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Translating data into policy informing decisions: current and future perspectives from the European Food Safety Authority (EFSA)

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Abstract

The European Food Safety Authority (EFSA) provides independent scientific advice to EU risk managers on a wide range of food safety issues and communicates on existing and emerging risks in the food chain. This advice helps to protect consumers, animals and the environment. Data are essential to EFSA's scientific assessments. EFSA collects data from various sources including scientific literature, biological and chemical monitoring programmes, as well as food consumption and composition databases. EFSA also assesses data from authorisation dossiers for regulated products submitted by the industry. To continue delivering the highest value for society, EFSA keeps abreast of new scientific, technological and societal developments. EFSA also engages in partnerships as an essential means to address the growing complexity in science and society and to better connect and integrate knowledge, data and expertise across sectors. This paper provides insights into EFSA's data-related activities and future perspectives in the following key areas of EFSA's 2027 strategy: one substance-one assessment, combined exposure to multiple chemicals, environmental risk assessment, new approach methodologies, antimicrobial resistance and risk–benefit assessment. EFSA's initiatives to integrate societal insights in its risk communication are also described.

The European Food Safety Authority (EFSA) is an EU agency responsible to deliver independent scientific advice on food safety to risk managers and communicate on risks in the food chain from farm to fork. EFSA was established in 2002 under Regulation (EC) No 178/2002[1] following the bovine spongiform encephalopathy and the dioxins incidents, with the ambition to ensure a high level of consumer, animal and environmental protection and strengthen consumer confidence in the EU food safety system. To this end, EFSA delivers scientific assessments that provide a basis for the protection of European consumers from food-related risks. Approximately 500 EFSA scientific assessments are delivered annually, spanning a wide portfolio of food-borne chemical and biological hazards (e.g. food and feed additives, food flavourings, food enzymes, food contact materials, plant protection products, novel foods, food and feed derived from GM organisms).

Data are essential to EFSA's scientific assessments. The Authority assesses data from various sources including scientific literature, biological and chemical monitoring programmes, food consumption and composition databases and market authorisation dossiers for regulated products (e.g. food additives, food flavourings, plant protection products, novel foods, GM organisms).

To deliver the highest societal value in response to its mandate, EFSA keeps up with the latest developments in science and technology, capitalises on new data[2] and works with experts, including national risk assessment organisations across the EU[3]. EFSA also collaborates with other EU agencies, that is, the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environmental Agency (EEA) and the European Medicines Agency (EMA), as well as with international organisations to share knowledge, data and expertise.

Amendments to EFSA's Founding Regulation[1] introduced by the Transparency Regulation[4], have further prompted EFSA to address societal demands for more transparency and openness in its risk assessment processes[3]. Industry applicants of market authorisation dossiers now have an obligation to notify in advance of EFSA studies intended to be included in a dossier. EFSA engages with interested stakeholders through public consultations to ensure that it has all relevant scientific data and studies for its assessments (https://open.efsa.europa.eu/).

In 2020, the European Commission adopted the EU Green Deal that sets new policy targets aiming for climate neutrality and sustainability[5]. With the strategic initiatives under the European Green Deal such as the Farm to Fork Strategy (https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy), the Chemicals Strategy for Sustainability (https://environment.ec.

europa.eu/strategy/chemicals-strategy) and the Biodiversity Strategy for 2030 (https://environment.ec.europa.eu/strategy/biodiversity-strategy-2030), the EU is pursuing its ambition for (i) making agrifood systems fair, healthy and environmentally friendly; (ii) ensuring that the use of chemicals is safe for health and the environment; and (iii) protecting and restoring biodiversity.

The implementation of the above-mentioned strategies will continue to shape EFSA's activities for the foreseeable future, as these strategies set new targets and actions across various policy areas that are relevant for EFSA. These include, for example, the need to:

(1) Move towards a 'one substance, one assessment' (1S1A) approach by improving the efficiency, effectiveness, coherence and transparency of chemical safety assessments across all relevant regulatory frameworks;
(2) Better protect human health and the environment from the effects of simultaneous exposure to multiple chemicals;
(3) Deliver sustainable food, while better protecting the environment;
(4) Reduce, refine or replace the use of animal testing for chemical safety assessments by optimising the use of alternative lines of evidence such as data derived from new approach methodologies (NAMs);
(5) Reduce the threat of antimicrobial resistance (AMR) caused by the excessive or inappropriate use of antimicrobials (antibiotics) by reducing their overall EU sales by 50 % for farmed animals and in aquaculture by 2030.

It is against this backdrop that EFSA has prepared its Strategy 2027. Thus, the Transparency Regulation, the Farm to Fork Strategy, the Chemicals Strategy for Sustainability and the Biodiversity Strategy for 2030 are at the heart of EFSA's 2027 Strategy[6]. Consequently, they are reflected in two strategic objectives: (i) deliver trustworthy scientific advice and communication of risks from farm to fork; and (ii) ensure preparedness for future risk analysis needs. Successfully achieving these strategic objectives would manifest in (i) public health being ensured, which takes account of the environment, animal health and welfare and plant health; and (ii) trust being sustained in a food safety system that ensures a high level of protection for human health and consumers' interests.

This paper elaborates on several activities within EFSA's 2027 Strategy[6] the frame of the above-mentioned EU strategic objectives. To demonstrate the wide spectrum of EFSA's remit, some of EFSA's data-related activities are described, as well as its future perspectives in the following areas: 1S1A, combined exposure to multiple chemicals, environmental risk assessment (ERA), NAMs, AMR and risk–benefit assessment (RBA). EFSA's initiatives to integrate societal insights in its risk communication plans are also described.

One substance, one assessment

Many substances in the food chain can be also present in non-food products (e.g. nitrosamines, azole fungicides) and thus are governed by different EU regulatory frameworks. In these cases, EFSA needs to think beyond the remit of its Founding Regulation[1] when undertaking safety assessments. Therefore, EFSA actively contributes to the implementation of 'one substance, one assessment' (1S1A), a key driver of the EU Chemicals Strategy for Sustainability[7]. The 1S1A approach aims to simplify and consolidate the legal frameworks concerning chemicals[7]. The goal is to deliver more consolidated scientific advice from EU agencies across the different regulatory frameworks in which the same chemical is assessed.

At the end of 2023, the European Commission published a 'Proposal for a Regulation establishing an EU common data platform on chemicals'[8]. The proposal is currently under scrutiny of the European Parliament and Council as part of the ordinary legislative procedure.

This platform will integrate several data tools and building blocks in a single space to facilitate the sharing, access and re-use of information on chemicals derived from various sources. One of those data tools will be the International Uniform ChemicaL Information Database (IUCLID), a software to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances co-developed by ECHA and the OECD that allows regulated product dossier submission under the IUCLID data format (https://echa.europa.eu/support/registration/creating-your-registration-dossier/what-is-iuclid-). The European Commission's Information Platform for Chemical Monitoring (https://ipchem.jrc.ec.europa.eu/), an open data repository containing chemical occurrence data from food, feed, human biomonitoring and environmental monitoring, as well as indoor air quality monitoring[9], will be also integrated into the EU common data platform on chemicals. Furthermore, the platform will serve as a centralised repository of health-based guidance values (HBGV), making all relevant HBGV easily available and accessible; among other existing databases, EFSA's OpenFoodTox[10] is being considered as a template for the development of the repository (https://www.efsa.europa.eu/en/data-report/chemical-hazards-database-openfoodtox). EFSA will participate in the EU common data platform steering committee and will contribute to the platform by delivering relevant data on chemicals that it holds.

Beyond the EU common data platform, the legislative proposal also foresees the establishment of a framework on chemical indicators to monitor the drivers and impacts of chemical pollution and measure the effectiveness of chemical legislation and an EU early warning and action system for chemicals to ensure that EU policies address emerging chemical risks as soon as identified by monitoring and research. Each EU agency relevant to 1S1A (i.e. the ECHA, the EEA, the EFSA, the EMA and the European Agency for Safety and Health at Work (EU-OSHA)) will contribute to these frameworks through the provision of relevant data collected.

The implementation of 1S1A requires harmonisation of data requirements (to fulfil the testing of specific safety endpoints when submitting dossiers under different regulatory frameworks) and risk assessment methodologies across the relevant regulatory frameworks for the assessment of chemicals in the EU. Therefore, EFSA commissioned a study to map data requirements across the EU agencies and the two non-food scientific committees of the European Commission (i.e. the Scientific Committee on Consumer Safety and the Scientific Committee on Health, Environmental and Emerging Risks). The study identified several discrepancies regarding terminology and data/methodologies used in different chemical regulatory frameworks[11]. Alignment in those areas, where needed, will facilitate the 1S1A implementation.

Meanwhile, EFSA is piloting the 1S1A implementation with other EU agencies within the frame of recent mandates; this entails sharing data, connecting experts (and staff) and discussing cross-cutting issues with the ultimate aim to avoid diverging opinions.

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An example of those pilots was the assessment of sulphur dioxide by EFSA (as a food additive) and by ECHA (as a biocide) in which scientific divergencies were identified; those evaluations were compared and the differences analysed through a 1S1A lens[12]. Another activity in which the 1S1A approach was tested related to the EFSA-EMA collaboration on the development of a harmonised approach for estimating human dietary exposure to veterinary medicinal product residues, feed additives and pesticides; the two agencies collaborated successfully with the publication in 2022 of a report containing the elements to deliver such harmonised framework[13]; as a follow-up, EFSA will develop a tool to harmonise the calculation of human dietary exposure to residues from chemicals assessed in different regulatory areas.

Combined exposure to multiple chemicals

Current regulatory frameworks for chemicals mainly rely on the risk assessment of individual substances. In practice, however, humans, animals and the environment are continuously exposed to a multitude of chemicals from different sources, and there is a growing scientific consensus that the effect of such simultaneous exposures must be better integrated into chemical risk assessment processes. In this context, the Chemicals Strategy for Sustainability has also set the objective to better address the combined effects of chemicals. This objective is now enshrined in the EFSA Strategy 2027[6], calling for specific action on the development of risk assessment of combined exposure to multiple chemicals across regulatory domains.

Considering the large number of chemicals potentially targeted by such assessments, either anthropogenic or natural, specific methodologies have been designed to address the complexity and the amount of data needed to describe the toxicological profiles of those chemicals as well as the associated exposure patterns[14]. Scientific criteria for the grouping of chemicals based on their toxicological profiles were also developed[15]. Whereas such methodologies were already regularly implemented for the assessment of well-known, pre-defined groups of chemicals (e.g. dioxins and dioxin-like polychlorinated biphenyls (DL-PCB), per- and polyfluoroalkyl substances), the assessment of potential effects resulting from simultaneous exposure to chemicals originating from different sources and uses, also referred to as coincidental mixtures, still poses important practical challenges.

Experience gained on the cumulative risk assessment of pesticides for the nervous system, thyroid and cranio-facial alterations[16–19] has demonstrated that the lack of structured data on chemical toxicity is a main limitation in the efficient identification of chemicals with common toxicological profiles. To address this challenge, further development of the EFSA OpenFoodTox database (https://www.efsa.europa.eu/en/microstrategy/openfoodtox) and integration of IUCLID in the EU common data platform on chemicals (as described above) will be key. In the first instance, these initiatives will facilitate the extraction of toxicological data and the identification of common toxicological profiles. In the longer term, however, such repositories may also facilitate the automation of data analysis and, where the toxicological data for a given chemical are scarce, predict toxicological properties through the application of NAMs.

Meanwhile, to make best use of its resources, EFSA can rely on a wealth of chemical monitoring data in food to identify substances that need to be prioritised for grouped assessments. Over the years, EFSA has collected over 400 million analytical measurements in food provided by Member States, and through the application of new statistical models, these data can be used to identify chemicals that are unlikely to contribute to combined health risks. Such a prioritisation method was recently implemented for the cumulative risk assessment of pesticides, where a probabilistic analysis was applied to around 30 million monitoring data points, reducing the scope for future cumulative risk assessment of pesticides by approximately 70–80 %[20]. In accordance with the roadmap for action on combined exposure to multiple chemicals[21], similar strategies will need to be developed for prioritisation of chemicals in other regulatory domains of EFSA, such chemical contaminants, food additives and food flavourings.

Furthermore, building on the scientific know-how acquired in dietary risk assessment of chemicals, EFSA will need to integrate non-dietary routes of exposure in its chemical risk assessment processes, which raises both scientific and regulatory challenges. The EU research community has produced valuable scientific knowledge in this field and new types of data, such as human biomonitoring data, have been generated. In close collaboration with the exposome research community and with the Partnership for the Assessment of Risks from Chemicals, EFSA is exploring how this science can be brought into daily practice. From a regulatory perspective, however, the responsibilities for chemical risk assessment are shared among different agencies. Therefore, ECHA, EEA, EMA and EFSA need to strengthen the collaboration in identifying and achieving common objectives, while operating within the boundaries defined by the different regulatory frameworks. Within this remit, the different initiatives and data repositories elaborated under the umbrella of 1S1A (as described above) will be key. EEA and EFSA, with the support of ECHA, recently initiated a joint assessment on the burden of disease for lead that will account for all sources and routes of exposure (https://open.efsa.europa.eu/questions/EFSA-Q-2024-00261). Such collaborations are crucial to continuously improve our chemical risk assessment framework and ensure the highest protection to humans, animals and the environment.

Integration of monitoring data in regulatory environmental risk assessments

The use of regulated substances (also termed 'products' at times, covering feed additives, food flavourings, GM organisms and plant protection products) is subject to a 'prospective' ERA and regulatory approval in the EU. ERA determines the risks that the deployment of a substance may pose to the environment.

The ERA of substances relies on substance-specific, risk-based approaches that are applied to (a) specific type(s) of use. While substantial protection progress has been made with current ERA frameworks, scientists have repeatedly highlighted the need to better align them with the latest scientific knowledge, ecological reality and new policy targets (e.g. European Green Deal). For example, they have advocated to follow a more holistic approach that integrates, among other aspects, environmental monitoring[22–24].

Environmental monitoring aims to identify changes in the environment and trends in specific indicators that could be caused by the exposure to an approved substance showing no cause for concern in the ERA. Such monitoring can be specific or general[25]. Specific monitoring is typically conducted by approval holders on a case-by-case basis, as it is tailored to individual approved substances and their intended uses. In contrast, general monitoring relies on existing monitoring/surveillance networks that operate at the EU, national and local levels to measure a range of natural

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resources and environmental characteristics related to protection goals, such as biodiversity, and water and air quality, independent of the factors influencing them.

Environmental monitoring data could be used to cross-validate assumptions made to predict risks against real-life outcomes, thus confirming that ERA conclusions are sufficiently protective. It may also help to identify the occurrence of adverse effects that were not anticipated and assess the effectiveness of implemented risk mitigation measures. In doing so, monitoring could serve as an early warning check of outcomes that diverge from expected results. Early detection of any adverse effects attributable to a substance may allow for a more rapid (i) reassessment/recalibration/refinement of the ERA, (ii) implementation or modification of risk mitigation measures and (iii) implementation of remedial measures, including the withdrawal of a critical substance. Therefore, integrating monitoring data in ERA has been identified by EFSA[6,26] and others[22–24,27,28], as an area requiring further development.

Environmental monitoring data remain largely unexplored in the ERA of regulated substances due to practical challenges. First, depending on sectoral legislation and ERA predictions, specific monitoring is conducted on a case-by-case basis only[27], meaning that specific monitoring data are not gathered systematically. Second, data derived from general monitoring do not necessarily comply with the FAIR principles of findability, accessibility, interoperability and reusability, as they are gathered for other purposes. Third, general monitoring delivers data on aggregate exposure of substances resulting from the sum of their uses. Such data cannot be integrated directly in ERA, which addresses single substance–use combinations and no mixtures. Properly integrating such data in ERA requires addressing use–exposure–impact relationships. This integration implies linking a specific use of a substance to a certain environmental exposure and subsequently such an exposure to a given environmental change or ecological trend. Linking chemical use to exposure is complicated, as chemicals are typically used in several different ways, their concentrations vary in space and time (e.g. chemicals can move within and between matrices once released into the environment, reaching considerable distances from their emission point) and spatio-temporally explicit data on actual uses are scattered (if available). Even in cases where it is possible to correlate uses with measured environmental concentrations, actual exposure to non-target organisms is determined by additional factors related, for example, to the organism's biology and behaviour. Finally, spatial or temporal ecological trends may be correlated to environmental exposure to a stressor but proving actual causality in the light of all possible confounding factors (e.g. resource availability, habitat quality, climate change, diseases) is an ever-increasing challenge.

To address the above challenges, further efforts are needed, aimed at (i) improving our understanding and knowledge of use–exposure–impact relationships and (ii) enhancing modelling and monitoring capabilities to predict and monitor environmental risks/impacts. Better integration of environmental monitoring data in the ERA of substances will represent an important transitional step towards the application of a more holistic approach to ERA.

New approach methodologies

A number of scientific, regulatory, economic and ethical drivers call for a reduction in the use of animal testing for the safety assessment of chemicals (e.g. EU Directive 2010/63 on the protection of animals used for scientific purposes[29]). To this end, the development and integration of NAMs for regulatory risk assessment is one of the key actions of EFSA's 2027 strategy for science, safe food and sustainability[6].

NAMs are an emerging set of alternative methods to traditional toxicity methods (e.g. animal testing) that can be used for predicting and assessing chemical risks and hazards, by providing mechanistic information for biologically complex endpoints[6,30]. Besides supporting the reduction of animal testing for the safety assessment of chemicals, NAMs can bring several advantages in the risk assessment of food and feed including a focus on the species of interest, on susceptible populations, providing mechanistic understanding and delivering toxicokinetic (TK) and toxicodynamic (TD) information[31].

NAMs include *in silico* (computational), *in chemico* and *in vitro* methods, as well as new technologies (e.g. genomics, proteomics and metabolomics), which may be used alone or in combination with other methods (e.g. integrated approaches) for hazard and risk characterisation[30,32,33]. Next-generation risk assessment requires integration of *in silico*, *in vitro*, *in vivo* animal data and human observational data, using, for example, integrated approaches to testing and assessment (IATA) and/or defined approaches to testing and assessment.

EFSA has commissioned several projects on the use of NAMs in risk assessment such as their use for hazard identification and characterisation (e.g. neurotoxicity, developmental toxicity, endocrine disruptors, immunotoxicity, allergenicity) and the prediction and modelling of interspecies differences and physiologically based kinetics (PBK). NAMs investigated include the use of artificial intelligence (AI), -omics-based approaches, computational modelling, nanomaterials, adverse outcome pathways (AOP) and IATA. An example is 'TKPlate 1·0' recently published by EFSA as an open access platform which allows predictions of TK and TD properties of chemicals using generic PBK models for humans, test species (rat, mouse, rabbit, dog), farm animals (cattle, sheep, pig, chicken), benchmark dose modelling and TK-TD models for ERA[34–36]. Another example is the development of IATA for developmental and adult neurotoxicity, based on an AOP-informed IATA framework in which NAMs are applied through an iterative process to providing mechanistic information where gaps are recognised to support the overall weight of evidence[37–40].

Some of the challenges raised by NAMs in regulatory science are the heterogeneity of methodologies applied, their standardisation and quality of results. For example, NAMs-data integration requires the use of harmonised reporting templates and data standardisation for their implementation into hazard identification and characterisation. To address such challenges, EFSA has investigated the use of AI for extracting and integrating results generated from NAMs (e.g. toxicity, mechanisms of action) that are useful for risk assessment[41]. Although further development is needed, a range of suitable AI tools and methodologies have been identified to support the search, extraction, harmonisation and integration of NAMs data for regulatory risk assessment purposes.

EFSA collaborates and exchanges data, expertise and methodologies with relevant stakeholders such as the Organisation for Economic Co-operation and Development (OECD), in order to reach consensus on the applicable criteria/standards for NAMs-based data and their integration for use in feed and food risk assessment. The harmonisation via ontologies and the transfer of data into the IUCLID data format used by ECHA were identified as a means to improve the availability of mechanistic data for risk assessment. In this regard, EFSA has contributed to an OECD

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Harmonised Templates structure in order to facilitate the reporting and structuring of quantitative structure–activity relationship (QSAR) data in the IUCLID database. The aim was to improve the availability of standardised data and facilitate the assessment of QSAR data within the development of a systematic and harmonised framework for the regulatory assessment of QSAR models, predictions and results based on multiple predictions (OECD GD 386[42]).

Finally, the utility of NAMs is also being explored for ERA. NAMs for ERA hold great promise by (i) providing alternative ERA test systems in terms of model species and endpoints; (ii) enabling prediction and extrapolation of effects from the laboratory to the field, across different levels of biological organisation (e.g. molecular, cellular, tissue, organ, organism, population, community, ecosystem) and across species (e.g. across species susceptibility); and (iii) improving the mechanistic knowledge of toxic effects on biological systems. The utility of NAMs for ERA is currently explored further at EFSA on a case-by-case basis using a weight of evidence approach.

Antimicrobial resistance

The European Commission's Farm to Fork Strategy, also part of the EU Green Deal[5], strives to achieve more sustainable agrifood systems (https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy). Among other measures, the strategy calls for an urgent need to address the global threat of AMR caused by excessive or inappropriate use of antimicrobials (antibiotics). EFSA contributes to this goal by monitoring annual trends in AMR in the EU in the food chain and by providing specifications for harmonised monitoring at the EU level.

AMR refers to the ability of microorganisms, such as bacteria, to become increasingly resistant to an antimicrobial to which they were previously susceptible. AMR can reduce the effectiveness of an antimicrobial to treat an infection, leading to therapy failure and prolonged illness. It leads to an estimate of more than 35 000 human deaths each year in the EU (including EEA)[43] and considerable healthcare costs due to longer hospital stays, more expensive drugs and decreased productivity. AMR is a global public health threat that transcends national borders and requires a multifaceted, coordinated effort at the global, national and local levels. The EU has been actively addressing AMR by adopting a 'One Health' approach[44] (https://health.ec.europa.eu/one-health), promoting strategies for the responsible use of antimicrobials, ensuring improved monitoring and surveillance, strengthening international cooperation and investing in research to develop new antibiotics and therapies.

The use of antimicrobials in animals is a known contributor to the emergence and spread of AMR to humans through the transmission of resistant bacteria via food or via direct contact with animals. The Farm to Fork Strategy aims to reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50 % by 2030 (https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy). EFSA assesses AMR monitoring data and provides scientific advice and risk assessments. Annually, EFSA and ECDC collect and analyse data from EU countries on zoonotic bacteria (*Salmonella, Campylobacter*) from humans, food-producing animals (pigs, calves, broilers and fattening turkeys) and their meat and on indicator bacteria (*E. coli*) from food-producing animals and their meat. Data reporting with a high level of granularity (single bacterial isolate level) enables analyses of AMR occurrence and patterns of multidrug resistance[45]. These data inform policymakers about progress in AMR, as a scientific basis for policy decisions. EFSA in collaboration with ECDC and EMA also analyses these AMR data together with data on antimicrobials' consumption (AMC) from EU-wide monitoring/surveillance programmes in humans and animals. These analyses aim to estimate the possible associations between AMC and AMR in bacteria in both sectors, to compare their trends and allow to formulate recommendations to combat[46].

In this context, the availability of comparable data is crucial because it provides a common basis for informing decision-making, guiding research and policy efforts and facilitating global collaboration. The main issues when comparing AMR data originating from different EU countries are the use of different laboratory methods and interpretive criteria. Moreover, several parameters of AMR monitoring (such as the bacterial agents, animal populations and food categories to be investigated, antimicrobials to be tested) require harmonisation.

The data harmonisation issue has been addressed by the ECDC's protocol for harmonised monitoring of AMR in humans[47] and by the legislation on harmonised monitoring in the veterinary sector. Directive 2003/99/EC has defined generic provisions for AMR monitoring in zoonotic and indicator bacteria in animals[48]. EFSA, ECDC and EMA have proposed a list of indicators suitable for monitoring AMR in key drug-resistant microorganisms and AMC in humans, food-producing animals and derived meat[49]. To respond effectively to the constantly evolving threat of AMR, EFSA has also prepared updated technical specifications on AMR monitoring that define the combinations of bacterial species and food-producing animals/meat to monitor (mainly the animal populations to which the consumer is most likely exposed through their food) and the antimicrobial panels (set of substances) to use. Over the years these specifications[50–54] have been used by the European Commission to lay down new AMR monitoring rules in the Commission Implementing Decisions 2013/652/EU and 2020/1729/EC, applicable for the period 2014–2020 and 2021-2027, respectively[55,56]. In particular, the latter addressed known implementation issues and ensured continuity in assessing AMR trends. To assist Member States in submitting data, EFSA publishes guidelines annually with the objective to streamline the reporting and ensure the ease of data analysis at the EU level[57].

Where the knowledge about AMR is very limited, EFSA prepares harmonised protocols for complementary surveys on specific AMR issues that are subsequently incorporated into a legislative framework (e.g. methicillin-resistant *Staphylococcus aureus*)[58,59]. EFSA scientific panels also conduct risk assessments on the AMR impact in the food chain, highlight data gaps and recommend areas where research should generate new data, for example, in relation to the role played by the environment in the emergence and spread through the food chain of resistant bacteria and genes[60] and to the risk factors during transport[61].

Risk-benefit assessment

Foods and substances can have both beneficial and adverse health effects. For example, while oily fish is an important source of beneficial long-chain fatty acids, it can contain contaminants such as methylmercury. Hence, food consumption will entail nutritional benefits and health risks due to the intake of hazardous substances or pathogens. In such cases, risk managers need to weigh risks against benefits to make informed decisions.

To address the complexity of weighing the risk against benefits from food, the use of integrated assessment approaches, that is,

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RBA, is required, as highlighted in EFSA's 2027 Strategy[6]. RBA is tailored to assess simultaneously beneficial and adverse effects of food components present in food (e.g. nutritional, microbiological and toxicological components), for each of the risk assessment steps[62]. RBA aims to provide risk managers with a comprehensive and objective evidence basis for public health and policy decisions, facilitating science-based decision-making in food-related areas.

A key challenge of RBA is that various factors (i.e. multiple constituents, multiple health effects, different populations) can impact the assessment of risks and benefits and thus lead to different RBA outcomes. Therefore, clear criteria must be applied for the identification and prioritisation of relevant food components and relevant hazards and benefits or for the assumptions made during the assessment[63]. The heterogeneity of RBA outcomes was showcased for the human health RBA of fish and seafood. This topic has been considerably explored and experts in the field urge for the development and implementation of more evidence-based and harmonised RBA approaches[64].

To harmonise the RBA process and meet the regulatory needs, EFSA has developed guidance on RBA in food[65]. EFSA subsequently delivered a statement on the benefits of fish consumption compared to the risks, specifically from methylmercury, based on the 2010 guidance[66]. The 2010 guidance has been updated recently[67] to integrate new developments and address limitations identified in the previous guidance. Following the update of EFSA's RBA guidance along with the update of the WHO's toxic equivalency factors for polychlorinated dibenzo-p-dioxins and furan and DL-PCB (https://open.efsa.europa.eu/questions/EFSA-Q-2024-00227), a comprehensive RBA of fish consumption is envisaged to inform risk management decision[67].

The updated EFSA guidance includes tiered methodological approaches to address the complexity of multiple risks and benefits beyond a single composite metric, based on the scope of the assessment and data availability. In particular, it is highlighted that for integration of risks and benefits via commonly used composite metrics such as disability-adjusted life years[68,69] and quality-adjusted life years[70], it is important to report them alongside other relevant metrics such as the number of cases, mortality rates and severity of effects. Other qualitative and quantitative methodologies for integrating risks and benefits are suggested. These methods build on methods introduced for characterising risks and benefits, such as measures of effect size, probability of effects and (benchmark) dose modelling of all relevant effects. Their integration is based on the probabilities of all relevant effects and/or effects of given severities using severity weight functions[67].

Moreover, the availability of high-quality data to inform RBA is essential. EFSA has setup and maintains a number of databases providing comprehensive and high-quality data, which are a useful source to support RBA (e.g. OpenFoodTox (https://www.efsa.europa.eu/en/microstrategy/openfoodtox), DRV Finder (https://multimedia.efsa.europa.eu/drvs/index.htm), Comprehensive European Food Consumption Database (https://www.efsa.europa.eu/en/microstrategy/food-consumption-survey). Common endpoints used in the RBA for positive and negative health outcomes include disease outcomes or surrogate markers of disease and intake below or above a health-based guidance value (HBGV)/dietary reference value (DRV). Other endpoints that could inform RBA are biomarkers of effect. While biomarkers of effect reveal intermediate changes, they may provide supportive information for RBA. EFSA is performing a feasibility study for biomarkers of effect with a view to the development of an internationally agreed guidance on the use of biomarkers of effect in regulatory risk assessment of chemicals by establishing consultation and co-creation mechanisms with EU and other international partners which will provide insights into the use of relevant biomarkers of effect for both risk and benefit endpoints (https://open.efsa.europa.eu/questions/EFSA-Q-2023-00583).

Different food components or dietary patterns may interact with each other in complex ways, making it challenging to evaluate their individual risks and benefits. Application of NAMs in RBA can support the identification and characterisation of the adverse and beneficial effects of a substance/product as well as provide (a) mechanistic understanding(s) of the chemical/product and its interactions in different levels of biological systems[71,72].

Integration of societal insights to risk communication

The Transparency Regulation[4] flags the need for EFSA to provide coherent, consistent and clear scientific advice about food-related risks. This endeavour is challenging in an EU composed of 27 Member States with different languages, cultures and food traditions[73]. This becomes even more complex nowadays where messages are easily created, shared and amplified within a highly interconnected, global environment[6].

To ensure effective risk communication, EFSA identifies and prioritises topics of relevance considering the nature of the food/feed hazard, institutional and stakeholder interests as well as societal needs, perceptions and concerns[74]. In this paper, we focus on EFSA's initiatives to understand and address societal needs, perceptions and concerns. Their importance in improving risk communication is reflected in the recommended actions of the EFSA 'ONE – Health, Environment & Society – Conference 2022' and in the EFSA 2027 strategic objective to 'deliver trustworthy scientific advice and communication of risks from farm to fork'[75,76].

To monitor and assess societal knowledge and perceptions in the areas where it operates, EFSA commissions surveys that help to better understand EU citizens' knowledge and cognitive factors affecting their judgements about risk. These surveys include targeted studies investigating consumer perceptions on specific areas, such as the impact of AMR on human health[77], perceptions on emerging risks[78], awareness of chemical mixtures[79], nutrition and dietary sugars awareness[80]. Other surveys consist of Eurobarometer studies and, more recently, flash citizen polls, as described in EFSA's social science roadmap (https://www.efsa.europa.eu/sites/default/files/event/mb-20211216/C16.Social-Science-Roadmap-9.mb211216-i5.pdf).

In its 2022 Eurobarometer report, EFSA investigated the interest of EU consumers in food safety based on feedback received from 26 509 EU participants[81]. The results of the survey showed that, for around half of responders, food safety is considered an important factor when making food-purchasing choices. Most responders valued the importance of a healthy diet and the impact of environmental health, plant and animal welfare to human health. Most responders acknowledged trust in the work of the EU institutions (66 % of responders) and regulations on food safety (73 % of responders).

EFSA's media specialists also collect and compile information stemming from social research, peer-reviewed literature, media coverage and social media listening and monitoring that is then analysed by EFSA's social scientists to understand the public's knowledge and perceptions on food safety[74]. The above surveys and media data collections aim to foster societal engagement in the areas within EFSA's remit and to frame improved risk

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communication action plans per topic and target audience to increase trust in science[82].

An example is the #Safe2Eat campaign that aims to raise awareness and help EU citizens to think critically about their everyday food choices and habits on a wide range of topics such as food hygiene, food waste, allergens, food supplements, food-borne disease, contaminants, novel foods, bee health, and others (https://www.efsa.europa.eu/en/news/safe2eat-2024-campaign-empowering-consumers-across-europe). Another example is the #PlantHealth4Life campaign that was launched by EFSA, the European Commission and Member State competent authorities to raise awareness about plant health and its impact on food security and the environment (https://www.efsa.europa.eu/en/plh4l). These campaigns are available in all EU languages. Finally, EFSA's podcast series 'Science on the Menu'(https://www.efsa.europa.eu/en/news/science-on-the-menu-podcast) takes the audience on audio journeys into key topics of EFSA such as 'One health' (https://health.ec.europa.eu/one-health), beyond animal testing, contaminants in food, food choices, etc.

Conclusion

Acknowledging the interconnection across different regulatory frameworks and the link between human, animal and environmental health, next-generation risk assessments point towards the adoption of 'One Health' approaches to support the implementation of policies on sustainable development.

Such integrated assessments will require high-quality data from a wide spectrum of areas (including social sciences) to be shared in a structural way in common repositories and be compliant with the FAIR principles. They also require the development of harmonised tools, standards and methodologies to allow data comparison and coherent outcomes that can be understood by all. Integration of non-animal-based approaches are good alternatives to animal testing to address data gaps and understand the mechanisms leading to adverse health outcomes.

The above can only be possible through continuous collaboration, exchange of data, knowledge and expertise across EU agencies, national and international risk assessment bodies, the establishment of common objectives and the performance of joint risk assessments for chemicals or biological agents of common interest within the boundaries of respective regulatory frameworks. Strong societal engagement to ensure that EU consumers' perceptions and knowledge about food/feed safety and sustainability are well understood and addressed is also essential in order for EFSA's risk assessments to continue to support the implementation of the new policies and deliver the highest value to society.

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