

One Life

INNOVATION IN FOOD AND FEED: KEEPING SAFETY ASSESSMENTS FIT FOR PURPOSE

Summary

Current societal demands call for more sustainable food and feed production systems and healthier food and feed products and diets. This demand is at the heart of European policies such as the Green Deal and Food2030. Through these policies, Europe is pursuing its ambition for the development of innovative and high-quality food and feed products that are safe and produced in a more sustainable manner. Hence, a wide range of innovative food and feed products is expected to reach the EU market in the future and novel (production, processing and application) technologies be applied (e.g. new or alternative protein sources, new whole foods and feeds such as insects or algae, in vitro meat or food and feed products obtained through synthetic biology, 3D food printing and nanotechnology). Some of these developments may pose risk assessment challenges, requiring new or updated safety assessment approaches. We will therefore explore risk assessment development needs for innovative food and feed products, and discuss how risk assessment approaches and post-market surveillance may need to be advanced to safeguard the safety of future food and feed. This should ensure preparedness and address societal demands for better protection of human and animal health as part of the One Health approach.

Vision

In the context of the European Green Deal and Food2030, the EU's research and innovation policy to transform food systems, a wide range of innovative food and feed products is expected to reach the EU market in the near future. Some of these products and the novel technologies that are increasingly used in food production and processing may pose future challenges for risk assessment. The session will focus on how to ensure risk assessment activities can keep pace with the development of these innovative food and feed products to ensure we maintain a high level of protection for human and animal health.

Background – Challenges and opportunities

In light of increasing societal demands for more sustainable food and feed systems, a range of novel products is expected to enter the food and feed system in the near future. Moreover, new policies such as the European Green Deal and Food2030 have

been developed with these demands in mind. Innovation will bring wide-reaching changes, challenging the way safety assessments are currently performed. Existing food and feed safety assessment approaches may need to be revisited as they risk lagging behind in a rapidly changing world with a strong drive for innovation. It is fundamental to ensure the development of food and feed safety standards keeps pace with the speed of innovation in the field of food and feed. The development and application of new assessment approaches, while anticipating potential emerging risks, is crucial to achieve this goal. Failure to do so would undermine the reliability of safety assessment outcomes and result in weaker public trust in the food and feed safety system. One of the EU's missions is to ensure that only high-quality and safe food and feed reaches the market. We should make sure that innovative food and feed do not pose unacceptable risks to human and animal health. A key question that needs a comprehensive answer is the following: "Is the current food and feed safety framework adequate for assessing the food and feed of the future?" To address this complex question, a broader collaborative and transdisciplinary approach may be needed that goes beyond the current way of performing safety assessments. In this session, we will discuss future food and feed safety challenges and make recommendations for how to address them.

Scope and objectives

The thematic session will focus on identifying and exploring how the safety assessment of innovative food and feed products (including novel food production and processing technologies) will need to be developed. The main objectives of the thematic sessions are to:

- Describe the types of innovative food and feed products (including alternative production, processing and application technologies) that will reach the EU market in the short, medium and long-term;
- Review potential novel hazards, routes/levels of exposure, and health risks associated with the deployment of those innovative products and production, processing and application technologies focussing on their impact on human and animal health;
- Identify new risk assessment challenges and other potential emerging issues that the deployment of innovative products and production, processing and application technologies may pose;
- Map out and provide suggestions for how risk assessment tools/approaches and post-market surveillance should be developed and prioritised to keep pace with innovation.

People behind the session

Session Coordinator: Antonio Fernandez Dumont (EFSA)

Chairpersons: Helle Katrine Knutsen, Norwegian Institute of Public Health (NIPH/FHI)

Moderators: Katrina Sichel, Wit and Word Communications SRL

Rapporteurs: Michele Ardizzone, European Food Safety Authority (EFSA); Antonio Fernandez Dumont, European Food Safety Authority (EFSA); Winy Messens, European Food Safety Authority (EFSA); Reinhilde Schoonjans, European Food Safety Authority (EFSA)

Organiser

Co-organisers

ONE Life – Session affiliate profiles

INNOVATION IN FOOD AND FEED: KEEPING SAFETY ASSESSMENTS FIT FOR PURPOSE

Helle Katrine Knutsen, Norwegian Institute of Public Health (NIPH/FHI)

Chair/Co-chair

Helle Katrine Knutsen is Senior Scientist at the Norwegian Institute of Public Health, where she started in 1999. She is a toxicologist with a PhD from the University in Oslo (1995) in cell and molecular biology and has more than 20 years' experience in risk assessment of contaminants in food. Her research started with transcriptional and post-transcriptional regulation of gene expression in primary testicular cells and continued with studies on intestinal carcinogenesis in mice *in vivo* and *in vitro*. Her current research engagement is related to biomonitoring of contaminants and effects of exposure to environmental contaminants on infant and child development, with particular interest in persistent organic pollutants and metals. Dr Knutsen is member of the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) and is chair of the EFSA NDA WG on Novel Foods since 2018. She is former member of the EFSA Panel on Contaminants (CONTAM) (2009-2018) and was CONTAM Chair 2015-2018. She is also chairing the panel on contaminant in the Norwegian Scientific Committee for Food and Environment (VKM) and is member of the VKM Steering Committee.

Antonio Fernandez Dumont, European Food Safety Authority (EFSA)

Rapporteur

Dr Antonio Fernandez Dumont is working at the European Food Safety Authority (EFSA). He joined EFSA in 2008 as a scientific officer in the GMO Unit dealing with GMO applications. He is currently coordinating the work of the food and feed risk assessment Team and he is specialised on protein safety assessment, in particular the allergenicity assessment and other adverse immune reactions. He achieved a BSc. in Veterinary Science at the Universidad Complutense de Madrid, Spain. During his PhD and subsequent Post-docs, he worked at the Institute of Food Research, Norwich, UK. His initial research aimed at investigating different approaches to address gastro-intestinal tract diseases, allergic and intolerance reactions using natural microorganisms. Subsequently, he was mainly interested in applying recombinant bacteria secreting cytokines for the treatment of food allergy disease,

covering two key areas: molecular biology and immunogenicity/food allergy. He is authored of several manuscripts in the field of biotechnology and risk assessment.

Daniela Battaglia, Food and Agriculture Organization of the United Nations (FAO)

Speaker and panellist

Daniela Battaglia is Livestock Production Officer at the Food and Agriculture Organization of the United Nations (FAO). Within FAO, she is responsible for the animal feeding programme, including feed safety and new and alternative source feed ingredients. She is coordinator of the FAO Sustainable Livestock Technical Network and member of the FAO Working Group on Antimicrobial Resistance. Daniela, holds an M.Sc. in Agricultural Science and another in Tropical Animal Health and Production. Before joining FAO in 2001, Daniela has worked for nine years for the European Commission and has been based in in several countries including Belgium, the United Kingdom, Peru, Suriname, and Nicaragua.

Title of talk: Safety of alternative and innovative feed sources and technologies in the context of sustainable development.

Kimberly Ong, Vireo Advisors

Speaker and panellist

Dr. Kimberly Ong is a safety and sustainability expert with Vireo Advisors. She supports public and private efforts toward safe commercialization of innovative products such as food ingredients, food contact substances, and other novel products designed to encourage sustainable development. Kim helps companies navigate the unique regulatory and safety challenges associated with novel products, including hazard and risk assessment of alternative proteins across the product life cycle. Experienced in development of safety testing strategies, she assesses and develops tailored approaches to demonstrating safety, helping evaluate and modify testing protocols, where needed, for emerging technologies such as cultured meat and seafood. Kim strongly believes in the power of collaboration and has helped create and manage partnerships and collaborative efforts between industry, government, academia, and not-for-profit organizations to work towards safe and efficient commercialization of groundbreaking products. Kim holds Ph.D. in Physiology, Cell, and Developmental Biology from the University of Alberta (Canada), an M.Sc. in Environmental Management and Policy at Lund

University (Sweden), and B.Sc. in Marine and Freshwater Biology from the University of Guelph (Canada). ologies in the context of sustainable development.

Title of talk: Cell-cultured meat: Safety considerations and research priorities

Abstract of talk:

Cultured meat and seafood are animal meat products manufactured through the cultivation of animal cells in vitro. Interest in development and manufacture of cultured meat products is rapidly increasing, with ingredients and products now being developed and even starting to enter the market. This presentation will provide an overview of the general manufacturing process and safety considerations related to various stages of production, and propose priority areas of research needed to advance safe commercialisation of cultured meat and seafood. As an initial step towards a thorough demonstration of safety of cultured meat and seafood, a series of collaborative workshops were held in 2020 by New Harvest and Vireo Advisors with 87 industry representatives and researchers which led to the creation of a generalised modular manufacturing process diagram, serving as a framework to identify potential chemical and biological hazards in each of the steps of the manufacturing process that could affect the safety of a final food product. Input was gathered from members of the cultured meat and seafood industry, researchers, regulators, and food safety experts. This presentation will provide an overview of potential hazards that could be introduced or produced during manufacturing, including adventitious agents and novel expression products, as well as inputs such as cell culture media, antibiotics, scaffolds, cryoprotectants and other substances. Many hazards are not expected to be novel; therefore, safety assessment methods from a range of fields, such as conventional and novel foods, foods produced from biotechnology, pharmaceuticals, etc., may be applicable. The applicability of existing safety assessment approaches to address these potential hazards is evaluated toward any gaps or uncertainties, highlighting research priorities that could support safe commercialisation of cultured meat and seafood. Further research on the safety of the inputs and associated residues, potential for contamination, and development of standardised safety assessment approaches (particularly animal-free methods) is recommended.

Matias Zurbriggen, University of Düsseldorf

Speaker and panellist

Matias Zurbriggen did his undergraduate studies in Biotechnology at the University of Rosario and IBR, Argentina followed by a joint PhD work on plant biotechnology

together with the Institute of Plant Genetics and Crop Research Leibniz-IPK, Gatersleben, Germany, graduating in 2009. After two years of postdoctoral work between the IBR, IPK and John Innes Centre, Norwich, UK, he moved to the University of Freiburg and BIOS as an Alexander von Humboldt Foundation Fellow to work on mammalian synthetic biology and optogenetics. He was appointed Assistant Professor and started his group working on mammalian and plant synthetic biology in 2012. He was awarded a full Professorship in Synthetic Biology at the University of Düsseldorf and the Cluster of Excellence on Plant Sciences (CEPLAS) in 2015. He is a member of the steering board of the Study Group Systems and Synthetic Biology of DECHEMA and co-founder member of the Study Group Synthetic Biology at the German Society of Biochemistry and Molecular Biology (GBM). He is the Chair and co-founder of the Joint Study Group Synthetic Biology of the German Society of Biochemistry and Molecular Biology (GBM), DECHEMA, German Society for Plant Sciences (DBG) and German Chemical Society (GDCh). He is coordinator of the Research Area Synthetic and Reconstruction Biology at CEPLAS, and organizes conferences and symposia on synthetic biology and optogenetics.

Title of talk: Synthetic biology – safety considerations

Abstract of talk:

Synthetic biology applies basic engineering principles for the rational assembly of functionally well-characterised biological modules into higher order complex biological systems with desired functionalities. In order to engineer such artificial biological systems with predictable output characteristics, the rational design and development of new biological parts from natural existing components is intrinsic to the strategy. In this way, synthetic biology facilitates the de novo engineering of genetic circuits, synthetic and metabolic pathways and the analysis of signalling processes. Synthetic biology research has already entered a phase of development of biotechnological applications. For instance, research on mammalian cell systems brought forth high impact novel strategies for drug discovery and delivery, vaccine development, characterization of disease symptoms, advanced diagnostics, and treatment of pathologies. Optogenetics, the derived discipline developing molecular tools for the control of cellular processes with light is revolutionising the neurobiology and cell biology. Efforts on microbial synthetic biology research have led to significant progress in metabolic engineering. A wealth of synthetic biology tools and strategies are readily available for biotechnological applications in bioremediation, biofuel production and the industrial production of fine and bulk chemicals. Finally, and matter of this presentation, synthetic biology approaches are enabling the development of novel feed and food with enhanced nutritional content,

sustainable and efficient production and tailor-designed for personalized nutrition programs. In the context of increased food demand, superior nutritional/content requirements, global climate change, soil and erosion and environmental pollution, these new scientific approaches might provide a most useful tool to overcome the challenges. These current and future innovative strategies and applications evolve at fast pace and are to be accompanied by corresponding risk/safety assessments.

Gabriele Reichmann, Paul-Ehrlich-Institut

Speaker and panellist

Gabriele Reichmann is educated as biologist and obtained her PhD in immunology. She spent several years in academic research before she joined the Paul-Ehrlich-Institut (PEI) in 2008. PEI is a Federal Agency in Germany responsible for biopharmaceuticals and vaccines. At PEI, Gabriele Reichmann holds a position as senior scientific reviewer in the section Monoclonal and Polyclonal Antibodies. She reviews non-clinical data for monoclonal antibodies and related biopharmaceuticals throughout the product lifecycle; starting with clinical trial applications, including First-in-Human studies and early clinical trials up to marketing authorisation applications across a wide array of therapeutic indications, such as autoimmune diseases, infectious diseases, and oncology indications. She is also regularly involved in scientific advice procedures, both at national and European level. Since 2008, she acts as expert to the Safety Working Party at the European Medicines Agency and is a member of the newly founded Non-clinical Working Party at EMA.

Title of talk: Safety of proteins - lessons from non-clinical assessment and in silico prediction of immunogenicity of therapeutic proteins

Abstract of talk:

Protein therapeutics, e.g. growth factors, cytokines or monoclonal antibodies, are a large group of pharmaceuticals which have revolutionised the treatment of many diseases. However, any protein therapeutic may be immunogenic and can induce an immune response to itself and to related proteins. Potential consequences of anti-therapeutic immune responses are loss of exposure, loss of efficacy and induction of severe adverse, sometimes life-threatening effects in patients. In order to minimise effects caused by the anti-therapeutic immune response, assessment of immunogenicity of therapeutic proteins during clinical development is critical, while predicting immunogenicity remains a challenge. It is generally assumed that anti-drug antibody (ADA) responses are associated with CD4+ T cell reactivity which is

restricted by major histocompatibility (MHC) II. Thus, for predicting T cell reactivity, the sequence of a protein therapeutic is analysed in silico for the presence T cell epitopes, i.e. peptides that bind strongly to HLA class II. In vitro assays, such as MHC-associated peptide proteomics, analyse if these peptides are indeed generated as natural HLA-ligands. Finally, T cell activation in response to the therapeutic or to selected peptide epitopes is evaluated in vitro. Together, such information may be used to prioritise drug candidates with a low risk of inducing an immune response or to 'de-immunise' the therapeutic by removing T cell epitopes from the protein sequence. A remaining challenge is the clinical validation of such prediction tools. More recently, quantitative systems pharmacology approaches are being developed which integrate data from in silico analyses, in vitro assays as well as data from the human population (e.g. HLA alleles) and clinical data (PK of the therapeutic, ADA titers, adverse events). Such model can then be used to simulate immunogenicity in virtual clinical trials. The talk will provide examples of how such strategy is used to predict immunogenicity and to 'de-immunise' protein therapeutics in order to reduce the risk for patients.

Remko Boom, Wageningen University and Research (WUR)

Speaker and panellist

Remko Boom received his MSc degree (cum laude; highest honours) at the University of Twente, in 1988. In 1992 he obtained his PhD degree (cum laude; highest honours) at the same institute. In 1993 he received the Royal Dutch Shell Study Tour Award for his PhD work. From 1992 to 1998 he worked for Unilever Research. In 1998, he was appointed as full professor of Food Process Engineering at Wageningen University. From 2011 to 2015 he was scientific director of the Graduate School / Programme VLAG (food technology, nutrition, molecular sciences and agro-biotechnology). He holds a visiting professorship at Tsukuba University in Japan since 2015.

His research interests revolve around the exploration of new principles to more sustainably produce healthier foods: new ways to isolate ingredients, new ways to structure foods, and thermodynamic assessment of complex production systems. His research group includes two other full professors, 6 assistant / associate professors, 5 technicians, and currently around 60 PhD students and postdocs (excluding BSc and MSc students). In the latest assessment by an international expert panel, his group was found to be excellent in all aspects (scientific quality, societal relevance and viability), and was characterised as globally leading in its fields. He has currently (co-)published more than 420 peer-reviewed publications (Scopus), and has successfully graduated 73 PhD students to date.

Title of talk: Safety of innovative foods and the role of processing - Brief foresight analysis of Innovative food/feed products and focus the presentation on food processing technology

Samuel Godefroy, Laval University

Speaker and panellist

Samuel Godefroy is the former Director-General of Health Canada's Food Directorate and a former Vice Chair of the FAO/WHO Codex Alimentarius Commission. Samuel is currently Full Professor in the Food Science Department at Université Laval (Québec, Canada), where he leads the Food Risk Analysis and Regulatory Excellence Platform. He is also the Board President and a founding member of the Global Food Regulatory Science Society (GForSS).

Dr Godefroy currently serves as a senior food science and regulatory expert on a number of advisory bodies and committees domestically and internationally, and as strategic and operational advisor to international food safety capacity-building initiatives focused on regulatory enhancement, implemented by UNIDO and FAO.

Dr Godefroy has authored over 80 scientific publications and book chapters, and is an editorial board member for various scientific journals.

He received his PhD in Analytical Chemistry from the University of Pierre et Marie Curie (Paris VI). He holds degrees in Chemistry, Biochemistry and Chemical Engineering from that university and from the École nationale supérieure de chimie de Paris, France.

Title of talk: General recommendations on safety assessment of innovative products and technology

Abstract of talk:

Availability of safe food, access to safe food, utilization of safe food and stability of availability, access and utilization over time are at the core of food security. As defined by the Food and Agriculture organization of the United Nations (FAO), food security is when all people, at all times, have physical and economic access to sufficient safe and nutritious food that meets their dietary needs and food preference for an active and health life. With a world population of 7.9 billion people growing at a rate of 1% per year and more than two billion people experiencing food insecurity, means that there is still much to do to meet this sustainable goal. The global marketplace is responding with the innovation by reimagining traditional food sources as well as emerging and novel food products such as fermented foods,

insect and plant derived protein sources, and laboratory developed foods to support variety and volume capacity needs. However, these applications need to receive a bill of safety, prior to being admitted into the marketplace, both in the way they are designed and produced. Food regulators are therefore looking into various approaches of risk assessment to review innovative products and processes, supporting the availability of new sources of proteins and other nutrients, which would also benefit from added consultation and collaborative action, to avoid the emergence of new trade barriers.

This presentation will review current practices in the regulatory management of novel foods and novel ingredients, including the availability of scientific information, the development and updates of risk assessment methodologies and the consideration of additional parameters that condition decision-making for risk management, such as sustainability of methods of production. It will attempt to discuss options to address the unequal ability of food regulators in developing countries to support the availability of novel ingredients and food production processes.

Michele Ardizzone, European Food Safety Authority (EFSA)

Rapporteur

Dr. Michele Ardizzone graduated in veterinary medicine with a PhD in animal pathology, at the University of Milan. He worked for over ten years in preclinical drug research and development, as a toxicological pathologist. Since 2014, Dr. Ardizzone has been working in the GMO Unit of the European Food Safety Authority, supporting the activities of the GMO Panel in the toxicological and nutritional risk assessment of genetically modified food and feed. He is supporting EFSA's projects in the field of emerging risks associated with innovative food and feed, aimed to prioritize future work to protect humans, animals and the environment and to further develop harmonised activities, in partnership with stakeholders.

Winy Messens, European Food Safety Authority (EFSA)

Rapporteur

Winy Messens is Senior Scientific Officer in the Unit on Biological Hazards & Animal Health and Welfare (BIOHAW) of the European Food Safety Authority (EFSA). Her role is as risk assessor in the field of biological hazards. She provides scientific support to the EFSA Scientific Panel on Biological Hazards (BIOHAZ Panel) in the area of food microbiology (e.g. high pressure processing of food, superchilling of fish, decontamination treatments of animal products, persistence of microbiological

hazards in food and feed production and processing environments). Winy joined EFSA in 2010 and previously worked as scientist and post-doc scientist at the Institute for Agricultural and Fisheries Research (ILVO), Vrije Universiteit Brussels and Ghent University (all in Belgium) coordinating both national and international research projects. She was a member of the EFSA BIOHAZ Panel (from June 2009 to July 2010). She holds a master as Bio-engineer, option Food Technology and a PhD in Applied Biological Sciences from Ghent University.

Reinhilde Schoonjans, European Food Safety Authority (EFSA)

Rapporteur

Dr. Reinhilde Schoonjans is a risk assessment scientist at the European Food Safety Authority. She leads the Team for GMO food feed comparative and environmental risk assessment in the Unit for Nutrition and Innovative food. The team assesses potential toxicity, allergenicity and nutritional aspects of genetically modified plants and microorganisms, as well as agronomic and environmental impacts in case of deliberate release of the organisms. Her current mandate from the European Commission is to coordinate opinions on the risk assessment of organisms developed by Synthetic Biology. Other topics of expertise include, the cloning of farmed animals, biodiversity-related protection goals for environmental risk assessment, epigenetics and risk assessment of nanomaterials/small particles used in the food and feed chain. She previously worked on hazard criteria for endocrine disruption. Reinhilde Schoonjans is a Molecular Biologist holding a PhD from the University of Ghent, where she performed research on bispecific antibodies for cancer immunotherapy. In October 2005 she qualified as European Patent Attorney for the European Patent Office in Munich.

Katrina Sichel, Wit and Word Communications SRL

Moderator

Katrina is a London-born and raised, Brussels-based moderator and communications specialist with a degree in Modern Languages from Oxford University. As part of an eclectic career path spanning steel-trading in West Africa to business development in the post-Soviet states, she spent four years as Director of an award-winning broadcast PR company. Here she produced news packages for the BBC, Sky News, Channel 4, ITV, AP and Reuters, interviewing well-known figures from the arts, scientific, fashion, sport and political arenas. Since 2007 when she moved to Brussels, Katrina has been moderating events covering diverse topics and policy areas. These span R&I, digital transformation; social affairs and development issues;

agriculture, environment, climate change; energy and transport; fisheries and maritime affairs; and health(care). Alongside, until 2017, she managed the creation and roll-out across Europe of multimedia, multilingual communications campaigns targeting the public, and EU and national stakeholders, from diverse sectors. Katrina speaks fluent French, rusty Russian and a dash of German alongside her native tongue. She is very fond of MGM musicals, Neuhaus pralines, skiing, choreography, walking her Border Collie, Pessac Leognan, and poetry (not in that order).

Organiser**Co-organisers**