European Food Safety Authority

ENGAGEMENT AND COOPERATION UNIT

Stakeholder Engagement

Workshop with Academia Stakeholders

FOOD SAFETY THROUGH SCIENCE –THE QUALITY OF RISK ASSESSMENT METHODOLOGY

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1. Introduction

The Stakeholder Engagement Approach (SEA) enables EFSA to benefit from stakeholders' input throughout different stages of the risk assessment process. The Stakeholder Forum and the Stakeholder Bureau are two permanent mechanisms where EFSA focuses on more strategic aspect, while targeted models such as discussion groups, roundtables, info sessions and public consultations offer opportunities to gather stakeholder input at a technical level. The SEA approach allows for the engagement with stakeholders from an early stage of the risk assessment process.

The objective of the workshop was to enable exchange of views on what evidence EFSA needs for 'regulatory' risk assessment, as well as what means are needed to integrate the evidence for risk assessment. With a due respect to the principles established under EFSA's policy for active engagement and cooperation with stakeholders, the workshop provided an opportunity for EFSA's Academic Stakeholders to present examples that may contribute in fostering state-of-the-art risk assessment approaches.

Initial idea to organise a workshop with all Academia Stakeholders came from the letter submitted by the European Network of Scientists for Social and Environmental Responsibility (ENSSER), at the margins of the first Stakeholder Forum meeting, where a number of issues related to the scientific quality and the risk assessment methodology, risk assessment of GMOs and pesticides were raised.

Dr Jose Julio Ortega (Society of Environmental Toxicology and Chemistry Europe – SETAC Europe), Member of the Stakeholder Bureau coordinated discussion among Academia Stakeholders to identify topics of interest and possible speakers. A draft concept note, and agenda were discussed at the second meeting of the EFSA Stakeholder Bureau (Brussels, 18th April 2018), where the Bureau agreed to proceed with the organisation.

The meeting was chaired by Dr Juliane Kleiner, Head of Risk Assessment & Scientific Assistance Department of EFSA, and co-chaired by Dr Jose Julio Ortega Calvo, Member of the Stakeholder Bureau representing Academia category of stakeholders.

In total, twenty-three participants representing four Academia Stakeholder organisations attended the meeting (Annex 2. List of participants). Representatives of the European Commission, DG SANTE attended in their capacity of observers.

2. General overview

The workshop programme has been designed as a one-day event divided in three main sessions; Risk assessment of pesticides; Risk assessment of genetically modified organisms; and Integrating evidence for Risk Assessment. Each of three specific but interconnected topics were presented by two leading keynote speakers and followed by a discussion session.

Dr Kleiner, the Chair of the meeting recalled that the workshop with representatives of the Academia Stakeholder Category was the first event under SEA specifically targeting scientific and technological communities, including scientific societies, universities and research institutes associations. This event presented a starting point to facilitate discussion and explore common topics of interest and to shape future collaboration.

Dr Ortega (SETAC Europe), welcomed the participants in his capacity of the Member of the Stakeholder Bureau and presented the role of the Stakeholder Bureau as an advisory body that provides input to EFSA at a high level with regards to societal concerns on health, environment, food production and other issues in the Authority's remit. Dr Ortega recalled that his role as the Bureau Member is to build-up confidence and strengthen the link between Academia Stakeholders and EFSA in promoting science.

The programme continued with a presentation on EFSA's role in a complex changing world where Dr Marta Hugas, EFSA's Chief Scientist recalled that during the twenty years of the risk analysis paradigm, the risk assessment has become more complex and challenging as a new knowledge becomes available. Combined exposure to multiple chemicals, antimicrobial resistance, and the African swine fever are just a proof of the need to support, shape and promote research and innovation in the food chains to allow regulatory agencies to be fit to face future challenges. Risk assessment will be expected to produce continuous outcomes providing real time analysis and communication around the opinion with all stakeholders. EFSA collaborates with other EU regulatory Agencies in providing high level strategic directions and prioritization of knowledge gaps in calls published by EU research funders.

Dr Didier Verloo, Head of Assessment and Methodological Support Unit presented EFSA's Science Quality Framework that enables EFSA a fit for purpose risk assessment that delivers the agreed 'scientific value' of EFSA outputs, with due respect to the extent of impartiality, methodological rigour, transparency and engagement. In addition, it ensures an efficiency gain, since preparing a protocol for the assessment upfront helps more streamlined processes throughout the implementation phase. Finally, such approach promotes the pioneering practice of 'planning before doing' for broad scientific assessments in regulatory science, and increased harmonisation and consistency of EFSA's and other assessments by sharing and re-using the risk assessment protocols.

Session 1: Risk assessment of pesticides

The second session allowed for an in-depth technical discussion and provided an update on EFSA's work on risk assessment of plant protection products and provided an opportunity to discuss the bioavailability science and its regulatory aspect.

Dr Tiramani, Head of Pesticides Peer Review Unit presented a general framework for the authorisation of plant protection products, and the role of the European Commission, the EU Member States, EFSA and the stakeholders who can provide comments on technical aspects during the different moments of public consultation. The presentation provided an overview of the opportunities and the needs of collaboration between Academia stakeholders and EFSA.

The session continued with the presentation of the scope of the bioavailability science and its regulatory aspect by Prof Kirk T. Semple, Director of International Engagement, Lancaster Environment Centre, Lancaster University. Prof Semple explained that the bioavailability of organic chemicals, including pesticides, in soil is an important research area for environmental scientists. This area of research remains only partially recognized by regulators and others working in the environmental sector. His presentation considered what bioavailability is, how it might be measured, as well as possible pathways for the implementation of bioavailability into risk assessment and regulation.

Session 2: Risk assessment of genetically modified plants

The session started with a presentation by Dr Pablo Steinberg, President of the Max Rubner-Institut, Federal Research Institute of Nutrition and Food in Karlsruhe on the main results from rodent feeding studies on the whole genetically modified food/feed obtained in the frame of the two research projects funded by the European Commission within the 7th Framework Programme, the GRACE (GMO Risk Assessment and Communication of Evidence) and G-TwYST (GM Plant Two Year Safety Testing). The conclusions and recommendations on the scientific justification and added value of such studies for the GM plant risk assessment based on the outcome of the above projects were presented. Dr Steinberg highlighted that the use of alternative tools to evaluate the safety of GM plants should be considered, such as in vitro test systems. Examples of in vitro systems applied in the GRACE project and tools such as microphysiological systems were presented, and their possible use and predictability discussed.

EFSA work and future perspectives in the area of the GMO risk assessment was presented by Dr Anna Lanzoni, Senior Scientific Officer, GMO Unit. Dr Lanzoni illustrated scientific and technological advances in molecular biology, *in silico* and *in vitro* science that could provide valuable information and could be used to integrate the current approaches and tools in GMO risk assessment. Areas under exploration by EFSA include the use of omics data in the context of compositional analysis of GM plants and the re-thinking and streamlining of the risk assessment of proteins newly expressed in GM plants. Dr Lanzoni presented a comprehensive overview of the EFSA initiatives and future perspectives in these areas that may foster a fruitful dialogue with the scientific community involved in the risk assessment of food and feed.

Session 3: Integrating Evidence for Risk Assessment

Dr Hilko van der Voet, Wageningen University & Research presented the application of the combined difference and equivalence testing in the risk assessment of GM plants. Dr van der Voet provided an overview of principles and practical methods used since 2010 in comparative analysis of GM field trials and presented the use of difference and equivalence testing in animal toxicity studies, as applied in rodent feeding trials on GM whole food/feed in the context of the EU project G-TwYST. Finally he presented the statistical analysis to untargeted metabolomics studies on GM plant composition.

Dr Georges Kass, Senior Scientific Officer, Scientific Committee and Emerging Risk Unit of EFSA presented EFSA's chemical risk assessment methodology, biological relevance & 3Rs approach to animal testing. Dr Kass recalled that data are fundamental to risk assessment in food and feed safety. The two main data streams needed are exposure and hazard data. In chemical risk assessment, the data needed to establish health-based guidance values such as an acceptable daily intake (ADI) value include an extensive characterisation of the hazard.

EFSA is currently exploring approaches that make better use of human data as provided by e.g. epidemiological studies. Other developments include the so-called New Approach Methodologies (NAM) that provide *in-silico* and *in vitro* systems aimed at replacing animal studies with human (cell) models. While these alternative approaches have become successful in predicting genotoxicity, their ability to predict more complex biological and toxicological phenomena such as reproductive and developmental toxicity is still limited.

3. General Remarks and Next Steps

The Academia Workshop enabled the participants to engage with EFSA and exchange views on the ongoing work and possible future engagement initiatives tailored to the Academia Stakeholder Category.

For EFSA, the engagement with Academia is key in promoting a trusted science. The stakeholder engagement approach follows principles of openness and transparency and EFSA is committed to continuous improvement of the way it interacts with stakeholders and the society.

In general terms, engaging with Academia stakeholders should be used to promote EFSA's key values and encourage scientists to engage more actively via different existing channels like membership in panels and working groups.

Based on the results of the post-event satisfaction questionnaire, participants appreciated the most the format of the meeting with time to interact with participants, quality of presentations, open-minded exchange and an open discussion between EFSA and Academia stakeholders.

Suggestions for the next events include a more focussed discussion on a specific topic to allow exchange of ideas, brainstorming on way to improve the risk assessment and a format that would allow more time for Academia stakeholder input that would result in a more tangible output/draft recommendations. Other participants, on the other hand proposed a more open, encompassing topic that would attract a wider Academia audience, in a format of a roundtable.

In addition, participants proposed the following topics for future events; the risk assessment of multiple stressors, "REACH" Regulation and the interaction with EFSA, food safety incidents, recycled nutrients, bio-based fertilisers. In addition, participants proposed trustworthiness in regulatory ecotoxicology, ecosystem service concept in environment risk assessment, societal context of decision making, endocrine disruption properties and reduction of animal testing, and the life science and digital farming as topics they would like to discuss with EFSA in similar future events.

The Workshop with Academia Stakeholders was the first event targeting this specific stakeholder category. Considering the resources and time limitation they face, the Academia Stakeholders demonstrated interest and readiness to explore together new models that would allow more active engagement with EFSA.

The engagement with Academia, in general terms aims to contribute to promotion of trusted science and building of a knowledge community, to further develop risk assessment methodologies and in defining future food safety research priorities.