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Conference conclusions: shaping the future of food safety, together

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Abstract

The EFSA 2nd Scientific Conference 'Shaping the Future of Food Safety, Together' gathered an international audience composed of scientists, risk assessors, risk managers, as well as non-governmental organisations and industry representatives. This article summarises the final plenary session where a panel was asked to draw out overall impressions and conclusions for the EFSA to take away for its strategic planning into the future. The main conclusions of the conference are presented under five major themes. With new methodologies, technologies, big data and the increased societal demand for enhanced engagement in the risk assessment process, there is a clear need to maintain levels of expertise from traditional areas and to consider the inclusion of new areas and sources of expertise to perform scientific assessments. Academia, industry, research and regulatory science should work together to achieve this goal. As science progresses at pace, the continued development of assessment methodologies to deal with increasingly complex assessment questions is necessary, as is the need for applied research to underpin the support to policy development that EFSA provides. Greater collaboration is needed to reach agreement on best methods and practices for scientific assessment not just internationally, but also, equally importantly, across legislative areas and scientific disciplines, and in consultation with society at large. The communication of complex science, including important concepts such as uncertainty and risk perception, is not a trivial task, and must be integrated into the scientific process. As such, the relationship between risk assessment and risk management must continue to mature, remaining close, yet independent.

Keywords: data, expertise, methods, risk assessment, risk management, scientific assessment

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1. Introduction

The 2nd EFSA Scientific Conference 'Shaping the Future of Food Safety, Together' gathered an international audience composed of scientists, risk assessors, risk managers, as well as non-governmental organisations (NGOs) and industry representatives. The conference was opened by a plenary session on 'What does the future hold for assessment science?' touching upon the interaction between science, society and regulatory frameworks. The conference proceeded then with a first set of parallel sessions discussing 'Open risk assessment: data', 'Weighing evidence and assessing uncertainty', 'Expertise for the future' and 'Nutrition challenges ahead'. A second plenary session on 'Science, innovation and society' offered the opportunity to explore the key developments that may affect the work of the European Food Safety Authority (EFSA) in the near future. Participants then had the opportunity to take part in a second set of parallel sessions discussing: 'Open risk assessment: methods and expertise', 'Novel chemical hazard characterisation approaches', 'Microbiological risk assessment', 'Drivers for emerging issues in animal and plant health' and 'Advancing environmental risk assessment'.

The conference was concluded by a final plenary session, where a panel was asked to draw out overall impressions and conclusions for EFSA to take away for its strategic planning into the future. The panellists were Elke Anklam (European Commission, DG Joint Research Centre, JRC), Panagiotis Daskaleros (European Commission, DG Health and Food Safety), Martin Dermine (Pesticide Action Network, PAN), Samuel Godefroy (Laval University, Canada), Patrick Hau (Ministry of Health, Luxembourg), Euros Jones (European Crop Protection Agency, ECPA), Derek Knight (European Chemicals Agency, ECHA) and Angelika Tritscher (World Health Organization, WHO). The session was co-chaired by Tony Hardy (EFSA) and Hubert Deluyker (EFSA) and facilitated by a moderator, Barbara Serra (Al-Jazeera).

The following sections summarise the final plenary session and incorporate the main outcomes, conclusions and recommendations of the conference.

2. Conclusions and recommendations of the conference

2.1. Prioritise public engagement in and the transparency of the scientific assessment process

2.1.1. Engagement

Public engagement in the process of risk assessment (RA) has been a recurring theme throughout the whole conference. An extensive debate took place on how much EFSA should be opening up RA, when it was appropriate to engage with the public and how it could be done. Also, the need to establish trust was considered, not only in terms of the public trusting scientists but also with respect to scientists and regulators recognising and trusting that the public can make a valuable contribution to the assessment process.

There was extensive discussion both about the need to identify and frame the right scientific assessment questions, how that process can be opened up to a broader range of people as well as how to enable input all the way through the assessment process. The breakout sessions brought up some very interesting ideas, such as the potential use of crowdsourcing. This might enable an organisation such as EFSA to open up to a wide online community. Enhancing collaboration with and openness to interested parties and external knowledge communities may positively contribute to addressing more complex food safety-related questions. It may also enhance scientific scrutiny, reproducibility and, overall, may produce better quality and more trusted outputs.

To effectively achieve this goal, information and communications technology options need to be developed to facilitate the secure and efficient exchange of data and ideas for use in crowdsourcing. It also remains to be explored how such input can practically be integrated into the scientific assessment processes without undermining either the quality or robustness of the science.

Greater involvement and participation could also introduce potential risks, such as the disproportionate influence of a limited number of actors or the loss of control by EFSA over the content of an output. It is therefore important to demonstrate the relative freedom from bias in the scientific assessment. Ultimately, the success of crowdsourcing can only be confirmed by demonstrating the benefit to the crowd involved and society at large.

2.1.2. Transparency

Transparency is also very important to increase trust. The European Medicines Agency (EMA) explained how they opened clinical trial data to the public, and EFSA might consider doing the same with safety data for regulated products.

As another example, the European Chemicals Agency (ECHA)-coordinated scientific assessment of chemicals is already very open. For those substances that potentially require risk management (RM) option analysis, it is possible to follow the nomination of those substances and the debate on them in ECHA's Committees through ECHA's register and track the technical dossiers as they go through the scientific assessment process. In the Committees' meetings, there are representatives from Industry, Member States and NGOs. Although some of the debate is confidential, the outcome is published through the minutes. Many of these initiatives have been or are being implemented in EFSA's working practices.

2.2. Broaden EFSA's evidence base and facilitate access to its data

The generation of new research data and access to existing data have been important themes throughout the conference, both in the plenary sessions and in some of the breakout sessions.

2.2.1. Research prioritisation

A key issue is the prioritisation of publicly funded research to enable agencies such as EFSA to fulfil their mandate of supporting policy. The model of identification, prioritisation, funding and coordination of such applied research through the National Toxicology Programme in the USA was considered to be an example that merits further consideration.

EFSA's contribution towards the setting of research priorities to generate knowledge, including methods and data on issues within its mandate, should be further explored in cooperation with sister agencies in the Member States, other scientific assessment bodies in Europe and worldwide, as well as with the scientific community at large.

2.2.2. Open data

The advent of a new era of open data (publicly accessible and readily interpretable) in food safety has enormous potential. The benefits associated with open data, such as increase in transparency, innovation, possibilities for global networking and a higher standard of scientific studies, may result in better support for and acceptance of the decision-making process. This probably outweighs its perceived risks (e.g. potential misuse/misinterpretation of data).

However, turning data into information to make it usable for activities such as RA has not accelerated to the same degree as the emergence of the open data concept. EFSA should invest in the establishment of collaborative processes across the European Union (EU) to ensure alignment of strategies towards investment in data governance, as well as interoperability, with the use of common data standards, infrastructure, capacity and capability to leverage the potential of open data in all areas of food safety.

2.3. Scientific assessment capacity and knowledge community

To be prepared for future food safety RA challenges in an ever-changing and increasingly complex environment, it is important to anticipate the required expertise and competence needs, and to put in place appropriate training activities to build the future required competences.

2.3.1. Computer-assisted decision-making

New approaches which extend the power of computers to tasks that were originally performed by humans have the potential to enhance, scale up and accelerate activities traditionally addressed through human expertise. Cognitive analytics such as machine learning and natural language processing can discover patterns and relationships in information from millions of texts, books, online articles and other data-rich sources of information that could otherwise take decades to discover and analyse. The integration of these new technologies into the RA process needs to be explored and tested to begin to exploit its potential.

2.3.2. Expertise

In order to achieve food safety globally, the EU needs to invest in food safety knowledge. Training is not only important in countries within the EU or OECD countries but also for developing economies. Such investment in food safety knowledge needs to include training in risk analysis, covering current best practices and emerging approaches in RA and risk communication to provide individuals with appropriate knowledge and practical training to understand and participate in the RA process. In this context, guidelines for the establishment of RA training programmes would be welcomed. Organisations such as the EFSA should play their role in identifying and determining the expertise and competencies needed and participate in setting up the curriculum of such training programmes.

Concern was expressed that some university and research centres in Europe have recently reduced or ended their teaching and applied research activities in disciplines that are highly relevant to food safety RA. It is of concern that relevant expertise, particularly in Europe, will not be replaced. There is therefore an urgent need for training and capacity building not only to bring innovation and to integrate new methodologies and technologies into the RA, but also, at a more fundamental level, to maintain current RA capacity.

2.4. Developments in scientific assessment methods

The RA environment is ever changing as more data and new types of data become available. Appropriate methods are needed to analyse this information in a way that is relevant to RA. However, this is not the only challenge.

2.4.1. Evolving nature of the requests

Questions related to food safety are increasing in complexity and require faster responses to help risk managers protect the EU's 500 million consumers. For example, in the area of environmental RA, the two biggest challenges in EFSA's work will be the assessment of multiple stressors and reaching agreement on the operational protection goals to be used in the assessment. In order to make these happen, further research and an eventual revision of current legislation may be required.

It is also important to identify challenges and opportunities arising from a changing food production environment, deriving from climate change or new technologies, for example, at the earliest stage possible in order to anticipate the needs for data and new RA methodologies and to provide timely advice to risk managers.

Finally, EFSA plays an increasingly important role in providing data analysis and scientific advice to help risk managers respond to urgent food safety-related questions. Greater complexity, where the analysis of big data is becoming a fundamental feature of scientific research, and increasing urgency require considerable resource investments, both in financial and human capital terms.

2.4.2. Scientific knowledge

Science is advancing the understanding of public health risks, and therefore regulatory science needs to keep abreast of fundamental advances in scientific knowledge.

Emerging knowledge in biomedical research, such as in neurology and endocrinology, is of key relevance to EFSA's work. Similarly, epigenetic changes caused by environmental, dietary, pharmaceutical, microbial or lifestyle influences modulate gene expression and are now known to have profound effects on health, life expectancy and the development of diseases such as neuro-degeneration and cancer. Likewise, our intestinal microbiota represents an important yet poorly understood metabolic mass that has an intimate interaction at the interface between our body and our food; a perturbation of its function has also been implicated in the aetiology of several diseases, including colorectal cancer. Thanks to major research efforts over the past decade, many of their potential disease determinants, including dietary and environmental factors, can now be better understood. Therefore, it is important that this rapid progress in our understanding of health and disease is reflected in the way that future RA is conducted, whether on chemicals or on microorganisms found in food.

2.4.3. Scientific evaluation process

Several sessions of the conference highlighted the fact that chemical substances are currently evaluated substance-by-substance, whereas, in real life, citizens are exposed to multiple compounds (food additives, pesticides, etc.) and through multiple routes of exposure, not just the food chain. It is therefore important to enable better, more comprehensive and holistic assessment of the real-life exposures of European citizens to multiple chemical hazards.

The Conference provided a useful overview on developments in the kinds of information that are becoming available for scientific assessment. New hazard characterisation approaches such as omics and high-throughput systems have the potential to be integrated into regulatory chemical safety assessment. These alternative methods would enable replacing or reducing the use of traditional animal testing with a predictive toxicology based on the comprehensive understanding of how chemicals can cause adverse effects in humans or adversely impact on the environment. This includes a heightened awareness of the importance of the fate of a chemical in the body and the consequent inducement of adverse effects. The combination of toxicity data generated by alternative methods with strategies to integrate computational modelling data and existing knowledge may provide a toxicological prediction with a level of confidence (uncertainty) that would usefully contribute to its application in regulatory frameworks.

Weighing scientific evidence and assessing uncertainties require the development of harmonised and robust methodologies. This should take place in the frame of inter-agency and international cooperation and should also aim to provide adequate, transparent and fit-for-purpose support to decision-makers. Furthermore, the coherent integration of the biological relevance with the results of weighting evidence and assessing uncertainty can provide a more robust basis to further support holistic approaches for RA and decision-making.

As is necessary during the development of all new methodologies, international acceptance is needed with respect to methodologies for combining evidence/data and for defining the biological relevance of exposure to hazards. International cooperation is also needed to spread the work load across organisations. Organisations such as the WHO, FAO (Food and Agriculture Organisation of the United Nations), OIE (World Organisation for Animal Health), OECD (Organisation for Economic Co-operation and Development), etc. could play an important role in the harmonisation, implementation and worldwide acceptance of these scientific approaches to advance regulatory science, with individual organisations then incorporating the approaches into their specific regulatory contexts.

2.5. The interface between risk assessment and risk management

2.5.1. Roles and responsibilities

The final plenary session devoted much time to discussing the relationship between RA and risk management (RM) activities. This interaction was recognised as being key to the success of the whole risk analysis paradigm and merits careful attention. The paradigm of separation of RA and RM is one of the guiding principles behind the establishment of the EFSA. The principle of separation is aimed at ensuring that scientific assessments are carried out independently from other considerations. The independence of the RA process from RM is important in contributing to the trust of the consumer and other stakeholders in the outcome of the whole scientific assessment process. With the growing emphasis on openness and transparency, there may be some shift from the independence of the individual expert towards a greater focus on the scientific process.

The separation between RA and RM can itself be implemented in different ways, at the institutional level, as in the European model where different institutions are responsible for RA and RM tasks. It can also happen within an institution by the separation of teams dealing with RA and RM. Although that separation is indeed important, conversely so is the relationship between the elements of the triad in the risk analysis paradigm. Indeed, the assessment, management and communication of risks are not to be carried out completely independently, but must rather continually interact, and this is definitely key to the success and acceptance of the whole scientific assessment process.

The precise delineation of responsibilities between RA and RM may vary from one area to another. For example, technically, ECHA can issue decisions relevant to particular companies but is not competent to issue legally binding decisions where wider socio-economic issues are balanced. There

are variations within EFSA too, where some Panels such as Plant Health, on request from the European Commission, give advice on RM options. Similarly, in the Codex Alimentarius system, there are differences in the roles of risk assessors between the panels dealing with pesticides, food contaminants or veterinary drugs. However, provided that there is good communication between risk assessors and risk managers, this is not considered to be an issue.

There also was debate about the perceived lack of transparency of the RM process. In part, this was attributed to the lengthy and complex processes and procedures involved, especially such as in the EU where many players are involved. Participants expressed a desire to improve communication in the area of RM to help ensure the credibility of the whole risk analysis paradigm.

2.5.2. Problem formulation

The initial problem formulation by risk managers and the importance of how that is done was raised because it conditions the outcome of the RA and influences the subsequent choice of assessment processes (data, methods, expertise). The process of problem formulation should therefore be an iterative one between risk managers and risk assessors, with the option of modifying the question as the assessment evolves in order to ensure the production of a RA output that is fit for purpose.

2.5.3. Fitness for purpose

To achieve the desired public health outcome, the contribution that scientific assessment can make is not only a matter of producing the best science but also concerns advice that is fit for purpose. This aspect is particularly important when developing new methodologies and tools. This is an area where the dialogue between the RA and RM is critically important.

Furthermore, concerns other than the traditional assessment of human, animal, plant or environmental safety are of relevance to society, and need to be addressed by the risk manager. For example, for new legislation, the European Commission systematically carries out an impact assessment. However, within existing legislation, the picture is rather more diverse. Comparing across EMA, ECHA and EFSA, for example, there is no socio-economic assessment for genetically modified organisms, whereas there is one, for example, for the reimbursement of medicines by Member States and a socio-economic assessment is also foreseen and carried out by ECHA under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals).

3. Concluding remarks

All scientific assessments start from data. High-quality, robust and relevant assessments, on which risk managers can take action, require high-quality, precise and relevant data. Now that information and data are available in volumes that until recently have been unimaginable, it is more vital than ever that our methodologies are adapted to selecting those key pieces of information that will lead us to the correct and transparently justified conclusions.

As science progresses at pace, the continued development of assessment methodologies to deal with increasingly complex assessment questions is necessary. Here, there is a clear need for greater collaboration and wide agreement on best methods and practices for scientific assessment, not just internationally, but also, equally importantly, across legislative areas and scientific disciplines, and in consultation with society at large.

In order to address such complexity, as well as to ensure that the work of agencies such as EFSA remains meaningful to the wider society, current levels of expertise need to be maintained and more people need to be given the opportunity to contribute and engage in scientific assessment, using methods and tools to do so meaningfully. Nevertheless, scientific accountability for the final outcome rests with agencies such as EFSA.

As new methodologies, technologies, big data and societal demand for enhanced engagement in the RA process increase, there is a clear need to consider the inclusion of additional expertise, including that coming from the social sciences, to perform adequate, fit-for-purpose scientific assessments. Academia, industry, research and regulatory scientists should work together to achieve this goal.

The communication of complex science, including important concepts such as uncertainty and risk perception, is not a trivial task, and must be integrated into the scientific process. As such, the relationship between RA and RM must continue to mature, remaining close, yet independent.

Abbreviations

ECHA	European Chemicals Agency
EMA	European Medicines Agency
FAO	Food and Agriculture Organisation of the United Nations
NGO	non-governmental organisation
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
RA	risk assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RM	risk management
WHO	World Health Organization