devos, Maria Arena, Sean Ashe, Max Blanck, Edward Bray, Alessandro Broglia, Stef Bronzwaer, Angelo Cafaro, Elisa Corsini, Bruno Dujardin, Antonio Fernandez Dumont, Matilde Gomez Garcia, Ciro Gardi, Beatriz Guerra, George E. N. Kass, Angelo Maggiore, Laura Martino, Caroline Merten, Cinzia Percivaldi, Andras Szoradi, Silvia Valtueña Martinez, Ermolaos Ververis, Domagoj Vrbos, Marta Hugas. (2022). Addressing the need for safe, nutritious and sustainable food: Outcomes of the 'ONE – Health, Environment & Society – Conference 2022', Trends in Food Science & Technology, 129, 164–178. https://doi.org/10.1016/j.tifs.2022.09.014.

[6]Pilar Garcia-Vello, Kiara Aiello, Nicola M. Smith, Julia Fabrega, Konstantinos Paraskevopoulos, Marta Hugas, Claudia Heppner. (2022). Preparing for future challenges in risk assessment in the European Union, Trends in Biotechnology, 40(10), 1137–1140. https://doi.org/10.1016/j.tibtech.2022.07.004.

[7]Rodes-Sanchez, M., Pozzi, F., Sunyer-Vidal, J., Puppo, F., Griepink, M., Santuccio, F., Stillitano, P., Folkvord, F., & Lupianez-Villanueva, F. (2024). Development of a roadmap for action on Evidence-based risk communication in the EU Food Safety System. EFSA Supporting Publications, EN-8863. https://doi.org/10.2903/sp.efsa.2024.EN-8863.

[8]Devos, Y., Bray, E., Bronzwaer, S., Gallani, G., & Url, B. (2022). Editorial Advancing food safety: strategic recommendations from the 'ONE – Health, Environment & Society – Conference 2022'. EFSA Journal, 20(11), e201101. https://doi.org/10.2903/j.efsa.2022.e201101.

[9]Radio, S., Di Marsico, M., Bersani, C., Malinverni, R., Casacuberta, J., Corpetti, C., Aiese Cigliano, R., & Sanseverino, W. (2024). Development of a roadmap for action on the application of Omics and associated Bioinformatics Approaches in Risk Assessment. EFSA Supporting Publication, 21(10), EN-9086. https://doi.org/10.2903/sp.efsa.2024.EN-9086.

[10]Garrido-Romero et al., (2024). Relevance of gut microbiome research in food safety assessment. https://www.tandfonline.com/doi/full/10.1080/19490976.2024.2410476#abstract.

inflammatory disorders; (2) identifying biological markers that reliably indicate adverse effects on microbiome function and host health; and (3) obtaining real-world evidence to link dietary exposures, microbiome changes and health outcomes in diverse human populations and establish what constitutes 'normal' microbiome variation versus harmful changes. Without addressing these gaps, and others identified in the roadmap for the integration of gastro-intestinal (GI) tract microbiomes (human and domestic animals) in RAs under EFSA's remit,[11] key toxicological pathways mediated by gut microorganisms may be overlooked.

Recent advances in microbiome science, including in silico and in vitro cell systems, as well as analytical approaches like omics technologies, offer an opportunity to enhance food RAs by incorporating gut microbiome data.

R&I will be needed to:

- Understand causality of chemical-provoked microbiome dysbiosis and its relationship to host metabolic and inflammatory disorders. For example, develop robust in vitro methods to obtain data on chemical-microbiome interactions, with a focus on identifying potentially hazardous metabolites stemming from the microbiome and associated metabolic and inflammatory pathways. This information can support the development of microbiome-specific endpoints for RA.
- Develop and validate biomarkers for assessing microbiome-related adverse effects. Focus on promising biomarkers related to intestinal epithelial integrity (e.g. mucus layer thickness or tight junction proteins), anti-inflammatory markers (e.g. cytokines, lipocalins) or metabolic functions (e.g. functional genes and enzymes involved in chemical metabolism).
- Gather data from targeted epidemiological cohort studies to establish links between dietary exposure to specific compounds, gut microbiome alterations and health outcomes. These studies should include diverse populations, considering factors such as age, health status and dietary patterns, to identify 'healthy microbiomes' and specific features associated with adverse responses to chemicals present in food. These data can serve as a baseline to more accurately identify when chemical-induced microbiome changes may affect host health.

4 | ADVANCING FOOD SAFETY RA THROUGH NEW APPROACH METHODOLOGIES

In 2022, EFSA published a roadmap on NAMs in RA (Escher et al., 2022).[12] This roadmap identified seven key areas requiring further R&I to integrate NAMs in next generation risk assessment (NGRA): (1) development of additional AOPs and AOP-associated networks; (2) advanced cell culture models including organ on a chip and micro-physiological systems; (3) toxicokinetic assessment with a focus on physiologically based kinetic (PBK) and toxicokinetic-toxicodynamic (TK-TD) modelling; (4) exposome research linking complex exposure patterns and quantitative AOPs; (5) human susceptibility to investigate impact of human variability on hazard assessment (pregnancy, neonates, genetic polymorphisms); (6) data integration including reporting templates for NAM integration; and (7) new concepts in human RA, particularly regarding acceptance, assessment criteria and guidance documents for integrating NAMs into NGRA.

Integrating NAM-based data in NGRA provides a robust means to derive reference points (RPs) or PoDs as the basis for safe levels of chemicals for human health, animal health and the environment. This approach also supports the principles of reducing, refining and replacing animal testing (Astuto et al., 2022; Di Nicola et al., 2023; Friedman et al., 2020, 2025).[13,14,15] However, such integration is hindered by regulatory data requirements that still mandate in vivo testing and the need to further validate NAMs and gain confidence in integrating them in NGRA through case studies applied across jurisdictions.

R&I will be needed to:

- Further validate in vitro cellular systems relevant to human RA to replace animal studies concerning TK (absorption, distribution, metabolism, excretion) and TD (i.e. sub-chronic and chronic toxicity for key systemic endpoints such as liver, kidney, central nervous system, endocrine) and move towards the derivation of in vitro-based PoDs.

[11]Francisco Javier Moreno, Florencio Pazos, Manuel Garrido-Romero, et al. (2024). Roadmap for the integration of gastro-intestinal (GI) tract microbiomes (human and domestic animal) in risk assessments under EFSA's remit. *EFSA Supporting Publication*, 21(2), EN-8597. https://doi.org/10.2903/sp.efsa.2024.EN-8597.

[12]Escher, S. E., Partosch, F., Konzok, S., Jennings, P., Luijten, M., Kienhuis, A., de Leeuw, V., Reuss, R., Lindemann, K.-M., & Bennekou, S. H. (2022). Development of a roadmap for action on new approach methodologies in risk assessment. EFSA Supporting Publications, 19(6), 7341E. https://doi.org/10.2903/sp.efsa.2022.EN7341.

[13]Katie Paul Friedman, Matthew Gagne, Lit-Hsin Loo, Panagiotis Karamertzanis, Tatiana Netzeva, Tomasz Sobanski, Jill A Franzosa, Ann M Richard, Ryan R Lougee, Andrea Gissi, Jia-Ying Joey Lee, Michelle Angrish, Jean Lou Dorne, Stiven Foster, Kathleen Raffaele, Tina Bahadori, Maureen R Gwinn, Jason Lambert, Maurice Whelan, Mike Rasenberg, Tara Barton-Maclaren, Russell S Thomas. (2020). Utility of In Vitro Bioactivity as a Lower Bound Estimate of In Vivo Adverse Effect Levels and in Risk-Based Prioritisation, Toxicological Sciences, 173(1), 202–225. https://doi.org/10.1093/toxsci/kfz201.

[14]Astuto, M. C., Di Nicola, M. R., Tarazona, J. V., Rortais, A., Devos, Y., Liem, A. K., Kass, G. E. N., Bastaki, M., Schoonjans, R., & Maggiore, A. (2022). In Silico Methods for Environmental Risk Assessment: Principles, Tiered Approaches, Applications, and Future Perspectives. In: In Silico Methods for Predicting Drug Toxicity. Humana, New York, NY. 589–636, https://doi.org/10.1007/978-1-0716-1960-5_23.

[15]Matteo Riccardo Di Nicola, Irene Cattaneo, Alexis V. Nathanail, Edoardo Carnesecchi, Maria Chiara Astuto, Melina Steinbach, Antony John Williams, Sandrine Charles, Ophélia Gestin, Christelle Lopes, Dominique Lamonica, Jose Vicente Tarazona, Jean Lou C. M. Dorne. (2023). The use of new approach methodologies for the environmental risk assessment of food and feed chemicals, Current Opinion in Environmental Science & Health, 31, 100416, https://doi.org/10.1016/j.coesh.2022.100416.

- Further validate and gain confidence in using in silico models in the human health, animal health and environmental areas for setting in silico-based safe levels. These include quantitative structure–activity relationship models, physiologically based kinetic models and quantitative in vitro to in vivo extrapolation models as well TK-TD models and microphysiological systems, among others.
- Develop a workflow and toolbox to integrate in vitro and in silico NAMs for deriving NAM-based PoDs using a weight of evidence for hazard characterisation and NGRA of chemicals in the human, animal and environmental health domains. Demonstrating practical examples of such NAM integration can facilitate the transition towards animal-free testing and significantly lower testing costs. This workflow and toolbox should be applicable across different regulatory frameworks (e.g. food and feed chemicals, industrial chemicals, pharmaceuticals) as well as for different RA contexts (data poor to data rich chemicals).

5 | ADVANCING ALLERGENICITY RA OF INNOVATIVE PROTEINS IN FOOD AND FEED

Allergenicity RA is becoming increasingly relevant to keep up with the rapid pace of food innovation and biotechnology advances, so that food products are safe for consumption and do not contribute to the burden of food allergies. Allergenicity RA concerns several EFSA's Scientific Panels dealing with proteins, mostly as regulated products. Current strategies for allergenicity RA of innovative proteins are based on Codex Alimentarius guidelines. However, scientific advances over the last two decades call for revisions to ensure that allergenicity RA methodologies and safety standards remain fit for purpose.

EFSA has dedicated resources to advance allergenicity RA and procured several studies that have made significant progress (Bebi et al., 2024; Doytchinova et al., 2023; Martínez et al., 2024; Mills et al., 2024).[16,17,18,19] In an EFSA's stakeholder workshop in 2021, further research needs for regulatory and technological developments were identified to improve the allergenicity RA of regulated products derived from biotechnology and other food and feed sources. This paved the way for EFSA's roadmap for an improved weight of evidence approach to allergenicity RA (EFSA, 2022).[20] EFSA has also raised awareness on allergenicity through updates to several guidance documents and scientific opinions (EFSA GMO Panel, 2025; EFSA NDA Panel, 2024).[21,22] For example, the recently updated EFSA guidance on novel foods proposes a tiered approach to investigate potential cross-allergenicity.

R&I will be needed to:

- Improve predictions to aid decision-making for de novo sensitisation (e.g. in silico assessment of the antigenic potential of innovative proteins) by modelling the protein binding capacity to human leukocyte antigen presenting cells;
- Improve predictions for cross-reactivity, supported by curated, clinically-relevant allergen databases fit for RA purposes, which integrate, e.g. phylogenetics, sequence homology and structural similarity and also take into consideration factors such as exposure, likelihood of allergenicity and clinical relevance.
- Establish criteria on when and how in vitro (and eventually, in vivo) testing would be needed to validate predictions for de novo sensitisation and cross-reactivity, including the generation of experimental data.

6 | ADVANCING AGGREGATE EXPOSURE TO MULTIPLE CHEMICALS

Exposure assessment is a key component of chemical RA. In line with its mandate, EFSA primarily focuses on dietary route of exposure, combining chemical occurrence data in food with food consumption data. However, consumers' exposures to chemicals occurs also through other routes and sources. Furthermore, as legislation is mostly based on the approval of individual substances, EFSA's RAs focus on single chemicals or small groups of chemicals. EFSA recognises the need for dietary exposure to multiple chemicals, considering all relevant sources and exposure routes, with the goal to establish an

[16]Doytchinova, I., Dimitrov, I., & Atanasova, M. (2023). PreDQ – a software tool for peptide binding prediction to HLA-DQ2 and HLA-DQ8. *EFSA Supporting Publication*, 20(7), EN-8108. https://doi.org/10.2903/sp.efsa.2023.EN-8108.

[17]Mills, E. N. C., Orsenigo, F., Salgado, D., Finglas, P. M., & Astley, S. (2024). Novel strategies for predicting allergenicity: development of a ranking method and screening tools to assess the allergy risk of innovative proteins. EFSA Supporting Publication, EN-8840. https://doi.org/10.2903/sp.efsa.2024.EN-8840.

[18]Bebi, C., Urbani, D., Evangelisti, M., Grossi, V., Russo, F., & Del Rio, A. (2024). Outsourcing external report on preparatory work for the development of adverse outcome pathways (AOPs) relevant for the capacity of proteins to trigger celiac disease. EFSA Supporting Publication, EN-8570. https://doi.org/10.2903/sp.efsa.2024.EN-8570.

[19]Martinez, J. M., Gutiérrez, M., Moreno, B., Calvo, M., Fondevila, M., Belanche, A., Raso, J., Moreno, J., Álvarez, I., & Cebrián, G. (2024). Investigating technological processing supporting the assessment of novel proteins in food and feed risk assessment scientific report. EFSA Supporting Publication, EN-9113. https://doi.org/10.2903/sp.efsa.2024.EN-9113.

[20]EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2022). Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology. EFSA Journal, 20(1), 7044. https://doi.org/10.2903/j.efsa.2022.7044.

[21]EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2024). Guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. EFSA Journal, 22(9), e8961. https://doi.org/10.2903/j.efsa.2024.8961.

[22]EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2025). Scientific Opinion on current practice, challenges, and future opportunities in the safety assessment of newly expressed proteins in genetically modified plants. https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000003SPsz/pc1278.

EU framework for assessing aggregated exposure to multiple chemicals by 2030 (EFSA, 2022).[23] EFSA is closely engaging with the European Commission and EU agencies involved in chemical safety assessments to develop an EU framework for aggregated exposure assessment.

Inspired by the 'one substance, one assessment' approach,[24] EFSA has commissioned two roadmaps on exposure assessment: RACEMiC (De Jong et al., 2022)[25] and EXPOADVANCE (Lamon et al., 2024).[26] These roadmaps provide an overview of current capacities for performing aggregated exposure assessments, considering achievements and developments in relevant research activities, such as the Partnership for the Assessment of Risks from Chemicals (PARC).[27] They also provide recommendations to address gaps in terms of methods, tools and data. Of the several R&I recommendations identified in these roadmaps, the top three priority recommendations for EFSA, which are deemed to be the most critical and urgent for action, are summarised below.

R&I will be needed to:

- Create an EU framework for performing aggregate exposure assessments and the development of guidance on the use of exposure models and human biomonitoring data.
- Develop a comprehensive approach for grouping chemicals, combining multiple lines of evidence gathered from different data sources and making use of latest technological developments to explore automation of such processes.
- Develop a more comprehensive understanding of the exposome and its role in shaping human health outcomes.

7 | ADVANCING ENVIRONMENTAL RISK ASSESSMENT WITH ECOLOGICAL REALISM

In the EU, regulated products, such as feed additives, food flavourings, genetically modified organisms and plant protection products, must undergo prospective ERA and obtain regulatory approval prior to use. ERA evaluates the potential adverse effects that regulated products may pose to the environment ensuring that their use does not result in unacceptable harm. This process is subject of periodic reviews as new data and knowledge emerge.

Despite ongoing efforts to advance ERA practices, ERAs have faced criticism for not sufficiently aligning with ecological and practical realities (Axelman et al., 2024; Topping et al., 2020).[28,29] Therefore, as outlined in the PERA (Sousa et al., 2022)[30] and IPOL-ERA (Williams et al., 2023)[31] roadmaps, advancing the ERA for regulated products requires integrating a more realistic understanding of the environmental context, including biodiversity, ecology, landscape aspects and cropping and farm management practices. Additionally, it requires fostering collaboration across various disciplines, such as agronomists, (agro)ecologists, ecotoxicologists and conservation biologists, and engaging stakeholders through knowledge-sharing platforms and partnerships.

R&I will be needed to:

- Develop and refine testing methods and approaches to assess the potential (sub)lethal, chronic and indirect effects of regulated products on relevant (i.e. focal) species selected based on the organism's biological and ecological traits.
- Develop approaches to integrate landscape aspects in regulatory ERA to provide more context-specific and ecologically relevant ERA predictions. This includes investigating approaches that address interactions between multiple chemicals and other environmental stressors, such as climate change.

[23]EFSA (European Food Safety Authority), Cascio, C., Dorne, J. L., Kass, G., Arcella, D., Binaglia, M., Dujardin, B., Fabrega, J., Heppner, C., & Liem, D. (2022). Advancing Aggregate Exposure to Chemicals in EU (ExpoAdvance). EFSA Supporting Publication, e201001. https://doi.org/10.2903/sp.efsa.2022.e201001.

[24]https://ec.europa.eu/commission/presscorner/detail/en/ip_23_6413.

[25]Esther de Jong, Hilko van der Voet, Philip Marx-Stoelting, Susanne Hougaard Bennekou, Corinne Sprong, Denise Bloch, Alina Burchardt, Alexandra Lasch, Tobias Opialla, Stefanie Rotter, Eva Bay Wedebye, Anne Zwartsen, Anke Leys, Maryam Zare Jeddi, Gerrit Wolterink, JohannesKruisselbrink, Waldo de Boer, Jacob van Klaveren. (2022). Roadmap for action on Risk Assessment of Combined Exposure to Multiple Chemicals (RACEMiC). EFSA Supporting Publication, EN-7555. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2022.EN-7555.

[26]Lamon, L., Doyle, J., Paini, A., Moeller, R., Viegas, S., Cubadda, F., Hoet, P., van Nieuwenhuyse, A., Louro, H., Dusinska, M,, Gale, K. S., Canham, R., Martins, C., Gama, A., Teófilo, V., Diniz-da-Costa, M., João Silva, M., Ventura, C., Alvito, P., El Yamani, N., Ghosh, M., Duca, R. C., Siccardi, M., Runden-Pran, E., McNamara, C., Price, P. (2024). Roadmap for action for advancing aggregate exposure to chemicals in the EU. EFSA Supporting Publication, EN-8971. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2024.EN-8971.

[27]https://www.eu-parc.eu/.

[28]C. J. Topping et al. (2020). Overhaul environmental risk assessment for pesticides. Science, 367, 360–363. https://doi.org/10.1126/science.aay1144.

[29]Johan Axelman, Annette Aldrich, Sabine Duquesne, Thomas Backhaus, Stephan Brendel, Andreas Focks, Sheila Holz, Saskia Knillmann, Silvia Pieper, Emilia Silva, Maria Schmied-Tobies, Christopher John Topping, Louise Wipfler, James Williams, José Paulo Sousa. (2024). A systems-based analysis to rethink the European environmental risk assessment of regulated chemicals using pesticides as a pilot case, Science of The Total Environment, 948, 174526. https://doi.org/10.1016/j.scitotenv.2024.174526.

[30]Sousa, J. P., Aldrich, A., Axelman, J., Backhaus, T., Brendel, S., Dorronsoro, B., Duquesne, S., Focks, A., Holz, S., Knillmann, S., Pieper, S., Schmied-Tobies, M., Silva, E., Topping, C., Wipfler, L., & Williams, J. (2022). Building a European Partnership for next generation, systems-based Environmental Risk Assessment (PERA). *EFSA Supporting Publication*, 19(8), EN-7546. https://doi.org/10.2903/sp.efsa.2022.EN-7546.

[31]Williams, J. H., Bordoni, A., Bednarska, A., Pinto, A., Henriques Martins, C. A., Henriques, D., Sgolastra, F., Knapp, J., Loureiro, J., Sousa, J. P., Gócs, K., Kondrup Marcussen, L., Rundlöf, M., von Post, M., Castro, M., Mølgaard, N., Simon, N., Capela, N., Thomsen, P., Casqueiro, R., Magagnoli, S., Holz, S., Castro, S., Dupont, Y. L., Filipiak, Z., & Topping, C. J. (2023). Roadmap for action on the environmental risk assessment of chemicals for insect pollinators (IPol-ERA). EFSA Supporting Publications, 20(11), EN-8431. https://doi.org/10.2903/sp.efsa.2023.EN-8431.

– Enhance in silico and monitoring capacities and their interplay. Enhanced modelling capabilities will enable more accurate, reliable and ecologically relevant ERA predictions and allow for extrapolating observed ecotoxicological effects across different levels of biological organisation (from molecules to cells, organisms, populations, communities and ecosystems). Improved monitoring capacities (e.g. pesticidovigilance) will facilitate the collection of real-world data (e.g. on usage intensity and frequency, measured concentrations, biological effects) for validating and refining ERA predictions. This will help to understand the broader ecological impacts of regulated products, including effects on biodiversity and ecosystems, across different spatial and temporal scales, encompassing both local and landscape scales.

8 | DISCUSSION

This editorial provides an update on R&I needs relevant to EFSA's work in the coming years. The authors acknowledge that this overview is not exhaustive and refer to earlier publications for additional R&I needs, as well as to the roadmaps for a more in-depth presentation.

The European Parliament, in its resolution on lessons learned from the COVID-19, called for the promotion of public scientific research to better understand and reflect the interdependencies between human, animal, plant and environmental health using a multi-sectoral, transdisciplinary and integrated approach.[32] The resolution advocates for a One Health approach and calls for the establishment of a European cross-agency task force to advance transdisciplinary research and cross-sectoral scientific advice on public health, environmental protection, food safety and nutrition. This Task Force has been established with its second strategic objective being the coordination of research engagement among the five One Health agencies (i.e. European Centre for Disease Prevention and Control, European Chemicals Agency, European Environmental Agency, EFSA and European Medicines Agency). While many of the needs highlighted in this editorial embody the One Health approach, the authors have not focused specifically on One Health implementation needs. The agencies are liaising with Commission services and Member States and are ready to support the formulation of One Health specific research needs.

The authors believe this editorial will be valuable to stakeholders, research agenda setters and funders, both public and private, in formulating calls for research and project funding related to food safety.

KEYWORDS
allergenicity, EFSA, environmental risk assessment, exposure, microbiome, new approach methodologies, omics, regulatory science, research & innovation

ABBREVIATIONS

AOPs	adverse outcome pathways
ERA	environmental risk assessment
GI	gastro-intestinal
NAMs	new approach methodologies
NGRA	next generation risk assessment
PARC	Partnership for the Assessment of Risks from Chemicals
PBK	physiologically based kinetic
PoD	points of departure
R&I	research & innovation
RA	risk assessment
RPs	reference points
TK-TD	toxicokinetic-toxicodynamic

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[32]COVID-19 pandemic: lessons learned and recommendations for the future. European Parliament resolution of 12 July 2023 on the COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI)). (C/2024/4003). http://data.europa.eu/eli/C/2024/4003/oj.

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