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SUPPLEMENT

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SUPPLEMENT

Conference Sessions

Foreword for the book of abstracts for the conference

On behalf of the organising committee, I am very happy to welcome all delegates, presenters and participants to the EFSA conference 2018 – Science, Food, Society in Parma.

The chosen motto “contextualising risk assessment” sets the stage for this exciting event.

In the upcoming days, researchers, risk assessors, social scientists, risk managers and stakeholders from around the world will gather to discuss issues pertaining to the complex interplay between science, food and society. We will tackle issues such as trust in science, the new frontiers in risk assessment and the unresolved challenges which the food safety and regulatory communities face. Together, we will develop scenarios on the future of food safety in Europe and beyond.

And we’ll do all this keeping into consideration the increasingly complex social and political context within which organisations like EFSA operate.

This book presents the abstracts of the conference as well as the biographies of speakers; it will serve as a useful guide to the subjects under discussion.

I hope that you will enjoy these three days in Parma!

Marta Hugas *European Food Safety Authority’s Chief Scientist*

Conference programme

18 SEPTEMBER 2018

Where science meets society: Putting risk assessment in context

13.30 - 18.00 | Plenary session | Plenary room
15:25 - 15:55 | Coffee break | Eat&meet area
18.15 - 18.45 | Poster exhibit and poster pitches | Poster area
19:00 - 20:00 | Cocktail | Eat&meet area

19 SEPTEMBER 2018

Advancing risk assessment science | Human Health

08:30 - 17:30 | Breakout session | Room 1
10:00 - 10:30 | Coffee break | Eat&meet area
12:15 - 13:45 | Lunch and poster exhibit | Eat&meet area, Poster area
15:15 - 15:45 | Coffee break | Eat&meet area
17:30 - 18:00 | Poster exhibit & poster pitch session | Poster Area

Advancing risk assessment science | Environment

08:30 - 17:30 | Breakout session | Room 2
10:00 - 10:30 | Coffee break | Eat&meet area
12:15 - 13:45 | Lunch and poster exhibit | Eat&meet area, Poster area
15:15 - 15:45 | Coffee break | Eat&meet area
17:30 - 18:00 | Poster exhibit & poster pitch session | Poster Area

Advancing risk assessment science | Nutrition

08:30 - 12:15 | Breakout session | Room 3
10:00 – 10:30 | Coffee break | Eat&meet area

Advancing risk assessment science | Biological hazards

13:45 - 17:30 | Breakout session | Room 3
15:15 - 15:45 | Coffee break | Eat&meet area
17:30-18:00 | Poster exhibit & poster pitch session | Poster Area

20 SEPTEMBER 2018

Advancing risk assessment science | Human Health (continued)

08:30 - 12:15 | Breakout session | Room 1
10:00 - 10:30 | Coffee break | Eat&meet area
12:15 - 13:45 | Lunch and poster exhibit | Eat&meet area, Poster Area

Envisioning the expertise of the future

13:45 - 17:30 | Breakout session | Room 1
15:15 - 15:45 | Coffee break | Eat&meet area
17:30-18:00 | Poster exhibit & poster pitch session | Poster Area

Engaging with society

08:30 - 17:30 | Breakout session | Room 2
10:00 - 10:30 | Coffee break | Eat&meet area
12:15 - 13:45 | Lunch and poster exhibit | Eat&meet area, Poster Area
15:15 - 15:45 | Coffee break | Eat&meet area
17:30-18:00 | Poster exhibit & poster pitch session | Poster Area

Managing evidence

08:30 - 17:30 | Breakout session | Room 3
10:00 - 10:30 | Coffee break | Eat&meet area
12:15 - 13:45 | Lunch and poster exhibit | Eat&meet area, Poster Area
15:15 - 15:45 | Coffee break | Eat&meet area
17:30-18:00 | Poster exhibit & poster pitch session | Poster Area

20 SEPTEMBER 2018

Staying relevant in a changing world

08:30 - 13:00 | Plenary session | Plenary Room
10:40 - 11:10 | Coffee break | Eat&meet area

Where science meets society: Putting risk assessment in context

The interplay between science, risk assessment and policy has become increasingly complex because we live in a world in which values are becoming more influential than facts in shaping public opinion. Science is increasingly mistrusted; discussions about risks are often polarised and politicised; scientific arguments serve as proxies for differences in values. In such a challenging time scientific advice is in high demand while risk managers need to balance facts and values effectively and be able to rely on robust and fit-for-purpose risk assessments. This session will explore approaches that can contribute to restoring the credibility of and trust in risk assessment, by placing it in a societal context. The session will end with a moderated panel discussion.

CHAIR

Barbara Gallani *European Food Safety Authority*

Barbara Gallani is head of EFSA's Communication, Engagement and Cooperation Department. Barbara is a chartered scientist and fellow of the Institute of Food Science and Technology and has had 16 years of professional experience, both in the public and private sector. Before joining EFSA, she worked in the UK at the Food and Drink Federation, at the British Retail Consortium and at the UK Food Standards Agency, including a secondment to the European Commission (DG SANCO) and a BA Media Fellowship on science communication at the Daily Telegraph. She also worked at the European Consumers' Organisation. Barbara holds a Bachelor's degree in physics, a post-graduate certificate in education PGCE (physics and sciences) and a Master's degree in advanced instrumentation systems.

RAPPORTEURS

Yann Devos *European Food Safety Authority*

Yann Devos is a senior scientific officer and team leader at EFSA's GMO Unit where he is involved in the risk assessment of genetically modified organisms (GMOs) and the development of risk assessment guidelines. He has been employed by EFSA since 2008, and previously worked at the Belgian Biosafety and Biotechnology Division of the Scientific Institute of Public Health. In 2015, Yann joined the OECD Steering Group drafting the consensus document on 'Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants'. He has a Master's degree in biology (ecology) and a supplementary degree in environmental sciences both from the University of Antwerp, and holds a PhD in applied biological sciences from the University of Ghent.

James Ramsay *European Food Safety Authority*

James Ramsay has been at EFSA since 2011, where he is currently Head of communication unit. Before EFSA, James worked as a communications consultant in London for public and voluntary sector clients, including UK government departments and the European Commission, as well as for the financial services industry. He has a Master's degree in international relations from Leicester University and a Bachelor's degree in Hispanic studies from Birmingham University.

Tobin Robinson *European Food Safety Authority*

Currently, Tobin Robinson is the head of EFSA's Scientific Committee and Emerging Risks Unit, where he is involved in the preparation of scientific advice in the area of new and harmonised approaches for risk assessment of food and feed, and putting in place a process for the early identification of emerging risks in the European food and feed chain, as well as preparation for responding to crises. He has been working for EFSA for over 11 years, including a period as acting head of the Science Strategy Department. He has previously worked in the dairy industry and started his career at the Reading Laboratory of the Institute of Food Research, working on microbiological food safety. He graduated from Cardiff University where he obtained both a degree and PhD in microbiology.

Victoria Villamar *European Food Safety Authority*

Victoria Villamar has been the head of the Unit for Engagement and Cooperation at EFSA since September 2018. Before this position, Victoria was leading a team of institutional and stakeholder engagement officers to support the implementation of EFSA 2020 strategic priorities. Victoria has held various positions within EFSA since she joined in 2004, starting as stakeholder officer, deputy head of Unit for Inter-Institutional Relations, strategic internal communications senior officer, and team leader for Institutional and Stakeholder Relations. Before her time with EFSA, Victoria worked at the European Consumers' Organisation from 1999 to 2004, holding the position of head of the Legal Department for her last 3 years. Previously, she worked at the European Parliament. Victoria holds a Master's degree in European law, EU decision making and EU institutions from the Université Libre de Bruxelles, which she obtained in 1998 after her 5-years studies in Law at the University of Santiago de Compostela.

SPEAKERS

Bernhard Url *European Food Safety Authority*

Bernhard Url was appointed executive director of EFSA in June 2014, having served as acting executive director for 7 months. Bernhard joined EFSA in June 2012 as head of the Risk Assessment and Scientific Assistance Department. Before joining EFSA, Bernhard was managing director of the Austrian Agency for Health and Food Safety. From 2008 to March 2012, he also served as a member of EFSA's management board. Previously, Bernhard had spent 5 years as an assistant professor at the Institute of Milk Hygiene and Milk Technology at the University of Veterinary Medicine, Vienna before running a food quality control laboratory from 1993 to 2002. Bernhard graduated as veterinary medicine doctor, and holds a PhD in veterinary medicine.

Science meeting society? The old, the new and the uncertain in-between

Silvio Funtowicz *University of Bergen*

Silvio Funtowicz began his career teaching mathematics, logic and research methodology in Buenos Aires, Argentina. During the 1980s he was a Research Fellow at the University of Leeds, England. Until his retirement in 2011 he was a scientific officer at the Institute for the Protection and Security of the Citizen (IPSC) of the Joint Research Centre of the European Commission (EC-JRC). Since February 2012 he has been Professor II at the Centre for the Study of the Sciences and the Humanities (SVT) at the University of Bergen, Norway. He is the author of numerous books and papers in the field of environmental and technological risks, and policy-related research. He has lectured extensively and participated in the editorial board of several publications and the scientific committee of many projects and international conferences. https://en.wikipedia.org/wiki/Silvio_Funtowicz

Reflecting on his times, Antonio Gramsci wrote: 'The crisis consists precisely in the fact that the old is dying and the new cannot be born; in this interregnum a great variety of morbid symptoms appear.' (Prison Notebooks 1929–1935, Q3 p. 311). It seems to be a fair description of the current time, and the evolving relation between 'science' and

'society', in particular on health, the environment, diet and lifestyles. That the crisis manifests itself so clearly in those realms is not by chance, but the result of their intimate relation to the human condition, and also the societal and personal stakes invested in them. An illustration of this ongoing change is in the role of facts and values (an instance of which is risk assessment and risk management). The 'old' here is represented by the modern ideal of their strict separation, whereas the 'new' is an emerging awareness that this distinction is difficult to justify, and no longer functional to the legitimacy of governance for contemporary societies. The morbid symptoms appear as part of the barriers for a new conceptual and practical models of legitimacy. As science-related policy issues have come to be recognised as complex, and more inherently difficult of resolution, the conception of the role of science has also developed and matured. Today, when science is deployed in the policy context, we are aware of the possibility that facts are uncertain, values in dispute, stakes high and decisions urgent. These last features illustrate a post normal science problem. In the light of this new understanding, we can identify several conceptual models of the relation between science and decision making in policy processes:

- The 'modern' model (perfection/perfectibility). Scientific facts (unproblematic), employed in rigorous demonstrations, would determine correct policy. In classical terms, the true entails the good; in modern terms, truth speaks to power. There are no limits to the progress of humans' control over their environment, and no limits to the material and moral progress of humankind. This is the 'technocratic' vision, dependent on an assumed perfection/perfectibility of science in theory and practice.

- Precautionary model (uncertain and inconclusive information). In real policy processes, it is discovered that the scientific facts are neither fully certain in themselves, nor conclusive for policy. Progress cannot be assumed and control can fail, leading sometimes to pathological situations. Because of this imperfection in the science, there is an extra, normative, element in policy decisions: precaution, which both protects and legitimises decisions.

- Framing (arbitrariness of choice and possible misuse). In the absence of conclusive facts, scientific information becomes one among many inputs to a policy process in which a plurality of actors have their own perspective and values. There are no simple 'facts' that resolve the relevant practical issue, and hence the framing of the relevant scientific problem to be investigated. Even the choice of the scientific discipline to which it belongs, becomes a prior policy decision. There is no conclusive scientific basis for the choice of framework, and hence to some extent the choice is arbitrary (or socio-political).

- Demarcation (possibility of abuse of science). The scientific evidence and advice used in the policy process are produced by people working in institutions with their own agendas. Experience shows that this context can affect the contents of what is offered, through the selection and shaping of methods, data and conclusions. A clear demarcation between the institutions (and individuals) providing the science, and those in which it is used, is advocated as a means of protecting science from the political interference threating its integrity. It also ensures that political accountability rests with policy makers. In addition, it prevents scientists from using the authority of their status as an illegitimate validation of their pronouncements when they engage in partisan advocacy on contentious policy issues.

- Extended participation (extended peer communities). Given the above-mentioned imperfections in the deployment of science in the policy process, it becomes ever more difficult to defend a monopoly of accredited expertise for providing advice. Science (understood as the activity of technical experts) is included as one part of the relevant knowledge. The ideal of rigorous scientific demonstration is replaced by that of open public dialogue. Citizens become both critics and creators in the knowledge production process as part of an extended peer community. Their contributions, sometimes described as 'local', 'practical', 'ethical' or 'spiritual', are part of the relevant knowledge. In the different models, we see that policy is modified by precaution, problems are framed by stakeholders, or scientists are protected from political interference. However, the core ideal of the modern model, the experts' (claims of) truth speaking to the politicians' (desire for) power, is unchanged. The final model of extended participation involves a new form of governance. Implementing this is a great challenge that will require scientific, institutional and constitutional changes.

Managing values in science and risk assessment

Kevin Elliott *Michigan State University*

Kevin Elliott is an Associate Professor with joint appointments in Lyman Briggs College, the Department of Fisheries and Wildlife, and the Department of Philosophy at Michigan State University, USA. He is a philosopher whose research focuses on the roles that values play in science and ethical issues related to scientific research. His publications include Is a Little Pollution Good for You? Incorporating Societal Values in Environmental Research (Oxford University Press, 2011), A Tapestry of Values: An Introduction to Values in Science (Oxford University Press, 2017), Current Controversies in Values and Science (edited with Daniel Steel, Routledge, 2017),

and Exploring Inductive Risk: Case Studies of Values in Science (edited with Ted Richards, Oxford University Press, 2017). His recently published articles have explored public perceptions of scientists who communicate about values, ethical responsibilities of scientists who communicate value-laden information, and strategies for handling conflicts of interest in research.

Scientific research and risk assessments on topics related to food safety, agriculture and the environment are subject to numerous value judgements. While it is tempting to try to prevent ethical and social value considerations from influencing these judgements, I will argue that this is often a mistake. It is typically unrealistic to think that these value influences can be removed, and efforts to undertake this so often prevent needed reflection about values and result in conflict and distrust. Instead, I will argue that values in science and risk assessment should be managed through efforts to promote reflection, openness and engagement.

Using problem formulation to identify relevant and reliable information for risk assessment to support decision-making

Philip Macdonald *Canadian Food Inspection Agency*

I have worked for nearly 20 years in government regulation, mostly related to biotechnology. In my current position, I supervise and lead a group of scientists that coordinate the Canadian Food Inspection Agency's plant health research and diagnostic initiatives, especially those related to the applications of genomics and how these tools can inform policy.

I have acted as the CFIA spokesperson on a number of scientific issues related to the environmental risks posed by GM crops, delivered risk assessment workshops and capacity building to the international regulatory and scientific community. I have also represented the Canadian Food Inspection Agency in national and international discussions on the environmental risks posed by plants modified by modern biotechnology, the application of genomic based plant breeding technologies and regulatory approaches to emerging technologies such as nanotechnology and synthetic biology. I represented Canada as a technical expert on the Ad-Hoc Technical Expert Group on Risk Assessment and Risk Management that developed further Guidance for Annex 3 on risk assessment of the Cartagena Protocol.

I have come to the regulatory environment after 10 years in a research laboratory, first working on herbicide tolerant plants, then transgenic animals. My graduate studies were completed at Carleton University in Ottawa, where I worked on molecular models for herbicide resistance.

Problem formulation is the devising of hypotheses and tests of those hypotheses that are useful for risk managers making decisions about whether a proposed activity ought to be permitted. Hypotheses take the form that the activity, such as cultivating a particular GM crop or using a pesticide, will not pose unacceptable risk. Existing or newly acquired data that provide rigorous tests of such hypotheses may be regarded as relevant for risk assessment. On the other hand, data that provide weak tests of these hypotheses, or test hypotheses unrelated to the acceptability of risk, ought to be seen as irrelevant for risk assessment. Hypotheses about the acceptability of risk have a vital role in establishing the correct relationship between policy and science in "science-based" risk assessment. "Unacceptable" and "risk" are statements of policy because they require definitions of what would be regarded as harmful effects of the proposed activity and how risk will be offset against opportunities provided by the activity; opportunities are also statements of policy as they encompass definitions of what would be regarded as beneficial effects of the proposed activity. Once definitions of "harm", "benefit", and "acceptability" are in place, science can estimate the probability and severity of any harmful effects (i.e., assess the risk), the probability and value of any beneficial effects (i.e., assess the opportunity), and the probability that opportunities outweigh risks (i.e., assess whether the risk is acceptable). This "policy-led" risk assessment is in contrast to "science-led" risk assessment that seeks exhaustive characterisation of the consequences of a proposed activity. Scientifically, such characterisation is a test of a null hypothesis of no effect or of no change from an existing acceptable activity that the new activity seeks to replace. This approach often uses profiling methods that compare numerous variables and policy decisions are made in response to effects or differences revealed by the profiles. "Science-led" risk assessment has significant disadvantages. First, decision-making is made in response to statistically significant differences that may be of unknown biological relevance and some of which are likely to be spurious. This leads to a second problem in that decisions based on such practices are likely to be controversial because regulatory policy appears to be made post hoc in response to whatever variables show statistically significant effects, not after careful consideration of societal needs. Unfortunately, several trends appear to be favouring science-led over policy-led risk assessment. These include proponents of big data questioning the continuing need for scientific hypotheses, the idea that prior definition of policy introduces bias into risk assessment, and the reluctance of risk managers to appear to be making decisions based on politics instead of science. These trends are based on mistaken assumptions about the nature of science and the purpose of risk assessment. Once these mistakes are recognised, the superiority of policy-led over science-led risk assessment ought to be clear.

David Spiegelhalter *University of Cambridge*

David Spiegelhalter is Winton Professor for the Public Understanding of Risk and Fellow of Churchill College at Cambridge University and, as Chair of the Winton Centre for Risk and Evidence Communication, he works to improve the way in which risk and statistical evidence are taught and discussed in society. He gives many presentations to schools and others, advises organisations on risk communication, and is a regular commentator on risk issues. He presented the BBC4 documentaries 'Tails you Win: the Science of Chance' and the award-winning 'Climate Change by Numbers'. He was elected FRS in 2005, awarded an OBE in 2006, and was knighted in 2014 for services to medical statistics. For 2017–2018 he is President of the Royal Statistical Society. In 2011 he came seventh in an episode of the television game programme Winter Wipeout.

Responsible research, innovation & risk assessment: Are we there yet?

Fern Wickson *Genøk*

Fern Wickson is a Senior Scientist and Research Leader at Genøk Centre for Biosafety in Tromsø, Norway, where she coordinates the transdisciplinary collaborative for Responsible and Sustainable Biotechnoscience (RootS). Committed to a politics of ecological care, her work integrates environmental science, policy and philosophy in pursuit of good governance of new and emerging technologies. With a PhD in biology and political science, she performs transdisciplinary research that specifically aims to advance ecological ethics, sustainable agriculture, responsible innovation and resilient socio-ecological futures. Her current research projects are on subjects such as: systems-based thinking for sustainable cultures of agriculture, integrating in situ and ex situ models of agricultural biodiversity conservation, advancing responsible research and innovation in European funding programmes, and improving the environmental governance of bio- and nano-technologies. Beyond her research, Fern also has experience in organizing and teaching capacity building courses around the world on biosafety assessment of GMOs and performing a range of policy advisory work. She is an expert member of the Norwegian Biotechnology Advisory Board and a past President of the international Society for the Study of New and Emerging Technologies (S.Net). She has also served in the recent expert working group of the Intergovernmental Panel on Biodiversity and Ecosystem Services (IPBES) on the diverse conceptualisation of values in nature. In her spare time, Fern enjoys hiking, snowboarding, and trying to grow her own food. She is also a trained yoga and meditation teacher and runs in her own studio in the north of Norway called The Peaceful Wild.

This talk will focus on challenges and opportunities for the contextualisation of risk assessment from the perspective of 'Responsible Research and Innovation' (RRI). The ongoing master narrative that innovation is inherently desirable and necessary for progress currently exists alongside an unsettling recognition that new technologies often create as many problems as they are introduced to solve and that significant resistance is encountered when science operates at a distance from social values and fails to actively engage with citizens. This contradiction and the set of challenges it poses has led to an increasing emphasis on the need to advance more 'responsible' forms of research and innovation. This is evidenced, for example, by RRI now being a cross-cutting theme in the European Horizon2020 funding programme. In this talk, I will begin by presenting the overarching concept of RRI and some of the different frameworks that have emerged for defining and enacting it in practice. This will include an overview of the five policy keys approach of the European Commission (i.e. societal engagement, gender, open access, science education, ethics) and the alternative approach of the AIRR dimensions (i.e. anticipation, inclusion, reflection, responsiveness) as articulated by academics from the UK and adopted by some national authorities. I will then use the remainder of the talk to reflect on the lessons that can be learned from these different approaches to RRI for efforts to contextualise risk assessment and make it more socially sound and accountable. This will include an assessment of how some of the current day risk assessment practices measure up against the keys and dimensions of RRI. For example, how principles such as those of gender equality, open access, inclusion and responsiveness are handled and addressed through risk assessment practices. The talk will then close with an invitation to the audience to collaboratively engage in the development of a vision for what responsible risk assessment requires, a discussion of how close we are to achieving that vision today, and a set of action plan steps to help move us closer to that goal in the future.

Frederic Simon *EurActiv*

Frédéric Simon is editor at EURACTIV, the leading online media specialised in EU affairs. Frédéric joined EURACTIV in 2003 as a reporter and has since covered about every aspect of EU policy topics, ranging from telecoms to economic and financial affairs, agriculture, transport, energy and climate legislation. He now leads EURACTIV's coverage on energy and the environment while continuing to write regularly about high-level politics.

Frédéric is also Brussels correspondent for France24, the 24/7 international TV channel. Mr Simon graduated in journalism from Brussels University (ULB) in 1998 and holds a Master's degree in EU politics from the Institut d'Etudes Européennes (IEE) in Brussels:

- since 2008: Brussels correspondent, France24
- since 2007: Editor, EURACTIV.com
- 2003–2007: Reporter, EURACTIV.com
- 2002: Master's degree, Institute of European Studies (IEE), Brussels
- 1998: Graduated in journalism and communication from the Université Libre de Bruxelles (ULB).

PANELLISTS

Klaus Berend *European Commission*

Dr Klaus Berend joined the European Commission in 1994 and is currently Head of Unit in the European Commission's Directorate-General Health and Food Safety, responsible for the implementation of the Pesticides and Biocides legislation.

Piro to that he was Head of Unit in the European Commission's Directorate-General Internal Market, Industry, Entrepreneurship & SMEs, in charge of the implementation of the EU Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Previously, he was Head of Unit in DG Enterprise & Industry, responsible for EU legislation on the Classification, Labelling and Packaging of substances and mixtures (CLP), Good Laboratory Practices (GLP), detergents, fertilisers, drug precursors, explosives and pyrotechnic articles. The Unit also dealt with the sustainability and competitiveness of the chemicals industry in the European Union.

Earlier, he was Deputy Head of Unit in the Commission's Directorate General for Environment, Unit Biotechnology & Pesticides, where he coordinated the work concerning biocides, plant protection products and the Community's participation in the Rotterdam Convention on Prior Informed Consent (PIC).

He studied chemistry at the universities of Heidelberg, Freiburg, and Stanford, and obtained a PhD in polymer chemistry from the University of Freiburg (Germany).

Julie Girling *European People's Party*

Julie Girling was elected as a Conservative Member of the European Parliament for South West England and Gibraltar in 2009 and was successfully re-elected for a second term in 2014.

She is currently sits on the Committees for Environment, Public Health and Food Safety and for Women's Rights and Gender Equality.

She also sits on the Delegation for relations with South East Asia and has previously served as Chief Whip for the Conservatives in the European Parliament.

Formerly a member of the European Conservatives and Reformists Group (ECR), she has recently moved to become a member of the European People's Party Group (EPP), the Conservatives in the European Parliament were members of this group until 2009, when the ECR Group was created.

During her time in the European Parliament she has worked on a number of important legislative files, covering areas such as air quality, emissions, food safety, reform of the Common Agriculture and Fisheries Policies, biodiversity, chemicals and animal welfare. Mrs Girling has recently been a rapporteur for both the ETS Phase IV and the Aviation ETS files.

Monique Goyens *The European Consumer Organisation*

As Director General of BEUC, Monique represents 43 independent national consumer associations in 31 European countries, acting as a strong consumer voice in Brussels, ensuring that consumer interests are given weight in the development of policies and raising the visibility and effectiveness of the consumer movement through lobbying EU institutions and media contacts.

As a consumer expert and advocate and, on behalf of BEUC, she is currently a member of the EU High Level Forum for a Better Functioning Food Supply Chain and a delegate in the Consultative Commission on Industrial Change of the European Economic and Social Committee. She is an effective member of the Euro Retail Payments Board. She has also been appointed to the expert group on 'fake news' (2018) and in the expert group on 'trade agreements' (2018–2019). She is member of the Advisory Group of Transparency International EU and of the European Advisory Board of the Open Society Foundations.

In her capacity as BEUC Director General, Monique is currently EU co-chair of the Transatlantic Consumer Dialogue (TACD) a network of EU and US

consumer organisations, and she also represents BEUC at Consumers International, the international consumer organisation.

Apart from championing consumers' rights, Monique's passions/challenges are her family, cooking for friends and long walks with her golden retriever.

Bjorn Hansen , *European Chemical Agency*

Bjorn Hansen is ECHA's Executive Director. He is ECHA's legal representative, in charge of the day-to-day management and all staff matters. Bjorn is ECHA's second Executive Director with a mandate running from 1 January 2018 to 31 December 2022. After a post-doc in probability theory in Germany, he joined the European Commissions in 1991. Working first at the European Chemicals Bureau at the JRC in Italy and then from 2003 in the Chemicals Unit of DG Environment in Belgium. There Bjorn became Head of Unit in 2012. He already spent 1 year in ECHA in 2007–2008 as Director of Operations. Bjorn was involved in the development of REACH and CLP from their very early days. He has been involved in international chemicals work since 1991, highlights being elected chair of the OECD Working Party on Manufactured Nanomaterials and having chaired several contact groups at three consecutive UN triple COPs.

Jorgo Riss *Greenpeace*

Jorgo Riss has been the Director of the Greenpeace European Unit since 2003. Mr Riss and his team analyse the work of the EU institutions, expose deficient policies and laws, and challenge decision-makers to implement progressive solutions in such areas as climate change, energy, forests, trade, chemicals and sustainable agriculture. The European Unit works closely with the Greenpeace Research Laboratories, based at the University of Exeter (UK), which provide scientific advice and analytical support. Mr Riss is also a co-founder and a member of the steering committee of the Alliance for Lobbying Transparency and Ethics Regulation in the EU (ALTER-EU), a coalition of over 200 public interest groups and trade unions concerned with the overwhelming influence of corporate lobbyists on the political agenda in Europe, the resulting loss of democracy in EU decision-making, and the weakening, when it is not full obstruction, of social, environmental and consumer-protection reforms. He is also a member of the board of Civil Society Europe, which brings together 27 European networks of civil society organisations (CSO) that work for the renewal of European Democracy, promoting full transparency within the European Institutions and the participation of civil society organisations in European decision-making processes. Jorgo Riss has a master's degree in political science, and worked as a journalist and academic before joining Greenpeace. Greenpeace is present in 55 countries world-wide and is funded by about 3 million individual supporters.

ADVANCING RISK ASSESSMENT SCIENCE

Environment

Environmental risk assessment (ERA) plays an important role in environmental protection by evaluating how likely it is that the environment, including biodiversity and ecosystems, may be affected by an activity. A potential avenue to the advancement of ERA is the consideration of ecosystem services, which are the benefits that humankind derives from healthy functioning ecosystems, as this would relate ERA directly and transparently to protection goals. The ecosystem services concept provides a comprehensive framework for evaluating the services provided by ecosystems, and for ensuring that society maintains a healthy and resilient natural environment for future generations.

While the ecosystem services concept holds much promise for environmental decision-making, putting the concept into practice can entail challenges due to the complexities of ecosystem components and their interactions, and lack of understanding of how specific activities may impact the delivery of ecosystem services across different spatial scales.

This session will address the opportunities and challenges involved in applying the ecosystem services concept to ERA and risk management.

In the context of emerging technologies being applied in practice, this session will also discuss ERA needs for the diverse array of products on the horizon. Problem formulation, which is a process for incorporating legal, social and scientific considerations into the planning for an ERA, will be used to formally identify the types of information that will be useful in conducting such assessments.

In addition, the usefulness of new tools and approaches for more integrated and predictive ERAs will be explored.

CHAIRS

Anthony Hardy *Formerly of EFSA's Scientific Committee*

An external expert and former Chair of EFSA's Scientific Committee, Tony Hardy is a biologist and environmental chemist with degrees at Oxford and Aberdeen Universities. He worked in the UK's Ministry of Agriculture, Fisheries and Food, the Department for Environment, Food and Rural Affairs and its Central Science Laboratory for 33 years before retiring. He has worked on the impact of farming and agricultural pesticides on wildlife, the wider environmental impact of chemicals, the risk assessment and management of agricultural pests and diseases, and food safety. Professor Hardy has been involved in national and international risk assessment, ecotoxicology and food safety for nearly 40 years. Before his 6-year term as Chair of EFSA's Scientific Committee, Professor Hardy chaired the EFSA Panel on Plant Protection Products and their Residues (dealing with pesticides) for 9 years from EFSA's establishment in 2003. Before that he chaired the Commission's Scientific Committee on Plants for 5 years.

Silvia Pieper *German Environment Agency*

Silvia Pieper is a biologist and ecotoxicologist with a focus on terrestrial ecosystems. She received her PhD at the Technische Universität Berlin in soil ecology. For 10 years, she has worked at the German Environment Agency in the environmental risk assessment of pesticides. She has been involved with EFSA since 2011 in several working groups (non-target arthropods, soil organisms, amphibians and reptiles). She is a member and vice-chair of the EFSA Panel on Plant Protection Products and their Residues (PPR). Silvia has a particular interest in exploring the impact of pollutants on biodiversity and on the consequences of biodiversity loss for the support and provision of ecosystem services. Her expertise covers in particular the characterisation of the impact of chemicals in terrestrial ecosystem at higher tier risk assessment steps.

Catherine Ganzleben *European Environment Agency*

Dr Catherine Ganzleben is acting Head of the Group on Environment and Health at the European Environment Agency. She is responsible for strands of work on a range of environmental risks to health, including air pollution, noise and chemicals, as well as the broader dynamic between ecosystem services and human health and well-being. From 2008 to 2013, Catherine was a Senior Policy Advisor at Milieu Ltd in Brussels, delivering contracts on environment and public health issues to international organisations. Before that, Catherine worked for two years at the United Nations Institute for Training and Research in Geneva, delivering technical assistance in support of multilateral environmental agreements on chemicals. Catherine has a post-doctorate from the United Nations Institute of Advanced Studies in Tokyo and a Doctorate from the University of Oxford. She has also worked for the NGO sector, including the European Environmental Bureau and the International Institute for Sustainable Development.

Juliane Kleiner *European Food Safety Authority*

Since July 2018, Juliane Kleiner has been the acting head of EFSA's Risk Assessment and Scientific Assistance Department. She has worked at EFSA since 2004, starting in the Contaminants Unit, and then as a team leader for the Scientific Committee. From 2008 to 2013 she led the Nutrition Unit. After that she took over the Directorate of Science Strategy and Coordination for 1.5 years, and then served for another 1.5 years as acting head of the Department for Regulated Products. In September 2016, she became senior science coordinator in EFSA's Executive Director Office. Before joining EFSA, she worked at the University of Marburg, and then at ILSI Europe in the private sector as senior scientist, responsible for the scientific management and support of the food safety programme. Juliane has a Master's degree in nutritional sciences from the University of Giessen, and holds a PhD in human biology from the University of Marburg.

RAPPORTEURS

Yann Devos *European Food Safety Authority*

See biography p.7

Ciro Gardi *European Food Safety Authority*

Ciro Gardi is a scientific officer at EFSA's Animal and Plant Health Unit. Before joining EFSA, he was a consultant and served as an independent expert for the European Commission, World Bank, OECD and several NGOs. Currently, he is a member of the Global Soil Partnership (FAO). He has in-depth knowledge of agricultural systems and interactions between land management, soil quality and ecosystem service provision. Ciro holds Master's degrees in agriculture, plant protection, and international cooperation and intervention politics in developing countries from the University of Bologna, and has a PhD in crop science shared between the University of Bologna and Washington State University.

Reinhilde Schoonjans *European Food Safety Authority*

Reinhilde Schoonjans is a scientific officer at EFSA's Scientific Committee and Emerging Risks Unit. She coordinates the expert Working Group on nanomaterials and chairs the Nano Network with EU Member States delegates. She also works on topics related to cloning of farmed animals, environmental protection goals, epigenetics and identification of endocrine active substance. Reinhilde is a molecular biologist holding a PhD from the University of Ghent. In October 2005, she qualified as European patent attorney from the European Patent Office in Munich.

Franz Streissl *European Food Safety Authority*

Franz Streissl is a senior scientific officer in EFSA's Pesticides Unit. The focus of his work is on developing guidance documents for pesticide risk assessments. In the past, he was responsible for assessment of environmental risks of pesticides at national and at the European level. He has contributed to a large number of governmental reports, presentations at conferences and workshops. He holds a PhD in Zoology from the University of Vienna, and the focus of his education is on physiology and ecology.

SPEAKERS

The elusive links between biodiversity, multifunctionality and ecosystem services

Lijbert Brussaard *Wageningen University & Research*

Lijbert Brussaard held the position of Professor of Soil Biology from 1988 and then guest worker since his retirement (2016) at Wageningen University and Research, The Netherlands. Over the years, his interest has broadened from straight soil biology to ecosystem services mediated by the soil biota, and how scientific knowledge may inform land-use planning and decision making by actors in agricultural landscapes. His most recent focus is on the scientific underpinning of the concept of soil quality and making it operational for farmers and other land users. Lijbert previously worked at the then Institute for Soil Fertility Research at Haren, The Netherlands. He obtained his Master's degree in biology (ecology) cum laude from VU University, Amsterdam, and holds a PhD in agricultural and environmental sciences (soil biology) from Wageningen University.

Although there is broad consensus on the usefulness of the concepts of biodiversity, multifunctionality and ecosystem services for understanding, exploiting and conserving nature and for protecting the environment, they share the fact that they cannot be measured directly in the field. Hence, there is considerable difference in the metrics used to express biodiversity (genes; traits; species; functional groups), multifunctionality (ecosystem function multifunctionality; ecosystem service multifunctionality) and ecosystem services (utilitarian focus on the benefits people derive from nature; culture/ local knowledge focus on nature's contributions to people). A challenge on top is the normative nature of some of the concepts. As a result, quantitatively linking biodiversity, multifunctionality and ecosystem services is not straightforward.

The challenges of linking the three concepts are also evidenced by the literature on functional redundancy of biodiversity; synergies and trade-offs between functions and between services; ecological and economic production functions; and the level of (desired) ecosystem functioning and services in the face of multiple stressors. I will address the state of the art, mainly - though not exclusively - using examples from soil quality assessment.

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Key words: biodiversity, multifunctionality, ecosystem services

Opportunities for and implications of including ecosystem services in risk assessments and risk management of regulated stressors

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Wayne R. Munns, Jr is the Director of the US Environmental Protection Agency's Atlantic Ecology Division (Office of Research and Development) in Narragansett, Rhode Island, USA. An aquatic ecologist by training, he is an expert in the fields of population modelling, ecosystem services, and ecological risk assessment. Wayne is a member of US EPA's Risk Assessment Forum, a past Chair of the Society of Environmental Toxicology and Chemistry's Ecological Risk Assessment Advisory Group. He has advised the World Health Organization on the integration of human health and ecological risk assessment, and has served on a number of interagency and international panels and working groups to advance methods to inform environmental policy and decisions. Wayne co-edited the 2008 Taylor & Francis books Valuation of Ecological Resources: Integration of Ecological Risk Assessment and Socio-Economics to Support Environmental Decisions and Population-Level Ecological Risk Assessment, and has authored several papers promoting the consideration of ecosystem services in decision making. Before joining US EPA in 1995, Wayne was a Senior Scientist, Division Manager, and Assistant Vice President for Science Applications International Corporation.

The ecosystem services (ES) concept can provide a comprehensive framework for considering nature's contributions to human well-being in risk assessment (RA) and risk management of regulated stressors. It has been asserted that the incorporation of ES as assessment endpoints in RA can: (1) enhance the transparency of RA results and decisions based on them; (2) articulate the benefits of trade-offs involved in environmental decisions, policies, and actions; (3) inform the derivation of operational protection goals and environmental quality standards; (4) enable integration of human health and ecological risk assessment; (5) facilitate horizontal integration of policies, regulations, and programmes; and (6) lead to more comprehensive and consistent environmental protection. Although some progress has been made towards developing specific approaches for including ES in RA and decision making, actual applications remain relatively scarce. As a result, many of the assertions about the benefits of doing so remain largely unverified. Realisation of these benefits will require procedural constructs and guidance for including ES-based assessment endpoints in RA for a variety of regulatory programmes. In addition, improvements are needed in the ways that ES relevant to decisions are identified and quantified, and in how institutions adapt ES in policies and protection goals. Broadly based efforts to educate society about the ES concept and its value to environmental and public health protection can help in these regards.

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Key words: ecosystem services, risk assessment, risk management

Challenges in applying the ecosystem service approach to risk assessments of regulated stressors

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Valery Forbes is Dean of the College of Biological Sciences at the University of Minnesota, USA. Previously, she served as Director of the School of Biological Sciences at the University of Nebraska-Lincoln and spent more than two decades at Roskilde University in Denmark, where she was founding Head of the Department of Environmental, Social and Spatial Change. Forbes' research extends across quantitative ecology and environmental management with particular focus on population ecology and modelling, fate and effects of toxic chemicals in aquatic systems, and ecological risk assessment. She received a doctorate in coastal oceanography and a master's degree in marine environmental science from the State University of New York at Stony Brook. She serves on the editorial boards of several international journals and provides advice to a wide range of government and industry bodies.

Formulating ecological protection goals in ecosystem service delivery offers a number of advantages over traditional approaches used in ecological risk assessment. To the extent that the outputs of risk assessments can be linked to impacts on ecosystem services, they can provide a more robust framework for risk management. However, for this framework to be more than just a new way of articulating what we have always done, there will be a need to develop quantitative approaches that are able to translate responses to chemicals by ecological entities (i.e. organisms and groups of organisms) to service delivery, and approaches that can put appropriate values on services so that trade-offs among different management options can be assessed. Although ecosystem services are increasingly gaining attention in risk assessment of regulated stressors, there are wide gaps in knowledge of how the toxicity of regulated stressors to test species translates into impacts on service-providing populations and on the ecosystem services they deliver. To effectively predict the impacts of chemicals and other human activities on ecosystem services, there is a need for quantitative approaches that link ecotoxicological exposure and effects data to ecosystem service delivery. With growing emphasis on the development and implementation of in vitro and high-throughput techniques to measure stressor impacts and the use of adverse outcome pathways to link these to consequences of importance for risk assessment, there is an urgent need for quantitative models that are robust, mechanistic, well tested and accepted so that these linkages can be made with confidence. In addition, there are ongoing debates over the degree to which ecosystem services can be valued and the most appropriate methods to undertake this. This talk will provide an overview of some of the main challenges in applying ecosystem services for risk assessment and provide some suggestions for how these challenges can be addressed.

Key words: ecological protection goals, mechanistic models, risk management, valuation

Ecosystem services-based environmental risk assessment for regulated stressors: Learnings from case studies on pesticides in agricultural systems

Anne Alix *DowDuPont*

Anne earned a PhD in Biology and Integrated Pest Management in vegetable crops at the University of Rennes, France, in 2000. She joined environmental risk assessment as an ecotoxicologist at the French National Institute on Research in Agronomy (INRA) in 2001, and then as a head of the Environment and Ecotoxicology unit at the French Agency on the safety of Food (AFSSA). She linked risk assessment to risk management at the French Ministry of Agriculture as the deputy head of the Section for Regulation and Placing Plant Protection Products on the Market, where she was in charge the implementation of risk mitigation measures for pesticides, and of post-registration monitoring. Anne joined Dow AgroSciences UK in 2011, as European Regulatory Risk Management Leader. She is now Regulatory Affairs and risk management leader for Europe Middle East and Africa.

Ecosystem Services (ES) describe the contributions of ecosystems to human wellbeing. In the case of agroecosystem, ES provide resources for food production, water purification, soil fertility maintenance, wildlife habitats and enjoyable landscapes. ES are inherently linked to the species living in the ecosystems, to the interactions between them and their environment. This led regulatory authorities in Europe and beyond to incorporate ES concepts when defining protection goals (EFSA, 2016) and risk assessment paradigms (e.g. Munns et al., 2016). The development of ES-based risk assessment approaches presents advantages but also challenges, which have been discussed in the CARES project (Maltby et al., 2018). While there is consensus within the scientific community of advantages and challenges of ES-based approaches in risk assessments, the means to address the challenges identified (i.e. tools to convert conventional ecotoxicity testing to ES, valuation of ES, costs of these developments, but also the complexity this may bring into a risk assessment and the risk of anthropocentrism in the decision making process) need further research (Maltby et al., 2018).

This presentation offers two case studies, developed in the context of risk assessment for pesticides, to illustrate how data generated in the conventional risk assessment process can fit in a holistic data analysis that uses ES as metrics. The first study, performed in tomato production farms in Italy, illustrates how data were collected and interpreted in the context of their production conditions, and refines the interpretation of the risk assessment by bringing additional scenarios involving alternative agricultural options (Deacon et al., 2016). The second study, is built on the same approach and compared different options of risk management in Spanish citrus orchards in terms of benefits to ESs such as habitat, landscape and carbon sequestration (Deacon et al., 2015). The two studies bring useful elements in interpreting the relevance of risks put into context and provide means to improve transparency and communication to support decision making. This echoes the outcome of an analysis of the potential of ES-based approaches to inform on trade-offs between farming options (Holt et al., 2016). However, these two studies also illustrate the need for further guidance to interpret conventional risk assessment into ES, as well as methods to compare and discuss ES values with clarity and transparency. This is the main challenge also identified during the CARES project, and will be the focus of the follow-up project.

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Valuing nature's contributions to people: the approach of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES)

Marie Stenseke *University of Gothenburg*

Marie Stenseke (born 22 August 1963 in Algutstorp, Sweden) is a social scientist with a PhD in Human and Economic Geography (Lund University, Sweden, 1997). She is a Professor in Human Geography at the Department for Economy and Society, University of Gothenburg, Sweden. Professor Stenseke's research concerns biodiversity, nature conservation and landscape management from a social science perspective. Her academic work has predominantly been carried out in an interdisciplinary context and

often in collaboration with governmental bodies and other stakeholders. She has been involved in a large number of national and international research projects and programmes, and engage with knowledge communication through various special commissions. At present she is the co-chair of the multidisciplinary expert panel of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES).

Nature and its contributions to a good quality of life are often perceived and valued by people in starkly different and often conflicting ways. It is, therefore, critical to acknowledge that the diversity of values of nature and its contributions to people's good quality of life are associated with different cultural and institutional contexts and are hard to compare on the same yardstick. The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) acknowledges that different types of values need to be promoted in decision making. In IPBES, scholars from a wide range of disciplines and other knowledge holders that assess the state of the planet's biodiversity (Stenseke and Larigauderie, 2018), developed a pluralistic approach to values (Pasucal et al., 2017), recognising that transformative practices aiming at sustainable futures would benefit from embracing the diversity of values on human-nature relations held by people. While the intrinsic values of 'nature' are recognised as important for decision making, IPBES also acknowledges that decision making relies to a great extent on instrumental values of what people obtain from the environment. Importantly, IPBES also pays attention to relational values, reflecting elements of cultural identity, social cohesion, social responsibility and moral responsibility towards nature. To facilitating comparability of valuation results, a bridging approach to pluralistic valuation and assessments has been developed and applied in IPBES.

IPBES's approach to values departs from IPBES conceptual framework (Diaz et al., 2015), in which nature's contributions to people is identified at a key element, given that they are the conduit between nature and a good quality of life (NCP). NCP are all the contributions, both positive and negative, of living nature to people's quality of life. Beneficial contributions include, for example, food provision (Diaz et al., 2018). NCP is a conceptual evolution from the Millennium Ecosystem Assessment (MA) ecosystem service framework to the nature's contributions to people (NCP) classification now applied in IPBES assessments. The NCP classification distinguishes three partly overlapping groups: regulating, material and non-material NCP. The classification places a major emphasis on the fact that the cultural context influences the perception and experiences by people of NCP, and stresses the importance of socio-cultural relations between people and nature. It means, for example, that food is not only recognised as a material nutrient provision, but also a non-material contribution to identity and social cohesion. It is, however, also recognised that NCP can be seen from a holistic and contextual perspective.

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Key words: biodiversity, pluralistic valuation, relational values

Using problem formulation to construct fit-for-purpose environmental risk assessments of regulated stressors

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Dr Mònica García-Alonso is an independent consultant and director at Estel Consult Ltd. She has been working in the area of risk assessment of genetically modified crops and regulatory affairs for more than 20 years. She has a degree in biology from the University of Barcelona, with speciality in zoology and entomology. Plus a Masters degree on insect physiology and ecology from the University of Barcelona and a PhD in neurobiology from the University of Reading. She worked for Syngenta for 19 years and set up her own consultancy 7 years ago. She now supports private and public research activities aimed at developing GM crop solutions and provides training on risk assessment to regulators and developers around the world.

Pre-market/prospective environmental risk assessments (ERA) are a key tool that contributes to the risk analyses performed to facilitate decision making on the market introduction of new products in the EU. These ERAs are conducted for a variety of products/stressors, such as pesticides, chemicals, pharmaceuticals, genetically modified organisms, some of which are assessed by EFSA. However, the methods used and data requirements for the ERA of each type of product can be very different as they typically fall under different legal frameworks. Indeed, for some of these products, a very specific set of studies and methods has been established over the years, and triggers and criteria for the

acceptability of risk have been set, as more familiarity has been gained and more scientific data have been made available to support these approaches. However, scientific advances are moving fast with a range of new products moving to commercial application, ranging from gene drive-modified mosquitoes, to RNA interference-based genetically modified plants and pesticides, to systemic insecticides, to genetically modified fish, to biological control agents and to nanoparticles and synthetic biotechnology products. For some of these products, ERAs will have to be performed and there may be challenges in directly applying the risk assessment tools developed for traditional products, so it may be necessary to find ways in which to perform fit-for-purpose ERAs. One option that has been identified is 'problem formulation'. This is a methodology that has been used implicitly for many years in pesticide and chemical risk assessments. More recently, EFSA has proposed a more explicit use in ERAs for genetically modified organisms (GMOs), the main reason being that GMO products can be very diverse and the assessments are conducted on a case-by-case basis. The methodology has gained support around the world and is now widely used (e.g. Raybould, 2006; Gray, 2012; Garcia-Alonso, 2013; Devos et al., 2018). This approach facilitates the performance of ERAs for this wide range of products in a scientific, logical and transparent way. This talk will explore the general concepts behind problem formulation as a tool to perform fit-for-purpose ERAs.

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Key words: environmental risk assessment, problem formulation

Problem formulation for the environmental risk assessment of insecticidal RNAi-based genetically modified plants and RNAi-based pesticides: effects on non-target arthropods

Jörg Romeis *Agroscope*

Dr Jörg Romeis heads the Biosafety Research Group at Agroscope in Zurich, Switzerland. Agroscope is the Swiss centre of excellence for agricultural research, and is affiliated to the Federal Office for Agriculture. In addition, he is a lecturer at the University of Bern and an adjunct professor at the Institute of Plant Protection of the Chinese Academy of Agricultural Sciences in Beijing.

Dr Romeis holds an MSc and a PhD in biology and was trained as an applied entomologist with a focus on biological pest control and multitrophic interactions. He has more than 17 years of experience in the risk assessment of genetically modified (GM) crops, with specific emphasis on the design and execution of non-target laboratory studies. His research has focused on the effects of insect-resistant GM plants, such as Bt maize and cotton, on arthropod herbivores and their predators and parasitoids. More recently, he also is studying the performance and non-target effects of GM plants that are based on RNA interference (RNAi).

In addition to primary research, Dr Romeis has been actively involved in developing guidelines and testing protocols for non-target risk assessment. He has organised and led several international expert panels in developing an approach for the evaluation of potential non-target effects, to propose design criteria for laboratory studies with non-target organisms, and to develop criteria for the selection of surrogate test species.

Dr Romeis has experience in the use of problem formulation to guide the environmental risk assessment of pest control technologies and in formulating operational protection goals. In total, his practical research and conceptual work related to GM plants has resulted in 130+ peer-reviewed publications.

RNA interference (RNAi) is an emerging and powerful technology that offers new opportunities for arthropod pest control through the silencing of target genes in arthropod pests. RNAi in arthropods involves small RNAs, derived from double-stranded RNA (dsRNA) that binds to messenger RNA with sequence homology leading to its cleavage and so silencing by an enzyme complex. Because the RNAi effect is sequence specific, dsRNA can be designed to have a very narrow spectrum of activity, allowing very targeted pest control. While functional RNAi has been reported from a number of arthropod species belonging to various orders, the impact of dietary or environmental RNAi (i.e. an RNAi response when dsRNA is ingested) is more limited. RNAi effects in pest control may, for example, be achieved by providing dsRNA in genetically modified (GM) plants, microorganisms, or baits or by applying them in foliar sprays.

One of the main concerns related to the use of dsRNA in pest control is that this could cause adverse effects to valued non-target species. Arthropods form a major part of the biodiversity in agricultural landscapes and contribute to important ecosystem services. This includes, in particular, regulating services such as biological control of herbivores and pollination, supporting services such as nutrient cycling, and cultural services for species of conservation concern. So, environmental risk assessment (ERA) to assess the potential impacts that GM plants or plant protection products (PPP) may have on valued non-target

arthropods (NTAs) is legally required before their placement in the market.

Early in the ERA, problem formulation is used to set the problem context and to develop plausible pathways on how the cultivation of dsRNA-producing GM plants or the application of PPPs containing dsRNA could harm valued non-target arthropod species. While the regulation (problem context) and the protection goals should be similar to other insecticidal GM plants or PPPs, differences may exist with respect to the relevant exposure scenarios and the potential adverse effects that result from those exposures. In this presentation, potential pathways that may harm selected protection goals will be presented and testable risk hypotheses will be identified. Furthermore, suggestions will be presented on how these hypotheses can be tested in a proportionate and tiered manner and the similarities and differences between RNAi-based GM plants and PPP will be elucidated.

Environmental risk assessment of neonicotinoid insecticides for bees: a retrospective analysis of the problem formulation

Alessio Ippolito *European Food Safety Authority*

Since 2014, Alessio Ippolito has worked as scientific officer at EFSA's Pesticides Unit, where he deals with the environmental risk assessment of pesticides, taking care of the peer review of active substances and of developing new methods for the risk assessment. Before joining EFSA, he worked at the Lombardy Regional Environmental Protection Agency, at the University of Milano-Bicocca, at the Helmholtz Centre for Environmental Research, at the International Centre for Pesticides and Health Risk Prevention, and at the Joint Research Centre of the EU Commission. Alessio holds a Master's degree in environmental sciences and a PhD in ecotoxicology from the University of Milano-Bicocca.

Since its foundation in 2002, the European Food Safety Authority (EFSA) has been responsible for producing up-to-date guidance documents for the environmental risk assessment (ERA) of pesticides. The role of these guidance documents is to provide risk assessment schemes, harmonised at EU level, with the aim of achieving specific protection goals (SPGs) (EFSA PPR Panel, 2010; EFSA Scientific Committee, 2016).

One of the latest guidance documents published by EFSA in the area of pesticide ERA is the one addressing risks to bees (EFSA, 2013). Within such guidance documents, the general problem formulation was considered by taking into account all appropriate steps, from the hazard and exposure pathways identification, the definition of the SPGs, to the risk hypothesis and the assessment methodology comprising different tiers.

Despite not being noted yet at the EU level, this guidance document has been already used by EFSA, particularly for assessing the risks to bees associated with the uses of neonicotinoid substances. This contribution offers a retrospective assessment of the problem formulation as it was set out in the guidance document, using the latest experience in bee risk assessment, with a particular focus on the recently published conclusions on imidacloprid, clothianidin, and thiamethoxam (EFSA, 2018a, 2018b, 2018c).

On a general level, according to one of the first analyses of the role of problem formulation within the ERA (US EPA, 1998), the main issues caused by an inappropriate problem formulation are the lack of clearly defined goals, the use of ambiguous endpoints (or that cannot be easily measured), and finally the failure to identify relevant risks. Therefore these aspects should be addressed in a retrospective assessment. Particularly, the first two issues will be discussed in light of the results of the weight of evidence exercise included in the latest conclusions, in which multiple endpoints with different levels of relevance for addressing the SPGs have been considered. The results of the systematic literature search, which served as input for the bee risk assessment conclusions on neonicotinoids, will be used to discuss the possibility that relevant risks were not fully considered in the assessment.

Overall, it will be shown that the guidance document represents a good example of ERA problem formulation, highlighting some aspects which may benefit from further revision. A brief comparison with the risk assessment schemes in place before introducing the EFSA guidance document confirms that tremendous improvements have been made in formulating the risk assessment procedure in advance, benefiting from the scientific experience gained over the years.

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Key words: bees, neonicotinoids, pesticide, problem formulation

Current scientific developments in the environmental risk assessment of nanomaterials

Claus Svendsen *Centre for Ecology & Hydrology*

Claus Svendsen works on fundamental and applied environmental research at the NERC Centre for Ecology and Hydrology (UK) in Wallingford, where he leads their Ecotoxicology and Chemical Risk Group. He has authored or co-authored over 100 papers and book chapters, and coordinated or been a WP leader or partner in many EU-funded projects on biomarkers, chemical mixtures and nano materials from FP4–H2020, with other major funding from NERC (UK), EFSA and Defra (UK).

The basic foundation of nanotechnology is that engineering the size and shape of materials at the nanometer scale produces distinct, novel properties with potential functional and commercial value. The specific properties of nanomaterials (NM) and their resulting unique environmental behaviour and potential effects have led to the concern that current chemical based environmental risk assessment (ERA) methods, endpoints and approaches may not be adequate. Progress is needed in the prediction of environmental distribution, concentration and form (speciation) of nanomaterials, to allow early assessment of potential environmental and human exposure and risks, to facilitate safe product design and to include these aspects in nano regulation. Over the recent years it has become clear that ranking toxicities of nanomaterials through the testing of 'pristine – as made particles' in standard clean media may not provide much relevance in the environmental risk their released forms potentially represents. While it is clear that dealing with detailed physical/chemical characterisation of the multiple forms in which the nanomaterials may be released from all stages (particle production; incorporation; use and disposal phases) of a nano-enabled products life-cycle is impossible. Then it is equally clear that adequate, realistic and efficient risk assessment cannot be done by simply comparing pulmonary neuroendocrine cells (PNECs) from 'short laboratory test with pristine NM forms' with the peritoneal exudate cells (PECs) from mass flow based models that do not take the transformations of nanomaterials both pre and post release to the environment into account. For one the fate processes and behaviour of the released materials depend on the new physical/chemical properties developed in such transformations. Again tracking such transformations in detail and doing so in environmentally relevant media and concentrations is technically challenging and resource intensive beyond most available means. Therefore, we propose to move focus away from the physical/chemical properties of pristine endothelial model cell membranes (ENMs) and to aim to understand the functional and behaviour patterns of release relevant ENMs in exposure relevant environments. The need for this will be highlighted through presentation of a series of recent non-standard experiments and studies that aim to get as relevant nanomaterial exposures as possible, each addressing a different element of fate, transformation or ageing and all focused on applications related to agricultural practices.

Key words: ageing, nano, non-standard tests, transformations

Problem formulation for the environmental risk assessment of GM growth-enhanced coho salmon

Rosalind Leggatt *Fisheries and Oceans Canada*

Rosalind Leggatt is a Biologist and Science Advisor for Fisheries and Oceans Canada (DFO). The focus of her research is to examine the potential environmental consequences of genetic modification in finfish for use in food-fish aquaculture and the ornamental aquarium trade. This work has included examining the influence of genetic engineering (e.g. transgenesis), domestication, and triploidy on physiology, gene expression, health, ecology and behaviour of finfish. Rosalind also contributes to environmental and indirect human health risk assessments for commercial use of genetically engineered finfish in Canada under the Canadian Environmental Protection Act.

In Canada, genetically engineered organisms are regulated under the Canadian Environmental Protection Act (CEPA) New Substances Notification Regulations (Organisms) [NSNR(O)]. The biotechnology provisions of CEPA take a preventative approach to regulation by requiring all new living organism products of biotechnology to be notified and assessed before import or manufacture to determine whether they are capable of harming the environment or indirectly human health. Fisheries and Oceans Canada (DFO) conducts an environmental risk assessment (ERA) of notified genetically engineered fish to provide science advice for regulatory decisions. Environmental risk is considered a function of the potential exposure of the environment to the

genetically modified organism and the potential for the organism to be a hazard to the environment (risk = exposure × hazard). Uncertainty is estimated and informs whether the application of precaution in regulatory decision making is needed. An Atlantic salmon containing a growth hormone (GH) transgene for fast growth is currently the only genetically engineered fish approved for human consumption in Canada. As a test case, we discuss the implementation of ERA processes for a line of GH transgenic coho salmon developed for research.

Environmental exposure of the GH salmon was estimated assuming land-based commercial production of all-female triploid salmon. While the organism would be expected to survive, disperse, and, in limited circumstances, reproduce in Canadian environments, an expected lack of entry results in negligible ranking for environmental exposure to the organism, with low uncertainty (DFO 2013). Research data indicate that GH transgenic coho salmon have strongly affected behaviour and physiology, are not 100% sterilised by triploidy, and would pose the highest environmental hazard through interactions with native organisms (e.g. through competition for food or mates, predation and hybridisation), with difficult-to-predict long-term consequences. Identified level of hazards of transgenic coho salmon to wild fish varied greatly depending on whether experiments were run in the laboratory or under semi-natural conditions, on rearing history of transgenic and wild-type fish, the age of escaped transgenic fish, environmental conditions, strain background, etc. (see Devlin et al., 2015). The estimated negligible exposure rank and high hazard rank results in an estimated low environmental risk ranking for hypothetical commercial use of GH transgenic coho salmon. High uncertainty in estimating levels of hazard to ecosystem components, incomplete sterility and lack of evidence indicating the organism will not be a hazard to the environment, demonstrate the importance of containment of GH transgenic coho salmon to minimise environmental risk.

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Problem formulation for the environmental risk assessment of gene drive-modified mosquitoes

Andrew Roberts *ILSI Research Foundation*

Dr Andrew Roberts joined the ILSI Research Foundation in December 2009 as the Deputy Director of the Centre for Environmental Risk Assessment (CERA), where his first tasks included developing tools and materials for use in training and capacity building, related to the problem formulation approach to environmental risk assessment published by the Research Foundation (Wolt et al., 2009). He has served as the coordinator for CERA's capacity building projects under the USAID-funded South Asia Biosafety Program (SABP) and the World Bank funded Partnership for Biosafety Risk Assessment and Regulation, in Bangladesh, Pakistan, and Vietnam as well as providing technical support for capacity building work in Brazil, India, Japan, Chile, and South Africa. In January of 2015 he became the director of CERA as well as the Centre for Safety Assessment of Food and Feed (CSAFF).

Before joining CERA, Andrew worked at the US Department of Agriculture in several different capacities, all related to the regulation of agricultural biotechnology. He began his career at USDA as an AAAS Risk Policy Fellow in the Office of Science of Biotechnology Regulatory Services (BRS), the group responsible for regulating genetically engineered plants at USDA. After spending a year in the New Technologies office of the Foreign Agricultural Service serving as the lead for USDA's efforts related to the Cartagena Protocol on Biosafety, he returned to BRS to serve in the International Affairs branch where he remained until joining ILSI RF.

Andrew received his PhD in Cell and Developmental Biology from Rutgers University where he worked on signal transduction in the model nematode C. elegans.

The potential to use gene-drive mechanisms to address intractable public health problems caused by vector-borne diseases has been of interest to scientists for decades, but recent advances in molecular biology have brought this idea closer to feasibility and so into the public consciousness. To begin discussions in Africa that will facilitate the consideration of potential future use of gene-drive technologies to control malaria, the New Partnership for African Development (NEPAD) organised a series of regional consultations taking place in 2016–2018. Drawing from experience in facilitating problem formulation exercises at these consultations, as well as other sources, I will share some of my own conclusions about the utility (and the necessity) of applying an organised scoping process such as problem formulation to better inform the risk assessment process, especially

as it relates to new technologies or new uses of technology. I will also review commonly identified assessment endpoints that can provide guidance to future risk assessments for gene-drive mosquitoes. These include potential alterations to vectorial capacity that might impact human or animal health, the potential for aquatic larvae to influence water quality, and the potential for harm resulting from altered ecosystem interactions.

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Key words: mosquito, problem formulation, risk assessment

Problem formulation for the environmental risk assessment of weed biological control agents: insects and fungi versus weeds

Richard Shaw *Centre for Agriculture and Biosciences International*

Dick Shaw is the Regional Coordinator for CABI's invasive species activities for Europe and the Americas as well as being Country Director for CABI's UK Centre in Egham. Dick has worked on the biological control of mainly weeds for CABI for 24 years and is an experienced applied entomologist having carried out fieldwork in more than 20 countries. He is currently overseeing a team of researchers working on weeds that could have an impact on aquatic and riparian weeds in the UK, including Japanese knotweed, which he has been studying since the last century!

Japanese knotweed is a notorious non-native invasive species that harms ecosystems and economies across northern Europe and North America. This noxious species arrived from its native range in Japan in the early 19th century. It is certainly beyond eradication and widespread management uses physical and chemical techniques. However, it may be susceptible to the use of natural enemies applied as biological control agents. Following almost 15 years of research, more than 200 natural enemies found attacking the plant in Japan have been whittled down to 2, a sap sucking psyllid and a leafspot fungus. From a risk assessment perspective, the former is an animal that is intended to be released on a few occasions for the permanent suppression of the target weed, while the latter is a microorganism that is intended to be applied as a mycoherbicide. However, both agents are likely to be injurious to plants in the risk assessment area when released into the environment.

In contrast, the invasive Himalayan balsam plant, which is equally widespread, is currently subject to a similar classical weed biocontrol project, but with a fungus not intended for use through a nozzle. The ecological principles, strategy and safety testing for this and the psyllid are almost identical, but because of their taxa and indeed differing size, they are regulated in a very different way. Thankfully, the risk assessment process based on the Organisation Européenne et Méditerranéenne pour la Protection des Plantes (EPPO) pest risk assessment form is similar. In general, risk assessments for classical biocontrol agents are focused on the consequences for the environment of a release of an exotic organism and can be direct, such as non-target attack, or indirect such as apparent competition. For an inundative and normally formulated organism then risk to the operator and consumers are added to the environmental risk consideration. The selection of an agent for a classical biocontrol programme is largely determined by host specificity and the vulnerability of the plant part attacked while mycoherbicides will be placed on the market, as efficacy and user safety are more important.

This presentation will cover the principles and practice of classical and inundative biological control using the knotweed and balsam projects as convenient and very current case studies that show the two different strategies and two different taxa of agents. It will also show that almost half of the questions in a standard pest risk assessment are not relevant to an intentional classical biocontrol release and raise the important issue of considering benefit alongside risk. If benefit is not considered alongside risk then it would be virtually impossible to utilise this tried-and-tested approach to weed management, as there is always a small risk in biological systems. For invasive species, doing nothing is not a low risk option.

Landscape-scale population-level ERA: current status and challenges

Christopher J. Topping *Aarhus University*

Christopher Topping is Professor MSO in Ecological Modelling at Aarhus University, Denmark. He has been working with modelling environmental impacts of primarily agricultural practices and agricultural policy affecting wildlife management and risk assessment for over 20 years. His primary field is development and testing of complex multifaceted agent-based models (ABMs), leading towards simulation of social-ecological systems and the use of models for wildlife management and environmental risk assessment of agricultural chemicals, crops, and practices. He is vice chair of the EFSA Plant Protection Products and Residues (PPR) Panel, a member of MUST-B, and has been involved in EFSA working groups since 2009. He is involved in developing pollinator models and landscape simulations in northern, eastern and southern Europe and is currently implementing

ApisRAM, the EFSA honey bee colony model.

Current guidance in ERA has its focus on toxicology, but it is becoming increasing clear that ecological aspects cannot be ignored. Landscape, its structure and function, have a very important role to play in determining the outcome of the assessment on populations of non-target organisms, as has been acknowledged in recent EFSA scientific opinions. The incorporation of landscape-scale risk assessment is also part of the EFSA strategy for 2020.

Naturally, when dealing with what amounts to a paradigm shift in ERA, there are both opportunities to grasp and challenges to overcome. The opportunities are primarily related to being better able to predict risk, related to the context the animals find themselves in, and to the interactions between stressors and animal populations in space and time. This has the knock-on benefit of being able to use the same tools to evaluate mitigation options. Challenges are both technical and conceptual. The technical challenges related to the need for accurate simulation of landscape structure and function, as well as the development and testing of models and obtaining the volume of data required to support these activities. The conceptual issues relate primarily to definition of specific protection goals at this scale, and decisions on choice of representative species and scenarios.

Several steps towards development of models suitable for supporting landscape-scale ERA have been taken already. EFSA is developing ApisRAM, an individual-based honey bee model that will utilise landscape structure and dynamics to predict impacts of pesticides and other stressors on bees. Other models of mammals, birds and terrestrial arthropods already exist and are being adapted for use.

Currently EFSA is working towards implementation of landscape-scale ERA for pesticides using a systems approach (EFSA Scientific Committee 2016). This endeavour will use those building blocks currently available and adapt them to provide a systems model that includes relevant local (Member State & regional) context. These building blocks include current models of non-target animals and environmental fate models. Landscape simulation will use existing EU datasets e.g. held by JRC, to generate regulatory scenarios, and existing landscape simulation and landscape capture methods provided by the ALMaSS framework (Topping, Dalby et al. 2016). This process has been initiated for a restricted set of species of terrestrial mammals, birds and insects but the aim is to expand to other systems, including aquatic systems in later developmental steps.

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Key words: ALMaSS, context-dependency, systems model

Wendy Craig *International Centre for Genetic Engineering & Biotechnology*

Group Leader – Biosafety, International Centre for Genetic Engineering and Biotechnology (ICGEB), Trieste, Italy. Dr Wendy Craig is currently the Group Leader of the ICGEB's Biosafety Group, which is principally involved in biosafety capacity enhancement in their Member States (primarily developing countries). She is actively managing projects targeting locally identified needs in GMO regulation and information dissemination, focusing on the governmental, institutional and individual levels. These activities rely on strengthening collaborations and creating synergies with international organisations and experts operating in similar or associated arenas. Dr Craig gained her PhD at Nottingham University, UK in 1996 studying approaches for the genetic manipulation of oilseed rape. This led to her conducting a series of plant biotechnology-based post-doctorate studies in various parts of the world before joining the ICGEB Biosafety Group in January 2005. She regularly authors articles and reviews in GMO biosafety. For further details, see https://www.linkedin.com/in/wendy-craig-3209785a/

ADVANCING RISK ASSESSMENT SCIENCE

Human health

The National Academies of Sciences, Engineering, and Medicine recently published a report that provides considerations and recommendations on how the latest scientific and technological advances in toxicology, exposure science and epidemiology could be integrated and used to further advance risk assessments. New tools are emerging that enable a better understanding of adverse effects at the molecular level, and more accurate predictions of biological responses. Most of these tools will be non-animal testing models. Moreover, epidemiological research is facing a transition from empirical observations alone to the provision of information on the pathogenesis. These developments are promising for the improvement of human health risk assessments as well as the reduction of animal testing.
This session will highlight relevant advances, unresolved challenges, and needs for human health risk assessment. The usefulness of the traditional risk assessment paradigm (hazard characterisation, exposure assessment and risk characterisation) will be addressed holistically, accounting for the challenges that a paradigm shift may entail. New tools that may facilitate this transition will be discussed.

CHAIRS

Guilhem De Seze *European Food Safety Authority*

Guilhem de Seze joined EFSA in 2016 as head of the Scientific Evaluation of Regulated Products Department. From 2008, he worked for the European Chemicals Agency in Helsinki, where in 2011 he became a head of Unit, first for Substance Identification and Data Sharing, and then for Evaluation; both Units were in charge of assessing scientific and technical information about chemical substances and their hazardous properties. Before this, Guilhem worked in hazardous chemicals management in academia and in the chemical industry for over 10 years. He holds a PhD in chemical engineering from Louisiana State University.

Maurice Whelan *Joint Research Centre*

Professor Maurice Whelan is head of the Chemical Safety and Alternative Methods Unit of the Directorate for Health, Consumers and Reference Materials of the European Commission's Joint Research Centre (JRC), based in Ispra, Italy. He also heads the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) of the JRC, established under EU Directive 2010/63 on the protection of animals used for scientific purposes, which builds on the 20 years of activities of ECVAM, the (former) European Centre for the Validation of Alternative Methods. Priorities of his work include the development, validation and promotion of alternative approaches to animal testing both for regulatory safety assessment of chemicals and for applications in biomedical research. Whelan is the EU co-chair of the OECD Advisory Group on Molecular Screening and Toxicogenomics that is responsible for the OECD programme on Adverse Outcome Pathways, and he is a member of the Steering Committee of the European Partnership for Alternative Approaches to Animal Testing (EPAA). He holds a number of external appointments including the 2017–2018 Francqui Chair for alternative methods at the Vrije Universiteit Brussel (Belgium) and visiting Professor of Bioengineering at the University of Liverpool (UK).

Angelika Tritscher *World Health Organisation*

Dr Angelika Tritscher is a registered toxicologist with extensive research and applied experience in toxicology and human health risk assessment. After a research carrier in environmental health she focused on applied science in food safety. With over 25 years experience in food safety she worked first in the private sector in corporate quality and safety assurance and joined WHO in 2003. In the Department of Food Safety and Zoonoses, she is heading the unit tasked with risk assessment and management, including the assessment of all food-related risks as basis for international, Codex, standards.

Heather Wallace *University of Aberdeen*

Heather is the Professor of Biochemical Pharmacology and Toxicology at the University of Aberdeen. Her research interests are in cancer therapeutics and prevention, selective drug delivery and the use of biomarkers for diagnosis and monitoring efficacy of anticancer drug therapy. She co-ordinates post-graduate and undergraduate teaching in Bio-Business and lectures in pharmacology, drug discovery and cancer biology. Heather is President-Elect of EUROTOX and is chair of the Scientific Programme Committee. She is a member of the Scientific Programme Committee of Society of Toxicology (USA) and is an adviser to IUTOX Scientific Programme Committee. She is Immediate Past President of the British Toxicology Society. Heather is a Fellow of the Royal College of Pathologists and is Specialty Advisor for Toxicology at the College. She is also a Fellow of four other learned Societies. Heather is a member of the UK Register of Toxicologists and a European Registered Toxicologist. She has recently been appointed Editor-in-Chief of Toxicology Research, a Royal Society of Chemistry Journal.

RAPPORTEURS

Anna Federica Castoldi *European Food Safety Authority*

Anna Castoldi is a senior scientific officer in EFSA's Unit on Food Ingredients and Packaging, where she leads the Team of Food Contact Materials. Over the past 9 years she has coordinated EFSA's extensive scientific work on bisphenol A. Before joining EFSA in 2008, she carried out research in the area of the molecular toxicology of food neurotoxicants and contaminants at the University of Washington, at the University of Konstanz and at a research Institute in Pavia. She has a PhD in food and environmental toxicology from the University of Milan, and further specialised in pharmacology and toxicology in 2002.

George Kass *European Food Safety Authority*

George Kass has been a senior scientific officer and toxicologist, at EFSA's Scientific Committee and Emerging Risks Unit since 2009. Before joining EFSA, he was professor of toxicology at the University of Surrey (1994–2009). Previously, he was a postdoctoral researcher at the Swiss Federal Institute of Technology in Zurich, and assistant professor at the Karolinska Institute. He has published over 100 papers and abstracts in toxicology. George has a degree in biochemistry, a Master's degree in toxicology and a PhD in biochemical toxicology from Stockholm's Karolinska Institute.

Anna Lanzoni *European Food Safety Authority*

Anna Lanzoni has been a senior scientific officer and toxicologist at EFSA's GMO Unit since 2013. She is involved in the risk assessment of GMOs and the development of risk assessment guidelines. Previously, she worked for 20 years in the pharmaceutical industry as a toxicological pathologist. Anna graduated as a veterinary medicine doctor, and has a PhD in veterinary hygiene and pathology from the University of Milan.

Andrea Terron *European Food Safety Authority*

Since 2012, Andrea Terron has been a senior scientific officer and toxicologist, at EFSA's Pesticide Unit. Andrea's expertise is in the risk assessment of medicinal and plant protection products. His professional involvement started in 1986 in the pharmaceutical industry as a toxicological pathologist. Andrea graduated as veterinary medicine doctor, and has a PhD in experimental and toxicological pathology from l'Ecole Nationale Vétérinaire d'Alfort.

SPEAKERS

How simple heuristics influence laypeople's risk perception

Michael Siegrist *ETH Zürich*

Michael Siegrist is a full Professor for Consumer Behaviour at the Institute for Environmental Decisions (IED), ETH Zurich, Switzerland. Professor Siegrist studied psychology, economics and mass communication at the University of Zurich. Professor Siegrist is an Associate Area Editor of the journal Risk Analysis and an Executive Editor of the journal Appetite. He has published numerous articles about risk perception, trust, risk communication, food behaviour and environmental decision making.

The qualitative characteristics of a hazard, and not relevant quantitative information, strongly influence laypeople's risk perception. Recent research has focused on the role of simple heuristics, for example, natural is good and synthetic is bad, in people's hazard evaluations. The results of such studies indicate that it is not only the negative consequences of a hazard that have a significant influence on people's perceptions, but also whether the hazard is made by humans (e.g. glyphosate) or naturally occurring (e.g. Campylobacter). Indeed, negative outcomes are perceived to be more severe if they are caused by humans than if they stem from nature. Perceiving gene technology to be unnatural also seems to be an important reason why the risks, as well as the benefits, associated with this technology are perceived differently when compared with the risks and benefits associated with conventional breeding technology. Another heuristic that people may apply when evaluating the healthiness of foods is that the absence of certain substances implies the product is healthier. Therefore, products with 'free from' labels (e.g. free from palm oil, free from genetically modified organisms) are perceived as healthier than products without such labels. Biased decisions that result from people's reliance on simple heuristics have been observed in different contexts, and they may result in non-optimal decisions being made. However, providing information to laypeople seems to have only a limited impact on how hazards are perceived. This poses a challenge for risk communication intended to change laypeople's perceptions so that they fall more in line with the best available scientific evidence.

Using 21st century science to improve risk assessment: opportunities and challenges

Ellen Mantus *US National Academies of Sciences, Engineering and Medicine*

Dr Mantus is a Scholar and Director of Risk Assessment on the Board on Environmental Studies and Toxicology at the National Academies of Sciences, Engineering, and Medicine, USA with over 20 years of experience in the fields of toxicology and risk assessment. She has served as the study director on numerous projects, including ones that have assessed the health implications of various chemical exposures, developed strategies for applying modern scientific approaches in toxicology and risk assessment, provided guidance to federal agencies on risk-based decision-making, and evaluated barriers to deployment of electric vehicles and associated charging infrastructure. Before joining the National Academies, Dr Mantus was a project manager with ICF Consulting, where she served as a primary reviewer for numerous toxicological studies and provided risk assessment and regulatory support on a wide array of projects. Dr Mantus received her PhD in organic chemistry from Cornell University in Ithaca, NY, USA.

In 2007, the National Academies of Sciences, Engineering and Medicine released a report, Toxicity Testing in the 21st Century: A Vision and a Strategy, which capitalised on the advances in biology and related fields and increases in computational power to envision a future in which toxicity testing primarily relies on high-throughput in vitro assays and computational tools to assess potential adverse effects from chemical exposure. A vision for exposure science was articulated several years later in the National Academies report, Exposure Science in the 21st Century: A Vision and a Strategy, which expanded the breadth and depth of exposure science given advances in, for example, monitoring technologies, analytical techniques and computational tools. Since the release of those reports, collaborations of various agencies and organisations within and outside the United States have formed to advance the visions, and generation of diverse data streams from government, industry and academic laboratories has accelerated. Although scientists and others expect that

implementation of the visions will take decades to achieve fully, the recent National Academies report, Using 21st Century Science to Improve Risk-Related Evaluations, examines how the data being generated today can be used in risk assessment applications. Four areas – priority setting, chemical assessment, site-specific assessment and assessment of new chemicals – were identified that could benefit by incorporating the 21st century science, and case studies were described. Although there are many technical challenges still to be resolved, the report identified one particular challenge that looms large. Technology has evolved far faster than our ability to analyse, interpret and integrate the diverse, complex and large data streams for risk assessment. However, there is a path forward, and a research agenda that develops, explores, and documents case studies that capture various scenarios of data availability for risk assessment applications will help to address the challenges. Multidisciplinary collaboration will also be critical. This presentation will briefly describe key findings and case studies from the recent National Academies report and highlight opportunities and challenges for incorporating 21st century science into risk assessment.

*The presentation will be based on a report of the National Academies of Sciences, Engineering and Medicine authored by the Committee on Incorporating 21st Century Science into Risk-Based Evaluations. Committee members were Jonathan Samet (chair), Melvin Andersen, Jon Arnot, Esteban Burchard, George Daston, David Dunson, Nigel Greene, Heather Patisaul, Kristi Pullen Fedinick, Beate Ritz, Ivan Rusyn, Robert Tanguay, Justin Teeguarden, James Tiedje, Paolo Vineis, Michelle Williams, Fred Wright and Lauren Zeise. Ellen Mantus was the study director.

Holistic approach to human health risk assessment – is the current approach fit for purpose?

Susanne Hougaard Bennekou *Danish Environmental Protection Agency*

Senior Advisor at the Pesticide Division of the Danish EPA. As a regulatory toxicologist also involved in risk assessment of biocides and REACH regulated chemicals. Vice-chair of EFSA's PPR 2010-medio 2018. Currently, I am involved in developing: the EFSA guidance document for harmonisation of risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals. Scientific outputs on establishment of cumulative assessment groups of pesticides for their effects on the nervous system and thyroid system. Cumulative risk assessment of pesticides for their effects on the nervous system and the thyroid system. Member of EFSA's Scientific Committee 2018–2021. Involved as a steering team member in the H2020 supported project 'EU-ToxRisk', which aim at driving mechanism-based toxicity testing and risk assessment, also to support mixture risk assessment. Member of the steering team on the OECD project 'OECD Guidance on the application and interpretation of in vitro developmental neurotoxicity assays and definition of a tiered approach to testing and assessment.

The previous presentation has provided reflections on the striving for a paradigm shift in risk assessment: from risk assessment based on identification of apical endpoints to a mechanism-based risk assessment. There is consensus that this has the potential to improve risk assessment, but the question is whether our current EU regulations are flexible enough to take full advantage of this potential? This talk will discuss several aspects of this, among:

- Are the standard requirements fit for purpose?
- Do we need more flexibility in these and the accompanying guidance documents?
- Do we make the most use of existing data?
- Can we at the same time ensure mutual recognition of the risk assessment outputs?

Finally, the talk will identify and discuss the 'most wanted' steps towards transition to a mechanism-based risk assessment of chemicals.

Use of epidemiological studies for chemical risk assessment: how to take advantage of their strengths and deal with their limitations

Thorhallur I Halldorsson *University of Iceland*

Professor at the Faculty of Food Science and Nutrition at the University of Iceland. Thorhallur also holds an external position as senior scientist at the Division of Health Surveillance and Research, Statens Serum Institut in Copenhagen and is a member of the EFSAs Scientific Committee (2018–2021). With background in Chemistry (BSc), Applied Mathematics (MSc) and Public Health Sciences (PhD) his research has mostly been focused within the fields of Nutritional and Environmental Epidemiology. His research also covers the development of dietary assessment methods for use in epidemiological studies and nutrition surveys. Since 2007 Thorhallur has published over 90 papers in international peer-reviewed international journals.

Chemical risk assessment should ideally be based on studies carried out under controlled experimental conditions. However, for humans,

such experiments cannot be performed for potentially harmful substances. Although human observational studies can be used as an alternative, the time needed to generate reliable results for new substances and methodological limitations have traditionally hampered their use. For these reasons, procedures and regulatory framework for chemical risk assessment have largely been driven by reliance on experimental studies in animals. The limitations of that approach are uncertainties related to extrapolating findings from animals to humans and use of doses that are usually far higher than those observed in humans. Although these limitations can be partly reduced by use of safety factors, it is increasingly acknowledged that precision in risk assessment can be improved by incorporating findings from human observational studies. Recent advancements in analytical chemistry in rapid method development, reduction in sample volume and cost; as well as improved access to computerised health data have made human observational studies of sufficient quality more frequently available for risk assessors. Apart from general limitations in bias (including confounding), use of human compared with animal studies are more complicated due to the occurrence of other co-exposures and the fact that unexposed individuals usually do not exist. In addition, the high variability in term of susceptibility to chemical exposures and interaction with other lifestyle factors means that results from different human studies can be conflicting. The current framework for chemical risk assessment is generally not compatible with these complexities and compromises are needed. A better understanding between strengths and weaknesses of classical toxicological studies and human observational studies is the key for further advancing the methodology for chemical risk assessment. The aim of this presentation is to address some of those issues drawing on examples from regulated products such as pesticides and less constrained areas such as for chemical contaminants.

New approach methods (NAM) in toxicology for mechanism-based hazard assessment.

Marcel Leist *University of Kostanz*

Marcel Leist, MSc (toxicology, 1989), PhD (pharmacology, 1993) has been head of the department of in vitro toxicology and biomedicine at the University of Konstanz (since 2006, sponsored by the Doerenkamp-Zbinden foundation), and director of the Centre for Alternatives to Animal Testing in Europe (CAAT-Europe). Marcel also worked as Head of Department of disease biology at the Danish pharmaceutical company Lundbeck A/S from 2000–2006. His research comprises stem-cell differentiation to neuronal lineages as well as the pharmacological and toxicological characterisation of test systems and in vitro disease models. His major focus is the establishment of human-cell-based toxicological tests for developmental toxicity and neurotoxicity. He has contributed to the field with >200 publications, cited over 15,000 times.

Multiple non-animal-based test methods have never been formally validated. To use such new approach methods (NAMs) in a regulatory context, a process and criteria to define the readiness of the NAM would be useful. The field of developmental neurotoxicity (DNT) testing has been chosen here to exemplify the application of readiness criteria. The numbers of chemicals not tested, and the testing cost per chemical are overwhelming for in vivo DNT testing. So, there is a need for inexpensive, high-throughput NAM approaches, to obtain initial information on potential hazards, and to allow prioritisation for further testing. We give here a background on the regulatory and scientific status of DNT testing, to show that different types of test readiness levels are useful, depending on the intended use of the data from NAMs. Readiness criteria are presented. On this basis a (semi) quantitative analysis process was assembled on test readiness of 17 NAMs with respect to various uses (e.g. prioritisation/screening, risk assessment). The scoring results suggest that several assays are currently at high readiness levels. Therefore, suggestions are made on how DNT NAM may be assembled into an integratead approach to testing and assessment (IATA). Finally, a vision is presented on how further NAM development may be guided by knowledge of signaling pathways necessary for normal brain development, DNT pathophysiology, and relevant adverse outcome pathways (AOP).

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Maged Younes *European Food Safety Authority's Panel on Food Additives and Nutrient Sources Added to Food*

Maged Younes holds an MSc and a PhD in Biochemistry and Physiological Chemistry from the University of Tübingen, Germany, and a degree of Dr habil. in Toxicology and Biochemical Pharmacology from the Medical University of Lübeck, Germany. Following an academic career as a researcher and Professor of Toxicology and Biochemical Pharmacology in Germany, Dr Younes joined the World Health Organization (including a two-year secondment to the United Nations Environment Programme). At WHO and UNEP, he managed and directed various technical and policy programmes, including chemical safety, environmental health, environmental conventions, governance and external relations, and food safety and zoonoses. Since his retirement as Director, Food Safety and Zoonoses at WHO in 2013, he has maintained his scientific activities as an Independent International Expert, Global Public Health. Among others, he is currently Chair of the Food Additives and Nutrient Supplements Panel (ANS) of the European Food Safety Agency (EFSA) and Member of EFSA's Scientific Committee. In addition, he has been an Adjunct Professor of Toxicology and Biochemical Pharmacology, University of Lübeck, Germany until 2015. He has been a Visiting Professor of Environmental and Occupational Health and Sustainability, Robert-Gordon University, Aberdeen, Scotland, a Visiting Professor at the Chulabhorn Research Institute Bangkok, Thailand, and a Professor of Public Health/ Environmental Health Studies of the Istituto dell'Approccio Centrato Sulla Persona (IACP) in Rome. Dr Younes has published around 150 original papers and 40 book chapters and review articles, and is editor/co-editor of six books and special journal issues. During his career, he gave numerous presentations and plenary lectures and chaired and moderated various scientific and policy meetings/sessions. He is a member of a number of professional societies.

Human biomonitoring: the European Joint Programme HBM4EU

Marike Kolossa-Gehring *German Environment Agency*

Head of Section 'Toxicology, Health-related Environmental Monitoring', German Environment Agency, Germany.

HBM4EU coordinator. She obtained her PhD from the Christian-Albrechts-University Kiel. In the German Environment Agency she is in charge of the scientific lead and management of the German Human Biomonitoring Program (German Environmental Survey GerES, the German Environmental Specimen Bank ESB, the German Human Biomonitoring Commission, and the HBM cooperation between the German Chemical Industry Association (VCI) and the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)). She has been involved in the development of assessment strategies and guidelines at national, EU and OECD levels and from 2006 to 2010 vice-chair and chair of the OECD Endocrine Disruptor and Assessment Task Force. She was work package leader in the EU HBM projects ESBIO, DEMOCOPHES and COPHES, the Consortium to Perform Human Biomonitoring on a European Scale preparing and piloting a European human biomonitoring study. From 2011 to 2014 she has been Governmental Councillor of the International Society of Exposure Science (ISES).

HBM4EU follows an innovative approach to generate the knowledge policy makers need to improve policy in environment and health. The overarching goal of HBM4EU is to generate new knowledge, to inform the safe management of chemicals, and so protect human health in Europe. Human biomonitoring data supply information on the aggregate exposure from all sources and by all pathways. They will serve as the basis to assess the risks from human exposure to chemicals. Intensive communication with policy makers from the state of planning onwards will ensure that HBM4EU results are used in the further development and design of new chemical policies as well as the evaluation of existing measures.

HBM4EU consists of 109 partner organisations from 28 countries, 27 European countries plus Israel, and is organised around 16 work packages led by key players of national HBM studies and research programmes. Major fields of activities are science-policy transfer, HBM studies and research to elucidate the impact of exposure on health. HBM data are currently fragmented in Europe. Exposure data valid for the whole of Europe, the identification of vulnerable or highly exposed subpopulations and the analysis of spatial and temporal exposure trends are major goals of HBM4EU. HBM reveals the extent and quality of multiple chemicals exposures. These data also demonstrate the need to develop concepts for health risk assessment beyond traditional single substance evaluation methods. The research programme is based on the policy needs and priority chemicals identified after consultation with European and national policy makers. It builds upon existing knowledge from national and EU monitoring and research programmes.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733032.

Internal dosimetrics enable holistic assessment of exposures to environmental and endogenous oestrogens

Daniel Doerge *US Food & Drug Administration*

Daniel R. Doerge was awarded the BS degree from Oregon State University and a PhD degree from University of California, Davis, USA. He was Assistant/Associate Professor of Environmental Biochemistry at the University of Hawaii. Since 1992, he has been a Research Chemist in the Division of Biochemical Toxicology at the US Food and Drug Administration's National Center for Toxicological Research in Jefferson, Arkansas, USA. His areas of research specialisation have been: chemical and biochemical mechanisms of toxicity; thyroid toxicology; toxicology of soy isoflavones, acrylamide, bisphenol A, and inorganic arsenic; applications of modern mass spectrometry that emphasise high throughput determinations of pharmacokinetics and DNA adducts; and chemical risk assessment. A common strategy in this food safety research is the integration of toxicokinetics and human biomonitoring with PBPK modelling to minimise uncertainty in the extrapolation of human risks from experimental animal toxicity testing. More than 280 peer-reviewed publications have resulted from this work. Dr Doerge has served on chemical risk assessment advisory committees for the European Food Safety Authority (2008–2016), the World Health Organization (2005, 2010, 2016), and the US Environmental Protection Agency (2008, 2014). He also served as Editor-in-Chief for Archives of Environmental Contamination and Toxicology (2006–2013).

Exposure to oestrogenic compounds through the diet and the environment is an ongoing public health focus. This focus is based on a hypothesis that some endocrine-active compounds bind to oestrogen receptors to a sufficient degree to affect genomic signalling and so adversely impact normal endocrine function in animals and humans that over time leads to a number of diseases. For example, extensive research and risk assessment activity has centred on the potential for adverse effects from exposure to the food contact-associated oestrogenic chemical bisphenol A (BPA), especially during the perinatal period. A large body of pharmacokinetic evidence from rodents, non-human primates and humans that includes exposures during early neonatal and adult life stages has been incorporated into PBPK models for BPA. Circulating concentrations of BPA in individuals with an average or high consumption of canned foods are consistently in the low picomolar range. The modelled outputs for internal dosimetry from rodent and human models can also provide chemical-specific factors for use in computing health-based guidance values from toxicological studies in rodents. In addition, the plausibility of oestrogen receptor-mediated effects from BPA, based on measurements in serum and/or urine of BPA, dietary oestrogens [genistein (GEN), daidzein (DDZ)], and endogenous hormones [estrone (E1), estradiol (E2), estriol (E3), and the fetal liver-derived estetrol (E4)], was evaluated using mathematical calculations of fractional receptor occupancy (FRO) and relative responses (RR) for activation of oestrogen receptors (ERα and ERβ) in the presence of serum binding proteins (SHBG and albumin) in a cohort of pregnant women. These comparisons were made to critically evaluate the hypothesis that serum BPA must contribute sufficient added activity to shift total oestrogenicity by a meaningful increment of normal intraindividual daily variability to be considered important. The median FRO for BPA was five orders of magnitude lower than E1, E2, or E3 and three orders of magnitude lower than E4, GEN or DDZ. Likewise, based on the RR values, E3 was the most potent serum oestrogen during pregnancy (median RR values of 0.746 and 0.794 for ERα and ERβ receptors, respectively). The median RR values for E2 were 0.243 for ERα and 0.167 for ERβ. The RR values for the remaining oestrogens were consistently less than 0.01. Moreover, RR values were even lower for the dietary oestrogens, GEN and DDZ and BPA. Also, these minor interactions with BPA were dwarfed by the intraday and interindividual variability in the activity from endogenous oestrogens present in the pregnant women. Similarly, the receptor-binding levels of endogenous oestrogens in normally cycling non-pregnant women suggest that BPA interactions would also be negligible. A consistent body of evidence comprising: (1) classical pharmacokinetic and PBPK modelling approaches that indicate minimal internal exposures from realistic doses; and (2) the implausibility of observable oestrogenic actions in ordinary pregnant women, reaffirms the conclusions of most regulatory bodies world-wide that exposure to BPA resulting from approved food contact uses is safe.

Integrating pharmacokinetics and pharmacodynamics in AOPs for next generation risk assessments

Frédéric Bois *French National Institute for Industrial Environment and Risks*

Frédéric Y. Bois is an internationally known expert in pharmacokinetics, toxicology and risk assessment. He is currently Research Director at L'Institut national de l'environnement industriel et des risques (INERIS). He has directed, at the University of California at Berkeley, at the Lawrence Berkeley Laboratory and at INERIS many research projects for the US Food and Drug Administration, the National Institute of Health, the US Environmental Protection Agency, the US Occupational Safety and Health Administration, and the European Commission

(currently, projects Euromix, StemBANCC, EU-ToxRisk, OpenRiskNet). His current research focuses on Bayesian and ab initio methods for PBPK and quantitative AOP models, with application to endocrine disruption and in vitro to in vivo extrapolation.

Quantitative analysis and modelling of data are some of the most important aspects of risk analysis and assessment. Relevant modelling activities are often divided into pharmacokinetics (PK; related to exposure assessment) and pharmacodynamics (PD; related to dose–response) in a rather simplistic way. We tend towards a fusion of the two disciplines into systems toxicology, at the point where they meet. In any case, modelling has always been important for low-dose extrapolation, exposure route adjustments or assessing the impact of inter-individual variability. Yet, new challenges are emerging that we will focus on in this talk: quantitative in vitro to in vivo extrapolation, high-throughput and high-content data integration, and integration within the adverse outcome pathway (AOP) framework. In response to the need for in vitro data integration and extrapolation, PK modelling has definitely taken a physiological (PBPK) turn in the last 10 years. Models of drug distribution of chemicals in animal and human bodies have dramatically improved, but new models are now being developed to address the complexity of the new in vitro systems. We have the example of a zebrafish model, useable for human and ecological risk assessments. A whole series of PK models of in vitro systems is also being developed in ongoing projects such as EU-ToxRisk. In parallel, the methods for fast simulations and calibration of complex models with experimental data have also been considerably improved over the last decade. AOP models are also being actively developed. Given their potential number and complexity, the best mathematical tools to use are not precisely known at the present time. For extrapolation purposes, we would probably favour systems toxicology models, which are fundamentally mechanistic, like physiologically based PK models. Yet, they can be extremely complex and data hungry. Statistical models (such as linked non-linear regression relationships or Bayesian networks) might be simpler to develop, but they may have more restricted applications. In-between, there is a whole range of pharmacodynamic models, such as the effect compartment model, often used in pharmacology, but much less so in toxicology. Research is very active in those areas and it is likely that, for quite a while, the various approaches will co-exist. To illustrate the above considerations, I will present our recent PK/PD modelling of the effects of random mixtures of aromatase inhibitors on the dynamics of women's menstrual cycles. Using high-speed computer code, we simulated random exposures to millions of potential mixtures of 86 aromatase inhibitors present both in the US EPA ToxCast and ExpoCast databases. A PK model of intake and disposition of the chemicals was used to predict their internal concentration as a function of time (up to 2 years). In vitro concentration–inhibition relationships for aromatase were collected from ToxCast and corrected for cytotoxicity. The resulting total aromatase inhibition was input into a mathematical model of the hormonal hypothalamus–pituitary–ovarian control of ovulation in women. At aromatase inhibitor concentrations leading to over 10% inhibition of estradiol synthesis, noticeable (eventually reversible) effects on ovulation were predicted. Exposures to single chemicals never led to such effects. However, a few per cent of the combined exposure scenarios were predicted to have potential impacts on ovulation, and hence fertility. These results demonstrate the possibility to predict large-scale mixture effects for endocrine disrupters with a predictive toxicology approach, suitable for high-throughput ranking and risk assessment.

The exposome in practice

Paolo Vineis *Imperial College*

Professor Paolo Vineis is a leading researcher in the fields of molecular epidemiology and exposomics. His latest research activities mainly focus on examining biomarkers of disease risk, complex exposures and intermediate biomarkers from 'omic platforms (including metabolomics and epigenetics) in large epidemiological studies as well as studying the effects of climate change on non-communicable diseases. He has more than 800 publications (many as leading author) in journals such as Nature, Nature Genetics, Lancet, Lancet Oncology. He is a member of various international scientific and ethics committees (including the Committee of the US National Academy of Sciences on 21st Century Risk Assessment) and vice-chair of the Ethics Committee at the International Agency for Research on Cancer (IARC,WHO). He has been a member of the Scientific Council of IARC. Professor Vineis has extensive experience in leading International projects. He is currently coordinating the European Commission-funded Exposomics project (valued at €8.7m, started in 2012) and the Horizon 2020-funded project Lifepath (valued at €6 million, started in 2015). He is a Principal Investigator/Co-investigator of numerous international research projects, such as the European Commission funded GENAIR, ECNIS2, Envirogenomarkers, Hypergenes, ESCAPE and Transphorm networks, in which he has led Work Packages. In addition he has attracted grants from the Leverhulme Trust, MRC, Cancer Research UK, and the US National Cancer Institute. He is the director of the Unit of Molecular and Genetic Epidemiology, HuGeF Foundation, Torino, Italy and leads the Exposome and Health theme of the MRC-PHE Centre for Environment and Health at Imperial College. http://www1.imperial.ac.uk/medicine/people/p.vineis

The identification of hazardous environmental pollutants is complex, particularly in relation to chronic, non-communicable diseases. The main contributors to this complexity are the diversity of hazards that may exist, the typically low levels of environmental contaminants/pollutants, long latency periods and largely unknown modes of action. The unravelling of environmental causes of disease is also limited by the technical difficulties in defining, and accurately measuring exposures and by considerable spatial, temporal and intraindividual variation. The complex and partially unknown interaction with underlying genetic and other factors that modulate susceptibility and response to environmental exposures further complicates the process of delineating and understanding environmental hazards. To address such difficulties, the concept of the 'exposome' was proposed, initially by Wild (2005), with more recent detailed development in relation to its application to population-based studies (Wild, 2012). The original concept was expanded by others, particularly Rappaport and Smith (2010) who functionalised the exposome in chemicals detectable in biospecimens. The exposome concept refers to the totality of exposures from a variety of sources including, but not limited to, chemical agents, biological agents, radiation and psychosocial component from conception onward, over a complete lifetime, and offers a conceptual leap in studying the role of the environment in human disease (Rappaport and Smith, 2010; Wild, 2012; Vineis et al., 2017). I will show examples from recent projects in the field.

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EU-ToxRisk: towards new chemical safety testing strategies using new approach methods

Bob van de Water *Leiden University*

Bob van de Water (Leiden University) received his PhD (cum laude) from Leiden University in 1995. Since 2006 he has been full professor for Drug Safety Sciences at the Leiden Academic Centre for Drug Research and chairs the Division of Drug Discovery and Safety. His research is focused on the mechanistic uncovering of chemical-induced target organ adversity through the application of 'omics approaches with a focus on liver and kidney toxicity. Molecular insights are used to establish fluorescent reporter-cell models for 2D and 3D application to quantitatively monitor adverse drug action using automated live-cell microscopy. These data are integrated in quantitative systems biology modelling approaches for safety testing. He is coordinator of the H2020 EU-ToxRisk project, a European flagship project for alternative-to-animal testing strategies for quantitative human chemical safety assessment. He participates in two translational drug safety projects supported by the Innovative Medicines Initiatives: TransQST and eTRANSAFE. He also leads the Eu-BioImaging Dutch High Throughput Microscopy Node, a screening facility for systematic imaging-based automated quantitative-cell biological 2D and 3D phenotyping.

The large-scale EU-ToxRisk project is an integrated European 'flagship' programme with the vision to establish a paradigm shift in toxicity testing and risk assessment for the 21st century by implementing mechanism-based integrated testing strategies using non-animal new approach methods (NAMs). To accomplish this the EU-ToxRisk project has united all relevant scientific disciplines covering in silico QSAR modelling, cellular toxicology, bioinformatics and PBPK modelling. We test the integration of the different NAMs in various case studies, ultimately establishing: (i) pragmatic, read-across procedures incorporating mechanistic and toxicokinetic knowledge; and (ii) from the beginning hazard and risk assessment strategies of chemicals with little background information. The case studies are focused on repeated dose systemic toxicity (RDT) targeting either liver, kidney, lung or nervous system toxicity, as well as developmental/reproduction toxicity (DART). The integration of the various NAMs in defined case studies allows the assessment of the overall applicability domain of these NAMs in chemical hazard and ultimate risk assessment. Case studies are centred around AOPs and include e.g. the application of NAMs for the assessment of: (i) microvesicular liver steatosis induced by valproic acid analogues; (ii) the prediction of teratogenic effects of valproic acid analogues; and (iii) the application of NAMs to assess the AOP pathway related to inhibition of the mitochondrial respiratory chain complex 1 of nigra striatal neurons leading to parkinsonian motor deficits. Importantly, the activities in the case studies are supported and guided by both cosmetics, (agro)chemical, pharma industry stakeholders as well as various European regulatory authorities. The final goal is to deliver testing strategies to enable reliable, animal-free hazard and risk assessment of chemicals based on mechanistic understanding of chemical toxicity.

Assessment of chemical mixture-induced developmental neurotoxicity using human in vitro model

Anna Price *Joint Research Centre*

Anna Price (Bal-Price) obtained her PhD in Life Sciences in 1990 at the Polish Academy of Sciences, Institute of Pharmacology in Krakow (Poland). With over 25 years of experience she has acquired a strong research background in the fields of neuroscience and in vitro neurotoxicology.

Before joining the European Commission Joint Research Centre (JRC) (Ispra, Italy) in 2002 she worked at the Department of Biochemistry of Cambridge University (Cambridge, UK) working on nitric oxide role in the central nervous system physiology and neuropathology of Parkinson's and Alzheimer disease.

Currently she is working for Directorate F: Health, Consumers and Reference Materials, Unit Chemicals Safety and Alternative Methods. She is working on a strategy for developmental neurotoxicity (DNT) testing using in vitro approaches based on human-induced pluripotent stem cells-derived neuronal/glial models, applying emerging technologies including 'omics analysis, microelectrode arrays (MEA chips), proteins and mRNA measurements. Recently, she has been strongly involved in the development of Adverse Outcome Pathways and Integrated Approaches to Testing and Assessment relevant to DNT evaluation for different regulatory purposes.

She is a member of the OECD steering committee on developing OECD Guidance Document for application of in vitro assays and interpretation of in vitro data for regulatory DNT testing.

She was also involved in the management of EU integrated FP 6 and FP7 projects including SEURAT (ScreenTox), DENAMIC, PREDICT IV, ARTEMIS, ACUTE-Tox as a leader of WPs linked to developmental and adult neurotoxicity evaluation.

She is a member of Neurotoxicology journal editorial board and a guest editor of Toxicology and Applied Pharmacology.

She has published many papers in peer-reviewed journals, and she is a co-editor of two books published by Springer: Cell Culture Techniques. Neuro-methods, Humana Press, NY, 2011 and In Vitro Toxicology Systems Springer, Humana Press, NY, 2015.

Chemicals that are known to trigger specific developmental neurotoxicity (DNT) effects belong to different chemical classes including industrial chemicals, persistent organic pollutants (POPs), metals and pesticides. These chemical belong to multiple regulatory silos on food and food quality, such as pesticides, food contact materials and food additives including flavourings, colourings and preservatives. These examples illustrate that common, similar or related toxic effects triggered by various chemicals may be differently regulated and that combined effects of these chemicals across different regulatory domains are not currently considered. At the same time it is well documented in the existing literature that 'mixture effects' can be greater than effects triggered by the most potent single chemical in a mixture, and that mixture effects may be additive or, in some cases, even synergistic. Therefore, the implementation of mixture risk assessments (MRA) for DNT evaluation, is strongly advocated as infants and children are indisputably co-exposed to more than one chemical at the time. Indeed, for example, breast milk has been found to contain chemicals regulated as pesticides, along with those regulated as cosmetics (including UV filters parabens, phthalates), together with POPs including polychlorinated biphenyls (PCBs), confirming that simultaneous co-exposure to multiple chemicals occurs in babies and during pregnancy (Schlumpf et al., 2010; de Cock et al., 2014). A challenge for the evaluation of DNT effects induced by chemicals is that the neurodevelopmental outcome depends not only on the kind of exposure (dose, duration) but also on the developmental stage of the brain at the time of exposure.

Therefore, in this study we proposed to use a mixed culture of neuronal and glial cells derived from human induced pluripotent stem cells as this in vitro model makes it possible to evaluate a chemical impact on key neurodevelopmental processes (including cell proliferation, migration and morphological/functional neuronal and glial differentiation) mimicking critical stages of the human brain development. Moreover, the applied in vitro assays were anchored to the selected neurodevelopmental processes that overlapped with common key events identified in adverse outcome pathways (AOPs) relevant to impairment of learning and memory in children that is the most frequent adverse outcome identified in the existing DNT AOPs (Bal-Price and Meek, 2017).

The effects of the selected compounds (administered as a single chemical or in mixtures) were assessed on human neural precursor cells that were undergoing differentiation to determine synergistic, antagonistic or additive effects on brain-derived neurotrophic factor (BDNF) level, neurite outgrowth and synaptogenesis after short-term (72 h) or long-term exposure (14 days in vitro).

The obtained data suggest that low, non-/cytotoxic concentrations, below lowest-observed-effect concentrations (LOAECs) of single chemicals become neurotoxic in mixtures, especially for the chemicals working through a similar mode of action and after 14 days of exposure. During this presentation the mixture-induced developmental neurotoxicity, in comparison with single compounds, will be discussed to determine whether it was induced by synergistic or additive effects.

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Assessing the safety of genetically modified food/feed: the GRACE and G-TwYST experience

Pablo Steinberg *Federal Research Institute of Nutrition and Food*

1976–1982 Pablo Steinberg studied Biochemistry at the Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Argentina;

1985 PhD in Pharmacology at the Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Argentina;

1986–1987 Scholarship of the Alexander von Humboldt-Foundation to work at the Institute of Toxicology, University of Mainz, Germany;

1988–1995 Research Group Head at the Institute of Toxicology, University of Mainz, Germany;

1996–1998 Heisenberg Fellowship from the German Research Council at the Institute of Toxicology, University of Mainz, Germany;

1998–2008 Chair of Nutritional Toxicology (Full Professorship) at the Institute of Nutritional Science, University of Potsdam, Germany;

2002–2008 Director of the Institute of Nutritional Science, University of Potsdam, Germany;

2008–2017 Full Professor for Food Toxicology and Replacement/Complementary Methods to Animal Testing, Institute for Food Toxicology and Analytical Chemistry, University of Veterinary Medicine Hannover, Germany;

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The classical risk assessment paradigm is based on the seminal report Risk Assessment in the Federal Government: Managing the Process (the so-called Red Book) by the National Research Council, an affiliate of the National Academy of Sciences in the USA. The 1983 National Research Council report identified four steps integral to any risk assessment: (1) hazard identification; (2) dose–response assessment; (3) exposure assessment; and (4) risk characterisation. While this four-step process has been used to assess the risk emanating from thousands of chemicals since the 1980s, a very controversially discussed issue is whether the above-mentioned paradigm can be applied to assess the risk derived from genetically modified (GM) plants, particularly as regards the use of animal studies. In this context, it is important to mention that on the 8 December 2013 Regulation (EU) No. 503/2013 on applications for EU market authorisation of genetically modified food and feed in accordance with Regulation (EC) 1829/2003 became fully effective and requires a mandatory 90-day rodent feeding study on the whole GM food/feed for single transformation events. Following a request from the European Commission, EFSA's Scientific Committee developed principles and guidance for the establishment of protocols for 90-day whole food/feed studies in rodents (EFSA, 2011). In a later explanatory statement (EFSA, 2014), EFSA provided instructions on how to apply the general principles described in the EFSA Scientific Committee Guidance for the study design and analysis of such 90-day oral for GMO risk assessment and described two possible scenarios:

- scenario 1 – when a specific hypothesis is available, i.e. the preceding analyses (the comparative assessment of the compositional and agronomic-phenotypic characteristics of the genetically modified crop) have identified a potential risk(s);
- scenario 2 – when no specific hypothesis is available, i.e. no potential risk has been identified.

Upon request from the European Commission, EFSA also prepared a scientific report that would aid the future establishment of protocols for chronic toxicity and/or carcinogenicity studies in rodents with whole food/feed (EFSA, 2013). Two EU-funded projects, GRACE (GMO Risk Assessment and Communication of Evidence) and G-TwYST (Genetically modified plants Two Year Safety Testing), performed animal feeding trials and alternative in vitro methods with two different genetically modified maize varieties to determine how suitable they are and what useful scientific information they provide for the health risk assessments of GM food and feed. Subchronic and chronic toxicity as well as carcinogenicity testing was conducted in rats by taking into account on the one hand published OECD Test Guidelines for the testing of single chemicals and conversely the above-mentioned EFSA documents. In the frame of the GRACE project, 90-day feeding trials as well as a 1-year feeding trial with two genetically modified MON810 maize varieties and several different near-isogenic varieties were performed (Zeijenkova et al., 2014; Zeijenkova et al., 2016; Schmidt et al., 2017). Moreover, 'omics as well as in vitro (cell culture) approaches were performed to evaluate their possible added value in the overall risk assessment of genetically modified crops (van Dijk et al., 2014;

Sharbati et al., 2017). Based on the EFSA explanatory statement (EFSA, 2014), the OECD Test Guideline 453 as well as the scientific report by EFSA on the applicability of the OECD Test Guideline 453 to whole food/feed testing (EFSA, 2013) and taking into account possible concerns raised by a publication on the long-term toxicity of the genetically modified maize NK603 (Séralini et al., 2012) the G-TwYST consortium performed, among a number of other tasks, two 90-day feeding trials as well as a combined 2-year chronic toxicity/carcinogenicity study in rats with the genetically modified maize NK603. In a first step, the main findings of the different experimental approaches in the GRACE and G-TwYST projects will be summarised. Based on the experience gained in these two EU-funded research projects, particular aspects of the study design (e.g. choice of the rodent strain, 'dose' of the genetically modified crop to be tested, etc.) as well as the added value of rodent feeding trials in the frame of the risk assessment of genetically modified crops under EFSA's scenario 2 (i.e. In the case that relevant changes and/or specific hazards have not been identified in preceding analyses) will be discussed. In this context, the advantages and limitations of presently available new tools ('omics as well as in vitro techniques) will be highlighted. Moreover, particular new developments in the statistical analysis of the data obtained in rodent feeding trials will be presented. Transparency, engagement of stakeholders and Responsible Research and Innovation (RRI) principles were considered.

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In silico tools to predict potential coeliac disease toxicity

Frits Koning *Leiden University Medical Center*

Professor of Immunology, Leiden University Medical Centre, Leiden, the Netherlands

Professor Frits Koning has been a staff member in the Department of Immunohematology and Blood Transfusion (150 fte) of the Leiden University Medical Centre since 1993. He is the chairman of the scientific advisory board of the LUMC and the CEO of the Dutch Coeliac Disease Consortium (CDC) in which immunologists, geneticists, food specialists and medical doctors collaborate with industrial partners to improve the quality of life of patients with coeliac disease (CD). He is well recognised for his contributions to the field of immune-mediated disorders, coeliac disease in particular. Through his work it is now well established which gluten fragments are disease causative and how they are recognised by disease-related T cells, providing a molecular basis for the genetic association between HLA-DQ and coeliac disease. In his most recent work he uses high dimensional flow cytometry to unravel the involvement of the innate and adaptive immune system in Inflammatory Bowel Diseases.

Coeliac disease (CD) is a disease of the small intestine characterised by flattening of the intestinal surface, resulting in a variety of clinical symptoms including malabsorption, failure to thrive, diarrhoea and stomach ache. The disease is caused by an uncontrolled intestinal CD4 T-cell response to gluten proteins in wheat (Triticum spp.) and to gluten-like hordeins and secalins in barley (Hordeum vulgare) and rye (Secale cereale). Oat (Avena sativa) is generally considered safe for patients, although exceptions have been reported. The only available treatment is a lifelong gluten-free diet implying the exclusion of all food products that contain wheat, barley and rye or gluten and gluten-like proteins from these grains.

CD has a strong genetic component as it is associated with particular immune response genes, called human leukocyte antigens (HLA) in man. Most CD patients express particular HLA-DQ molecules. HLA-DQ molecules are dimers composed of an alpha-chain (DQA1) and a beta-chain (DQB1). Like all HLA molecules HLA-DQ molecules bind short peptides and present these to T cells from the immune system. The large majority of CD patients expresses HLA-DQ2.5 while the remainders are usually HLA-DQ8 positive. In patients, but not in healthy individuals, pro-inflammatory gluten-specific CD4+ T cells are present in the lamina propria of the affected duodenum. Importantly, these CD4+ T cells recognise gluten peptides only when presented by the disease-associated HLA-DQ molecules. In essence, in patients with CD, the immune system

makes a mistake: the harmless gluten proteins in food are recognised as if they are derived from a pathogen, leading to a pro-inflammatory response as long as gluten is consumed. Elimination of gluten from the diet constitutes an effective treatment as the T-cell stimulatory gluten peptides are no longer present. Unfortunately, once a gluten-specific T-cell response has developed, this results in immunological memory. Therefore, every subsequent exposure to gluten will reactivate the gluten-reactive T cells and results in inflammation. A lifelong gluten-free diet is thus required.

T-cell epitopes derived from the α-, γ- and ω-gliadins as well as from high-molecular-weight (HMW) and low-molecular-weight (LMW) glutenins have been reported. In addition, T-cell epitopes in both hordeins and secalins have been identified that are highly homologous or even similar to those found in wheat. Detailed knowledge on these known disease-causative sequences in gluten allows the design of a specific strategy to identify potential harmful sequences in other proteins, a strategy presented in the EFSA guidance on allergenicity assessment of genetically modified plants and will be discussed during the presentation.

Ellen Fritsche *Leibniz Research Institute for Environmental Medicine*

Professor Ellen Fritsche, MD, holds a Professorship for Environmental Toxicology within the Heinrich-Heine University of Düsseldorf. She has a joint affiliation with the IUF – Leibniz Research Institute for Environmental Medicine in Dusseldorf where she leads the Sphere Models and Risk Assessment group. She has been developing species-overarching 3D in vitro models for studying modes-of-action of compounds for developmental neurotoxicity (DNT) in vitro. She has also been involved in AOP generation for (developmental) neurotoxicity. Professor Fritsch was an EFSA working group member and has been working on several EFSA procurements since 2014. Currently, she is a member of the OECD expert group for creating a guidance document for in vitro DNT evaluation.

ADVANCING RISK ASSESSMENT SCIENCE

Nutrition

Single nutrient deficiencies were the major public health concern in the nutrition area for most of the last century. As a consequence, single nutrient diseases, the estimation of the nutrient content of foods and nutrient intakes, and the estimation of minimum nutrient requirements compatible with good health were a main target for nutrition research and dietary advice. However, in the last quarter of the last century, the prevalence of diet-related chronic metabolic diseases – such as obesity, cardiovascular diseases and type 2 diabetes – and their impact on the morbidity and mortality of Western populations increased steadily, shifting the spotlight in the nutrition area.
The session aims at fostering the ongoing debate on the power of single nutrients, foods and diets to impact human health in wealthy populations, as well as at exploring how societal and technological developments could impact food choices and diets in the future. The overarching goal of the session is to explore how dietary guidelines should evolve to address the switch from nutrient deficiencies to diseases of excess as the predominant public health concern in developed countries.

CHAIRS

Valeriu Curtui *European Food Safety Authority*

Valeriu Curtui is head of EFSA's Nutrition Unit. His role is to manage the Unit in providing scientific and administrative support to the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies. Valeriu joined EFSA in 2008 as a scientific officer working on chemical occurrence in food and dietary exposure and took up his current role in 2013. Before his employment with EFSA, he was an academic at universities in Romania and Germany. His teaching and research activity focused on toxicology and chemical food safety. He holds a PhD in veterinary medicine.

Jayne Woodside *Queen's University Belfast*

Professor Jayne Woodside is Professor of Human Nutrition within the Institute for Global Food Security (Centre for Public Health) at Queen's University Belfast. She specialises in the use of biomarkers to assess dietary intake, the conduct of human nutrition intervention studies examining clinically relevant endpoints, and also in interventions to promote long-term dietary change. She has published widely in the nutrition field and has current funding from the Medical Research Council, National Prevention Research Initiative, National Institute for Health Research and Safefood.

RAPPORTEURS

Andrea Germini *European Food Safety Authority*

Andrea Germini is a food scientist currently working as a scientific officer at EFSA's Nutrition Unit. Before joining EFSA, he was assistant professor at the University of Parma. Since joining EFSA, he has been working on the development of cross-cutting guidance documents for EFSA risk

assessment and the characterisation and safety assessment of regulated products in the area of GMOs, novel foods and food supplements. Andrea holds a PhD in food science and technology with a focus on food biomolecules.

Silvia Valtueña Martinez *European Food Safety Authority*

Silvia Valtueña Martínez is senior scientific officer at EFSA's Nutrition Unit, where she deals with the scientific evaluation of health claims made on foods, novel foods, infant formulas/ dietetic foods, dietary reference values and upper tolerable intake levels of nutrients, and food allergens for labelling purposes. She holds a PhD in human nutrition, and has conducted independent research on the relationship between diet and development of chronic disease, namely obesity, osteoporosis, diabetes and cardiovascular diseases.

SPEAKERS

Socratic debate: Do sugars cause chronic metabolic diseases?

Graham MacGregor *Queen Mary University of London*

Professor MacGregor is Professor of Cardiovascular Medicine at the Wolfson Institute of Preventive Medicine and Honorary Consultant Physician at Barts and The London. He is Chairman of Blood Pressure UK, recently served as President of the British Hypertension Society, and is founder and Chairman of CASH (Consensus Action on Salt and Health) and WASH (World Action on Salt and Health) and Action on Sugar, which has been working with great success to slowly reduce the salt and sugar of all processed foods and increase public awareness surrounding salt, sugar and its effects on health. Professor MacGregor's research work has focused on the mechanisms underlying the rise in blood pressure in hypertension, the importance of the renin–angiotensin system, and the influence of salt and potassium intake. His research has also focused on better ways of treating patients, particularly non-pharmacological ways, and also the better use of drugs for the treatment of high blood pressure.

The Global Burden of Disease study clearly demonstrates that a diet containing unhealthy food that is high in sugar, salt and fat and lacks fruit and vegetables is by far the biggest cause of death and disability. Sugar is an unnecessary source of calories that was not consumed in any quantity until quite recently. It plays an important role in obesity because it does not give any feeling of satiation, e.g. sugars in soft drinks. It also causes dental caries. Whether sugar has direct toxic effects independently of this is a matter of controversy. Several studies have suggested that increased sugar intake particularly in sugar-sweetened drinks is a direct cause of type 2 diabetes and some evidence suggests that excessive sugar intake may be associated with fatty liver disease. But the evidence for other harmful effects of sugar, independent of its obesogenic and cariogenic properties, is controversial.

Socratic debate: Do sugars cause chronic metabolic diseases?

John Sievenpiper *University of Toronto*

Dr Sievenpiper is a Clinician Scientist who holds appointments as an Associate Professor in the Department of Nutritional Sciences and the Lifestyle Medicine Lead in the MD Program at the University of Toronto, Canada. He also holds appointments as a Staff Physician in the Division of Endocrinology and Metabolism and Scientist in the La Ka Shing Knowledge Institute at St Michael's Hospital. Dr Sievenpiper completed his MSc, PhD and Post-doctoral Fellowship training in the Department of Nutritional Sciences at the University of Toronto. He completed his MD at St Matthew's University followed by residency training in Medical Biochemistry at McMaster University leading to his certification as a Fellow of the Royal College of Physicians of Canada (FRCPC). His research is focused on using randomised controlled trials and systematic reviews and meta-analyses to address questions of clinical and public health importance in relation to diet and chronic disease prevention. He currently holds a Diabetes Canada Clinician Scientist Award and Banting and Best Diabetes Centre Sun Life Financial New Investigator Award. He has authored more than 150 scientific papers and 13 book chapters. Dr Sievenpiper is directly involved in knowledge translation with appointments to the nutrition guidelines' committees of Diabetes Canada, European Association for the study of Diabetes (EASD), Canadian Cardiovascular Society (CCS), and the Canadian Obesity Network.

Sugars have replaced fat as the dominant public health target of chronic metabolic diseases. Special attention has focused on the fructose moiety of sugars due to its unique metabolic and endocrine responses. Low quality ecological studies, animal models and select human trials of overfeeding at levels of exposure far beyond mean population levels of intake have been used to support this view. If one considers the totality of the highest level of evidence from prospective cohort studies and controlled feeding trials, then different conclusions are reached. Although systematic reviews and meta-analyses of cohort studies have shown a significant positive association of sugar-sweetened

beverages (SSBs) with incident obesity, diabetes, heart disease and stroke, systematic reviews and meta-analyses involving the same cohorts have failed to show the same adverse associations for total sugars, sucrose, or fructose (all of which include SSBs) or other important food sources of sugars including fruit, fruit juice, yogurt and breakfast cereals, many of which show protective associations. Similarly, systematic reviews and meta-analyses of controlled feeding trials have shown that sugars behave no worse than other sources of carbohydrates likely to replace them in energy matched comparisons. Sugars only appear to contribute to weight gain and cardiometabolic disturbances (increased blood lipids, uric acid, glucose, insulin resistance, and markers of non-alcoholic fatty liver disease) in hypercaloric comparisons in which excess calories from sugars (especially from SSBs) are added to diets compared with the same diets without excess calories. Taken together, sugars do not appear to contribute uniquely to obesity and diabetes. Any adverse effects of sugars appear to be mediated by excess calories and food form rather than any special metabolic or endocrine responses to the fructose in sugars.

Socratic debate: Do saturated fats cause chronic metabolic diseases?

Philippe Legrand *National Institute of Agricultural Research*

PhD in Nutritional Biochemistry from University of Paris in 1987 and post-doc at Cornell University (USA) in the Division of Nutritional Sciences. He is Professor and chairman of the laboratory of Biochemistry and Human Nutrition in the Agronomic University of Rennes (Agrocampus). For more than 30 years, he has performed research on fundamental aspects of fatty acid synthesis and metabolism. More precisely, he has worked on the role of fatty acid desaturases showing the importance of stearic acid desaturase, showing that the conversion of poly-unsaturated n-6 and n-3 fatty acid shared the same desaturases, leading to the recommendations on the required n-6/n-3 balance in human diet. He has also worked for 15 years on saturated fatty acids, showing their nutritional interest and the necessary evolution to distinguish between short / middle chain / long chain saturated fatty acids. He is chairman since 1998 of the French guidelines committees for the fatty acid dietary recommendations, in the Food Safety Agency (ANSES) where he proposed a new approach for considering lipids in general, and more precisely saturated fatty acids. Author of more than 300 publications on Lipids, he recently received the CHEVREUL Medal award in Uppsala (Sweden) for his research production in the field of lipids in Nutrition. He is a member of the International Society for the Study of Fatty Acids and Lipids (ISSFAL), a member of the board of the French Nutrition Society (SFN) and has worked several times as an expert for European institutions.

Dietary saturated fatty acids (SFA) were usually associated with negative consequences for human health because of their negative impact on some atherosclerosis biomarkers in cases of excess. However, we must first be reminded that SFAs are nutrients and not poisons and have different types of metabolism depending on their chain length, for instance. Moreover, the literature demonstrates that all SFA have important and specific biological roles in the cell, showing that they cannot be considered as a single and homogenous group anymore, in term of structure, metabolism and function. In addition to their energetic function, they are required for membrane structure in phosphoglycerides, sphingolipids, rafts and for elucidating biochemical mechanisms such as protein acylation (N-myristoylation, S-palmitoylation, octanoylation) and have physiological roles such as pulmonary surfactant and other specific nutritional functions.

Even for cardiovascular disease (CVD) prevention, new data and meta-analysis allow a balanced view in terms of risk and suggest a reassessment of the recommendations. Most reports supporting the risks are not isoenergetic nor isocaloric and do not even precisely describe the short, middle or long chain saturated fatty acids. Such weakness in the epidemiological data invites a reassessment of the current nutritional dietary recommendations for saturated fatty acids, as recently carried out in France under the ANSES guidelines. In these guidelines, distinction among saturated fatty acids has been made, and only the lauric, myristic and palmitic acid subgroups were considered the ones being atherogenic and only in cases of excess.

We need more information on doses, physiological effects, specificities and functions of individual saturated fatty acids. Hence, its time for up-to-date recommendations without the caricatural old statements of SFAs toxicity or eviction.

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Socratic debate: Do saturated fats cause chronic metabolic diseases?

Ronald Mensink *Maastrick University*

Ronald P. Mensink received an MSc degree in human nutrition at the Agricultural University in Wageningen. In addition, he has an MSc degree in epidemiology. His primary research interests are the relationships between nutritive and non-nutritive components in the diet with chronic metabolic stress, particularly related to cardiovascular disease. For this, dietary intervention studies have been carried out with human volunteers. Studies are designed not only to look at physiological and functional effects, but also to unravel the biochemical and molecular mechanisms underlying these effects. Knowledge obtained from studies under 'normal' conditions is applied to study and understand metabolic disturbances involved in etiology of cardiovascular disease. Using non-invasive techniques, the strong focus is on components that affect peripheral vascular function and lipid metabolism. Whenever possible, other aspects of chronic metabolic stress (e.g. low-grade systemic inflammation, insulin-resistance) are studied, frequently in collaboration with other researchers. This has resulted in a new line of research on the interplay between low-grade systemic inflammation, HDL metabolism and vascular function. Also, in recent projects cerebrovascular function as related to cognitive performance plays a central role. The ultimate aim of the studies is to provide evidence-based information supporting the development of foods, dietary guidelines or health claims.

One key recommendation in many dietary guidelines for reducing the risk of coronary heart disease (CHD) is to consume not more than 10% of energy from saturated fatty acids (SFA). This advice is partly based on the overwhelming evidence from controlled dietary intervention studies that a mixture of SFA increases LDL-cholesterol concentrations. For dietary recommendations, we have to rely often on biomarkers and LDL-cholesterol is an accepted biomarker to estimate CHD risk. Further, also randomised controlled trials have suggested that replacement of SFA with polyunsaturated fatty acids reduces cardiovascular events. Prospective epidemiological studies, however, have not consistently shown an association between SFA intakes with CHD. These latter findings should not be ignored but should also not be used as a conclusive argument that SFA intake is not related to CHD. For example, epidemiological studies do often also not show a relationship between SFA intake with LDL-cholesterol. This is not only related to the fact that it is difficult to estimate accurately dietary intakes at the individual level, but also because of variations in serum LDL-cholesterol concentrations between and within individuals, which are only partly due to differences in dietary composition. Further, it should be appreciated that – when energy intake does not change – reducing the intake of SFA means increasing the intake of another macronutrient. SFA can be replaced by other types of fatty acids, by carbohydrates and by proteins. Each replacement may result in different metabolic effects. It is also known that the different SFA are different metabolic effects, but not much is known whether these different SFA have different health effects. Another important question is what the best (set of) biomarker(s) is to predict CHD. In addition, the different SFA may differently affect pathways not related to lipoprotein metabolism. These outstanding questions must be answered in future studies. For now, the most convincing evidence is that – as long as SFA intakes is above recommended intakes – substitution of a mixture of SFA by cis-unsaturated fatty acids is preferred over substitution by high-glycaemic index carbohydrates.

Dietary prevention of chronic metabolic diseases: single-nutrient and popular diets vs whole dietary patterns

Dariush Mozaffarian *Tufts Friedman School of Nutrition Science & Policy*

Dariush Mozaffarian is a cardiologist, a Jean Mayer Professor of Nutrition and Medicine, and Dean of the Friedman School of Nutrition Science and Policy at Tufts University, USA. The oldest and most renowned graduate school of nutrition in North America, the Friedman School's mission is to produce trusted science, future leaders, and real-world impact. He has authored more than 300 scientific publications on the dietary priorities to reduce cardiovascular disease, diabetes, and obesity in the USA, and globally, and on evidence-based systems innovations and policies to effectively reduce these burdens. Dr Mozaffarian has served in numerous advisory roles including for the US and Canadian governments, American Heart Association, Global Burden of Diseases study, World Health Organization, and United Nations. His work has been featured in the New York Times, Washington Post, Wall Street Journal, National Public Radio, Time Magazine, and many other outlets. In 2016, Thomson Reuters named him as one of the World's Most Influential Scientific Minds.

Dr Mozaffarian received his BS in biological sciences from Stanford (Phi Beta Kappa), an MD from Columbia (Alpha Omega Alpha), and clinical training in internal medicine and cardiovascular medicine from Stanford and the University of Washington. He also holds an MPH from the University of Washington and a Doctorate in Public Health from Harvard. Before being appointed as Dean at Tufts in 2014, Dr Mozaffarian

was at Harvard Medical School and Harvard School of Public Health for a decade and clinically active in cardiology at Brigham and Women's Hospital. He is married, has three children, and actively trains as a Black Belt (second degree) in Taekwondo.

The Friedman School pursues cutting-edge research and education across five Divisions from cell to society. Areas of faculty expertise include molecular nutrition, human metabolism, data sciences, clinical trials, behavior change, community and organizational interventions, media and communication, food systems and sustainability, global food security, humanitarian crises, and food economics and policy. Friedman School graduates are active in academics, policy, advocacy, government, industry, public health, community service, and entrepreneurship. The School's unique breadth, engagement with the world, and entrepreneurial spirit make it a leading institution for nutrition education, research, and public impact.

In recent years, global dietary patterns have shifted dramatically. At the same time, nutrition science has been transformed by rigorous evidence from well designed metabolic studies, prospective cohorts and randomised trials. Several key lessons have emerged:

- First, dietary habits influence diverse cardiometabolic risk factors, including obesity, blood cholesterol, blood pressure, glucose–insulin homeostasis, lipoproteins, inflammation, endothelial health, liver, fat cell, and heart function, energy expenditure, weight regulation and the microbiome. So, recommendations for any nutrient, food or overall diet should not be extrapolated from any single surrogate outcome, but from the totality of evidence including trials that evaluate multiple risk pathways and prospective cohorts and trials of clinical events. For example, a focus on weight and obesity alone, just like a focus on blood cholesterol in the 1980s, may miss key effects based on other important pathways of diet-related disease. Diet quality influences a myriad of other risk pathways and conditions that together produce larger health burdens other than those related to obesity alone.

- Second, for long-term weight gain and risk of obesity, all calories are not created equally. Different foods have divergent effects on diverse, complex physiological mechanisms of long-term weight homeostasis. Although each calorie of food provides equal in vitro energy, human beings are complex organisms, in whom different foods and drinks produce diverse effects on overlapping pathways related to weight control including hunger, satiety, brain reward, glucose–insulin responses, liver fat production, the microbiome and metabolic expenditure. We should be consuming fewer calories from some foods, especially food rich in refined starches, grains, and sugars and more calories from others, especially fruits, nuts, beans, vegetables, plant oils, seafood, plain yogurt and whole grains.

- A third key lesson is the importance of specific foods and overall diet patterns, rather than single isolated nutrients. Focusing on isolated nutrients often leads to paradoxical dietary choices and industry formulations. So, improving overall food-based patterns should be the primary target of dietary policies. Yet, national and international dietary guidelines and policies in many cases reductionist: reduce calories, total fat, added sugar. This produces peculiar strategies that shun whole milk but recommend sugar-sweetened skimmed milk; recommend lean beef and fat-free salad dressing but warn against vegetables with added fat, nuts, tuna in oil and peanut butter; warn against healthy foods with a little added sugar but not sugar-free foods loaded with starch; and mandate labelling of total calories of foods and meals rather than their overall healthfulness.

This reductionist focus leads to paradoxical consumer decisions, organisational priorities and government policies. At the same time, the public is increasingly confused by an explosion of popular diets, often based on partial and incomplete science. As the global pandemics of obesity and diabetes raise awareness of the immense importance of optimal nutrition, we must remain cautious about accepting dietary targets and policy approaches based on outdated or insufficient science. Advances in nutrition and policy science provide us with a menu of strong, complementary strategies to improve food choices and reduce disease risk. It is among the greatest priorities of the 21st century to now bring stakeholders together to implement and evaluate these strategies.

Food innovation and consumer trends: impact on food consumption and dietary pattern

Petra Klassen Wigger *Nestlé Research Center*

Dr Petra Klassen Wigger is head of the global Nutrition, Health and Wellness Unit at Nestlé Research in Lausanne, Switzerland. She holds a PhD in Nutrition from the University of Hohenheim, Stuttgart. After five years of research activities in Guatemala she joined Nestlé working in different functions, first at the Nestlé Research Centre and later in different marketing functions. During her time as Medical and Scientific Affairs Manager at the Nestlé Nutrition Institute she implemented a digital strategy that strengthened the institute's contribution to the nutrition communication for healthcare professionals. Later on, as Scientific Advisor in the Corporate Nutrition, Health and Wellness Unit she drove the strategy to tackle undernutrition with micronutrient fortification. She also works on understanding and leveraging nutrition and health relevant consumer trends.

The dual burden of malnutrition, manifesting itself in undernutrition, and overweight and obesity, remains a significant public health concern globally. Demographic shifts towards ageing populations do contribute significantly to the increasing

prevalence of non-communicable diseases and the related cost for society. At the same time, digital advances provide consumers with access to an unprecedented amount of information at their fingertips, resulting in increased knowledge and awareness including on nutrition and health. We observe a trend of increased confidence to self-define what healthy eating means, fostered by an endless number of online and offline influencers. This influences the food culture in a way that food is viewed differently and sometimes even as a medicine. As a consequence, the demand for more personalised diet and food choices based on genetic tests, microbiome and metabolic analyses to prevent, or even as therapy for, chronic diseases is increasing.

In many parts of the world we observe an explosion of food and beverage choices at low cost and high availability, contributing to the risk of excessive calorie intake but low nutrient density. Recently a trend towards 'natural foods' has increased and these the consumer often perceive as healthier. While some choices in this context contribute to a balanced diet, there is a risk that some choices may lead to an unbalanced diet. For example, we are seeing in some parts of the world, an emerging trend calling to reduce consumption of fortified foods that may further widen the nutrient gap in vulnerable populations.

There are also ongoing efforts to decrease certain nutrients, such as sugar, sodium, and saturated fats, that are associated with non-communicable diseases. To deliver against the above trends, the development of technological solutions to reformulate products with lower levels of these nutrients, while maintaining palatability, needs to be accelerated. Dietary choices, e.g. the trend towards vegetarian, flexitarian or even vegan diets driven by personal health benefits and environmental sustainability concerns, result in challenges to meet certain nutritional requirements, e.g. for vitamin B12 or iron. Conversely, they come along with opportunities to improve certain nutritional aspects of the diet, e.g. increased intake in fibre, micronutrients, vegetables or pulses. When improving the nutritional profile of products it is important to deliver good taste and a pleasurable sensory experience as these are well recognised drivers of consumption.

While reformulation to improve the nutritional profile of products is important, it is also important to additionally address consumer behaviour towards healthier diets and meet dietary recommendations. As an example, research has demonstrated that consumer preference can be negatively influenced when communicating on pack reduction in sugars or fat and so can have the opposite effect than the desired behaviour change.

For that, collective efforts to educate consumers about safe and nutritious food choices are necessary. Along with these efforts, consumers are increasingly expecting more transparency from food manufacturers about sourcing, processing and ingredient contents. To achieve the goal of improved diets and health, single or isolated interventions are unlikely to have a long-lasting impact. A holistic and multi-stakeholder approach is needed and can help to ensure that the various aspects of a consumer's diet are considered as part of the larger health and wellness ecosystem that supports healthier diets for society.

ADVANCING RISK ASSESSMENT SCIENCE

Biological hazards

Globalisation encompasses the spread and movement of people, animals, food and feed around the planet. Advances in transport and communication technology have intensified the rate of globalisation in the last decade. This increasingly globalised trade in food and feed is associated with the "trade" of hazards and risk. Tracing those threats will be challenging due to the increased complexity of the food supply chain. This session focuses on biological hazards/ threats at global scale and considers the challenges to risk assessment, from a One Health perspective. Three topics – vector-borne zoonoses, microorganisms intentionally introduced to the food chain, and antimicrobial resistance – will be used to illustrate the challenges ahead. The opportunities that new methodologies, such as Next Generation Sequencing (NGS), can offer will be explored and disseminated.

CHAIRS

Mike Catchpole *European Centre for Disease Prevention and Control*

Professor Mike Catchpole is Chief Scientist, at the European Centre for Disease prevention and Control (ECDC), Stockholm. He is a medical doctor who has worked in infectious disease epidemiology and response at national and international levels since 1991. Before working at the ECDC he was Director of Public Health England's National Centre for Infectious Disease Surveillance and Control, and was the UK member of the ECDC Advisory Forum from 2007 until 2014. He has over 20 years' experience of management of communicable disease surveillance and response, including the management of many national outbreak investigations and leadership of the national epidemiological response to the 2009 influenza A(H1N1) pandemic in England, leading the public health follow-up of those exposed to the terrorist bombings in London in 2005, and developing and managing the surveillance systems for the 2012 London Olympics and the surveillance systems that were instrumental in driving the dramatic reductions in MRSA and C. difficile in England. His primary research interests have included HIV and other sexually transmitted infections, the wider health effects of major incidents, and public health information systems development. He has also been a member of the steering groups for a number of European projects, and chaired the Steering Committee of the European Programme for Intervention Epidemiology Training (EPIET) from 2001 to 2006. He has academic appointments, as a visiting professor, at Imperial College London and City University London.

Marta Hugas *European Food Safety Authority*

Marta Hugas is serving as a chief scientist at EFSA. Since Marta joined EFSA in 2003, she has held several positions: head of Biological Hazards Unit, acting head of the Risk Assessment and Scientific Assistance Department, and head of the Biological Hazards and Contaminants Unit. Before joining EFSA, she worked for the Institute for Food and

Agricultural Research and Technology, where she was head of the Food Microbiology and Biotechnology Unit and led a research group on applied research on meat and food safety. From 1992 to 2004, she was an associate professor at the University of Barcelona. Marta has a Bachelor's degree in biological sciences, a Master's degree in genetics and microbial biotechnology and a PhD in food microbiology.

RAPPORTEURS

Ana Afonso *European Food Safety Authority*

Ana Afonso is a senior scientific officer and team leader at EFSA's Scientific Committee and Emerging Risks Unit. Ana joined EFSA in 2006 as a scientific officer for the Animal Health and Welfare Unit, where she was involved in risk assessments on animal health, including, among others, the coordination of working groups and the drafting of scientific reports on emerging vector-borne diseases. Before EFSA, she worked as a veterinary official responsible for approval and inspection of food establishments, as a veterinary assistant for hygiene and animal health issues on fish farming, and as a research/lecturer assistant at the Portuguese Veterinary Faculty of Lisbon and Vila Real. She is a veterinarian specialised in aquatic veterinary studies and animal epidemiology.

Jaime Aguilera *European Food Safety Authority*

Jaime Aguilera is senior scientific officer at EFSA's FEED Unit. He is specialist in the regulatory risk assessment of food and feed products obtained through biotechnology, including the characterisation of microbial strains introduced in the food chain or used as a source of fermentation products. Before joining EFSA in 2008, he was a researcher in evolutionary genetics and plant virology, and subsequently food biotechnology. He obtained his PhD in biological sciences at the University of Valencia in 2003.

Sofie Dhollander *European Food Safety Authority*

Sofie Dhollander is currently senior scientific officer at EFSA's Animal Health and Plant Health Unit, where provides scientific support to the Animal Health and Welfare Panel and its working groups dealing with risk assessments on animal health, including, among others, the coordination of working groups and the drafting of scientific reports on emerging vector-borne diseases and African swine fever. She started her carrier in Africa, where she worked at the International Trypano-tolerance Centre. In 2005, she continued as project coordinator of a veterinary research and development project at the Institute of Agricultural Sciences of South Vietnam until September 2007. Sofie graduated as veterinarian in 1998, and has specialised further in tropical animal health and production and veterinary epidemiology.

Winy Messens *European Food Safety Authority*

Winy Messens is senior scientific officer at EFSA's Biological Hazards and Contaminants Unit, where she provides scientific support to the EFSA Scientific Panel on Biological Hazards in the area of food microbiology. Winy joined EFSA in 2010 and previously worked as a scientist and postdoctoral researcher at the Institute for Agricultural and Fisheries Research, Vrije Universiteit Brussels and the Ghent University. She was a member of EFSA's BIOHAZ Panel. She holds a Master's degree in bioengineering (food technology) and a PhD in applied biological sciences from the University of Ghent.

Pietro Stella *European Food Safety Authority*

Pietro Stella is a scientific officer and acting team leader at EFSA's Biological Hazards and Contaminants Unit. Before joining EFSA in 2007, he worked as a practitioner and in the meat sector. Pietro is a veterinarian, with a Master's degree in veterinary epidemiology and public health.

SPEAKERS

David Waltner-Toews *University of Guelph*

A University Professor Emeritus at the University of Guelph, and Associate Researcher at the Community of Practice for Ecosystem Approaches to Health-Canada (CoPEH-Canada), Centre de Recherche Interdisciplinaire sur le bien-être, la santé, la société et l'environnement (CINBIOSE), Université du Quebec à Montrèal, Waltner-Toews was founding president of Veterinarians without Borders/Vétérinaires sans

Frontières – Canada. In 2010, in London, England, the International Association for Ecology and Health presented him with the inaugural award for contributions to ecosystem approaches to health; same year he was a speaker in the 'Speakers of Renown' series that celebrated the 40th anniversary of Canada's International Development Research Centre.

His textbooks include Ecosystem Sustainability and Health: A Practical Approach (Cambridge University Press, 2004), The Ecosystem Approach: Complexity, Uncertainty, and Managing for Sustainability (with Nina-Marie Lister and James Kay, Columbia University Press, 2008), and Integrated Assessment of Health and Sustainability of Agroecosytems (with Thomas Gitau and Margaret Gitau, Taylor and Francis/CRC Press, 2008). He co-edited and co-wrote several chapters in One Health: The Theory and Practice of Integrated Health, eds Zinsstag J, Schelling E, Waltner-Toews D, Whittaker M, Tanner M. (CABI, 2015).

Besides being an author or co-author of textbooks and more than 100 peer-reviewed scholarly papers and book chapters, he has published six books of poetry, a collection of recipes and dramatic monologues, a collection of short stories, a murder mystery, and four books of popular science on the natural and cultural history of zoonoses and foodborne diseases. His most recent books were The Origin of Feces: what excrement tells us about evolution, ecology and a sustainable society (ECW, 2013); and Eat the Beetles! an exploration into our conflicted relationship with insects. (ECW, 2017).

Molecular epidemiology of AMR in bacteria causing foodborne human infections: what do we know, what should we find out?

Alessandra Carattoli *National Institute of Health*

Dr Alessandra Carattoli received a PhD degree in Molecular and Cellular Biology in 1989 at the Faculty of Medicine of the University of Rome 'La Sapienza'. Since 1997 she has been a member of the permanent staff at the Istituto Superiore di Sanità of Rome, currently as Research Director. From 2013 to 2015, she was visiting Professor at the Institute of Infectious Diseases of the University of Bern in Switzerland. She is author of 148 papers listed in PubMed, H-index = 57 (Google Scholar April 2018), and an internationally recognised expert on plasmid identification and typing, being the inventor of PCR-Based Replicon Typing, plasmid MLST and the author of the PlasmidFinder database. These methods have been adopted world-wide for in vitro and in silico identification of plasmids, and has changed over the last decade the concept of bacterial typing, impacting on knowledge of horizontal transmission of resistance determinants in bacteria of clinical relevance. She has won twice (in 2011 and 2013) the Outstanding ICAAC Program Committee Award in the Resistance Mechanisms and Consequences area, and since 2014 she has been a member of the Program Committee of the ICAAC-Microbe ASM Conference. In 2014 she was given Honorary Membership of the Hungarian Society of Microbiology by the Hungarian Academy of Science. She was listed in 2015 and 2016 in the World's Most Influential Scientific Minds by ISI-Thompson Reuters Pharmacology and Toxicology,

(http://hcr.stateofinnovation.thomsonreuters.com/) and in 2017 was in the list of the Top 1% Highly Cited Researcher by Clarivate Analytics Web of Science;

(https://publons.com/blog/2017-most-cited-researchers-announced-2017/).
On 9th January 2017 she received the honour 'Commendatore Ordine di Merito della Repubblica Italiana' conferred by the President of the Italian Republic.

The relatively few bacteria species that cause foodborne human infections represent a subset of bacteria involved in antimicrobial resistance (AMR) transmission and dissemination. To link AMR in bacteria from humans to microbial populations from animals, a detailed, quantitative understanding of the dynamics of bacteria is needed. The ability to trace the circulation within different bacterial populations of resistance determinants located on mobile genetic elements helps to clarify all the routes by which AMR bacteria and their related genes can arise in the human patient. The development of new molecular approaches can help to recognise and describe how food can be a vehicle for AMR bacteria or a source of AMR genes. For example, phylogenetic analysis of bacterial genomes, combined with a profile of mobile genetic elements (plasmids) and epidemiological data offer some explanation about the impact of specific antimicrobial drugs used in farm animals on the selection of resistance determinants also identified in strains from human clinical cases. In several studies, retail meat samples from beef, pork and other food products did not harbour strains clonally related to those causing human infections. However, the dynamics of plasmid-mediated transmission of AMR genes between food-producing animals and humans, appear useful to trace the spread of common AMR features between the two sources. Whole genome sequencing is revealing and beginning to quantify the two-way traffic of AMR bacteria between the farm and the clinic. Data also suggest some clues about the route of transmission and dissemination of extended-spectrum beta-lactamases (ESBLs) in bacteria from animals and humans and the circulation of mobile colistin resistance in bacteria that cause foodborne human infections.

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Key words: Escherichia coli, ESBL, mcr, plasmids, Salmonella

Wastewater treatment plant effluents and their implications for antimicrobial resistance in surface water and water reuse

Thomas U. Berendonk, *Technical University of Dresden*

Prof. Dr. Thomas Berendonk is Professor of Limnology and Director of the Institute for Hydrobiology at the Faculty of Environmental Sciences at the Technische Universität Dresden. He is spokesman for water quality and quantity of the water cycle at the Centre for Advanced Water Research (CAWR) – (one of Europe's largest centres for water research, a formal partnership between TUD and the Helmholtz Centre for Environmental Research (UFZ)) and spokesman for the Universities in the Helmholtz Interdisciplinary GRADuate School for Environmental Research (HIGRADE). He has held the position of Full Professor at Technische Universität Dresden since 2008. He graduated with a PhD “magna cum laude” (1.0) from Max-Planck-Institute Plön, Germany in 1998 and his PhD thesis received the Otto Hahn award of the Max-Planck Society. Following that he undertook 4 years post-doctoral research training in the United Kingdom. He held postdoctoral research positions at the Museum of Natural History, London (1999-2000), NERC Centre for Population Biology (2000-2002), Imperial College London, and the Department of Zoology, Oxford University (2002-2003). He returned to Germany in 2003 to take up a position as Wissenschaftlicher Assistent (USA = assistant Prof, without tenure track, Australia = departmental lecturer) at the Zoological Institute (Biology II) at Leipzig University and continued in that position until 2008. He completed his habilitation in Zoology (“Analyses of historic and recent ecological processes and their influence on the genetic diversity of species”) and became a Full Professor in 2007. He took up employment with the Technische Universität Dresden in that capacity in 2008.

Due to the worldwide health impact of antibiotic resistant pathogens, scientists are increasingly interested in the role of wastewater treatment plants (WWTPs) as a sink and source for antibiotic resistant bacteria and their genes. To date, the dynamics of resistant bacteria and associated genes in municipal WWTPs has just began to be explored, but there is clear evidence that antibiotic resistant organisms and genes are released with WWTP effluents to receiving environments (Berendonk et al. 2015). Studies have demonstrated that the absolute quantity of antibiotic resistance gene copies are reduced during conventional wastewater treatment, but it is also apparent that relative abundances of key resistance genes normalized by 16S rRNA copy numbers frequently show no significant reduction and sometimes even increase. In this presentation I summarize these results and discuss their implications for the spread of resistance genes within the context of water reuse. I will show some results of my group and the COST action NEREUS focusing on the fate of antibiotic resistance when wastewater is used for irrigation (Fatta-Kassinos et al. 2015; Gatica et al. 2016).

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Keywords: Wastewater, treatment plant, surface water, water reuse

Vector-borne diseases in Europe: what can we expect and how well are we prepared?

Jolyon Medlock *Public Health England*

Dr Jolyon Medlock has worked on vector-borne diseases for 20 years. Having trained at the Universities of Manchester and Bristol and the Liverpool School of Tropical Medicine (LSTM), he spent 4 years working on malaria control in various parts of Africa with Oxfam’s Humanitarian Department and conducting research on malaria and lymphatic filariasis with the LSTM. Since 2002, he has worked at Porton Down, for the Health Protection Agency and now Public Health England. He leads the Medical Entomology group, responsible for advising UK government on vector-borne disease risk. This involves managing UK-wide vector surveillance systems and coordinating research on a range of mosquito-borne and tick-borne diseases, and has published >100 peer-reviewed scientific papers. He has been a member of UK Government One Health risk assessment groups for about 15 years and is the UK government’s lead on vector-related issues. Since 2009 he has also been involved with leading European-wide vector-surveillance programmes, managing a programme for enhancing tick surveillance in >30 European countries. His group has been involved with tick surveillance and detection in the UK since 2005, and since 2009 he has been involved in ECDC-funded VBORNET and ECDC/EFSA-funded VECTORNET in which he led

the tick consortium. This involved supporting capacity building, training and surveillance in more than 30 countries in Europe and North Africa. He has also recently led UK support to seven countries in the Caribbean in relation to surveillance and control of Zika vectors, including rapid deployment to UK's Overseas Territories from Hurricane Irma.

Emerging infectious diseases (EID) are now tackled using a One Health approach, bringing together experts in human and veterinary health, as well as expert in bacteriology, virology, entomology and wildlife disease. As a large proportion of EIDs are wildlife zoonoses (pathogens transferred between animals and humans) this multidisciplinary approach is paramount for risk assessment and for mounting a response. Failure to consider all aspects of disease ecology and epidemiology hinders successful control and proportionate response. For vector-borne diseases (those transmitted by arthropods) knowledge of the arthropod vector and their relative roles in transmission is an important first step. This paper will detail experiences from >15 years of contributing to government risk assessment on vector-borne diseases from a medical entomologist's perspective. It will highlight the need for ongoing vector surveillance to detect and respond to changes in distribution, the emergence of new vector-related issues and the importance of non-native species. Routine surveillance triggers alerts that require further enhanced targeted surveillance and research to better inform the risk, mitigate any disease implications and ensure that government has the empirical evidence to be well informed, both for the ministers and public, and to be better placed to prevent and control any emerging disease. This will be illustrated by examples on the surveillance of invasive mosquitoes and concerns over local transmission of Zika and chikungunya virus. It will highlight the importance of routine native mosquito surveillance in relation to West Nile virus risks, and the need to incorporate vector data into ongoing clinical virology diagnostics. On ticks, it will highlight the importance of monitoring imported ticks, in relation to developing evidence of policy change on tick controls on travelling pets, as well as guiding risk assessment on emerging arboviruses in western Europe such as Crimean–Congo haemorrhagic fever virus and tickborne encephalitis virus. Finally it will present data on 12 years of tick surveillance, and the many outputs that lead to better public awareness, discovery of new foci of disease importance, and a better informed government on both public and veterinary vector-borne disease issues.

Next generation sequencing as a tool in foodborne disease surveillance and outbreak investigation – Challenges and opportunities

Peter Gerner-Smidt *Center for Diseases Control and Prevention*

Dr Peter Gerner-Smidt is a Danish/American MD, DSc with specialty in clinical microbiology. He is the chief of the Enteric Diseases Laboratory Branch in the Division for Foodborne, Waterborne and Environmental Diseases at the Centers for Disease Control and Prevention in Atlanta, United States. He is leading the effort to implement whole genome sequencing for public health surveillance of bacterial foodborne infections at the CDC and in the United States. He is also involved in its implementation globally through the Global Microbial Identifier initiative and PulseNet International.

Foodborne illnesses are common but preventable. With ever-increasing international travel by people and globalisation of trade of animals, food and feed, foodborne infections no longer respect any borders: the source of an infection may be in a different continent than where the patient becomes ill. Outbreaks are common. A One Health approach involving stakeholders from the whole food production and public health is needed to efficiently control the problem. Monitoring and comparing pathogens isolated from people and throughout food production is a critical component to detect and investigate outbreaks and determining the major sources of human infections is essential in order to control and prevent them. In the last decade, next generation sequencing (NGS) has emerged as a cost-efficient way to determine the whole genome sequence (WGS) of a microorganism, providing authorities, academia and industry with hitherto unheard of detailed knowledge on pathogens and their routes of transmission. Because of WGS, it is now possible to detect, investigate and control more outbreaks faster and keep them smaller. The information from WGS is also used to predict characteristics of the pathogens like species, serotype, comprehensive virulence and antimicrobial resistance profiles, replacing a multitude of different traditional microbiological workflows with one efficient NGS workflow. However, sequences generated on different NGS platforms and analytical applications ('pipelines') do not provide exactly the same results and there are no internationally agreed upon standards for sequence quality. This poses a challenge when comparing WGS data generated in different laboratories nationally, regionally and globally. Some NGS platforms are more accurate than others; some tend to produce specific errors. Why do some laboratories use single nucleotide polymorphisms (SNPs) while others use whole genome or core genome multi-locus sequence

typing (wg/cgMLST) for subtyping? Are the genotypic pipelines used to predict the same phenotypic characteristics, e.g. serotype, virulence profile and antimicrobial resistance, equally reliable and accurate? How much do food safety decision makers need to know about NGS and WGS? To avoid having to consider these issues, PulseNet International together with its partners work towards creating international standards for WGS analysis and validating different sequencing platforms and workflows to ensure accurate comparisons of data generated in any laboratory. And finally, it should be remembered that WGS data will always need to be interpreted along with other supporting data in any given context to ensure correct decision making in food safety

PANELLISTS

Nikolaus Kriz *European Food Safety Authority*

Nikolaus Kriz is head of EFSA's Animal and Plant Health Unit. Nik has 25 years of professional experience on four continents in general practice, specialised clinics and academia, and has worked in regulatory bodies in both the animal health and food safety area mainly in infectious diseases and veterinary medicines with a particular emphasis on vaccines and innovative products. He is a veterinary surgeon, holding a Master's degree in veterinary clinical studies from the University of Sydney and a PhD from the University of Veterinary Medicine.

Ernesto Liebana Criado , *European Food Safety Authority*

Ernesto Liebana is a senior scientific officer, team leader and acting head of EFSA's Biological Hazards and Contaminants Unit. In 2007, he joined EFSA as a senior scientific officer, where he has been dedicated to the scientific coordination of risk assessment activities in the area of biological hazards. Before joining EFSA, he was researcher in the area of zoonoses and public health at the Complutense University of Madrid, the Veterinary Sciences Division (Department of Agriculture Northern Ireland), and the Departments of Food and Environmental Safety, and Pathology in the Veterinary Laboratories Agency. He graduated as a veterinary surgeon, and holds a PhD in microbiology. He is a fellow of the Royal College of Pathologists.

ADVANCING RISK ASSESSMENT SCIENCE

Human health (continued)

The National Academies of Sciences, Engineering, and Medicine recently published a report that provides considerations and recommendations on how the latest scientific and technological advances in toxicology, exposure science and epidemiology could be integrated and used to further advance risk assessments. New tools are emerging that enable a better understanding of adverse effects at the molecular level, and more accurate predictions of biological responses. Most of these tools will be non-animal testing models. Moreover, epidemiological research is facing a transition from empirical observations alone to the provision of information on the pathogenesis. These developments are promising for the improvement of human health risk assessments as well as the reduction of animal testing.
This session will highlight relevant advances, unresolved challenges, and needs for human health risk assessment. The usefulness of the traditional risk assessment paradigm (hazard characterisation, exposure assessment and risk characterisation) will be addressed holistically, accounting for the challenges that a paradigm shift may entail. New tools that may facilitate this transition will be discussed.

CHAIRS

Angelika Tritscher *World Health Organisation*

See biography p.27

Heather Wallace *University of Aberdeen*

See biography p.27

SPEAKERS

CLARITY-BPA core study: a perinatal and chronic extended dose-range study of bisphenol A (BPA) in rats

Barry Delclos *US Food & Drug Administration*

Barry Delclos is a Research Pharmacologist in the Division of Biochemical Toxicology at the FDA's National Center for Toxicological Research in Jefferson, Arkansas, USA. In recent years, his research efforts have focused on toxicities associated with endocrine active agents and modulation of toxicity by dietary factors. He has served as Principal Investigator on a series of studies conducted under an Interagency Agreement between the FDA and the National Toxicology Program to evaluate aspects of the hypothesis that exposure to low levels of hormonally active agents, particularly during development, adversely affects human health, including

reproductive function and carcinogenesis. These studies have been designed to address data gaps and provide data of utility in safety assessments conducted by FDA and other regulatory agencies.

The CLARITY-BPA research programme was conducted under an Interagency Agreement between the National Institute of Environmental Health Sciences and the US Food and Drug Administration to attempt to address scientific uncertainties on BPA toxicity. The programme consisted of a core modified guideline-compliant chronic rat study that also provided animals and tissues to 14 academic groups for assessment of a range of molecular, structural and functional endpoints not typically assessed in guideline-compliant studies. In the core study, the toxicity of BPA administered by oral gavage from gestation day 6 through the start of labour and then directly to pups by daily gavage from postnatal day 1 was examined in Sprague-Dawley rats. Study materials were monitored for background BPA levels throughout. A wide range of BPA doses was used ranging from as close as feasible to estimated human exposure levels to a reasonable margin of exposure (2.5, 25, 250, 2,500, and 25,000 µg/kg body weight (bw)/day). Because many of the reported effects of BPA are associated with oestrogen signalling pathways, two doses (0.05 and 0.5 µg/kg bw/day) of ethinyl estradiol (EE2) were also included to monitor the response of the model to an oestrogen. The vehicle was 0.3% carboxymethylcellulose. In addition to animals dosed daily throughout the study (continuous-dose arm), a stop-dose study arm was included for the BPA doses only, with animals dosed until postnatal day 21 and then held without further treatment until termination, to assess any effects that were due to early exposure. In both study arms, animals were terminated at 1 year (interim) and 2 years (terminal). Statistical comparisons were conducted within sex, study arm, and sacrifice time and BPA and EE2 groups were analysed separately. Data collected included survival, body weights, litter parameters, age at vaginal opening, vaginal cytology, including an assessment of the onset of aberrant cycles, clinical chemistry (interim sacrifice only), sperm parameters (interim sacrifice only), organ weights (interim sacrifice only), and histopathology (both interim and terminal sacrifices). The 0.5 µg EE2/kg bw/day dose elicited strong responses in females. More than 90% of the animals in this group exhibited prolonged oestrus by 16 weeks of age. Multiple organ weights were affected at the interim sacrifice and non-neoplastic lesions, particularly in female reproductive organs, were increased at interim and terminal sacrifices. At terminal sacrifice, there was a statistically significant increase in the incidence of mammary gland adenocarcinomas and pituitary combined adenomas/carcinomas. EE2 had few effects in males; an increase in hyperplasia in the pars distalis of the pituitary at 2 years was noted. There were few significant effects of BPA treatment among the in-life or non-histopathology data collected at the interim sacrifice in either sex. In the late stages of the study (weeks 96–104), mean female body weights in the 250 µg BPA/kg bw/day continuous-dose group were significantly higher than the mean vehicle control body weights. For clinical chemistry endpoints or organ weights, the few statistically significant effects in BPA groups were of small magnitude and not considered adverse. In the histopathological evaluations, neoplastic and non-neoplastic lesions associated with ageing in this strain of rats in both males and females were observed that were variable across control and BPA treatment levels. Statistical analyses designed to minimise false negatives were applied to the histopathology data and results were interpreted considering all available evidence from the study on the biological plausibility of a true treatment effect. In the stop-dose BPA study arm at terminal sacrifice, there was a statistically significant increase in the incidence of female mammary gland adenocarcinoma (22% versus 6%) or the combination of adenoma and adenocarcinoma (24% versus 8%) only in the 2.5 µg BPA/kg bw/day dose group. No increase in female mammary gland neoplasms was observed in the continuous BPA dose arm. The elevated incidences in the stop-dose arm treated group were above those observed in earlier studies conducted with these rats in this laboratory while the control incidences were lower. There were no significant treatment-related non-neoplastic lesions in the mammary gland of interim or terminal sacrifice stop-dose BPA groups, while in the continuous dosing arm, there was an increase in female mammary gland atypical foci at 2.5 µg BPA/kg bw/day. A significant trend for uterine stromal polyps was also observed in the interim sacrifice animals in the continuous BPA dose arm, but this was not observed in the terminal sacrifice animals. Among the non-neoplastic lesions in females, there was an increased trend and significant increase in follicular cysts in the ovary at 25,000 µg BPA/kg bw/day in stop-dose interim sacrifice BPA animals. An increase in cystic endometrial hyperplasia was noted at 2,500 and 25,000 µg BPA/kg bw/day in the terminal stop-dose animals. In continuous-dose interim females, apoptosis of the luminal epithelium of the endometrium and vaginal epithelial hyperplasia were elevated at 25,000 µg BPA/kg bw/day. Vaginal epithelial hyperplasia was also increased in terminal continuous-dose BPA animals at doses from 25 to 25,000 µg BPA/kg bw/day, with a similar response across each of those dose levels. There were no treatment-related neoplastic effects in BPA stop-dose or continuous-dose interim or terminal sacrifice males. In terminal sacrifice stop- and continuous-dose males, an increase of hyperplasia in the pars distalis of the pituitary at 25,000 µg BPA/kg bw/day was noted, with a statistically significant effect also seen at the 25 µg BPA/kg bw/day in the continuous-dose animals. In continuous-dose interim sacrifice males, but not in continuous-dose terminal sacrifice males, there was an increase in exfoliated germ cells and an increase in lymphocyte infiltration in the epididymis at 25,000 µg BPA/kg bw/day. For most of the statistically significant BPA effects observed in this study, the lack of dose-response, the fact that they often occurred in only a single low or middle dose

group, and the lack of a clear pattern of consistent responses within the stop- and continuous-dose study arms and across endpoints made it difficult to establish the effects, particularly in the lower dose range, as biologically meaningful treatment effects.

Integrating regulatory and academic investigations in hazard assessments by the US National Toxicology Program. Lessons learned from the CLARITY-BPA initiative

Nigel Walker *National Institute of Environmental Health Sciences*

Dr Nigel Walker is the Deputy Director for Research for the Division of the National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences (NIEHS), one of National Institutes of Health (NIH), USA. Dr Walker has been at the NIEHS for over 20 years and during this time has worked on numerous initiatives understanding the potential toxicity and carcinogenicity of compounds under investigation by the NTP including nanoscale materials, occupational and environmental mixtures, dioxins, persistent organic pollutants, and botanical dietary supplements. Dr Walker has over 140 peer-reviewed publications, including 60 peer reviewed reports on the toxicity and carcinogenicity of compounds studied by the NTP. In his current role as Deputy Director for Research he is involved in the formulation, coordination and implementation of activities necessary to carry out the scientific goals of the NTP, a US Federal government interagency program whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. He received his BSc in Biochemistry from the University of Bath, UK and his PhD in Biochemistry from the University of Liverpool, UK.

The health impact of low-level exposure to bisphenol A (BPA) has been a topic of considerable debate. BPA is a chemical produced in large quantities for use primarily in the production of polycarbonate plastics and epoxy resins, that are used as lacquers to coat metal products such as food cans, bottle tops and water supply pipes. Human exposure to BPA is widespread, with 93% of Americans 6 years and older having detectable levels of BPA in their urine. In 2008, the National Toxicology Program (NTP) evaluated the available scientific literature about the possible effects of BPA on human development and reproduction. The NTP concluded there was 'some concern' for BPA's effects on the brain, behaviour, and prostate gland in fetuses, infants, and children at current exposure levels and 'minimal concern' for other health endpoints that had been studied. The US Food and Drug Administration (FDA), one of the core agencies of the NTP, maintains that BPA is safe at the current levels occurring in foods and supports currently approved uses of BPA in food containers and packaging. These conclusions are based on FDA's most recent safety assessment, and its ongoing review of scientific evidence. One of the challenges through these assessments and reviews has been the integration of data from investigative academic studies with those Good Laboratory Practice (GLP) studies conducted according to guidelines for submission to regulatory agencies for making risk assessment decisions. The way in which these different types of studies are conducted and reported is a challenge when trying to integrate different data streams. These issues are often related to exposure levels, study design and conduct, chemical purity, statistical power, reporting of study details, selective reporting of data, risk of bias, directness of end-point measures to a health outcome, and data reporting transparency. To address some of these issues and study a broader range of potential health effects from exposure to BPA that could inform regulatory decision making, NIEHS, NTP, and the FDA developed a research programme called Consortium Linking Academic and Regulatory Insights on BPA Toxicity (CLARITY-BPA). The aim of the CLARITY-BPA program was to attempt to bridge guideline-compliant research with hypothesis-based research projects on the toxicity of BPA. The CLARITY-BPA research programme has two components: (1) A 'core' guideline-compliant chronic study conducted at FDA's National Center for Toxicological Research (NCTR) according to FDA Good Laboratory Practice (GLP) regulations (2-year perinatal only or chronic BPA exposure, including perinatal); and (2) CLARITY-BPA grantee studies of various health endpoints, conducted by NIEHS-funded researchers at academic institutions using animals born to the same pregnant rats and exposed under identical conditions as the core GLP study. The key strengths of this consortium approach, included; (1) the identical BPA exposure conditions used for both components of the consortium, which were provided at the same facility (NCTR); (2) blinding of the core study samples received by the academic grantees, and minimising the potential risk of bias; and (3) the development of an a priori list of endpoints to be collected per study and the requirement that all data be deposited in a private workspace in the NTP's database before decoding. This allowed for confidential data acquisition and blinded deposition of data and also ensured that subsequent public access to data had no bias in end-point data acquisition. There were limitations to this approach. Academic investigators were limited to using a specific shared design and model that may not have been optimal for the specific endpoints proposed. Sample acquisition was centralised and coordinated so highly specialised sample preparation or animal handling procedures required additional coordination, training and resources. Thirdly the scheme for peer review and selection of grantee proposals followed traditional the United States National Institutes of Health (NIH) peer review procedures such that guidance was

more general in nature and submitted proposals were not specifically aligned to address specific regulatory needs, but rather hypothesis generated research questions. Looking forward, a key lesson learned from the CLARITY-BPA program is that for future initiatives a less resource intensive approach is needed with much more targeted and integrated problem formulation and consortia development phase more direct communication between what the regulatory scientists need to make decisions and what the academic scientists can provide. This would result in closer alignment between the identified regulatory data gaps and the design of the studies and would maximise the utility of such collaborative programmes, while decreasing their costs.

Use of epidemiological studies for setting a health-based guidance value

Thorhallur I Halldorsson *University of Iceland*

See biography p.29

The potential impact of toxicogenomics on modern chemical risk assessment – 3-MCPD as an example

Alfonso Lampen *Federal Institute for Risk Assessment*

Professor Dr Alfonso Lampen is the Head of the Department of Food Safety at the Federal Institute for Risk Assessment (BfR). He is an extra Professor for Food Toxicology at the University of Veterinary Medicine Hannover, Germany. He has managed several national and international grants (DFG, BMBF, EU). Professor Lampen is author of many peer reviewed papers in highly ranked international journals. He was nationally and internationally awarded several times e.g. for the development of new in vitro methods for food safety investigation in particularly for studies regarding the gastrointestinal barrier. He is member of several national and international expert groups in food safety. Major research activities are focused on open questions in risk assessment such as the molecular mechanism of detoxification/toxification in the gastrointestinal barrier using toxicogenomics, establishment of effect directed analysis, and search for new effect and exposition marker using human nutrition studies.

Omics methods addressing the whole genome (genomics), the transcriptome (transcriptomics), the proteome (proteomics) and the metabolome (metabolomics), respectively, have been established substantially in toxicological research over the past decade. Currently, the adverse outcome pathway concept (AOP), which tries to link adverse to molecular effects, has been proposed by OECD, WHO and others to be the way forward to regulatory toxicology. In risk assessments (RA), however, these methods only play a significant role in hazard identification, but not significant in risk characterisation due to the lack of relevant quantitative data on dose–response relationships. Therefore, one goal in the future may be the integration of 'omics data into the risk characterisation of chemicals.

From food toxicology examples, it will be demonstrated how 'omics data may be used in RA and points the way forward for their possible future role in RA. By using in silico methods (QSAR), we could differentiate mutagenic and carcinogenic chemicals among more than 800 heat-induced processing contaminants and established a priority list of compounds. In this approach, 3-monochloropropanediol (3-MCPD) was identified. Our detailed analysis of the proteome and transcriptome of 3-MCPD-treated rats recovered molecular targets of 3-MCPD, e.g. related to glucose utilisation and oxidative stress. The antioxidant protein DJ-1 was strongly deregulated at the protein level in kidney, liver, and testis, giving new insights into the mode of action (MOA) of this relevant food contaminant. These new results were recently taken up by EFSA in the course of the RA of 3-MCPD, showing that 'omics data could be used in RA for determining MOA. So far, there has been only limited use of 'omics techniques in standard toxicity tests performed to identify adverse effects, because of existing limitations. However, by implementation of relevant MOA data into the AOP concept, it will be possible to link MOA effects observed by 'omics methods to adversity in the near future. Furthermore, it will also be possible to develop appropriate in vitro test systems to predict adverse outcomes with significant evidence. Then, it may be possible to modulate the margin of exposure concept by comparing relevant human in vitro 'omics data together with biological endpoints (AOP data) with human endogenic endpoints (metabolomics data, biomarker of exposure).

In summary new techniques such as in silico methods (e.g. QSAR, PBPK modelling) as well as 'omics data, together with endogenic biomarkers, will fundamentally improve RA in the future.

Keywords: MCPD, molecular docking, 'omics, PBPK modelling, QSAR, risk assessment

Use of modelisation tools to assess risks related to cadmium exposure for workers and consumers

Christophe Rousselle *French Agency for Food, Environmental and Occupational Health & Safety*

Christophe Rousselle graduated from the Veterinary School of Lyon. He then was awarded a PhD in Toxicology from Paris (2000) and more recently an International Master in Public Health from Rennes (2016). He has been working for more than 15 years in regulatory toxicology, first in the French Agency for Medicines (AFSSAPS) and then at the French Agency for Environment and Occupational Health and Safety (AFSSET) and now at the French Agency for Food, Environment and Occupational Health and Safety (ANSES). He is currently the head of the Chemical Risk Assessment Unit dealing with chemicals in consumer products and also with Reach regulation and CLP. He has also been an expert on the Scientific Committee for Consumer Safety at the European level from 2009.

Cadmium (Cd) is a highly persistent environmental toxicant that exhibits high rates of soil-to-plant transfer, making Cd a food-chain contaminant of great concern. Foodstuffs are considered the main source of Cd exposure for the non-smoking general population as it enters plants generally by their roots, or sometimes also by their aerial parts, thereby entering the food chain and exerting its recognised toxicity for humans.

At the request of various ministries, ANSES worked at revising its toxicological reference value (TRV) for ingestion of Cd and on a proposal for Cd maximum levels in fertilising materials and culture media (MFSC), to control agricultural soil pollution and the subsequent contamination of plant productions consumed by humans.

ANSES will propose a new toxicological reference value (TRV) for Cd, via oral chronic exposure. After reviewing the effects of Cd on human health, ANSES has identified bone effects as the key effects to be used to derive the TRV. The experts adopted epidemiological studies published by Engström et al. as key studies. The critical internal dose chosen is 0.5 µg of Cd/g creatinine [considered as a no-observed-adverse-effect level (NOAEL) value for a population over 60 years of age].

Based on a PBPK model including data on the variation of creatinine excretion according to body weight and age, and that links Cd urinary concentration values with Cd oral exposition values, a tolerable daily intake (TDI) of 0.35 µg Cd/kg bw/day was derived [corresponding to a tolerable weekly intake (TWI) of 2.45 µg/kg bw/w]. The PBPK model also made it possible to estimate the change in the limit urinary Cd concentration (Cd HBGV in µg/g of creatinine as a function of age) not to be exceeded to avoid exceeding the internal TRV (0.5 µg/g creatinine in adulthood).

A predictive model for estimating the development of contamination of Cd in plants intended for human consumption from the input of Cd in soils over a projection time of 99 years (due to the persistence behaviour of Cd) was elaborated. The assessment focused more particularly on wheat and potatoes, two plants identified as the origin of major food contributors to Cd exposure of French consumers, together with the use of various scenarios of soil fertilisation via fertiliser materials, resulting in a major supply of Cd in the food chain.

The construction of the model was carried out in two stages:

- Firstly, the transfer of Cd from its input via fertilisers on agricultural soils to the plant production (potato and wheat grain) was modelled. This part of the model was built on the basis of a 'mass-balance' approach, taking into account: (1) all the routes of Cd entry into the agricultural soil (fertilising materials, atmospheric deposition, irrigation water); (2) routes of Cd release from the soil (food crops, leaching); (3) variabilities; and also (4) French specificities along this transfer. This first phase of the model makes it possible to study the Cd contamination of agricultural soils, the Cd contamination of crops as well as the Cd leached, as a function of cadmium inputs via fertiliser materials and their agricultural practice over a projection time of 99 years.

- In a second step, the transfer of Cd from the plant production to the consumers through food was modelled, to estimate the impact on consumer exposure. This second part of the model was based on an existing model implemented by ANSES, as part of the referral 2011-SA-0194 on the revision of maximum levels of cadmium in foodstuffs. This model has been updated to evaluate the dietary exposure associated. Simulations of various fertilisation scenarios were then run with the updated ANSES model to obtain the Cd concentration variations (reduction or increase) in the wheat grain and potatoes. The obtained variations of the Cd concentration in plants allowed then to estimate the impact on consumer Cd exposure.

So, the elaborated model based on Cd flux is a predictive support to estimate Cd levels in plants and in the final related food products. The output data of the model allow derivation of the adult and child consumer's average chronic exposure and 95th percentile, as a function of the projection time of the model (10, 20, 60, 99 years), in correlation with study of development of Cd contamination in crops (wheat grain and potato) linked to fertilisation scenarios. It is also feasible to identify a possible percentage of excess of the TRV.

Engaging with society

Public trust in risk governance is waning. Societal engagement has been proposed as a mode of science communication that could lead to better trusted risk decision-making by addressing both facts and values in an open two-way dialogue. Moving towards deliberatively engaging society about societal issues could contribute to improving the quality, legitimacy and sustainability of the decision- and policy-making process. So far, risk communication has typically focused on communicating facts instead of values as a one-way process to deliver information, attempting to convince audiences of the legitimacy and authority of an expert-informed assessment. This session will address: the relevance of societal engagement in regulatory science and decision-making; whether this engagement could be achieved in a meaningful manner, accounting for the latest developments in the field; and challenges associated with considering the wide range of societal concerns in risk governance and in communicating scientific uncertainties.

CHAIR

Barbara Gallani *European Food Safety Authority*

See biography p.7

Ellen Vos *Maastricht University*

Professor Dr Ellen Vos is professor of EU law at the Law Faculty of Maastricht University. She is co-director of the Maastricht Centre for European Law of Maastricht University (MCEL) and the Centre for European Research in Maastricht (CERiM). She wrote and obtained her PhD in Law at the European University Institute in Florence. Ellen's main areas of interest are EU law and governance (comitology and agencies), market integration and EU risk regulation (precautionary principle, food safety, pharmaceuticals, nanotechnology). She has published extensively in these areas. She supervises (and has supervised) numerous Master and PhD theses in these areas.

The Treaty of Lisbon has elevated participation as a founding legal principle. Hence, based on Article 11 TEU, we can say today that participation is one of the foundations of democracy in the EU. This requires that participation should be considered as giving voice to individuals and representative associations, as well as strengthening their position in their relationship with the EU institutions, in access to decision-making procedures and of justification of decisions. It means that the relationship between EU institutions and representative associations and the public at large needs to be reconsidered so as to ensure voice independently of problem-solving needs as well as equal treatment of participants. This presentation will discuss the requirements and possibilities for involvement of stakeholders (including representative associations) and citizens in decision making by the EU institutions, and in science making by EU agencies and research institutions. It will discuss various models of engagement with stakeholders and citizens.

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Key words: EU agencies, EU decision making, citizens, participation, stakeholders

Cissi Askwall *European Science Engagement Association*

Cissi Askwall has been the Secretary General of the Swedish non-profit association Vetenskap and Allmänhet, VA (Public and Science) since 2011. She has a diploma in Journalism from the University of Gothenburg and has also studied political science, psychology and theology. She worked previously as a news journalist and producer at Swedish Radio, the national public service broadcaster, as well as at the national news agency TT. She has also been the Head of Communications at VA and at the Royal Swedish Academy of Engineering Sciences. Furthermore, she was the Principal Secretary of a governmental investigation into how to digitalise and make Swedish cultural life more accessible, following which she was given responsibility for implementing the proposed web portal. She is a member of several international expert and advisory groups and Vice President of the European Science Engagement Association, EUSEA.

Junshi Chen *Chinese Center for Disease Control and Prevention*

Dr Junshi Chen graduated from Beijing Medical College in 1956 and has been engaged in nutrition and food safety research for more than 50 years at the Institute of Nutrition and Food Safety, Chinese Center for Disease Control and Prevention (the former Chinese Academy of Preventive Medicine), Beijing. Since 2011, he has had the position of Senior Research Professor at the China National Center for Food Safety Risk Assessment.

He has conducted large epidemiological studies on diet, nutrition and chronic diseases, in collaboration with Dr T. Colin Campbell, Cornell University and Prof. Richard Peto, University of Oxford since 1983. From late 1980s, he conducted a series of studies on the protective effects of tea on cancer, including laboratory study and human intervention trials. He is the member of the expert panel who wrote the WCRF/AICR report 'Food, Nutrition and the Prevention of Cancer: a Global Perspective' (1997). Recently, he was appointed as the Chair of the Chinese National Expert Committee for Food Safety Risk Assessment and the Vice-Chair of the National Food Safety Standard Reviewing Committee. Internationally, he serves as the chairperson of the Codex Committee on Food Additives (CCFA) (2007–2017), UN co-convener of the AMR Inter-Agency Coordination Group (IACG), member of the WHO Food Safety Expert Panel and Director of ILSI (International Life Sciences Institute) Focal Point in China.

Dr Chen's research interests focus on nutrition epidemiology as well as food safety surveillance and risk assessment in the following areas: food safety risk assessment and risk communication; food toxicology; epidemiological studies on diet, nutrition and chronic diseases; food fortification; and the Total Diet Study in China.

RAPPORTEURS

Giulia Nicolini *European Food Safety Authority*

Giulia Nicolini is currently a trainee at EFSA's Communication, Engagement and Cooperation Department. Her main responsibilities relate to social science and internal communications activities. She previously completed internships at Chatham House and the Food Foundation. Giulia holds a Master's degree in anthropology of food from SOAS, University of London.

Lucia Parrino *European Food Safety Authority*

Lucia Parrino is currently in charge of designing and managing events for EFSA. She has a background in economics and sociology, and holds a PhD in communication and service design from Politecnico di Milano. Both as a researcher and a practitioner, she has been working at the intersection between social research and communication, focusing particularly on community development and participatory processes.

Anthony Smith *European Food Safety Authority*

Anthony Smith currently works at EFSA's Communication, Engagement and Cooperation Department. He is a communications professional who is involved in research at EFSA on communication of uncertainty in scientific

assessments, public perceptions and risk communication best practices. He is a graduate of European studies and international relations and did post-graduate research on the geopolitics of energy.

Domagoj Vrbos *European Food Safety Authority*

Domagoj Vrbos works in EFSA's Communication, Engagement and Cooperation Department. His responsibilities relate to providing social science perspectives to risk assessment and communication. He has a background in economics and communications, and holds a master degree in development studies. Prior to this assignment, he worked in areas of research and communication related to food and nutrition in multilateral organizational settings.

SPEAKERS

Quality of information, public engagement and the challenges of science communication 2.0

Massimiano Bucchi *University of Trento*

Massimiano Bucchi is Professor of Science and Technology in Society at the University of Trento, Italy and has been visiting professor in academic and research institutions in Asia, Europe, North America and Oceania. He is the editor of the international journal Public Understanding of Science (Sage). He has published papers in journals such as Nature and Science and has written several books published in more than 20 countries, including Science in Society (London and New York, Routledge, 2004), Beyond Technocracy (New York, Springer, 2009); Handbook of Public Communication of Science and Technology (London and New York, Routledge, 2014) and the four volumes anthology The Public Communication of Science (London and New York, Routledge, 2016, both as editor with B. Trench). He regularly contributes to newspapers and TV programmes. www.massimianobucchi.it https://unitn.academia.edu/MassimianoBucchi

What are the key challenges for science communication in the age of digital media? And are they entirely new or rather place in a different communicative context longstanding issues like credibility and reliability of information and the public role of expertise? Mystification for propaganda, also involving scientific content and scientists themselves, has certainly not been introduced with the internet. In a context of 'crisis of mediators', the quality of public communication of science is – even more than in the past – highly dependent on the quality of research produced and published in specialised contexts. New research is increasingly pushed in real time into the public domain without being 'filtered', as was the case in the past decades, by professional mediators and popularisers. This inevitably connects science communication at large with trends causing major concerns in the world of research policy and academic publishing: a significant rise in the number of retracted papers (an estimated 1000% in the last 10 years, rising from 30 cases in 2002 to more than 600 only in Medline, 2016), the emergence of 'predatory journals' available to publish any content regardless of its quality, and lack of and failure in replicating studies. The contemporary communicative landscape clearly places new and greater responsibility on researchers and their institutions, who are increasingly active in communication to the 'end-user' and not always prepared to deal with the dynamics and potential risks of such engagement. More in general, we could see in this landscape relevant challenges and opportunities for our research and discussions, as well as an opportunity to rethink some of our key concepts.

Key words: credibility of information, expertise, public engagement, science communication

Conceptualising and communicating risk in "post-trust societies".

Ragnar Löfstedt *King's Centre for Risk Management*

Education: Dr Löfstedt earned his BA and MA degrees at University of California Los Angeles (1988) and Clark University (1991), respectively, before completing his PhD in geography at Clark University (1993). After a post-doctorate position at the Risk, Society and Policy Group at the International Institute for Applied Systems Analysis (IIASA) (Laxenburg, Austria), he joined the University of Surrey as a lecturer in social geography in 1993.

· Present organisation and position: Ragnar E. Löfstedt is Professor of Risk Management and the Director of King's Centre of Risk Management, King's College London, UK where he teaches and conducts research on risk communication and management. Previously he was a Reader in Social Geography at the University of Surrey, UK. He was also an Instructor at the Harvard Center for Risk Analysis, Harvard School of Public Health where he directed the Risk Communication Challenge Course for continuing education professionals. He is Adjunct Professor at the Department of Engineering and Public Policy, Carnegie Mellon University, and he is a Visiting Professor at the Centre for Public Sector Research, Gothenburg University, Sweden.

· Experience and research in risk perception and

risk communications: He has conducted research in risk communication and management in such areas as renewable energy policy, food safety issues, pharmaceutical recalls, telecommunications, biosafety, and the siting of building of incinerators, nuclear waste installations and railways. He is a believer in the building of public trust in regulators and industry via proactive risk communication and argues that high regulatory/ industry trust is equivalent to low public perceived risk.

People perceive some risks differently than others. Research shows, for example, that we are all worried more about risks that are seen as involuntary rather than voluntary, unfamiliar rather than familiar, and technological rather than natural. Communicating risks that people are concerned about is difficult at the best of the times, but made worse in an era of 'post trust' as the risk communicators themselves are not trusted. In this talk I give examples from the food and related sector of how to and how not to communicate risks in the post-trust era and conclude by putting forward a number of policy recommendations.

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Key words: post-trust, risk communication, societies

Biases, illusions, and noise: why providing scientific facts is good – but not enough

Lucia Reisch *Copenhagen Business School*

Lucia A. Reisch is a German behavioural economist and full professor for intercultural consumer research and European consumer policy at the Copenhagen Business School in Denmark. She is also a Visiting Professor at Friedrichshafen's Zeppelin University, Germany and is currently working as a Principle Investigator on several German, Nordic, and European research projects. In the past decades, she has published more than 400 publications and disseminations covering her main research areas: consumer, health and sustainability policy, empirical research into consumer behaviour (in particular sustainable consumption and production) as well as behaviourally based regulation. As an academic policy consultant, she chairs the Advisory Council for Consumer Affairs of the German Federal Ministry of Justice and Consumer Protection (since 2014), is a long-time member of the German Council for Sustainable Development as well as of the German Bioeconomy Council. She serves on several boards (e.g., Stiftung Warentest, Berlin; Robert Bosch Foundation, Stuttgart; Stockholm School of Economics, Stockholm). She has been elected a lifelong member of acatech, the German Academy of Technical Sciences (Section 'Economics') and has serves for15 years as Editor-in-chief of the Journal of Consumer Policy (Springer).

Communicating scientific facts as a one-way process to deliver information has been the dominant mode of risk communication for long. However, consumer research, decision sciences and cognitive psychology increasingly provide empirical evidence that people's beliefs and preferences are shaped by much more than deliberative cognitive processes: emotions such as fears, physical (e.g. being tired) and neuronal states (e.g. being stressed) at the time of decision making, cultural and group variables, as well as systematic biases and 'noise' (i.e. chance variability of judgements) do influence people's decision making and formation of attitudes. For a successful communication of scientific information, the sender must be aware of these biases, suboptimal heuristics, and 'noise'. There are basically three approaches. First, the sender can make use of 'informational nudges' to increase the relevance, salience and hence effectiveness of the information. This is what behavioural insights-based policies aim to carry out. Second, one can educate people on the limits of the cognitive system and increase their decision-making capacity and try to make them more resistant to manipulation. Third, the sender can harness the biases, which requires good governance, transparency and a generally accepted and welfare-enhancing goal.

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Key words: attitudes, biases and heuristics, decision making, nudges

Observing news media in the misinformation ecosystem: the case of public health communications

Kannan Krishnaswamy *The George Institute for Global Health*

Kannan Krishnasawmy has had professional experience of around 27 years as a journalist, public relations professional, communicator and trainer in communication and media skills for people at the grassroots. He has have spent enough time in both the development sector and in the media world to gain insights into what works for an organisation in using communication for development and how this can be done in an effective manner. While working in The Hindu as a journalist, he learnt how media works and how communications can be pressed into the service of the development sector. In Plan India, he led large projects around children's media demonstrating the effectiveness of the use of media by children and how cutting-edge projects that give a voice to the voiceless can amplify development at regional

as well as global levels. In his latest stint at the George Institute, he has introduced a unique programme called critical appraisal skills for health reporting, which combines two unique innovations from different geographies in the world – media doctor from Australia and Critical Appraisal skills program from UK – to bring to bear a training programme involving evidence, research, and data. Many journalists and media students have been trained in critical appraisal skills. He has also worked as part of the advocacy team of the George Institute to look at disseminating research to policy-makers. Other research projects include a study on mental health of journalists and another one on fake news.

News media face a huge challenge in covering public health issues such as immunisation in which science is pitted against people's emotions. The misinformation ecosystem is characterised by a lack of understanding of an evidence-based approach due to which the media often fail to comprehend the science behind such events – the invisible underlying cause behind the seemingly visible effect. Understanding evidence, research and data can help the media to take a more scientific approach to covering such stories. But there is another side to this story as well. The often-held premise is that journalists are starved of information and, if this is provided to them, they will be able to write good stories. So the emphasis is on getting the science right. But this always does not work. Between 2014 and 2016, we implemented a project in India aimed at developing the critical thinking skills of journalists and media students to improve reporting on public health issues. What we found was that the information-deficit model has to be complemented by a model that combines critical thinking and analysis, understanding science and taking an evidence-based approach. Future directions could be taking a social science research approach to understanding such issues and also addressing the disinformation ecosystem, which essentially is all about understanding and fighting fake news. In the information ecosystem, there are three levels of content creation: the base level, which is about belief (our worldview) and critical thinking (understanding the context well) which is usually the formative part of engagement; the mid-level, which is about getting the science right; and the top level, which is about the social and cultural contexts that influence the other two levels. And finally, what also matters is the clear distinctions between misinformation, disinformation and mal information, which is produced as a result of the influence of the three levels on each other. Our project was implemented at the second level, but for any future intervention it has produced valuable information for future interventions such as belief systems cannot be ignored – or social and cultural contexts play an equally important role, etc. And this has relevance for all media including social media.

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Dealing with digital misinformation: a polarised context of narratives and tribes

Fabiana Zollo *Ca' Foscari University of Venice*

Fabiana Zollo is an Assistant Professor in the Department of Environmental Sciences, Informatics and Statistics and fellow member of the Laboratory of Data Science and Complexity coordinated by Walter Quattrociocchi. She is also Research Fellow at the Humanities and Social Change International Foundation (Venice Centre) led by Shaul Bassi.

Her research investigates (mis)information spreading with a special focus on the dynamics of polarisation and intolerance and the evolution of collective narratives on online social media. She has collected several papers on the topic, both with national and International co-authors. Her results have been included in the Global Risk Report 2017 of the World Economic Forum and have been widely covered by the media (among the others: The New York Times, The Washington Post, The Economist, Bloomberg View, The Guardian, Phys.org, El Pais) and disseminated internationally (Le Scienze, Pour La Science, Spektrum, Scientific American, Investigatión y Ciencia).

The advent of the Internet and web technologies have radically changed the paradigm of news consumption, leading up to the formation of a new scenario in which people actively participate not only in the diffusion of content, but also its production. In this context, social media have become central not only to our social lives, but also to the political and civic world, rapidly establishing as the main information source for many of their users (Newman et al. 2016). However, social media are riddled with unsubstantiated and often untruthful rumours that can influence public opinion negatively. Since 2013 the World Economic Forum has been placing the global danger of massive digital misinformation at the core of other technological and geopolitical risks, ranging from terrorism to cyber-attacks (Howell, 2013). The phenomenon is alarming. When people are misinformed, they hold beliefs neglecting factual evidence. Moreover, in general, people tend to resist facts (Kuklinski et al., 2000), and corrections frequently fail to reduce misperceptions, instead producing a backfire effect (Nyhan and Reifler, 2010). So, understanding the main determinants behind content consumption and the emergence of narratives on social media are crucial. In this talk, we address such a challenge by applying a cross-methodological, interdisciplinary approach that accounts for the socio-cognitive factors underlying

the phenomenon. We analyse massive data from online social media and provide the empirical existence of the so-called echo chambers, polarised groups of like-minded people in which users reinforce and polarise their pre-existing opinions. We show that confirmation bias is the main driver behind content consumption (Del Vicario et al., 2016), address the emotional dynamics inside and between different narratives (Zollo et al., 2015), and investigate users' response to both confirmatory and contrasting information (Zollo et al., 2017). Our findings reveal that similar patterns hold for political (the Brexit, the Italian Constitutional Referendum) and public (climate change, vaccines) debates, in which we observe the spontaneous emergence of well-segregated groups of users around news sources and the natural tendency of users to focus on a limited set of pages (selective exposure) eliciting a sharp and polarised community structure (Del Vicario et al., 2017a, Del Vicario et al., 2017b, Schmidt et al., 2017, Schmidt et al., 2018, Zollo et al., 2018). Our results provide interesting insights about the determinants of polarisation and the development of core narratives on online debating, highlighting the crucial role of data science techniques to map the information space on social media.

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Key words: echo chambers, misinformation, polarisation, social media

We don't live in a post-truth society

Tracey Brown *Sense about Science*

Tracey Brown has been the director of Sense about Science since 2002. Under her leadership, the charity has turned the case for sound science and evidence into popular campaigns to urge scientific thinking among the public and the people who answer to them. It has launched important initiatives including AllTrials, a global campaign for the reporting of all clinical trial outcomes; and the Ask for Evidence campaign, which engages the public in requesting evidence for claims. In 2010, the Times newspaper named Tracey as one of the 10 most influential figures in science policy in Britain and in 2014 she was recognised by the Science Council for her work on evidence-based policymaking. In June 2017 Tracey was made an OBE for services to science.

The success of populist campaigns has given rise to some serious questions about the public regard for standards and norms of evidence and anxiety that carefully assembled facts and data are becoming seemingly dispensable. Announcements about gross domestic product (GDP), climate, pollution, food and energy appear to have had little purchase if they do not describe the experience that people wanted to articulate. In 2016, the Oxford English Dictionary made 'post-truth' the word of the year. Across Europe, conferences have sprung up among research and regulatory bodies disturbed about how to operate in a world of Facebook filter bubbles and alternative facts. Despite all their appeals to greater public engagement, people in public life are losing faith with the public. Amid this anxiety, we are in danger of seeing only memes that reinforce it, of believing that people just hear what they are already disposed to hear, that there is no scope for persuasion or challenge and factual credibility counts for nothing. This would be wrong. In fact, 2016 could just as easily have been considered the year of truth seeking – a year in which thousands of people sought truth about all manner of things in the natural and social world, from heart surgery outcomes to police statistics. That interest in science and evidence was borne out in surveys: Pew found that scientists are still trusted to tell the truth and noted that they are the only group to enjoy consistently strong trust since the 1970s. In the UK, in the wake of post-referendum concern about the public's attitude to experts, an Ipsos MORI 2016 poll found that 86% of people want the government to consult experts on complex subjects. The question before us is not how to function in a post-truth society but how to equip people better to make sense of their natural and social systems: are we grappling alongside the public, to ask testable questions, to crunch the numbers? To transcend how things appear and find out how they really are? How can we truly embark on those journeys together, with the public and in the public interest?

Working with the public reminds us that monitoring, regulating and assessing are key to public empowerment and democratic accountability; and it expands our social imagination about how to communicate and collaborate more effectively. At Sense about Science, our public-led, expert-fed approach has served up some interesting lessons for discussion.

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Key words: public engagement, science communication, statistics

EMA's approach to stakeholder engagement

Melanie Carr *European Medicines Agency*

Melanie Carr is currently Head of the Stakeholders and Communication Division and acting Head of the Corporate Stakeholders Department at the European Medicines Agency (EMA). Melanie is a pharmacist and has been working at the Agency for 22 years. She joined the Pharmacovigilance department of the EMA in 1996 and transferred to the New Chemical Substances Sector of the Agency in 1998 as a Project Manager for Centralised Applications for Marketing Authorisation. In 1999, she became a member of the EMA task force responsible for implementing the EU legislation on Orphan Medicinal Products and setting up the Committee for Orphan Medicinal Products (COMP). From 2005 to 2014, she was responsible for implementing the Agency's SME initiative, setting up and running the EMA SME Office. In 2014, she was appointed Head of the Corporate Stakeholders Department and in 2016 took on the role of Head of Stakeholders and Communication Division on an ad interim basis, with formal appointment to that position in 2018.

Since its creation in 1995, EMA has recognised the need for interaction with its various stakeholder groups and the added value this provides, and has consistently given priority to such interaction. Today, EMA has an overarching set of principles in place for managing it stakeholder relations. Aligned with these, the Agency has developed more specific frameworks for interaction with each of its key stakeholder groups: patients and consumers, healthcare professionals, industry and academia. These frameworks identify the objectives to be achieved and the methodology to be used for engaging with each group. Of the four frameworks, interactions with patients and consumers are perhaps the most mature and fully developed, and EMA's model for engaging with patients is currently acknowledged as a reference point in medicines regulation. Patients are involved throughout the entire life cycle of medicines – from early development and assessment of benefit–risk to safety monitoring once medicines are released onto the market. In 2017 alone, patients participated in nearly 900 different EMA activities, the highest level to date. New methods for interaction and engagement are constantly being developed. In 2017, the Agency implemented the first EU public hearing on medicines regulation during its assessment of valproate. The success of this hearing once again made clear the value that patients' input in benefit–risk evaluation adds to decision making. The Agency is fully committed to the continued active involvement of patients (and other stakeholders) in its activities and confirms the value and contribution this makes to public health.

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Key words: EMA, stakeholders

Engaging stakeholders in science-based consumer protection: practices and perspectives from the German Federal Institute for Risk Assessment

Leonie Dendler *German Federal Institute for Risk Assessment*

Leonie Dendler is a postdoctoral research fellow at the German Federal Institute for Risk Assessment working for the crisis prevention and coordination unit within the risk communication department. Her project focusses on stakeholder management and public engagement in science-based consumer protection. She has previously worked for the Sustainable Consumption Institute and the Tyndall Centre for Climate Change Research at the University of Manchester (UK) and Fudan University (China). An environmental scientist by training with a PhD from Manchester Business School (UK), her wider research interest lies in understanding institutional change processes across international consumption and production systems with a particular focus on food. She is a board member of several international research networks and has written, reviewed and edited for

different peer-reviewed journals, including the Journal of Cleaner Production and Energy Policy.

Stakeholder management has long been established as a key variable for the success of corporations. More recently, its relevance has been increasingly discussed for governmental, non-governmental and academic organisations. This builds on longstanding calls for more public engagement in governance and societal processes at large, which find their roots in strategic as well as normative lines of argumentation. Many argue that such demands also extend to public scientific organisations, such as the German Federal Institute for Risk Assessment (BfR), with the statutory task to conduct independent risk assessment for consumer health protection. Against this context the BfR is currently investigating facilitators, barriers and potential implementation pathways for successful stakeholder engagement in the context of science-based consumer protection. Next to literature reviews and documentary analyses the research involves participant observations, 40 qualitative interviews with BfR stakeholders from governmental, supragovernmental, non-governmental, corporate, academic and media organisations and a structured survey of 414 BfR stakeholders and 1,004 members of the public. Drawing upon these data, the first part of the presentation will shed light on important criteria for the successful enactment of stakeholder management processes. Summarising three sets of planning, process and outcome related criteria it will show how normative demands increase as we move out of the purely profit-oriented realm. As a result, a number of conflicts emerge. To address these, organisations need not only strong leadership and organisational support but also a clear understanding of their goals and priorities as well as their wider social context. The second part of the presentation will focus on challenges for a participatory opening of the risk assessment process. These include epistemological, regulative and discursive challenges. In particular, the presentation will point to current contradictions within political and wider societal discourse and lay out the need for a more open debate about what calls for more public participation imply for science, government and society as a whole. The presentation will close with a reflection on future prospects and potential pathways for stakeholder management in the context of science-based consumer protection.

Key words: public engagement, risk assessment, risk communication, stakeholder management

Opening up expertise to civil society: case study of the French Agency for Food, Environmental and Occupational Health and Safety (ANSES)

Régine Fraysse-Boutrais *French Agency for Food, Environmental and Occupational Health & Safety*

Education:

- PhD in Sociology, Paris Dauphine University, 2011, Thesis on the 'The dynamics of NGOs mobilisations around environmental health issues: A way to question development?
- Master in Sustainable Development and Organisations, Paris Dauphine University, 2005.
- Master in Management of NGOs, Paris Panthéon Sorbonne University – Sorbonne Business School (IAE) PARIS, 2004.
- Current positions:
- Sociologist, In charge of developing relationships with stakeholders since 2010 Social Sciences Expertise and Society Unit, Science for Expertise Division, French Agency for Food, Environmental and Occupational Health and Safety, 94 MAISONS-ALFORT
- Professor in Environmental Health, Paris Dauphine University and member of the educational team of the 'Sustainable Development and Organisations' Master degree in charge of the division 'Social progress, work and common well-being'.

As part of its global process of contribution to public debate and of developing relationships with stakeholders, ANSES signed a charter in 2011. This document aims at promoting the opening up of expertise to society and has been endorsed by seven public organisations in France dealing with research and sanitary/environmental risk assessment. The Agency's commitments towards civil society are three-fold: improve transparency on the results of expertise and methods used in risk assessment, share scientific knowledge and uncertainties, favour public engagement and capacity building. The implementation of this charter within ANSES has resulted in several participatory processes at various levels of governance and along the risk assessment process. Stakeholders are involved in governance bodies: Board of Directors, five Thematic Steering Committees, three Dialogue Committees and a Platform on controversial issues such as radiofrequencies, nanomaterials or pesticides. They are also invited to contribute to the risk assessment process through hearings and consultations and finally to feedback meetings and training sessions. This talk will draw some conclusions on the impacts of public engagement in facilitating the understanding of the opinions and recommendations delivered and in sharing scientific knowledge.

Key words: civil society, expertise, public engagement

Optimising scientific value through engagement with society. Steps taken and direction to go

Didier Verloo *European Food Safety Authority*

Didier Verloo has been working for EFSA since 2005, where he has been heading the Assessment and Methodological Support Unit since 2008. Didier started his professional career at the Institute of Tropical Medicine on the development of diagnostics, interpretation and medical decision making based on diagnostic test results in human and animal trypanosomiasis (sleeping sickness) and worked from 2000–2005 for the Belgian government as an epidemiologist and risk assessor mainly in the area of antimicrobial resistance and infectious diseases. Over the years he has built up academic and hands-on experience in biostatistics, epidemiology, risk analysis, test validation and provided risk analysis consultancy in public health, construction, finance and engineering. Didier graduated as a veterinarian in 1995.

EFSA provides upon request scientific recommendations to inform managerial decisions. Good managerial decisions can only be based on methodologically sound and unbiased scientific advice, hence the importance to measure and define the scientific quality of the advice given. Following ISO quality management standards, quality means 'meeting customer needs' so given EFSA's role there is an obvious direct link between societal expectations and scientific quality. Guided by the EFSA core values scientific quality then becomes the measure of how far the EFSA scientific advice meets the expectation in scientific value based on the degree of accomplishment of four fundamental principles being: (1) impartiality; (2) methodological rigour; (3) transparency; and (4) engagement. All four principles benefit from societal interaction and have evolving societal expectations. Several examples will be given on how EFSA is moving forward on this going from stakeholder and public consultations on risk assessment protocols to innovation crowd sourcing.

Key words: engagement, open risk assessment, openness, risk assessment, science and society

Social research-based engagement processes reshaping information strategies (to improve trust in the regulator and the food system)

Michelle Patel *UK Food Standards Agency*

After serving as Director of Communications at the Food Standards Agency and in senior marketing, insight and communications roles within UK Government, Michelle now runs the Social Science function at the FSA, leading the team that ensures that the understanding of human behaviour informs the assessment and management of food risk and safety in England, Wales and Northern Ireland.

The Food Standards Agency's (FSA's) strategic aim is 'Food we can trust'. However, current discourse suggests that world-wide, trust in government, NGOs, business and media has declined. Some commentators blame this 'crisis of trust' on the rise of social media and the democratisation of information. In an increasingly uncertain world where we expect significant change, this is not something that an organisation with a role for communicating science to protect consumers can take for granted, and nor can a food business.

We explore trust in the food system and its regulator, using a multimethod approach that includes quantitative tracking, more in-depth quantitative work to inform the development of a composite measure for trust, and iterative public dialogues in England, Wales and Northern Ireland to explore trust with citizens.

In parallel, we conducted a literature review covering the contemporary drivers and barriers to trust in industry, the food system and in regulators and workshops with industry and civil society.

Finally, a peer-reviewed synthesis brings this together with existing research from the FSA and elsewhere, including our previously published studies on the connection between consumers and the wider food system (Our Food Future) and on consumers' expectations for transparency of information about their food.

The intention is to continue to develop an evidence base that will help locate UK food policy decisions in a sound knowledge of what drives trust in a regulator and trust in the food system in an increasingly complex world.

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Key words: dialogue, reputation, research, social research, trust

The involvement of civil society in risk communication activities

Pierdavide Lecchini, *Italian Ministry of Health*

Pierdavide Lecchini is a veterinarian, an expert in public health and veterinary public health. He is Director of Office 3 of the General Secretariat of the Italian Ministry of Health (covering health prevention, research, international relationships, communication, food, veterinary medicine and collegial bodies). He gained his Bachelor and Master degrees in veterinary science, control of food and feed of animal origin and national and European veterinary legislation from the University of Pisa and the University of Parma, Italy, and after five years in mixed veterinary practice joined the government veterinary authority in 1991. Over a 16-year period, Pierdavide Lecchini worked in numerous veterinary and management roles, with responsibilities for international trade, border inspection post control, twinning projects with Third Countries for accession to the EU, food safety and animal welfare. In 2007, he became the Italian Delegate to the EU for health and veterinary matters, and in that capacity served as an expert in Health, Veterinary matters, Food Safety and Pharmaceuticals within the Italian Permanent Representation to the EU. He acted as spokesman for Italy and delegate of the Ministry of Health to the sectorial working groups of the European Council and the European Commission. From March 2016 to April 2018, he served in the role of Director of the animal health and crisis unit office of the General Directorate for Animal Health and Veterinary Medicine of the Ministry of Health. He took up his current position of Director of the Office 3 of the General Secretariat of the Ministry of Health in May 2018

Italy's national authority for risk assessment and communication, located at the Directorate-General of Collegial bodies for health protection of the Ministry of Health, has always had as its mission the involvement of stakeholders represented by consumer and producer associations. It is carried out through a body that allows a constant and constructive dialogue with public authorities having competence in food and feed issues. A specific section called 'Consulta delle associazioni dei produttori e dei consumatori – CNSA2' (Council of Producer and Consumer Associations) actively works within the 'Comitato nazionale per la sicurezza alimentare' (National Committee for Food Safety). The Council represents the forum for comparing and sharing information to facilitate conscious consumption and healthy diet among citizens. Therefore it serves as a sounding board for main measures that have been adopted by the technical and scientific section. It also represents a further source of questions and requests, as well as a boost for the activity of both the Directorate-General and the Committee. Main activities undertaken during recent years are described, based on information documents for all those involved in communication and the 'Guidelines for a proper risk communication in the food sector'. Other relevant activities that will be illustrated are its structure and contents shared with the Council members, concern for training programmes, and the involvement of both specialised press and communicators and the adoption of innovative approaches.

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Key words: involvement, risk communication, stakeholders

Managing evidence

The world is going through an exponential explosion of data, potentially increasing the evidence base for risk assessments. But how do we explore and analyse all this data? This session will investigate the opportunities and challenges associated with the how, what and why linked to accessibility, use and analysis of the right data in the context of regulatory-driven science.
Besides the requirements of new tools and approaches such as machine learning and artificial intelligence, the session will address the challenges ahead – are we targeting, analysing and accessing the right data serving as evidence? How can this diverse body of evidence be used to provide fit-for-purpose risk assessments?

CHAIRS

Mary Gilsenan *European Food Safety Authority*

Mary Gilsenan is head of EFSA's Evidence Management Unit, where she is responsible for the collection, collation, management and publication of (meta)data on food consumption, as well as food-borne biological and chemical hazards, to support EFSA's scientific assessments. Before joining EFSA in 2012, Mary managed the Global Regulatory Services Department at Leatherhead Food Research, and worked as a researcher in the food industry, as well as at Trinity College, Dublin. Mary holds a Bachelor's degree in human nutrition from the University of Ulster and a PhD in dietary exposure from Trinity College, Dublin.

Danica Grahek-Ogden *Norwegian Scientific Committee for Food and Environment*

Danica Grahek-Ogden was educated as DVM at the University of Zagreb and has a Masters of Executive Management degree from the Norwegian Business School.

- First employment was as a microbiologist at the Institut Ruder Boskovic at Institute for Marine Research and moved to Norway 1994 and continued to work in food microbiology.
- Food Safety Authority as a microbiologist at the laboratory.
- MATFORSK (Norwegian Food Research Institute) and Prior Norge BA as project manager for research and development projects, reporting to funding bodies and ensuring food safety throughout the chain 'from farm to fork'. Projects involved identification, ranking and mitigation of risk factors using process mapping, risk assessment, change management, internal audit and training.
- Det Norske Veritas (in Norway and for a year in Aberdeen, UK) as a senior adviser with food safety and risk management in the area of microbiological risk assessment (biorisk) and business risk within the food sector as a main field.

- Norwegian Veterinary Institute – project management of EU's SAFEFOODERA project CAMPEC net.
- At the Norwegian Institute of Public Health jobs included tasks with foodborne diseases and zoonosis as a main field. Jobs included an advisory role for health institutions and food safety authorities, development, use and maintenance of surveillance database, rapid response to and management of outbreaks and reporting to national and international bodies. Other tasks included development and management of scientific projects, preparation and delivery of lectures and training sessions.
- I am presently employed in the Norwegian scientific committee for food safety (as part of the Norwegian Public Health Institute) with risk assessment of biological hazards as a main field. Job includes coordinating the work of an expert panel, project management from budgeting to delivery of finished assessment and evaluation of the project. As a part of the job I am Norwegian representative in EFSAs: network for microbiological risk assessment and Advisory Forum.

Hans Verhagen *European Food Safety Authority*

Hans Verhagen is EFSA's senior scientific adviser. Hans has 35 years of professional experience, both in the public and private sector. He held management positions at the National Institute for Public Health and the Environment, TNO Nutrition and Food Research Institute, and in EFSA. Hans has worked for Unilever Research and at the Universities of Maastricht, Nijmegen and Ulster. He was a member of EFSA's NDA Panel from 2006 till 2015. Hans has published widely on subjects related to toxicology and nutrition. He holds a Master's degree in chemistry from the University Nijmegen, and has a PhD in toxicology from the University of Maastricht. He is a board-certified toxicologist and a board-certified nutritionist, and is a visiting professor at the University of Ulster.

RAPPORTEURS

Fabrizio Abbinante *European Food Safety Authority*

Fabrizio Abbinante is presently programme manager of EFSA's Information Management Programme. He has been a Data Manager and IT Business Analyst for EFSA (2008–2014) and the European Medicines Agency (2004–2008). He has managed several projects in the area of data warehousing, data collection, data harmonisation, web reporting, interoperability, data standards, controlled terminology and information management in general. From 2002 to 2004, Fabrizio worked for Bassilichi SpA, first as a software developer, then as an IT business analyst in the 'EudraVigilance project' at the European Medicines Agency. He graduated in 2002 as a software engineer at the University of Pisa.

Claudia Cascio *European Food Safety Authority*

Claudia Cascio has been a scientific officer at the Exposure Assessment Team of EFSA's Evidence Management Unit since 2017. Before joining EFSA, Claudia was postdoctoral researcher in nano-analytics for the German Federal Institute for Risk Assessment, RIKILT-Institute of Food Safety of the Wageningen University and Institute for the Health and Consumer Protection of the Joint Research Centre. From 2007 till 2010, Claudia was a Marie Curie Actions Early Stage researcher working on biomonitoring studies to assess human exposure to arsenic and other trace elements in EU. She worked as research assistant at the Faculty of Health and Life Sciences of the De Montfort University of Leicester and as honorary research assistant at the Institute of Biological and Environmental Sciences of the University of Aberdeen. Before 2007, she worked as junior researcher in characterisation of surfaces and nanomaterials at SuperLab. She has a Master's degree in biology and a supplementary degree in economics of cultural heritage both from the University of Catania, and holds a PhD in biochemistry from De Montfort University of Leicester.

Ermanno Cavalli *European Food Safety Authority*

Ermanno Cavalli is a senior scientific officer and team leader at EFSA's Digital Transformation Services Unit where he is involved in the digital transformation of EFSA, with responsibility for technology strategy and architecture. He has been employed by EFSA since 2006, and previously worked in the private sector. Ermanno has in total 30+ years in managing information technology, of which 20+ years in managerial roles, from software development manager to CIO, plus 10 years in technical roles, from software developer to system engineer. He has developed a sound managerial role built on strong technological experience. He has a Master's degree in computer engineering from the University of Bologna.

Paul Devalier *European Food Safety Authority*

Paul Devalier is a European technologist with 30 years of experience in leading the application of technology to business. He trained in cognitive science and history at Brown University, and served as chief information officer for the private sector before serving as EFSA's digital transformation leader.

SPEAKERS

Evidence we can believe in: the Bermuda Triangle of Policy in a data age

Robert Madelin *Foresight International Policy and Regulatory Advisers*

Robert Madelin is a Visiting Fellow at Oxford University's Centre for Technology and Global Affairs, and Chairman of the public affairs consultancy Fipra International Ltd. He serves on the Scientific Committee of the recently launched European initiative 'AI for People'. His previous career was in UK public service and the European Commission and he is the author of the report Opportunity Now: Europe's Mission to Innovate (2016).

Science for risk assessment is making huge strides in the age of big data and high-performance computing:

- Science can feed ever clearer and faster risk assessment.
- Real-world – and real time – evidence from dynamic data can both improve the iterative maintenance of risk knowledge and create opportunities for lighter and still more effective management steps.
- These revolutionary changes affect a world where the human mind evolves at a different rate. The evolution gap drives much of the cognitive dissonance, distrust and dystopia around the ongoing Fourth Industrial Revolution.
- In the absence of new frameworks for society, as it confronts risk in the data age, science is lost as a driver of democratic policy.
- But with modest adjustment, the existing model can guide us into the coming decades, with Europe still a creative and respected thought leader in the global risk community:
- By re-engaging with what we know about human society's needs in terms of explanation and empowerment, as well as risk management, institutions can better fulfil their ever-legitimate roles.
- By focusing on the outcomes for which food safety systems stand, scientific evidence can also guide and underpin the changes in method and tools that offer better results with lower 'compliance friction'.

The challenges of Big Data for European Agencies

Nikolai Constantin Brun *Danish Medical Agency*

Nikolai C. Brun has had background and experience for 17 years in the clinical field and afterward in the research and development of pharmaceuticals in the Biotech and Pharmaceutical Industry, with a long list of publications in high-impact journals.

His has spent 1.5 years as Medical Director responsible for Medical Evaluation and Biostatistics and, as of 1 June 2018, both for Human and Veterinary Medical Evaluation.

He is Acting Co-Chair of the EMA/HMA Big Data Task Force.

Big Data, i.e. Real World Data, in large amounts are increasingly becoming available for regulatory decision makers. The path from Real World Data to Real World Evidence is, however, full of challenges but also many opportunities for new ways of arriving at evidence-based decisions for the benefit of patients.

In the European Medicines Agency (EMA)/HMA Big Data Task Force co-chaired by the speaker we are looking to solve some of these challenges. The talk will aim to enlighten the audience on the work ongoing at a European level, and around the world for perspective.

Blockchain for good governance in the food industry: opportunities and challenges

Claudia Pagliari *University of Edinburgh*

Claudia Pagliari BSc, PhD, FRCEP is a senior researcher and eHealth programme director at The University of Edinburgh's medical school. She leads the interdisciplinary eHealth Research Group and the masters programme in Global eHealth and is one of the academic leaders of the new NHS Digital Academy. Dr Pagliari has a longstanding research interest in the use of ICT and data for health. This includes analysing the emerging technology and policy landscape,

synthesising research evidence, evaluating large-scale NHS ICT implementation programmes, and studying innovations such as remote telehealth, mHealth, assistive robots, social media, big data and blockchain. Underpinning her research is a strong focus on patient/consumer protection, policy and governance, both in terms of information practices and organisational accountability. Recent examples include her reports on the role of ICT innovations as enablers of transparency and accountability in low and little income countries; the readiness of UK research councils and researchers to handle the ethical challenges of big data mining from social media, the use of crowdsourcing for health surveillance and research, and quality of online information from direct-to-consumer genetic testing companies.

The global food industry faces important governance challenges for which blockchain has been proposed as a solution. This presentation will briefly explain the concept of distributed ledger technology and examine its value proposition from the perspective of different actors in the food supply chain (producer, distributor, retailer, consumer, regulator, enforcer, etc.). It will seek to separate the truth from the hype surrounding blockchain and present examples to show how it is being used to promote transparency, traceability, accountability, reduce fraud and improve consumer trust. Injecting a note of caution, however, it will also examine some of the ways in which this new 'trust machine' could potentially be subverted by vested interests, and consider what the industry and regulators might be able to perform to prevent this, as well as how innovations such as artificial intelligence and social machines might help.

Keywords: accountability, blockchain, consumer protection, fraud prevention, global trade, governance, regulation, public health, supply chain, transparency

Software Beats Animal Testing at predicting Toxicity of chemicals

Thomas Hartung *CAAT Europe*

Thomas Hartung, MD PhD, is the Doerenkamp-Zbinden-Chair for Evidence-based Toxicology with a joint appointment for Molecular Microbiology and Immunology at Johns Hopkins Bloomberg School of Public Health, Baltimore. He holds a joint appointment as Professor for Pharmacology and Toxicology at University of Konstanz, Germany; he also is Director of Centers for Alternatives to Animal Testing (CAAT, http://caat.jhsph.edu) of both universities with the portal AltWeb (http://altweb.jhsph.edu).

CAAT hosts the secretariat of the Evidence-based Toxicology Collaboration (http://www.ebtox.org), the Good Read-Across Practice Collaboration, the Good Cell Culture Practice Collaboration, the Green Toxicology Collaboration and the Industry Refinement Working Group. As PI, he headed the Human Toxome project (http://humantoxome.com) funded as an NIH Transformative Research Grant.

He is the former Head of the European Commission's Center for the Validation of Alternative Methods (ECVAM), Ispra, Italy, and has authored more than 530 scientific publications.

Much chemical safety information is now publicly available, raising the hope of predicting the toxicity of new chemicals. Read across (RAx) is the approach to estimate the toxicity of a substance by comparison of known properties of similar substances. REACH (Regulation 1907/2006) was probably the first regulation that formally gave the possibility of using non-testing opportunities, including QSAR (Quantitative Structure Activity Relationship) and RAx. By analysing the data submitted after the first REACH deadlines in 2010 and 2013, RAx resulted as the predominant method to avoid new tests on animals.

This triggered new general initiatives with the common goal of improving the robustness of the approach and the scientific endorsement for better regulatory acceptance. For example, ECHA has published their Read-Across Assessment Framework (RAAF) to guide the formal presentation of RAx data and the European project EU-ToxRisk (www.eu-toxrisk.eu) works on 8 case studies on RAx with the engagement of industry and regulators.

The Center for Alternatives to Animal Testing (CAAT) in the US and Europe has started a RAx program in 2014 to develop Good Read-Across Parctice and through the analyses of the data in the ECHA database of registered substances. At that time, the number of substances was about 10,000 and after a proper transformation of the records into a computer-readable format, it was possible to improve toxicity predictions exploiting the big data available. Analysing the 6 most common OECD toxicity tests for reproducibility (consuming 55% of animals in safety testing in Europe), a reproducibility of 81% (balanced accuracy, sensitivity 70%) was found.

Today, the system has expanded with data from PubMed and the US National Toxicology Program to 10 million structures, including 800,000 chemicals with millions of information on physicochemical and toxicological endpoints. The constructed models automate and extend the RA method of chemical classification. The new approach, called RASAR (read-across structure activity relationship) uses machine learning to combine binary fingerprints and Jaccard distance to define chemical similarity and feature vectors for supervised learning. A boost in predictivity was achieved by data fusion, i.e. each prediction was deduced from 74 different features.

The results are focused on 9 endpoints: skin/eye irritation, skin sensitisation, acute oral/dermal/inhalation toxicity, mutagenicity and acute/chronic aquatic toxicity. Predicting 190,000 toxicity

classifications of chemicals, this system provided high sensitivities and specificities to equal or even surpass the predictivity of animal tests. For the six tests, where animal study reproducibility could be assessed, the RASAR resulted in 87% accuracy (sensitivity 89%).

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Key words: toxicity prediction, Read Across Structure Activity Relationship (RASAR), machine learning, big data

Ignorance and the Community of Knowledge

Steven Sloman *Brown University*

Steven Sloman is a Professor of Cognitive, Linguistic, and Psychological Sciences at Brown University, USA where he has worked since 1992. He did his PhD in Psychology at Stanford University from 1986–1990 and then did post-doctoral research for 2 years at the University of Michigan. He is ex-Editor-in-Chief of the journal Cognition. Steven is a cognitive scientist who studies how people think. He has studied how our habits of thought influence the way we see the world, how the different systems that constitute thought interact to produce conclusions, conflict, and conversation, and how our construal of how the world works influences how we evaluate events and decide what actions to take. In 2005, he published the book Causal Models: How We Think About the World and Its Alternatives with Oxford University Press. His recent book with Phil Fernbach, The Knowledge Illusion: Why We Never Think Alone, came out in March, 2017.

Asking people to explain how something works reveals an illusion of explanatory depth. Typically, people know less about how things work than they think they do. We overestimate our knowledge of common objects. We similarly overestimate our understanding of political policies. I will argue that the reason we live in this illusion of understanding is that we live in a community of knowledge, guided by shared intentionality. Our communities understand how things work and we fail to distinguish what we know from the knowledge that resides in other people's heads. I will draw out some of the implications of these ideas for the importance of ferreting out expertise in whatever part of society it resides.

Managing Data to Manage Evidence: Social and Technical Challenges

Irene Pasquetto *University of California*

Irene Pasquetto obtained her Ph.D. from the Department of Information Studies at UCLA, where she works as a research assistant at the UCLA Center for Knowledge Infrastructures and also at the Participation Lab (PartLab) in the UCLA Institute for Society and Genetics. She teaches and co-teaches classes on data management, information ethics, and data economies. Her overarching research interest lies in the analysis of data-centric scientific practices and technologies, especially in relation to science policy-making. For her doctoral research, Irene investigated the epistemic, socio-technical, and ethical challenges related to the open circulation of biomedical data and software. She has also published on issues of genetic ancestry testing, open data, and identity, on the challenges of archiving and reusing climate-change data. With her work, Irene aims at informing the design and implementation of governance models for data and code infrastructures.

This talk examines the social and technical challenges of reusing research data. 'Reuse' refers to the usage of a dataset by someone other than the originator. It is the practice of conducting novel analyses of available datasets that has been accessed either on open digital repositories, or shared in between laboratories. Calls for increasing the sharing and reuse of research datasets have recently gained traction among science stakeholders. From a funding agency's perspective, data reuse speeds up the scientific discovery process, avoids duplication of efforts, and maximises the return on investment (ROI) on research. By accessing and combining multiple datasets, scientists can perform large-scale meta-analyses, train predictive algorithms, or reproduce prior results. But for research data to perform as 'fungible commodities' (i.e. inherently interchangeable goods), a set of technical and social factors needs to be taken into consideration. These include ensuring data quality and relevance, providing access to specialised skills and tacit knowledge, promoting trust towards the data producers, and designing novel strategies for credit attribution. Concrete examples of how such challenges can be overcome will be presented in the talk.

Human-computer sensemaking models and the challenges of incorporating artificial intelligence

Peter Pirolli *Florida Institute for Human and Machine Cognition*

Peter Pirolli is a Senior Research Scientist at the Institute for Human and Machine Cognition. His research involves a mix of cognitive science, artificial intelligence, and human–computer interaction, with applications in digital health, sense making, and information foraging, among other things. Previously he was at the Palo Alto Research Center and he was a Professor in the School of Education at the University of California, Berkeley, USA. He received his doctorate in cognitive psychology from Carnegie Mellon University in 1985, and a BSc in psychology and anthropology from Trent University. He is a Fellow of the American Association for the Advancement of Science, the American Psychological Association (Div 3 and Div 21), the Association for Psychological Science, the National Academy of Education, the ACM Computer-Human Interaction Academy, and the National Academy of Inventors.

It is estimated that 70% of healthcare costs are due to changeable behaviour (diet, fitness, smoking), and behavioural and environmental factors account for more deaths than genetics. Mobile health (mHealth) systems and pervasive technologies such as the Internet of Things, offer novel ways for supporting people in monitoring and changing their behaviour in the actual ecology of their everyday environments, and they offer incredible opportunities for advances in scientific psychology (e.g. measurement, in vivo experimentation and predictive fine-grained dynamical models). I will present research from our Fettle+ project on a series of multiweek mobile health studies in which we guide people in the formation of healthy habits (e.g. eating habits, exercise, physical activity) using 'scaffolding interventions' such as small online support groups, self-affirmations, implementation intentions and goals that are personalised to improve achievement and build self-efficacy. Computational cognitive models refine 'macro-theories' about some of these interventions (self-efficacy and implementation intentions) into individual-level simulations of the dynamics of observed intervention effects on daily goal achievement. Computational cognitive models and artificial intelligence provide opportunities for integrating specialised and vaguely specified domains of behaviour-change psychology, and decomposing and bridging long-term behavioural change (weeks, months) to intervention and learning events at the much briefer time scales that occur within the day.

Open Source Software paradigm: using ethics to promote technology and minimise its risks

Lazaros Tossounidis *European Centre for Development of Vocational Training*

Lazaros Tossounidis, senior strategy adviser at the EU's reference centre for vocational education and training. For the past 30 years he has been actively involved in the EU IT arena. Between 1988 and 1998, he held various posts of responsibility at DIGIT, the European Commission's internal IT service renowned for its open systems legacy, before assuming the direction of the IT Department at Cedefop. He worked closely with the IT industry in Europe and the USA, with repeated working visits to Silicon Valley and made significant contributions to the European Commission's IT environment in the field of software internationalisation. He has played an instrumental role in convincing leading technology companies to support open standards in systems used by EU institutions and he is known for the world-wide introduction of the Euro sign in IT systems (1997).

He is the founder (2003) of the EU agencies IT Advisory Committee (ICTAC), comprising more that 40 EU agencies and bodies, and, since 2003, has been a member of the European Institutions' high-level Committee for Information Technologies (CII). During the recent euro crisis, he served (2012–2016) as senior cabinet adviser with the Ministry for Administrative Reform and e-Governance. He worked on Greece's digital strategies and on major e-government projects in the context of large-scale reforms undertaken by consecutive governments to remodel the public sector.

Before his EU career, Lazaros worked at the IBM Scientific Centre, and as researcher in the French Universities Paris III and VII in the field of AI with a scholarship of the French Government. He holds MSc degrees in Applied Mathematics from University René Descartes, (Paris V), and of AI in Natural Language Processing and computational linguistics – University Paris VII. He received his BSc in Mathematics from the Faculty of Science, Aristotle University of Thessaloniki.

Free and open and source software (FOSS) has been at the heart of the ongoing information age for more than three decades now – to an extent that today it is impossible to underrate its value, ignore its influence or challenge its momentum. By too many and for too long, FOSS has been perceived not only as the driving force of innovation but also as an inspirational moral architecture, warranting the equitable sharing of benefits from the digital transformation of society.

Addressed to a wide interdisciplinary audience, the presentation adopts an evidence-based approach to show the overall potential and the perspectives

offered by FOSS today. The central tenet of the presentation revolves around FOSS maturity. We showcase FOSS readiness to support effectively today's complex information architectures, to operate reliably critical business applications, to help reduce the risks of proprietary solutions by avoiding costly vendor lock-in.

The first part of the discussion is devoted to capturing the fabric and spirit of FOSS. By compiling key events, facts and figures of its development, we review the expansion of FOSS throughout successive innovation waves shaping the information age. We portray FOSS emblematic technologies that have enabled its steady evolution. The technical, economic, legal, organisational and cultural underpinnings of FOSS are summarised to explain its success and the nature of its moral imprint.

The synthesis illustrates how the FOSS socioeconomic paradigm allies life-changing technological innovation with a moral order that reframes and revolutionises the conventional concept of intellectual property articulated around values such as: inclusive governance, shared creation and freedom of sharing, open standards, open anti-monopoly markets and fair anti-oligopolistic competition.

The second part looks at the capabilities offered by FOSS today and how they co-shape new technologies such as AI, Cloud computing and big data. Emerging FOSS products, new licensing modes and business models, costs, benefits and risks are revisited with a view to understand the current FOSS potential at a time of transition and its present relevance in a context of financial, social and environmental crisis.

A brief overview of the use of FOSS in global organisations including the EU bodies outlines best practices and strategic policy initiatives e.g. the digital single market, the new General Data Protection Regulation (GDPR), the digital workplace, the future of work, etc. We highlight FOSS capabilities to support reliably complex processes in public organisations at optimal cost, flexibility and innovation responsiveness. Finally, strategic considerations and key drivers in selecting, building and operating FOSS solutions are set in perspective with technology governance and policy implications for the society and for the economy at large.

The second part acknowledges the lessons learned from software-enabled work organisation over the past decades. It attempts to answer whether public bodies' mission can be better served through the use of FOSS. Whether beyond the political correctness, often ascribed to public organisations' obligation to support FOSS, there is an authentic case for its adoption. Also, whether, ultimately, this institutional attitude is in the best interest of the common good.

Looking beyond the software industry, the third part of the discussion explores a recurrent thesis: the attitudes and idiosyncrasies underpinning the culture of FOSS may thrive and produce similar results in other human endeavours. Examples supporting the thesis are shortlisted from a variety of fields in which FOSS motivations have inspired successful projects. We explore the huge importance of replicating the FOSS paradigm in research, production and dissemination of agricultural and food products. We assess the significant potential of the paradigm to help mitigate the risk of abusive practices for accessing natural resources universally perceived as public goods, and to help reduce major risks for the society.

Taping into the FOSS legacy, today's software technology can boost shared, collaborative creation, to unparalleled levels of productivity creating value surplus never attained in the past. The proven, highly effective compensatory mechanism of the FOSS paradigm ensures an equitable and transparent redistribution of benefits to every contributor. Fair dividends and recognition from shared cutting-edge innovation, richly rewarded business partnerships through complementary ventures sharing resources, are valid alternatives to conventional proprietary models of competition that also lead to substantial material profits for vendors and to savings for customers. We argue that at the same time, such alternatives are conducive to minimising various risks linked to selfish, profit-seeking excesses detrimental to sustainable economic progress, to a safe environment and to an equitable society.

Integrating and weighting mechanistic evidence in hazard and risk assessment

Bette Meek *University of Ottawa*

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Bette Meek is currently the Associate Director of Chemical Risk Assessment at the McLaughlin Centre for Risk Science in the Faculty of Medicine at the University of Ottawa, Canada. She has extensive experience in the conduct and management of chemical risk assessment programmes at Health Canada, most recently in the assessment of Existing Substances under the Canadian Environmental Protection Act (CEPA). Before this appointment, Bette managed and contributed to programmes to assess chemical contaminants in air and drinking water

With colleagues within Canada and internationally, Dr Meek has contributed to or led initiatives to increase transparency and efficiency in chemical risk assessment, having convened and participated in initiatives in this area for international organisations and national agencies, including the World Health Organization International Programme on Chemical Safety, the Organization for Economic Cooperation and Development, the

US Environmental Protection Agency, the European Joint Research Centre and the Agency for Food, Environmental and Occupational Health and Safety of France (ANSES). Areas of contribution have included the development of frameworks to assess weight of evidence, mode of action, chemical-specific adjustment factors, physiologically based pharmacokinetic modelling, combined exposures and predictive modelling. She has authored approximately 200 publications on chemical risk assessment and received several awards for contribution in this domain.

Dr Meek has a background in toxicology receiving her MSc. in Toxicology (with distinction) from the University of Surrey, UK and her PhD in risk assessment from the University of Utrecht, the Netherlands.

Mode of action (MOA) and adverse outcome pathways (AOP) are conceptually similar constructs that organise mechanistic knowledge as a sequence of measurable key events at different levels of biological organisation. AOPs address chemically agnostic key events between the initial interaction of a chemical with a molecular target (the molecular initiating event or MIE) and adverse or disease outcomes. Mode of action analysis for hazard characterisation includes additional consideration of the chemical-specific aspects of disposition to the target (toxicokinetics and metabolism).

These pathway descriptions facilitate integrating and assessing mechanistic data in hazard and risk assessment from a broad range of sources including structure activity analysis, in vitro assays, toxicity tests in animals and observational or clinical studies in humans. Linkage of MIEs and early key events measured in higher throughput systems to adverse effects characterised in traditional testing strategies is also anticipated to advance more tailored, efficient and predictive testing strategies.

The development and description of AOPs has been formalised in a public knowledge base to support their use for various applications in testing and assessment within an OECD programme. The associated Guidance and Users Handbook outline conventions, terminology and relevant information content, including structured assessment of the extent of supporting evidence. Weight of evidence is characterised based on a subset of the Bradford Hill (B/H) considerations introduced to assess causality in epidemiological studies and tailored more recently for application to mechanistic data in international frameworks for mode of action analysis. Examples of the nature of datasets associated with high, moderate and low confidence for the defined considerations are provided. The considerations have also been rank ordered to reflect their relative importance and extension of the approach to enable quantitation of comparative weight of evidence is being considered.

This structured and systematic consideration of the extent of mechanistic evidence in a coordinated construct such as the AOP facilitates its use for various regulatory applications for which different degrees of confidence are required. Coordinated consideration early in AOP development also focuses research efforts to meet specific regulatory need, based on critical data gaps. Aspects of the approach facilitating application will be addressed.

Foodomics 2.0

Wim Van Criekinge *Ghent University*

Professor Wim Van Criekinge: The core competences of BIOBIX (founded and chaired by Professor Wim Van Criekinge) are bioinformatics, data-integration and analysis, particularly in combination with high-throughput applications. Wim Van Criekinge graduated in 1994 as a Chemical Engineer from the University of Ghent, Belgium, where he also earned his PhD degree in Molecular Biology in 1998. He was founder of different successful biotech companies including Devgen, Genohm and MDxHealth.

Foodomics is defined a decade ago as 'a discipline that studies the food and nutrition domains through the application and integration of advanced 'omics technologies to improve consumer's well-being, health and knowledge'. Foodomics 2.0 is warranted as all of the underlying technologies have had significant upgrades the past years. Especially molecular characterisation is currently available at an unprecedented scale. In addition, the downstream (big) data analysis had evolved and adopted insights/methods from fields ranging from ICT (computer science & database technology) through statistics/machine learning and artificial intelligence. In many ways our biggest bottleneck is our ability to formulate realistic, interesting but non-trivial questions around nutrition and health. A plethora of current and (near) future applications of molecular profiling in food sciences will be presented as Foodomics 2.0 is getting ready for personalised nutrition.

Keywords: big data, bioinformatics, nutri(epi)genetics, 'omics, personalized nutrition

Network-based integration of molecular omics data

Kathleen Marchal *University of Leuven*

Kathleen Marchal is Professor at the Department of Plant Biotechnology and Bioinformatics and at the Department of Information Technology (IDLab, IMEC) at Ghent University. Her laboratory focuses on developing

computational methods for the analysis, integration and interpretation of systems biology and systems genetics data.

The group's research has contributed to the development of methods for motif-detection, network inference, and network-based data interpretation. Since 2013 the group's interest has been in the use of network methods for integrative genotype–phenotype mapping.

Interaction networks in which nodes represent biological entities such as genes, gene products, metabolites, etc., and edges the interactions between the nodes, provide a comprehensive way of summarising all available molecular information known on an organism of interest. These prior networks cannot only be used to visualise biological data, but also as a scaffold to analyse own in-house generated datasets. In this presentation we will show how network models, built on prior interaction networks, provide an intuitive way to integrate heterogeneous 'omics data and indicate why network models are particularly relevant when solving statistically ill-defined problems. We will show, for instance, how cohort analysis can be used to assess the efficiency of drug responses or to unveil the molecular mechanisms that result in antibiotic resistance development.

Outcomes from EFSA's Scientific Colloquium on 'omics in risk assessment

Elisabeth Waigmann *European Food Safety Authority*

Elisabeth Waigmann is head of EFSA's GMO Unit. Before joining EFSA in 2008, she was post-doctoral researcher at the University of California, and research group leader and lecturer at the Max F Perutz Laboratories at the Vienna Biocentre. Elisabeth holds a Master's degree in chemistry with a major in biochemistry, and has PhD in biochemistry from the University of Vienna. She has extensive teaching experience in the areas of biochemistry and cell biology, and holds a habilitation in molecular cell biology from the University of Vienna.

In recent years the development of innovative tools in genomics, transcriptomics, proteomics and metabolomics (designated collectively as 'omics technologies) has opened up new possibilities for applications in scientific research and led to the availability of vast amounts of analytical data. 'Omics is used to characterise and quantify the roles and relationships of large sets of different types of molecules in an organism. Genomics can facilitate analysis of entire or component genome sequences of an organism. Transcriptomics and proteomics provide significant bodies of information on temporal and spatial expression of genes and gene products, respectively, while metabolomics capture data for a large pool of metabolites. The interpretation and integration of 'omics data can provide valuable information on the functional status of an organism and on the impact of external factors e.g. stressors.

In 2014, EFSA started mapping the use of 'omics tools in the risk assessment related to food and feed safety (EFSA, 2014). This process has continued with EFSA's 24th Scientific Colloquium on ''Omics in risk assessment: state-of-the-art and next steps' that has taken place in Berlin, Germany on 24–25 April 2018 (for programme and presentations see http://www.efsa.europa.eu/en/events/event/180424–0).

The colloquium has explored the opportunities for integration of datasets produced via specific 'omics tools within the remit of EFSA's risk assessment approaches and has built further towards a concrete path of implementation. Discussions in the colloquium have focused on a set of topics for which EFSA intends to exploit 'omics datasets to support the scientific safety evaluation. These topics are: genomics in microbial strain characterisation, metabolomics for the comparative assessment of GM plants and the use of 'omics for toxicological and environmental risk assessment.

The outcome of this colloquium intends to support risk assessors in the process of incorporating 'omics tools in the risk assessment of food and feed products. An event report summarising the outcomes of the colloquium will be published during 2018 on EFSA's webpage.

References

EFSA (European Food Safety Authority), 2014. Modern methodologies and tools for human hazard assessment of chemicals. EFSA Journal 2014;12(4):3638, 87 pp. doi:10.2903/j.efsa.2014.3638

Key words: large data sets, 'omics, risk assessment

From "weight of evidence" to quantitative data integration

Igor Linkov *Adjunct Professor at Carnegie Mellon University*

Dr Linkov leads the Risk and Decision Science Team at the US Army Corps of Engineers and is Adjunct Professor at Carnegie Mellon University. Dr Linkov has managed multiple risk assessments and risk management projects utilizing advanced method of risk assessment, life cycle assessment and decision analysis . Many of his projects have included the application of state-of-the-science modelling and decision-analytical tools (e.g. risk-based decision analysis, probabilistic risk assessment, portfolio analysis) to highly complex sites (e.g. Hudson River, Katrina and Sandy restoration) and project needs

(e.g. bioinformatics, stakeholder engagement). He currently supports basic and applied research projects on evaluation of the use of nanotechnology, synthetic biology, additive manufacturing in military and civilian settings. He leads several efforts on the use of data and decision fusion, including the use of Weight of Evidence techniques for assessing Adverse Outcome Pathways. He supports development of computational tools for exposure and toxicity assessment for several agencies, including US EPE, FDA and Consumer Product Safety Commission. Dr Linkov has published widely on environmental policy, modelling, and risk analysis, including 20 books and over 300 peer-reviewed papers and book chapters. Dr Linkov has served on many review and advisory panels for EPA, FDA, DOD, DHS, NSF, EU and other US and international agencies. He served as EPA SAB committee member. Dr Linkov has received three Army medals for outstanding civilian service. He is the recipient of the 2014 Outstanding Practitioner and 2005 Chauncey Starr Award for exceptional contribution to Risk Analysis from the Society for Risk Analysis (SRA). He is Elected Fellow with the Society for Risk Analysis and American Association for the Advancement of Science. He is Army representative in the National Nanotechnology Initiative. He leads the Programme Committee for the 2019 SRA World Congress on Risk.

Weight of evidence (WoE) is an approach that, by means of qualitative or quantitative methods, integrates individual lines of evidence to form a conclusion. Contemporary WoE methodologies have advanced with the development of statistical science. In the 1960s, it was proposed that WoE processes should follow an inherently Bayesian statistical approach in which 'prior' beliefs for or against a particular hypothesis are updated after evaluation of information or evidence to achieve a 'posterior' belief. It has evolved in multiple methods and tools with varying degree of quantitative rigour and reliance on judgement. From commonly used listing evidence and best professional judgement, all the way through to quantitative multiple-criteria decision analysis (MCDA) and Bayesian methods, all the methods are captured to varying degrees by recent WoE recommendations and approaches that have been mushrooming recently. Multiple applications of these methods for food safety and related areas have been reported and will be summarised in this presentation. I will argue that successful application of WoE to food safety requires standardisation to establish consistency and comparability across ongoing WoE efforts.

Holger Schünemann *McMaster University*

Dr Holger Schünemann is chair of the Department of Health Research Methods, Evidence, and Impact at McMaster University. He began his research career in respiratory and exercise physiology (Dr.med.) as a medical student and in nutritional epidemiology (PhD) and molecular biology (post-doc) in the Department of Physiology at the Medical School of Hannover and the University at Buffalo (UB), State of New York, USA. He trained in internal medicine, epidemiology and preventive medicine. Having contributed to over 600 peer-reviewed publications, he has been listed among the most influential 3,000 scientific minds of current times (Thomson Reuters) across all scientific disciplines since 2015 and has an h-index of 123/85 (google scholar/web of science) and is among the 1,500 most cited scientists of all times (www.webometrics.info). He is co-chair of the GRADE working group for which he coined the name and has had major responsibility for disseminating its spirit of collaboration, openness and advancement of evidence assessment. He is co-director of the World Health Organization (WHO) collaborating centre for evidence informed policy-making, the director of Cochrane Canada, a member of the Guidelines International Network Board of Trustees. He has led or participated in numerous high profile guideline panels, including for the WHO and numerous professional societies and he was a key contributor to the revised methods for WHO guideline development in 2006. He is an adviser to ministries of health, other governmental organisations and professional societies for their guideline programmes. His work also focuses on practical application of his work by researchers and clinicians through the guideline development tool (www.gradepro.org), the guideline checklist (heigrade.mcmaster.ca/guidecheck.html) and GRADE evidence to decision frameworks (www.decide-collaboration.eu). Maintaining an active clinical practice fulfils his passion for patient care and ensures his research is people oriented.

Envisioning the expertise of the future

Science is advancing faster than ever, future scientific needs are not always predictable and society is playing a greater role in the production of scientific evidence.
Complex challenges call for multiple responses. Regulatory agencies and scientific organisations need to take these scientific and social advances into account to ensure they can continue to protect humans, animals and the environment. The session will look at how regulatory agencies can respond to future developments and discuss the key ingredients for a successful recipe for the future such as the importance of working across disciplines, the added value of international cooperation, and working with society. This will provide us with relevant and appropriate methodologies and expertise for the future.

CHAIRS

Alison Brimelow *Former President of the European Patent Office*

Alison Brimelow took office as President of the European Patent Office in July 2007 and served until June 2010. Before that, she served as president-elect from 2004–2007.

She joined the British Diplomatic Service in 1973 and later transferred to the Department of Trade and Industry (DTI), where she worked in a variety of posts, mostly concerned with policy in the EU.

In retirement, she is or has been a trustee of several charities and chaired the Programme Advisory Committee of CREATe, the UK centre for research into copyright and the digital economy.

Alison Brimelow was born in Havana in 1949 and attended schools in the USA, USSR and the UK. She holds a degree from the University of East Anglia. She has also been awarded honorary doctorates in Law and Science. In 2005 she was appointed Commander of the Order of the British Empire and in 2011 she received the Grosses Bundesverdienstkreuz of the Federal Republic of Germany.

Selomey Yamadjako *European Food Safety Authority*

Selomey Yamadjako is head of EFSA's Business Services Department. Selomey has over 20 years of professional experience among which 13 years were spent at the United Nations Development Programme, where she also served as Director of Programme and Operations in Togo and Tunisia. She holds a Master degree in Economics from the Université Paris, 1 Panthéon-Sorbonne, and an Executive Master in consulting and coaching for change from HEC Paris.

RAPPORTEURS

Federica Barrucci *European Food Safety Authority*

Federica Barrucci is a statistician working as a scientific officer at EFSA's Assessment and Methodological Support Unit, where she supports the development, implementation and review of evidence-based risk assessment guidance, methodologies and tools. Previously, Federica worked at the Public Health and Risk Analysis Department of Istituto Zooprofilattico Sperimentale delle Venezie. She has more than 10 years of experience in working on multidisciplinary projects, involving food microbiologists, chemists, veterinarians, epidemiologists, mathematicians, communication scientists and many others. She has a Master's degree in statistics and economics and a PhD in statistics both from the University of Padua.

Lucia de Luca *European Food Safety Authority*

Lucia de Luca is a communication and public affairs professional with more than 16 years of experience in risk communications, stakeholder engagement and media relations. Currently, Lucia is a global cooperation and communication expert at EFSA. Since Lucia joined EFSA in 2004, she has contributed to the development of EFSA's risk communications strategy. In 2007, she became deputy head of the Press Office. Lucia also managed stakeholder relations and coordinated the design of EFSA's new approach towards stakeholder engagement for 4 years. Previously, she worked as a European media relations specialist, lobbying consultant and marketing expert. Lucia also acts as an academic lecturer and workshop moderator. Lucia holds a Master's degree in modern languages and literature.

George Kass *European Food Safety Authority*

See biography p.27

Svetla Naydenova *European Food Safety Authority*

Svetla Naydenova works in human resources and in her current role she leads the Talent Development and Learning Solutions Team at EFSA. Before joining EFSA, Svetla worked in the private sector where she held various roles in human resources, i.e. leadership development manager, staffing manager and talent acquisition lead. Svetla holds a Master's degree in business administration from Thames Valley University, and is a certified coach and career counsellor.

SPEAKERS

Learning from others, re-thinking the way to manage your business and be ready to embrace the future

Ciarán McGinley *NormannPartners*

Email: ciaran.mginley@normannpartners.com

Ciarán McGinley has been a Senior Associate at NormannPartners since January 2017. Before joining NormannPartners, Ciarán focused for 35 years on Intellectual Property and worked under and directly with every President of the European Patent Office (EPO), where he held a wide range of senior Board positions, as well as being in charge of major operational units.

Ciarán is regarded as having a unique and comprehensive understanding of the global patent process operationally and economically. During his time at the EPO, he created the Chief Economist function, initiated the OECD working relationship and set-up the acclaimed Scenarios for the Future of Global Patenting.

Ciarán has extensive experience spanning two decades with Scenario Planning across a wide range of industries and topics. In addition to Global Patenting, he has contributed to the RiskWorld scenarios jointly carried out with Shell, EDF and the UK Health and Safety Board and, more recently, to scenarios in the mining, construction and food safety areas.

Languages: English mother tongue, and very good French, Dutch and German.

Education: Since 1997 Ciarán has held a (bi-lingual) Master of Business Administration from HEC-Paris. In 1981 he received a Bachelor of Science (Hons) in Aeronautical Engineering from the University of Bristol.

We live in a world that is increasingly turbulent, uncertain, innovative and full of ambiguity. How do others successfully plan in such an environment? How do they decide which expertise is required and which human capital elements will be essential? How do they navigate this complexity? With so many contextual drivers changing at the same time and with increasing speed, which success factors will help regulatory science be at the cornerstone of systems aimed at protecting humans, animals and the environment? Are there any key elements to be kept in mind by regulatory agencies? How can 'the regulatory risk assessment industry' anticipate future needs and be prepared for them?'

Develop new approaches to the use of future scientific evidence: A must?

Matthew Wood *University of Sheffield*

Matthew Wood is a lecturer at the University of Sheffield. His current research funded by the Economic and Social Research Council focuses on expertise and stakeholder engagement by EU agencies.

Scientific bodies like EFSA need to be attentive to how stakeholders and the wider public view their work. Do they see their evidence as more or less authoritative? How might they establish a good reputation among their audiences? This is not merely a matter of 'communication', but also of engagement with relevant stakeholders in person, at conferences and workshops, networking and making sure good scientific evidence gets traction and legitimacy. In other words, scientific bodies need to be entrepreneurial. We know relatively little, however, about the best ways to be entrepreneurial as a scientific body. Different scientific bodies have different levels of resources, some are politically salient while others are not, and some have a wide remit while others have very specific tasks. This presentation will discuss results from a forthcoming study to be published in the European Journal of Political Research, which establishes a typology of EU scientific agencies and their entrepreneurial strategies. It will discuss the ways in which different approaches to being entrepreneurial might match different types of agencies, and the wider applicability of the typology in thinking about scientific bodies and how they can get good science recognised as authoritative and legitimate.

Dealing with a new kind of team: The crowd

Anna Noel-Storr *University of Oxford*

Anna Noel-Storr has worked for Cochrane since 2008 as an Information Specialist for the Cochrane Dementia and Cognitive Improvement Group based at the University of Oxford. During that time she has played a leading role in the development and implementation of crowdsourcing in health evidence production. This began with the Trial Blazers study, led by Anna and for which she won the Thomas C Chalmers award in 2013. Since then, she has led a number of initiatives exploring the role of crowdsourcing and citizen science in systematic review production and evidence synthesis. She currently leads a component of Cochrane's first Game Changer initiative called Cochrane Crowd. This work involves the development of a crowd platform offering willing contributors a range of microtasks to dive into, all of which are designed to enhance Cochrane's content and speed up the review production process without any compromise on the exceptionally high quality expected of Cochrane systematic reviews.

At a time when research output is expanding exponentially, citizen science, the process of engaging willing volunteers in scientific research activities, has an important role to play in helping to manage the information overload. It also creates a model of contribution that enables anyone with an interest in health to contribute meaningfully and in a way that is flexible. Citizen science models have been shown to be extremely effective in other domains such as astronomy and ecology. Cochrane Crowd (crowd.cochrane.org) is a citizen science platform that offers contributors a range of microtasks, designed to help identify and describe health research. The platform enables contributors to dive into needed tasks that capture and describe health evidence. Brief interactive training modules and agreement algorithms help ensure accurate collective decision making. Contributors can work online or offline; they can view their activity and performance in detail. They can choose to work in topic areas of interest to them such dementia or diabetes, and as contributors progress, they unlock milestone rewards and new tasks. Cochrane Crowd was launched in May 2016. It now hosts a range of microtasks which help to identify health evidence and then describe it according to a PICO (Population; Intervention; Comparator; Outcome) ontology. The microtasks are either at 'citation level' in which a contributor is presented with a title and abstract to classify or annotate, or at the full-text level in which a whole or a portion of a full paper is displayed. To date, (May 2018) the Cochrane Crowd community comprises over 9000 contributors from more than 150 countries. Almost 2 million individual classifications have been made, and around 70,000 reports of randomised trials have been identified for Cochrane's Central Register of Controlled Trials. Performance evaluations to assess crowd accuracy have shown crowd sensitivity is 99.1%, and crowd specificity is 99%. Main motivations for involvement are that people want to help Cochrane, and people want to learn. This model of contribution is now an established part of Cochrane's effort to manage the deluge of information produced in a way that offers contributors a chance to get involved, learn and play a crucial role in evidence production. Our experience has shown that people want to be involved and that, with little or no prior experience, can do certain tasks to a very high degree of collective accuracy. Using a citizen science approach effectively has enabled Cochrane to better support its expert community through better use of human effort. It has also generated large, high quality datasets on a scale not done before which has provided training material for machine learning routines. Citizen science is not an easy option but done well it brings a wealth of advantages to both the citizen and the organisation.

Building more bridges and less walls (the role of communities and infrastructure to enhance responsiveness)

Hilary Hanahoe *Research Data Alliance*

Secretary General, Research Data Alliance

Hilary Hanahoe was appointed Secretary General of the Research Data Alliance (RDA) in February 2018, having covered a multiple of roles within the alliance, including the coordinator of the RDA Europe initiative, the Communications and Plenary Manager for the RDA global secretariat. In recent years, she has also managed the process for the recognition of RDA recommendations as ICT technical specifications in Europe.

She has considerable experience in community development and data infrastructures specifically in the delivery and implementation of the user-centric communication platform and communications and outreach strategies. She has edited and written many reports and publications in the field of data, research and e-infrastructures (e.g. Hanahoe, H. et al. (2014) 'The Data Harvest: How sharing research data can yield knowledge, jobs and growth' RDA Europe Report, December 2014.).

The Research Data Alliance (RDA) builds the social and technical bridges that enable sharing and reuse of research data. The RDA is made up of over 6,900 volunteer members from over 135 countries world-wide working together to achieve a collective vision of researchers and innovators openly sharing data across technologies, disciplines and countries to address the grand challenges of society. Since 2013, RDA has been building these bridges across disciplines, countries and technologies. We have learned that bridges are not built in a day but they are fundamental in today's landscape of ever increasing and urgent needs for data management solutions. Our guiding principles of openness, harmonisation, consensus, community-driven, balance and non-profit are the foundations upon which we build. RDA is unique in the fact that it is a bottom-up organisation, in other words those on the ground propose and deliver the technical solutions that are urgently needed bearing in mind the multi and cross- disciplinary as well as geographical challenges that form part of the landscape today. The Research Data Alliance is a unique example of how working across disciplines and collaborating globally to enhance society and tackle grand societal challenges is an excellent way to implement relevant and appropriate methodologies to enhance responsiveness.

The added value of international and inter-sectoral collaboration towards better human health risk assessment

Kaoruko Tachibana *Food Safety Commission of Japan*

Dr Kaoruko Tachibana is currently Director of Risk Assessment Coordination at the Food Safety Commission of Japan, providing cross-cutting perspectives across different risk assessment activities on chemical or microbiological hazards. She is also taking a leadership role in supporting the expert working group on new risk assessment methodologies. Dr Tachibana, a physician by training, joined the Ministry of Health, Labour and Welfare of Japan in 2000 as a medical officer, where she had contributed to developing health policies in different positions such as health financing, health system strengthening and international cooperation. As an international civil servant, she worked at WHO headquarters where she liaised with the Member States and the WHO departments to facilitate communication and collaboration, as well as at UNAIDS headquarter as a senior adviser for the global AIDS response monitoring and evaluation. She has received two post-graduate degrees: a Master's degree in Health Policy Planning and Financing from the London School of Hygiene and Tropical Medicine and London School of Economics in the UK; and a Master's degree in International Negotiation and Policymaking from the Graduate Institute of International and Development Studies in Geneva, Switzerland.

Protecting public health is the ultimate purpose of our risk assessment work in Food Safety Commission of Japan. One of our key challenges is to improve human health risk assessment through a more precise understanding of human relevance of animal toxicological experiments.

Data-sharing or mutual data reference with different food safety regulatory agencies or learning from different sectors could facilitate the development of methodologies, which would enable us to better tackle with our common challenges, such as overcoming data gaps, understanding more clearly about Mode of Actions and human relevance. For example, reuse of existing database that has already been started in human pharmaceutical community, could potentially support our efforts in food safety community to better understand human relevance in food-related materials.

To make a step further, we should also be reminded that the premise for meaningful integration of databases is that we should build together a common basis of understanding on data eligibility and data property management.

This talk will highlight the added value of international and cross-disciplinary collaboration in making good use of our existing knowledge for addressing our common challenges towards more reliable and efficient risk assessment.

The importance of the "C" factor when responding to future challenges

Ian Cotgreave *Swetox*

Ian Cotgreave has been a resident of Sweden since 1984, with a PhD from St Mary's Hospital Medical School London in drug metabolism, and several junior academic positions within the Karolinska Institute in Sweden. Ian has been Professor of Toxicology at the Karolinska Institute since 2002, where he also had responsibility for toxicology teaching/training programmes at the undergraduate and post-graduate level. Other positions include Director of Molecular Toxicology at AstraZeneca between 2004 and 2013 and Director of Strategic Scientific Development within the Swedish Toxicology Sciences Research Center (Swetox; www.swetox.se) from 2014. Ian was previously a member of the Board of the Swedish Society of Toxicology (SFT) from 1997–2001, was a member of the Medicinal Committee of the Swedish Medicinal Protection agency from 2001–2003, a member of the Swedish Central Committee for Alternatives to Animals (CFN), the Swedish Animal Protection Agency from 2002–2004 and the Chairman of the Swedish Central Committee for Alternatives to Animals (CFN), the Swedish Animal Protection Agency, and the Department of Agriculture from 2005–2008. More recently, Ian was a member of the Swedish Science Research Councils M3R research grant committee from 2009–2014. From its inception, Ian was Co-Chair of the Scientific Advisory Board of SEURAT-1 and is a PI in the follow-up H2020 program, EuToxRisk. Ian was also active in initiating the Innovative Medicines Initiative (IMI) STEMBANCC programme, as well as the UK government SC4SM project, both aimed at stem cell-based models for predictive toxicology. Ian is currently a partner in the IMI antibiotic program ENABLE. From 2018 has also been a member of the EU Commissions EURL-ECVAMs scientific advisory panel, ESAC, dealing with European validation of alternative methods in chemical risk assessment and disease modelling. Ian has many years of experience (circa 150 publications in peer reviewed journals) of mechanism-based risk assessment.

The enormous pace of development of both the content and context of the knowledge base available for predicting hazard and quantifying risk is placing considerable contemporary demands on those individuals currently conducting regulatory risk assessments. Societal calls for a paradigm shift in the manner by which data from different sources, including so-called New Assessment Methods, are utilised in quantitative risk assessment will require a commensurate shift in the combinations of skill sets, some of them entirely new to the area, required to perform this at a regulatory level. To illustrate the current conundrum, the lecture will consider scientific experience in new assessment method development and qualification for human risk assessment from the SEURAT-1 program and its successor, the EU-ToxRisk program. Concomitantly, the demands for coordinating this with competence development and maintenance in society will be considered. Focus here will be on the de novo training of the 'next generation' of toxicologists at an academic level, as well as continued professional education in, for example, computational techniques in 'big data' analysis, quantitation of uncertainty and the use of artificial intelligence (AI). This coordination will require commitment from all parties, courage to be open to new concepts, practices and possibilities and strategic collaborations between all affected parties to ensure coordinated and timely changes

Using citizen science platforms and how to develop new capabilities to validate a broader set of information

John Palmer *Pompeu Fabra University*

John Palmer is a tenure-track professor in the Department of Political and Social Sciences at Universitat Pompeu Fabra (UPF) and a founding member of Mosquito Alert, an expert-validated citizen science system for studying and managing disease-vector mosquitoes. At UPF he works on questions arising in demography, law, and public policy related to human mobility and migration, social segregation, and disease ecology in the Sociodemography Research Group (DemoSoc) and the Interdisciplinary Research Group on Immigration (GRITIM). John's training is in a combination of ecology (BS, Cornell University, 1997), law (JD, Cornell University, 2003), and demography (PhD, Princeton University, 2013). In addition to his research, he has managed refugee relief projects in Bosnia, Albania, and Kosovo, and has worked as a protection officer for the UN High Commissioner for Refugees in Kosovo and Montenegro. He has also served as a law clerk to Judge Richard J Cardamone, and as a mediator and a staff attorney supervisor for the US Court of Appeals for the Second Circuit.

The problems regulatory agencies confront increasingly require solutions that can be implemented across multiple geographic and temporal scales. They require recognition that knowledge and expertise are not limited to professional scientists but distributed throughout society. By embracing the paradigm of citizen science, agencies and researchers can gain new perspectives and tools that will be crucial for addressing the problems of the future. Doing this, however, requires thinking about and organising our work in new ways. It requires careful attention to problems of data quality and sampling effort. It requires attention to social science and to the dynamic nature of individual and collective

behaviour. This talk will address these challenges along with the potential that citizen science holds, offering practical lessons and advice from ongoing initiatives around the world.

Collaboration - the agony and the ecstasy

Alisdair Wotherspoon *Formerly of the Food Standards Agency*

Over 35 years experience in the UK public sector, with around 25 years in the food science area. Retired in 2016 after 14 years as Head of Research Coordination/Head of Science Delivery at the Food Standards Agency. Responsible for:

- Development/implementation of the governance around how the FSA prioritised, commissioned, managed and communicated its evidence portfolio.
- Development of partnership working with national/international organisations.
- UK EFSA Focal Point and EFSA Advisory Forum alternate.
- Current activities: Elected Fellow of the Institute of Food Science and Technology and deputy chair of its Science Committee; Science Governor on the Council of the British Nutrition Foundation; Member of advisory groups for the Innovative Food Systems Teaching and Learning (IFSTAL) initiative (www.ifstal.ac.uk) and the H2020 funded project COMPARE (www.compare-europe.eu) Significant representational experience at national/international level over career including:
  - member of international steering committee of the Global Microbial Identifier Initiative (www.globalmicrobialidentifier.org);
  - member of the cross-government/funder UK Global Food Security Programme and a member of the Programme Management Group;
  - impact assessor for Research Excellence Framework 2014 in Agriculture, Veterinary and Food Science area;
  - FSA research contact with national/international funding organisations.
- Work package leader on the EU FP6 funded food safety and quality focused ERANET, Safefoodera; head of the international steering committee for latter part of the project.
- Science lead of the UK delegation to the EU Commission WG on feed additives and bioproteins and the food and agriculture conformation of the EU FP6/7 Programme Management Committee.
- Regularly invited to participate/present at national and international meetings, particularly on the impact of science on policy. LinkedIn: https://uk.linkedin.com/in/ajw

Using the EFSA Risk Assessment Research Assembly, held earlier in 2018, as a case study, the presentation will focus on how collaboration between regulatory agencies, research funders and others can be a driving force in informing and shaping future research agendas and delivering impactful solutions to the complex problems faced. It will highlight the many potential advantages that effective collaborations can bring to all concerned, not least in efficient use of increasingly pressured resources (both funds and expertise). It will also highlight some of the challenges to be faced in developing fruitful collaborations and key elements to overcoming these.

Networking as a tool to scan the horizon and increase preparedness for regulatory agencies

Djien Liem *European Food Safety Authority*

Djien Liem leads the scientific support Team at EFSA's Scientific Committee and Emerging Risks Unit. He joined EFSA in 2003 as head of EFSA's Scientific Committee Unit and was lead expert in International Scientific Cooperation from 2013 until 2018. Djien began his career at the Department of Industrial Contaminants of the Dutch National Institute of Public Health and the Environment. In 2000, he took up a secondment at the secretariat of the European Commission's Scientific Committee on Food. Djien holds a Master's degree in environmental chemistry and toxicology from the University of Amsterdam, and has a PhD in biology from the Utrecht University.

An important challenge for risk assessment agencies such as EFSA is the extent to which we apply risk assessment methodologies, using the best available science in a harmonised and consistent way, particularly for the evaluation of chemicals in food. Differences can still happen in the way we interpret and weigh the available data and how we implement innovative features, knowledge and concepts. This may lead to divergent views of different agencies on similar topics and creating undue confusion among scientists, risk managers and in the public at large.

To keep up with development in science, agencies conducting risk assessments informing regulatory measures in the area of food safety may need to find effective ways to increasingly work together. The validation, implementation and acceptance of potential improvements take time, and resources required to innovate methodologies often compete

with the experts' time needed to carry out the numerous assessments included in our work programmes.

The new International Liaison Group for Methods on Risk Assessment of Chemicals in Food (ILMERAC) will be presented as an example of how, thanks to networking, regulatory agencies can cooperate to ensure that they apply the best available science in their risk assessments in a harmonised and consistent way. Participants share and exchange experience on ongoing and planned activities aimed at developing and implementing methods for risk assessment of chemicals in food. Through conference calls and physical meetings, ILMERAC provides opportunities to share work, avoid duplication, identify knowledge gaps and recommend harmonisation activities to be considered as a joint activity under the umbrella of international organisations such as WHO, FAO and OECD.

Staying relevant in a changing world

This session will explore how science, food and society might change in the future. Speakers will present scenarios addressing different elements of the environment-agriculture-food-diet-health spectrum. Panellists will then discuss how such changes may impact food safety, risk assessment and communication, and how to ensure that we are prepared to deal with these consequences.
Relevant points emerging from the moderated panel discussion as well as the break-out sessions of the previous days will feed into EFSA's Strategy 2027.

CHAIR

Elke Anklam *Joint Research Centre*

Elke Anklam is a chemist, with specialisation in food, organic and radiation chemistry. After obtaining her PhD from the University Hamburg, Germany, she worked in various European Research Institutions and was a Teaching Professor at the Applied University of Fulda, Germany. Since 1991, she has been working at the European Commission's Joint Research Centre (EC-JRC). From 2006–2012, she was Director of the JRC-Institute for Health and Consumer Protection (IHCP) in Ispra, Italy and from 2012–July 2016, Director of the JRC-Institute for Reference Materials and Measurements in Geel, Belgium. Since July 2016, she has been the Director of the JRC-Geel site and the new JRC Directorate F: Health, Consumers and Reference Material (a merger of the former IHCP and IRMM), located at the JRC-Geel and JRC-Ispra site.

RAPPORTEURS

Yann Devos *European Food Safety Authority*

See biography p.7

Barbara Gallani *European Food Safety Authority*

See biography p.7

Tobin Robinson *European Food Safety Authority*

See biography p.8

Ilias Papatryfon *European Food Safety Authority*

Ilias Papatryfon is acting head of EFSA's Global Performance Services, with main responsibilities in strategic planning, budgeting, organisational performance monitoring and quality. Ilias has held various positions within EFSA, first in the area of scientific cooperation with Member States and then moving in corporate planning and monitoring. Before joining EFSA, he worked for the Joint Research Centre of the Institute for Prospective Technological Studies and the French National Institute for Agricultural Research. Ilias holds a Master's degree in applied economics from the Universidad Nacional de Educacion a Distancia, and has a PhD in marine estuarine environmental sciences from the University of Maryland.

SPEAKERS

How global drivers of/shaping the future bioeconomy

John Bell *Directorate-General for Research and Innovation, European Commission*

Dr John Bell is Director for the Bioeconomy in DG Research and Innovation. He is responsible for leading the definition, implementation and investment of EU Research and Innovation policy and programming across the Bioeconomy; from agriculture and food systems, oceans, marine and maritime issues to investment in new sustainable bio-based industries. This includes Horizon 2020, 3.8 billion Societal Challenge 2, the EU Bioeconomy Strategy, the 3.7 billion euro Bio-Based Industries Joint Undertaking and Food and Nutrition Security FOOD2030. He leads Oceans R&I strategies including the Atlantic Ocean Research Alliance, the Bonus programme (Baltic Sea) and the BlueMed Initiative (Mediterranean). His professional background was in academia (Anglo-Irish Studies) and in business journalism in London. During his EC career he has worked in External Relations on financial assistance programmes in the former Yugoslavia, public administration reform in Central and Eastern Europe, and on Poland's accession to the EU. Dr Bell was a member of the Cabinet of Commissioner David Byrne with responsibility for enlargement, food safety, tobacco control, public health and global health security issues, including bioterrorism. He was Head of Cabinet to European Commissioner Meglena Kuneva on Consumer Affairs. As Head of Cabinet to Commissioner Máire Geoghegan-Quinn on Research and Innovation, he was responsible for developing and funding Horizon 2020, mainstreaming innovation, financial investment and simplification. A native of Dublin, Ireland, he was educated at University College Dublin and completed his Doctorate (D.Phil.) in 'Cultural Nationalism in Northern Ireland' at St John's College, Oxford University.

Europe's innovative bioeconomy is moving from niche to economic norm and is delivering the European agenda to create jobs and growth, to renew and green industry, to ensure food and nutrition security and to sustain the environment. If Europe wants to maintain its current global bioeconomy leadership and meet the commitments of the Paris Climate agreement and UN Agenda 2030, it must advance its transition towards a sustainable, circular, zero-waste and low-carbon society. The future bioeconomy must drive a systemic change across the various policies, bioeconomy sectors, industries, value chains and people's behaviour, and consumption pattern. To achieve this, Europe needs to support strategic research and innovation, foster the development of bioeconomy skills and education, upscale investments in bio-based sectors, generate knowledge through monitoring and deploy bioeconomy opportunities across Member States, regions and cities. A sufficient and sustainable supply of biological resources to feed a growing world population, while providing low-carbon, sustainable materials and energy within the limits of the planet, remains a global challenge.

Key words: bio-based, bioeconomy, biological resources, innovation

The future of food: scenarios analyses

Tim Benton *University of Leeds*

Professor Tim Benton is Dean of Strategic Research Initiatives at the University of Leeds and Distinguished Visiting Fellow at the Energy, Environment and Resources Department at the Royal Institute of International Affairs at Chatham House, UK. From 2011–2016 he was the 'Champion' of the UK's Global Food Security (GFS)

programme, which was a multiagency partnership of the UK's public bodies (government departments, devolved governments and research councils) with an interest in the challenges around food. The key role of GFS was to undertake systemic analysis and horizon scanning, to identify research priorities to mitigate the challenges of providing sufficient, sustainable and nutritious diets for all. He is an Agenda Steward for the World Economic Forum's Food Systems and Nutrition topic, and Lead Author for the Intergovernmental Panel on Climate Change's (IPCC's) Special Report on Food, Land and Climate. His work focuses on global and local food systems (with a focus on the UK and countries in sub-Saharan Africa), and the need for them to become more sustainable and resilient. He has published over 150 academic papers, and contributed to many reports on food systems and food security.

We have evolved food systems based on the notion that cheap food is a public good, and liberalised global markets to support international competition. Our current food system now leaves more people globally with an unhealthy weight rather than a healthy weight, with the economic costs associated with food-related ill-health, and creates a significant economic burden from environmental degradation, including being a major contributor to climate change. As such, the economic costs far exceed the economic benefits from the agricultural economy. Given the growing recognition, following the launch of the Sustainable Development Goals and the Paris Climate agreement, that the future of food systems cannot be 'business as usual', what might a food system that delivers healthy diets, sustainably, look like? Following reviews of some recent scenarios analyses, I will highlight some different potential futures, their costs and benefits and the barriers to transformation from the present day to potential better futures.

Consumer archetypes in future food systems

Sandra Caldeira *Joint Research Centre*

Sandra joined the European Commission in 2010 and has been working in science for policy in the area of Public Health ever since, first as project manager in the area of prevention of non-communicable disease and now as Deputy Head of the Health in Society Unit at the DG Joint Research Centre. The Unit's mission is to support EU policies in public health, to promote excellence and equality of health-care in all member states and to facilitate the implementation of associated EU legislation. This is to include: (i) prevention of non-communicable diseases, (ii) improved health information on cancer and rare diseases, and (iii) cancer healthcare quality. Sandra holds degrees in Microbiology and in Biotechnology as well as a PhD in Biomedical Sciences. She worked as a postdoctoral researcher in Lisbon University (PT) and Cambridge University (UK) as well as Stanford University (USA) and held positions as an invited professor of Genetics at the University of Lisbon and as a Scientific Editor at the European Molecular Biology Organisation (EMBO) in Heidelberg (DE). At the EFSA Conference, Sandra will discuss the outcome of the Unit's foresight activities in the area of future food safety and nutrition.

Consumers are key drivers of food systems; it is important to understand what shapes their aspirations, food and lifestyle choices as well as how these choices affect the system itself. In the context of its foresight work, the Joint Research Centre (JRC) has developed several EU food-related future scenarios, with very different characteristics and consumer roles (Bock et al., 2014; Mylona et al., 2016). This presentation will describe some of the developed scenarios and typical examples of consumers. These range from health- or sustainability minded consumers, to price-focused ones, purely hedonic or those that follow strict diets or are very trendy and highly technological. These consumer types can already be observed in our contemporary societies, among our families and our peers. However, the scenarios approach allows us to explore how future food systems may look, if one or the other consumer type dominates. What are these consumers' needs and which challenges to the system can derive from these? How can societies, governments and players in food systems respond to these challenges? Are there policies, regulations, risk assessment strategies or research priorities that need redesigning or prioritisation to respond to future needs? Structured reflections on these questions set the basis to a better understanding of a food system that responds to current and future consumer choices in safe, healthy, nutritious diets in a sustainable and fair manner.

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The future of research in personalised nutrition

John C. Mathers *Newcastle University*

John Mathers is Professor of Human Nutrition and Director of the Human Nutrition Research Centre in the Institute of Cellular Medicine at Newcastle University, UK. He is a past President of the Nutrition Society and former Scientific Director of the Institute for Ageing and Health, Newcastle University. John Mathers undertook undergraduate studies in Newcastle University and PhD training in Nutrition at Cambridge University. He was a post-doc at Cambridge University and a Research Fellow in Edinburgh University before being appointed to Newcastle University. John Mathers' major research interests are in understanding how eating patterns influence risks of common age-related diseases such as heart disease, diabetes, dementia and bowel cancer. He was a founding member, and is currently Chair, of NuGO (the European Nutrigenomics Organisation) and his research includes the use of genomic and epigenomics tools to understand the mechanisms though which nutrition influences cell function and, ultimately, health. He led the LiveWell Programme of research, which developed and piloted an internet-based intervention designed to help older people improve lifestyle and to promote better health and independence into old age. John Mathers also led the EU FP7-funded Food4Me intervention study across seven European countries that tested the idea that a personalised nutrition approach is more effective than the conventional 'one-size-fits-all' approach in improving dietary behaviour. These web-delivered personalised approaches are also being investigated in the current MedEx-UK project – a collaboration between the Universities of East Anglia, Birmingham and Newcastle – that aims to improve lifestyle and to reduce the risk of Alzheimer's disease.

As each individual person differs from the next in multiple ways, it is a beguiling idea that the nutritional needs of each person are also different. In support of this idea, findings from well conducted nutritional intervention studies provide ample evidence that there is considerable inter-individual variation in response to exactly the same dietary exposure. To date, we have only a limited understanding of the physiological mechanisms responsible for this variation but, following sequencing of the human genome, there has been much excitement about the role of genes in explaining inter-individual differences. In addition, the growing evidence of diet–gene interactions that influence phenotype, including health, emphasises the importance of both nature and nurture. Eating patterns have a major influence on health, so much public health advice to reduce the risk of common complex diseases aims to improve diet. However, most dietary interventions are relatively ineffective and it has been proposed that personalised approaches that tailor the intervention to the individual may be both more acceptable and more effective (Celis-Morales et al., 2015). This idea was tested in the pan-European Food4Me Study in which adults from seven countries were randomised to one of four treatment groups in an internet-delivered dietary intervention. Compared with the control (standardised healthy eating advice), those people randomised to a personalised nutrition intervention has bigger sustained changes in eating behaviour after 6 months (Celis-Morales et al., 2017). However, the inclusion of more complex phenotypic and or genotypic information in developing the personalised nutrition advice had no added benefit (Celis-Morales et al., 2017). Around the world, prevalence rates of obesity are rising and it is clear that an individual's risk of being obese is influenced by his/her genetic make-up. In the general population, variants in the fat mass and obesity-associated (FTO) gene have the biggest effect on adiposity so we asked the question 'If the risk variant in FTO helps to make people fatter, does it also make it more difficult to lose weight?'. Using data from eight large weight loss studies involving about 9,500 participants, we found that carriage of the risk allele for FTO had no effect of weight loss (Livingstone et al., 2016). Similarly, a recent intervention study carried out in the USA found that there was no effect of variants in three other genes, i.e. PPARG, ADRB2 and FABP2, on weight loss (Gardner et al., 2018). This is good news for those wishing to lose weight as it shows that one's genes are not always one's destiny and that weight loss is just as successful in those that carry risk alleles for increased adiposity. Research into personalised nutrition is now broadening its scope to consider the effects mediated by the gut microbiome, as well as multiple aspects of genotype and phenotype (Zeevi et al., 2015). Such research has the potential to explain inter-individual differences in the response to specific dietary factors and may provide a scientific basis for more refined approaches to personalised nutrition. However, if this research is to make a significant contribution to improving public health, it will need to address the psychological, social, economic and cultural factors that influence eating patterns to ensure that advice is converted into action and that improved dietary habits are sustained in perpetuity.

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Communication challenges of the future: recognition, reconciliation and rewards

Katherine McComas

Dr Katherine A. McComas is a Professor of the Department of Communication at Cornell University, USA where she specialises in risk, science, and environmental communication. In July 2018, she will also become Cornell University's Vice Provost for Engagement and Land Grant Affairs. Dr McComas' research and teaching focus on understanding motivations and barriers surrounding communication about scientific and environmental risk issues. She is the author or co-author of 70+ refereed journal articles and two books, including co-editing the SAGE Handbook of Risk Communication. Her work has been supported by the National Science Foundation (NSF), National Parks Service, US Environmental Protection Agency, US Food and Drug Administration (FDA), and US Department of Agriculture (USDA), among others. From 2008–2013, she was the Societal and Ethical Issues (SEI) Coordinator for the NSF-supported National Nanotechnology Infrastructure Network, for which she oversaw the coordination of SEI research and educational activities for the 14-member network. She served on the FDA's Transmissible Spongiform Encephalopathies Advisory Committee and its Blood Products Advisory Committee. She is the Area Editor for Risk Communication for the journal Risk Analysis, a Fellow for the Society for Risk Analysis, and currently President-Elect for the Society for Risk Analysis. In Fall 2017, she was a Visiting Professor at King's College London, UK.

Efforts to address future communication challenges on science and society must first recognise the irrefutable evidence that the landscape of communication has changed and will continue to change, with implications at the individual, group, societal and global levels. The Internet has opened a veritable Pandora's box, providing unparalleled access to thousands of sources of information about any given topic of risk. To meet this challenge, effective communication must reconcile itself to the reality that former, outdated models of communication, which sought to convince audiences of the primacy of a single scientific authority, are competing with a plethora of other sources that may be as convincing and more trusted, due to aspects beyond the control of any one source. In all candour, any honest effort to communicate risk today must recognise that 'controlling' the field of messages is a bygone concept, if it ever truly described how communication took place. It also must acknowledge that audiences are active seekers of information, and not from traditional channels. Recognition and reconciliation of these realities can lead to rewards if communicators accept this knowledge and adopt more interactive communication approaches that respond to audience needs and incorporate stakeholder values into decision making. And, while face-to-face interactions will continue to play a vital role in understanding risk, the communication landscape of today and the future offers many options to engage with audiences in meaningful and creative ways. From telepresence robots that are first responders to environmental disasters, to social media sites that influence healthy behaviours, to mobile devices that monitor pain management, to virtual reality headsets that allow people to experience new worlds, the list of these technologies and their potential affordances is profound. Looking towards the future, those best able to respond to communication challenges will invest the time and resources to understand how best to work with, not against, the new communication landscape.

PANELLISTS

Renata Clarke

Renata Clarke leads the FAO Food Safety and Quality Unit since 2011 and has worked within FAO on food safety issues for almost 20 years. As Head of the FAO Food Safety and Quality Unit, she oversees a diverse programme of food safety capacity development and the FAO Programme of Food Safety Scientific Advice. The former programme emphasises partnership with FAO's networks of experts to generate proven guidance on good practice in the management and regulation and food safety and quality. It also emphasises innovation in the tools and the approaches to responding to countries' capacity development needs and maintains a critical eye on impact on the ground. The FAO Programme on Food Safety Scientific Advice, jointly with WHO, primarily provides the scientific advice that underpins the standard setting work of the Codex Alimentarius Commission. Current priorities of that programme are the scaling up of the delivery of scientific advice to meet the demands of Codex and regular review and updating of methods and processes to guarantee the continued excellence and recognized independence of the FAO's food safety scientific advice.

Martin Dermine

Martin Dermine is a doctor in veterinary medicine and holds a PhD in veterinary pathology. He joined the Pesticide Action Network (PAN) Europe in 2012 to work on the toxicity of pesticides on pollinators, using his expertise on honey bees as a beekeeper since the age of 14. Martin has been engaged in EFSA's work on pesticides and as an EFSA stakeholder for many years. Martin is a member of the EFSA Stakeholders' bureau, representing EU NGOs. He is also involved in the EFSA stakeholder discussion group on emerging risks.

Mella Frewen

Director General of FoodDrinkEurope, representing Europe's largest manufacturing industry, since July 2007.

Mella Frewen's previous positions include Director for Government Affairs EMEA at Monsanto, dealing with agricultural biotechnology, conventional agriculture, seeds and agri-chemistry.

Before that, she was Director, International Relations for Cerestar, then Europe's biggest starch producer. From this role and her earlier ones in the Ferruzzi and Eridania Bégin-Say Groups, stationed in Brussels, she has a wide experience of relations with International institutions, with the Institutions of the European Union and trade associations within the food chain, as well as with the agri-food and non-food, and chemical sectors.

Ms Frewen has represented the Food Industry in the several EU Commission Advisory Committees and Standing Committees. She is currently a member of the EU Commission's High Level Steering Board for the European Innovation Partnership for Agricultural Productivity and Sustainability, of its High Level Platform for the Implementation of the SDGs and of its Scientific Jury for EUCYS (Competition for Young Scientists), among others. She is also member of several food industry-related Boards.

At the OECD and FAO, Ms Frewen is Vice President of the Advisory Group for Responsible Business Conduct along Agricultural Supply Chains.

She has worked in the Agri-food sector in Europe for 27 years. She has a Master of Science degree from the National University of Ireland, and completed a post-graduate course at the University of Brussels (ULB). She also holds a Harvard certificate on Agribusiness and an INSEAD certificate on International Operations Management.

Michael Scannel

Michael Scannell is an official of the European Commission since 1991. He is currently Director for the Food Chain – Stakeholder and International Relations in the Directorate General for Health and Food Safety. He was until recently Director of the Food and Veterinary Office which is responsible for promoting proper enforcement and compliance with EU requirements on food safety, animal and plant health in both EU Member States and third countries. His previous positions included chief spokesperson for the EU in the Codex Commission and in the Sanitary and Phytosanitary Committee of the World Trade Organisation between 2002 and 2010. He also worked from 1995 to 2002 in the private offices of Commissioners, with particular responsibilities in the area of tobacco control, trade, economic, food safety and animal health regulatory issues. This period included the BSE and foot and mouth diseases crisis and the creation of a specific Directorate General for Health Protection and of the European Food Safety Authority. Mr Scannell is Irish and a graduate in economics and politics from University College Dublin.

William Slikker

Dr William Slikker, Jr is the director of FDA's National Center for Toxicological Research (NCTR). He received his PhD in Pharmacology and Toxicology from the University of California at Davis, USA. Dr Slikker holds adjunct professorships in the Departments of Pediatrics, and Pharmacology/ Toxicology at the University of Arkansas for Medical Sciences. He is currently associate editor for NeuroToxicology and for Experimental Biology and Medicine. He has served as president of the Academy of Toxicological Sciences, the Teratology Society and the Society of Toxicology. Dr Slikker has co-authored over 350 publications in the areas of transplacental pharmacokinetics, developmental neurotoxicology, systems biology, and risk assessment.

Poster session

Human health

1. Risk assessment of arsenic exposure from gluten-free cereal food in children with coeliac disease: exposure assessment, study of urinary metabolic profiles and genetic polymorphisms

AURELI Federica
Istituto Superiore di Sanità

Federica Aureli, Francesca Ferraris, Andrea Raggi, Marco Silano, Francesco Cubadda – Istituto Superiore di Sanità-National Institute of Health, Rome, Italy

Monica Ancinelli, Mariangela Caruso, Cristina Felli, Francesca Ferretti, Andrea Masotti, Valerio Nobili – Bambino Gesù Children's Hospital-IRCCS, Rome, Italy

Carlo Catassi, Elisa Franceschini, Simona Gatti, Elena Lionetti – Università Politécnica delle Marche, Ancona, Italy

Ruggiero Francavilla, Maria Elena Tripaldi – University of Bari, Bari, Italy.

Massimiliano Copetti – Casa Sollievo della Sofferenza-IRCCS, San Giovanni Rotondo (Foggia), Italy

In the general population the main source of inorganic arsenic (iAs) is food, with rice playing an important role depending on consumption figures. Chronic oral exposure to iAs, depending on its duration and magnitude, may lead to different types of cancer, skin lesions and other adverse outcomes. Rice is used as a substitute for wheat in the diet of children affected by coeliac disease (CD), a condition caused by an abnormal immune response to gluten. This paediatric population may have a higher dietary exposure to iAs and might be more vulnerable to iAs toxicity.

A multicentric study involving 160 CD and 160 healthy children aged 3–10 has been launched to test this hypothesis.

A Food Frequency Questionnaire was administered to identify the types and amount of rice and gluten-free products eaten by CD children. The selected products were then characterised for the content of iAs. The iAs intake of CD children was estimated combining analytical data and food consumption data. The additional exposure associated to consumption of gluten-free food is estimated by considering the 'cereal grains' food group from the Italian Total Diet Study for children of the same age. Additionally, As in nails was used as a biomarker of long-term iAs exposure.

Urine from children were collected after a 5-day diet with exclusion of food containing (or being metabolised to) DMA and analysed for iAs and its methylated metabolites, MMA and DMA. The relative proportions of the species were used as measure of the individual methylation capacity, i.e. as an estimate of the detoxification efficiency by As-exposed children.

Genetic markers (SNPs) in genes regulating As methylation and detoxification were investigated to clarify how genetics affects As metabolism and individual susceptibility to iAs in children with CD.

Project Ricerca Finalizzata GR-2011-02349632 supported by the Italian Ministry of Health.

2. Predictive mechanistic in silico simulations of mixture of azole fungicides acting on cranio-facial morphogenesis

BATTISTONI Maria
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The huge number of combinations of chemical, the paucity of efficient test strategies for the risk assessment of mixtures, and the increasing societal need to reduce animal testing make the study of mixtures a very complex issue. Single azole fungicides, can affect cranio-facial morphogenesis during the early development. Data previously obtained in post-implantation rat whole embryo cultured *in vitro* described specific teratogenic effects at the branchial structures, while the co-exposure resulted in mixture effects, accounting for a common mode of action (MoA) for the azole fungicides. The proposed MoA for azoles is the inhibition of CYP26 enzymes, involved in the retinoic acid (RA) catabolism, with a consequent indirect increase in the local endogenous concentration of RA at the branchial apparatus level. With the aim of investigating this hypothetical mechanism, the specific teratogenic effect of some azole fungicides, alone or in mixture, has been tested *in vitro*. Then, data were interpreted developing an innovative in silico tool, combining *in vitro* experiments and mathematical and probabilistic modelling of RA pathway enzymes. After training with single azoles dose–response data, predictive simulations for the mixtures were performed. The model appears to be reasonably predictive for the mixture effects (experimental data and model predictions are in promising agreement) confirming the accuracy of the hypothesised pathogenic pathway. In addition, the formation of physiological RA levels in the rat

embryo hindbrain can be reasonably estimated after azole exposures. This research will provide a better understanding of the toxicity mechanism of single and combined chemicals affecting RA (not just azole fungicides), and a predictive tool for human risk assessment for all mixtures acting on cranio-facial morphogenesis. Finally, predictive mechanistic simulations of mixture effects, just using dose–response data for single chemicals, will significantly reduce the use of animals in developmental toxicity studies

3. Food safety and its regulation practice in developing countries like Nepal

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Healthy and safe food is one of the fundamental rights of the living being. Naturally, food is pure and safe but during the processing and preparation, it is being adulterated by different means. It is a matter of global concern guaranteeing long-term availability of safe food. Therefore, different activities including research, policy development and implementing the food act and food safety have been practised globally. This paper aims to analyse the safety concern and the food adulteration in different food products like milk oil and water in Nepal. The paper further explains the harmful biological and chemical components that are found in the food and their hazard in the human being. It also focuses the functioning of present food act and policies related to the food safety and adulteration in Nepal.

The data obtained from various foods regulating bodies and consumer rights activists were collected and analysed both qualitatively and quantitatively. A study shows that the adulteration in the food is perpetual for sudden benefit besides natural means. The results revealed a higher degree of adulteration in liquid as compared to solid food. Awareness to producers, traders and consumers in partnership with government agencies is to be enhanced. To assure the quality of food and to mitigate the adulteration, the government has to form and implement strong food act and policy along with the regular inspection of the industry.

4. Distribution of ^{35}S-labelled perfluorinated compounds in C57Bl/6 mouse after a short-term dietary exposure – the main route of exposition of humans

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Perfluorooctanesulfonate (PFOS) has been used world-wide for decades due to its unique characteristics, but has been withdrawn due to its bioaccumulative and toxic properties. Therefore the manufacturers of fluorochemicals started with perfluorobutanesulfonyl fluoride (PFBS) production, which tended to be more rapidly eliminated in animals. Due to the limited data of detailed distribution of PDOS and almost no data of PFBS distribution in experimental animals the present study was designed to characterise the tissue distribution of both compounds in mice.

The ^{35}S-labelled PFOS and ^{35}S-labelled PFBS were used for dietary exposure of male C57Bl/6 mice for 1, 3 and 5 days in a dose(s) of 23 mg/kg/day. After treatment the mice were sacrificed, the organs were dissected and the detection of the presence of radiolabelled chemicals was performed using liquid scintillation counting in a Beckman LS 6000TA Liquid scintillation counter. All statistical analyses were performed using statistical packet Winstat for Excel.

PFOS has been distributed mainly in the liver (40–50% day one and day 5 respectively) followed by the skin (20%), blood (15%), bone (10%), and muscle (10%) with a tendency of now saturation (except for the bone). PFBS has been mostly recovered in the bone (15–22% on a day 1 and day 5 respectively) followed by the liver (20%), blood (20%), skin (18%) and muscle (13%). There was no saturation of PFBS in bones, in contrast to PFOS, after 5 days of exposure. PFBS distribution in the liver has shown differences in comparison to PFOS showing saturation after 3 and 5 days of exposure. The distribution in other organs of both compounds was similar.

We may conclude that the major compartments for both PFOS and PFBS in C57Bl/6 mice are the liver and the bone, followed by blood, skin and muscle. We have demonstrated the presence of PFBS in the examined organs was similar to the PFOS, which should be considered in the future studies.

Key words: PFOS, PFBS, Distribution, Dietary exposure.

5. The exposure to Fipronil within an One Health approach

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Fipronil as a non-competitive blocker of γ-aminobutyric acid (GABA)-gated chloride channels is a registered insecticide present in pesticide and biocide formulations for the agronomic use and to control insects and ecto-parasites in indoor and in pets, respectively. Recently, its off-label use in poultry farming determined residues of fipronil and its metabolite sulfone in dropped eggs of potential risk for acute neuro-toxicity in children under a worst-case food intake scenario. Furthermore, the risk assessment suggest the consideration of aggregate exposure from house dust. Vacuum cleaner bags from 176 Italian households indicated a declared pet's presence (N = 114 samples) was significantly associated with a higher fipronil + fipronil sulfone contamination in dust. Within this context, the 64% of samples fell above the reporting limit of 0.01 mg/kg, with occurrence descriptors for P50, P75 and P99 at 0.31, 3.18, and 62.2 mg/kg dry weight, respectively. The identified presence in dust of fipronil desulfinyl as a degradation product was reported to be 10× more active on the GABA type A receptor of vertebrates than fipronil, and would represent an opportunity to set toxicity equivalency factors. In this approach, *in silico* QSAR approaches are envisaged to refine the uncertainties within cumulative and aggregate exposure assessment in toddlers as a sensitive and vulnerable group. Other advancing aspects would be based on a regular post-marketing monitoring of the non-professional use of biocides, and on the epidemiology of children admitted to antipoisoning centres for suspect intoxication. The systematic presence of fipronil products indoors would represent evidence by which to direct and prioritise environmental and food risks including the persistence of fipronil products in remediated waters and biosolids from civil wastewater treatment plants, and that proposed for agriculture use and for the pest resistance outcomes.

6. Risk assessment of arsenic (As) in rice and rice-based products consumed by toddlers in Switzerland

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Because rice has the ability to accumulate arsenic, the levels of inorganic arsenic (iAs) in rice are generally 10-fold higher than in other cereals. Therefore, rice and rice-based products contribute significantly to dietary arsenic exposure. In this study, the occurrence of arsenic was measured in rice and rice-based products intended for toddlers (N = 105). As arsenic toxicity is highly dependent on species and oxidative state, not only total arsenic content, but also species, such as As(III), As(V), MMA(V) and DMA(V), were measured using an ion chromatography-inductively coupled plasma-mass spectroscopy technique. The predominant arsenic species was As(III), with 60–80% of the total arsenic content, followed by DMA(V) and As(V). MMA(V) was measured only at low levels (<3%). Based on German food consumption VELS data, the iAs exposure for toddlers (1–3 years) was estimated in different scenarios. For 'only consumers', rice drinks were the predominant contributor for iAs intake in all scenarios followed by rice-based cereals. In several scenarios, iAs intake was estimated to be higher than EFSA's lower BMDL01 of 0.3 μg kg^{-1} bw day^{-1} for 1% excess cancer risk, but in no scenario higher than EFSA's upper BMDL01 of 8 μg kg^{-1} bw day^{-1}. Potential health risks cannot be excluded, in particular for toddlers: (1) with coeliac disease, when rice and rice-based products are consumed instead of gluten-containing cereals; (2) with cows' milk allergy, for whom rice drinks replace cows' milk; (3) vegans, who do not drink cows' milk and consume rice drink instead; and (4) from specific ethnic groups who cover their carbohydrate needs mainly through rice. Based on the study results, the FSVO established recommendations for the consumption of rice and rice-based products for parents and their toddlers in Switzerland.

7. Study the occurrence of acrylamide in food in comparison with the long-term trend in the Czech Republic and Slovakia

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Acrylamide (AA) is a contaminant formed in carbohydrate-rich foods during ordinary heat treatment of food at temperatures above 120°C, such as baking, frying, roasting, etc. This is classified as a process contaminant with negative effects on human health. Acrylamide negatively affects the nervous system, reproduction, prenatal and post-natal development. IARC has included acrylamide as a substance that is probably carcinogenic to humans (group 2A). Food safety authorities have recommended the long-term monitoring of acrylamide levels in food.

The aim of our study was to determine the acrylamide content in samples of commonly available foods from market chains in the Czech Republic (CR) and compare these with data on long-term occurrence of acrylamide in food in the CR and the Slovakia (SR). In total, 42 food samples were analysed: potato chips, biscuits, popcorn, cornflakes, extruded breakfast cereals for children and baked muesli. The analysis was carried out in

an accredited laboratory using high pressure liquid chromatography (HPLC). The results confirmed that the lowest content of acrylamide was in extruded breakfast cereals (mean 89 µg kg^{-1}). The low AA content was determined in roasted muesli (mean 126 µg kg^{-1}) and cornflakes (mean 115 µg kg^{-1}). The highest AA values were determined in potato chips (mean 982 µg kg^{-1}) and popcorn (mean 761 µg kg^{-1}). Eleven products (potato chips, popcorn and corn biscuits) exceeded the recommended guideline values for acrylamide given by the Commission Recommendation (2013/647/EU) 8 November 2013. For samples of corn products, it can be seen that the used technology can affect the total AA content in the final product. According to the results of long-term monitoring of acrylamide levels in common foods in the SR from a total of 544 specimens in the period 2006–2014, the highest average amount of AA was found in coffee (707.8 µg kg^{-1}), potato products (409.8 µg kg^{-1}), durable pastry (318.6 µg kg^{-1}) and other cereal products (302.6 µg kg^{-1}).

Our study showed results that were consistent with long-term monitoring of food in the Czech Republic and the Slovak Republic. The highest concentration of acrylamide was found in foods made from potatoes and corn flour. Since 11 April, Commission Regulation (EU) 2017/2158 20 November 2017 has entered into force establishing mitigation measures and reference values for reducing the presence of acrylamide in foods.

8. Risk characterisation of ciguatera food poisoning in Europe. GP/EFSA/AFSCO/2015/03 (EUROCIGUA): preliminary results

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Ciguatera food poisoning is one of the most common foodborne illnesses related to seafood consumption world-wide, mainly in tropical and subtropical areas. However autochthonous outbreaks have been reported in Spain and Portugal, specifically in Macaronesia. The EuroCigua project focuses on characterising the risk of ciguatera food poisoning in Europe. The main objectives are: to determine the incidence of ciguatera in Europe; to assess the presence of ciguatoxin in food; and to develop and validate methods for the determination of ciguatoxin contaminated specimens. In this manuscript, an update of results is presented. First an epidemiological surveillance protocol for ciguatera in the EU has been developed. This protocol includes a consensus definition for ciguatera food poisoning, the recommended public health measures and two specific questionnaires for ciguatera cases and outbreaks. Secondly, potentially ciguatoxin (CTX) producing species of the genera *Gambierdiscus* and *Fukuyoa* have been identified in Macaronesia (Canary Islands and Madeira) and in the Mediterranean area. *Gambierdiscus* has been described for the first time in the western Mediterranean in the Balearic Islands. Taxonomic evaluation, implementing morphological evaluation and molecular genetics have been carried out. Cultures of these species have been established and, in some strains, production of CTX-like compounds has been identified. Finally, EuroCigua is also focused on the development and optimisation of an LC-MS/MS method for the confirmation of the CTX toxicity in fish samples from the Canary Islands and Madeira, previously identified as positive by neuroblastoma cell assay (N2a). The purification steps of sample preparation and the optimised conditions for an increased sensitivity of the mass spectrometry analyser have been evaluated, allowing the detection of CFP toxins at ppb levels. At this stage of the project, the studies show that Caribbean ciguatoxin, and in particular C-CTX1, is the main responsible agent for the contamination of fish from the Canary Islands and Madeira.

9. Risk assessment of nitrates as food additives: an integrated approach

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The Panel on Food Additives and Nutrient Sources added to Food (ANS) provided a scientific opinion re-evaluating the safety of sodium nitrate (E 251) and potassium nitrate (E 252) when used as food additives. The current acceptable daily intakes (ADIs) for nitrate of 3.7 mg/kg body weight (bw) per day were established by the SCF (1997) and JECFA (2002). The available data did not indicate genotoxic potential for sodium and potassium nitrate. The carcinogenicity studies in mice and rats

were negative. The Panel considered the derivation of an ADI for nitrate based on the formation of methaemoglobin, following the conversion of nitrate, excreted in the saliva, to nitrite. However, there were large variations in the data on the nitrate-to-nitrite conversion in the saliva in humans. Therefore, the Panel considered that it was not possible to derive a single value of the ADI from the available data. The Panel noticed that even using the highest nitrate-to-nitrite conversion factor the methaemoglobin levels produced due to nitrite obtained from this conversion would not be clinically significant and would result to a theoretically estimated endogenous *N*-nitroso compounds (ENOC) production at levels which would be of low concern. Hence, and despite the uncertainty associated with the ADI established by the SCF, the Panel concluded that currently there was insufficient evidence to withdraw this ADI. The exposure to nitrate solely from its use as a food additive was estimated to be less than 5% of the overall exposure to nitrate in food based on a refined estimated exposure scenario. This exposure did not exceed the current ADI (SCF, 1997). However, if all sources of exposure to dietary nitrate are considered (food additive, natural presence and contamination), the ADI would be exceeded for all age groups at the mean and the highest exposure.

10.The relevance of mouse as second animal species for the identification of carcinogenesis hazard

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Animal testing is still part of the current standard to explore the potential carcinogenic effect of chemical substances. In particular, the 2-year studies performed in laboratory rodents have been for years the primary method by which chemicals are identified as having the potential to be hazardous to humans.

For plant protection products (PPPs), Regulation (EU) 283/2013, setting out the data requirements for active substances, indicates that long-term carcinogenicity studies should be conducted in two rodent species, with a default preference for rat and mouse.

Several reviews published in the last 3 decades from the pharmaceutical, industrial and agro-chemical sectors (von Wittenau and Estes, 1983; Alden et al., 1996; Doe et al., 2006; EFSA 2007; Billington et al., 2010; Boobis 2016) highlighted the low impact of having information from a mouse carcinogenicity study in the assessment of human safety and classification.

However, conducting a mouse carcinogenicity study currently remains a global requirement for the successful registration of agrochemicals.

The present study reviewed pesticide evaluations to determine studies and endpoints used to derive guidance values and safety factors applied. From this evaluation, the frequency of species used to set regulatory reference values, main targets/end points and the impact of the studies conducted in mouse on these parameters were extrapolated.

The analysis is expected to contribute to a weighted assessment of the utility of including the mouse as a second rodent species in pesticide risk assessment, also in the light of the principles of the 3Rs (Replacement, Reduction and Refinement) in animal research. Moreover, such analysis will mainly focus on the evaluation of the mouse and its contribution to carcinogenesis risk assessment.

11. EFSA scientific protocol for the re-assessment of the safety for consumers of bisphenol A (BPA)

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To ensure an efficient, transparent and rigorous re-assessment of the safety for consumers of bisphenol A (BPA), the European Food Safety Authority (EFSA) has developed a protocol detailing *a priori* the approach and methodology to be used. The protocol defines upfront methods and criteria for data collection, study inclusion, evidence appraisal (internal and external validity) and evidence integration (e.g. weight of evidence, confidence in the body of evidence). Pre-defined inclusion criteria (e.g. publication date after December 2012 or data submission via a call for data, any exposure route, any toxicological end-point, etc.) are considered. A systematic review approach is applied to human and animal evidence, potentially suitable for deriving a reference dose for setting a tolerable daily intake (TDI), whereas other types of evidence, e.g. cross-sectional and toxicokinetic studies, are dealt with narratively. An appraisal tool adapted from the 2015 NTP-OHAT is employed to rate the internal validity of human or animal studies, according to design and end-point. The external validity is assessed only on the animal studies by criteria taken from the 2014 Science in Risk Assessment and Policy (SciRAP). The experts next assign confidence ratings (High, Moderate, Low or Very Low/missing data) to the body of evidence for each end-point and translate them into levels of evidence for a certain health or no health effect. The final integration of the levels of evidence from the human and animal streams into the likelihood of a health or no health effect identifies the effects/studies on BPA suitable for the hazard characterisation. We believe the correct implementation of such a structured protocol will result into a methodologically rigorous re-evaluation of the temporary TDI for BPA of 4 µg/kg bw per day set by EFSA in 2015 and will in turn enhance the public trust in EFSA's risk assessment work.

12. Acute exposure of the Italian young population to tropane alkaloids through cereal-based food consumption: a preliminary estimate at a local level

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Tropane alkaloids (TAs) are secondary metabolites of several plants, characterised by an acute toxicity on the nervous system. EFSA established a group ARfD of 0.016 µg/kg bw expressed as the sum of (−)-hyoscyamine and (−)-scopolamine, assuming equivalent potency.

The present study was carried out on 82 cereal-based food samples collected in Lombardia and Emilia-Romagna regions during 2016–2017 and analysed for TAs by the Food Chemical Department of the IZSLER using a validated LC-MS/MS method. LOQ value was 0.3 µg/kg for cereals.

Most sample concentrations (97.6%) were below the LOQ. Four samples showed the presence of atropine or scopolamine, namely: a rice-based cream and a maize-based cream intended for infant consumption, and two buckwheat products.

A preliminary investigation was performed on the acute exposure to the sum of atropine and scopolamine by infants, young children and teenagers consuming cereal products. Two scenarios were assessed.

First scenario considered real data for mean and high consumers. Infant exposure ranged from 0.0008 to 0.0104 µg/kg b.w./day; children exposure ranged from 0.0012 to 0.0045 µg/kg bw/day; teenagers exposure ranged from 0.0011 to 0.0031 µg/kg bw/day.

A worst-case scenario was calculated taking into account left-censored data in an UB approach, assuming a concentration of 0.29 µg/kg for samples below the LOQ. Infants exposure ranged from 0.0011 to 0.0431 µg/kg b.w./day; children exposure ranged from 0.0006 to 0.0089 µg/kg b.w./day; teenagers exposure ranged from 0.0004 to 0.0066 µg/kg b.w./day.

The preliminary study shows that the group ARfD is not exceeded within the first scenario. If left-censored data are assessed, the acute exposure of infants to the sum of TAs could exceed the ARfD. However, the worst-case assessment was very conservative and affected by severe uncertainties, mostly related to a large number of left-censored data and the lack of updated consumption information.

13. Risk assessment of nanomaterials used in food-related applications: in vitro tests to assess dissolution and biological fate

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In the food sector, applications of nanotechnologies to agricultural production, food processing and food-contact materials are rapidly developing. Nanotechnology applications in the food sector may bring benefits; conversely, potential risks have to be assessed and excluded since, if nanoparticles persist as such after gastrointestinal digestion, they may be absorbed in the gut.

Nanomaterials that quickly and completely dissolve/degrade in the gastrointestinal tract do not give rise to nanospecific concerns as in the absence of exposure no risk is expected. In the NANO-PERSIST project, carried out within the Open Access initiative in collaboration with the EC-JRC, the transformations and potential dissolution of nanoparticles under conditions representative of the gastrointestinal tract will be studied by means of an *in vitro* method simulating human digestion that mimics physiological conditions *in vivo*, taking into account the presence of digestive enzymes and their concentrations, pH, digestion time and salt concentrations.

If there is potential for systemic exposure, i.e. if nanoparticles persist as such after gastrointestinal digestion and are absorbed, their biopersistence in the human body is an essential driver of their toxicokinetics behaviour and potential toxicity. An *in vitro* test in artificial lysosomal fluid will be used to have an insight into the bio persistence and the biological fate of nanoparticles in the human body.

The above-mentioned acellular *in vitro* tests are key to assess the dissolution/bio persistence of nanomaterials used in the food and nutrition sector and form the basis of the risk assessment strategy for these materials. Validation and standardisation of these methods for the assessment of nanotechnology products is therefore an urgent research need. In the NANO-PERSIST project they will be applied for the first time to a range of nanomaterials of relevance for the agri-food sector and fit for purpose, state-of-the-art analytical methods will be used for the physicochemical characterisation of the particles.

14. Assessment of food contamination and dietary intake of lead and thallium in a Northern Italy population

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Lead and thallium are heavy metals released in the environment after natural and anthropogenic activities. Food and water intake are the major sources of human exposure to these elements. In this study, we aimed at characterising lead and thallium content in foods consumed in northern Italy population, to estimate the dietary intake of these metals. To undertake this that we bought food samples in markets and groceries collected during the period from October 2016 to February 2017 in the Emilia-Romagna region, and we measured their element content using inductively coupled plasma-mass spectrometry. Finally, after assessing dietary habits of an Emilia-Romagna community by using a validated food frequency questionnaire, we eventually estimated dietary intake of these metals in that community. In the 890 analysed food samples, the highest lead contamination levels were found in seafood, vegetables, sweets and beverages. The estimated dietary intake of lead was 5.758 (interquartile range (IQR): 4.547–7.427) µg/day, corresponding to 0.089 (IQR: 0.069–0.113) µg/kg of body weight per day, with cereals, beverages and vegetables as major contributors. For thallium, one-third of specimens showed very low levels below the limit of detection, with the highest contamination levels in vegetables, dry fruits and sweets. The dietary intake of thallium was 0.236 (IQR: 0.183–0.312) µg/day, mainly from vegetables, beverages, cereals and sweets. In conclusion, our study provides an estimation of lead and thallium intake in a northern Italian community and shows a generally low exposure levels from dietary sources.

15. Exposure estimation for ochratoxin A and aflatoxins due to red chilli powder consumption in a Chilean rural area

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Ochratoxin A (OTA) and aflatoxins (AFs) are carcinogenic toxins produced by fungi, whose exposure is associated with the consumption and handling of contaminated foods. In Chile, the National Programme of Surveillance (PNV) of Mycotoxins in Food of the Ministry of Health has found both mycotoxins in dry chilli pepper often in high levels. The aim was to estimate OTA and AFs exposure by red chilli powder consumption in a Chilean rural area by the Probable Intake (PI) estimation, based on: (a) reported consumption of red chilli powder; and (b) OTA and AFs concentration in red dry chilli according to the PNV of Mycotoxins of 2016. Normal distribution of data and probabilistic models based on Monte Carlo simulation were assumed. According to the food consumption survey, 26% of the subjects are dry chilli consumers, with a mean of 1.93 (± 2.26) g/day, without significant differences between gender and ages. The reported 2016 prevalences of OTA and AFs in red chilli powder were 45% (13/29) and 21% (6/29), with average levels of 19.87 (± 20.36) and 1.8 (± 0.72) ng/kg respectively. The estimated mean IP was 1.185 (± 1.172) ng/kg weight/day for OTA and 0.082 (± 0.065) ng/kg weight/day for AFs. In a worst-case scenario, the IP would be 33.5 ng/kg weight/day for OTA and 1.5 ng/kg weight/day for AFs. In Chilean rural areas, exposure to OTA due to red dry chilli consumption would be low in average consumption but could reach dangerous levels in the worst-case scenario. Both toxins are present in foods consumed in Chile, so it is urgent to study other sources and measure biomarkers in the population for a more accurate exposure assessment.

16. Occurrence of different mycotoxins (including emerging mycotoxins and ergot alkaloids) in feeds from Spain

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Mycotoxins are toxic secondary metabolites produced by certain fungi. Among these, there are well known hazards such as aflatoxins (considered as carcinogenic by the IARC) or ochratoxin A. Currently, several mycotoxins are considered in the EU legislation and maximum contents have been established in different food commodities. However, there are still some mycotoxins with no limits established, but with some evidences of adverse effects on human health. These are the so-called emerging mycotoxins, including some *Fusarium* toxins such as enniantins and beauvericin.

In a recent survey, 228 feed samples for pigs from different locations in Spain have been analysed in our laboratory, trying to explore the occurrence of mycotoxins (including aflatoxins B1, B2, G1 and G2, ochratoxin A, fumonisins B1 and B2, citrinin, zearalenone, deoxynivalenol, fusarenone X, sterismatocystin, T2-toxin, HT2-toxin, enniantins A, A1, B and B2, beauvericin and 12 ergot alkaloids). The

results showed that the 100% of the samples gave positive results for enniantin B (up to 1,200 µg/kg) and more than 90% for beauvericin. Moreover, more than 40% samples were contaminated with more than five different mycotoxins. In the EFSA Scientific Opinion on the risks to human and animal health related to the presence of beauvericin and enniatins in food and feed, it was concluded 'the chronic exposure for poultry indicated that adverse health effects from beauvericin and enniatins were unlikely. For other considered animals, the lack of LOAELs/ NOAELs precluded the estimation of chronic health risk from beauvericin and enniatins'. These results, show the necessity of establishing an estimation of this risk and, if necessary, the proposal of maximum limits also for these emerging mycotoxins. Moreover, the synergic effect of different mycotoxins should also be explored.

17. Multimycotoxin exposure assessment in children using urinary biomarkers

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Cereal foods are commonly contaminated with multiple mycotoxins resulting in frequent mycotoxin exposure in humans. Tolerable daily intakes (TDI) and maximum permitted levels are set by food safety authorities world-wide to protect consumers from mycotoxin toxicity. Children have been described at high risk to be exposed to high levels of mycotoxins due to their high intake of cereal foods in relation to body weight. Here we use a multimycotoxin detection method in urine to assess mycotoxin exposure in children.

Spot urine samples were collected from 21 children (age 2–6 years) following their habitual diet. 4 ml of urine sample were spiked with internal standards (^{13}C labelled DON, ZEN, HT2, OTA, AFB1), incubated with β-glucuronidase (37°C, 18 h) and passed through Myco6in1 immunoaffinity columns. Eluents were dried, reconstituted in 10% ethanol and injected (10 µl) into a Shimadzu Nexera X2 LC coupled to a Shimadzu 8,060 triple-quadrupole MS. The mobile phase gradient changed linearly from 95% A (10 mM ammonium acetate) to 95%B (methanol) over 10 min. Daily exposure to DON, ZEN and OTA was estimated from urinary mycotoxin concentrations using urinary creatinine excretion, renal clearance rate and mycotoxin excretion rate [1] and expressed as% of TDI.

Urinary levels were high for DON (14.65 ± 12.69 ng/ml) but low for NIV (0.34 ± 0.21), OTA (0.05 ± 0.02) and ZEN (0.08 ± 0.06). Some of the urine samples contained DOM-1 (2/21), T2 (1/21), HT2 (1/21), αZEL (3/21) and βZEL (2/21) and none of the samples contained AFB1, AFM1 or OTα. Children were exposed to levels above the TDI in 58% of cases (DON), 8% of cases (OTA) and none of the cases for ZEN. Our data clearly demonstrate that children are exposed to high levels of some mycotoxins through their habitual diet and that maximum permitted levels in food do not fully protect them from exceeding TDI.

Reference

[1] Gratz SW, Richardson A, Duncan G, Holtrop G (2014): Annual variation of dietary deoxynivalenol exposure during years of different Fusarium prevalence: a pilot biomonitoring study. Food Additiv Contamin A 31(9), 1579–1585.

18. Assessing the safety of ethnic foods consumed in the United Kingdom

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We have been engaged in research monitoring the presence of toxic elements, including arsenic, in different foods that are imported into the United Kingdom (UK) that are consumed by different population groups. Exposure to toxic elements can lead to development of different diseases and therefore a knowledge of foods that are potentially harmful is needed. In this context, our research is directed at protecting public health and nutrition by identifying foods that have high content of arsenic, cadmium and lead and also looking for alternatives that have lower content of such elements. Foods sold in the UK market were purchased and analysed using inductively coupled plasma-mass spectrometry. Our analysis reveal that rice and certain types of vegetables have high content of toxic elements which may increase human exposure to these elements in those populations that consume large quantities of these foods on a regular basis. We have also identified certain types of rice, especially aromatic rice, that are very low in arsenic that could be consumed by people who eat large quantities of rice on a regular basis. Findings of our studies and the potential risk to human health will be presented.

19. The impact of synthetic amorphous silica (E 551) on advanced in vitro models of the human intestinal barrier

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In recent years food industry faced different aspects of nanotechnology. Engineered nanomaterials (ENM) may have been developed to provide for example new tastes, antimicrobial properties or to improve the nutritional value of food (novel food). Alternatively, nanostructured synthetic amorphous silica has been mainly used as anticaking agent for

decades. It does not generate novel food characteristics but rather serves as a technological additive.

The impact of nanomaterials on the gut epithelium and their translocation through the intestinal barrier is poorly investigated and understood. Therefore, we aim to mechanistically study the interaction of nanostructured silica with the mucosal lining and distinct cell types of the intestinal barrier. A panel of 10 different synthetic amorphous silica products, suitable as E 551, which differ in size, surface area and production route will be assessed to identify potential structure-activity relationships.

To elucidate the impact of synthetic amorphous silica on enterocytes, the most prevalent cell type of the intestinal barrier, 21-day fully differentiated Caco-2 monocultures were employed. The Caco-2 monocultures displayed cell type-specific morphology, formed intact barriers and expressed cell type-specific antigens. All investigated nanostructured silica products did not affect barrier integrity, cell viability or the formation of reactive oxygen species up to a concentration of 50 µg/ml in differentiated Caco-2 cells.

The next steps will be the establishment of co- and triple cultures of enterocytes (Caco-2), goblet cells (HT-29-MTX) and B-lymphocytes (Raji) and subsequent studies on the impact and translocation of synthetic amorphous silica, suitable as E 551, in these more physiological models.

20. Monitoring on the presence of 12 dyes in fresh meat preparations and meat products as a contribution to risk assessment

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The External Scientific Report of the European Commission entitled: 'Analysis of needs in post-market monitoring of food additives and preparatory work for future projects in this field', concludes that 'The groups of sweeteners and food colours were identified as priority substances to be addressed in post-market monitoring'. In effect, data related to the food dyes quantification in foodstuffs are lacking. Regarding meat products, this gap is also due to the attention of official controls, usually focused on other food additives (i.e. nitrites/nitrate and sulphites, etc.). However, the use/abuse of food dyes in meats has to be constantly monitored, due to several food safety concerns.

Recently, a fully validated method for the determination of 12 food dyes in meat products, based on HPLC coupled with UV-Diode Array Detection, was proposed [1]. This method was applied for developing a survey of the levels of these 12 dyes (Amaranth, Ponceau 4R, Carmine, Ponceau SX, Ponceau 3R, Allura Red AC, Carmoisine, Erythrosine, Sudan I, Sudan II, Sudan III and Sudan IV) both in fresh meat preparations and in meat products.

In total, 130 samples (65 meat products and 65 fresh meat preparations) were analysed. Carmine and Ponceau 4R were the only dyes quantified in meat products. Except for one sample of salami, they were regularly indicated on the label, and their concentrations were lower than legal limits (in the range 1.3–8.1 and 6.2–86.4 mg kg^{-1} for Ponceau 4R and Carmine, respectively). Regarding fresh meat preparations, Carmine was detected in two samples, confirming that this dye is still used, although it is no longer authorised.

Reference

[1] Iammarino M. et al. 2017. Abstract Book 8th RAFA. 279.

Funding

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21. Possible health risks of nanotechnology in the food industry

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Nanotechnology is a field of applied sciences and technologies focusing on the characterisation, fabrication and manipulation of biological and non-biological structures below 100 nanometres. Nanotechnology offers a wide range of opportunities in food sector involving food manufacturing, processing and food packaging. While this technology brings many advantages such as improved bioavailability, sensorial attributes and solubility, the safety risks associated with nanomaterials should be considered. Nanomaterials exhibit different properties compared to their micro form and this can lead changes in the absorption profile and metabolism in the body. They have potential to carry undesirable molecules across gastrointestinal tract. Another issue that should be handled is the potential toxicity of particles when transformed into nanoscale. Once they ingested, it is possible to migrate and accumulate in different tissues and organs such as brain, kidney and liver. *In vitro* studies have shown that nanomaterials can interact with normal cellular barriers by crossing cellular barriers and cause oxidative damage. This review provides an overview of the potential health risks such as heavy metal release, allergen carbon nanomaterials and silicium oxide nanoparticles in nanotechnology applications. Suggestions and corrective actions (e.g. categorising nanomaterials for risk assessment and multicriteria decision analysis) will be given to researchers and producers in food industry with a future outlook.

22. Transfer of deoxynivalenol in herbal tea infusions

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Deoxynivalenol (DON) is a mycotoxin belonging to the group of trichothecenes, produced by various *Fusarium* species. It contaminates mainly grains and cereal-based food and feed, however it could be found in herbs as well. The aim of this study was to assess DON transfer into tea infusions. This type of preparation (putting a tea bag into boiling water) is very common world-wide. An infusion usually brings the soluble ingredients into solution. Therefore, DON with its good solubility in water could be a potential risk for human health. This study focuses on peppermint tea because it is most commonly consumed in Serbia. To determine the transfer rate, 10 samples of naturally contaminated peppermint teas were used to prepare infusions. Quantification of DON in infusions was determined by HPLC-UV with DONStar R immunoaffinity clean-up columns. Concentration of DON in prepared tea infusions was no significantly different from naturally contaminated raw samples which means that transfer of DON was complete (100%). These data are important for the realisation of a 'Total Diet Study' (TDS). The TDS can be a complementary tool to estimate the population dietary exposure to DON across the entire diet by analysing main foods prepared 'as consumed', however in this case could be analysed 'as purchased' (raw tea). A provisional tolerable daily intake (TDI) for DON was set in 2002 by the Scientific Committee for Food (SCF) at 1 µg/kg body weight (bw) per day. At the moment maximum limit (ML) for deoxynivalenol in tea is not set.

23. Safe use of plant derived ingredients known to have type I allergen in cosmetics

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The safety of cosmetics used daily by consumers is critical and assurance of product safety is one of the most important factors considered by the cosmetics company. As consumer issues grow related to food (such as hydrolysed wheat protein, peanut, and soybean) and skin allergies, managing standards for food allergy-related components of cosmetic ingredients are needed. Recently, the European Commission issued a new Regulation (EU) 2017/2228, regarding the safe use of peanut oil, its extracts, its derivatives and hydrolysed wheat proteins in cosmetics, to amend Annex III of (EC) No. 1223/2009.

It is still controversial whether or not a consumer having a food allergy can cause contact dermatitis or allergic dermatitis when they use cosmetic products containing food allergens. The susceptibility of skin sensitisation might be different depending on individual susceptibility and potency of food allergens. Furthermore, the sensitivity of the consumer's allergic reaction might be influenced by the processing and refining process of food ingredients.

Soybean allergy is one of the most common food allergies, especially in babies and children. Allergic reactions to soy are typically mild, but all reactions can be unpredictable. There are number of potential soybean allergens such as glycinin 11S globulin fraction and beta-conglycinin subunit. Most of their allergenic activity could be described by IgE binding.

The quantitative analysis of soy residue of 20 soybean-derived cosmetic ingredients is performed using Veratox for Soy allergen No. 841. Although many of the issues surrounding variability in analytical techniques can be addressed, controlling the limit of soy protein content might be the first step of securing the safety of raw materials.

Although there is an argument about the connection between food allergies and contact dermatitis, plants known to have type I allergen are required more safety studies related to skin sensitisation.

24. Acute toxicity assessment of combined pesticide formulation taking into account adjuvants and in silico modelling to address further risk assessment of mixtures.

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Results presented are development of research idea reported on EFSA Risk Assessment Research Assembly in February 2018 in Utrecht.

Mixture toxicity is on growing interest of society, regulatory authorities and researchers. Number of studies show possibilities of adverse effect of mixtures where substances presented in doses not causing effect individually. Given whole mixture approach is not feasible as regular practice for risk assessment of mixtures, there is need to develop integrated testing strategy using alternative methods. In this work, we present acute *in vivo* testing and first steps in selection of in silico methods.

We conducted studies of acute toxicity (Wistar Han rats, OECD 425) of eight pesticide formulations, contained 2 or 3 pesticides (azoxystrobin, cyproconazole, difenoconazole, flutriafol, imidacloprid, lambda-cyhalothrin, propiconazole, spiroxamine, tebuconazole, thiabendazole, thiram, triadimefon, triadimenol). Results showed that coefficient of additivity calculated on the basis of active ingredients (AI) LD50 characterise potentiation of toxicity (4 formulations); in two formulation we have observed antagonistic interaction; one formulation caused dose addition

effect for males and synergistic effect for females. Results of calculation of additivity coefficient taking into account other than AI components of formulation will also be presented.

Data on repeated dose, reproductive and other long-term effects of pesticide active ingredients is available. So, we decided to discover if in silico tools may be used to decide if further toxicity studies and mixture risk assessment for tested in acute experiment active ingredients and adjuvants is needed. We conducted in silico toxicity modelling of AI and adjuvants using different publicly available QSAR and molecular docking models (with accent on endocrine disruption mode of action and developmental and reproductive toxicity), compared with available experimental data and presenting results.

25. Trace heavy metals in dietary supplements – analysis of market products

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JARS sp. z o. o.

The growing trend in consumption of dietary supplements must be followed by specific risk assessment connected with them. Those products, comprising of heavily concentrated nutritional components, vitamins and minerals, carry with themselves a number of risks, typically not found in normal foods. One of these is heavy metal contamination and, in turn, the risk of heavy metal poisoning in consumers who often treat a supplement as a replacement for a meal. Specific supplements carry with them a hazard connected with specific heavy metals – animal oil-based products often contain elevated levels of mercury, calcium and magnesium preparations may contain traces of barium. Despite more and more harsh regulations being imposed on this class of 'borderline' products and the knowledge of risks associated with ingestion of heavy metals, the analysis of market-available preparations shows, that producers often walk on the border between acceptable and hazardous products.

The analysis concerns a number of (anonymously presented) dietary supplements available in Poland that underwent trace metal analyses in JARS Laboratories and, using the suggested producer intake limits, assessed the risk of heavy metal accumulation and poisoning in occasional and regular users of such preparations.

The topic presented here seems all the more important as the lifestyle of European and global consumers is changing and is faster and faster, which forces many of them to treat dietary supplements as a panacea for tiredness, bad health and mood swings. Such users stand at a higher risk of potential health hazards connected with regular uptake of even the smallest amounts of heavy metals with food and supplements.

26. Risk thermometer-based ranking of chemical food contaminants and additives

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Food regulatory agencies have to plan their workload and directions of work. For this purpose, risk ranking of chemicals in foods is an important tool to set priorities and to enable a more risk-based transparent decision on prioritisation of health issues.

Risk Thermometer is a novel food chemical ranking tool, that has been recently developed at the Swedish National Food Agency (NFA). Ranking of chemicals by this tool is based on consumer exposure data and health-based guidance vales (HBGVs), but it also takes into account severity of the critical adverse health effects. For this purpose, EFSA risk assessment reports on chemical food contaminants were used to extract required data on consumption, HBGVs and tolerable daily intake (TDI)/Allowed Daily Intake (ADI) values when applicable. In addition to contaminants, data on allowed representative food additives from diverse groups (colours, emulsifiers, sweeteners) have been included in the ranking along with contaminants.

The risk ranking results have provided a new insight into the risks posed to consumers by contaminants as well as additives in use by the food industry. The ranking can be used as a basis for future mitigation activities by authorities and communication between professional sectors and stakeholders involved, bridging the three aspects of risk analysis (risk assessment, risk management and risk communication).

27. From cats to cattle: physiologically based models for risk assessment in farm and companion animals

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Radboud University

Jean-Lou Dorne – European Food Safety Authority
Ad Ragas – Radboud University

The assessment of animal health risks due to chemical exposure has been highlighted as an area which requires further development. We developed generic physiologically based toxicokinetics models for five domestic animals, i.e. chicken, cattle, cat, swine and sheep, based on a systematic literature search of data on physiological parameters. The models were applied to four compounds, i.e. melamine, monensin, fipronil, oxytetracycline, covering a broad range of chemical classes. The models were tested in a data-rich environment, with necessary model input parameters available, as well as in a data poor environment, where input parameters were extrapolated from other species. Overall, the models performed within a

factor 10 when compared with measured blood concentrations and tissue residues. The developed models are useful for potential application in risk assessment of animals, as they can be calibrated to fit the particularities of a variety of compounds and species. Furthermore, the calculated concentrations in animal residues (i.e. meat, fat, milk, eggs) can be used to estimate the risk for human health.

28. Integrating alternative methods to establish a residue definition for dietary risk assessment

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EFSA

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Pesticides are metabolised and transformed following their application on crops. This may lead to pesticide residues which can be composed of the parent compound and/or of a variety of metabolites. It needs to be assessed whether these residues are safe for the consumer.

A recent guidance of the EFSA Panel on Pesticide Residues [1] aims to transparently define the compounds to be included in the residue definition for dietary risk assessment based on their toxicological significance and the amounts likely to be present.

The innovative aspect of the EFSA guidance is a multidisciplinary approach combining dietary exposure assessment, pesticide residue science, toxicology and computational science. The assessment is following a structured decision tree approach composed of three modules.

Genotoxicity and general toxicity assessment of metabolites, carried out in the first two modules, employs computational toxicology and non-animal testing methods such as (Q)SAR modelling, grouping, read across in combination with available data and scientific information.

In addition, the toxicological threshold of concern (TTC) can be applied to exclude metabolites from further assessments based on a cumulative exposure assessment.

In the third module a decision on the residue definition for dietary risk assessment is derived, considering the contribution of relevant metabolites to the toxicological burden.

The guidance can benefit from the EFSA's pesticide genotoxicity database and the OECD MetaPath Project.

The positions and opinions presented in this poster are those of the authors and are not intended to represent the views or scientific works of EFSA.

Reference

[1] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2016. Guidance on the establishment of the residue definition for dietary risk assessment. EFSA Journal 2016;14(12):4549, 129 pp.

29. Contribution of dermal and oral uptake to internal bisphenol A exposure using physiologically based pharmacokinetic modelling

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Physiologically based pharmacokinetic (PBPK) modelling plays an increasing role in the pharmaceutical area as well as in the risk assessment of industrial chemicals [1]. Flexible and advanced software solutions for PBPK modelling are able to support the risk assessment of industrial chemicals. The dermal and oral uptake, and the toxicokinetics of bisphenol A (BPA) are not completely understood and existing uncertainties can be reduced by applying PBPK modelling.

The aim of the present study is to determine the contribution of dermal and oral uptake to internal exposure of unconjugated BPA. The internal exposure after dermal uptake is different from that after oral absorption. This is due to very efficient metabolism in the gut wall and the first pass effect of the liver.

The software Simcyp simulator was used to set up PBPK models for humans for the oral and dermal routes. It provides the parametrisation for the physiological parameters for different ages, sex and body weights (e.g. blood flows, organ volumes). Substance-specific parameters (e.g. pKa, logP, partition coefficients) were taken from the literature or predicted based on quantitative structure-activity relationships (QSAR). Several studies on *in vitro* clearance were taken into account. Finally, *in vitro* data on substance metabolism from the literature was scaled to intrinsic organ clearance. The contribution of dermal and oral exposure was assessed.

PBPK modelling is an appropriate way to predict the internal exposure to consumer-relevant chemicals such as BPA. It is a powerful tool to simulate various exposure scenarios (e.g. different dosing regimens, exposure routes). The influence of the variability within a population and uncertainties of input parameters can be addressed.

Reference

[1] World Health Organisation: Characterisation and application of physiologically based pharmacokinetic models in risk assessment, WHO Library, 2010.

30. Non-linear associations between dietary exposures to perfluorooctanoic acid or perfluorooctane sulfonate and type 2 diabetes risk in women: findings from the E3N cohort

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Background: The incidence of type 2 diabetes (T2D) is rising world-wide: there is increasing interest in understanding the role played by endocrine-disrupting chemicals (EDCs). Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) are stable and persistent synthetic compounds, suspected to act as EDCs and for which the diet is the main route of exposure.

Objective: To investigate the associations between dietary exposure to PFOS and PFOA and the risk of T2D in the large E3N cohort study.

Materials: This study included 71,294 women, free from T2D at baseline, who had answered semi-quantitative food questionnaire containing 208 food items. Overall, 2,680 women developed T2D during follow-up (1993–2012).

Methods: Dietary exposure to PFOA and PFOS was estimated for each study subject. Cox proportional hazards models, adjusted for the main know risk factors of T2D, were used to estimate hazard ratios (HR) and 95% confidence intervals (CI). Women were classified into 10 groups using the deciles of the distribution of PFOA and PFOS exposure, and the lowest group was used as the reference category.

Results: Mean dietary exposure to PFOS and PFOA was 0.50 ng/kg body weight/day and 0.86 ng/kg body weight/day, respectively. PFOA and T2D had an inverse U-shape association: women in the fourth, fifth, and sixth decile groups had a HR (95%CI) of 1.21 (1.06–1.46), 1.35 (1.15–1.59), and 1.33 (1.05–1.41), respectively, while the other decile groups were not associated to T2D. No association was found between PFOS and T2D, except when considering only women with body mass index (BMI) ≤ 25 kg/m^2, for which a positive non-linear association was observed.

Conclusion: Our findings highlight the importance of considering PFOS and PFOA low-dose exposure as a relevant risk factor for T2D.

31. Acrylamide: the carcinogen in your food

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Potatoes, cereals, bread: correlation between acrylamide content and colour changes.

Chiara Manzi, the president of Art joins the Nutrition Academy, EUROPEAN ANTIAGING CULINARY NUTRITION ACADEMY, together with ASSIC (The Italian Association for Nutritional Safety) and reviewed the available scientific literature and data to analyse the best cooking and processing methods to reduce the exposure to acrylamide in foods.

As potatoes are one of the food that contribute most to overall dietary human exposure of acrylamide, Chiara Manzi, together with Parma University and Art joins the Nutrition Academy, investigated the correlation between acrylamide content and colour of cooked potatoes.

The purpose of the present study was:

To develop a photographic tool to help consumers recognise acrylamide in foods. Results showed that the darker the colour of the potatoes, the more acrylamide is present.

To develop a method of cooking potatoes to be very low in acrylamide. potatoes were cooked in the oven (140–180°C) for 10 to 60 min (steam/hot air and no steam).

To develop a special cereal mix for cooking pizza with very low levels of acrylamide.

Acrylamide is a potentially cancer-causing substance that naturally forms in starchy food products during high-temperature cooking, above about 120°C and low moisture. It is mainly formed from sugars and the amino acid asparagine that are naturally present in many foods.

In June 2015, EFSA confirmed that acrylamide in food potentially increases the risk of developing cancer and causes neuronal changes for consumers in all age groups. As acrylamide is present in a wide range of everyday foods, EFSA concluded that acrylamide is a public health concern that applies to all consumers, but children are the most exposed age group on a body weight basis.

Certain foods are more likely to contain acrylamide than others. These include potato products (especially french fries and potato chips), coffee, and foods made from grain (such as breakfast cereals, cookies, bread, crisp bread). Wholemeal products have been shown to contain more acrylamide.

Acrylamide content can be related to colour: cooking starchy food to a golden yellow colour, rather than a dark brown colour, lowers the amount of acrylamide. Very brown areas contain more acrylamide.

Since any level of exposure to a genotoxic substance could potentially damage DNA and lead to cancer, EFSA's scientists conclude that they cannot set a

tolerable daily intake (TDI) of acrylamide in food. Instead, EFSA's experts estimated the dose range within which acrylamide is not a concern for public health as 1 µg of acrylamide a day. This dose may be found in 1 g of potato chips, 3 g of french fries, 4 g of biscuits and 3 g of First Born biscuits.

The conclusion of the present study was:

A photographic tool has been developed to help consumers recognise acrylamide in foods. Results showed that the darker the colour of the potatoes, the more acrylamide is present.

A method of cooking potatoes very low in acrylamide has been developed: potatoes were cooked in an oven (140–180°C) for 10 to 60 min (steam/hot air).

A special cereal mix for cooking pizza to be very low in acrylamide has been developed and produced.

Biography

Chiara Manzi graduated in Science in Human Nutrition and Dietetics (University of Navarra – Spain) and specialised in Antiaging Nutrition (Tufts University of Boston). She is the founder of tCucina Evolution Academy, the first and only Academy of Antiaging Culinary Nutrition in Europe. Partners of the Academy are the Universities of Parma and Milan. The Academy is sponsored by the Italian Ministry of Health. She is the president of the Italian Association for Nutritional Safety, one member of its scientific committee is Massimo Bottura (3 Michelin stars and best Chef of the world 2016). She is the teacher of Culinary and Antiaging Nutrition at the University of Milan (Faculty of Medicine) and an expert for the class of Culinary Medicine at the University of Ferrara. She is involved in many research projects together with the University of Parma that have been published in international scientific journals. She is the author of five books on Culinary Nutrition.

32. Importance of pathology peer review in evaluating comet assays for genotoxicity

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Shim-mo Hayashi – Scientific Director, Japan Flavour and Fragrance Materials Association

Safety assessment of flavouring agents includes the successful completion of a battery of *in vitro* and *in vivo* genotoxicity assays. Regulatory authorities may request a mouse or rat comet assay for detection of DNA strand breaks in first contact tissues (stomach, duodenum) and the major site of metabolism (liver). Histopathology on these tissues is necessary to rule out test agent toxicity that could cause false-positive comet assay results. Since exposure to the test agent is only 3 days, very subtle tissue changes may be present that are easily missed during routine histopathological examination. So, careful pathology assessment of anatomical and clinical pathology data are critically important for proper interpretation of the comet assay results. Two flavouring agents, perillaldehyde and 4,5-epoxydec-2(*trans*)-enal, were recently tested in a rat comet assay and the highest administered dose was considered positive for DNA strand breaks. Subsequent pathology peer review identified evidence of hepatotoxic effects challenging the appropriateness of that interpretation and clearly demonstrate the importance of careful pathology evaluation of target tissues in the comet assay. Pathology peer review on comet assay tissues is strongly recommended.

33. Testing new methodologies for identification of emerging chemical risks in food

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The objective of this study was to develop and test a procedure for the identification of chemicals registered under the REACH Regulation that are of potential health concern and are likely to occur in the food chain. For this purpose, 100 data-rich substances registered under REACH, together with four positive controls, were evaluated. The procedure consisted of a multistep selection process following a sequence of selection criteria. The evaluation criteria of the 104 substances took into account parameters related to exposure (tonnage, release, biodegradation and potential bioaccumulation) and toxicity (repeated dose toxicity, genotoxicity and reproductive toxicity) organised in six blocks. All substances were scored for each block. ACC-HUMANsteady software was used to evaluate the potential for bioaccumulation in 11 different food items using input data derived from QSAR predictions. Several weighting scenarios were tested to aggregate scores for the six blocks into a total score to enable a ranking of the 104 substances. In addition, a Pivot table selection was implemented that can be used without weighting. Further analyses compared the scores derived from experimental data with those derived from predicted data. These analyses found a good agreement of scores for biodegradability, but considerable disagreement of scores for toxicity endpoints. In conclusion, a scoring and ranking procedure was developed for the identification of chemicals of potential concern in the food chain

(potential emerging risks) that showed a good level of differentiation. The focus on (semi-)automated processes ensures that this procedure can be applied to all chemicals registered under the REACH Regulation.

34. Adverse Outcome Pathway: redox-cycling of a chemical initiated by mitochondrial respiratory chain's released electrons leading to parkinsonian motor deficits

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The Adverse Outcome Pathway (AOP) is a conceptual framework describing the chain of events leading from the first interaction of any chemical with a target (molecular initiating event, MIE) to an adverse outcome (AO), generally an apical end-point in accepted regulatory toxicity testing (EFSA, 2017). According to the OECD conceptual framework (OECD 2013, 2014) MIE and AO are sequentially linked by a series of biologically plausible and essential key events (KEs) and their relationship (key event relationships, KERs) should be concordant on dose–response, temporality and incidence.

The present AOP describes the linkage between excessive reactive oxygen species (ROS) production in the mitochondrial respiratory chain and parkinsonian motor deficits, including Parkinson's disease (PD). Interaction of a compound with complexes I and/or III of the mitochondrial respiratory chain has been defined as the MIE that triggers mitochondrial dysfunction leading to impaired proteostasis, which then causes degeneration of dopaminergic (DA) neurons of the nigrostriatal pathway. These causatively linked KERs result in motor deficit symptoms typical of parkinsonian disorders including PD and described in this AOP as an AO. Neuroinflammation has been placed as a late KE, paralleling degeneration of DA neurons of the nigrostriatal pathway. As DA-releasing neurons of the substantia nigra pars compacta (SNpc) projecting into the striatum are essential for motor control, the KEs also refer to these two brain structures, i.e. SNpc and striatum. The weight of evidence (WoE) supporting the relationship between the described KEs is mainly based on effects observed after exposure to the stressor chemical paraquat, which will be used as a tool to support the empirical evidence for this AOP.

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*The positions and opinions presented in this poster are those of the authors and are not intended to represent the views or scientific works of EFSA.

35. High-resolution mass spectrometry as a tool for detection and identification of organic substances of concern in food commodities as a part of the human exposome study

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The concept of the exposome was first defined in 2005 as 'the life course environmental exposures, from the prenatal period onwards' [1]. Ever since, it is considered a powerful approach in environmental health research, linking exposure and their effects on human health.

External exposure to anthropogenic chemicals – including dietary exposure – is well known to play an important role in human health. So, external exposure assessment was included in the multidisciplinary workshop held by the National Institute of Environmental Health Sciences (NIEHS) in 2015. On it, the exposome was reviewed from diverse research approaches, promoting so its incorporation within the concept of environmental health [2].

In parallel to the exposome, the interest in high-resolution mass spectrometry (HRMS) applications in exposure studies has been actively methods applied to target, suspect and non-target screening analysis for the determination of a broad variety of organic pollutants, residues and substances of emerging concern have been applied to a selection of environmental [5] and food matrices [6,7]. However, the advantages of HRMS technology as a tool for the analysis of markers of exposure and its applicability to environmental health growing for the last decade [3,4]. Full-scan acquisition from LC and GC-HRMS studies have not been fully exploited.

In this work, we present a multitiered approach for the rapid screening of a large number of pesticides, drugs, natural toxins and organic pollutants of emerging concern. This relies on the capability of both, GC and LC, coupled to HRMS combining target, suspect and non-target screening techniques. The application of this approach to food commodities provides quantitative data akin to traditional approaches. Under the scope of external exposure assessment, our proposed workflow combines the study of environmental and human biomonitoring exposure pathways to legacy and emerging contaminants, facilitating a robust and comprehensive understanding and evaluation of the exposome.

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36. Case study of a exposure assessment using various statistical methods to deal with non-detection

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In dietary exposure assessments, it is important to handle concentration data that are reported to be below the limit of detection (LOD). Generally, the resulting distribution of chemical occurrence values is left censored. NIFDS has treated left-censored data with the widely used substitution method recommended by international organisations. However, this approach has limitations in exposure assessment of some food items that are consumed frequently in our country. For example, aflatoxins were detected in some food items such as nut and spices but not detected in other food items according to the specified domestic monitoring system regularly being carried out. Although the detection rate of aflatoxins was under 5%, its exposure level was over-estimated in the high intake group. Therefore, the handling of left-censored data has raised a challenge for NIFDS's statistical analysis of chemical occurrence data in exposure assessment. In this study, we compared methods used to deal with non-detected items: the substitution method used to date and parametric maximum likelihood (ML) models, the log-probit regression method and the non-parametric Kaplan–Meier (KM) test, which EFSA proposed in 2010 as a more advanced alternative statistical approach. We estimated the parameters of occurrence data such as mean and statistical deviation with these advanced approaches. Based on this study, we will revise NIFDS's guideline for appropriate handling of left-censored distribution of chemical contaminant data in the exposure assessment.

37. Assessment of the health risks for the Spanish consumer associated with arsenic, cadmium and lead content in tuna

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The consumption of canned tuna in Spain is first in the world rankings. Tuna, as predatory fish, is subjected to bioaccumulation and magnification of pollutants such as metals in its body. Total As, Cd and Pb concentrations in different tuna samples marketed in Galicia (NW Spain) were determined by ICP-MS spectrometry. The maximum concentrations observed for Cd and Pb were: 0.045 ppm and 0.091 ppm, respectively, and were below the maximum levels (ML) set by European regulations. Because of its high consumption, the risk of chronic effects of all three metals and the risk of cancer for As were calculated based on estimated daily intake (EDI) as suggested by the Joint FAO/WHO, Target Hazard Quotient (THQ) and Cancer Risk (CR) models provided by the US-EPA. For these purposes, the results of this study were crossed with consumption data of tuna in Spain provided by the Agencia Española de Consumo, Seguridad Alimentaria y Nutrición (AECOSAN) through official consumer surveys (ENALIA 1 and ENALIA 2). A 3% level of total As was assumed to be inorganic As (iAs) for calculations, and the previously RfDo proposed for Pb was employed.

The EDIs estimated for adults were far below the tolerable daily intake (TDI). All THQs calculated were lower than 1, the limit value. A decreasing degree of magnitude was observed: THQiAs 2.8×10^{-2} > THQCd 2.4×10^{-3} > THQPb 2.2×10^{-4}, accounting for a Total THQ (TTHQ) 3.1×10^{-2}. Likewise, the CR did not surpass the level assumed to be the acceptable risk (10^{-5}) for iAs.

According to these results, tuna consumption could be considered as safe for human health regarding these pollutants.

38. Simultaneous screening of environmental phenolic compounds from the South Korean population

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Phenolic compounds are widely used in cosmetics, personal care products and food packaging ink, which indicates there should be various routes to human exposure. The use of phenolic compounds has raised concerns about the potential health risks associated with its endocrine-disrupting effects.

In this study, 12-hour urine samples (n = 1,326) collected from the South Korean adults over 18 years between 2010 and 2012 were analysed. Twenty-seven deconjugated phenolic compounds (eight alkyl phenols, four chlorophenols, six benzophenones, three bisphenols, one triclosan, and five parbens) were simultaneously determined from urinary samples using online solid phase extraction (SPE) and liquid chromatography-tandem mass spectrometry (LC-MS/MS). The analytical method was validated by means of selectivity, linearity, intra-day and inter-days accuracy and precision. The most prevalent compounds in the Korean population were parabens that were detected with 79–100% rate, followed by t-butylphenol, benzophenone-1 and 4-hydroxy benzophenone. Detection rates of 16 compounds were less than 50%, and nine compounds among them (n-pentylphenol, n-hexylphenol, n-heptylphenol, n-octylphenol, 2,5-dichlorophenol, 2,4,5-trichlorophenol, 2,4,6-trichlorophenol, benzophenone-2, bisphenol F) were detected less than 20%, which is difficult for statistical determination. This screening method can be suitable for the analysis of a large number of human urinary samples to assess the exposure to environmental phenolic compounds.

39. Comparison of exposure to marine biotoxins of different population groups in Bulgaria

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Phycotoxins are produced by some phytoplankton species and accumulate in filter feeding bivalves. Once ingested they could pose serious risk to human health.

The aim of the study was to determine the occurrence of marine biotoxins in wild and farmed mussels *Myrtillus galloprovincialis* in the year 2017 in Bulgaria, and to estimate the exposure of two adult population subgroups: general consumers and recreational harvesters through consumption of mussels.

Wild and farmed mussels (N = 47) from two harvesting periods in 2017: spring and autumn were analysed with multiphycotoxin method using LC-MS/MS. Exposure assessment for the two population subgroups were obtained through integration of levels established in phycotoxins analysis combined with the food consumption data of population groups and body weight (bw). Three scenarios were evaluated based on: (1) data from mean concentrations of positive samples; (2) data from mean concentration of all analysed samples where 'non-detect' was replaced by LOD/2; and (3) maximum concentration found.

Three phycotoxins were detected in the investigated samples: domoic acid (DA), yessotoxin (YTX) and pectenotoxin-2 (PTX-2). The incidence of toxins determined in all samples was respectively 29.8% for DA, 46.6 for YTX and 8.5% for PTX-2. Determined concentrations were not beyond the EU reference limits.

As expected the third scenario was the worst-case scenario with DA, YTX and PTX-2 exposures estimated respectively for general consumers and recreational harvesters as follows: 0.000068 and 0.077943 mg DA/kg bw; 0.000003 and 0.014912 mg YTX/kg bw and 0.000179 and 0.565613 µg PTX-2/kg bw.

Analysis of data obtained from the three scenarios showed more than 100 times higher exposure of recreational harvesters to phycotoxins than that of general consumers. Nevertheless exposure values did not exceed the recognised acute reference doses.

These results indicated that more attention should be paid to wild mussel harvesting and the control of their supply for consumption.

40. Risk assessment of ethyl carbamate in major alcoholic beverages in Chinese population

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Objective: To assess the health risk of exposure to ethyl carbamate (EC) from alcoholic beverages in Chinese adult drinkers.

Methods: The simple distribution method was introduced in dietary exposure assessment of ethyl carbamate from alcoholic beverages consumed by the population aged 15 and above. The human dietary intake of EC via alcoholic beverages was estimated based on nine provinces (municipalities) of alcoholic beverages consumption data in combination with national food safety risk monitoring occurrence data in China. The occurrence data comprises the EC contents of different alcoholic beverages including distilled spirit, yellow wine, wine, beer and liqueur. The risk assessment was conducted using the Margin of Exposure (MOE) approach with benchmark doses obtained from dose–response modelling of animal experiments.

Results: The overall average EC content of alcoholic beverages was 61.1 µg/kg (ND ≈5,170 µg/kg) and the median was 21.4 µg/kg, showing obvious positive skewed distribution. Yellow wine had the highest average EC content up to 125.1 µg/kg. The estimated average dietary exposure to EC was about 62.8 and 217.9 ng/kg bw per day for alcoholic beverages consumers and high consumption population (exposed to P95) respectively. The MOEs of alcoholic beverage consumers and high consumption populations exposed to EC were calculated to range between 1,000 and 5,000 (less than 10,000), indicating a health concern. According

to the individual distribution of EC exposure, the proportion of individuals with exposure to MOE of less than 10,000 for the exposure of alcohol drinkers was high as 43.6%.

Conclusion: Given the dose–response relationship between the EC doses used in the animal experiment and the tumour incidences, it is concluded that EC exposure poses a significant cancer risk for the alcohol-drinking population in China.

41. Health risk assessment of Cu and Mo in vegetables grown under the impact of Kajaran's mining complex

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Mining industry is one of the priority branches of Armenia's economy. Activity of mining complexes without treatment facilities, abandonment of tailings dams and many other violations have a grave impact on the environment (Saghatelyan et al. 2010).

Transfer of trace aspects from soil to plant cannot be underestimated as it is the major pathway of human exposure. For this purpose, firstly, trace element contents in soils and plant species were determined, afterwards, transfer factor (TF) and estimated daily intakes (EDI) were calculated.

Topsoil sampling was performed according to Standard Operation Procedures (SOPs). Locally grown and widely consumed plant samples were collected from the same soil sampling points according to WHO and FAO requirements (WHO/FAO 2008). Overall, 12 samples of soil and 32 samples of vegetables (potato, carrot, bean, fennel and pumpkin) were collected. Concentrations of trace elements (Cu and Mo) in soil and plant samples were estimated using atomic absorption spectrophotometry. This study included the development of a food frequency questionnaire (FFQ).

In the present study the obtained results indicated that TF values varied from element to element depending on type of vegetable. The smallest value of TF was obtained for Cu (carrot) and the highest one for Mo (fennel). Soil to plant transfer factors were less than 1. Lower values indicated the poor response of plants towards element uptake. However, it should be stressed that EDIs of Cu and Mo for all investigated vegetables exceeded the health-based guidelines values.

Furthermore, detailed investigations need to be performed for the overall assessment of health risks, taking into consideration not only adverse health effects posed by more than one toxic trace element, but also other exposure pathways (inhalation, dermal, etc.).

42. In silico toxicity prediction for ethoxyquin and its transformation products.

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Ethoxyquin (EQ; 6-ethoxy-2,2,4-trimethyl-1,2-dihydroquinoline) has been used as an antioxidant in feed for pets, livestock and aquaculture. Concerns regarding the safe use of ethoxyquin as an antioxidant feed additive have recently arisen due to its potential conversion into a series of transformation products (TPs). Using travelling-wave ion mobility spectrometry (TWIMS) coupled to quadrupole time-of-flight mass spectrometry (QTOFMS) at the Institute of Marine Research (IMR) in Norway, 27 EQ TPs were identified in oxidation experiments; 25 of these were detected in fish feed and 24 in fish from EQ exposure experiments. In the present work in the course of an EFSA EU-FORA fellowship programme we used a computational toxicity pipeline developed and implemented at the Federal Institute for Risk Assessment (BfR) in Germany to predict *in silico* the toxicity of EQ TPs. The data obtained facilitates the prioritisation of EQ TPs according to their theoretical toxicities and highlights the compounds of most concern that need to be analysed further using *in vitro* or *in vivo* models of toxicity. It is expected that the present work will aid current efforts to fill data gaps in the assessment of the exposure and the safety of EQ and its TPs for animals, consumers and the environment.

43. Testing the TTC using EFSA's OpenFoodTox database

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Improving analytical methodologies have led to the detection of an increasing number of compounds present at low concentrations but with insufficient toxicity data for risk assessment. Alternative methods such as the Threshold of Toxicological Concern (TTC) approach could be used as a prioritisation tool for a large cohort of compounds requiring toxicity testing. The TTC concept integrates data on exposure, structure, toxicity and metabolism to identify a safe exposure threshold value. TTC threshold values were originally derived from a non-cancer dataset of 613 compounds often criticised for not representing the 'world' of chemicals. So, there is an expressed need to expand the current TTC dataset. This study aims to test the TTC concept using EFSA's new OpenFoodTox database. The TTC concept was

applied *in silico* using the OECD's QSAR toolbox to categorise over 300 compounds from EFSA's database into one of three classes, under the Cramer decision tree. These three classes are reflective of toxicity and identify low (class I), moderate (class II), and high (class III) toxicity. The lognormal cumulative distributions of reference points for compounds were plotted for each of the three classes. The fifth percentile of each cumulative distribution was used to derive a TTC value by applying an uncertainty factor of 100, and factoring in average human weight. EFSA's TTC values were used to compare against the original threshold values for protectiveness. Results showed the threshold value derived for Cramer class III was protective of the original threshold value. However, Cramer class I fell below the original threshold value, while Cramer class II had too few compounds to carry statistical weight. Our analysis shows that the TTC approach is protective for chemicals pertinent to food safety. However, further expansion of the TTC dataset would be beneficial for refining TTC values.

44. Food packaging contaminants: estimating dietary exposure

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The safety of packaging materials is of great concern for food safety as low-molecular-weight substances can migrate from the packaging into the food and can cause harmful effects to human health through dietary exposure. Exposure assessment is one of the essential aspects in the risk assessment process. To estimate the exposure to migrated substances from food-contact materials several methods have been applied. In the European Union, a conservative assumption is adopted, namely a person of 60 kg body weight consumes daily 1 kg of food packed in a cubic container of 6 dm^2. The exposure can also be estimated more realistically by combining the migrated substance concentration in food and the consumption data obtained from consumer surveys. More refined approaches have also been used; as part of the European Project FACET (Flavours, Additives and Food-Contact Materials Exposure Task) a probabilistic modelling tool to estimate the exposure to migrated substances from food-contact materials was designed. This model allows the exposure assessment of migrated substances using information on packaging (use, composition), consumption data, etc.

In the present work, the dietary exposure from cereal-based foods in plastic packaging, to acetyl tributyl citrate (ATBC), a common plasticizer used in the manufacture of packaging materials was determined using a Total Diet Study (TDS) approach and was also estimated using the FACET exposure tool.

The results obtained with the TDS approach agree closely with those estimated with the FACET exposure model. So, for example the mean dietary exposures of ATBC were 1.01 µg/kg bw/day for the group 1–3 years; 2.01 µg/kg bw/day for the group 3–9 years and 1.27 µg/kg bw/day for the group 10–17 years. Those obtained with the FACET tool were 1.5 µg/kg bw/day for the group 1–3 years; 1.52 µg/kg bw/day for the group 3–9 years and 0.9362 µg/kg bw/day for the group 10–17 years. In all cases, mean dietary exposures to ATBC were below the tolerable daily intake (TDI) of 1.0 mg/kg body weight set by the EU for ATBC.

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Key words: exposure assessment, TDS, ATBC, FACET exposure model

45. Metals in Undaria pinnatifida

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There is no doubt that the dietary consumption of algae that has been traditionally consumed in Asia is expanding to Europe. *Undaria pinnatifida* or wakame, belonging to the brown algae, is one of the most widely consumed algae, especially for its beneficial properties. Numerous studies have shown that *U. pinnatifida* has a high capacity for metal absorption, which is of both nutritional and toxicological interest. However, its full metal profile has been little studied.

The objective of this study is to determine the levels of 20 metals (Na, K, Mg, Ca, Fe, Zn, Cu, Cr, B, Ba, Pb, Cd, Al, Sr, Li, Ni, Co, Mn, Mo and V) in 25 *U. pinnatifida* samples from two geographical areas (Asia n = 10; Europe n = 15), using Inductively Coupled Plasma–Optical Emission Spectrometry (ICP–OES) to evaluate the nutritional value and toxicological risk of its metal content based on the recommended consumption of *U. pinnatifida* (5 g dehydrated algae/day) and the Recommended Daily Intake and maximum tolerated intakes.

While samples of *U. pinnatifida* from Asia have the highest concentrations of elements such as Na (28.2 ± 2.71 g/kg dry weight) or Fe (58.8 ± 17.3 mg/kg dw), the samples from the European coastal waters contain the highest levels of Zn (40 ± 32 mg/kg dw). Among the metals of toxicological interest, Al stands out with levels of 31.5 ± 17.3 mg/kg dw in algae from Europe that are higher than those found in samples from Asia (20.0 ± 4.4 mg/kg dw). The

highest contents of Cd (1.11 ± 0.33 mg/kg dw) were detected in algae from Asia, and were much higher than those found in algae from Europe. Significant differences were found (P <0.05) in the contents of Al, B, Ba, Cd, Fe, K, Li, Mg, Mn and Zn between algae from Asia and those from Europe.

Considering a consumption of 5 g/day of *U. pinnatifida* from Asia, the consumer would be exposed to a metal intake that contributes 23% of the TWI of Cd, which is set at 2.5 µg Cd/kg bw/week. These new data highlight the need to monitor the metal content of edible algae, to consider algae as a new dietary source of metals and include maximum permitted levels of toxic metals in this new group of foods formed by algae.

46.How EFSA contributes to ensure that European consumers are protected from pesticide residues in food – the MRL review process

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The cooperation between EFSA, Member States and the European Commission is essential to ensure that European consumers are protected from pesticide residues in food. In the European Union (EU) plant protection products can only be placed on the market or used with prior authorisation. Regulation (EC) No. 396/2005 covers all matters related to legal limits (maximum residue levels (MRLs)) for pesticide residues in food and feed.

Maximum residue level means the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice (GAP) and the lowest consumer exposure necessary to protect vulnerable consumers. For crops grown outside the EU, MRLs are set on the request of the exporting country (important tolerances) and are also assessed by EFSA.

Following approval of an active substance in the EU, all GAPs (detailing the quantity, frequency and plant growth stage of the pesticide applied) authorised in the different Member States are assessed by EFSA in a process called MRL review, under Article 12 of Regulation (EC) No. 396/2005. This process is performed in cooperation with Member States, which are collecting and reporting the GAPs authorised in their countries and are evaluating the data supporting these GAPs. EFSA then performs a dietary risk assessment to ensure that MRLs are safe for consumers. If the risk assessment provided by EFSA does not identify any unacceptable risks to consumers, the MRLs can be set at the European level as legal limits in food by the European Commission.

47. A statistical approach to integrate analytical data distribution and cumulative intake over time into the definition of 'safety-based guidance values' for chemical contaminants in raw materials

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We have recently developed a globally applicable scientific tool for the assessment and prioritisation of chemical hazards in food raw materials. In the tool, we defined so-called safety targets (STs) as concentrations of chemical contaminants in raw materials below (or at which) no safety concern is foreseen when ingested over a lifetime in the context of overall exposure. Average concentrations of contaminants are used to derive STs along with average food intake data and established health-based guidance values (HBGVs). In reality, contaminant levels in a particular raw material can incidentally exceed 'safety targets'. We have recently asked the question how such variability in occurrence in consumption over time can be incorporated into the concept of 'safety-based guidance values' (SBGVs), making sure that over time, food safety is not compromised even with incidental deviation. This is based on the assumption that occasional exposures above the HBGV do not in general represent a health concern (e.g. seasonal increases in mycotoxin concentrations in cereals), as long as average exposure to a contaminant over a relevant period of time remains below the HBGV, and extreme exposures potentially leading to acute effects are excluded.

The present work describes the development of a statistical tool, based on the distribution of the contaminant in raw material and resampling technique, to calculate SBGVs that take these aspects into account and that can be used as an input for quality management of chemical contaminants in raw materials. The tool is flexible and applicable to different chemical contaminants and datasets and case studies are in progress to evaluate and verify its protectiveness for consumers.

48. Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. Part 1: Human and animal health

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The European Food Safety Authority has produced guidance on human and animal health aspects (Part 1) of the risk assessment of nanoscience and nanotechnology applications in the food and feed chain. It covers the application areas within EFSA's remit, e.g. novel foods, food-contact materials, food/feed additives and pesticides. The Guidance takes account of the new developments that have taken place since publication of the previous Guidance in 2011. It specifically elaborates on physicochemical characterisation of nanomaterials in how to establish whether a material is a nanomaterial, the key parameters that should be measured, the methods and techniques that can be used for characterisation of nanomaterials and their determination in complex matrices. It also details the aspects on exposure assessment and hazard identification and characterisation. In particular, nanospecific considerations on in vivo/in vitro toxicological studies are discussed and a tiered framework for toxicological testing is outlined. Depending on the initial tier results, studies may be needed to investigate reproductive and developmental toxicity, immunotoxicity, allergenicity, neurotoxicity, effects on gut microbiome and endocrine activity. It also touches upon the possible use of read across to fill data gaps, in vitro digestion, toxicokinetics, genotoxicity, as well as general issues on in vitro testing of nanomaterials. The potential use of integrated testing strategies and the knowledge of modes/mechanisms of action are also discussed. The Guidance proposes approaches to risk characterisation and uncertainty analysis, and provides recommendations for further research in this area.

49.Food additives Italian official control: dehydroacetic acid in cheese and cheese coating

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This work reports the occurrence of dehydroacetic acid in cheese and cheese coatings collected in Italy during Agricultural Ministry Official control in 2017. Dehydroacetic acid is an antimicrobial substance not allowed to be used in EU countries as a food additive, with unknown effects on human health. Dehydroacetic acid was measured by a validated HPLC method according to Commission Decision 2002/657/EC criteria in terms of specificity, linearity, precision and accuracy, limit of detection and limit of quantification. The method was successfully applied to about 160 samples of commercial cheese coatings and related treated cheeses collected in Italy during 2017. The overall results demonstrated that about 40% of the investigated cheese coatings contained dehydroacetic acid, ranging from 0.010% to 2.5% w/w, evidencing illicit employment of this substance. Moreover, about 25% of treated cheeses contained dehydroacetic acid, from 5 to 250 mg/kg, proving transfer of this substance from crust to cheese. After this investigation, alert messages were sent to the Rapid Alert System for Food and Feed of the European Commission (RASFF) and products were withdrawn from the market.

50. Role of OLIG2 expression in motor neurone progenitor cells in the differentiation of human-induced pluripotent stem cells to motor neurons for Botulinum neurotoxin potency testing

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Botulinum neurotoxins (BoNTs) are potent neurotoxins that are used as therapeutics. An ethically questionable mouse lethality assay is widely used to test BoNT activity. The aim of the project is to develop a cell-based toxicity assay to replace the animal experiment. To this end, induced human pluripotent stem cells (hiPSCs) need to be differentiated into motor neurons, the natural target of BoNTs.

OLIG2 plays a pivotal role in the dorsal–ventral patterning of the motor neurone progenitor cells during differentiation, as only cells expressing OLIG2 are able to differentiate to mature motor neurons. hiPSCs were cultured according to three different differentiation protocols using small molecules to direct cellular differentiation. OLIG2 expression was quantified at the progenitor cell stage to correlate the yield of motor neurons, BoNT receptor structures and BoNT targets to subsequently optimise the protocols.

OLIG2 and NKX6.1 expression in the progenitor cell stage correlated with the differentiation into adult motor neurons, which was verified by confirming the expression of motor neurone markers MNX1, ISL1 and CHAT by RT-qPCR and by immunocytochemistry.

BoNTs enter motor neurons by the interaction with receptor structures, namely SYTI/II, SV2A/B/C, and then cleaves SNARE proteins involved in neurotransmitter release, i.e. STX1A/B, VAMP1/2 and SNAP25. The expression of the motor neurone markers appears not to correlate with the expression of the receptor structures and SNARE proteins. This disparity in expression levels must be investigated while the differentiation protocols are further optimised. As the uptake of BoNTs also depends on gangliosides as co-receptors, their cell surface concentration must be determined and the expression studies must be complemented by functional assays for uptake of the different BoNT serotypes.

Funding

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51. Exposure to chemicals from food packaging materials: a total diet study approach

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Nowadays most foods are marketed as packaged and, as a result of the interaction between the packaging and the food, migration of packaging components can occur. Therefore packaging materials are a potential source of contamination and are subject to risk assessment.

The Total Diet Studies (TDS) are widely used to provide dietary exposure data to both beneficial substances and contaminants. The essential steps of a TDS are the following: should be representative of the whole diet; pooling of foods; and foods are analysed as consumed.

In the present work a methodology based on a TDS to evaluate the exposure to chemicals from food packaging materials was developed. The experimental design involves the following steps:

1. a non-target analysis was conducted to identify potential migrated substances, for that purpose gas chromatography-mass spectrometry (GC-MS) was applied;

2. pooling of foods according the consumer survey data;

3. the potential migrated substances previously identified in the packaging were determined in pooled foods;

4. the exposure was estimated by using migrated substance concentration data in food and consumption data.

The method was successfully applied to estimate the dietary exposure to chemicals from cereal-based food packed with plastic materials in the Spanish population. Different compounds such as acetyl tributyl citrate (ATBC), diethyl phthalate (DEP), diisobutyl phthalate (DIBP) and bis (2-ethylhexyl) adipate (DEHA) among others were identified in the packaging materials and the exposure to these contaminants were estimated by using the Spanish national dietary survey Enalia. So, the mean dietary exposure to DEP was 0.179 mg/kg bw/day for people aged 10–17 years and 0.332 mg/kg bw/day for people aged 3–9 years, or for example the mean dietary exposure to DEHA was 0.365 mg/kg bw/day for people aged 6–11 months and 0.104 mg/kg bw/day for people aged 1–3 years. This approach is a simple and useful screening tool for estimating dietary exposure to chemicals from the packaging.

Funding

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Key words: exposure assessment, TDS approach, packaging contaminants

52. Deoxynivalenol vs lactic acid bacteria: a biodegradation competition

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The mycotoxin deoxynivalenol (DON) is a secondary metabolite produced by the plant pathogen *Fusarium* spp. It causes serious problems in cereal crops, because of its toxicity in humans and livestock, and it is also responsible for huge economical losses. Biological methods that are specific for degradation, biotransformation and/or reduction of the mycotoxin content in grains, feed and food using microorganisms have gained growing interest over the last few years. In this context, lactic acid bacteria (LAB) represent a promising group and are indicated as 'Generally Recognised as Safe' (GRaS) by the Food and Drug Administration of the United States (USFDA) and by the EU Scientific Committee on Animal Nutrition (SCAN).

This study investigated the ability of two lactic acid bacteria (LAB) strains to remove DON. LAB strains, *L. plantarum* Z1 and *L. rhamnosus* 2411, isolated from various sources, were screened *in vitro*

to evaluate their capability to reduce mycotoxin concentrations (100 µg/ml). Two protocols were tested to better understand the mechanism of putative biodegradation. In the first protocol, bacteria cells were inoculated into medium containing mycotoxins and then incubated, while in the second, grown cultures were pelleted and separated from the growth medium before incubation with the mycotoxins. Positive (non-inoculated MRS with added DON) and negative (mycotoxin-free MRS broth) controls were always included in the experimental design. Samples were incubated at 37°C for 48 h. DON content before and after the fermentation process was monitored using an UHPLC-MS/MS method. The mycotoxin content decreased after the fermentation process, more particularly when the second protocol was applied. Therefore, this study may represent a starting point in selecting the most efficient LAB strains for detoxifying a particular mycotoxin and represents a useful tool to ensure greater safety in fermented foods. Furthermore, attention should also be paid to the method of toxin reduction. In fact, it has been shown that in DON reduction of the 12,13 epoxide group or oxidation of the hydroxyl group on carbon 3 by the microbial strains causes decreased toxicity. Nevertheless, the exact mechanism of toxin reduction warrants further investigation.

Key words: deoxynivalenol (DON), lactic acid bacteria (LAB), biodegradation, reduction ability

53. Multiple Fusarium mycotoxins in wheat-based products: occurrence and exposure assessment for the Romanian population

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A dietary exposure assessment to mycotoxins was conducted for the Romanian population using the contamination data of various wheat products for human consumption. Wheat-based foods (n = 181) commercialised in Romania, including flour, bread, biscuits, breakfast cereals and pasta, were analysed by gas chromatography-tandem mass spectrometry (GC-QqQ-MS/MS) for the presence of deoxynivalenol (DON), 3-acetyldeoxynivalenol (3AcDON), 15-acetyldeoxynivalenol (15AcDON), fusarenon-X, nivalenol, HT-2 toxin, T-2 toxin, diacetoxyscirpenol, neosolaniol and zearalenone (ZEA). Exposure of the Romanian adult population was assessed by combining national consumption data of wheat products (365 g kg^{-1} body weight day^{-1}) with the analytical results, supposing two scenarios: one underestimating (lower bound – LB) and another one overestimating (upper bound – UB) exposure. The estimated daily intake (EDI) values calculated were compared with the available tolerable daily intake (TDI) values established or proposed (EFSA, 2011; JECFA, 2001). The highest EDI values were observed for the sum of DON+3AcDON+15AcDON (669 ng kg^{-1} body weight day^{-1} at LB, and 689 ng kg^{-1} body weight day^{-1} at UB), being lower than the TDI set (1,000 ng kg^{-1} body weight day^{-1}). For ZEA, a maximum EDI of 26 ng kg^{-1} body weight day^{-1} was calculated, below the TDI set (200 ng kg^{-1} body weight day^{-1}). These results were obtained using data for a wide category of wheat-based foods and are part of the first study estimating exposure to mycotoxins of the Romanian population. Although all the exposures assessed were lower than the TDIs, the results indicated the need for more studies regarding risk assessment of mycotoxins.

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Key words: deoxynivalenol, EDI, mycotoxins, wheat products

54.Acrylamide in food: official control and dietary exposure assessment in Cyprus

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Acrylamide (AA) is present in a variety of foods consumed by children and, due to its possible harmful effects, the results of official monitoring for the period 2007–2016 were used for dietary exposure assessment of adolescents in Cyprus. The determination method is based on a single extraction step with water, followed by the clean-up of the extract using solid phase extraction columns and, finally, the determination of AA using ultrahigh performance liquid chromatography with tandem mass spectrometry. The method performance characteristics were determined after spiking blank samples. The mean recoveries in spiked coffee samples, potato chips, breakfast cereals and crispbread ranged from 93% to 99%, with relative standard deviations lower than 5% for both repeatability and reproducibility conditions. The estimated limits of detection and quantification of

the method were 10 and 32 µg kg^{-1}, respectively. The method was used for monitoring AA in 473 samples for the period 2007–2016. AA amounts ranged from <32 to 2,450 µg kg^{-1}. In total, 393 samples (83%) were contaminated with AA, but only 12% of the samples exceeded the indicative values of the EU legislation. Foods with the highest mean AA amounts were potato crisps (642 µg kg^{-1}), french fries (383 µg kg^{-1}) and biscuits (353 µg kg^{-1}).

Using the ImproRisk model, the mean and 95th percentile dietary intake values, based on mean AA concentrations, were 0.8 and 1.8 µg kg^{-1} bw per day, respectively. The estimated levels of dietary exposure to AA are not of concern with respect to neurotoxicity. However the margins of exposure (MOEs) indicate a concern for carcinogenicity. Potato fried products (45%), fine bakery ware (biscuits, rusks, crackers, pastries and cakes) (21%) and potato chips (14%) contributed the most to overall AA exposure.

55. Risk assessment of tetracycline residues in chicken meat, Yerevan, Armenia

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Objectives: There is an extensive use of antibiotics, especially tetracycline residues in poultry to prevent various diseases and to enhance animal growth. Inappropriate use may result in the presence of antibiotic residues in poultry meat at unsafe concentrations that can adversely affect public health. The aim of the current study was to evaluate the risk of tetracycline residue intake through local and imported poultry meat consumption among the Yerevan population.

Methods: The concentration of tetracycline residues was determined using enzyme-linked immunosorbent assay analysis. Poultry consumption amount was determined based on a food frequency questionnaire conducted in Yerevan.

Results: The average concentration of tetracycline in local and imported poultry meat was determined to be very negligible and 0.01 mg/kg, respectively. The latter is slightly greater than the maximum allowable level set by the customs union.

Conclusions: Daily exposure to tetracycline through poultry meat using average daily chicken consumption was estimated to be 0.001 mg/kg bw/day. Risk characterisation of dietary exposure to tetracycline residues via imported poultry intake among Yerevan population showed that, according to the standard dietary recommendation of poultry (200 grams per day), consumers can receive approximately 7% of acceptable daily intake. Taking into consideration that imported poultry constitutes the largest part in the consumer's diet and that tetracycline residues can also be present in other food types such as fruits, vegetables, dairy products, there is a health risk that the estimated daily intake of this drug can exceed the defined ADI level.

56. Risk assessment of trace elements in fruits and vegetables of Kapan, Armenia

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Food is a major source of toxic trace element intake for people, so contamination of food by trace elements is a global issue. Fruits and vegetables, in particular, constitute a fundamental part of a balanced diet. They are consumed all over the world, and particularly in Armenia, where the consumption of fruits and vegetables is approximately five times higher than the WHO/FAO recommended amount. Hence, the estimation of dietary intakes of trace elements through fruit and vegetable consumption is of particular importance in Armenia for observing the underlying health risks to local people. This study was carried out for assessing the dietary exposure of toxic trace elements via the intake of fruits and vegetables sold in markets of Kapan, a town located in the largest mining region of Armenia. For studying the consumption patterns of fruits and vegetables among the local population, a food frequency questionnaire (FFQ) was developed and utilised to carry out surveys. The concentrations of Pb, As, Cd, Hg, Ni, Cr, Mo, Cu and Zn in different types of fruits and vegetables were determined. Moreover, by combining concentration data with consumption data, the estimated daily intake (EDI) and target hazard quotient (THQ) were calculated for *a priori* specified trace elements. Eventually, the obtained values were compared with health-based guidance values. The obtained results indicated that although the estimated daily intakes of trace elements for each studied fruits and vegetables did not exceed health-based guideline values, for the combined consumption of these food items estimated cumulative daily intakes exceeded reference doses for Cu and Mo.

57. A tool to integrate scientific risk assessment principles into the management and prioritisation of chemical contaminants in raw materials

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We have developed a new globally applicable scientific tool for the assessment and prioritisation of chemical hazards in food raw materials. The tool is based on the four principles of risk assessment, considering overall exposure to chemical contaminants. From these calculations, and the application of a decision tree, the tool provides the user with a level of risk (or 'likelihood to cause harm'). For each individual contaminant, a severity grade was set according to the use of an additional decision tree based on toxicological characteristics of the chemical (e.g. carcinogenicity, reprotoxicity or developmental toxicity). Both decision trees imply scientific, objective and transparent selection criteria. Taken together, severity and risk are positioned in a matrix informing on the prioritisation level of each combination of chemical hazard and raw material. The proposed model is intended to be adequately protective for the consumer's health, as it considers a conservative food intake scenario, as well as various sources of contaminant exposure. The model's design is flexible and can easily be adapted to the needs of different food product categories and scenarios. The model was tested using several examples, the results of which are consistent with existing data in the literature.

58. Acute reference dose setting for agrochemicals in Europe: a retrospective analysis

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The acute reference dose (ARfD) is designed to protect consumers from adverse effects following acute (24 hour) oral exposure to pesticide residues. While it is entirely appropriate to set an ARfD for acutely toxic molecules (such as neurotoxic insecticides), ARfDs are increasingly set for chemicals of low acute toxicity. Numerous study endpoints are used, of which many appear not appropriate against the protection goal. The purpose of this analysis was to review the basis on which ARfDs were set to better understand if these were necessary and relevant. A 130 ARfDs set of agrochemicals was analysed for the study type used and effects driving the point of departure. 26 were based on acute (neuro-)toxicity studies and the majority was deemed appropriately set. Developmental toxicity studies were used extensively (70 of 130 ARfDs; with rabbit used twice as often as rat). While rat developmental toxicity studies were mostly appropriately interpreted, 85% of the ARfDs based on rabbit studies appear questionable or irrelevant to acute effects. Similar ratios between appropriate and questionable/irrelevant were identified in ARfDs based on rat repeated dose studies (3 of 8) and generational studies (3 of 10). Dog repeated dose studies appeared to provide a clearer basis with about 50% of the ARfDs set based on appropriate effects (8 of 16). In conclusion, ARfDs are set most appropriately when the effects are truly acute in nature (acute toxicity, acute clinical signs in dogs). ARfDs derived from repeated dose, rat developmental toxicity or generational studies are often set conservatively and it appears questionable if assignment of an ARfD was necessary, in particular if the LD50 was high. A high rate of inappropriate ARfDs are set based on rabbit developmental toxicity studies, indicating that the rabbit as a test system may not be well understood for this purpose.

59. Adapting to the 2018 Novel Foods Regulation: risk profiling the rearing of house crickets, Acheta domesticus

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Novel foods represent a sustainable alternative to traditional farming and conventional food. Hence, the interest for their scientific risk assessment as safe

for human consumption. Starting 2018, Regulation (EU) 2015/2283 entered into force, regulating novel foods in Europe. It lays down the requirements enabling FBOs to bring innovative foods to the EU market, while ensuring high levels of food safety for European consumers. The risk profile assessed the hazards for one of the most promising novel foods, *Acheta domesticus* crickets. The food model envisaged a closed-circle *Acheta domesticus* crickets rearing system, under HACCP and good farming practices, differentiating itself from outdoor cricket farms. The methodology used involved scouting the literature and identifying possible hazards, followed by adding relevant inclusion criteria for the food model. These criteria engaged animal health and food safety aspects, for the entire lifespan of crickets, complying with the 'from farm-to-fork' One Health principle. When data were scarce, comparative evidence from close relatives of the *Ortheoptera* genus, like grasshoppers and locusts, was added. Significant data gaps in animal health and food safety were identified. Even if HACCP-type systems exist, the risk profile identified the following considerable risks: (1) high total aerobic bacterial counts; (2) survival of spore-forming bacteria post-thermal processing; (3) allergenicity of insects and insect-derived products; and (4) the bioaccumulation of heavy metals (e.g. cadmium). Other hazards like parasites, fungi, viruses, prions, antimicrobial resistance and toxins were risk-ranked low to medium. For some hazards, an acute need for additional research was identified (especially chemical contaminants). To our knowledge, the present risk profile is the first assessing the rearing of *Acheta domesticus* as novel foods and presents an example for risk profiling other novel food insects.

60. Summary results from Bulgaria for food-contact materials obtained from the official control

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Food-contact materials are all materials and articles intended to come into contact with food, such as packaging, containers, kitchen equipment, cutlery and dishes, bottles. Also included are those used in processing equipment – coffee makers or production machinery as well as containers used in transport, materials that can reasonably be expected to transfer their constituents to food such as a cardboard box around a plastic bag of cereals etc.

The packaging that we use in our daily lives plays an important role in the quality of food as it provides food with permanent protection from their surroundings, as well as from chemical and physical contaminants.

In the production of food packaging and food-contact materials only materials and objects shall be used that are not released into food ingredients during storage and used in quantities that present a danger to human health, and also do not change its appearance, smell, taste and composition.

The European legislation on materials and articles intended to come into contact with food includes harmonised rules in this area to protect consumers' health and the removal of technical barriers to free trade within the European Union. Manufacturers and retailers of food-contact materials and articles must comply with the requirements of traceability as defined in the Framework Regulation (EC) No. 1935/2004.

The policy of the Republic of Bulgaria is synchronised with that of the European Union with respect to food safety and is regulated by laws that aim to establish the food requirements obligations of producers, processors and traders of food and packaging.

The purpose of the present work is to draw trends from the data obtained from the official control of materials and articles coming into contact with food in the territory of Bulgaria, such as bisphenol A, phthalates, etc.

Key words: food-contact materials, official control, Bulgaria

61. Wines from Fruška Gora region of Serbia – what about ochratoxin A?

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The region of Fruška Gora in the northern part of the Republic of Serbia is well known for its winemaking tradition, dating from the third century, when Roman emperor Probus planted the first vines and initiated viticulture in this region. The link between the diet and wine consumption is strengthened both by pleasure and the health benefits of wine, related mostly to cardiovascular and neurodegenerative diseases. However, wine is also recognised as one of the main contributors to the dietary intake of ochratoxin A, widely known mycotoxin with carcinogenic, nephrotoxic, teratogenic and immunotoxic effects that could be produced on grapes and transferred into wines.

To evaluate the presence of ochratoxin A in wines from Fruška Gora, 91 bottled wines, produced in 24 wineries over 2009–2015, were analysed using immunoaffinity columns for sample clean-up before quantification of the toxin by high performance liquid chromatography with fluorescence detection.

Quantifiable amounts of ochratoxin A (above 0.01 ng/ml) were found in 52% of the samples, and roughly the same incidence was selected when samples were grouped according to the colour of wine (red, rose or white). Overall mean level of ochratoxin A was 0.021 ng/ml, namely 0.024, 0.028 and 0.017 ng/ml, in red, rose and white wines, respectively, without statistically significant difference between red and white wines. Maximum concentration of ochratoxin

A (0.153 ng/ml) was found in a rose wine, however, it was far below the allowed level of 2 ng/ml.

It could be concluded that levels of ochratoxin A in wines from the Fruška Gora region do not pose a risk for human health, and this finding should promote their recognition and social popularity.

62. Cyanotoxin-rich irrigation water causes extensive toxin bioaccumulation in spinach indicating considerable health risk

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Cyanotoxin-rich irrigation water was applied by spraying and root irrigation on spinach (*Spinacia oleracea* L.) and the effect on growth and toxin loading in the edible tissues, subsequently health risk, was investigated. The degraded water was collected from the Karla Lake, Central Greece, which is characterised by eutrophic conditions and increased microcystin – an hepatotoxic cyanotoxin – concentration. The plants were divided into four groups, i.e. two of these receiving Karla's water to the root (KR) or by spraying (KS) and the corresponding controls receiving tap water (TR and TS). The experimental period lasted for three months, covering the whole growth period from the seed to the final harvest at marketable size. The MCs were analysed with enzyme-linked immunosorbent assay (ELISA) and detected on all the samples that received Karla's water (roots, leaves and soil), while no toxin were recorded to TR and TS. Significantly high concentrations of bacteria attached on leaf surface were measured by SEM in the two Karla treatments, ranging from two to six times over corresponding control plants. KS had more than 12.5 million bacteria per square centimetre of leaf surface, while control plants hardly reached 3 million bacteria. For toxin accumulation in edible tissues, KS leaves exhibited a significant toxin load, which was not considerably decreased after extensive washing of the leaves. Toxin bioaccumulation in KS leaves showed a 66% increase compared with KR. In contrast, the KR roots absorbed more microcystins from the soil, so depleting its toxin content, while the KS roots accumulated less microcystins, leaving the soil with a higher toxin content compared with KR. On human health risk, the estimated daily intake values of both leaves from Karla treatments exceeded the tolerable daily intake limit (set by WHO) by a factor of 83 (KS) and 50 (KR). Our results indicate that irrigation of spinach with microcystins-rich water constitutes a serious public health risk. Subsequently, irrigation water quality monitoring is considered indispensable and the relevant legislation urgent.

63. Comparison of two methods for dietary exposure assessment to pesticide residues

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To perform consumer intake assessments of pesticide residues in food, EFSA and other organisations use data on residue levels in food and consumption data from dietary surveys. It is sometimes questioned if this method reflects the actual exposure, or if it over- or underestimates the intakes. In this project, the exposure of pesticide residues was estimated using two different methods, firstly based on data on the mean residue levels in food from the Swedish monitoring programme in 2008–2012 and mean consumption data for 197 women aged 50–60 years from a dietary survey, and secondly based on mean levels of metabolites of pesticides in urine from a group of 128 women in the same age, converted to an estimated intake. The pesticides included in the study were 2,4-D, chlormequate, mepiquate, chlorpyrifos and the groups dithiocarbamates and pyrethroids. None of the estimated intakes exceeded the respective ADI of the substances (0.01–18% of the ADI). It was shown that for chlormequat and the sum of pyrethroids, the estimated intakes were similar. However, for 2,4-D and dithiocarbamates the estimated intakes based on residue and consumption data were higher than when based on biomonitoring data, whereas the estimated intakes of mepiquat and chlorpyrifos were higher when based on levels of metabolites in urine. Possible explanations for these deviations are discussed. The study shows that both methods can be used to estimate the intake of pesticide residues, but they both have strengths and weaknesses. Based on the estimated intakes among this subpopulation which has a relatively high consumption of fruits and vegetables that contribute much to the exposure of pesticide residues, there is no concern for adverse health effects.

64.TKPlate: an open-source web platform for toxicokinetic models in food safety

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TKPlate is a web platform for running and working with results of toxicokinetic (TK) models. Its defining feature is a 'workflow model', connecting any number of generic models and data sources. This software is written in R and is open-source, with the web interface programmed in Shiny.

Such workflow contains models or rules for dealing with available and missing inputs, e.g. performing *in vitro* extrapolation automatically if *in vivo* data are not available. Multiple models can then be linked

together, e.g. TK-TD models or Dynamic Energy Budget (DEB) models.

Pre-sets and default values are available for all parameters. Inputs are not 'hard-coded' in the platform and can be stored in an up-to-date relational database.

Monte Carlo method is used to propagate variability/uncertainty from all inputs through all linked models. Platform can work with a single mean (no variability) or with multiple populations (e.g. poor and extensive metabolisers). Populations can be defined in terms of customisable distributions on chosen parameters (e.g. clearance) and pre-sets are available.

An automated report is generated in Word or PDF, summarising the models applied, input values, TK parameters, generic plots. Full numerical outputs can also be exported. Experimental data can be used for validation of the models and displayed alongside the outputs.

Currently, the models implemented in TK plate have been developed for humans and rats in the context of exposure to single compounds and binary mixtures. These models are based on extension of functions and compound-specific data from the US-EPA 'httk' R package. Default mean and variability values for physiological and TK parameters are based on our meta-analyses of the literature. Performance of the current version of the tool has been demonstrated in case studies modelling single compounds and binary mixtures.

Staying relevant in a changing world

65. Risk–benefit assessment in foods: a tool for a better food and health policy in Europe

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Risk–benefit assessment in foods: a tool for a better food and health policy in Europe

RiskBenefit4EU – Partnering to strengthen the risk–benefit assessment within EU using a holistic approach, is a recent European pilot project funded by EFSA and coordinated by Portugal (PT), integrating a multidisciplinary team from health and food institutes, national food safety authorities, R&D institutions and academia from PT, Denmark (DK) and France (FR). The main objectives of RiskBenefit4EU concerns the development of a set of Risk–Benefit Assessment (RBA) tools to assess and integrate food risks and benefits in the areas of microbiological, nutritional and chemical components through the development of a harmonised framework. This pilot project will validate the RBA framework created using a Portuguese case study on cereal-based foods. The research idea for food safety risk assessment is to create an international network on RBA to promote and disseminate the outputs and knowledge acquired under RiskBenefir4EU, at European level. This network aims to promote knowledge and capacity building on RBA (acquired under RiskBenefit4EU) among European early stage researchers and to apply the harmonised framework on their countries. Health risks associated with consumption of cereal-based foods, an important source of nutrients with beneficial health effects, could increase soon due to climate changes in Europe (dry conditions and increased ambient temperatures could promote an increase in toxins production; occurrence of emergent compounds) so the dissemination and use of the RBA harmonised tools related with ingestion of cereal-based foods and derivatives could contribute to support future food and health policy in Europe.

66. Food risk–benefit assessment: 'methodological development based on an infant milk diet case study

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Food risk–benefit assessment (RBA) aims to scientifically assess human health risks and benefits associated with food consumption in the same integrative methodology, regardless of the field of research; including microbiology, chemistry and/or nutrition. Although these three components are often present simultaneously on consumers plates and in their diets, up until the last decade they have been traditionally studied independently. Since the beginning of the 21st century, RBA has emerged resulting from activities and development under EFSA guidance, European projects (Brafo, Qalibra, Bepraribean…) and in particular RBA case studies.

The objective of the present work was to propose a method to perform a three-disciplinary RBA, including microbiological, chemical and nutritional dimensions. This work was performed as part of a PhD project focusing on the infant milk-based diet (breast milk and infant formulas), taking into account a selection of risk or beneficial factors;

namely *Cronobacter sakazakii*, *Cryptosporidium*, arsenic, dioxin-like polychlorinated biphenyls and docosahexaenoic acid.

An updated RBA framework was then suggested, based on current trends and lessons learned from the particular case study. In addition, four research questions were investigated: (i) how to carry out a multidisciplinary RBA considering microbiological, chemical and nutritional aspects, is it possible to set a generic framework? (ii) How to compare health impacts, is it possible to use a common metric? (iii) How to consider variability and uncertainty in RBA? and (iv) How to communicate and interpret RBA results? In the present communication, the developed framework will be presented as well as the main conclusions related to each question.

RBA currently appears to be an essential tool to provide comprehensive recommendations in terms of the food and human health nexus. It is also a complex and multidisciplinary approach which has to face challenges from conventional risk assessment but also challenges to aggregate, interpret and communicate all RBA results together to provide an overall health impact.

67. Safety assessment of nano-fertilisers: time to take action?

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Fertilisers are chemical compounds intended to enrich agricultural soils and provide nutrients to plants. So-called EC fertilisers are regulated by Regulation EC 2003/2003 on mineral fertilisers and may circulate freely within the EU market. The rules for other fertilisers (national fertilisers) are currently not harmonised at EU level and are governed by national laws, although mutual recognition applies.

In March 2016 the Commission put forwards a legislative proposal on fertilising products, with two main objectives: (1) sustainable fertiliser production from domestic sources, transforming waste into nutrients for crops; and (2) harmonised cadmium limits for phosphate fertilisers. However, a consistent assessment framework on fertilisers is still unavailable. Some EFSA opinions on contaminants (e.g. nitrates, perchlorate) considered also the presence in fertilisers. The DG SANTE Scientific Committee on Health and Environmental Risks (SCHER) has provided scientific advice on specific fertilisers issues (presence of cadmium, use of calcium cyanamide), but paid limited attention to the potential human exposure via the soil-food chain.

Nano-agrochemicals are an important application area of nanotechnologies in the agri-food sector with nano-fertilisers featuring among the key innovative products. The extensive body of evidence on the fate and effects of nanoparticles in (edible) plants raises potential concerns in relation to:

food safety (deposition of particles in plant tissues and soil-forage-animal carry-over)

plant health (phytotoxicity)

environmental impact (build-up in soil and adverse effects on soil organisms).

Nanomaterials may pose hazards and risks that are considerably different from conventional chemicals: the new conceptual framework of nano safety assessment should support a robust scientific approach to nano-fertilisers. Nano-fertilisers may lead to considerable agricultural benefits (e.g. enhanced nutrient bioavailability), but also to potential risks. However, these issues are currently not addressed in the Guidance on Nano Risk Assessment under development.

68. Environmental impact assessment of the food supply chain at various geographical levels

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Food production and processing have a high impact on the environment and there is much concern about environmental pollution and demand for resources in intensive farming systems. Food-related emissions account for 31% of the total greenhouse gas emissions of the European Union. This is expected to get worse as the world population is constantly growing and it is estimated to reach around 9 billion people by the middle of this century, with Europe increasing its population by around 4%. In addition, a shift from a vegetable-based to a more meat-based diet has been observed, particularly in developing countries in the last years.

The patterns of food consumption of the populations are clearly the main driver of the food supply chain. This project is aimed at assessing the environmental footprint (carbon, water and ecological) of the food consumed in the European Union at a different level of resolution (region, country, EU), taking into account the food supply chain. Impact analysis focuses mainly on greenhouse gas emissions, water consumption and land use. Data from the EFSA Comprehensive European Food Consumption Database are used for this assessment and statistical analyses are carried out to identify the role of possible drivers (e.g. age, gender and country) of food consumption. A more in-depth analysis using a spatial scale model based on data from the Po Valley (Italy) is presented for the livestock sector, which is responsible for 14.5% of total annual anthropogenic emissions world-wide'.

69. Risks and benefits associated with sharing of food

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Reduction in food losses is of high priority in making agro-food systems more sustainable. In Germany and other industrialised countries, losses in private and institutional households account for a major part of total losses. There is rising concern among consumers about these losses. Current information and communication technologies facilitate the sharing of foods between private households, and internet platforms such as 'Foodsharing.de' were established. Moreover, 'foodsharing fridges' for use by consumers to deposit and withdraw food have been set up in some (mainly urban) locations. Based mainly on experiences from Germany, we analysed the risks and benefits associated with food sharing. We found the initiatives to reduce food losses by sharing food to be a useful tool in raising the appreciation of food and promoting knowledge and skills related to food handling and food storage. Conversely, certain hazards that are not noticed through spoilage symptoms may be introduced by the donator of foods, as a consequence of possible poor handling and storage. In particular, food sharing fridges must be operated in a responsible manner, as the responsible individuals may be considered as 'food business operators' in the legal sense, and traceability of the food becomes an issue. However, we found it possible to set up and implement simple, plausible rules for users of food sharing platforms and fridges. We also propose an approach to be taken by food inspectors in assessing the safety of operation of food sharing fridges in a risk-based way. So, a sound compromise appears to be feasible to maintain the benefits of food sharing systems while keeping food safety risks at a minimum.

70. Climate change and emerging risks for food safety

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According to the General Food Law, the European Food Safety Authority (EFSA) is required to identify emerging risks in the fields within its mission. EFSA has developed a methodological framework for identification of emerging risk, starting from a preliminary identification of priority emerging issues through knowledge networking activities. The long-term anticipation of emerging risks includes the identification of drivers. Drivers are the underlying natural or human-induced factors that directly or indirectly cause emerging risks. Climate change is recognised as a critical driver and its impact on the occurrence and toxicity of toxin producing phytoplankton, bacteria and pathogenic viruses and on other food safety domains was demonstrated.

With the aim of further exploring tools to identify and prioritise emerging risks, EFSA initiated a project focusing on climate change as a driver of emerging risks for food and feed safety, including plant and animal health.

A knowledge discussion group involving the major institutions involved with climate change has been created. The group will define criteria to identify relevant subdrivers (e.g. rising and more fluctuating temperatures, changing precipitation patterns, increase in natural disasters etc.), the issues relevant to different food safety domains including plant health and animal health, and to develop a harmonised and transparent scoring system applicable to the identified emerging issues to prioritise future research and risk assessment activities.

71. SEAFOODTOMORROW: nutritious, safe and sustainable seafood for consumers of tomorrow

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Introduction: SEAFOODTOMORROW is an H2020 European-funded innovation action led by IPMA that started on the 1 November 2017 and will end on 31 October 2020. This project's large consortium is composed of institutions from 15 European countries, with 19 interdisciplinary research teams, four Interest Association Groups and 13 Small and Medium Enterprise.

Objectives: The project aims to optimise and validate eco-innovative sustainable solutions to improve the socioeconomic and environmental sustainability of seafood production and processing sectors, while preserving seafood quality and safety and promoting seafood consumption in a healthy diet.

Methodology: SEAFOODTOMORROW activities include, among others: (a) utilisation of sustainable agro-food byproducts to develop more sustainable and adequate feeds for aquaculture; (b) design of seafood products targeted to different population segments (elderly, pregnant women and youth); (c) reduction of salt (sodium) in processed seafood; (d) validation of strategies to reduce contaminant levels in seafood; (e) optimisation of sensors and biosensors as rapid screening tools for the assessment of seafood safety; (f) validation of environmentally sustainable and more effective seafood processing methodologies; g) optimisation of seafood production in multitrophic aquaculture; (h) implementation of digital traceability systems with labelling systems that provide consumers and the food industry with real-time information about products quality; (i) improvement of an online information tool for consumers that balances the benefits and risks associated with their seafood

intake; and (j) establish a baseline for seafood quality certification schemes in Europe.

This project is organised in five innovation Work Packages (WPs), each addressing specific objectives and three WPs focused on communication, dissemination and exploitation, management and coordination and ethics.

To secure a successful outcome and achieve the highest return of public investment, the SEAFOODTOMORROW consortium covers a wide geographic area across Europe, including the most relevant seafood producers, processors and countries consuming seafood products.

Website address: http://www.seafoodtomorrow.eu/

72. Risk–benefit assessment of foods: key findings from an international workshop

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While protection of public health and the environment from untoward risks is a key goal of regulation, risk management options, including food policy ones, may be associated with a corresponding reduction in benefit, direct or indirect. Policy decisions require consideration of the necessary trade-offs, and hence there is an increasing need to apply formal risk–benefit assessment (RBA) of foods. In this context, the European Food Safety Authority sponsored a Risk–Benefit Assessment Workshop on 'past, current and future developments within the risk–benefit assessment of foods (RBA)' held in May 2017. The overall aims of the RBA Workshop were to discuss existing methods, challenges and needs within RBA, and to draft a roadmap for future development of RBA. The specific objectives were to: (i) identify RBA activities in Europe and globally; (ii) discuss how to further develop and optimise RBA methodology; (iii) identify challenges and opportunities within RBA; and (iv) increase collaboration internationally. The two-day workshop gathered 28 participants from 16 institutions in 11 countries. It included technical presentations of RBA methods and case studies, and two break-out sessions for group discussions. All participants agreed that RBA has substantial potential to inform risk management decisions in the areas of food safety, nutrition and public health. Several activities to optimise further developments within RBA were suggested. We present a summary of workshop presentations, a discussion of challenges that limit progress in this area, and suggestions of next steps for this promising approach supporting a science-based decision process in the area of risk–benefit management of foods.

73. Is EFSA addressing environmental risk related to food production?

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Independent researcher

Christoph Eugen – Independent researcher

A case is here made on the role that the General Food Law (GFL) legal framework and EFSA could play in addressing the risk related to the impact that food production is causing on the environment including biodiversity loss, habitat degradation and destruction, climate change, ecosystem services disruption, pollution and waste of resources.

The recent REFIT (EC 2015) audit of the GFL found that "although no systemic failure was detected, the General Food Law might be inadequate to address food sustainability…". Currently no action on this fundamental aspect is included in the EC new proposal for amendment of the GFL launched in 2018. The author propose that the GFL and EFSA could take a wider responsibility over food sustainability by fully acknowledging the scientific evidence on the environmental impacts of the current food production system and consumption patterns, and applying an ecosystem-based approach to environmental risk assessment. The GFL framework could recognise the fundamental transformation that needs to be applied to the food production system to achieve sustainability while EFSA could take a leading role in assessing and communicating all the risks related to industrial agriculture practices, run holistic cost/benefits analysis, establish appropriated targets and indicators, identify and communicate available alternatives, and provide independent information and advice to be passed on to farmers, consumers, food industry representatives, retailers and all stakeholders involved in the food chain. This work would be in line with the mentioned international and European efforts towards environmental sustainability. It would also support the objectives of the Directive on Sustainable Use of Pesticides that, despite its good intentions, seems ineffective so far, while pesticides sales in the EU have even increased since its adoption. Viable alternatives to intensive industrial agriculture based on the ecology of diversified agricultural systems and natural ecosystem services and, where appropriate, mutual funds, are available and should be better supported and developed through measures that could allow the shift from an unsustainable industrial agriculture infrastructure and paradigm to sustainable agroecology. The next EFSA Strategy could be drafted on the basis of a vision on what needs to be done to achieve a desirable and sustainable future built around food sustainability, to continue ensuring safe food to EU citizens and in support of international and European efforts such as the UN Sustainable Development Goals, the EU Biodiversity

Strategy and the 7th Environment Action Program. According to the strategic objective "Create an environment and culture that reflects EFSA's values", EFSA could actively engage into raising awareness among staff and experts over the impacts that current food production and consumption patterns, and related individual choices, have on the environment, and use food sustainability guidelines as a code of cinduct when organizing events and outsourcing catering services. Evolving towards the establishment of a European Food Sustainability Authority and challenging the current major crisis, not only on the basis of societal expectations and values, but on the solid and extensive available scientific evidence, is what could be truly called "contextualising risk assessment", "advancing risk assessment science" and "staying relevant in a changing world", the themes of this year conference.

74. Protecting the EU plant health: assessing the risk of plant pests under global change

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With global change the risk of biological invasions of new exotic plant pests into Europe has dramatically increased, threatening agriculture production, forestry, biodiversity and the environment. EFSA activities in plant health risk assessment include continuous support for the new EU plant health law (pest categorisation, pest risk assessment, commodity risk assessment and impact assessment for prioritisation of risk mitigation measures) as well as crisis preparedness, such as horizon scanning for identification of new plant health threats and the development of risk-based surveillance guidelines. For new plant pests, scientific advice to risk managers is provided on risk and risk mitigation measures, whereas the analysis of uncertainties helps to identify key knowledge gaps and research priorities. The principal flows of activities of EFSA in plant health are presented, including the interactions with risk managers, researchers and stakeholders.

75. Opportunities to integrate biological and chemical hazard prevention in a disruptive food landscape

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Jovana Kovacevic – Oregon State University

Across the world, the way in which food is grown, transported and consumed is rapidly changing. Many consumers, particularly from developed and emerging countries, are increasingly seeking foods that are grown locally with minimal ingredients or those that contain only natural constituents. Others are seeking exploring alternatives to traditional foods, such as plant-based meat and convenience in how food is delivered. While this disruptive landscape has numerous benefits, it can also present challenges in food safety for both chemical and biological hazards. Here we explore how these trend shifts pose a dilemma challenge for toxicologists and microbiologists that are tasked with risk assessment, management and communication. In particular, we examine a separate approach to assessment. In the United States (USA), the risks posted by chemicals in the diet and pathogens in food are typically assessed separately. This divide is further exacerbated by unaligned training and workshops that focus on either chemical safety, such as pesticide applicator training, or prevention of biological hazards, such as USDA GAP, GlobalGAP and produce grower training. The recent Food Safety Modernisation Act (FSMA) provides an opportunity to harmonise these fields through better integration of biological and chemical hazard prevention and mitigation approaches. While FSMA is a good platform to coordinate efforts from a regulatory perspective, it is insufficient to maintain relevancy in a fast-moving society. As entrepreneurs and companies continue to innovate, it is critical that food safety scientists engage with stakeholders across agricultural, commercial and public sectors. This includes industry food scientists, marketers, culinary professionals, nutritionists, packaging engineers, consumer groups and many others who are at the forefront of food development. Working towards integration will improve our ability This diverse group will help to guide scientists to prioritise hazards, estimate exposure, identify data gaps and manage risks posed by changing dietary trends.

76. EFSA's Emerging Risk Identification process

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According to the European Food Safety Authority's (EFSA) Founding Regulation EFSA is required to establish procedures for the screening and analysis of information with a view of identifying emerging risks in the fields within its mission.

Identification of emerging risks prepares for future risk assessment needs on new food supply chains and technological developments. The definition of an emerging risk encompasses the context of novelty, a new hazard or a known hazards emerging in new conditions. The challenges for identification arise from the uncertainty, lack of data and the

difficulty to quantify the risk. The European Food Safety Authority has developed a process for the identification of emerging risks in food and feed that relies on networks of knowledge with multidisciplinary expertise.

Between 2010 and 2017 the Emerging Risks Exchange Network (EREN) (collaboration with Member States) and the Stakeholder Discussion Group on Emerging Risk (StaDG-ER) (collaboration with civil society and private sector) assessed more than 120 potential emerging issues. The issues discussed were mainly microbiological and chemical hazards, but also food safety issues such as those resulting from unlawful activity, new consumption trends, biotoxins, new technologies and processes, allergens, animal health, environmental pollution, new analytical methods, new food packaging technology and unknown hazards. Based on the available evidence, the networks recommended whether an issue merited follow-up actions, such as generation of new data, a full risk assessment and/or consultation with other bodies.

Further efforts are needed to create a common mechanism to share experiences across Europe on the different methodologies applied, as well as to pool the intelligence gathered. EFSA has initiated the development of a data management system to facilitate access, review and analysis of identified issues and a collaboration system for knowledge sharing between networks of expertise.

Envisioning the expertise of the future

77. Strategic programme for promoting university engagement with food risk assessment science

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Risk assessment science should be built from integrative approaches that should be synergic and convergent to face complex global food safety issues. Nowadays, one essential task is to transfer to the civil society the relevance of risk assessment science, especially in food and feed and its impact in health and nutrition. It is mandatory to put in value the work already performed over decades, problems faced, achievements and future needs and challenges.

The Universities have a strategic position to send an impacting message with a wide scope within the students that will become a key part of the future society. The main objective is to draft a complementary formative plan for potential future food risk assessors, regulatory scientist and other figures that could facilitate fruitful and successful communication and discussions with e.g. policy makers, industry and healthcare systems.

The strategy to execute the objective will be performed through the insertion of specific designed training programmes at different docent levels: bachelor degrees, masters and doctorate. Moreover, a search will be performed to find other international universities or research institutes engaged with similar objectives. It is also essential to identify the right competence and skills to be acquired related to the specific formation plans: e.g. Specific food regulations, database collection management, omics and bioinformatic tools and negotiation and communication skills. The programme should be presented to the suitable University entities to be approved. A pilot plan will be presented at the faculty of Pharmacy, Human Nutrition and Food Science at the University of Granada.

78. The Italian cooperation with EFSA: strategies and actions

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Camilla Marchiafava – Istituto Superior di Sanità

Working together and exchanging knowledge between food safety experts ensures excellence and efficiency and maximises Europe's risk assessment capacity and potential is the European Food Safety Authority (EFSA) strategy and the commitment of the Italian Food Safety Authority, the Direzione Generale degli Organi Collegiali per la Tutela della Salute (DGOCTS) of the Ministry of Health.

The DGOCTS and National EFSA Focal Point in 2013 developed a strategy for the improvement of the national risk assessment capacity, mainly through the promotion of the cooperation with EFSA. The target was the national competent organisations network (Article 36 organisations). From 2013, the quality and the number of competent organisations increased constantly. These achievements were also reflected in the increase of the number and success rate of the applications to EFSA calls. In addition, two Italian researchers and one national competent organisation are involved in the EU-FORA programme.

The actions were implemented according to two principles: assessment of the capacities of the competent organisations and promotion of the national and EFSA cooperation strategy.

A formal assessment process of the organisations was established, to ensure the accomplishment of the criteria according to the EU regulations and the scientific and technical capacities of the organisations.

A communication-based programme of workshops and trainings was developed and delivered in several rounds in different places, involving all the competent organisations and also research institutes outside the Article 36 network, to promote

contacts and networking. Moreover, a regular contact by email and telephone with the researchers of the competent organisations was maintained, to ensure a constant update of the organisation profile, and to inform them about cooperation opportunities, national initiatives and trainings.

This national strategy, allows the DGOCTS to maintain operational a network of excellence institutions that are competent in risk assessments for the national authority.

79. Risk Assessment Methodologies Programme (RAM-Pro)

ERYASA Berrak
EFSA

Background: EFSA has set its strategic objectives to drive efforts for the next five years (2016–2020) to steer the organisation to the future in its Strategy 2020 plan. Specifically, the strategic objective 4 (SO4) is about EFSA being prepared for future risk assessment challenges. In this five-year implementation plan, a large number of EFSA's scientific development projects was identified and included in the Risk Assessment Methodologies Programme (RAM-Pro) to achieve EFSA's strategy in relation to development of new RA methodologies and their harmonised use.

Objective: to identify, coordinate and monitor all projects dealing with risk assessment cross-cutting methodologies development, and aligned to ensure EFSA is prepared for present and future challenges in a dynamic food safety system.

Method(s): RAM-Pro coordinates 40 EFSA scientific projects dealing with cross-cutting RA methodologies in three thematic areas: Chemicals RA for human health, Environmental RA with a focus on chemicals and Harmonisation of RA methodologies. Continuous cooperation and facilitating communication among projects, mainly by three multiproject Steering Committee meetings (mPSC) separately for each cluster allow project managers to exchange information on their ongoing projects.

Expected Results: RAM-Pro plays a major role in identifying and prioritising projects, by fostering a collective approach, cooperation and communication between EFSA Units. The programme helps to identify, at an early stage, gaps and synergies between projects together with expected benefits, risks and lessons learned. In addition, the main outcome of RAM-Pro is promoting accessibility and the use of EFSA methods/tools inside and outside, endorsing trust in EFSA's work and stakeholder satisfaction.

Conclusion: All projects in the RAM-Pro contributing to the development of cross-cutting methodologies in risk assessment are coordinated in an efficient manner that allows harmonisation of the best practices to keep EFSA up to date in facing challenges in European food safety.

80. Next Generation Chef: foods 4 sharing

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The Next Generation Chef survey (2015) and the lesson 'Perspectives in food sustainability' (2016) have enabled us to draw up an additional document – called MAGNA CARTA (published in 2017) – that let people believe, observe, be aware and work to enhance world's resources and it ensure that new cooks, pastry chefs and professionals are the main people to save our planet and its biodiversity. Article 1, generate culture; Article 2, right to choose their own food; Article 3, right to healthy food availability; Article 4, right to information and education; Article 5, food safety assurance; Article 6, safeguarding the territory; Article 7, sense of responsibility; Article 8, company's progress; Article 9, correct information; Article 10, the role of cooking schools.

The new goal of the project Next Generation Chef wants to improve the dialogue between them and the scientific community to satisfy one of people's primary needs: safe and good food. In this way, we want to create a network to revolutionise the way of teaching in the culinary field, motivate students and professionals to collaborate with each other in the promotion of the value of food. The goal is to create an international platform for cooking schools, where professionals can meet and discuss food preparations and provide their views about it.

82. Leveraging scientific cooperation with EFSA: a pilot pesticide dietary exposure assessment in Chile

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Introduction: Chile has two pesticides surveillance programmes, one under the Ministry of Health and another under the Ministry of Agriculture. Both have been working for almost 10 years collecting valuable data for analysis. Nonetheless, insufficient scientific-based evaluation of the results has been made. So, the Chilean Food Safety Agency (ACHIPIA) engaged into a collaboration with EFSA to strengthen the skills to run critical analysis of the current pesticide surveillance programmes. The main objectives of this collaboration were to develop: (1) an integrated pesticide surveillance programme; and (2) a dietary exposure assessment using the data from the current programmes. Here we present the main findings of the dietary exposure assessment.

Material and methods: For the dietary exposure assessment, results of the surveillance programme from the Ministry of Agriculture of 2016 were used, with 1,956 samples and 180 analytes. The tool used

to conduct this assessment was EFSA PRIMo. Most of the working principles, concepts and tools used were learned through the collaboration agreement between EFSA and ACHIPIA signed in 2017.

Results, discussion and steps forwards: Chronic exposure assessment indicates that only methamidophos is over 100% of the ADI. Only eight pesticides were in the range of 11–100% ADI, 43 in the range of 1–10% ADI and 30 below 1% ADI. From an acute exposure perspective, none of the data exceeded 100% ARfD. All these results correspond to local consumption produce and fruits data indicate no problems. These results provide strong science-based evidence to local surveillance programmes and risk management decisions. Additionally, it shows how fruitful can be these technical collaborations between agencies, to further implement skills and tools learned, such as the Standard Sample Description and PRIMo to improve local capacities, surveillance programmes, MRL setting process, among others.

83. One Health in science and society. A glimpse into the future: its students!

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As One Health builds up momentum in our society, construction on an international system of values, goals and connections based on this concept has already started. Human and veterinary medicine, the environment, biology, social sciences, art, mathematical sciences, IT, risk assessment and management, all are under the One Health umbrella and have a shared mission. We are building pioneer bridges between academia, NGOs, institutions, industry and consumers. But what are we doing to pass on all of this to the future One Health generation? Is the current One Health framework providing them with sufficient resources? Will it be sustainable?

The scope of the present work, started in 2017 and still ongoing, is to identify, at an international level, One Health resources available, in all aspects, to students. The inclusion criteria were education and work opportunities, alongside other benefits that can be monetised by students in pursuit of a One Health career.

We have identified over 60 active One Health student hubs world-wide, from One Health university clubs, autonomous groups to international aggregator movements, as Students for One Health. We also highlight 70 academic and non-academic educational opportunities (from bachelor to post-doc level). Moreover, online data indicates that over 5,000 students are connected to the One Health information sharing networks. Almost 25% of online visits to One Health specific sites are performed by students. These encouraging results represent only half of a win, due to the few opportunities to land a job in One Health. In other words, we are training One Health minds that will not be used in practice.

This concept paper represents, from our knowledge, the first one to reveal the situation of the future of One Health: its students!

Environment

84. Evaluation of marking methods in farmed salmonids for tracing purposes – impact on fish welfare

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Angelika Agdestein – VKM staff
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Escaped farmed Atlantic salmon (*Salmo salar*) is considered a threat to wild salmon. The Norwegian authorities are aiming at preventing escapes from occurring and remove escapees from the environment, following the 'polluter pays' principle. To take action to reduce the impact of escapees, methods to distinguish escapees from wild fish and to trace them back to their origin are in demand. The Norwegian Scientific Committee for Food and Environment (VKM) assessed the risks of reduced welfare for farmed salmonid fish, associated with the different marking and tracing methods. A variety of marking methods such as fin clipping, freeze branding, different external and internal tags, as well as natural and chemical marks, were considered. Visible marks may be combined with either tracing of natural marks or the use of coded wire tags or passive integrated transponder tags, which have a sufficient number of available codes, enabling identification of the fish on an individual – or batch level. Natural or chemical marks were assessed as having the lowest risk on reduced fish welfare, although analysis of marks may require killing the fish after a catch. By contrast, spraying of pigments and most externally attached tags represents a high risk of reduced welfare, both on short-term and long-term perspectives. The overall conclusion by VKM is that no combinations of marking and tracing methods exist that are feasible without an increased risk of reduced animal welfare. Data gaps related to the impact of marks on fish welfare were identified. These include the functional role of the adipose fin, making assessment difficult about how fin clipping affects the fish on a long-term basis. Regardless of the method used to tag fish, large-scale marking will always represent higher risks of human errors and reduced fish welfare as opposed to small-scale marking.

85. ECPA proposal for an expert judgement based approach to Specific Protection Goals (SPGs) for EFSA Non-Target Terrestrial Plants, Non-Target Arthropods and Soil Organisms Guidance Documents based on the EFSA Ecosystem Services Approach

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Currently there are three Scientific Opinions from EFSA that are waiting to be developed into Guidance Documents i.e. Effects of Pesticides on Non-Target Terrestrial Plants, Soil Organisms and Non-Target Arthropods. While each of these Scientific Opinions makes proposals for SPGs, the European Commission and Member States should agree on the SPGs before they can be taken forwards to be used in the Guidance document development phase. The purpose of this paper is to provide input for consideration and discussion during this process.

The predicted impact of any effect of a plant protection product (PPP) on an invertebrate/plant population should be described using expert judgement, which combines the predictions using the following EFSA 2010 dimensions (i.e. attribute/nature of effect, magnitude, temporal and spatial scales of effects) as well as the number and importance (e.g. keystone species) of species potentially affected,. This expert judgement must be carried out within the context of the intended field conditions of use of the PPP and should also take into account any proposed risk management measures. An additional element that should be taken into consideration when setting SPGs, which was not listed in the EFSA SPG Opinion (EFSA 2010; EFSA 2016) is the frequency of occurrence of an impact. For example a 1 in 20 year event should be of much less concern that an impact that occurred after every application. Then using this described expert prediction of the impact of the PPP, an informed choice can be made by all stakeholders as to the acceptability or otherwise of the effects being predicted in the risk assessment.

86. Development of innovative open-source QSAR models for human and ecological risk assessment of emerging contaminants and their mixtures

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Humans and ecosystems are continually exposed to very complex mixtures of chemicals, the composition of which is continuously changing. Human Health (HHRA) and Environmental Risk Assessment (ERA) of combined exposure to multiple chemicals raised concerns among scientists, risk assessors and risk managers, particularly due to the complexity of the problem formulation, the huge number of chemicals involved, the toxicological profiles and different routes of exposure of these chemicals. From a risk assessment perspective, it is practically impossible to test all possible mixtures experimentally, therefore it is needed to find smart strategies to assess the potential hazards using new tools that rely less on *in vivo* testing and incorporate instead alternative experimental and computational tools. The European Food Safety Authority (EFSA) has identified as a key priority the development of harmonised methodologies for HHRA and ERA of combined exposure to multiple chemicals, initiating 'MixTox' Working Group. In 2017, EFSA published an External Scientific Report summarising the development of innovative in silico QSAR models as tools to predict toxicity values or classify thresholds of single chemicals for HRA and ERA by using EFSA's OpenFoodTox database.

Our research project aims at applying and further developing current QSAR models (e.g. CORAL) for hazard characterisation of binary mixtures in species of human health (rats, mice) and of ecological relevance (bees, *Daphnia*). Mathematical models such as Concentration Addition (CA) and Independent Action (IA) as well as the Toxic Unit (TU) approach will be applied and tested within different case studies. QSAR modelling will be based on the sum of toxic units (sTU) derived from single chemical; this will provide a basic risk characterisation for the compound of concern in the mixture. QSARs models will applied to (a) predict (missing) information on individual compounds; (b) predict directly or stepwise the combined effects and interactions of chemicals in the mixture; and (c) assess whether chemicals will act in a similar or dissimilar way to perform their grouping. Overall, this project will allow EFSA's Working Group 'MixTox' to develop its Guidance document aimed at harmonising the current methodologies for HHRA and ERA of multiple chemicals due in 2019.

87. Traceability of cooper along of soil-plant-bee products chain

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The study presents the influence of the soil's pollution with heavy metals influences the mineral content of honey bees and implicitly the honey quality. The study was performed *in situ* by location the bee hive in two areas: non-polluted area (as reference area) and a strongly polluted area with

heavy metals. Samples of soil, mellifera plants, bees and bee products were collected from both areas and analysed using AAS method to establish the total and leachable content of cooper. The positive relationship regarding the copper traceability was validated along the soil–melliferous flora–honeybees–honey and propolis chain. Honeybees can be treated as 'bio-indicators' for copper pollution within their environment.

88.EFSA develops scientifically based plant pest survey guidelines for EU Member States

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The European Commission requested EFSA to facilitate the Member States (MS) in the planning and execution of their survey activities. In particular, EFSA is asked to provide scientific and technical guidelines in the context of the new plant health regime (Regulation (EU) 2016/2031), which gives an extra focus to prevention and risk assessments.

In this context, 47 pest survey cards are being developed for pests of EU relevance (Regulation (EU) No. 652/2014) within the European Commission co-financing programme of the annual MS survey activities.

Each survey pest card summarises the biological and epidemiological key information relevant for the detection and identification of the pests by inspectors and laboratory technicians in the MSs. Moreover, guidelines for three pilot pests are being prepared for the survey planners and designers in the MSs, providing them with:

(i) support on the underpinning statistical methods, and use of the EFSA WEB-based tools RiBESS+ and SAMPELATOR to inform sampling strategy design, including sample size calculations;

(ii) the relevant practical information for the implementation of surveys.

In the development of these deliverables, interaction with the MSs is needed before and after implementation of the pilot guidelines for ensuring there are fit for purpose and harmonisable across the EU.

89.Appraising the representativeness of field trial sites for the agronomic/phenotypic and compositional characterisation of transgenic plants

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The agronomic/phenotypic and compositional characterisation of genetically modified (GM) plants is an important pillar for the risk assessment of GM plants and derived food/feed products. Compositional and agronomic/phenotypic data are determined to identify similarities and differences between the GM plant and its conventional counterpart. Agronomic/phenotypic and compositional data should be gathered from plants grown under environmental and agronomic conditions which are representative of possible receiving environments in which the GM plants can be grown (EFSA GMO Panel, 2015).

Here, we present an approach based on climatic and land suitability classes reported by Sys et al. (1993) to appraise the representativeness of field trial sites in a transparent and repeatable way. Crop-specific requirements corresponding to different conditions for cultivation (ranging from optimal to non-suitable) are used graphically to show the specific characteristics of the field trials against the different classes identified. Similarly, additional analyses are integrated to evaluate the representativeness of the farm management practices applied in the selected field trials. This approach enables you to: (1) facilitate the selection of representative sites based on historical meteorological data, soil characteristics and site distribution against maturity groups of the test materials (*a priori*); (2) assess the representativeness of selected sites taking into account the specific conditions of the year/s of the field trials (e.g. agro-meteorological conditions and crop management practices) (*a posteriori*). This approach is now routinely applied by EFSA to appraise the representativeness of field trial sites submitted as part of the data package for the authorisation of GM plants for food/feed uses, import and processing in the EU.

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90.A global database of the host plants of Xylella spp.

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Xylella fastidiosa was first detected under field conditions in Lecce province in Apulia (Italy) in October 2013, where the outbreak was mainly characterised by extensive leaf scorch and dieback in olive trees. Since then, *X. fastidiosa* has been reported outdoors in many different plant species also in Corsica, South France (Provence-Alpes Côte d'Azur), the Balearic Islands and mainland Spain (Alicante).

The European Food Safety Authority (EFSA) produced urgent advice and a pest risk assessment together with the evaluation of risk reduction options (EFSA, 2015) to scientifically support the EU risk managers in the identification of measures to prevent further introduction and spread of this quarantine pathogen.

Moreover, EFSA has developed and maintained a database of the reported host plants of *Xylella* spp. A list of *Xylella* spp. host plant species derived from an extensive literature search up to November 2015 included 359 plant species from 204 genera in 75 different botanical families (EFSA, 2016).

EFSA was then tasked by the European Commission to periodically update the database to retrieve all the new scientific developments published on the topic, including information on results of experimental infections and on plant varietal responses. A systematic approach was applied for this update according to the EFSA guidance on systematic literature review (EFSA, 2010) to collect the studies, select the relevant ones and extract the informative data. The results and conclusions of the new version of the Xylella spp. host plants global database will be presented.

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91. Using artificial caterpillars to monitor predation intensity in genetically modified maize

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Humankind draws important benefits from large-scale ecological processes termed ecosystem services, yet the status of several of them is declining. Reliable monitoring methods are essential for tracking the status of ecosystem services. Predation is the mainstay of natural pest control, a key ecosystem service. We used green plasticine caterpillars to monitor predation pressure, and to obtain baseline data on predator activity in transgenic Bt versus non-Bt maize. Predation pressure was measured at ground and canopy levels using an identical, small-plot experimental design in four European countries (Denmark, Slovakia, Romania and Italy) and Argentina. Total predation rate in maize was 11.7% day^{-1} (min. 7.2% day^{-1} in Argentina, max. 29.0% d^{-1} in Romania). Artificial caterpillars were attacked both by invertebrates (mostly chewing insects with 42.0% of the attack marks, and ants with 7.1%, but also predatory and parasitoid wasps, spiders and slugs), and vertebrates (small mammals 25.5%, and birds 20.2%). Total predation at ground level (15.7% day^{-1}) was significantly higher than in maize canopies (6.0% day^{-1}) in all countries, except Argentina. We found no significant differences between predator pressure in Bt versus non-Bt maize plots. The artificial caterpillar method provided comparable, quantitative data on predation intensity, and proved to be suitable for monitoring natural pest control. This method usefully expands the existing toolkit by directly measuring ecological function rather than structure.

92. Titanium dioxide nanoparticles and edible mussels: a potential consumers' exposure to nanoparticles?

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Despite the widespread production and use of engineered nanoparticles (NPs) and their foreseen increased release into the aquatic environment, relatively little information is known about NP interaction with, bioaccumulation in or transfer to the aquatic food web.

Due to the high diffraction index and strong light scattering and incident-light reflection capability, titanium dioxide (TiO_2) NPs are widely used, mostly as white pigment in cosmetics, paints, dyes and varnishes, textiles, paper and plastics, food and drugs and even paving stones. Indeed, evidence has been collected of urban runoff water contamination by TiO_2 nanomaterial (NM).

Aquatic ecosystems, such as the marine environment, are therefore likely to be potential sinks for these NPs. Edible bivalve molluscs are known to be strong natural filtrating systems: by accumulating NPs, they might represent a potential vector of such contaminants and a consequent route of exposure of humans to NPs.

Therefore, *in vivo* studies, carried out by exposing mussels (*Myrtillus galloprovincialis*) to TiO_2 NPs in

a controlled artificial marine environment, can give important clues to understand NPs behaviour in the aquatic environment as well as the bioaccumulation of NPs in edible marine animals.

The detection and characterisation of NPs in marine environment and in marine species are quite complicated due to NPs' unpredictable behaviour, fate and low concentrations. This makes the determination of the bioavailability and bioaccumulation of NPs in marines species a challenge. However, a recently developed analytical technique, known as single particle inductively coupled plasma-mass spectrometry (spICP-MS), represents a powerful and reliable tool for the determination of NPs in complex matrices. By means of this analytical approach, the levels of contamination of mussels exposed to controlled concentrations of NPs can be determined and the analytical results can provide indication of potential human exposure to NPs when mussels harvested in polluted environment are consumed.

93. Detailed vegetation maps as support of pest risk assessment: the case of Xylella fastidiosa in Apulia (Italy)

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The vast majority of pest modelling processes, from the regional to the global scale, relies on land cover maps for the definition of habitat suitability. These maps however report only extremely broad indications on the type of vegetation, and the possible extrapolation to the presence and abundance of a pest host plant are extremely weak and uncertain.

When available, vegetation maps with the indication of the dominant plant association, can significantly improve the accuracy in the definition of the habitat suitability.

In this poster we report the example of the application of 'Carta della Natura', a 1:250:000 vegetation map of the Apulia region, for the evaluation of habitat suitability for Xylella fastidiosa. The results have been validated using the data on the spread of Xylella in Apulia (Salento).

94. EFSA plant pest categorisations: an example of how to make risk assessment fit for purpose

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The Plant Health (PLH) Panel of the European Food Safety Authority (EFSA) has a two-step approach for its pest risk assessments: a pest categorisation is prepared in the first step and, if needed, a more detailed risk assessment is carried out in the second step. The PLH Panel is currently performing a large number of plant pest categorisations (on bacteria, fungi, viruses/viroids, insects, mites, nematodes and parasitic plants included in the annexes of Council Directive 2000/29/EC). This work, in collaboration with experts from throughout Europe, supports the ongoing revision of the EU plant health legislation. Only for some selected pests, where more details are needed based on the categorisation, a quantitative risk assessment is performed on the request of the European Commission. For each pest categorisation, criteria are assessed for consideration as a potential:

Quarantine pest (absence in the EU, or (if present) under official control; ability to enter, establish, spread and cause impacts in the EU; availability of control measures).

Regulated non-quarantine pest (presence in the EU; spread mainly via plants for planting rather than natural dispersal; ability to cause impacts on the use of plants for planting; availability of control measures on this pathway).

Protected zone quarantine pest (same criteria as for quarantine pests, but referred to a restricted and geographically separated area of the EU, where the pest is still absent, e.g. the British Isles).

Instead, for a pest risk assessment, quantitative models are developed to estimate the risk of entry, establishment, spread and impact. This poster provides an overview of the progress on the pest categorisation mandate and the remaining work to complete the project. The relevance of the two-step approach (1: pest categorisation; 2: quantitative risk assessment when needed) for making EFSA activities more fit for purpose will be highlighted.

95. Occurrence of deoxynivalenol in cereals and cereal products in Hungary

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Due to changing climate-weather conditions, similarly to other countries, Hungary has to count on seriously decreasing or missing crops, increasing contamination of cereals with moulds and, in connection with this, increasing mycotoxin contamination. One of the most important mycotoxins that can often be found in crops is deoxynivalenol (DON).

The aim of our study was to monitor the DON contamination of cereal and cereal product samples in Hungary and combine these results with official recordings of the Hungarian Meteorological Country Service, to analyse the effect of weather data on

DON contamination.

In this study, Hungarian wheat (n = 305), maize (n = 108), wheat flour (n = 179) and pasta (n = 226) samples (collected during 2008–2015) were analysed (N = 818). Enzyme-linked immunosorbent assay and liquid chromatography coupled with a mass spectrometry were applied to determine DON toxin contamination.

Among cereal samples, in 2011, wheat was contaminated with DON (overall average ± SD; 2,159 ± 2,818 µg kg−1), which was above the maximum limit (ML). For wheat flour and pasta, no average values above ML were found during 2008–2015, but higher DON contamination could be observed in 2011 as well (wheat flour: 537 ± 573 µg kg^{-1}; pasta: 511 ± 175 µg kg^{-1}).

Based on our survey not only weather conditions, such as temperature, rainfall quantity and distribution, affect the level of DON toxin contamination of cereals and cereal products. A new risk factor – extremely dry weather, very low annual average rainfall quantity – was determined for wheat samples and very high yearly average temperatures for maize samples. This highlights that consideration of other extreme weather conditions is also needed when planning monitoring strategies. More than the previously determined weather conditions should be consdered when monitoring matrix–DON toxin relationships.

96. Learnings from a meta-analysis covering a decade of post-market environmental monitoring of MON 810 maize cultivation in the European Union

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The controversial debate on the assessment of genetically modified crops has led to over-regulation and restricted cultivation of MON 810 maize in the European Union (EU). MON 810 maize produces the insecticidal bacterial protein Cry1Ab which protects the maize against European corn borer (Ostrinia nubilalis) and Mediterranean corn borer (*Sesamia nonagrioides*). The authorisation holder Monsanto has implemented the Post-Market Environmental Monitoring (PMEM) of MON 810 cultivation in the EU using different tools including monitoring of target pests' susceptibility, structured refuge compliance, farmer questionnaires, farmer complaint systems and assessment of scientific publications. The results have been reported to the European Commission (EC) on a yearly basis, and the full PMEM reports are available on the EC website. The present study includes a meta-analysis of data from the PMEM reports collected in the period 2006–2015 based on 2 627 farmer questionnaires across eight EU countries and the assessment of more than 375 relevant published studies. The overall analysis confirms the validity of the outcomes of the initial safety assessments that MON 810 has no adverse effects on human, animal health or the environment. The MON 810 cultivation in the EU has provided efficient protection against the target pests resulting in higher yielding crop, a significant decrease in insecticide use and a reduced susceptibility to diseases and pests compared to conventional maize. The farmers' high compliance to the agronomic requirements for insect resistance management (IRM), as established in the harmonised IRM plan developed by industry in the EU, has proven to be sufficient to sustain the efficacy of MON 810 maize. The evidence above should be considered as valuable data in the risk management. The absence of any indication of adverse effects over a decade of MON 810 cultivation invites the adaptation of the current monitoring practices.

97. Quantitative pest risk assessment: the case of Spodoptera frugiperda

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Following its introduction and rapid spread in sub-Saharan Africa, the European Commission asked EFSA to conduct a pest risk assessment of *Spodoptera frugiperda* (Lep: Noctuidae), the fall armyworm, for the territory of the European Union. *S. frugiperda* is a highly polyphagous pest from the Americas and its favoured hosts are maize, rice and sorghum. It has been intercepted in the EU on a range of fresh produce from the Americas and more recently from Africa. The remit of the assessment was limited to the assessment of entry, establishment and risk reduction options. We will present the quantitative assessment of entry into specific EU NUTS 2 regions where climatic factors indicate that establishment is likely to be possible. We will also present comparisons of the likelihood of entry via trade pathways with entry via migration of adults on suitable air currents from sub-Saharan Africa using a recently developed quantitative framework. It is recognised that the pest's rapid spread in Africa could lead to additional pathways originating in northern Africa, making entry into the EU even more likely. The effect of risk reduction options on lowering the likelihood of entry via trade will be presented.

98. Media and literature monitoring on plant pests

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Abstract: Following a request from the European Commission (EC), EFSA provides monthly

newsletters summarising media and literature monitoring results obtained through a horizon scanning procedure.

The aim is to identify relevant information on pests that can be of great interest for risk managers, plant health specialists and civil society as well.

Currently about 350 pests are monitored from the EU legislation and EPPO lists. In addition, the monitoring is active to retrieve information on new and unlisted plant pests. The media are screened using the MEDISYS (Medical Information System) platform, developed by the General Directorate Joint Research Centre of the EC. The items coming from the sources are filtered using categories with given key words to identify their plant health relevance.

In total, MEDISYS retrieves and analyses more than 200,000 items per day. Each monthly newsletter contains: a summary of the main issues, the links to the articles, the publication date, the first lines of the original articles, the automatic English translation of the title and of the first lines.

The monitoring shows that plant pests are a highly discussed topic in the media and in literature. Many items retrieved by the tool refer to detection, prevention and control of organisms harmful to the EU agricultural and environmental sectors.

The EFSA newsletter can be a useful tool to gather information and contribute to public awareness on plant health risks.

99. Protecting biodiversity from unacceptable pesticide effects through the ecosystem service concept is more than challenging

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The ecosystem services concept was originally developed as an idea to increase the support for nature conservation by highlighting the benefits that nature provides to human beings (Ehrlich & Ehrlich, 1981). However, during the last decade the concept became increasingly attractive as central idea behind approaches for the management of biodiversity and ecosystems (Costanza et al., 1997, MEA, 2005). With the Millennium Ecosystem Assessment in 2005 the first conceptual framework with a classification scheme for ecosystem services has been published. Further conceptual developments followed and pushed the implementation of the concept into the policy making forwards (Haines-Young and Potschin, 2010, De Groot et al., 2010, Luck et al., 2009). However, there exists also much deb (Mace, 2012, Cornell, 2011).

In 2010, EFSA proposed to adopt the concept to environmental risk assessment as a tool to identify and communicate Specific Protection Goal options (SPG) for non-target organisms exposed to pesticides (e.g. EFSA 2010). The aim was to operationalise the rather general environmental protection goals as laid down in the European pesticide legislation.

In this contribution, we aim at illustrating the challenges we recognise for the implementation of the ecosystem service concept in the risk assessment of pesticides considering the uncertainties and knowledge gaps regarding the linkage between ecosystem services and biodiversity and the limitations that arise for the protection of structural biodiversity. We argue that the ecosystem services driven by non-target organisms in agricultural landscapes should be addressed with a focus on their sustainable provision in space and time. Co-occurring stressors, entangled community interactions, knowledge gaps in species functions and the need of preserving sustainable systems for the future are some of the features that may well frame the dialogue on ecosystem services and protection goals in European agricultural landscapes.

100. Mapping the environmental risk of Bacillus thuringiensis var. israelensis by the metabolic foot-printing approach

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Presence and establishment of invasive mosquito species such as *Aedes aegypti* and *Aedes albopictus* is rapidly increasing in the European environment. The European Directive in 1998 led to the increasing use of biological insecticides such as cry proteins produced by the bacterium *Bacillus thuringiensis* var. *israelensis* (Bti) that kill mosquito larvae after being ingested. Considering the interest in Bti as a more environmentally sustainable bioinsecticide, it is important to examine in detail the environmental fate and impact of Bti. The available tool such as half-life, t½, does not considers the biodegradation and biotransformation phenomenon of complex formulations. To address this challenge, 'Environmental Metabolic Foot-printing' (EMF), giving an idea of the resilience time was recently developed in the laboratory (Patil et al. 2016; Salvia et al., 2017) to evaluate the impact of synthetic, botanical and microbial insecticides on soil and sediment matrix respectively.

The project 'EnvFate' aims to employ an EMF approach, to dynamically characterise environmental markers of Bti pollution found among the sediment matrix meta-metabolome. Metabolome characterisation will require the development and optimisation of extraction and detection protocols using the LC-MS platform. In addition, the metabarcoding approach will allow us to understand microbial community responses to Bti pollution. Emphasis will be placed on better

standardisation, data interpretation and evaluation that will build confidence in the value of 'omics technologies – this being essential to increase their (regulatory) use. These activities will advance our understanding of environmental risks associated with Bti, and pave the way for the development and adaptation of new environmental monitoring tools.

We will present preliminary findings from metabolomics data. The changes in the meta-metabolome after Bti and α-cypermethrin treatment is investigated at various time intervals and compared with a control to evaluate the resilience time of the sediment.

101. Robust estimates of winter loss in honey bees – an evaluation of data collected in Sweden

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In Sweden, data on honey bee losses are currently collected by voluntary reporting in three channels: the Swedish beekeeping organisation, the professional beekeeping organisation and COLOSS. These data are not harmonised and there is no systematic analysis of winter losses, which can follow trends or detect anomalies in different regions across Sweden. A recent evaluation of the quality of data and statistical properties from current data collection schemes show that data are heavily biased, that temporal and spatial variability in losses are not properly understood, and that the aggregation of data influences the robustness of loss estimates. We give recommendations for how to improve data collection and analyses of honey bee winter loss in Sweden.

102. Comparison of pesticide residues in ground waters and agricultural lands in Czech Republic

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This study provides the first review of the national occurrence of 64 currently used pesticides (CUPs) and their transformation products (TPs) in soils and groundwaters of Czech Republic. The pesticides were monitored in 2014–2017 at 216 agricultural areas and at 689 groundwater monitoring sites. Multiresidue analysis on LC-MS/MS was used for determination and identification of the pesticides.

The resulting data for soil and water samples were highly variable as the persistence of pesticide compounds is soils and their potential leaching into groundwater is determined mainly by their physicochemical properties.

The soils contained multiple pesticide residues (e.g. 53% of soils with ≥ 4 CUPs and/or TPs) the levels of which were noticeable (e.g. 7% of soils with ≥ 4 pesticide residues exceeding the threshold level of 10 µg/kg). Of the analysed pesticides, four compounds were present in > 15% of the sampled soils at concentrations exceeding the threshold level of 10 µg/kg. These compounds included terbuthylazine-2-hydroxy (80%) > epoxiconazole (56%) > atrazine-2-hydroxy (49%) > tebuconazole (40%) where the values in brackets show the overall number of positive soils at which the compounds were above the LOQ.

In the groundwaters, pesticides based on ethanesulfonic acids (ESA) and atrazine-based herbicides were mostly observed. Several of the most frequently detected pesticides also exceeded the threshold level of 0.1 µg/L. These compounds included alachlor ESA (23%), metazachlor ESA (19%) and metolachlor ESA (17%) where the values in brackets show the overall number of positive samples at which the compounds were above the threshold level.

Finally, because the high levels of water-soluble pollutants in groundwaters can result in temporarily enhanced levels in surface and drinking water, the environmental and human health risk assessment based on measured data were also provided.

103. iPlanta: modifying plants to produce interfering RNA

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Background: Methods to exploit plant defence mechanisms or changing plant metabolism by RNA silencing show great potential. Interfering RNA can be used to improve plant composition while enhancing levels of beneficial nutrients, and to improve plant productivity by suppressing undesirable traits and switching resources to more beneficial quality and yield traits. Gene expression in pathogens and pests can be targeted and plants modified to produce dsRNAs that trigger silencing and affect essential physiological functions in pest or disease-causing organisms. Many of the modes of activity of the micro- and small interfering RNAs (miRNAs, siRNAs) that mediate the silencing effect are not yet fully understood and knowledge of systemic propagation, turnover, specificity etc. of these molecules is limited.

Objectives: This COST Action will define and coordinate the most important research tasks for the development of these novel transgenic strategies across many EU and nearby countries with inputs from cooperating researchers in associated countries in North and South America,

Australasia etc.

Activities:

Evaluation of the efficacy of the RNA molecules for the induction of disease and pest resistance and metabolic changes.

Examination of the specificity of the selected miRNAs and siRNAs and their impacts on both target and non-target/off-target systems.

Developing specific risk assessment and risk management guidelines that relate specific effects of the miRNAs and siRNAs on food, feed and the environment.

Understanding the modes of transmission, uptake, systemic spread and degradation of dsRNAs, miRNAs and siRNAs.

Determining the environmental and socioeconomic impacts of plant RNAi technology and products.

Communication through workshops, conferences and various media.

Members: Scientists from 31 European countries.

104. Synergy as future challenge for risk assessment: pesticides, nutrition and behaviour

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Animals are exposed to multiple stressors simultaneously, such as pesticides (including chemical mixtures of multiple active ingredients), nutrition deficiencies and diseases. Combined exposure to multiple stressors can cause interactive effects, amplifying the risk if the two agents (i.e. two pesticides) interact synergistically on animal survival and behaviour. However, the Regulatory Risk Assessment (RA) generally evaluates the risks posed by only one agent at the time (i.e. one pesticide), and mainly addresses effects on animal survival. The European Food Safety Authority (EFSA) has identified the RA of chemical mixtures as one of its current priority tasks, but synergistic effects on animal behaviour, as well as synergies caused by non-pesticide stressors, are still currently not taken into account in the RA. The lack of appropriate scientific studies and methodologies about these key topics partially explains the respective lack of advances in RA. However, the difference between the complexity of real world situations (i.e. exposure to multiple stressors affecting survival and behaviour) and the simplified RA scenario leads to uncertainties in RA conclusions. So, we developed methodologies to assess synergistic effects of key animal stressors on bee survival and behaviour. Our work was based on the LD_{50} standard test, which is already commonly used in RA, to facilitate implementation and comparisons. Honey bees were used as RA animal model. Our work demonstrated that animal health can be synergistically impaired by the combination of two major common stressors, pesticides and poor nutrition, at field-realistic exposures. We also demonstrated that combined chemical stresses synergistically impaired animal behaviour and survival. Because the stressors did not cause significant effects individually, our results suggest that the standard RA results could lead to underestimation of risks. The consequences for RA are discussed, as well as possible future directions towards an advancement of environmental RA that integrates multiple stressors.

Managing evidence

105. EFSA Knowledge and Innovation Community (KIC) on Exposure Science

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Levels of chemicals in food are an important aspect of food quality and safety. The assessment of dietary exposure to hazardous substances is a crucial component of the risk assessment work carried out by EFSA's Scientific Panels. In the last years, significant steps have been performed by EFSA in relation to the collection and standardisation of food consumption and chemical occurrence data and in the development of new statistical methods (e.g. probabilistic, cumulative, etc.) for the assessment of exposure. Projects (such as HMB4EU) and collaborations with national and international institutions (such as with the International Society of Exposure Science and ECHA) in the area of exposure assessments have been established and training on dietary exposure assessment delivered to both EFSA staff and experts.

However, exposure science is moving from a single-domain approach to a multidisciplinary efforts for the characterisation of the 'exposome' as the totality of an individual's environmental exposures from conception onwards. As the agency responsible for assessing the risk of hazards in the food chain, EFSA needs to stay abreast of these developments and further develop its exposure methodology taking into account non-dietary exposure and to ensure world class exposure methodology.

In February 2018 EFSA initiated a Knowledge & Innovation Community (KIC) on Exposure Science with the aim to promote within and outside of EFSA: (i) the exchange of knowledge in the area of human exposure science; (ii) the exchange, integration and harmonisation of data and methodologies in the areas of dietary exposure assessment, non-dietary exposure assessment, human biomonitoring; and (iii) collaboration between EFSA, EU Scientific Advice Agencies, research communities and other stakeholders. The KIC on Exposure Science represents an opportunity for content-driven networking and brainstorming on new challenges in the field of exposure science among interested scientists. The poster presents the KIC concept, activities and goals.

106. pestr – tools to mine EPPO Data Services with R

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One of the basic procedures in every risk assessment is extracting information from online resources. Assessors without programming skills are often struggling with time-consuming and boring procedures for finding relevant information and copy–pasting it into their reports. What is even more problematic is the fact that this procedure is error prone and non-reproducible. Many of the databases offer an application programming interface (API) that, when correctly used, allows reproducibility, saves time and limits errors.

Some other databases are more complicated as their APIs have limited use. So, to use full spectrum of information stored, other techniques (e.g. SQL queries or web-scraping) are necessary. One of the examples of databases that require a broad set of tools to receive information is the EPPO data services. It is one of the most important information resources for pest risk assessors in Europe. To extract different types of information on pests and hosts, one needs to use SQL queries, REST (REpresentational State Transfer) API and web-scraping. Moreover, data obtained from web services are stored in machine-friendly formats, which are difficult to read by humans. The broadness of techniques might overwhelm assessors with no to limited programming skills.

Here we present a package of R functions to easily receive information from EPPO data services and to use them to create human-readable tables. Advanced users will be able to use this function to automatise filling standardised risk assessment reports with basic information on investigated pests. Moreover, it will also help risk managers to quickly build tables with information on multiple species for comparison and communication of potential risk.

107. Identification of potential emerging risks in the salmon and oyster food chain – piloting an innovative text mining tool

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It is part of EFSA's remit in food and feed safety to evaluate the application of innovative technologies to support the identification of emerging risks. This pilot project aimed to assess the applicability and capability of the Emerging Risk Identification Support System (ERIS), developed by The Netherlands Organisation for Applied Scientific Research (TNO), to identify emerging hazards in the Atlantic salmon (*Salmo salar*) and pacific oyster (*Crassostrea gigas*). ERIS applies text mining rules to identify grammatical and contextual relationships in article titles and abstracts, between potential hazards, effects and exposure.

During the pilot phase, ERIS' ontology was adapted in an iterative and interactive process according EFSA's needs followed by a blind trial to align the expert's evaluation from EFSA and TNO. In the second phase the text mining tool was applied to abstracts from two different databases MEDLINE®/PubMed® and FSTA®, published January 2015-June 2016. The output was evaluated by experts to identify potential emerging risks according to an accepted quality assured protocol based on a multieye principle including a benchmark of the relationships found against a database containing scientific literature of 10 years (2005–2014).

ERIS processed 1,821,576 abstracts and retrieved 707 abstracts (422 for salmon and 285 for oyster). After a first round of expert evaluation, 67 articles for salmon and 47 for oyster were pre-selected. A second round of expert evaluation comparing the pre-selected abstracts with the benchmark lead to 28 potential emerging risks identified; 18 in salmon and 10 in oyster. Although significant resources were invested from EFSA and TNO to improve the precision of the ERIS tool in identifying potential emerging risks, ERIS has been proven to be a valuable tool to automatically select relevant research abstracts allowing the identification of potential emerging risks from a trusted and manageable data set after expert evaluation.

Key words: emerging risk identification; text mining; ontology; semantic relationship, food safety; expert evaluation; salmon; oyster.

108. A systematic review comparing the zebrafish embryotoxicity test and mammalian developmental toxicity tests

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The Evidence-based Toxicology Collaboration (EBTC) is exploring the novel application of systematic review (SR) methodology to comparisons of the

performance of toxicity test methods. An SR group, which covered the required areas of expertise, was convened. The group systematically compared the standard *in vivo* prenatal developmental toxicity test in rats and rabbits (similar or identical to Test Guideline 414 of the Organisation for Economic Cooperation and Development), i.e. the comparator test, with the zebrafish embryotoxicity test (ZET) as the index test. The SR focused on malformations as the outcomes, which expressed as a dichotomous variable, i.e. as the presence or absence of malformations. First, an SR protocol was finalised and registered at PROSPERO, based on the learnings of a pilot study. Second, we conducted a comprehensive search of the ZET literature to identify chemicals in eligible studies, resulting in 1,436 chemicals in 342 studies. In this step, the unstructured format of abstracts and the heterogeneity in the reported ZET protocols posed the main challenges. Third, a search was conducted to identify mammalian studies on these chemicals. Here, the major obstacle was to efficiently incorporate the desired chemicals in the search. When standard SR methodology needed to be adapted to the task of toxicological test method comparison, the group ensured that the solution still abided by the evidence-based principles of transparency, objectivity and reproducibility. The project is entering the final SR steps of data extraction and analysis. We can provisionally conclude that SR will be a valuable tool for evaluating available evidence on test method performance.

109. EU Menu: experiences and perspectives

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Since 2005, the European Food Safety Authority (EFSA) has worked in close cooperation with all organisations operating in the field towards harmonising dietary survey methodology and building a common European Union (EU) food consumption database. Harmonised food consumption data are the basis for improving accuracy of EU-wide exposure assessments and can also assist in serving the needs of nutrition surveillance and of further diet and health related studies. Improved risk assessments can assure more targeted risk management and permit more accurate risk communication resulting in increased consumer confidence.

The first step in this direction was the development of the EFSA Comprehensive European Food Consumption Database which compiles existing national dietary information from the Member States (MS). MS used different methods to collect food consumption data, which makes it difficult to carry out EU-wide analyses or country-to-country comparisons. Furthermore, there is a need to regularly update the available information, as the consumption patterns are continuously changing which may have impact on the exposure of consumers. Therefore, in 2011 EFSA launched the 'What's on the Menu in Europe? – EU Menu' project, with the aim of providing financial and technical support to MS and pre-accession countries to carry out a dietary survey at national level.

The methodology used in the national food consumption surveys is expected to follow the principles described in the EFSA Guidance on the EU Menu methodology, published in 2009 and updated in 2014. It focuses on collecting data from six population groups, ranging in age from 3 months to 74 years with a harmonised methodology and has been endorsed by the EU institutions through EFSA Network on Food Consumption Data. EFSA is currently supporting dietary surveys on children and/or adults from 21 countries. The projects are expected to be finalised by 2022.

110. FoodEx2 – an international food classification and description standard for describing data collections

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A strategic objective of EFSA is to enhance the quality of its outputs by giving direct access to data, promoting the development of international collaborative platforms and fostering data re-use and innovation. In this remit, the use of common data standards is a prerequisite to improve data interoperability and facilitate data sharing and exchange. In particular, a standardised system for classifying and describing food is essential to compare data from different domains and perform more detailed data analysis. To this aim, EFSA developed FoodEx2, a standardised food classification and description system. This is a comprehensive standard aimed at describing food in data collections across different domains.

FoodEx2 consists of descriptions of a large number of individual food items aggregated into food groups and broader food categories in a hierarchical parent–child relationship structure. The description of individual foods can be complemented by additional information through the use of facets.

After its first release in 2011, FoodEx2 was intensively tested with regard to the collection of food consumption and chemical occurrence data and this involved several EU Member State organisations operating in data collection. The testing highlighted strengths and weaknesses of the system and provided suggestions for improvement. As a consequence, FoodEx2 was reviewed and revised to match the needs expressed by the different users.

FoodEx2 is already used by Member States when exchanging data with EFSA. In addition, it boasts an international reach with the Food and Agriculture Organisation and the World Health Organisation

using FoodEx2 to facilitate the collection of food consumption and food composition data on a global level. EFSA is engaged in improving and promoting best practice regarding its use. FoodEx2 is freely available for download and use.

111. Refined risk assessment using ImproRisk

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ImproRisk, an excel-based model, is a tool for conducting rapid risk assessment analysis. It is an empirical distribution model using the deterministic method of dietary exposure assessment to contaminants. Its most important feature is the derivation of probability and cumulative distributions of exposure. The model has been upgraded to meet the needs of risk assessors within the EU and the non-member countries. It abridges the gap between screening and probabilistic models and is compatible to the approach applied by EFSA for dietary exposure assessment. The model can easily be applied to food additives and other chemicals. It is a simple, straightforward and a user-friendly model, validated by EFSA.

ImproRisk combines Food Consumption Data with Occurrence Data and calculates the exposure rate for the population of interest. The model embeds the EFSA FoodEx system version 1. It has the capacity to work with individual Food Consumption Data; therefore, it supports exposure calculation at each food consumption instance.

The capacity of the model to use Occurrence Data at FoodEx Level 3 makes the exposure assessments quite refined. This is shown in the estimation of the dietary intake of Aflatoxin B1, which has been recently conducted in Cyprus. Aflatoxin B1 occurrence data in 1,231 food samples, for the years 2006–2015, were used for the calculation of the dietary exposure. The exposure calculation was performed and compared, using both Occurrence Data at FoodEx Level 2 and Level 3. To carry out risk characterisation, the Margin of Exposure (MOE) approach was applied. The calculated MOE values for Aflatoxin B1 were substantially lower than 10,000, indicating a health concern for carcinogenicity. The highest contribution of exposure was observed for nuts, cereals and spices. The results were comparable with the findings of EFSA and other research groups.

112. The Raw Primary Commodity (RPC) Model

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EFSA's dietary exposure assessments to chemicals are informed by both dietary consumption data and chemical occurrence data. Dietary consumption data are stored in EFSA's Comprehensive European Food Consumption Database and are formatted either as composite foods or as Raw Primary Commodity (RPC) derivatives (i.e. food ingredients). In several food sector areas however, chemical occurrence data are reported to EFSA for the RPC. These can be provided either through EU monitoring programmes or within a specific regulatory framework as trial data. In these cases, the dietary consumption data available in the EFSA Comprehensive Database are not compatible with the chemical occurrence data provided. The objective of the RPC model is to facilitate the standardised conversion of dietary consumption data for composite foods and RPC derivatives into their corresponding amounts of RPC. The RPC model functions in three main steps. In the adjustment step, the classification of the initial consumption data are optimised for disaggregation. In the disaggregation step, the adjusted foods are disassembled into their RPC derivatives, with a probability analysis step employed where required. In the final conversion step, descriptive facets are allocated to the RPC derivatives and the initial amount of RPC required to produce each RPC derivative is estimated through the use of reverse yield factors. A cross-check was executed against the RPC consumption estimates currently used in the area of feed additives and pesticides. Overall, the consumption outputs of the model were consistent with previous estimates. The availability of the Comprehensive Database at various consumption levels will enhance EFSA's capacity to utilise the Comprehensive Database in areas where it is not currently applicable, allowing for the implementation of more proficient exposure assessment methodologies in the future.

113. An adaptive, mechanistic and quantitative approach for plant pest risk assessment

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Plant pest risk assessment at EFSA consists of two phases: (i) a pest categorisation; and, if needed, (ii) a more detailed risk assessment.

For the second phase, the EFSA Plant Health Panel developed a novel approach for quantitative pest

risk assessment which increases the transparency and objectivity of the process. This methodological framework is based on three pillars:

An adaptive approach (scenario-based analyses and conditional assessments). For ensuring fit-for-purpose risk assessment, special care is given to the problem formulation, with interactions between the requestor of the assessment and the risk assessors. During this activity, the risk assessment scenarios are chosen and the risk assessment strategy is defined based on the available resources and data.

A mechanistic and population-based approach (the risk assessment model is based on the biology of the pest, in particular on the pest abundance). For each assessment a model is developed estimating pest abundance from the place of production in the country of origin to the endangered area in the EU.

A quantitative and evidence-based approach (expression of the model parameters as probability distributions integrating both risk estimates and related uncertainties). Pest entry, establishment, spread and impact may be assessed directly, using weight of evidence and expert knowledge. Each assessment model is developed using Monte Carlo simulations, which can compare scenarios for relevant factors, e.g. with or without risk reduction options (RRO). Comparisons between scenarios are made to draw conclusions on the magnitude of pest risks and the effectiveness of RRO.

This new approach is detailed in the PLH Guidance Document for quantitative pest risk assessment that provides explanations on the application of the two-phase assessment method and on how to communicate its results.

114. Use of human biomonitoring data and ICF classification to develop targeted vertical public health policies

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Introduction: Human biomonitoring is a relatively new scientific field aiming at the detection of potentially hazardous chemicals and their metabolites in human biological samples and their association with undesirable health outcomes. Despite gradual accumulation of experience and harmonisation initiatives, no uniform approach exists at an EU level yet, resulting in significant variance in priority areas and populations, screening algorithms or result communication. The aim of this presentation is to present existing Cypriot experience in human biomonitoring and its potential implication for focused policy making

Materials and methods: Since 2013 Cyprus has participated in a number of consortia to develop and apply harmonised human biomonitoring studies along with most other EU Member States. At the same time, it has restructured its disability assessment system to use ICF for a holistic assessment of patient needs and priorities.

Results: About 120 individuals have participated in pilot Cypriot biomonitoring studies and more than 4,000 have been enrolled in the ICF-based national disability registry to this date. Participation rates have been more than 60% for both processes, which are among the best compared to other EU countries using comparable approaches. Information from these databases has already been used to adapt national legislation and regional health and nutrition measures resulting in improved satisfaction and more efficient resource allocation.

Discussion: Health and nutrition public health policies have to surpass resistance and financial barriers to be effectively applied. The use of comprehensive and comparable needs assessment data can facilitate raising public awareness and coordinating different services towards the achievement of improved outcomes.

115. In situ spectral sensing to support evidence-based risk assessment for food safety, traceability and authenticity

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In situ generation of chemical information for food products can enhance the risk assessment task performed for food safety, traceability and authenticity issues. Due to the recent development of advanced optics, different modes of molecular spectroscopy such as visible (VIS) and near-infrared (NIR) can be deployed rapidly and in real time. Even miniature sensors for molecular spectroscopy can be combined with smartphones to support data acquisition. Further, advanced chemometic analysis can be performed to derive conclusions from the data recorded by the sensors. The information provided by the techniques can be used to perform non-destructive classification and chemical composition estimation, which can potentially support rapid generation of evidence for assessing the risk for cases of food safety, traceability and authenticity. In the present poster, application of a miniature mobile phone operated NIR spectral sensor is presented for locating the geographic origin of green tea products originating from seven different parts of the world. It was possible to locate the geographical origin of the samples based on the NIR spectral signatures and chemometrics modelling. Furthermore, black cut–tear–curl (CTC) teas with known chemical profile differences could be classified using a hierarchy of similarities using the same sensor. In conclusion, miniature spectral sensors could support in *in situ* evidence generation for food risk assessment.

116. Increasing transparency with Knowledge Junction

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Open government data relates to the wide and free availability of public information created or collected by public entities. The availability of datasets to citizens improves the transparency and accountability of public institutions. Governmental promotion of the use, re-use and free distribution of datasets may result in an improved understanding of their work, the formation of new businesses and creation of innovative services. Food and feed safety organisations in EU Member States are at various stages of open government data adoption. The International Open Data Charter and the FAIR data principles (Findable, Accessible, Interoperable, Reusable) function to advance public understanding of the European Food Safety Authority's (EFSA) scientific work through the availability of scientific data to citizens.

EFSA is striving to move beyond existing data limitation rules. The publication of scientific data will allow EFSA to move towards an open by default approach. EFSA aims to employ a proactive publication process which publishes scientific outputs, related data and associated data in the Scientific Data Warehouse (SDWH), in line with the General Data Protection Regulation (GDPR). These will be available in Knowledge Junction (KJ), an open evidence community. KJ is a curated, open repository for the exchange of evidence and supporting materials used in food and feed safety risk assessments. In this repository, publications will be assigned a Digital Object Identifier to enable the identification, traceability and relatability of scientific outputs and datasets. The process of publication has already started in EFSA.

Public availability of datasets used in EFSA's scientific outputs will result in an improved public awareness, understanding and trust in EFSA's scientific work.

117.The meaningful vocabulary of EFSA: mapping its risk assessment activities through a text analysis of 3,744 Opinions issued by EFSA up to 2014

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Introduction: In 2014, EFSA commissioned an evaluation of the potential use of machine learning techniques (MLT) within EFSA's assessments. A specific aim was to classify the risk questions (RQs) asked to EFSA and identify the statistical techniques (ST) applied.

Materials and Methods: All 3,744 EFSA Opinions published up to 2014 were retrieved and converted into a dataset based on a dictionary of 15,475 words. Both Latent Dirichlet Allocation (LDA) and Correlated Topic Modelling (CTM) were used to create two separate sets of 20 topics, each of these built up of a cluster of 100 ranked words. Meaningful themes, as proxies of the RQs, were recognised by inspecting each topic. The two 20-topic outputs were compared through Spearman's rho to identify any overlapping. A vocabulary of statistical techniques was developed and used for further text mining and matching STs to RQs. Finally, how 12 main statistical approaches were used to address 10 main themes was investigated by a questionnaire to 49 EFSA staff from all Panels and Units.

Results: The combination of the LDA and CTM 20-topic series resulted in a total of 28 distinct main themes, easily recognisable within the remits of EFSA. The top-five themes were: MRL setting/revision; safety/efficacy evaluation of additives/ingredients; health claims evaluation; pesticides peer review; flavouring toxicity evaluation. In total, 829 EFSA Opinions showed the application of statistical techniques, with meta-analysis, ANOVA, benchmark dose methods, linear regression, ROC modelling, simulation methods, logistic regression, generalised linear models and dose–response models accounting for 80% of all statistical methods applied. The team-specific use of statistical approaches to address the main themes was shown through Sankey diagrams.

Conclusion: As an added value of the EFSA assessments, a large collection of texts was made available for further analysis: MLTs applied on such a large amount of unstructured text provided a fruitful insight of the EFSA assessment process.

118. Review of the national control plan

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The purpose of this study was to devise an action plan for a more risk-based implementation of the National Plan for Residues (NPR) (Directive 96/23/EC) to comply with the new Control Regulation ((EC) No. 882/2004). The study examines the extent to

which monitoring can be made more effective and efficient.

By developing a risk-based monitoring programme, current monitoring can be made more effective. Therefore three decision trees were created: (I) prohibited substances; (II) contaminants, natural substances and pesticide residues; and (III) substances authorised for veterinary drugs and feed additives. These decision trees can be used to classify substances, per type of animal, as having 'high', 'medium' or 'low' priority for inclusion in the NPR.

Moreover, the study examines whether current monitoring could be made more efficient by pooling samples. Calculations were performed on the basis of the current monitoring data and experiments with cattle urine enriched with β-agonists. Both the calculations and the experiments showed that, for some substances, up to five samples could be pooled, whereas a maximum of two samples could be pooled for substances whose detection limit is close to the legal limit.

The study also looked at the identification of emerging risks. An analytical approach to emerging risks is possible by using broad screening techniques, which also allow retrospective searches.

This risk-based monitoring plan has to be updated every year on the basis of acquired knowledge and analytical findings. Moreover, some of the monitoring has to be performed on a random basis to ensure that hazards are not overlooked. It is recommended that broad screening methods be used that not only detect prioritised substances but also have a broader focus, so that emerging risks can be detected.

119. Big data and food risk communication. Analysis of the online debate on fipronil using the web monitoring technique

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Fipronil is an insecticide that is banned by the European Union for food production for human consumption. However, in August 2017, 15 EU Member States were found to have imported fipronil-contaminated chicken eggs, as the substance had been illegally used in the production chain. The incident rapidly raised public health authorities' and consumers' concerns, which was matched with an abundant coverage of the event in the online media arena.

To this extent, web monitoring techniques and content analysis methods were used to analyse food risk communication about the fipronil incident. Based on a system of key words and rules, a web monitoring application was instructed to automatically monitor online sources (e.g. news websites, blogs, social network) and collect relevant contents referring to food risks, among which the ones dealing with fipronil were selected and analysed. Data on fipronil were gathered from July 2017 to February 2018. Data analysis defined: how much the fipronil incident was discussed online (numbers of relevant mentions); which online sources preferably talked about the incident; which aspects received major attention in coverage and online users' engagement; which figures (e.g. politics, research institutions, associations,...) were mainly mentioned in the online debate.

This study served to assess to which information online users have been exposed, possibly influencing risk perception and attitude towards the fipronil incident, and how much they engaged with. Results suggest that web monitoring techniques can be a valid tool to manage data referring to food risk communication, as they provide public health authorities with data and useful evidence-based insights to infer what happens in crisis communication and how it works.

120. SIGMA – EFSA comprehensive animal disease data collection

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Risk assessors are being asked to provide better technical support to risk managers in the field of animal diseases after limitations were identified during recent outbreaks of animal diseases in Europe. The European Food Safety Authority (EFSA) therefore decided to harmonise data collection activities related to animal disease outbreaks and disease surveillance. The result will benefit all involved stakeholders: EFSA will have high quality and up-to-date data, risk managers will get timely and robust scientific advice, Member States will be able to query the data they submitted, produce national reports, and have an overview of the European situation in 'real time'.

The foundation of this harmonisation process will be a unique EFSA Animal Disease Data Model as part of a project called SIGMA (σ-ADM). Once the σ-ADM is established, EFSA will work together with the Member States, as part of the SIGMA project, to improve and automate the flow of data from the national databases to EFSA's Data Warehouse. The idea is to automatically extract, upon agreement with the MSs, the relevant data and transform those data so that they match the σ-ADM. This approach means the Member States do not have to modify the way they work. The data will be then pre-validated by the data provider and uploaded to the EFSA Data Collection Framework (DCF) for analysis.

Engaging with society

121. DecodE – An integrated approach to improve awareness and aid transition to natural additives in collaboration with the food industry

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Recent studies indicate that consumers have a higher awareness of what they eat and are paying more attention to labels to consume healthier food. For food additives, there is still a high percentage of the population that does not understand their different classes, or origin (natural or artificial), along with many misconceptions. In line with consumer's volition to reduce the consumption of processed foods and their tendency to prefer them non- or minimally processed, the DecodE project aims to help clarify the mystification of food additives, helping consumers and the general public know the differences between them, their implications on food and especially, their impact on consumer health. Furthermore, DecodE also aims at helping the gradual transition from artificial to natural preservatives and colourants, with research being carried out on both topics. This is performed in close collaboration with pastries and bakeries to help substitute the artificial additives used in these industries, and create sustainable methods of obtaining safe natural counterparts to be gradually introduced into the market, so, reducing their drawbacks, namely stability, high obtainment cost and low efficacy. All this is carried out in an integrated framework based on the cumulative knowledge of the research centre where the project is being executed, the Mountain Research Centre in Bragança, Portugal (www.cimo.ipb.pt), supported by various researchers with expertise in different topics. One of the main focuses of the project is to be open to society, hence the open data strategy, to reduce the gap between scientific data and the public's knowledge of important aspects regarding their food.

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124. Food safety communication strategy in the Basque country

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The consumer perception on Food Safety depends mostly on the ways in which the information is received. Therefore, it becomes essential to establish a communication strategy carefully planned and based on a proactive and anticipatory focus.

In every situation, during current times or crisis times, the communication strategic guidelines must be oriented to answer WHAT, WHO, WHERE and HOW it is going to be performed. So, the coordination and collaboration of governments, food producers, consumers and other stakeholders along the food chain is needed to exchange information and knowledge.

In this paper, the work performed in the Basque country to establish a collaborative and joint strategy to face Food Safety Communication is presented. The methodology used has been displayed as workshops and seminars where several tools have been developed among the risks assessors, managers and communication coordinators, previously identified.

The steps as follows:

First of all, the food safety topics have been classified according to the risk origin, food related to and the public health effects, considering that the way of facing communication is different in each case.

In a second phase, an 'internal reply note' has been designed as a tool to identify all the relevant information on the topic and to agree on a common message to communicate. That note becomes a practical and useful tool to support the management of the communication in a crisis situation.

Finally, a communication protocol for crisis situations has been developed. This protocol helps to share information and to assess the crisis in a coordinated way by the risk managers.

Overall, the Food Safety Communication Strategy in Basque Country helps to prepare a unique and common message addressed to the Basque population to guarantee their trust and credibility on the food safety information received.

125. Media portrayal of GM food in the light of Brexit: a qualitative content analysis of British newspaper articles

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Genetically modified organisms (GMOs) are a controversial topic. In the past, the media has been implicated in shaping public attitudes to GMOs by sensational reporting and polarisation of the debate. This study examines portrayal of GM food in British print and digital newspapers in relation to reporting of Brexit negotiations. A qualitative content analysis has revealed an alignment between anti-GM food and anti-Brexit sentiment. It was unusual to find articles that were pro-GM food and anti-Brexit. GM food largely appeared in anti-Brexit articles and was often positioned alongside other controversial North American food manufacturing practices. So GM food carried negative sentiment in the context of a possible post-Brexit trade deal with the United States. Furthermore, articles which put forwards both pro- and anti-GM food arguments showed a clear contrast in the language used; anti-GM food sentiment tended to be expressed using hyperbolic language in contrast to the rational tone of pro-GM food writing.

These results show how GM food is still carrying negative connotations and, in the context of Brexit, is used to support political agendas.

126. Food risk and safety newsworthiness: comparing contexts and differently covered alarms

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Food risk is a well renowned issue in the media. Since the BSE crisis daily news has dedicated a considerable amount of coverage about food risk alarms. Nonetheless, not every single food risk case becomes a news story. Media theory about newsworthiness traditionally frames such a process of agenda setting. To deepen evidence about food risk and food safety it is necessary to go beyond the mere count of articles, namely to move further trend analysis about news coverage. Rather it is worth concentrating on features of a set of news about specific alarms. This is to try to understand how the risks that have been more covered are different – and about what – from those covered less. The poster relies on the comparison of narrative frames about the highly covered alarms (e.g. *Escherichia coli*) and less considered by the media (e.g. Anisakis). In the literature there are already attempts to define newsworthiness key points for food risk but still they need to be tested extensively on corpora. To this end, the analysis starts from the new project 'Food Media Monitor' deriving from the collaboration within the activities of TIPS project between the University of Padua and the University of Gastronomic Sciences. The analysis matches Italian and English daily press to add a further level of interest: international comparison to highlight different cultural frames about food risk and food safety.

127. Human biomonitoring – an essential tool for effective risk management: a case study from Cyprus

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Groundwater in Cyprus is a valuable natural resource for human consumption and as such is routinely monitored. In 2009, levels exceeding the permitted level of arsenic were found in the drinking water supply of a small community (legal limit: 10 µg As/L, found: 18–19 µg As/L), causing great anxiety and fear among inhabitants. The government took immediate action by terminating the water supply from the contaminated boreholes and supplying clean drinking water to the community. For effective risk management, the Ministers of Environment and Health mandated respective scientific committees to investigate the situation and support policy decision-making. The authorities were in close communication with the affected community throughout the investigation and an expert appointed by the inhabitants represented them in the scientific committees. The environmental committee found the pollution sources to be both natural (occurring in bedrock) and man-made (byproducts from animal farming, light industry). The medical committee assessed residents' exposure using toenail arsenic biomonitoring (statistically increased compared to a control community, but well below health-guidance values) and possible health effects by dermatological examination of a representative sample of residents (no pathologies found) and by comparing cancer incidence in the community to the rest of Cyprus (no increased incidence). The results were communicated by the Ministers at press conferences and directly to the inhabitants in visits to the community, giving the opportunity for discussions. A layman leaflet summarising the findings and giving related information was also distributed. The government announced that although no health effects were expected, the community would continue to be followed for possible future medical occurrences. Prompt governmental response, societal engagement

and solid scientific support of decision-making were instrumental to building citizens' trust in the authorities' risk management actions.

128. Consumer information on the prevention of microbiological risks: assessment of the effectiveness of communication strategies

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Almost one-third of foodborne outbreaks reported in France occur at home. Some of these outbreaks are related to improper food handling and preparation practices. Consumer information are needed to raise awareness of the foodborne diseases that may occur at home and on the measures that consumers can take to prevent them. In this context, ANSES was requested by the French food safety competence authority to provide a scientific opinion on the health and socioeconomic impact of different communication strategies aimed at consumers.

The collective expertise was conducted by a multidisciplinary working group including experts in social sciences, biological hazards and risk assessment. The working group addressed the request in two steps:

1. The identification of the hazard/food combinations that pose the greatest risk and for which preventive measures can be applied by consumers, as well as an inventory of relevant communication strategies. (Opinion of 9 May 2014_ https://www.anses.fr/en/system/files/BIORISK2012sa0118EN.pdf)

2. The evaluation of the effectiveness of communication strategies on foodborne risk reduction (Opinion of 14 October 2015_ https://www.anses.fr/en/system/files/BIORISK2012sa0118Ra-02EN.pdf), focusing on:

The identification of conditions and criteria of effectiveness for communication strategies on the prevention of biological risks.

The quantitative assessment of the health impact of a communication campaign on food handling (three case studies: VTEC/minced meat, *Listeria monocytogenes*/RTE food, *Campylobacter*/poultry meat).

The assessment of cost–effectiveness of communication campaigns (three case studies).

This work led to a prioritisation of various communication strategies in the area of prevention of food microbiological risks, taking into account the targeted populations, the complexity of the message and the cost–effectiveness of the campaign.

129. Consumer awareness in Greece of issues of antibiotic use and the risk of antimicrobial resistance in bacteria

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The prevalence of antimicrobial resistance (AMR) in medically significant bacteria is of increasing concern in the medical and wider scientific community. The challenge posed by AMR must be met on a number of fronts, including restriction on the use of antibiotics in animals and humans, research into new antibiotics and understanding the mechanisms and transmission of resistance. For the first, it is important that the public are informed of the issues surrounding AMR, as informed choice and appropriate use of antibiotics are responsibilities of individual patients as well as the prescribing doctors. To determine the level of knowledge about antibiotics and the practices adopted by private individuals in Greece, a survey questionnaire was developed and distributed as widely as possible via consumer organisations, professional bodies, educational establishments and social media. The survey questions were designed to obtain the following information: (1) demographic information; (2) antibiotic consumption and practice when taking antibiotics; (3) knowledge of general antibiotic use and regulation; (4) sources of information on antibiotics; (5) effect of knowledge of AMR on personal practice and choices; and (6) perception of the risk posed by AMR. Analysis of the data gathered by the survey will identify specific needs and omissions in the information provided to the public about the dangers associated with AMR and will facilitate the more responsible use of antibiotics by consumers.

130. Applying the World Café method to engage pregnant women in food risk communication

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The project piloted a participatory communication method designed to share knowledge on food risks during pregnancy and to frame communication

content to be disseminated among pregnant women. This group is considered to be more exposed to microbiological food risks and more vulnerable to contracting foodborne diseases that could be dangerous for the fetus. Therefore, it is essential to debunk the misinformation on food safety and provide pregnant women with reliable information.

Pregnant women were engaged through the World Café method, which focus on the dialogue among participants that stimulate self narratives and foster informal communication on practical issues related to daily life. The narrative approach was used as an investigation tool to understand behaviours and perception of risk in the involved group and as a learning tool, which allowed the analysis of experiences and the generation of new knowledge.

During the World Café, participants discussed on selected topics in small groups around the café tables and moved to a new table at regular intervals, so conversations were cross-fertilised with the ideas generated in former dialogue with other participants. At the end of the process, the main ideas were summarised and discussed in a plenary session with the involvement of scientific experts (microbiology, nutrition, gynaecology and infectious diseases specialists) who answered women's questions with information on how to prevent food risks.

The results of the World Café were used to select concise communication contents based on perceptions, behaviours and fact-finding needs of the target. These qualitative data were integrated with quantitative ones coming from an online national survey with a sample of both pregnant and non-pregnant women. The two groups' perception and knowledge were investigated to identify any differences in their level of food risks awareness.

As a result, a website (www.alimentigravidanza.it) and multilingual brochures were created and disseminated to promote correct food practices during pregnancy.

131. MaestraNatura: education programme to promote healthy nutrition habits and food safety in schools

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Promoting healthy diet, mainly in youth, is the most effective action to prevent and fight dietary excesses and nutrition imbalance in the population. Gender-related factors influencing lifestyle and exposition to risk factors seem to play major roles in the rising prevalence of obesity. Recent data show lower percentages of obese/overweight girls than boys in primary school. Girls consume less sugar-sweetened beverages and more fruit/vegetables. Food acceptance is a learned process that occurs through experiences. Children become familiar with food through exposure. The simple transfer of knowledge, in fact, is not enough for changing habits. It is so mandatory to define new effective strategies for nutrition education based on practical activities and improved engagement strategies.

'MaestraNatura' is an innovative nutrition education programme started from 2012 in six Italian regions involving about 100 schools, 1,000 teachers and 20,000 students (aged 6–13) and their parents. The aim was to fill the gaps in children's knowledge on nutritional issues overcoming possible gender differences.

The didactical contents on food, food origin and processing, food safety and questionnaires about dietary habits were distributed by a web platform. To check the transfer of the theoretical information contained in the food pyramid into practice, at the beginning and at the end of the didactical path, students were asked to organise daily menus for one week. The menus were scored allowing the statistical analysis of the results. Girls scored significantly higher than boys (T0 $F1,532 = 9.20$ $P = 0.0025$). This difference disappeared at the end of the didactic path (T1 $F1,471 = 2.96$ $P = 0.0861$), supporting the efficacy of the contribution. 'MaestraNatura' programme might represent a useful new tool for carrying out education intervention on nutrition and food safety among children, to reduce the gaps in knowledge and the gender influences on dietary choices.

132. Transferring food safety knowledge from university to society in Indonesia: challenges and opportunities

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The foremost common problem in the farmer or the small-scale food industry level in Indonesia is the lack of knowledge on good handling/manufacturing process and the food safety aspect. A university is an appropriate agent to overcome this issue as community service is one of the main duties of a university in Indonesia. Moreover, a university plays an important role in the development of science in a particular area. The Department of Food Science, Universitas Sebelas Maret regularly organises science and technology transfer to society, targeting the farmer or small-scale food industry through community service activity. This activity has been successfully carried out in many regions in Java, Indonesia with the main sponsor being the Ministry of Research Technology and Higher Education of the Republic of Indonesia. To achieve the objective of European Union development, knowledge transfer from university to society was carried out by consecutive steps: (1) introduction of good handling/manufacturing processes; (2) comprehensive training on food quality management systems; and (3) developing entrepreneurship skills. Implementation of food quality and food safety

management systems will certainly bring advantages for both the food producer and the consumer. However, in fact, the small-scale food industry might rule out the food safety aspect. This is because this aspect is also ignored by their potential consumer. Therefore, food safety education for both the producer and the consumer sides is highly important. We found that promoting food safety in small-scale industry should be carried out by considering the characteristics and the local knowledge of the society to ensure the success of food safety campaigns.

133. Lessons learned from a pan-European questionnaire on consumers' awareness and risk perception of antimicrobial resistance

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Antimicrobial resistance (AMR) and its impact on human health is of great concern and requires urgent attention. Awareness of this topic among the general population in Europe varies depending on country of origin and on the availability of specialised information via different means. A questionnaire-based study has been developed aimed at contributing, at a European level, to the overall awareness and the risk perceived by the general population with respect to the transmission of antibiotic-resistant bacteria from farmed animals and associated foodstuffs to humans. Consumers of different age groups (age 12–17; 18–34; 35–54; 55–74 and 75 years or older), different educational backgrounds, who might or might not be related to the health or food safety sectors, from different regions and areas of living, and with varied diets and household composition were invited to participate in the survey. An online survey as well as written forms of the survey were distributed to participants. The socio-demographic questions were designed to determine which factors may influence a respondent's answer or opinion. Each respondent was asked to complete the questionnaire by selecting the options that felt most appropriate for them. The main objectives of the questionnaire were focused on gathering information regarding the risk perceived on human health. More specifically, awareness of antimicrobial use, development of resistances, and the presence and risk of transmission of antibiotic-resistant bacteria to consumers via food and other reservoirs, were evaluated and the answers provided exhibited the channels through which consumers' perceptions were influenced. The information gathered will help to develop new strategies and policy agenda in risk communication at the European level, while increasing awareness in the use of antimicrobials among consumers.

134. We-Lab & We-Map: a School-Based Environmental Service Learning project. A virtuous model for bringing together educational stakeholders

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We-Lab & We-Map is a science-based educational project developed through a collaborative process among different stakeholders of the educational systems. The 2-years project involves:

Students from 35 schools of the province of Parma (Italy), scattered in the Parma River watershed. Each school has adopted an aquatic environment (canal, river, small lake or well) where nitrate concentration is measured using the educational platform We-Lab and an analytical method. Students monitor, analyse and map a key critical compound for the quality of water, strongly affected by land use, agriculture, animal farming and wastewater. They disseminate results through the creation of an open data map and public events for the local community.

The University of Parma (Department of Chemistry, Life Sciences and Environmental Sustainability) provides:

a method for on-site nitrate analysis, affordable, robust, safe to handle for students and usable with We-Lab;

scientific contents (cause–effect relationship altering the global N-cycle and environmental consequences);

training to teachers and students.

A local Small-Medium Enterprise (SME): DNAPhone srl provided We-Lab, the technological and educational platform employed for sample analysis and laboratory activities.

Some local no-profit organisations active at cultural and social level focused on youth intervention (Distretto cinema Parma, Gruppo Scuola Cooperativa Sociale and On/Off co-working space) that produce multimedia documentation.

A local banking foundation (Fondazione Cariparma), which has provided financial support.

We-Lab & We-Map represents an example of local action in wich stakeholders cooperate to promote

and disseminate scientific culture through the primary role of local schools. We-Lab & We- Map make students aware of concepts such as ecological footprint, sustainability and environmental monitoring. All stakeholders had the possibility to experiment on: innovative education approaches such as service learning and STEAM; citizen science; environmental and digital literacy; community engagement; and open data creation and access. We-Lab & We-Map has been awarded with 'Special mention' by the MIUR. It could represent a 'model approach' adaptable in multiple contexts and subjects and repeatable over larger areas such as the Po River Basin, a leading European area for food production provinces.

135. Eliciting consumers' preferences for risk communication strategies: a discrete choice experiment

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The communication of food safety and risk information to consumers plays an important role in public health policies. Studying how best to design effective communication strategies has been central to the policy makers.

A considerable amount of literature has investigated how effective public communication strategies should be [1–4]. These studies showed that, when designing communication strategies, it is critical to consider consumers' risk perceptions, risk attitudes, intentions and behaviours. However, most of the previous food safety interventions highlighted that risk communication strategies were designed around the findings of technical risk assessments without addressing factors that might influence consumers' risk perceptions. Some of these factors include consumers' preferences for how to be informed about risks, their understanding of risks and consequences of not mitigating such risks.

This study investigates consumers' preferences for communication campaigns regarding food safety risks and issues and how preferences vary with consumer characteristics and their food risk knowledge and perceptions. The data used for this research were collected via a web-based discrete choice survey. Employing probabilistic choice models, we analysed consumers' preferences, perceptions, food safety attitudes and decision-making processes. The results showed the heterogeneity in consumers' preferences and highlighted the need for designing targeted communication strategies for effective health outcomes.

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136. Risk communication strategies to support public participation in the GMO decision-making process

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Most countries provide for public input in the decision-making process on the use of Genetically Modified Organisms (GMOs). As a result, countries have developed and/or adopted risk communication strategies to support the active participation of the public. Such strategies not only facilitate the exchange of information and opinions on risk factors by regulators and decision-makers with the public and other stakeholders, but also help build trust in the resulting decision. In the developing world, however, most countries have yet to establish viable mechanisms for such public participation, therefore their knowledge of the GMO decision-making process and their potential role in it has been limited. In recent years, the International Centre for Genetic Engineering and Biotechnology (ICGEB) has provided risk communication training to a number of beneficiary countries, in which mechanisms and procedures to involve the public in GMO decision-making have been discussed and developed. This review describes key risk communication strategies comprising the description of standard administrative arrangements and examples of communication tools to enable public participation during the lodgement of GMO applications, processing of said applications and for making final decisions. Adopting these strategies into national biosafety regulatory systems may assist developing countries in the establishment of transparent, effective and reliable GMO decision-making.

Key words: biosafety, GMO decision-making process, public participation, risk communication

137. Social representations of food and risk in the public sphere

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Recently, nutrition has been linked to many interests: social, economical, industrial, commercial, political but also scientific. These are significant issues that concern public opinion and attract

media attention. In a society that revolves strongly around the media, it becomes relevant to observe how public discourse on themes such as food and nutrition is being shaped among the public sphere. In addition, the rise of several techno-scientific projects that concern the field of nutrition cannot help but suggest that nutrition is scrutenised, together with its symbolism, like a privileged object through which one can also observe the existing ties between science, technology and society. This study started by exploring the characteristics of the narrative of food themes and their presence in the public arena through an analysis of the main Italian daily newspapers. One former longitudinal analysis in the time-span 1992–2013, found – through an innovative tool of textual analysis (topic detection) – the presence of some emerging themes. Next, we shifted our attention to the later period (2010–2016), with the aim to focus on most recent events and to verify whether media discourse on food and nutrition had gained new relevance or forms within the media agenda and in the public discussion. Furthermore, I wished to test the 'Mazur's hypothesis', and sought to identify a relationship between media coverage and the attitudes of the public opinion by adopting a 'risk indicator' and the data from certain European surveys.

138. Social media responses to probiotics and GM foods – a chronological and cross-cultural analysis

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Technological advances in the food industry during the 21st century have been accompanied by the rise of social media as a channel of communication and influence. This has led to new challenges for a sector in which the successful translation of innovations is highly dependent on public attitudes. Such attitudes are also shaped by the socio-political and cultural context in which science takes place.

We investigate these co-dependencies by chronicling the evolution of consumer sentiments on social media related to two food innovations: genetically modified (GM) foods and probiotics. While both derive from advances in biotechnology, public responses to them have been markedly different.

Even though GM foods have been endorsed by the scientific community for safety and global sustainability, demand for products labelled 'non-GMO' have spiralled from $12.9 bn. (2012) to $21.1 bn (2016), reflecting widespread public scepticism. Contrastingly, public confidence in probiotics products continues largely unhindered despite inconclusive scientific evidence surrounding the health efficacy of these products. This is illustrated in the growth of the probiotics segment – from US$30.4 bn. (2010) to US$39.9 bn. (2016) – in the global retail market.

Drawing upon theories from communication and public trust in science, we unpack this paradox by analysing GMC and probiotics-related narratives over the past decade from Twitter, Facebook, Instagram and food blogs. Our investigation seeks answers to the following questions:

RQ1) How have consumer sentiments and emotions associated with GMC and probiotics shifted over the past decade?

RQ2) Which key stakeholders or events have markedly influenced the direction of social media sentiment?

RQ3) Which are the key demographic and interest groups engaged in relevant social media conversations?

RQ 4) In what ways do these patterns differ between the USA, UK and Singapore?

The findings of this study will be used to inform public engagement strategies around food policy, marketing and consumer safety.

Biological hazards

139. The overview of a Trichinella outbreak in Cajetina, Serbia, 2016

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Background: Trichinellosis is a disease caused by *Trichinella*, which belong to the group of zoonoses. A trichinellosis disease outbreak in Cajetina was discovered on 22 January 2016 when a hunter from Cajetina was hospitalised at the infectious department of the General Hospital in Uzice under suspicion of trichinellosis. The patient had consumed dried wild boar meat in late December 2016. During the outbreak, 300 people consumed infected meat, sausages and ham from two wild boars and a deer.

Methods: For the analysis of the outbreak, the descriptive epidemiological method was applied. We described the basic clinical and epidemiological characteristics of the patients as well as the most important results of the epidemiological–epizootiological research of this outbreak. The survey instrument was an epidemiological questionnaire.

Results: In Uzice General Hospital, since the detection of the outbreak, 273 people had been examined and 120 of them were reported as infected. In Uzice General Hospital there were 19 hospitalised patients (14 adults and 5 children). The mean age of the patients was 32.3 years, ranging from 3 to 64 years. Male to female ratio

of cases was 1.75:1. The diagnosis was based on the epidemiological data, clinical and laboratory findings. *Trichinella britovi* was identified using multiplex PCR at the National Laboratory for parasites.

Conclusions: The way of transmission in this outbreak was eating sausages and hams originating from wild pork infected by *Trichinella britovi*. Trichinoscopic examination (digestion method) of each slaughtered boar's meat and the underlying thermal processing of meat and meat products prevents the infection. For the prevention of similar outbreaks, it is highly important to improve knowledge of people working on the preparation food about the risk of foodborne diseases.

140. Monitoring of resistance genes in Listeria monocytogenes isolates and their presence in extracellular DNA of the biofilm

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The alarming occurrence of antibiotic resistance genes in food production demands continuous monitoring world-wide. One reservoir of resistance genes is thought to be eDNA. There is currently little available information in Europe about either the extracellular DNA distribution of the bacterium or the spread of resistance genes. Therefore, our aim was to give insight into the *L.* monocytogenes resistance situation in the Czech Republic and assess the presence of resistance genes in their extracellular DNA (eDNA). First, susceptibility tests were performed on 49 isolates of *L. monocytogenes* with selected antibiotics. Next, we tested the DNA of suspected isolates for the presence of resistance genes in both planktonic cells and the eDNA of biofilms. Finally, fluorescence confocal microscopy was used to observe the eDNA pattern of selected isolates under conditions that mimicked the food processing environment and the human body. Susceptibility tests found isolates with intermediate resistant to chloramphenicol, tetracycline and ciprofloxacin as well as isolates resistant to ciprofloxacin. For all suspected isolates, PCR confirmed the presence of the gene *lde* encoding an efflux pump in both types of DNA. The presence of an efflux pump in both types of DNA suggests that the eDNA might serve as a reservoir of resistance genes. Our results suggest that the current risk of the spread of *L. monocytogenes* resistance genes is low in the Czech Republic, but they also indicate the need for continuous long-term monitoring of the situation.

141. Risk assessment of Listeria monocytogenes in dry-cured ham: a tool to assess the compliance with the Listeria zero policy.

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The present study aimed to develop a QMRA model of *Listeria monocytogenes* in dry-cured ham. The study included the modelling of the behaviour of *L. monocytogenes* in Serrano and Iberian dry-cured ham as a function of the water activity (aw) and storage temperature through challenge testing.

Sliced ham was inoculated at ca. 6 log cfu/g with a four-strain *L. monocytogenes* isolate (serotypes 1/2a, 1/2b, 1/2c and 4b), vacuum packaged and stored at 2, 8, 15 and 25°C for up to 6 months. The pathogen was periodically enumerated on Chromogenic *Listeria* Agar. The Weibull model was used to estimate inactivation kinetic parameters. The impact of temperature and aw was modelled using a polynomial equation. A QMRA model was built from data distributions obtained from manufacturers, regarding initial pathogen concentration, aw and storage time/temperature.

Dry-cured ham did not favour the growth of the pathogen but exerts a temperature – and aw-dependent bactericidal effect, suggesting the potential interest of designing risk minimisation strategies based on the non-thermal inactivation in the final product.

According to the developed QMRA model, the estimated probability of listeriosis due to the consumption of dry-cured ham is very low (in the order of 1·EXP-14 and 1·EXP-12 cases/serving for healthy and susceptible population, respectively), corresponding to the 'Very Low Risk' cluster of foods established by the risk assessment published by FDA/USDA in 2003. However, from the industrial sector point of view and regarding the compliance of regulations derived from the zero tolerance policy for L. monocytogenes, the concern is related to the non-negligible probability that the pathogen is present at detectable levels. To minimise this risk, producers can assess the application of different strategies either focused on the minimisation of the contamination or the application of post-lethality treatments.

142. A semi-quantitative model for ranking the risk of incursion of exotic animal pathogens into Europe

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Several risk ranking methods have been developed to prioritise the impact of exotic animal diseases in a specific EU MS country/area (i.e. effects on animal health, welfare or trade consequences). Such tools are used to assist risk managers in optimising the allocation of available resources for the prevention and control of infectious diseases. However, few models focus on prioritisation methods on the probability of entry of an exotic pathogen into a territory (Roberts, 2011). To fill this gap, we have developed a multicriteria model to estimate the probability of incursion of an exotic pathogen into a European country. The tool uses a score system method and it has been developed using Italy as a case study. A selection approach, taken from the EU SPARE project (using Shiny app), has been applied to produce a list of infectious diseases that are non-endemic in Italy and subject to OIE notification. We divided the world into different areas and used OIE data to allocate to them a 'disease status' for each of the selected diseases (i.e. endemic, absent…). Then, we identified several possible pathways for a pathogen introduction (i.e. animal trade, vectors…) and we defined the relevant factors for each specific pathogen. Import trade data regarding animal and animal products were collected to estimate the potential likelihood of entry of the different pathogens through an associated commodity as well as information about people and wild animal movements which can be routes of introduction of some pathogens. Finally, an algorithm is proposed to calculate an overall risk score for each pathogen. The results can be used by official authorities to strengthen the border surveillance towards those pathogens with higher probabilities of entry.

143. The relevance of stress adaptation for risk assessment. Comparison of the resistance of two bacterial strains to survive dynamic thermal treatments

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Quantitative microbial risk assessment relies on an accurate description of the bacterial response to the environmental conditions during the farm-to-fork cycle of the food product. This includes the modelling of the microbial inactivation during processing. The possibility for bacterial cells to adapt to the stress, increasing their resistance, has been reported by several authors (e.g. Hill et al., 2002; Richter et al., 2010). This adaptation may be developed because of a short sublethal stress (such as a heat shock) or during a dynamic heat treatment, if it starts with a slow heating phase.

A mathematical model was recently developed to describe such a situation (Garre et al., 2018). This model allows the clear differentiation between the static thermal resistance (the one due to the instantaneous temperature without taking into account the heating history of the cells) and stress adaptation. It has been used to describe the inactivation of two different strains of *Escherichia coli* (K12 MG1655 and CECT 515) during mild dynamic inactivation treatments. The results of this investigation show that, although strain K12 MG1655 has a higher resistance to isothermal treatments, strain CECT 515 is able to adapt better to the thermal stress. As a consequence, strain CECT 515 is more resistant for thermal treatments allowing for the development of stress adaptation.

This result is especially relevant for microbiological risk assessment, in which the calculations are usually limited to a handful of bacterial cells considered as the most resistant. This selection is usually performed according to the bacterial resistance to isothermal treatments; i.e. without any consideration for the stress adaptation. The results of this investigation show that this criterion may lead to the selection of bacterial strains which are not the most resistant to the particular treatment considered.

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144. Microbial quality and safety of raw edible house crickets (Acheta domesticus)

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Entomophagy is a growing in western countries where insects have not been traditionally used as food. Since January 2018, edible insects are regulated under the novel foods Regulation (EU) 2015/2283. Despite their inclusion as novel foods, there is a lack of EU hygiene legislation regarding edible insects. However, a few EU countries such as Belgium and the Netherlands have presented specific microbial hygiene criteria recommendations. This lack of common regulatory framework within Europe is explained by the lack of data available regarding microbial loads in edible insects. Comparative evidence might be derived from studies of insects belonging to different species or reared under completely different conditions (e.g. field-collected insects). Moreover, insect's biodiversity is huge with species estimations ranging from 2.6 to 7.8 million and reinforcing the idea that microbial criteria for one species should not be presumed suitable for another species.

House cricket (*Acheta domesticus*), previously used as pet food, represents one of the reared insects with more potential for human consumption. In the present study the microbial load and microbiome of *Acheta domesticus* from Sweden that was feed with eight different feed based on red clover (Trifolium pratense), will be studied by using culture-dependent and high-throughput sequencing (HTS) approaches.

To assess the food safety and microbial quality of edible crickets, they will be analysed for *Salmonella*, *Listeria monocytogenes* (qualitative methods), *Clostridium perfringens*, Total Aerobic Counts (TAC), Enterobacteriaceae, yeasts and moulds (quantitative methods). Preliminary results on edible raw crickets showed TAC and Enterobacteriaceae microbial loads ranging from 7.9 Log CFU/g and 7.0 Log CFU/g, respectively. None of the samples were positive for *Clostridium perfringens* (<1.0 Log CFU/g). The high observed microbial loads on raw edible crickets suggests the need of a heat treatment before consumption both to control food pathogens and spoilage flora and extending the shelf life. These findings highlight that specific microbial hygienic criteria for reared crickets should be considered.

145. Comparison of different multicriteria decision analysis algorithms for prioritising emerging zoonoses

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Decision-making in food safety is a complex process, which involves several factors of different nature such as the expected reduction in the number of illnesses, the potential economic cost, the environmental impact or others. Multi Criteria Decision Analysis (MCDA) algorithms have been developed to help decision-making process by ranking different options in a multifactorial environment. Initially, MCDA algorithms only allowed to rank the different options using the expected value of the factors considered. However, uncertainty and variability play an important role in MCDA, especially in microbial risk assessment (Nauta, 2000). So, algorithms have been developed (usually based on the application of fuzzy sets) to consider uncertainty and variability in every factor.

The aim of the present work is to investigate which MCDA algorithm might be used to support food safety decision-making process in a multifactorial environment. To undertake this, a dataset published by Havelaar et al. (2010) ranking emerging zoonoses in the Netherlands according to various criteria (probability of introduction, transmission between animals, economical damage, transmission from animals to humans, transmission between humans, morbidity and mortality) is analysed. Havelaar et al. (2010) devised a multicriteria decision analysis (MCDA) algorithm, able to account for uncertainty and variability, specifically for this dataset. We compare their results against those obtained using other algorithms extensively used in the MCDA literature: MMORA, TOPSIS, VIKOR, WASPAS and ELECTE. All of these algorithms are able to take into account uncertainty and variability, or to perform the calculation using expected values.

The results show differences between the rankings calculated using each algorithm. The results provided by the WASPAS algorithm are the closest to the ones calculated by Havelaar et al. (2010) (correlation coefficient 0.89), whereas VIKOR presents the highest discrepancies (correlation coefficient 0.55). Furthermore, the relevance that uncertainty and variability have on the ranking is demonstrated.

146. Real-time PCR development for Anisakis larvae quantification in commercial fish

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Through food supply chain, humans are exposed to a variety of foodborne zoonoses, seafood has been reported to be parasitised by *Anisakis* in the major part of oceans and seas around the word, which could represent a hazard to consumers due to larvae L3's ability to cause gastrointestinal symptoms and allergic reactions. A SYBR Green qPCR-based protocol was validated to quantify the number of *Anisakis* larvae in commercial fish using a mathematic model, avoiding the visual inspection. Fillets of hake were verified for *Anisakis* absence by visual inspection and qPCR. Samples of 15 g of *Anisakis*-free fillets were experimentally contaminated and homogenised with different number of A. simplex (s. l.) L3 larvae. DNA extraction was performed employing the Wizard Genomic DNA Purification Kit. An *Anisakis*-specific SYBR Green qPCR assay was performed, using a pair of primers previously described which amplify a fragment of the mitochondrial cytochrome c oxidase II gene. The results showed a logarithmic behaviour, which allowed to obtain a mathematic model to estimate the number of larvae in samples of unknown parasitisation samples using the Cq value of the sample. Furthermore, 42 specimens of blue whiting, purchased at the supermarket in Barcelona, where analysed by visual inspection and using the developed SYBR Green qPCR technique, the correlation analysis revealed the high concordance between both methods (R2 = 0.92). The developed assay is able to ensure the Anisakis absence and to quantify with enough accuracy from one to 35 larvae, including the detection of traces (CV = 3.39%), which avoids false-negative results. The optimised SYBR Green technique for Anisakis larvae quantification could be used not only in the food industry but also for research centres and the public health prevention programmes, contributing to improve the safety and quality of fish products.

147. Listeria monocytogenes – health advice for pregnant women and vulnerable groups

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The Norwegian Food Safety Authority (NFSA) provides health advice to different groups and is revising health advices given to pregnant women and vulnerable groups on *Listeria monocytogenes*. To support the revision NFSA requested an assessment from the Norwegian Scientific Committee for Food and Environment (VKM). To specify their request the NFSA divided it into the four product groups they wanted assessed: fish and seafood, meat products, cheese/dairy products and vegetables. All food groups were further divided into subgroups. Ready-to-eat (RTE) products were not grouped separately, but were to be assessed within the four product groups.

In addition, the Norwegian Food Safety Authority wanted an assessment of the effect of various measures that the consumer can take: storage at refrigerator temperature <4°C; eating the food early in the shelf life period; avoiding food leftovers kept in the fridge for several days; only eating small amounts of the food; choosing products with additives/modified atmosphere that reduce growth of *Listeria*; heating the food before consumption (criteria for good heat treatment); and reducing the storage time for leftovers in the refrigerator.

VKM has prepared a quantitative assessment of exposure to *L. monocytogenes* from fish, meat and cheese/milk products using Food Safety and Spoilage Predictor (FSSP), while vegetables were assessed qualitatively.

148. Understanding prophylactic usage of antimicrobials in British sheep flocks at the time of lambing: results from a large-scale survey

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The largest annual amount of lamb meat produced in Europe originates from extensive, grass-based systems located in the United Kingdom. Low record keeping traditionally associated with these farming systems was recently brought to attention due to the raising concerns on antimicrobial resistance in livestock production. Although believed to be lower than in pig and poultry industries, there is currently little knowledge on antimicrobial usage (AMU) in sheep farming. This study aimed at building evidence on prophylactic usage of antimicrobials during lambing time, which is considered a period with higher risk for AMU.

A survey on farm characteristics, antimicrobial usage and flock productivity was distributed among 740 commercial British sheep farmers during summer 2016. The Kruskal–Wallis statistical test was used to explore associations between prophylactic antimicrobial usage and flock characteristics, and a multivariable linear regression model was built to analyse the relationship between antimicrobial usage and flock productivity while controlling for confounders.

More than one-third of the surveyed farmers (35%, 259/740) administered spectinomycin orally and prophylactically to new-born lambs, and 7% (32/431) administered amoxicillin or penicillin parenterally. Using antibiotics prophylactically did not provide an additional advantage in relation to flock productivity (no significant association between prophylactic antimicrobials usage and flock production in multivariable analysis ($P \geq 0.05$)). Farms where lambs were administered antibiotics prophylactically had a significantly lower median flock size than farms not providing them (470 and 616 ewes, respectively ($P \leq 0.05$)). No association was found between farm region and prophylactic use of antibiotics during lambing.

These results suggest that prophylactic usage of oral antimicrobials in neonatal lambs is relatively common and that smaller flocks have a significantly greater prophylactic AMU. Importantly, the products used are not are not classified as critically important antimicrobials. Promotion of alternative disease prevention practices such as better hygiene and vaccination may aid lowering AMU in sheep flocks.

149. Raw milk in vending machines – results Austria 2017

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AGES

In Austria an increasing trend for organic products and purchase of raw products from local producers is recognised. Raw milk is sold on farm, by vending machines or delivered locally. Most of the consumers lack of fundamental knowledge on pathogens and do not link them to raw milk. Supplementary to EU regulations (No. 178/2002, etc.) the 'national raw milk regulation' dictates a clear warning 'raw milk, to be boiled before consumption' on the vending machine or in the salesroom. Additionally the aerobic mesophilic total plate count (TPC) of 50,000 CFU/ml must not be exceeded. Samples with detected pathogens are deemed as 'injurious to health' only if no warning is in place.

Official controls of 74 vending machines were performed in July/August 2017. TPC, identification of pathogens (VTEC, *Campylobacter*, *Salmonella*, *Listeria*) and detection of quaternary ammonium cations (Quats) have been performed. Additionally specific attention was given to labelling and warnings at the vending machine.

Conformity assessment indicated accordance to all regulations for 38 vending machines, including their raw milk samples. The TPC of 22 samples (29.7%) exceeded 50,000 CFU/ml, with a maximum of 1.8×10^7 CFU/ml. *Salmonella dublin* and *Campylobacter jejuni* have been detected once whereas two samples contained Verotoxin producing *E. coli*. No *Listeria* could be isolated. In two samples the limit of detection was exceeded for Quats.

The General Food Law indicates whether any food is unsafe, the normal conditions of use by the consumers should be regarded – which might be the consumption of raw milk as raw milk.

Nevertheless the following clause refers to available information. Interpretation Article 14 could be reconsidered, but further education of the consumer has to be encouraged for this increasing trend. Pathogens and the education of consumers will stay relevant in our changing world.

150. First comprehensive study on West Nile in Former Yugoslav Republic of the former Yugoslav Republic of Macedonia (FYROM)

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In the last decade recurrent outbreaks of West Nile Disease were reported in humans and animals in Balkan areas, including FYROM. To investigate virus spread in this last, during 2017 a comprehensive study (aimed to define the risk assessment for WNV in FYROM) was conducted by IZS dell'Umbria e delle Marche in collaboration with the Institute of Public Health, Faculty of Veterinary Medicine and Food and Veterinary Agency, that have provided all WNV data available in the country. The study was performed in the contest of the EU twinning project 'Further development of competent authorities control systems to protect the human, animal and plant health'.

On the basis of data provided from IPH, from 2011 to 2017, 22 human cases of WND were notified in FYROM the majority of which (81.8%) without a recent story of travel abroad; 50% of cases showed neurological signs and three patients died (all in 2012). No systematic information about WNV lineages are available, although lineage 2 is the most probable.

Regarding WNV surveillance in animals, during 2011–2012 an active sero-surveillance plan was implemented in domestic birds highlighting viral circulation also in animals with 5.6% and 3.2% of birds and horses tested positive for IgG Ab. All analysis were performed in the laboratory of the FVM.

Finally, the mosquito population in the country was investigated using both adults traps (CDC light traps BG sentinels), ovitraps and larval stages captures confirming the presence of *Culex pipiens*, the main vector of WNV. Serendipitously, presence of adult *Aedes albopictus* was confirmed for the first time in FYROM raising a lot of concern due to his competence for many viral diseases.

In conclusion, due to wide circulation of WNV in the country in the presence of a competent vector, a systematic surveillance plan involving birds and equids is strongly suggested.

151. A predictive model for survival of Escherichia coli O157:H7 in manure-amended soil

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Untreated biological soil amendments of animal origin (BSAAO), such as raw bovine manure and poultry litter, are known reservoirs for enteric pathogens such as *Escherichia coli* O157:H7 and *Salmonella*. Once introduced into the soil through the application of untreated BSAAO, these pathogens have been shown to survive and may contaminate fresh fruits and vegetables growing in or near the contaminated soil. Characterising the impact of agricultural and environmental factors on survival of enteric pathogens in untreated BSAAO-amended soil is an essential part of understanding public health risks associated with application of untreated BSAAO. The aim of this study was to develop a predictive model to characterise the relationship between a variety of agro-ecological factors and changes in populations of *E. coli* O157:H7 in manure-amended soil under dynamic environmental conditions. We developed and validated a Random Forest model using data from a longitudinal study investigating the survival of *E. coli* O157:H7 in BSAAO-amended soils. Initial inoculation level, days post-inoculation, soil moisture content, and cumulative rainfall since the last sampling day were identified as the most influential factors impacting the *E. coli* O157:H7 concentration in amended soil. The Random Forest model outperformed direct data fitting using classic log-linear and Weibull survival kinetics models when observed data showed non-linearity and fluctuations due to pathogen growth or regrowth. With available data, the modelling framework reported here can also be adapted for similar enteric pathogens such as *Salmonella*.

152. Safety evaluation of an innovative fermented nut-based product

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The set-up of a new food requires the study of the biological risks associated to the product and the implementation of strategies to avoid or reduce these risks. The present study started from the characterisation of a fermented nut-based vegan food produced under domestic conditions. Lactic acid bacteria (LAB) responsible for the natural fermentation process were identified, revealing a succession of hetero- and homo-fermentative species during fermentation. Some autochthonous strains isolated from this product were then used, in combination also with other commercial LAB strains, to reproduce the domestic process at industrial level. Before commercialisation, the definition of risk points was fundamental and the set-up of microbial challenge test to define the safety aspects associated to this new fermented product was necessary. Given its characteristics, the major risk could be associated with the presence of Enterobacteriaceae (in particular, *Escherichia coli*) and *Listeria monocytogenes*. Therefore, these pathogens were deliberately inoculated in the nuts at the beginning of the process together with different mixtures of autochthonous or commercial LAB starters. The results showed that the fermentation could contribute to inhibit *E. coli* and *L. monocytogenes* proliferation, depending on the LAB starter used. Not all the starters were able to counteract the pathogens because the accumulation of organic acids did not allowed to reach a pH value below 4.4, considered a safe threshold for *L. monocytogenes* (EU Regulation 2073/2005). The use of strains endowed with antimicrobial activity resulted in a reduction of L. monocytogenes cell counts from the earliest phases of production.

This study allowed the set-up of a guided vegan 'cheese' fermentation process, where the main biological hazards were controlled through a proper and rapid acidification (able to inhibit Enterobacteriaceae), combined also with strains exerting antimicrobial activity against *L. monocytogenes*.

153. Campylobacter jejuni food isolates harbouring different types of tetracycline resistance

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Tetracycline resistance in *Campylobacter* food isolates is quite common. Most *Campylobacter* isolates harbour *tetO*, a gene coding for a ribosomal protection protein. Epidemiological resistance to tetracycline in *Campylobacter* is defined by an harmonised epidemiological cut-off value of 1 mg/L in Europe according to EUCAST. Most resistant isolates display resistance to 64–128 mg/L tetracycline. Here we describe two isolates of *C. jejuni* (named FC77 and FC88) isolated from chicken meat harbouring a functional *tetO* coding sequence, but expressing tetracycline resistance below the

epidemiological cut-off value. For detailed analysis, both isolates and a high level tetracycline-resistant isolate of *C. jejuni* (GC119) were sequenced by whole-genome sequencing using Illumina technology.

Genome assembly was conducted using the INNUca pipeline, followed by genome annotation using prokka (v 1.12). Detection of antimicrobial resistance and virulence genes was performed using ABRicate (v 0.8) bundled with CARD, Resfinder, ARG-ANNOT, NCBI and VFDB databases.

The assembled genomes have between 29 and 36 contigs, representing a genome sequence length between 1.73 and 1.75 Mbp. All isolates have between 1,791 and 1,814 coding sequences, 40 tRNAs, two rRNAs and one mRNA; *tetO* was identified in all three isolates by the multiple databases used. The Resfinder database showed that the *tetO* gene of isolate GC119 is 99.53% similar to the *tetO* described for *C. jejuni* (GenBank: M18896.2), while the *tetO* of FC77 and FC88 is 99.64% similar to the *tetO* gene of *Streptococcus pneumoniae* (GenBank: Y07780.1) which harbours a truncated form of the promoter region. Nevertheless, there is transcription of the gene in both isolates as detected by RT-PCR.

Although using the current epidemiological cut-off value for *C. jejuni* these strains would be considered susceptible to tetracycline, the presence of a functional gene encoding resistance to this antibiotic may challenge this definition and appeal to its reconsideration.

154. Foodborne illness control by using marine bacteria

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Nowadays, a common problem for both developed and developing countries is represented by foodborne pathogenic bacteria. Among the most dangerous include *S. aureus*, *E. coli*, *Listeria monocytogenes*, *Campylobacter* sp., *Salmonella* sp. and to make the situation worse, many strains become resistant to most of the common antibiotics released on the market. Although a good food safety practice is necessary to prevent the spread of foodborne bacteria, new antimicrobials are needed to fight and control this threat. During the last years, the sustainable exploitation of natural products derived from marine microorganisms demonstrated to be a promising strategy to obtain new bioactive compounds for biotechnological applications. In this work we showed the strong antimicrobial activity of an extract produced by a marine bacterium, towards a wide panel of foodborne pathogenic bacteria. A double approach, which include metagenomics and classic isolation techniques, was applied as part of '1st EMBRIC Transnational Access programme'. The producer strain was isolated, among others, during a sampling campaign in Ria Formosa lagoon (Faro, Portugal). A rapid antimicrobial screening in multiwell plates was developed identifying 10 bacteria able to inhibit foodborne pathogenic strains. The most active, named *Pseudomonas* sp. 8C, was cultivated under different conditions, extracted by organic solvents and the obtained extract submitted to liquid inhibition assay. The results showed a high antimicrobial effect against *S. aureus*, *P. fragi*, *E. coli*, *C. jejuni* and *L. monocytogenes* with a Minimal Inhibitory Concentration range between 20–90 µg/ml. The promising results of the crude extract will lead to further investigation, which will involve the purification, isolation and identification of the compounds responsible for this bioactivity. This work confirms the great potential of marine microorganisms in foodborne illness control.

155. Antimicrobial resistance of broilers in Bulgaria in 2014 and 2016

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Results of the implementation of the Commission Decision on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (2013/652/EU) in broiler production in 2014 and 2016 in Bulgaria are presented. Samples from broiler caeca were collected from single epidemiological units in all slaughterhouses in Bulgaria. The numbers of tested caeca samples in 2014 were 412 and in 2016 were 442. In 2014, 85 commensal *Escherichia coli* and 110 *Campylobacter jejuni* isolates were tested and reported to EFSA. In 2016, 111 commensal *Escherichia coli* and 55 *Campylobacter jejuni* isolates were tested and reported to EFSA. In 2016, all 442 caeca samples were tested for ESBL/AmpC/carbapenemase-producing *E. coli* and 123 of these were positive. High levels of antimicrobial resistance in *E.coli* isolates against ampicillin (76.6%), tetracycline (68.5%), sulfamethoxazole (79.3%) and cyprofloxacinae (86.5%) were detected. A high percentage of multidrug-resistant isolates were found. In total, 27.8% of caeca samples were positive for ESBL/AmpC/carbapenemase-producing *E. coli*. A high level of resistance of *C. jejuni* against ciprofloxacin (85.5%) and tetracycline (43.6%) was detected. The data for antimicrobial resistance of *C. jejuni* and *E. coli* from caeca samples are discussed.

Key words: antimicrobial resistance, Escherichia coli, Campylobacter jejuni, antibiotics

156. Intestinal health problems in broilers in Belgium; risk factors and preventive measurements

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Objectives: Intestinal health problems and wet litter are the main indicators for antimicrobial usage (AMU) in the broiler industry. The first goal of this project was to determine the prevalence of dysbacteriosis (DB) in broilers in Belgium. Followed by the identification of risk factors and protective factors for the development of DB or aspecific intestinal health problems. This will lead to a more objective diagnosis and specific treatment of intestinal health problems in broilers.

Methods: First, 50 broiler farms were randomly selected. Farm-specific information was collected on technical results, AMU and biosecurity. On 10 broilers (age 28 days) necropsy was performed. Macroscopic lesion scoring for DB (Teirlynck et al., 2011), coccidiosis, presence of crop filling, hock burns and footpad lesions and collection of intestinal segments was executed. Also water, feed and litter samples were collected. In the second study, 20 farms were followed during five visits in one production round. Each visit, necropsy was performed on 10 animals to score for DB and coccidiosis. On day 28, the same data and samples were collected as in the study described above.

Results: Preliminary results show no significant correlation between footpad lesions, hock burns or crop filling and the DB score. A significant association was found between gender and the DB score. Also analysis showed that some parameters have only little influence on the total DB score. A strong and significant correlation was present between the DB score on D10 and the score on D20. Dysbacteriosis and coccidiosis show a significant correlation in the animal until about 3 weeks of age.

Conclusion: The macroscopic lesion scoring is the only method to diagnose DB, this study shows that this method is very subjective and an objective method is needed. This study also points out that screening of broilers on an earlier age for dysbacteriosis can be indicative for the further development of the disease, making it possible to ensure a more adequate approach.

157. Understanding swine veterinarians' treatments decisions by unravelling the complexity of the swine health system

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Given the public health threat posed by antimicrobial resistance, voluntary and mandatory policies have been developed to reduce antimicrobial usage (AMU). To enforce these, the veterinarian plays a crucial role by providing farm-specific advice. However, there are other private/public people and institutions, all part of the swine health system (SHS), that influence the veterinarians' advice and treatment decisions. Understanding the functioning of the SHS is crucial to identify incentives and barriers for implementing policies to reduce the AMU. To understand the functioning of the SHS in Flanders (northern part of Belgium), we used a systems thinking approach. To that end, qualitative interviews were held with 33 relevant stakeholders such as veterinarians (18), pig farmers (10), and others (5). The themes emerging from the thematic analysis were analysed by using a structural, functional and transformational analysis by which the SHS merits and failures were identified. A remarkable merit is the synchronisation of sector's agreements and policies to reduce AMU in the pig sector. Nevertheless, several systemic failures were observed such as the tradition that veterinary advice is provided for 'free' by feed mill companies, and the shortage of farm production data. Both failures may hinder swine practitioners to provide integrative advice. The fact that the sale of medicines is the largest constituent of veterinarians income constitutes a conflict of interest when veterinarians advise treatments (e.g. vaccines, antimicrobials). As a result farmers distrust often veterinarians vaccination advice. On a positive note, veterinarians and farmers suggested alternatives to the traditional business model. However, the broader institutional and socio-cultural environment does not facilitate this evolution. Our findings provide information on barriers and incentives influencing the implementation of policies and can aid policy makers and risk managers to anticipate the effects of their proposed policies, so that they can be fine-tuned before being enforced.

158. Antimicrobial resistance of E. coli and Salmonella in broiler chicken along the food chain in Canada

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Antimicrobial resistance is a major global public health threat today. The main purpose of this study was to determine antimicrobial resistance in generic *E. coli* and *Salmonella* from broiler chickens and broiler chicken meat along the food chain (from entry into the slaughterhouse through to sale at retail outlets) in various geographical areas across Canada. Isolates from a national microbiological baseline study conducted in 2012–2013 were subject to antimicrobial susceptibility testing for a set of 15 antimicrobials, using the same methods as those performed by the Canadian Integrated Programme for Antimicrobial Resistance Surveillance. Analysis of the results showed that of the 1,135 generic *E. coli* isolates tested, 940 (83%) were resistant to at least one antimicrobial, as were 879 (59%) of the 1,495 *Salmonella* isolates tested. Resistance was most common to aminoglycosides, β-lactams, tetracyclines and, for generic *E. coli* isolates only, to folate inhibitors. Differences in antimicrobial resistance patterns were observed across the provinces or regions, but not between the different stages of the food chain, season or the type of product sampled. There were also considerable differences in resistance among *Salmonella* serovars, with most *S. enteritidis* isolates being susceptible. This work provides a good cross-sectional representation of the patterns of antimicrobial resistance in the poultry production chain in Canada and serves as a useful benchmark for ongoing and future surveillance efforts.

159. Systematic literature review of antimicrobial resistance in bacteria isolated from retail food as a prerequisite for a consumer exposure assessment

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Antimicrobial resistance poses serious threats to public health. The spread of AMR bacteria (AMRB) and the exchange of resistant genes between animals and humans via the food chain requires holistic approaches for risk mitigation. This study aimed to assess: (i) the AMRB prevalence in retail food produced in Switzerland or imported; and (ii) the exposure of Swiss consumers in a systematic literature review of data published between 1996 and 2016. Data from 313 out of 9,473 collected studies were extracted yielding 122,438 food samples and 38,362 bacteria isolates of which 30,092 samples and 8,799 isolates were AMR positive. A median AMRB prevalence of >50% was observed for meat and seafood harbouring *Campylobacter*, *Enterococcus*, *Salmonella*, *E. coli*, *Listeria* and *Vibrio* spp. and to a lesser prevalence for milk products harbouring starter culture bacteria. Gram-negative AMRB featured AMR against aminoglycosides, cephalosporins, fluoroquinolones, penicillins, sulfonamides and tetracyclines observed at AMR exposures scores of levels 1 (medium) and 2 (high) for *Campylobacter*, *Salmonella*, *E. coli* in meat as well as *Vibrio* and *E. coli* in seafood. Gram-positive AMRB featured AMR against glycoproteins, lincosamides, macrolides and nitrofurans for *Staphylococcus* and *Enterococcus* in meat sources, *Staphylococcus* in seafood as well as *Enterococcus* and technologically important bacteria (incl. starters) in fermented or processed dairy products. Knowledge gaps were identified for AMR prevalence in dairy, plant, fermented meat and novel food products and for the role of specific indicator bacteria (*Staphylococcus*, *Enterococcus*), starter culture bacteria and their mobile genetic elements in AMR gene transfer. Raw meat, milk, seafood and certain fermented dairy products featured a medium to high potential of AMR exposure for Gram-negative and Gram-positive foodborne pathogens and indicator bacteria. For retail food, additional food categories including fermented and novel foods as well as technologically important bacteria and AMR genetics are recommended to be better integrated into systematic One Health AMR surveillance and mitigation strategies to close observed knowledge gaps and enable a comprehensive AMR risk assessment for consumers.

160. Identification of antimicrobial resistance genes occurring in the diary food chain through functional metagenomics

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Functional metagenomics is a valuable culture-independent tool for studying the composition and evolution of different complex microbial ecosystems. Indeed, it has taken precedent over the traditional culture-dependent methods, by

bringing new insights into genomes of difficult-to-culture or non-culturable microorganisms. Such complex bacterial communities can be found in fermented foods, in which different microorganisms (lactic acid bacteria) can be added to the final food matrix as a commercial starter or can be acquired from the processing environment. Food-related microbes can act as potential reservoirs of different antimicrobial resistance genes (ARG), which, in addition, may be transferred horizontally to different foodborne pathogens. Having this in mind, this study aimed at identifying ARG occurring in the complex microbiota of fermented foods (milk and dairy products) and their associated processing environment using a functional metagenomics approach. A metagenomics library comprising ≈22,000 recombinant clones was built containing microbial DNA isolated from raw milk, dairy products and environmental reservoirs within dairy processing industries. The recombinant library was plated on Luria Bertani agar supplemented with different concentrations of the antimicrobials ampicillin, gentamicin, ciprofloxacin, tetracycline, cefotaxime, colistin, peracetic acid, benzalkonium chloride and sodium hypochlorite. Thirty-two clones showing an increased resistance to one of the tested antimicrobials were identified: one for ciprofloxacin (minimum inhibitory concentration (MIC) – 0.5 µg/ml), one for gentamicin (MIC – 8 µg/ml), two for tetracycline (MIC – 16 µg/ml), three for cefotaxime (MIC – 0.008 µg/ml) and 25 for ampicillin (MIC – 16 µg/ml). Fosmid DNA from those resistant clones was purified, subjected to restriction analysis using *Apa*I endonuclease, and sequenced to identify the ARG conveying resistance to those antimicrobials. This study evidences the usefulness of functional metagenomics for the identification of ARG, also from difficult-to-culture or non-culturable microorganisms, and shows that the dairy food chain may serve as a reservoir for ARG.

161. Developing natural bacteriophages, friendly viruses, as an alternative to antibiotics in the UK pig industry

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The World Health Organisation has reported that 1 in 10 people world-wide suffer from food poisoning each year. In total, 11.7% of infections are caused by contaminated pigmeat, as over a third of pigs are infected with *Salmonella* when slaughtered. However, treating infections by antibiotics in pigs is becoming less effective due to the surge in infections caused by multidrug-resistant (MDR) *Salmonella* strains on farms that have also entered the human food chain. Natural bacteriophages can provide a safe and effective alternative to antibiotics in controlling *Salmonella* in agriculture and food. Bacteriophages are viruses capable of only killing bacteria, and cannot infect animals or plants. As they are naturally abundant in the environment, harmless to the human body, tasteless and odourless, the Food and Drug Administration (FDA) has granted bacteriophages the status 'Generally Regarded as Safe' (GRaS) for use in food products. The aim of my research was to isolate a panel of bacteriophages that could be developed to treat and prevent *Salmonella* infection in pigs. Twenty-two examples of bacteriophages were isolated and all could lyse/kill 74 MDR strains that had been isolated from outbreaks on pig farms by the Animal and Plant Health Agency, UK. Genetic analysis revealed that the bacteriophages have desired virulence genotypes that validate their use therapeutically. Furthermore two-bacteriophage combinations could rapidly kill *Salmonella* in 2 h at a 10,000-fold increase *in vitro* and in the *in vivo* moth larva infection models. The phages are heat-stable, which allows them to be dehydrated and stored as a powder, increasing their shelf life and versatility for use in the pig industry. Our important research could hugely improve animal and human health by providing a very effective tool to tackle the ever-growing issue of antibiotic resistance.

162. Methicillin-resistant Staphylococcus aureus in bulk milk of dairy farms and exposed workers in the north-east of Italy

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Background: *Staphylococcus aureus* is a causative agent of bovine mastitis in dairy herds. Due to its zoonotic potential, control of *S. aureus* is a significant economic and public health concern. The emergence of methicillin-resistant *S. aureus* (MRSA) and the capacity of livestock-associated (LA) MRSA strains to infect humans pose the farming community a risk for the acquisition of LA-MRSA. We

characterised MRSA isolates from bulk milk in dairy farms in the north-east of Italy. Nasal swabs from workers of the MRSA-positive farms were obtained and all isolates were characterised by phenotypic and genotypic techniques.

Methods: 618 dairy farms were enrolled, and each farm was sampled three times over 3 months. In MRSA-positive farms, nasal swabs were collected from workers to assess *S. aureus* and MRSA carriage. Molecular characterisation of MRSA isolates included SCCmec, spa and multilocus sequence typing and antimicrobial susceptibility testing.

Results: 24 farms (3.9%) were found to be positive for MRSA in dairy herds. Different STs types were found: ST398, ST1, ST22, ST3, ST1476. Sixty-two per cent of these were characteristic of LA-MRSA. Eleven workers (out of 70 screened) belonging to nine different farms were positive for MRSA. In 8/9 farms a correspondence between MRSA isolates from nasal swab and bulk tank milk was found.

Conclusions: MRSA strains in farm workers and bulk milk showed strong genetic and epidemiological correlation. Some strains showed the typical genotype of LA-MRSA, while others belonged to genotypes more commonly associated with humans. These findings suggest transmission of the same strains from animals to humans or *vice versa*. Moreover, the study showed human MRSA carriage to be related to animal exposure, frequency of animal contact and number of MRSA-positive animals in the farm. Farming practices should be implemented to avoid the transmission and spread of MRSA among animals and between animals and farm workers.

164. Next generation sequencing in microbial food risk assessment: are we there yet?

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Despite the continued increase in rigorous control and monitoring measures to assure safe food along the entire farm-to-fork chain, the past decade has also witnessed an increase in microbial food alerts. Hence, research on food safety and quality remain of utmost importance. Complementary, at least as important, is the necessity to be able to assess the potential microbial risks along the food chain.

Risk assessment relies on sound scientific data. Unfortunately, often, quality data are limited if not lacking. High-throughput tools such as next generation sequencing (NGS) potentially could fill this gap. NGS applications are not new in the field of food microbiology with applications ranging from pathogen detection along the food chain, food epidemiology studies, whole-genome analysis of food-associated microorganisms up to describing complete food microbiomes. Yet, its application in the area of microbial risk assessment is still largely unexplored and faces important challenges.

The possibilities of NGS for risk assessment are ample, but so are the questions on the subject that need to be addressed. In this work, we present a state-of-the-art review on the application of NGS in relation to microbial food risk assessment. One of the major strengths of NGS lies in its capacity to generate a lot of data, but to what extend can this wealth be of use as part of hazard identification, hazard characterisation and exposure assessment to perform a sound risk characterisation which in turn will allow to make evidence-based risk management decisions.

165. Mastitis pathogens isolated from samples of milk in dairy cows and sheep and their resistance against antimicrobial agents

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The aim of this study was to evaluate the prevalence and effectiveness of different antibiotics against mastitis-causing microorganisms in two herds of dairy cows and in two herds of dairy sheep. The diagnosis of mastitis was performed on the basis of clinical examination of the udder, macroscopic evaluation of milk, determination of somatic cell count (SCC) and bacteriological examination of raw milk samples. All isolated pathogens were tested by *in vitro* test on Mueller-Hinton agar by disc methods for resistance to 14 types of antibiotics. From a total of 1,120 samples about a quarter of the cow's milk samples (22.3%) were positive in the California mastitis test (CMT). Of these 15.2% contained pathogenic microorganisms that caused intramammary infection (IMI); subclinical mastitis (11.3%) with SCC under 400,000 was mainly due to coagulase-negative staphylococci (CNS), *Streptococcus uberis* and coliform bacteria *E. coli* and *Enterobacter aerogenes*. From a total of 820 sheep milk samples, 11.5% were positive for pathogenic microorganisms that caused IMI, mainly due to *Staphylococcus aureus, Streptococcus agalactiae* and CNS. From all tested bacteria that cause mastitis in cows and sheep, higher sensitivity against tetradelta was observed (100% of *Streptococcus agalactiae* and *Streptococcus uberis*, CNS), (94.4% of *Staphylococcus aureus*) with the highest number of bacterial isolates, followed by cefalexin + kanamycin amoxicillin plus clavulanat acid and ceftiotur (100% of *Streptococcus agalactiae* and *Streptococcus uberis*). Resistance was observed against penicillin (22.2% of *Staphylococcus aureus*), amoxicillin (22.2% of *Staphylococcus aureus* and 10.5% of *Streptococcus uberis*) and streptomycin (22.2% of *Staphylococcus aureus* and 52.7% of *Streptococcus uberis*). The use of antibiotics in the treatment of mastitis and other diseases in dairy ruminants can have a negative impact on public health through the increase in resistant bacteria or bacteria that produce resistance genes that pass into people directly or indirectly.

Nutrition

166. Association between nutrition and fertility in women of reproductive age in the Netherlands

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The prevalence of subfertility in the world's population is approximately 10%. Some risk factors related to subfertility have been identified, but it is still essential to investigate modifiable risk factors involved in the deterioration of reproductive health, such as nutrition. The present study aims to explore to what extent subfertility is associated with preconceptional nutrition in women. This is a large exploratory study involving women of reproductive age enrolled in the PRegnancy and Infant DEvelopment (PRIDE) Study. Energy-adjusted macro- and micronutrient data from diet only (dietary intake) and from diet and dietary supplements (total intake) were modelled in 3 different ways: in quartiles; per increment of daily consumption; and compared to dietary reference values. Time-to-pregnancy (TTP) was the biological measure of subfertility. Cox proportional hazard regression models were used to estimate hazard ratios, with right censoring time of 12 months. The analyses were adjusted for age, gravidity, smoking status, and caffeine consumption. 1,283 women were eligible for the current study. Higher intake of folate (dietary and total intake), vitamin A (total intake), vitamin B1 (dietary intake), vitamin B6 (dietary and total intake), vitamin D (dietary and total intake), vitamin E (dietary and total intake), and linoleic acid (dietary intake) were associated with prolonged TTP. Weaker associations were suggested between longer TTP and higher intake of alpha-linolenic acid (dietary intake), iron (dietary and total intake), and zinc (total intake). In summary, higher intake of several micronutrients seemed to be associated with subfertility in women of reproductive age in the Netherlands.

167. Safety assessment of insects and their products as food by the European Food Safety Authority (EFSA)

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With globalisation, an increasing number of foodstuffs is trying to have a share in the European Union (EU) market. Increasing demand for nutrient sources has raised western world's interest towards edible insects. To date, approximately 2000 insect species are consumed by various cultures world-wide. In the EU, all insects and their products are considered as novel foods (NF) according to the provisions of Regulation (EU) 2015/2283. The safety of such products must be evaluated before EU market authorisation may be granted.

EFSA's Panel on Dietetic Products, Nutrition and Allergies assesses the safety of NF. The scientific and technical guidance for the preparation of applications for authorisation of NF issued by EFSA assists applicants to prepare a comprehensive and complete report to demonstrate the safety of the under-evaluation NF. Compositional characterisation including, chemical and microbiological quality and stability, production process, proposed uses, anticipated intakes, nutritional value and toxicological parameters should be addressed. In particular, regarding insects, the species, the substrate used (i.e. Feed for the insects), and the methods for farming and processing and existing information on allergenicity may be important aspects to demonstrate safety.

A food derived from insects may be submitted as a NF pursuant to Article 11 of the Regulation but may also qualify as so-called traditional foods (TF) from non-member countries, provided there is a history of food use outside the EU. EFSA will not perform a full safety assessment on such foods but focus on hazard identification and evaluate whether identified hazards may pose risks to the EU consumers.

168. The role of traditional nutrition of indigenous people in the Arctic zone of Western Siberia in managing the risks of hypertension

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Nenets people belong to the Samoyedic language group and inhabit the vast area that stretches along the coast of the Arctic Ocean from the Kola

Peninsula in the west to the Taymyr Peninsula in the east. Their traditional occupation is nomadic herding and river fishing. It is crucial to provide the native population of the Far North with venison and local fish to maintain their health. The cross-sectional study of diets of the indigenous population (Nenets) (n = 590, aged 42.2 ± 13.3 years) was carried out during expeditions to villages which are located in the north of Western Siberia (Yamal). All the patients were examined by physician, cardiologist and pulmonologist. The actual diet during the previous month was studied by means of frequency method.

Non-linear logit regression with step-by-step inclusion of variables using the maximum likelihood method was used to construct risk models. Quantitative assessment of the risk of hypertension was calculated as the odds ratio (OR). To the greatest extent, the risk of developing hypertension reduced the consumption of pike (*Esox lucius*) OR – 11,4. Fish consumption of the Sig family influenced the decline in hypertension is somewhat smaller: shokur (*Coregonus nasus*) OR – 2.0; vendace (*Coregonus albula*) OR – 1.9; muksun (*Coregonus muksun*) OR – 1.4. The most favourable combination of products is reindeer meat + berries (OR – 1.39) and shokur + pike (OR – 1.67). The greatest flexibility preventive action combined with efficiency has venison, pike and shokur that allows them to recommend as priority components of preventive nutrition.

169. The EFSA Compendium of Botanicals reported to contain naturally occurring substances of possible concern for human health and its use for the assessment of plant-based novel foods

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Botanicals and derived preparations made from plants have become widely available on the EU market. Such products are typically labelled as natural foods and various claims are made regarding their possible health benefits. They can be bought over the counter in pharmacies, supermarkets, specialist shops and via the internet. While most of these products have a long history of use in Europe, some concerns exist about their safety and quality. Member States Competent Authorities expressed the need for a toolkit to help them assessing the safety of the plant-based products on their market. The EFSA Scientific Committee therefore developed a compendium of botanicals reported to contain naturally occurring substances of possible concern for human health. Such compendium is not intended to conclude on the safety or non-safety of the listed botanical species but to help with the safety assessment of botanicals and botanical preparations intended for use in food, including supplements, by facilitating hazard identification. Starting from plant lists existing at national level both within and outside of Europe, EFSA outsourced the literature search for around 2,600 plant species, and the extraction of information regarding the plant composition, toxicity and case reports of adverse effects. Once the collected information has been validated by the EFSA Scientific Committee Working Group on botanicals, it is then made freely available on the EFSA website. The Compendium is intended for Member States Competent Authorities, for manufacturers who are responsible for the safety of the products that they are marketing, and for EFSA itself: it is currently used by the EFSA NUTRI Unit and EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) for the assessment of novel foods as defined by Regulation (EU) 2015/2283.

170. Lactobacillus and Bifidobacterium strains and compositions with nanoceria reduce cholesterol levels in an obesity mouse model

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Background: *Lactobacillus* and *Bifidobacterium* strains demonstrated efficacy to reduce cholesterol on obesity model in our recent study. New updated prebiotic concept on supposes perspectives to search for new substances. The aim of this study was to evaluate ability of Lactobacillus and Bifidobacteria strains and compositions with nanoceria to reduce cholesterol level on obesity model in mice.

Materials and Methods: We used female mice of two lines: BALB/c 6–8 weeks mice (18–24 g), and mice of the CVA line, aged 11–12 months (20–26 g), experimental animals were fed by fat-enriched diet. Animals were divided into 15 groups to test probiotic strains and nanoceria. All groups except the control received a special diet during three weeks before the experiment. All groups received probiotic strains and orally and intravenously cerium dioxide in various composition. One groups of intact animals was control. Cholesterol level, liver morphology and gut microbiota of mice were studied.

Results: We revealed that all of studied probiotic bacteria and composition of *B. animalis* VKL/B. animalis VKB /*L. casei* IMV B-7280 decreased the weight of obese BALB/c mice; nanoceria and probiotic strains of *L. casei* IMB B-7280, *B. animalis* VKB and *B. animalis* VKL reduced levels of free and bound cholesterol in serum. The combination of 0.01 M nanoceria and probiotic strain *L. casei* IMB B-7280 at initial administration resulted in the fastest decrease in cholesterol levels in young and adult animals.

Conclusion: Nanocerium and probiotic strains of *L. casei* IMV B-7280, *B. animalis* VKB and *B. animalis* VKL reduce the levels of free and bound cholesterol in serum. This finding provides novel nutritional insight for using probiotics compositions and for considering nanomaterials as safe and effective prebiotic substances.

171. ChoEasy: a new tool developed to encourage healthier food choices

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Background: Poor nutrition plays a major role in the epidemic of various diseases, including obesity, type 2 diabetes (T2D) and cardiovascular disease (CVD). Recently, nutrition research and public health institutions are focusing on the effectiveness of various types of intervention encouraging healthier food choices. Based on the current state of the art, we developed a new tool supporting healthier food choices practically at a population level.

Methods: We went through four phases to develop our innovative tool: (i) design of scientific evaluation model, based on scientific literature and on reference intakes for nutrients (RI, EU Reg No. 1169/2011); (ii) tool implementation, by setting an international food repository to hold all the products data; (iii) data capture, to collect all the products information through an ad hoc smartphone App based on the optical character recognition (OCR) technology; and (iv) data analysis and nutritional products scoring according to their nutrients content.

Results: More than 100,000 packed foods (85% from European countries) were scanned and classed into categories according to consumers purchasing needs (e.g. raw cookies, skimmed yogurt). We observed an important variability among scores of products in the same category.

Conclusions: Considering the wide variability among similar products, a tool like ChoEasy (e.g. used by consumers through a dedicated App) could easily support the identification of healthier options with less salt, sugars and saturates. Considering a daily breakfast with cereals, whole yogurt and orange juice, we calculated that with ChoEasy it is possible to reduce up to 5 kg of sugars and 700 g of saturates in 1 year without changing people breakfast habits. Along with other educational programmes, ChoEasy could easily and effectively improve the diet composition in the population. Furthermore, it may give a new momentum to products reformulation.

172. Protein profile and allergenicity of edible silkworm (Bombyx mori) pupae as affected by gender, rearing substrate and processing

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Edible insects, a traditionally food in Asia, can be a source of sustainable protein with low environmental impact [1]. Among these, the silkworm (*Bombyx mori*) pupae (SWP) has been included in the list of insect species with the biggest potential to be used as food and feed in the EU, even if a specific risk assessment should be performed, including the evaluation of the allergenic potential associated to entomophagy [2]. In this work, the protein profile of SWP was characterised by 2D-PAGE coupled to LC-MS/MS, to detect differences in protein expression related to the gender and to the diet (artificial or mulberry leaves). The SWP proteome analysis highlighted differences in abundance of several proteins, some of them strictly related to a single condition (gender or diet). Considering the sex-differentially regulated proteins, seven proteins better discriminated the sex effect (e.g. vitellogenin). As far as diet was concerned, five proteins were found highly related to the diet effect (e.g. bifunctional purine biosynthesis protein). Allergenicity of raw and fried SWP proteins was assessed by immunoblotting with sera of patients who were allergic to a different insect species (*Tenebrio molitor*). Processing (frying) was shown to enhance the IgE binding of both SWP reared on artificial and mulberry leaves diet. Moreover, overall proteomic investigation of SPW revealed the presence of three known allergens: arginine kinase, chitinase and 27-kDa glycoprotein. In conclusion, the study supports the importance of the comprehensive protein characterisation of novel foods, to assess the risk associated to their consumption.

References

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173. Iron intake in the Portuguese university population

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Introduction: University students have disturbed lifestyles and eating habits. Although iron is found in very small quantities in our bodies, it participates as a cofactor in numerous biological processes that are essential for life, such as oxygen transport, oxidative phosphorylation, neurotransmitter metabolism and deoxyribonucleic acid synthesis. Iron deficiency is the most prevalent nutritional deficiency world-wide and the leading cause of anaemia.

Objective: Evaluation of iron intake by sex in the Portuguese university population through the 24 hours recall.

Methods: The population is made up of 159 students from the University of Porto. The population sample is made up of 159 students from the University of Porto and is between 17 and 36 years old with a mean age of 21.57 years (Standard Deviation (SD) 3.00), distributed among 54.1% of women and 45.9% of men. A 3-day 24 hours recall questionnaire were used. For the study of iron intake by gender, the *T*-test ($P \leq 0.05$) was used, together with the minimum, maximum, mean and SD values. For the evaluation of the diet the programme © Healthium 2017 was used. Nutrium.io used Microsoft Excel 2010 and IBM SPSS Statistics Version 23 for the nutritional evaluation of the foods contained in the 24 hours recall and for statistical evaluation.

Results and conclusion: The mean iron intake for men was 8.83 mg (SD 2.77) and 8.09 mg (SD 2.69) for women, the recommendations for the Portuguese population being 10 mg for men and 16 mg for women, with no statistically significant differences when comparing iron intake by gender.

174. Jellyfish proteins as bioactive compounds in novel foods

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The edible jellyfish world fishery, mostly based in Southeast Asia, generates a global catch annually exceeding 750,000 tonnes, with increasing demands expanding outside Asian markets. Known for its nutritional and medical value in the Chinese pharmacopoeia, jellyfish seem to have characteristics of healthy food. Some Mediterranean jellyfish species (phylum Cnidaria) can represent a low-cost raw material for innovative medical, nutraceutical or cosmeceutical products. Jellyfish are rich in protein, mainly collagen and are recently designated as novel foods in Europe. Several compounds isolated from jellyfish, including proteins, can exert high antioxidant and other biological activities. GoJelly is a new H2020-funded project addressing the potential exploitation of jellyfish biomass and derived compounds for multiple purposes. Here we report on the protein characterisation of *Rhizostoma pulmo*, an edible scyphozoan jellyfish regularly found with large populations along Italian sandy coastlines. We show that hydrolysed proteins, including hydrolysed jellyfish collagen, have strong antioxidant activity, particularly low-molecular-weight fractions (less than 10 kDa). Moreover, the cytotoxicity of different fractions of jellyfish hydrolysed protein on cancer cells (MCF7) and human keratinocytes (HEKa) was investigated, as well as their protective effect on UV-irradiated HEKa. In combination with food safety assessments and improvements in jellyfish processing technology, scientific evidence demonstrating edible jellyfish as functional food may promote the future expansion of jellyfish fishery world-wide.

175. Dietary supplement use in Europe – an overview based on national dietary surveys

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Background: The percentage of dietary supplement users has increased over the last decades in several European countries. Dietary supplements may be used to correct nutritional deficiencies or maintain an adequate intake of certain nutrients.

Objective: Data from national dietary surveys on available data on the percentage of dietary supplement consumers and the level of intakes of dietary supplements in adults (12 countries).

Results: The frequency of participants using dietary supplements ranged from 5% (Italy) to 62% (Denmark). Frequency of supplement use was higher in women compared with men and increased with age and duration of education in most countries. Multivitamins/minerals and omega-3 fatty acids were the most frequent used supplements. Vitamin D was the single vitamin that was most often used. Different assessment methods made the comparison between countries difficult.

Conclusion: The frequency of dietary supplement use is relatively high in most of the European

countries investigated, but further harmonised investigation is needed. There is a need for more accurate and detailed dietary supplement consumption data derived form a harmonised methodology across Europe. The national food consumption surveys also need to adapt methodology to include estimates from supplement sources in the surveys, and to develop improved methods for estimating intakes of micronutrients from dietary supplements.

176. The effect of the regulation on the trans-fatty acid content of foods in Hungary

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Artificial *trans*-fatty acids (TFA) are formed during the industrial processing of foods, and are proven to be harmful for the human body. Their consumption has been associated with an increased risk of cardiovascular disease, abdominal obesity, diabetes and certain types of cancer. Decree 71/2013. (XI. 20.) of the Ministry of Human Capacities, which has been in force since 18 February 2014, defines the highest permitted amount of TFA in food products placed on the market in Hungary. The official control of TFA content of foods is performed by the food chain safety and animal health directorates of the capital and county government offices. The National Food Chain Safety Office aggregates and forwards the data to the National Institute of Pharmacy and Nutrition (OGYÉI). Data of the TFA content of food products for the pre-regulation period were derived from the database of the National Institute for Food and Nutrition Science.

Between 2010 and 2016 the total number of the measured products was 1,586 with special emphasis on biscuits, cakes, wafers, bakery products/fine bakery products, chocolates, products made from chocolate compound, vegetable fats. 900 products were measured before the Regulation (2010–2013) and 686 products were measured after (2014–2016). Before the regulation an average of 20% of the food products had *trans*-fatty acid content above the threshold and after the regulation entered into force a significant improvement was observed. In 2016, only less than 2% of the products exceeded the permitted limits.

The regulation has reached its goal, due to the legislation the number of food products with high trans-fatty acid content has been drastically declined.

177. A Geography of Nutrition: eating habits, mobility and school performance, a study in the city of Lisbon

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According to the World Health Organisation (WHO), overweight and childhood obesity are one of the major public health problems of the 21st century. This pathology has increased at a high rate, being very common in urban areas. By 2013, overweight affected about 42 million children under the age of five world-wide. By 2015 in Portugal, 25% of boys and 31% of girls between the ages of 11 and 15 were overweight or obese, which were only surpassed by the United Kingdom and Greece.

On a daily basis, children spend much of their time in school where they eat most of their meals. Taking these data into account, it will be important to understand which factors influence young people's nutrition, so that the incidence of overweight and obesity can be prevented and reduced.

The mobility of the student will also be studied, especially the routes between the school and the catering establishments where the students can move, in a normal day of school activity.

This research will use spatial analysis, namely Geographic Information Systems (GIS). These will allow overlapping layers of information from multiple sources, so integrating two fields of study that usually do not intersect: Geography and Nutrition.

The aim is to relate dietary habits, physical activity, mobility and nutritional status with the food supply in the school geographic zone and the students' school performance. So, this study will allow:

georeferencing the availability of catering establishments and the like in a certain area of influence with school equipment;

correlating the nutritional variables with the performance of the school population (12 and 17 years);

analysing variations in eating habits in two areas of the city of Lisbon.

178. Impact of drought on the nutrient content of food crops: A neglected climate change issue?

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Plants are the main source of human nutrients, and in turn gather their nutrients from the soil. Together soil and environmental factors like weather control bioavailability of nutrients to plants, and so

to food. With increasing extreme weather events, drought periods affect plant growth but also affect bioavailability of nutrients and hence severely affect food quality. This study compares two regions in East Africa (Kapchorwa, Uganda; Busia, Kenya) that experienced drought during the second growing season in 2016. The main research questions were: (i) does drought have an impact on the nutrient composition of produced food; and (ii) does drought affect crops differently when grown on soils of varying fertility?

For this study, we collected 127 maize (*Zea mays*) grain samples per region and season from 142 randomly selected households during the long rain season (March to August) (LRS) and the short rain season (October to December) (SRS) of 2016. Crop and soil samples were analysed using a pX rheumatoid factor (RF) (Bruker©) for magnesium, phosphorus, sulfur, potassium, calcium, manganese, iron, zinc and copper. Soil properties nitrogen, carbon, C:N, texture, pH and eCEC were measured.

Kapchorwa has higher soil fertility than Busia, and during the LRS all monitored grain nutrients were significantly higher in Kapchorwa. Yield decreased significantly between LRS and SRS due to drought, in both regions. In Kapchorwa, maize showed a significant decrease of 42% in nutrient content from the LRS to the SRS. In Busia, however, maize showed a significant increase of 41% in nutrient content from the LRS to the SRS. The contradicting results are due to a complete cessation of rainfall in Kapchorwa before grain filling, whereas in Busia rainfall ceased directly after. These unexpected results indicate that extreme weather events have unpredictable effects on quantity and quality of food. There is need for more research into bioavailability of crop nutrients.

179. Diet habits and nutritional status in school aged children in Serbia – data from Health Behaviour in School-age Children Survey study 2017

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Aim: The aim was to examine diet habits and nutritional status and their association with demographic, socioeconomic and lifestyle factors among Serbian schoolaged children.

Method: Data were obtained from the Pilot Health Behaviour in School-age Children Survey (HBSC) performed in spring 2017. Self-completion questionnaire was administered in 86 schools and completed by 3,267 students aged 10 to 17 years (1,682 boys i.e. 51%, 1,585 girls i.e. 49%).

Results: Results showed that during the working week, more than half of the students (54.3%) consume breakfast every day, while 6.7% never eat breakfast. Among those who never consume breakfast on weekdays or weekends are predominantly students with low socioeconomic status. Every fifth student (19.3%) consume fruit once a day every day, 10% eat fruit less than once a week, while 2% of students never consume fruit. Vegetable consumption showed similar frequency. Fruit and vegetables were more likely to be consumed by younger and students with better socioeconomic status. Every fourth student consumed sweets more than once a day (23.6%) and every tenth student consumed cola or similar non-alcoholic beverages every day. Underweight as well as overweight and obesity prevalence decreases with age: the highest prevalence of underweight students was among girls aged 11 (6.2%), while in the same age group boys were more often overweight (25.6%) and obese (19.3%).

Conclusion: There is increasing need for further preventive interventions targeting younger adolescents aiming at improving diet habits and nutritional status.

180. From a mechanistic risk assessment to a global risk management, from total to free sugars

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Background and objectives: This work aims to assess the scientific evidence linking sugar intake and health in the adult population to establish recommendations for consumers and risk managers taking into account the social and political context of sugar consumption

Material and methods: A literature search on the effects of sugar intake on overweight/obesity, diabetes/insulin resistance, dyslipidaemia/ cardiovascular diseases, non-alcoholic fatty liver diseases and uric acid concentrations focused on controlled mechanistic studies, prospective cohort studies and randomised clinical trials.

Result: Literature analysis supported a direct link between fructose intake and blood lipids and an indirect link, mediated by an increase in total energy intake, between sugar intake (mainly documented for sugar-sweetened beverages, SSBs) and body weight. In addition, prospective cohort studies showed associations between sugar intake and risk of diabetes/insulin resistance, cardiovascular diseases, NAFLD and hyperuricemia. These results allow setting a maximum limit to the intake of total sugars containing fructose (sucrose, glucose–fructose syrups, honey or other syrups and natural concentrates, etc.) at 100 g/day. Moreover, as there was no evidence that sugars naturally present in fruits and vegetables and 'free sugars' (including added sugars and fruit juices) would be differentially metabolised in the body, this maximum limit comprises all sources of sugars, excluding lactose and galactose.

Conclusions: This recommendation of a maximal daily intake of 100 g for total sugar does by no means challenge the beneficial effects of fruit and vegetable consumption that has to be promoted. Indeed, the optimisation tool deployed by ANSES to update food consumption guidelines for the French population shows that when this limit is observed simultaneously with other constrains (41 dietary reference values and toxicological reference values for around a hundred contaminants), fruits provide around 40 g of sugars and vegetables 6 g of sugars. This result is consistent with the WHO recommendation to limit free sugar intake to less than 10% of the total energy intake. As it is estimated that 20 to 30% of French adults (in the INCA 2 survey) currently have daily sugar intakes (excluding lactose and galactose) above 100 g/day, effective public health actions will be needed to reduce free sugar consumption, especially SSBs. These actions should target a wide range of spheres, from consumer education and information to regulatory measures aimed at decreasing the levels of free sugars in strategic food products.

181.Dietary intake of calcium, phosphorus and magnesium in a northern Italian community

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Minerals are essential micronutrients for growth, development and maintenance of healthy tissues, the long-term insufficient intake of minerals may lead to bone demineralisation and often requires the use of food supplements. The ratios of certain minerals intake like calcium and phosphorus are also proved to affect the bioavailability of calcium and even lead to adverse health consequence. This study was designed to explore the dietary sources of calcium (Ca), phosphorus (P), and magnesium (Mg) and the ratios between different minerals (Ca/P). We measured the content of these elements in foods that compose a typical Italian diet using inductively coupled plasma-mass spectrometry and we estimated their daily dietary intakes assessed through a semi-quantitative food frequency questionnaire specifically developed within the European Prospective Investigation into Cancer and Nutrition (EPIC) study in a northern Italian community. In 890 analysed food samples the main contributors to calcium are milk and dietary products, dry fruits, legumes and sweet products. Important sources of phosphorus are represented by dry fruits, legumes, milk and dairy products and meat. While dry fruits, legumes, cereals and fish symbolised the most important sources for magnesium. In our Italian population sample, the estimated median (interquartile range) dietary daily intakes are 786.3 (592.2–1062.7) µg/day for calcium; 1,291.7 (1,017.2–1,591.4) mg/day for phosphorus and 323.2 (260.3–396.6) mg/day for magnesium. The calcium–phosphorus (Ca/P) ratio in this study was 0.63 (0.52–0.73). These values are in agreement with those suggested by European and international recommended intake for adult population, with the exception of calcium which is slightly lower than recommended values and suggests that this population does not present nutritional deficiencies requiring any supplementation.

182. Risk assessment of Gymnema sylvestre preparations in food supplements

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The plant *Gymnema sylvestre* and its botanical preparations have a long tradition of use for medicinal purposes. *Gymnema* preparations are currently being marketed as an ingredient of certain food supplements, either alone or in combination with other herbs and/or micronutrients, and are typically being used by people displaying one or more symptoms of metabolic syndrome. Food supplement use may occur without medical supervision; it is therefore not unlikely that *Gymnema*-based food supplements may also be consumed instead of or in combination with allopathic drugs.

In the present project, an assessment of potential health risks associated with the use of *Gymnema* botanical preparations was performed. Electronic searches of the literature were conducted in PubMed Medline and EMBASE databases.

The limited information currently provided by animal toxicological studies has so far not suggested serious adverse effects on organ functions. Clinical trials mainly involving type I and type II diabetic patients have suggested the potential for specific *Gymnema* preparations to lower blood sugar levels, but also to promote hypoglycaemia when administered together with insulin or antidiabetic drugs. A number of *in vitro* studies have demonstrated that certain *Gymnema* extracts modulated the activity of particular xenobiotic-metabolising cytochrome P450 enzymes and of certain xenobiotic (ABC) transporters, indicating possible pharmacokinetically based interactions of *Gymnema* with certain drugs. Moreover, *in vivo* studies suggested that certain extracts may potentiate the glucose and lipid lowering effects of specific drugs. Finally, a case report of liver toxicity related to the consumption of *Gymnema* tea has raised concern regarding the possibility of adulteration or contamination of the tea with hepatotoxic substances. Considering the uncertainties regarding the composition of different *Gymnema* preparations, potential herb–drug interactions and concerns about hypoglycaemic effects, the use of *Gymnema*-based

food supplements without medical supervision as a substitute for (or in combination with) authorised antidiabetic drugs may be associated with risks. Georgios Marakisis an EFSA EU-FORA fellow at BfR.

183. Intake of iodine in Mediterranean population with elevated thyroid disease index

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Introduction: The murcian population (southeast of Spain) exhibit a high risk of thyroid diseases.

Objective: To know the iodine intake of the murcian adult population and the foods through which this population access this nutrient.

Method: The population studied was composed of 150 individuals (18–80 years), (33.8% women and 65.6% men). The nutrient and food intake was evaluated by means of a 24-hour recall (R24h) and a questionnaire on the frequency of food consumption (FFQ). Iodine intake was assessed through the foods consumed by the population and that contribute this nutrient with linear regression.

Results: There were no statistically significant differences between men and women in iodine intake in the population under study, so it was determined to treat the population as a whole. This population has an iodine intake of 88.43 µg/day, data obtained through the FFQ, showed that its main source of iodine came from fish (R2 = 0.78), followed by molluscs, shellfish, spinach, canned fish, garlic, egg and carrot. Approximately 1/3 (30.66%) of the individuals suffered from diseases related to the thyroid gland or were at risk of suffering from disease.

Conclusions: Knowing that the recommended iodine intake is 150 µg for a healthy adult population according to the recommendations for the adult Spanish population, this population had a significant iodine deficit of almost 1/3 lower than the recommendation. Its main source of this nutrient is fish. Deficient iodine intake in the population is related to thyroid problems, so an increase in the consumption of food from the area with good sources of iodine should be recommended and that is characteristic of a Mediterranean Diet.

184. Pre-clinical safety assessment of human-identical milk oligosaccharides in neonatal rats

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After lactose and lipids, human milk oligosaccharides (HMOs) are recognised as the third largest solid component of human breast milk, with a wide diversity of over 200 identified structures and concentrations significantly higher than in most other mammalian milks. HMOs offer numerous potential health benefits to infants, children and adults, so they are recognised as a novel, important and attractive food ingredient category, particularly in infant nutrition. To simulate the composition of human breast milk more closely, commercial infant formula can be supplemented with human-identical milk oligosaccharides (HiMOs), which are manufactured to be structurally identical versions of their naturally occurring counterparts. However, before their commercialisation as infant formula ingredients, the newly developed HiMOs should be subjected to pre-clinical safety assessment followed by clinical trial. In this study, as part of the safety evaluation, two *in vitro* genotoxicity tests and a subchronic oral gavage toxicity study (in neonatal Sprague-Dawley rats) were conducted. In the subchronic study, HiMOs were administered orally (by gavage) at three dose levels, once daily for at least 90 days, followed by a 4-week treatment-free period. An identically comprised reference control group received fructooligosaccharides powder (a non-digestible oligosaccharide used in infant formula) to allow for direct comparison against the high-dose group. Measurements included food consumption, body weight, clinical observations, blood biochemistry and haematology, urinalysis, ophthalmic and histopathological examination. The studied HiMOs were non-genotoxic in the *in vitro* tests. There were no compound-related adverse effects in the 90-day study. These results support the safe use of HiMOs in infant formula and as a food ingredient, at levels not exceeding those found naturally in human breast milk.

185. A new approach to define food-based dietary guidelines

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The development of food-based dietary guidelines (FBDG) usually involves translating nutritional references into food combinations. In 2001, the FBDG were based on the dietary patterns observed in the French adult population that provided the best coverage of nutrient requirements. To define the new FBDG, an innovative approach was followed. This approach is not based on observed dietary patterns but on the public health goals considered here:

to cover nutrient requirement for almost all the French population;

to prevent chronic non-communicable disease, especially cardiovascular disease, cancers, diabetes, obesity;

to limit contaminant exposition and to prevent the risk with regard to the contaminants.

Moreover, to facilitate the acceptance and implementation of FBDG, French eating habits have been taken into account. So, this global approach is similar to a benefit–risk balance. To our knowledge, it is the first time that FBDG integrate all these dimensions.

To define food patterns that reach these goals, a mathematical algorithm has been developed. It integrates:

scientific data such as the updated French nutrient references, data from analysis of articles on the relationship between food group consumption and the risk of chronic non-communicable diseases and the health-based guidance values used in the French Total Diet Study;

and ANSES databases for food consumption, nutrient composition and contaminant content of food, (respectively from INCA2, CIQUAL and TDS2).

For the needs of the mathematical algorithm, a new food categorisation based on dietetic and usage considerations was defined.

Optimised solutions proposed by the algorithm represent combinations of food groups that meet the set objectives by construction.

So the approach developed for the elaboration of FBDG is innovative, global and is conceived to be the more objective as possible.

186. Effect of thermal processing on the proteins profile and allergenicity of edible insects

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Edible insects are currently under study as an alternative and sustainable protein source for humans, to meet the nutritional needs for the growing world population. In Asia, where insects are routinely consumed as food, cases of allergic reactions have been reported. The evaluation of the allergenic potential associated to entomophagy is so a priority. Preliminary data on European patients indicate that the consumption of edible insects can trigger IgE-mediate reactions in subjects allergic to proteins contained in animals belonging to the same phylum, such as crustaceans and mites. Additional data generation, needed for risk assessment on this topic, has been highly recommended by EFSA.

Four edible insects species were considered: buffalo worms (*Alphitobius diaperinus*), mealworms (*Tenbrio molitor*), cricket (*Gryllodes sigillatus*) and grasshopper (*Locusta migratoria*). Soluble and insoluble proteins were extracted from raw and processed (boiled and fried) insects and the proteins profiles were analysed with SDS-PAGE electrophoresis.

In the two worms, similar proteins profile separation were observed in raw and boiled insects, while in the cricket and grasshopper boiling modified protein profiles. In all the insects, the protein profile of the fried samples strongly differed from the raw protein profile. Aggregation phenomena were observed, as the processing temperature increased, with a consequent increase in the insoluble proteins fraction extract.

To evaluate the allergenicity of the four insects, IgE cross-reactivity with crustaceans (n = 15) and house dust mite (n = 30) in Italian patients was assessed, by immunoblotting and LC-MS/MS analysis on raw or processed insect proteins. Processing differentially affected IgE immunoreactivity, depending on processing intensity and insect species. IgE cross-reactivity of insects proteins with crustaceans and house dust mite allergens is discussed.

187. Diet adjustment in later life: a grounded theory study of eating behaviours among the ageing population of Limerick

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Ageing of the population going forwards will embody one of the most momentous demographic and social developments encountered by Irish society. Falling fertility rates and ever-increasing life expectancy will see the number of older people aged 60 or more almost double, with those over the age of 75 expected to almost triple by the year 2050. Older individuals are the fastest growing segment of the world's population, yet they are often overlooked by the food industry, with most food products being targeted at those aged 21 to 49. Disruptions in diet and eating behaviours are common among older adults however, little information is known about the processes underlying these disruptions. The central goal for assisting individuals to age well is by promoting a healthy and nutritious diet however, 'Eating behaviour is the result of a complex interaction of physical, psycho-social, cultural and environmental factors that impact food choices and dietary practices' (Brownie & Coutts, 2014, p. 182). Conversely, the extent to which food shopping can constitute a manageable part of older adult's daily/weekly routines is strongly influenced by their economic means and health status. Addressing diet deficiencies will reduce diet-related chronic metabolic diseases and diminish malnourishment, by promoting positive health outcomes for older cohorts. The aim of this study was to identify potential barriers and motivators for food intake in the ageing population. Qualitative methods based on a Constructivist Grounded theory approach, guided by a Critical Realist worldview were used. A mixture of 16 intensive interviews and 10 observations was carried out to accomplish the research objectives. Data analysis was conducted using the software package NVivo. The sample criteria included those over the age of 65, living independent lives and who were responsible for most of their own shopping and cooking needs. An applicable theory of why and how older adult eating behaviours change in later life will be developed. Results from this study indicate that dietary changes in later life are often the result of changing family structures and older people's perceptions of what they believe they should eat. Participants from this study indicated their need for less food as a natural process of ageing, However, research suggests older adults should consume the same, if not higher levels of protein to offset malnourishment and prevent anorexia of ageing. Findings from this study will provide a body of evidence that may help form policies that are person centred and cost effective to health and social care sectors.

188. Antinutritional factors, in vitro trypsin, chymotrypsin and peptidase multienzyme protein digestibility of some melon (egusi) seeds and their protein isolates

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In vitro multienzyme protein digestibility (IVMPD) and antinutritional factors (ANF): tannin, phytate and oxalate of five melon (egusi) seed flours (MSF) and their protein isolates (PI) were carried out. Their PI have potential comparable with that of soya bean. It is important to know the IVMPD and ANF of these protein sources to ensure their safety when adapted for use as alternate protein sources as a substitute for cow's milk, which is relatively expensive in Nigeria. Standard methods were used to produce PI from *Citrullus colocynthis*, *Citrullus vulgaris*, African Wine Kettle gourd (*Lageneria siceraria* I), Basket Ball gourd (*Lagenaria siceraria* II) and Bushel Giant Gourd (*Lageneria siceraria* III) seeds and to determine the ANF and IVMPD of the MSF and PI unheated and at 37°C. Multienzymes used were trypsin, chymotrypsin and peptidase. IVMPD of MSF ranged from (70.67 ± 0.70)% (*C. vulgaris*) to (72.07 ± 1.79)% (*L. siceraria* I) while for PI ranged from 74.33% (*C. vulgaris*) to 77.55% (*L. siceraria* III). IVMPD of the PI were higher than those of MSF. Heating increased the IVMPD of MSF with average value of 79.40% and those of PI with average of 84.14%. ANF averages in MSF are tannin (0.11 mg/g), phytate (0.23%). Differences in IVMPD of MSF and their PI at different temperatures may arise from processing conditions that alter the release of amino acids from proteins by enzymatic processes. ANF in MSF were relatively low, but were found to be lower in the PI, therefore making the PI safer for human consumption as an alternate source of protein.

189. The addictive behaviour and brain – leptin levels in long-term MSG-treated rats

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Monosodium glutamate (MSG) is used as a flavour enhancer in many processed foods. In many countries there are no limitations on the amount of MSG intake that is questioned due to its toxic effects on human health. Previous studies have shown that MSG administration during the early post-natal period results in neurodegenerative changes in several forebrain regions, characterised by neuronal loss and neuroendocrine abnormalities. No consensus has been reached between food committees and researchers on the harmful effects of MSG. Experimental animal studies of MSG are

carried out at high doses and on the developing brain. The present study was designed to investigate the *in vivo* effects of MSG on the addicted behaviour and brain leptin levels in rats. In this study, 8-week-old male rats (n = 10) were given MSG (with gastric gavage) only one day in a week for 12 weeks. The control group rats (n = 10) were given saline at the same time and period. After the exposure period, the animals were subjected to behavioural tests in conditioned place preference (CPP) test and brain leptin levels were analysed. There was no significant difference between MSG and control groups in the time spent in the target segment ($P > 0.05$). There was no significant difference in the brain leptin levels of MSG and control groups rats ($P > 0.05$). These findings indicate that MSG has no addictive effect at this dose in rats. However, MSG administration at higher doses (two to three times a week) can be tried in another group of animals. Further research is needed on the relationship between MSG and its addictive effect.

Funding

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Key words: monosodium glutamate, addictive behaviour, leptine levels, condition place preference

190. AlgaeCeuticals: development of microalgae-based natural UV sunscreens and proteins as cosmeceuticals and nutraceuticals

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Microalgae biomass represents a rich source for discovery. The potential for algae-based ingredients in the industry relies on the manipulation and targeting of ingredients to fit increasingly niche product specifications. Algae are exposed to extreme environment and so have developed unique mechanism for protection. Furthermore, algae produce for the same reason different metabolites which we need to identify and exploit in a sustainable way for the production of food, drugs and cosmetics. The AlgaeCeuticals project will take advantage of the native algae strains producing high added value products and through the application of novel 'omics technologies (genomics, transcriptomics, proteomics, enzymomics and metabolomics) as well as algae culture technologies and production of novel products. AlgaeCeuticals will screen and characterise algae biodiversity, develop and optimise algae culture systems, develop 'omics resources for algae and also develop downstream processing strategies and also develop novel products. For this reason and to achieve its object three academic and research centres from Greece (CERTH/INAB; AUA) and Italy (FEM) will collaborate for 4 years with four industrial R&D partners from Greece (Fresh Formula), Spain (Bionos Biotech ND; Centro Tecnológico Nacional de la Conserva y Alimentación) and Austria (Ecoduna AG). Through this collaboration the academic partners will work closely with the industrial R&D and form a complementary and highly competitive team that will promote transfer of knowledge and excellence to industrial partners. This will strengthen the industrial competitiveness in the field of food and cosmetics in the process of the design, development, testing of the products proposed by the project.

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191. Use of mathematical optimisation to derive personalised dietary recommendations

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Consumption patterns in a population often vary greatly and national dietary guidelines may be perceived as unrealistic by a substantial part of the population, as they differ considerably from individual preferences. Personalised recommendations may be more relevant and have stronger motivational effects, because these can account for e.g. personal preferences, needs and beliefs. Hence, personalised recommendations may have a positive impact on public health, as higher compliance to the recommendations can be expected.

We developed a method for modelling personalised dietary recommendations. The method is applied to estimate optimised fish intake in Denmark, taking into account maximum levels of chemical contaminants and minimum levels of nutrients in different fish species.

A mathematical optimisation model that applies quadratic programming was used to model personalised fish intake recommendations that deviate as little as possible from observed individual fish intake. Model constraints ensure that modelled intake levels meet the general recommendations

for eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), and vitamin D without violating the tolerable intake recommendations for methyl mercury, dioxins and dioxin-like polychlorinated biphenyls. Recommendations for 11 fish species were generated for each individual in a group of 3,016 Danish adults, whose fish intakes and body weights were recorded in a national dietary survey.

Our results suggest that 55% of the study population should be recommended to increase their intake of fish with up to 184 g/week (24% with more than 100 g/week) and that 2% should be recommended to decrease their fish intake.

Our method is appropriate for translating recommendations for single nutrients and contaminates into personalised dietary recommendations, thanks to its multidimensional property. The method has great potential for evolving dietary guidelines by accounting for personal preference, and it can also be extended to include economy and sustainability.

192. Iodine levels in cow's milk: a survey of milk from several European countries

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Iodine is an essential micronutrient for mammals, required for the synthesis of the thyroid hormones triiodothyronine (T_3) and thyroxine (T_4), key effectors in metabolism regulation. In fetuses and infants, these hormones play a key role in the adequate growth, development and maturation of many target tissues, namely the skeleton and central nervous system [1].

According to WHO, iodine deficiency is the leading preventable global cause of mental illness and development disorders [2]. In 2011, about 44% of the European population had insufficient iodine intakes. Although iodine deficiency has been reducing over the last years through the efficient application of the universal salt iodisation programmes, insufficient iodine intakes remain a public health problem in some European countries [3].

Daily iodine requirements vary throughout the life cycle from 40 µg/day at birth to 150 µg/day daily in adulthood. Pregnant and lactating women have increased needs (175 µg/day and 200 µg/day, respectively) [1].

Cow's milk is an important source of iodine in western diets. The concentration of iodine in milk depends on several factors, namely the iodine content of feed, iodine source, farm management, teat dipping with iodine-containing substances, and milk processing in the dairy [4]

This study aimed to determine the iodine levels in cow's milk from different origins (i.e. countries). Using a validated analytical procedure – alkaline digestion of the samples with TMAH and iodine determination by ICP-MS – the levels of iodine in the most consumed brands of cow's milk for sale in Portugal, Spain, France, Italy, Germany, Poland, UK are being determined. Results will be presented in the present communication.

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193. Epigenetic changes induced by docosahexaenoic acid on breast cancer cells

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Docosahexaenoic acid (DHA) is an omega-3 fatty acid derived from fish oil that has been associated with multiple benefits for human health, including antitumor properties. Epidemiological evidence strongly links fish oil consumption with reduce incidence of several types of cancer including breast cancer. The bioactive nutrients such as DHA can reverse the epigenetic marks that are associated with cancer initiation and development. Experimentally, DHA can reduce proliferation, induce apoptosis and decrease invasive potential of breast cancer cells. Recently, several studies have demonstrated the ability of DHA to act like epigenetic modulator on global or local DNA methylation profile in cancer cells. Besides DNA methylation, the histone post-translational modifications are part of epigenetic mechanism involved in gene expression regulation. The degree of acetylation/deacetylation or methylation/demethylation of lysine residues (K) within the N-terminal tail from histone H3 and H4 mark the activation or silencing of gene transcription. In human cancer the loss of acetylation at K16 and trimethylation at K20 of histone H4 are common hallmarks.

Here we have analysed the effect of prolong DHA treatment on epigenetic modification at histone H3 and H4 in breast cancer cell line (MCF-7) in comparison with non-tumour cell line (MCF-12A). Specific H3 and H4 modifications were detected and analysed by enzyme-linked immunosorbent assay (ELISA) like multiplex assay. Immunofluorescence and western blot experiments were used to investigate the degree of acetylation

at histone H4K16, H3K9, trimethylation at H3K9 and H4K20. DHA treatment induced a high degree of hyperacetylation at H4K16 and hypermethylation at H4K20me3 for MCF-7 cells in comparison with MCF-12A. This study highlights the capacity of a bioactive nutrient (DHA) to modulate epigenetic alterations in breast cancer cell lines demonstrating its therapeutic potential.

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194. New food habits in Romanian population – an extensive study

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In the modern era, basic patterns like feeding have suffered major changes. Many researchers connect these changes to the increased incidence of chronic or lethal diseases such as cancer. My survey put together questionnaires regarding feeding habits in families, adolescents, and a list of detailed analyses of the type and quantity of food consumed by a whole family in a certain period of time, for the number of N = 282 families. All the data were analysed and compared with data from other research and studies. Results showed a large change in the feeding habits for adolescences (fast food preferences, variable feeding schedule) and for the whole family (more processed meat, less vegetables etc.), compared with previous studies and recommendations in the literature. Some considerations on the correlations between feeding habits and increasing incidence of disease are made.

195. A Marie Curie project on healthy eating behaviour: a case study among college students

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Overweight and obesity rates have dramatically increased over the past decades in the United States and especially in the young adult population, aged between of 18 and 29, the incidence rate is the highest (Gordon et al., 2004; Flegal et al. 2010).

According to literature (Crombie et al., 2009; Vella-Zarb and Elgar, 2008; Racette et al., 2008), the university period is critical for young adults regarding food choices and the relationship with weight gain.

Six focus group discussions have been conducted until saturation of new information was reached. The final sample consisted of 33 students (22 women and 11 men) from a variety of study disciplines and different college years. A semi-structured question guide was developed starting with the appropriate literature (Deliens, Clarys, Bourdeaudhuij and Deforche, 2014) to identify the key questions for the research problem (eating habits, physical activity levels and weight change).

Projective techniques have been used to understand better emotional connections and cognitions towards the topic of interest (Mesías and Escribano, 2018). According to the literature (Bloor et al., 2001), the researchers reviewed the transcript encoding and classified the text (using NVivo 11 plus software). An ecological model has been developed using as factors: individual (intrapersonal), social environment (interpersonal), physical environment (community settings), macroenvironment and an additional level of students' attributes. Finally, ideas and recommendations to facilitate the development of effective and tailored intervention programmes or environmental modifications that support healthy eating have been proposed. This study, which is part of a European project Marie Skłodowska-Curie Action (MSCA) 'CONSUMEHealth', investigates the relationship between consumers and healthy eating habits and changes in life course.

196. Risk assessments of 'other substances' in food supplements and energy drinks on the Norwegian market

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The Norwegian Scientific Committee for Food and Environment (VKM) have, on request from the Norwegian Food Safety Authority, performed 44 risk assessments of 'other substances' in 2015–2017. 'Other substances' are defined as substances with a nutritional or physiological effect that are not vitamins and minerals, according to Directive 2002/46/EC. These substances are used in food supplements, energy drinks and sports products, and comprise a variety of chemical substances. They may be botanicals, for instance caffeine, piperine and curcumin and they may occur in regular foods. Others are found in the body naturally, such as coenzyme Q10, carnithine and choline, but may still be harmful if consumed in too high amounts. There have been incidents of serious health problems, e.g. liver failure, from intake of food supplements. These risk assessments were based on an approach established by VKM. As these substances are produced naturally in the body and occur in food, most of the available literature is on positive effects. Therefore, sufficient toxicity data are often lacking. The recommended doses of the products sold on the Norwegian market as given by the producers and/or importers were evaluated for safety, using information from previous risk assessments from the European Food Safety Authority (EFSA) and other risk assessment institutions and scientific

publications found by literature searches. Some such substances were found to be of potential health risk for one or several groups of consumers (among adult men and women, adolescents and children down to the age of 3 years). Within the EU and the European Economic Area, 'other substances' remain largely unregulated. To ensure safe use of 'other substances', some countries have therefore established a national regulation of these substances. These risk assessments performed by VKM will be the basis for a national regulation in Norway.

197. Nutraceuticals role in modulation of gut–brain axis in elderly people

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A rather new and somewhat unusual concept connects brain functions to gut microbiota. It is called the 'gut–brain axis' (or 'microbiota–gut–brain axis') and states that probiotics consumption and a healthy gut microbiota positively influence brain functions related to behaviour and cognition. This concept is even more intriguing when regarded from the perspective of blood–brain barrier, which was supposed to isolate the central nervous system from peripheral influences and to control and direct the traffic of selected mediators in and out of the brain. This barrier is, however, altered in ageing by multiple factors, from hypercholesterolemia and hypertension to cerebral amyloidopathy. Synergistic with a low chronic grade peripheral inflammation, this faulty barrier exposes the aged brain to negative extra-cerebral signals. Given the quasi-constant failure of pharmacological treatments in neurodegenerative diseases, increased interest is directed towards allopathic medicine, including dietary supplements. Currently, there is an increasing amounts of evidence that nutraceuticals, mostly those with anti-inflammatory action, are protective against blood–brain barrier alteration and against neuroinflammation itself. But most recently interplay between gut microbiota and the central nervous system by immune, neural and metabolic pathways is being explored as a possible modulator of cognitive impairment and behaviour disorders. In elderly people, this axis has been reported to be altered, contributing to systemic inflammation and was also indicated as a possible marker for early frailty in the younger population. Currently, there are several clinical trials addressing the relationship between gut microbiota and central nervous system psychiatric disorders and at least one directly investigating whether there is a correlation between the composition of the gut microbiome, permeability of the intestinal barrier and systemic inflammation in patients with dementia. This chapter discusses evidence-based data on positive modulation of the gut–brain axis to alleviate behaviour and cognition alterations in the elderly.

198. A 10-year monitoring of allergens in foodstuffs in Cyprus

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According to the World Allergy Organisation, even traces of undeclared allergens can cause an allergic reaction to certain individuals. Currently, there are 14 categories of substances or products causing allergies or intolerances covered by the EU legislation (1169/2011). However there are no legislative concentration limits covering their presence in food.

Over the last 10 years (2008–2017), 2,773 food samples (local and international), taken from retail stores and import warehouses in Cyprus, were analysed with enzyme-linked immunosorbent assay (ELISA) or real-time PCR to detect allergens. The number of samples that contained an allergen (protein or DNA) above the limit of quantification, without the relevant labelling, was 196 (7.1%). An additional 47 samples (1.7%), contained the allergen in concentrations higher than the limit of detection and lower than the limit of quantification, according to the validation of the method used. The most frequent undeclared allergen in the tested samples was milk protein, followed by tree nuts (almond, hazelnut, walnut and pistachio) and peanuts.

Our results declare the presence of a significant number of food samples containing undeclared allergens in the EU market, so posing a risk to consumers' health. This highlights the need for a harmonised policy on the methodology and risk assessment for food allergens in EU, in an effort to eliminate the problems caused to the consumers, authorities and food businesses.

199. Use of biomarkers in the setting of dietary reference values (DRVs) for micronutrients – experience deriving from recent revisions

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The European Commission requested the European Food Safety Authority (EFSA) to update the DRVs established by the Scientific Committee on Food in 1993. DRVs are evidence-based reference values for the nutrient intake of healthy populations. We present an approach for setting DRVs for micronutrients for adults based on the use of biomarkers.

Biomarkers can refer to the levels in biological specimens of a nutrient, its metabolites, or enzymes and cofactors involved in biochemical activities, and can indicate nutrient intake, metabolism of dietary constituents or nutritional status.

Appraising new scientific evidence to set DRVs, EFSA reviewed for each vitamin and mineral the dose–response relationship between nutrient intakes and biomarkers, and the relationship between biomarkers and health outcomes. Biomarkers were selected as indicators for setting DRVs for vitamins D and B_6, folate, riboflavin, cobalamin, niacin, thiamin and selenium. For example, the levelling off of plasma selenoprotein P concentration was selected to indicate adequate supply of selenium to body tissues and saturation of the functional selenium body pool. Serum 25(OH)D concentration, reflecting the amount of vitamin D from cutaneous synthesis and dietary sources, was used as a biomarker of vitamin D status and of vitamin D intake in populations with low exposure to UV-B irradiation, and evidence showed an increased risk of adverse health outcomes at 25(OH)D concentrations below 50 nmol/L.

Barriers to the use of biomarkers included lack of validation, lack of standardised protocol for collection and storage, or no/unclear dose–response relationship between biomarker and nutrient intake/nutrient status/health outcome. Less attention has also been paid to the evaluation of their reproducibility and sensitivity in detecting changes in intakes and over time.

Development and improvement of biomarkers and relevant analytical methods may gradually contribute to new/more robust approaches to reflect intake or status for certain micronutrients, and to be used to set DRVs.

200. Safety assessment of genetically modified brown rice in the nutritional compositions through multiple statistical analysis

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Safety assessment of genetically modified GM rice, which were OsCk1 (disease resistant), Agb0102 (resveratrol synthase), and Agb0103 (drought-tolerant) was conducted by comparing nutrients, antinutrient and phenolic compound equivalences with their non-GM comparators and reference commercial rice. The analysed components for OsCK1 were proximate, amino acids, minerals, fatty acids, vitamins, and. Phytic acid, trypsin inhibitors, and phenolic acids of Agb0102 and Agb0103 were analysed to identify the biological equivalences with their non-GM comparators and the impacts of GM and the environment. The analytical tools used were principal component analysis (PCA), and hierarchical clustering analysis (HCA) with Pearson's correlation analysis. The GM rice varieties were biologically and substantially equivalent in all of the nutrients and antinutrients evaluated. Statistical analysis showed that the proximate, amino acid, mineral, vitamin and antinutrient components were not biologically different between OsCk1 and non-GM rice. The PCA results of phytic acid and trypsin inhibitors revealed no clear separation among rice varieties due to breeding conditions, environmental conditions or among the various cultivars. The phenolic acids were not separated clearly and overlapped in the environmental conditions and different cultivars, respectively. The Pearson correlation and HCA analysis showed strong relationship between GMO and non-GMO. These results indicated that the contents of antinutrient and phenolic compounds of the GM rice were not different from those of their non-GM comparators.

Where science meets society

201. Communication inside Risk Assessment and Risk Management (COMRISK)

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The goal of the COMRISK project is to identify current practices and challenges in communication between risk assessors and risk managers and

so increase the understanding of the interaction between risk assessing and risk managing organisations. The main question is 'How can we make a risk assessment that helps the risk managers to make an informed decision, balancing risk and benefits associated with feeds and foods without telling them what decision to take?'.

The project is structured in different phases: startup, collection, synthesis and reporting phase. In addition, four tasks were defined including horizontal activities (0), and vertical tasks like risk assessment in current decision-making (1), management strategies in risk assessment (2) as well as interaction between risk assessment and risk management – regulation, policy, agreements, culture and tools (3). Related to these tasks, relevant data will be extracted and used to set up a questionnaire that will be the basis for interviews with experts in the field of risk assessment and risk management. Each interview will target questions from all three vertical tasks. Results are intended to give an overview of the practical implementation of regulations and policies, and the agreements and culture prevalent within each body.

As an outcome we expect that good practices and challenges in communication of risk assessment results to risk managers will be identified to improve the process of risk analysis within Europe. In addition, it is our intention to follow up the project with future grant applications.

The consortium of this EFSA Partnering Grant (GP/EFSA/AFSCO/2017/01–GA05) is composed of experienced institutions including partners from four different European countries: National Veterinary Institute (SVA, Sweden, Coordinator), The German Federal Institute for Risk Assessment (BfR), Finnish Food Safety Authority (EVIRA), Wageningen University (WU, the Netherlands). The project started in January 2018 and will run for 2 years.

202.Based on current legislation should meat be banned?

CHRISTOPH Eugen H.
Independent expert

Francesca Riolo – Independent expert

This provocative poster highlights selected scientific evidence available on the impact of meat production and consumption on human and animal health and the environment, making meat qualifying for being a food that "is likely to constitute a serious risk to human health, animal health or the environment" for which, according to current legislation (e.g. article 53 of Regulation (EC) 178/2002), one or more restricting measures including the suspension of the placing on the market or use of the food in question could be adopted.

Scientific evidence indicates that meat consumption and production could constitute a serious risk to human health, animal health and the environment.

Moving towards mostly vegetable-based diets brings several environmental and human and animal health benefits while being a fundamental action to meet future challenges on food security and European and international environmental sustainability targets such as those set by the EU 7th Environmental Action Program and by the UN Sustainable Development Goals.

The authors suggests EFSA to perform a systematic review of all recent studies and evidence to establish an EFSA opinion on the risks associated with the consumption and production of meat and other animal products on human health, animal health and the environment and to take appropriate steps to inform the general public of the nature of these risks, including health risk as provided by article 10 of the General Food Law. Furthermore, EFSA could include environmental concerns in dietary guidelines and develop science based sustainable diets recommendations.

According to the strategy objective "Create an environment and culture that reflects EFSA's values", EFSA could actively engage into raising awareness among staff and experts over the impacts that current dietary choices have on human health and on the environment and use food sustainability guidelines when organizing events and outsourcing catering services.

Evolving towards the establishment of a European Food Sustainability Authority and challenging the current major crisis, not only on the basis of societal expectations and values, but on the solid and extensive available scientific evidence, is what could be truly called "contextualising risk assessment", "advancing risk assessment science" and "staying relevant in a changing world", the themes of this year conference.

203.Dietary exposure uncertainties mapping

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Uncertainty analysis is a vital component of dietary exposure assessment, which is necessary to understand the strengths and limitations of the results. However, the sources and types of uncertainties in deterministic and probabilistic exposure models can vary widely. We present a method for mapping different sources and types of uncertainties to better describe uncertainty analyses and to generate a more realistic understanding of dietary exposures. Parameter and model uncertainties are identified for each modelling approach (from a simple deterministic and to a more sophisticated probabilistic exposure

assessment). The relative importance of each source of uncertainty is then evaluated using a semi-quantitative scale and the results expressed using different forms of graphical representation. The value of this approach in expressing uncertainties in a manner that is relevant and useful to risk managers and the wider public is discussed.

204. Uncertainty communication – EFSA's approach to communicating scientific uncertainties in food safety assessments

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Communicating scientific uncertainties is an important component of EFSA's broader practices of risk assessment and risk communication. EFSA communicates the results of its scientific assessments to decision-makers, stakeholders (e.g. safety risk managers, assessors, consumer/non-governmental organisations, media, food chain businesses) and the public at large. A clear and unambiguous communication of scientific uncertainty helps them to understand the range and likelihood of possible consequences, and acts as an enabling mechanism providing scientific grounds for risk-based decision-making. While developing its 'Guidance on Uncertainty Analysis in Scientific Assessments, EFSA's Scientific Committee recommended EFSA to develop further guidance on communication. The resulting 'Guidance on Communication of Uncertainty in Scientific Assessments' here presented contains general recommendations for communicating uncertainty and specific advice on how to communicate the various expressions of uncertainty produced by the methods described in the 'Guidance on Uncertainty Analysis in Scientific Assessments'. Such recommendations are tailored according to EFSA's three categories of target audience–'entry', 'informed' and 'technical'. The key evidence sources include an expert analysis of selected academic literature, extracts from frameworks or documents similar in scope and purpose from other advisory bodies, and the results of EFSA target research – a focus group study and an online survey carried out in six languages and eight EU countries. Expertise in social sciences, scientific assessment and communications were vital to set down this approach to aid risk communicators at EFSA, but which can also be applied by risk communicators working in the food safety, public health and related areas.

205.Methodology to evaluate pesticide active substances for the essential control of a serious danger to plant health

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EFSA

Fernando Álvarez-Alfageme, Ciro Gardi, Christina Riemenschneider, Claudia Heppner – EFSA

*The positions and opinions presented in this poster are those of the authors and are not intended to represent the views or scientific works of EFSA.

In the European Union the evaluation of active substances (a.s.) used in plant protection products (PPP), and their residues in food and feed is regulated and follows a comprehensive process with responsibilities of risk assessors in Member States (MSs), the European Food Safety Authority (EFSA), and risk managers in the European Commission (EC) and MSs.

The objective of the risk assessment is concluding whether the a.s. can be expected to meet the approval criteria in Article 4 of Regulation (EC) No. 1107/2009. A request of derogation can be requested by applicants and/or MSs in specific cases i.e. (1) under Article 4(7) (approval of substances which are so essential but may be non-approved, even if there is an acceptable risk assessment); or (2) under Article 53 (emergency authorisations of PPP due to a danger which cannot be contained by any other reasonable means).

The EC requested EFSA to develop a methodology for the evaluation of data on the necessity of the application of herbicides, insecticides and fungicides a.s. to control a serious danger to plant health that cannot be contained by other available means, including non-chemical methods. EFSA delivered three protocols, proposing a harmonised methodology for the evaluation of the request of derogation. The methodology is based on: (1) alternative a.s. and risk of resistance; (2) non-chemical alternatives; and (3) resistance management scores.

Since 2016, EFSA has evaluated the request of derogation for six a.s. (flumioxazin, flupyrsulfuron-methyl, isoxaflutole, pymetrozine, bromoxynil and thiacloprid) under Article 4(7). To date EC did not grant an approval under this provision. In 2018 EFSA applied the Article 4(7) insecticide protocol to evaluate whether Article 53 emergency authorisations granted by several MSs for three neonicotinoids were scientifically supported.

206. Food innovation requires transparency and efficiency in risk assessment

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Strengthening of public trust in the EU risk assessment model requires a holistic approach, which aims at ensuring the sustainability, efficiency and transparency of the risk assessment in the food and feed chain. Consistent science-based decision-making by risk managers along with improved risk communications by the European Commission, the EU Member States and EFSA would contribute to enhance public trust in the current system.

To increase public confidence, the public demand for more transparency needs to be embraced by all players and across all processes. A balanced approach to transparency requires a mechanism for disclosure of information, which ensures the protection of legitimate private and public interests, including innovation and competitiveness.

Sustainability of the EU risk assessment model also necessitates a mechanism to attract the best expertise in EFSA to guarantee continuity and in-depth understanding of the risk assessment principles. Stakeholder consultations during the development of EFSA mandates and pre-submission activities for obtaining scientific advice from EFSA would enhance the quality of product applications as well as the level of engagement of society.

Effective communication addressing the broad public is essential. Improved communication should highlight the integrity and quality of EFSA's Scientific Opinions in a manner that is understandable for the general audience. Major strengths of the current system, which is the most rigorous in the world, like adherence to EU and international guidelines for conduct of scientific studies, independence of the EFSA review and quality systems under independent control, need to be proactively explained and communicated to EU citizens. The European Commission and other EU institutions should address the spread and sources of misinformation that undermine science-based risk assessment and the credibility of EFSA.

207. Building a framework to help define a tolerable risk in food allergy

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Tolerable risk links risk assessment and risk management, driving the necessary measures to ensure that risk management objectives are attained. Yet, while risk assessment and management measures are intensely debated, formulation of food allergy risk lacks clarity and the rationale and values underlying decisions about tolerable risk are often not explicit. This lack of clarity has significantly affected definition of appropriate risk benchmarks for food allergens, hindering improvements in their management. To address this issue, the ILSI Europe Food Allergy Task Force has assembled a multistakeholder Expert Group to investigate a potential framework to make definition of tolerable risk clearer and more consensual. This project will identify participants in the framework (expertise, stakeholders) as well as what parameters the framework will need to consider. Together with risk assessment scientists from academia, industry and government, food allergy clinicians and psychologists, the Expert Group includes representatives of those most closely affected, i.e. people with food allergies. Successful development and implementation of such a framework in food allergy could also point to applications in other areas of food safety, and helping to promote greater trust in food safety assurance.

208. On 'fakebook science' and democracy

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The 2018 EFSA Conference is on 'Science, Food, Society'; the main theme of the first day is 'Where science meets society: putting risk assessment in context'. It is claimed that 'values are becoming more influential than facts in shaping public opinion' and 'risk managers need to balance facts and values effectively'. Therefore, we are in need of 'restoring the credibility of and trust in risk assessment, by placing it in a societal context'.

These statements are problematic, in that they seem to oppose 'facts' to 'values'. In discussing such possible confusion, I will make a few points:

The concept of evidence, with relation to the base of data and science-informed analyses (risk assessment) that should guide the outlines of policies to be implemented (risk management), is contentious. Yet, many experts still think that, once the due dose of humility has been applied in recognising the limits of our knowledge and of the tools we use to investigate reality, the search for objective truths remains the necessary premise to good policy decisions. The insistence of some scholars (mostly sociologists) in warning that scientific results – particularly in risk assessment – are always value-laden, or even biased, may drive us down the slippery slope of total relativism: worse than being an oxymoron, that position is logically contradictory. Therefore, a rational and healthy distinction between facts and values is to be reaffirmed and buttressed.

The search for evidence must follow scientific guidelines: the risk assessment should not be influenced by the moving tides of public opinion. EFSA's chief, Dr Bernhard Url, warned about 'Facebook science' (www.youtube.com/watch?v = ivQ0Ph9OWZU&feature = youtu.be), i.e. the untenable belief that risk managers (political decision-makers) should be offered evaluations that are carved out according to demands coming from sectors of society, frequently supported by online petitions. Moreover, those referenda may be deceitful, as they often rely on fake news and 'alternative facts': since internet websites and social networks are too often sources of misinformation, I propose to call this phenomenon 'fakebook science'.

Indeed, politicians who are looking for easy consensus can elect to put aside a sound scientific approach and follow the groundless stances of influential pressure groups: risk managers may voluntarily argue against risk assessors. Two sad examples are the prevalent unscientific regulation of so-called Genetically Modified Organisms in most countries and the recent debate about the re-authorisation of the herbicide glyphosate in the European Union. In these cases, office-holders decided either to ignore or to question the overwhelming scientific consensus. This opportunistic behaviour is called demagoguery by political scientists.

Such a dubious course of action is allegedly based on a pillar of our democratic framework: it is maintained that, when a great number of people express their preference for certain options, their will must be followed. But this conviction reveals a deep lack of understanding of what democracy is: basic values are not dependent on the variable moods of the public, but are established and rooted in constitutions. The majority rule is a necessary, but not sufficient, condition of democratic collective choices.

In this sense, not all 'values' are equal: decision-makers should have the constitutional principles as a constant reference. Consider the two situations mentioned above: most life scientists have always pointed out that the biotech processes used to create agricultural novelties have no relevance for the evaluation of the outcomes, and therefore any sectarian regulation for 'GMOs' is unjustified; as for glyphosate, almost all the international organisations which oversee the safety of chemicals (EFSA, FAO+WHO, ECHA, EPA) concluded that the product is relatively benign. Following those science-informed risk assessments, risk managers should not have any doubt about legitimate authorisations. In any such case, the principle to be preserved is the economic freedom of a fairly regulated market – one cherished value in democracies.

209. Exploring a future model for the scientific risk assessment of pesticides

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Based on internal reflections and dedicated consultations with the EFSA Pesticides Steering Network (PSN) and the PPR Panel, the poster will explore the possibility of extending the scientific risk assessment at EU level, to include also of the scientific assessment of plant protection products (PPP). The separation between risk assessment and risk management and the direct involvement of the network of Member State (MS) risk assessment organisations coordinated by EFSA are key strengths to be maintained. In addition, some scientific and technical assessments such as efficacy or integration of plant protection alternatives for ensuring sustainable use are better suited for national evaluations; while risks to human health and the environment could be efficiently covered at EU level using landscape considerations supported by spatially explicit tools.

For dietary risk assessments, Regulation (EC) No. 396/2005 already requires harmonised scientific assessments at EU level covering all uses, as well as specific provisions for updating the risk assessment to account for the authorised uses of PPPs by the MS. The proposal focuses on the pre-market scientific review process described under Regulation (EC) No. 1107/2009 focusing on options for extending both concepts – meaning an EU assessment of all uses and an update of the risk according to the MS authorisations – to the non-dietary human health

assessments and to environmental risks. Innovative ways for addressing the zonal and regional variability within a single but spatially explicit assessment at EU level are proposed; those could cover the environmental assessments as well as non-dietary risks for workers, residents and bystanders. A key driver is to produce pesticides risk assessment outcomes relevant not only for decision-makers at EU and MS level, but also for farmers, practitioners and citizens in general.


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