International Conference on Uncertainty in Risk Analysis

Challenges and Advances in Assessing, Managing and Communicating Uncertainty

February 20–22, 2019, Berlin

BfR
Bundesinstitut für Risikobewertung

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European Food Safety Authority

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Imprint

BfR Abstracts

International Conference on Uncertainty in Risk Analysis

All authors are responsible for the content of their respective abstracts.

German Federal Institute for Risk Assessment
Max-Dohrn-Straße 8–10
10589 Berlin
Germany

Berlin 2019
133 Pages

DOI 10.17590/9cry-3643

Printing: BfR-printing house Marienfelde

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Dear readers,

"*Measuring and Communicating the Unknown*" is the motto of the International Conference on Uncertainty in Risk Analysis in Berlin, February 20–22, jointly organised by the German Federal Institute for Risk Assessment (BfR) and the European Food Safety Authority (EFSA). The goal of this conference is to explore the wide scope of uncertainty. The conference features contributions ranging from cognitive science, methodology, communication, decision making to dialogue in an open society.

As scientists and risk assessors we are committed to making uncertainties explicit. We have to call a poor data basis a poor data basis if this is what we have. We are also facing misconceptions about science as such. The truth is: science cannot prove everything. The nature of the scientist is to be unsure and curious. I mention here also the so-called reproducibility crisis. The body of scientific information is partially distorted because basic principles of good scientific practice are violated. You may know that this year, the BfR has launched its "*Animal Study Registry*", a worldwide platform for pre-registration of animal studies. It is expected that the practice of pre-registration counteracts the known publication biases as has been shown for clinical studies.

As risk assessors, we need to account for limitations of the scientific evidence and additional uncertainties that are associated with integrating all the evidence to answer a given question. The effects of the uncertainties on our conclusions should be shown clearly. At the end, a rational decision making can be achieved, facilitated through effective communication among all involved parties. Is this fiction or reality? In any case, this is a challenge at the interface of science, policy, stakeholder and interest groups. This conference will be a place to exchange experiences about this process.

The Federal Institute for Risk Assessment and the European Food Safety Authority have cooperated on the topic of uncertainty analysis for example by comparing our respective guidance documents. The findings are published as EFSA report and a synopsis can be found in this abstract book. This conference is also part of a BfR-EFSA Framework partnership Agreement.

I would like to thank our colleagues from EFSA and the international experts of the Scientific Committee for their support in preparing this conference. My thanks go to all who have contributed to this event as workshop presenters, speakers and participants in discussions.

I wish you an interesting and inspiring reading.

Professor Dr Reiner Wittkowski
Vice-President of the German Federal Institute for Risk Assessment

Dear readers,

We can never be completely certain about the future, either in science, or in everyday life. Assessing and taking account of uncertainties is a normal part of scientific work and of everyday life. For example, meteorologists review satellite images to make predictions about the weather. They are rarely 100 per cent certain what will happen. So when they make a forecast, they usually indicate how likely it is. If they say there is a “strong chance” of rain, you will probably decide to take your umbrella when you go outside. If the chance of rain is “slight”, you are more likely to decide to leave your umbrella at home. If the forecaster uses percentages – a 90 % or 10 % chance of rain – for many of us the message becomes even clearer. Therefore, not only the conclusion but also the way in which it is communicated is important to fully share an understanding of the uncertainties involved.

The same principles apply to food safety. For example, scientists may be asked to assess the safety of a new food, pesticide or food-borne bacteria. When evidence or knowledge is incomplete, they try to explain how the uncertainty may affect their conclusions.

The European Food Safety Authority (EFSA) is committed to providing EU risk managers with transparent and robust scientific advice. Decision-makers need clear advice if the scientific evidence indicates different outcomes might be possible and how likely they are. EFSA also wants the wider scientific community to understand its work better and to create the conditions for others to repeat our assessments if they wish, or contribute with additional information and insights.

EFSA has developed a harmonised approach, setting common standards and criteria for assessing and communicating the uncertainties in all of EFSA’s scientific areas. This will improve the transparency and robustness of EFSA’s scientific advice and help to contextualise assessment conclusions better. The communication aspects of uncertainty are equally critical to EFSA’s dialogue with risk managers and civil society, and for ensuring public confidence in the EU food safety system.

The main aim of this conference is to bring together risk assessors, communicators and managers to exchange on the science behind uncertainty analysis and show case best practices in conducting and communicating uncertainty analysis as well as for addressing uncertainty in decision making. In line with the aim of the conference EFSA’s new approach to communicating scientific uncertainties was made possible by fusing the expertise of social scientists, natural scientists and communicators.

I would like to thank our colleagues from BfR and the international experts of the Scientific Committee for their support in putting together an interesting programme. I would also like to thank all who have contributed to this event as workshop presenters, speakers and participants in discussions. Finally, special thanks to the BfR colleagues for their past and future collaboration on this subject, and in particular for hosting the conference and providing the logistical support for helping to make this conference a success.

I wish all participants a successful conference and fruitful discussion. I hope you will all enjoy your stay in Berlin.

Dr Tobin Robinson
Head of the Scientific Committee and Emerging Risks Unit at the European Food Safety Authority

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Frederic Müller
German Federal Institute for Risk Assessment (BfR), Germany

Programme

Thursday, 21 February 2019

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Reiner Wittkowski, Federal Institute for Risk Assessment, Germany
Tobin Robinson, European Food Safety Authority, Italy

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Caroline Merten, European Food Safety Agency, Italy

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The taming of uncertainty: How we make sense of chance by words and numbers
Karl H. Teigen, University of Oslo, Norway

09:45–10:05 am
Cognitive biases arise from conflating epistemic and aleatory uncertainty
Scott Ferson, University of Liverpool, United Kingdom

10:05–10:25 am
Using games to train or test our ability to express epistemic uncertainty
Ullrika Sahlin, Lund University, Sweden

10:25–11:00 am Coffee break and poster viewing

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Chris Roth, French Agency for Food, Environmental and Occupational Health & Safety, France

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Uncertainty with and beyond the data: approaches to deal with different types of unknowns
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Application of Dempster-Shafer theory to estimate uncertainty and combine diverse sources of evidence in chemical risk assessment
James Rathman, Molecular Networks GmbH and Altamira, LLC, Germany

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Uncertainty and variability in Bayesian inference for dietary risk: *Listeria* in RTE fish
Jukka Ranta, Finnish Food Authority, Finland

12:10–12:30 pm
APROBA-Plus: A probabilistic tool to evaluate and express uncertainty in hazard characterisation and exposure assessment of substances
Bas Bokkers, National Institute for Public Health and the Environment, The Netherlands

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Olaf Mosbach-Schulz, European Food Safety Agency, Italy

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John Paul Gosling, University of Leeds, United Kingdom

02:15–02:35 pm
Performance weighting and the IDEA Protocol for expert elicitation
Victoria Hemming, University of Melbourne, Australia

02:35–02:55 pm
Uncertainty assessment for interdependent parameters, exemplified by PBPK modelling for risk assessment
Natalie von Goetz, Swiss Federal Office of Public Health, Switzerland

02:55–03:15 pm
Managing uncertainty and variability when assessing beneficial source of iron brought by red meat consumption in France
Juliana De Oliveira Mota, National Institute of Agricultural Research, France

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Oliver Lindtner, Federal Institute for Risk Assessment, Germany

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Alberto Garre, University of Cartagena, Spain

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How evidence-based methodology can contribute to uncertainty assessment
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Assessing the borderline range of prediction models: Method and implications for decision-making
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Characterisation of the conceptual model uncertainty in radioecology
Laura Urso, Federal Office for Radiation Protection, Germany

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Christine Müller-Graf, Federal Institute for Risk Assessment, Germany

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Michael Siegrist, ETH Zurich, Switzerland

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Matthias Greiner, Federal Institute for Risk Assessment, Germany

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Karen Luyckx, Global Feedback Ltd, United Kingdom

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Piet Sellke, Ortwin Renn, Institute for Advanced Sustainability Studies, Germany

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Sabine Hoffmann, Ludwig-Maximilians-Universität München, Germany

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Poster guide: Caroline Merten, European Food Safety Agency, Italy

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Podium discussion and closing
Magda Osman, Queen Mary University of London, United Kingdom
Key speakers
Moderation: Suzan Fiack, Federal Institute for Risk Assessment, Germany

1 Lecture abstracts

1.1 Topic I: Uncertainty from a cognitive science point of view

1.1.1 The taming of uncertainty: How we make sense of chance by words and numbers

Karl H. Teigen
University of Oslo, Norway

Approximate knowledge about quantities can be embedded in our estimates in many ways. For instance, estimates can be given verbal qualifiers (likely, perhaps) or be presented as ranges (10–30 %). Both are informative about external facts as well as the amount and type of (un)certainty involved. We have in addition studied their pragmatic implications, which are produced by their ability to direct the listeners' attention to various aspects of the target issue. Verbal expressions can be directed toward a target's occurrence ("it is likely") or its non-occurrence ("not quite certain"). Range boundaries are also directional ("more than 10 %" vs. "at most 30 %"). Directionality is a product of context and communicative intentions, and makes readers infer attitudes, expertise, recommendations, warnings, and trends. Some verbal qualifiers (can, is possible) are typically used about extreme and hence unlikely outcomes, but are often perceived to indicate intermediate probabilities. Range estimates function as categories defining the demarcation line between hits and misses; their probabilistic nature is rarely considered and often misunderstood. The surplus meaning hidden in the way we frame approximate knowledge is rarely discussed but important for the sense we make of numerical estimates.

1.1.2 Cognitive biases arise from conflating epistemic and aleatory uncertainty

Scott Ferson
University of Liverpool, United Kingdom

Decision scientists and psychometricians have described many cognitive biases over the last several decades, which are widely considered to be manifestations of human irrationality about risks and decision making. These phenomena include probability distortion, neglect of probability, loss aversion, ambiguity aversion and the Ellsberg Paradox, hyperbolic discounting, among others. We suggest that all these and perhaps other biases arise from the interplay between distinct special-purpose processors within the multicameral human brain whose existence is implied by recent clinical and neuroimaging evidence. Although these phenomena are usually presumed to be misperceptions or cognitive illusions, we describe the evolutionary significance of these phenomena in humans and other species, and we place them in their biological context where they do not appear to be failings of the human brain but rather evolutionary adaptations. Apparent paradoxes arise when psychometricians attempt to interpret human behaviors against the inappropriate norm of the theory of probability, which turns out to be an overly precise calculus of uncertainty when in reality the different mental processors give contradictory results. This view of the psychological and neurological evidence also suggests why risk communication efforts so often dramatically fail and how they might be substantially improved. For instance, it now seems clear that what risk analysts call epistemic uncertainty (i.e., lack of knowledge or ambiguity) and aleatory uncertainty (variation or stochasticity) should not be rolled up into one mathematical probabilistic concept in risk assessments, but they instead require an analysis that distinguishes them and keeps them separate in a way that respects the cognitive functions within the decision makers to whom risk communications are directed.

1.1.3 Using games to train or test our ability to express epistemic uncertainty

Ullrika Sahlin
Lund University, Sweden

Expressing and understanding epistemic uncertainty are important skills for risk assessors and scientific experts to successfully assess and communicate uncertainty. It is relevant to ask if the ability to express uncertainty can be improved and, if so, how? One way is to use computer games to make people curious about expressing epistemic uncertainty. We demonstrate games developed for this purpose which allow the players to explore their ability to express uncertainty by a probability interval (Bean Guesser, Probability Guess), a lower bound on a frequency (Frequency Guesser), a probability density function (Probability Bee) and as a belief in a proposition (Quiztimate). The feedback in the games relies on proper scoring rules that motivates the players to express their uncertainty as honestly as possible. We plan to use these scores to measure the ability to express and understand epistemic uncertainty (or in short “uncertaincy”). We have looked for individual differences and learning trends in players’ performances of the games. We discuss if the games can be used to measure “uncertaincy”.

1.2 Topic II: Methods of uncertainty analysis

1.2.1 Uncertainty with and beyond the data: approaches to deal with different types of unknowns

Zora Kovacic
University of Bergen, Norway

Uncertainty cannot always be quantified. While in some cases risks can be associated with probabilities, phenomena like hurricanes and earthquakes are known to be more recurrent in certain areas, but their occurrence in a specific point in time cannot be predicted. For this reason, uncertainty scholars often distinguish between risk (a situation in which the possible outcomes are known and their probabilities can be estimated), and strict uncertainty (a situation in which the possible outcomes are known but their probabilities cannot be calculated). Moreover, even when quantification may be technically possible, it may not be advisable to rely solely on probability analysis in cases that involve public safety, such as risks related to earthquakes, endocrine disruptors, and carcinogenic substances. A deeper understanding of the implications of uncertainty for decision-making and for the relationship between science and society may be necessary. In this presentation, I will give an overview of the theoretical basis of uncertainty analysis and of the development and practical applications of approaches that characterise uncertainty within and beyond the data, taking into account uncertainties in methodology, in the knowledge base, in social and ethical aspects. I will give an overview of the theoretical concepts of risk, uncertainty, ignorance, indeterminacy, and ambiguity, and of approaches such as NUSAP, the analysis of technical, methodological and epistemic uncertainty.

1.2.2 Application of Dempster-Shafer theory to estimate uncertainty and combine diverse sources of evidence in chemical risk assessment

James Rathman[1,2], Chihae Yang[1], Mark Cronin[3]

[1] Molecular Networks GmbH and Altamira, LLC, Germany
[2] Ohio State University, USA
[3] Liverpool John Moores University, United Kingdom

In safety and risk assessment of chemicals, multiple and diverse sources of evidence can be used to predict whether a given substance may pose a risk for a particular type of toxicity. Evidence may come from in silico (computational) approaches, such as quantitative structure-activity relationship (QSAR) models, rule-based structural alerts, or experimental data from assays relevant to the toxicity endpoint of interest. Dempster-Shafer theory (DST) is a rigorous decision-theory approach that provides a way to make assessment decisions, estimate the uncertainty associated with each decision, and combine multiple sources of evidence to obtain a weight-of-evidence decision. The DST approach involves quantitatively accounting for the reliability of each of the evidence sources being combined. Methods are presented for deriving reliability scores from different types of evidence; e.g., reliabilities based on the quality of data from experimental studies or the documented performance of an in silico QSAR model or rule-based alert. The general approach is described for binary, ordinal, and multinomial classification models. The DST approach is also ideally suited for read-across, the process of assessing the risk of a data-poor target compound by analysis of data-rich analogue compounds. A read-across example is presented using information from the EFSA genetic toxicity database for pesticides. The goal is to estimate the genetic toxicity of metabolites based on information provided in the submission for parent compounds. Results show how analogue similarity, based on structural features, properties, or metabolic reactivity, is factored into the uncertainty estimation, and how uncertainty in the read-across outcome can be reduced using this weight-of-evidence approach to combine multiple sources of information for the target and analogue substances.

1.2.3 Uncertainty and variability in Bayesian inference for dietary risk: *Listeria* in RTE fish

Jukka Ranta, Petra Pasonen, Pirkko Tuominen
Finnish Food Authority, Finland

Dietary intake models are usually a combination of two modules with two data sources: occurrence data and consumption data. Occurrence data provides knowledge of prevalence and concentration of hazards in named foods, and consumption data provides knowledge of consumption frequency and consumption amounts for those foods. With sufficient data, a Monte Carlo approach may be used for sampling random acute exposures. With more limited data, the uncertainty of the underlying distributions needs to be addressed too. With microbiological hazards, data may also be available on the reported cases in populations. A Bayesian population risk model was constructed for utilising all data for a joint estimation of all model parameters. The combined model provides uncertainty distribution for underlying core-parameters which depends on the amount of given data. The combined modules include a Markov chain for the consumption variability between consecutive days, a growth model for *Listeria* in ready-to-eat (RTE) fish products, variability in initial concentrations, dose-response model over consumption days, and Poisson model for population incidence of reported cases per age-group. The model was implemented as a combination of R and OpenBUGS.

1.2.4 APROBA-Plus: A probabilistic tool to evaluate and express uncertainty in hazard characterisation and exposure assessment of substances

Bas Bokkers, Martine Bakker, Wout Slob

National Institute for Public Health and the Environment, The Netherlands

The user-friendly Excel tool APROBA-plus facilitates probabilistic risk assessment of substances. It plots the uncertainty in the probabilistic health-based guidance value against the exposure uncertainty, hereby transparently visualising the uncertainty about the distance between hazard and exposure. The tool is developed as an addition to the WHO-IPCS tool APROBA, which is a part of the guidance on “Evaluating and expressing uncertainty in hazard assessment” (2017). APROBA can do probabilistic calculations in an approximate but quick and easy way by applying lognormal uncertainty distributions to the different aspects of the hazard characterisation (such as Point of Departure, inter-, and intraspecies extrapolation). This results in a probabilistic health-based guidance value rather than the usual deterministic point estimate (such as RfD, ADI). In the extended APROBA-plus, exposure estimates with an uncertainty range can be included to create a single plot, which visualises the uncertainties in exposure and hazard.

The use of APROBA-Plus was evaluated by applying it to 19 different substances, showing that APROBA-Plus can indeed be used as a quick tool for risk assessment while making the (approximate) uncertainties in both the hazard and the exposure visible. By making the uncertainties visible, the outcome from a risk assessment becomes more transparent and informative than the more usual deterministic approaches, so that risk managers can make better-informed decisions, e.g. directly taking measures or asking for refinement of the risk assessment. If the latter, APROBA-Plus can help in showing which aspects in the risk assessment contributed most to the overall uncertainty, as an indication what type of refinement would be most effective. This tool could easily serve as a standard extension of routine risk assessments. The link to the tool is:
https:/www.researchgate.net/publication/326422432_APROBA_PLUS-V100_v012_TEMPLATE

1.2.5 Uncertainty quantification in next generation risk assessment

John Paul Gosling
University of Leeds, United Kingdom

Quantification of uncertainty allows practitioners to use a common and unambiguous language that encourages transparency about analyses. Quantified uncertainty can be used in formal decision making so that the decision makers can understand the relative likelihoods of various outcomes and robustness of their decisions, which are both beneficial when justifying choices. Historically, there has been reluctance to handle uncertainty in a quantitative way in many areas of science, but, recently, there have been more and more examples of quantitative methods being used to aid decision making. Also, there is a great deal of guidance on how to accommodate quantitative analyses (e.g., the 2018 EFSA guidance on uncertainty analysis) and software available. In this talk, I will discuss uncertainty quantification in the context of next generation risk assessment of the toxic effects of chemicals. In this area, researchers wish to characterise the potential hazards and exposures to the chemicals of interest in the light of various data sources including in vitro experiments and computer-based simulations. I will talk about quantitative methods for capturing uncertainty including elicitation of expert knowledge, probabilistic uncertainty propagation and Bayesian methodologies.

1.2.6 Performance weighting and the IDEA Protocol for expert elicitation

Victoria Hemming[1], Anca Hanea[1], Mark Burgman[2]

[1] University of Melbourne, Australia
[2] Imperial College London, United Kingdom

In this talk, I will present the IDEA protocol (“Investigate”, “Discuss”, “Estimate”, and “Aggregate”) for structured expert elicitation. I will describe how the protocol is being applied across a broad range of case studies to elicit expert judgements. I will then demonstrate how application of the protocol with the four-step elicitation and equal weighted aggregation helps to improve judgements under uncertainty. Following this, I look at how the judgements may be further improved by incorporating the aggregation methods and scoring rules of the Classical Model. In particular I discuss the problems that may arise if unwary practitioners do not completely understand the reward structure of the scoring rules and naively apply them. The IDEA protocol provides a simple and effective means to improve judgements under uncertainty, and while performance weighted aggregations can improve judgement, one must understand the reward structure of the scoring rules and ensure it matches the aspects of good judgement that they wish to reward, this may differ for interval judgements and distributions.

1.2.7 Uncertainty assessment for interdependent parameters, exemplified by PBPK modelling for risk assessment

Cecile Karrer[1], Natalie von Goetz[1,2]

[1] ETH Zurich, Switzerland
[2] Swiss Federal Office of Public Health, Switzerland

Exposure assessments are an integrative part of the risk assessment for chemicals and ideally chemical risk assessment is based on internal exposure estimates. Internal exposure estimates in turn rely on external exposure assessment and for their conversion on absorption fractions and/or a physiologically based pharmacokinetic (PBPK) model, so that the uncertainty assessment around calculated internal exposure estimates needs to encompass both types of models. While external exposure estimates can often circumvent the interdependence of model parameters (e.g. by basing the estimates on individual consumption of sources), this is more difficult for PBPK models. Chemical-specific parameters for human PBPK models are mostly based on animal in vivo studies or in vitro experiments. For example, the parameters for substance distribution in the body are estimated based on the distribution in the different organs after sacrificing the animals and the time course of the substance in the animal's blood and urine during the study. These parameters are interdependent: e.g. if more substance is transferred to the gonads, less substance is available to be transferred to the brain, so that a higher partition to the gonads must result in a lower partition to another organ (or organs). It is clear that there will be inter- and intra-individual variability around the respective parameters. However, usually for in vivo studies only summary data are reported (and not the datasets of single animals), so that the resulting animal-PBPK model is deterministic and does not account for natural variability. Consequently, uncertainty about variability translates from the model parameters to the internal exposure estimates. Extrapolation of the animal model to a human model introduces further uncertainties. This presentation intends to explore ways to quantitatively assess uncertainties in PBPK modelling, with a focus on uncertainties around interdependent parameters.

1.2.8 Managing uncertainty and variability when assessing beneficial source of iron brought by red meat consumption in France

Juliana De Oliveira Mota[1], Patrick Tounian[2], Sandrine Guillou[1], Fabrice Pierre[1], Jeanne-Marie Membré[1]

[1] National Institute of Agricultural Research, France
[2] Hôpital Trousseau, France

Dietary iron deficiency is the first nutritional deficiency in the world, and the third in France, in terms of disability adjusted life years (DALY). This nutritional deficiency may lead to anaemia, especially among children, adolescents and adult women. Red meat is the richest source of this nutrient in developed countries and must be considered as a strategy to reduce the risk of anaemia. The aim of this study was to assess the proportion and the number of iron deficiencies in France and evaluate its potential reduction thanks to red meat consumption.

The main challenge when making this assessment was to identify the sources and quantify the effect of variability (heterogeneity between individuals) and uncertainty (lack of knowledge). A probabilistic benefit assessment model was built, per age class and gender, to quantitatively assess the effect of iron from red meat on anaemia, this latter disease being expressed in number of cases but also in DALY. The model took into account the distribution of absorbed iron intake by the French population and the iron requirement distribution established by EFSA. Variability and uncertainty were propagated through the model using second-order Monte Carlo techniques. Variability sources come from the intake of absorbed iron and from iron requirements due to the heterogenic biological needs in iron. The sources of uncertainty taken into account in the assessment were due to the iron intake per class and gender, fitted by a lognormal probability distribution, and due to anaemia disability weight.

Our study contributed to determine the optimal quantity of red meat to be consumed to meet population iron needs, while meeting the recommendations of not exceeding 500 g of red meat per week.

Separating uncertainty and variability enables to identify data gap while facilitating decision-making. More generally, uncertainty and variability analysis has to be encouraged in risk and risk-benefit assessment research area.

1.2.9 Quantifying the bias of the viable cell enumeration process and its impact on microbial inactivation

Alberto Garre, Jose A. Egea, Paula M. Periago, Alfredo Palop, Pablo S. Fernandez
Technical University of Cartagena, Spain

The measurement of the microbial concentration is basic for Quantitative Microbial Risk Assessment (QMRA), being required for the estimation of the prevalence of microbial pathogens, as well as for the characterisation of microbial growth and/or inactivation kinetics. The serial dilution and viable plate count methodology is one of the most applied techniques. However, being the microbial count a discrete variable, it is strongly affected by experimental error and uncertainty. In this work, we analyse models based on the Binomial and Poisson distributions for describing the uncertainty of the microbial count due to the serial dilutions. Through a theoretical mathematical analysis we demonstrate that the Binomial distribution is more suitable for this task, whereas the Poisson distribution is only applicable when it is a good approximation to the Binomial (i.e. large n and small p). However, the Binomial distribution also introduces bias for low microbial concentrations. We show the implications of these results by Monte Carlo simulations of a microbial inactivation experiment, considering the uncertainty introduced by the cell enumeration methodology. We demonstrate that tail effects (usually associated to biological variability) can be an artefact introduced by the uncertainty in the cell enumeration methodology. Finally, we provide guidelines to identify whether tails observed in microbial inactivation experiments are artefacts or biological effects.

1.2.10 How evidence-based methodology can contribute to uncertainty assessment

Sebastian Hoffmann[1,2], Katya Tsaioun[1]

[1] Johns Hopkins Bloomberg School of Public Health, USA
[2] seh consulting + services, Germany

Evidence-based methodological approaches, especially systematic reviews, are being more and more introduced to the hazard and risk assessment of chemicals. The main reasons are to increase transparency, to comprehensively include all relevant evidence and to agree on a systematic assessment methodology up-front. In addition, such methodology offers opportunities to contribute to the assessment of the uncertainty inherent to chemical safety evaluations. Focusing on a few methodological approaches, including drafting and registration of an evaluation protocol, systematic literature searches, evidence selection and evidence assessment, we demonstrate their potential contribution, either conceptual, qualitative or quantitative, to uncertainty assessment. In addition, their merits and challenges in terms of scope, feasibility and timeliness will be discussed.

1.2.11 Assessing the borderline range of prediction models: Method and implications for decision-making

Silke Gabbert[1], Susanne N. Kolle[2], Miriam Mathea[2], Bennard van Ravenzwaay[2], Robert Landsiedel[2]

[1] Wageningen University & Research, The Netherlands
[2] BASF SE, Germany

For hazard classifications, continuous data from animal- or non-animal testing methods are often dichotomised into binary positive/negative outcomes by classification thresholds (CT). Experimental data are, however, subject to biological and technical variability. This results in uncertainty of the positive/negative outcome if the experimental result is close to the CT. The borderline range (BR) addresses this uncertainty and represents a range around the CT in which ambiguous outcomes are expected. Several analyses of the intra-assay variability of the animal test, the local lymph node assay (LLNA), have been published [1–5]. Previously, a BR of the LLNA has been defined [1]. In the following, BRs were determined for three non-animal methods assessing skin sensitisation hazard based on pooled standard deviations [6]. Our recent research presented here explores different ways to quantify the BR, using pooled standard deviations, pooled mean average deviation and resampling methods such as non-parametric bootstrap analysis from existing data of eye irritation and skin sensitisation non-animal methods as well as the animal method, the LLNA. The results demonstrate that (i) for given chemical training sets the precision of the methods is determining the size of their BRs, (ii) there is no 'perfect' method to derive a BR, alas (iii) a consensus on BR is needed to account for the limited precision of testing methods.

[1] Kolle *et al.* (2013) doi:10.1016/j.yrtph.2012.12.006
[2] Hoffmann (2015) doi:10.14573/altex.1505051
[3] Dumont *et al.* (2016) doi:10.1016/j.tiv.2016.04.008
[4] Dimitrov *et al.* (2016) doi:10.1002/jat.3318
[5] Luechtefeld *et al.* (2016) doi:10.14573/altex.1510055
[6] Leontaridou *et al.* (2017) doi:10.14573/altex.1606271

1.2.12 Characterisation of the conceptual model uncertainty in radioecology

Laura Urso[1], Moustapha Sy[2], Philipp Hartmann[1], Marc-Andre Gonze[3], Martin Steiner[1]

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Conceptual model uncertainty in environmental sciences originates from an incomplete understanding of the processes to be modelled and from simplifications needed to translate knowledge on phenomena of concern into a mathematical framework. This epistemic contribution to uncertainty is often neglected or mixed up with uncertainty on models parameters when quantifying the total uncertainty budget of an environmental model output, resulting in uncertainty bands that might be vastly underestimated. In various fields of research, such as hydrology, epidemiology, ecology and agronomy, conceptual model uncertainty has already been treated quantitatively. Various techniques have been developed to quantify this type of uncertainty if experimental data are available. These range from the combination of residual analysis and the standard Bayesian method to multi-model inference techniques. In the radioecological field, however, conceptual model uncertainty has not been addressed in a systematic way so far, although it can play a major role in various models. In this contribution, two models and their associated conceptual uncertainty are qualitatively described in detail, namely a model for quantifying the radiocaesium levels in wild boar and a model for quantifying the interception of wet deposited radionuclides onto plants. For these two examples, alternative model structures are discussed and approaches for estimating the conceptual model uncertainty are presented.

Acknowledgments
This work is partly supported by the EU project TERRITORIES. TERRITORIES is part of CONCERT and has received funding from the Euratom research and training programme 2014–2018 under grant agreement No 662287.

1.3 Topic III: Communication of uncertainties

1.3.1 Uncertainties about the communication of uncertainties

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Decision-making processes differ considerably across situations and individuals. This is a challenge for the communication of risks and uncertainties. Communication is especially challenging because there are large individual differences in how various communication formats about risks/uncertainties (e.g., pictogram) are processed by different people. People's processing of simple graphical displays of risk information depends on their skills and abilities. Most people avoid uncertainties if possible. In many important situations, however, a decision must be made under uncertainty. Even more challenging, when it comes to controversial topics, we usually do not have frequentist information but have to rely on experts' assessments. There is a lack of research, however, examining how experts' assessments should be communicated to the public so that they are correctly understood. In my talk, I will show that lay people often do not expect uncertainties associated with scientific outcomes. Furthermore, communication of uncertainty does not increase, but sometimes decrease trust in the outcome. Uncertainty communication may, therefore, have some unwanted side effects.

1.3.2 Communicating probability with natural frequencies and the equivalent binomial count

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Risk communication strategies for expressing a probability presume the probability is precisely characterised as a real number. In practice, however, such probabilities can often only be estimated from data limited in abundance and precision. Likewise, risk analyses often yield imprecisely specified probabilities because of measurement error, small sample sizes, and model uncertainty. Under the theory of confidence structures, the probability of an event estimated from binary data with k successes out of n trials is associated with a particular structure that has the form of a p-box, i.e., bounds on a cumulative distribution function. When n is large, this structure approximates the beta distribution obtained by a Bayesian analysis under a binomial sampling model and Jeffreys prior, and asymptotically it tends to the frequentist estimate k/n. But when n is small, it is imprecise and cannot be approximated by any single distribution. Confidence structures emphasise the importance of n to the reliability of the estimate. If n is large, the probability estimate is more reliable than if n is small. A probability resulting from a risk analysis can be approximated by a confidence structure corresponding to some values of k and n. Thus we can characterise the probability with a terse, natural-language expression of the form "k out of n", where k and n are nonnegative integers and $0 \le k \le n$. We call this an equivalent binomial count, and argue that it condenses both the probability and uncertainty about that probability into a form that psychometry suggests will be intelligible to humans. Gigerenzer calls such integer pairs "natural frequencies" because humans appear to natively understand their implications, including what the size of n says about the reliability of the probability estimate. We describe data collected via Amazon Mechanical Turk showing that humans correctly interpret these expressions.

1.3.3 Representing and expressing uncertainties and risk in a scientific context

Terje Aven
University of Stavanger, Norway

In this talk Professor Terje Aven will discuss some fundamental issues linked to the challenge of representing and expressing uncertainties and risk in a scientific setting. A key point made is that successful communication of uncertainties and risk requires a proper scientific platform – but unfortunately such a platform is often lacking in practice: How is it possible to meaningfully communicate uncertainties and risk, when for example an interpretation of the most basic tool – probability – is not available? It is simply not possible. It will fail. In the talk Aven will review basic risk science explaining the differences between different types of probabilities, and how risk is linked to uncertainties, knowledge and surprises. The use of subjective probabilities based on betting types of interpretations is rejected. In the talk Aven will also discuss implications for science in general and for judgments about what can be considered safe in particular.

1.4 Topic IV: Accounting for uncertainty in decision making

1.4.1 Reflections on framing and making decisions in the face of uncertainty

M. Granger Morgan
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Virtually all important decisions are made in the presence of considerable and often irreducible uncertainty. At a personal level we decide where to go to college, who to marry, when and whether to have kids. Nations decide how best to structure taxes, how best to deal with social services and health care, whether to go to war, and when to sue for peace – all in the face of deep uncertainty. Of course, the presence of uncertainty should not by itself be grounds for inaction. Indeed, the consequences of doing nothing often involve comparable or even larger uncertainty. There is a large literature on prescriptive analytical strategies for how people should frame and make decisions in the face of uncertainty. There is also a large descriptive literature on how people actually make such decisions. I will talk briefly about both and also discuss: methods for formal quantitative expert elicitation; the problem of ubiquitous overconfidence, problems with the use of scenarios, and problems with integrated assessment models that focus on finding optimal long-term global policies.

1.4.2 Scenario comprehensiveness in risk analysis

Edoardo Tosoni[1,2], Ahti Salo[1], Enrico Zio[2,3]

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The risk of safety-critical facilities must be assessed with regard to harmful consequences, e.g. human exposure to hazardous substances. Risk is often studied through methods of scenario analysis. However, the evolution of these systems being highly uncertain, there may be concerns about the comprehensiveness of the analysis.

The notions of comprehensiveness in the literature on scenario analysis are various. Here, we postulate that comprehensiveness is achieved if the residual uncertainty on the system risk is sufficiently small to warrant conclusive statements about it. Specifically, embracing the view of probabilistic approaches that quantify residual uncertainty by establishing lower and upper bounds on risk, comprehensiveness can be considered achieved if a predefined level of acceptable risk is not contained within the interval defined by these bounds.

Thus, we propose a Bayesian network-based scenario analysis method to quantify risk as the overall probability of unacceptable consequences. The parameters required for the analysis consist of probabilities, which are estimated through computational simulations and expert judgments. The associated epistemic uncertainties are addressed by considering all the probabilities contained in sets of plausible values. The propagation of these uncertainties leads to lower and upper bounds on risk, whereby comprehensiveness can be assessed by comparing the resulting interval with a predefined acceptable level. We offer guidelines to perform simulations and elicit expert judgments with the aim of achieving comprehensiveness.

Because the aggregate risk does not identify the most significant risk contributors, we associate risk importance measures with scenarios made by combinations of states of the variables in the Bayesian network. We illustrate our approach through the risk assessment of a nuclear waste repository, specifically considering the risk of ingesting water contaminated with radionuclides from the repository.

1.4.3 Accounting for uncertainty under REACH registration versus authorisation decision making processes

Frederik Verdonck
ARCHE-Consulting, Belgium

This presentation will outline the strengths, weaknesses and opportunities on how to account for uncertainty in the EU REACH registration and authorisation processes.

Handling uncertainty under the REACH registration process is, in practice, still insufficiently addressed despite there is a specific ECHA Guidance on uncertainty analysis. Mainly the known or quantifiable sources of uncertainty are considered. Uncertainty is insufficiently, explicitly communicated to risk managers and decision makers but hidden and concealed in risk characterisation ratio numbers that appear to be certain and, therefore, create a false sense of certainty and protectiveness (Verdonck *et al.*, 2007).

Under the REACH authorisation process for substances for which a threshold could not be determined, applicants have to demonstrate that the social benefit of continuing to use the substances of very high concern outweighs the associated risks to human health and the environment. This is assessed in a socio-economic analysis. In such analysis, it is more relevant to estimate and monetise the real impact of substances on human health or environment (instead of a conservatively derived risk characterisation ratio). This requires a more explicit quantification and communication of uncertainty in the decision-making process.

Reference:
Verdonck FAM, Souren A, van Asselt MBA, Van Sprang P, Vanrolleghem P. 2007. Improving Uncertainty Analysis in European Union Risk Assessment of Chemicals. Integrated Environmental Assessment and Management - 3(3), 333–343.

1.4.4 Uncertainty characterisation in Integrated Approaches to Testing and Assessment (IATA) for chemical risk assessment – mapping of available guidance and identification of gaps

Andrea Richarz[1], Tara S. Barton-Maclaren[2], Stephanie K. Bopp[1], Tanja Burgdorf[3], Raffaella Corvi[1], Lidka Maslankiewicz[4], Sharon Munn[1], Cindy L. A. Woodland[2], Andrew P. Worth[1]

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Integrated Approaches to Testing and Assessment (IATA) constitute a flexible framework for chemical risk assessment, allowing various lines of evidence to be combined to reach a conclusion in a weight of evidence approach. Uncertainties are associated with every step of the assessment, and need to be taken into consideration at different levels. Overall two main categories can be distinguished: 1) uncertainties related to the input data, including data and methodological quality, such as reliability and relevance of the methods and information sources used; and 2) uncertainties related to the extrapolations made, including interpretation and integration of the data, assumptions and methodological choices made. It is essential to characterise, transparently document and communicate uncertainties encountered in the assessment to allow for informed decision making and risk management.

A scoping exercise has been undertaken to identify existing guidance related to IATA and their components, and evaluate especially whether, and at what practical level, guidance on uncertainty assessment is included. It was found that a plethora of guidance documents are available, in different forms and levels of detail, and for different types of uncertainty. However, the guidance is fragmented and sometimes duplicated across sectors, scientific areas, countries and pieces of legislation. To help risk assessors navigate this complex guidance landscape, a project under the OECD's Working Party on Hazard Assessment (WPHA) was initiated to compile a comprehensive and structured overview of the available guidance, including a one-stop web-based inventory, as a means of facilitating IATA-based safety assessment and its reporting. From this overview, gaps and needs for additional (overarching) guidance or harmonisation, in particular regarding the characterisation and reporting of uncertainties in the context of IATA, will become transparent and can be addressed in the future.

1.4.5 Surplus food as animal feed: risks, benefits and uncertainties

Karen Luyckx[1], Hannah Van Zanten[2], Jennifer Davis[3], Fabio de Menna[4], Matteo Vittuari[4]

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[4] University of Bologna, Italy

In legislating for the use of treated meat-containing surplus food in omnivore non-ruminant feed, how can decision-makers account for uncertainty when balancing known animal disease risk with emerging risks of food security, climate change, and unknown disease? This presentation seeks to stimulate debate and elicit expert insight on uncertainty in feed safety risk assessment when taking a broad One Health approach that bears in mind emerging risks such as climate change and food security. We will elaborate the above question through a risk-benefit discussion on the use in animal feed of residual food side flows that contain meat and would otherwise become wasted. This practice is currently permitted in Japan and the US. First, we will discuss REFRESH findings on the acid and heat inactivation of known disease pathogens and other disease-related risk management options. Existing bio-security standards (EC Reg 142/2011) can be applied, but there are uncertainties such as human error that could lead to cross-contamination.

Further, how do we balance uncertainties in the proposed disease risk management against the need to mitigate climate change as a driver of other disease risks, for example through increased virus persistence during winter? Second, we will discuss forecast environmental and food security benefits in terms of reduced greenhouse gas emissions, land and water use and the circular food economy by preventing food from leaving the food supply chain. Alongside these benefits we will consider how uncertainties such as those affecting global agricultural yield and feed crop forecasts affect our risk-benefit analysis. Finally, bearing in mind the potential benefits of feeding treated surplus food to pigs, may it be of interest to review how the precautionary principle was applied when extending the intra-species recycling ban to pigs even though “no naturally occurring TSE, including BSE, have been detected so far in pigs” (EFSA 2007)?

1.5 Topic V: Dialogues on uncertainty in an open society

1.5.1 Governing and communicating risks in a post-truth era

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The paper introduces an integrated analytic framework for risk governance which provides guidance for the development of comprehensive assessment and management strategies to cope with risks, in particular at the global level. The framework integrates scientific, economic, social and cultural aspects and includes the effective engagement of stakeholders. The concept of risk governance comprises a broad picture of risk: not only does it include what has been termed ‘risk management’ or ‘risk analysis’, it also looks at how risk-related decision-making unfolds when a range of actors is involved, requiring co-ordination and possibly reconciliation between a profusion of roles, perspectives, goals and activities. The framework’s risk process breaks down into three main phases: ‘pre-assessment’, ‘appraisal’, and ‘management’. A further phase, comprising the ‘characterisation’ and ‘evaluation’ of risk, is placed between the appraisal and management phases and, depending on whether those charged with the assessment or those responsible for management are better equipped to perform the associated tasks, can be assigned to either of them – thus concluding the appraisal phase or marking the start of the management phase. The risk process has ‘communication’ as a companion to all phases of addressing and handling risk and is itself of a cyclical nature. However, the clear sequence of phases and steps offered by this process is primarily a logical and functional one and will not always correspond to reality. The presentation will address in particular the role of recent debates on alternative facts and the post-truth era.

1.5.2 The multiplicity of possible analysis strategies and how it is handled across scientific disciplines

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In a large number of disciplines, an important part of research projects consists in the generation of numerical results through computational analyses (a phrase to be understood in a broad sense), for instance through the statistical analysis of empirical data or through the application of a physical model. In the following, we will denote the specification of the whole computational analysis pipeline as “analysis strategy”. For a given research question, there is usually a large variety of possible analysis strategies that are acceptable according to the scientific standards of the field. These choices are also referred to as researcher degrees of freedom. When analysing data from an observational study in psychology or epidemiology, for instance, there are numerous judgements and choices to be made concerning data-preprocessing, including the definition of predictor and outcome variables, but also data inclusion and exclusion criteria and the treatment of outliers and missing values. After these data-preprocessing steps, a probability model is typically chosen to describe the association between the outcome of interest and an uncertain number of predictor variables. After these decisions, there are still many judgments that have to be made concerning the method and the method setting to use in order to conduct statistical inference for the specified probability model. In light of concerns that researcher degrees of freedom may play an important part in the non-replicability of research findings by systematically leading to an increase in false positive results and inflated effect sizes, a number of approaches for the handling of the multiplicity of possible analysis strategies have been proposed in psychology and in epidemiology. In other disciplines, including climatology, ecology and risk analysis, there is a long-standing tradition of accounting for the multiplicity of possible analysis strategies. As the non-replicability of research findings is a problem touching many fields in a similar way, the aim of this work is to take an interdisciplinary view and to compare approaches and ideas that have been proposed in the different fields to handle the multiplicity of possible analysis strategies.

2 Poster abstracts

2.1 Topic I: Uncertainty from a cognitive science point of view

2.1.1 Human exposure to pesticide drift – identification of hidden safety factors

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In European pesticide registration processes applicants routinely have to demonstrate that the exposure of their product is within acceptable hazard thresholds. Hereby, non-dietary risk assessment has to be conducted for occupational staff, like operators applying pesticides or worker performing re-entry activities. In addition bystanders and residents have to be considered, whose presence is quite incidental and unrelated to work involving pesticide products, e.g. joggers or toddlers. In Europe four routes of exposure need to be addressed, whereby the child exposed to direct vertical drift became one of the most conservative exposure scenarios. In the USA such a scenario of a farmer continuing to spray in the presence of residents is illegal and addressed through enforcement. In Europe applicants of pesticides have to follow the respective EFSA guidance, in which the direct drift exposure became up to 100 times more conservative than in previous approaches. While for operators the exposure scenario is straight forward and unquestionable (since tied to a well-defined use pattern), the bystander drift scenario is by nature not well defined and EFSA covers this uncertainty by artificially conservative parameters: A 10 kg toddler, almost naked, stands at two meter distance from a field that is simultaneously treated with a pesticide. The farmer uses rarely common nozzles without drift reducing properties. The boom height is significantly higher than recommended. The operator does not stop the engine, the child stands still. In addition, the wind is coming from a worst case angle with a high wind speed. All the above mentioned parameters increase the calculated drift exposure. The multiplication of hidden safety factors makes this scenario a bottleneck for European pesticide registrations. We would like to start a discussion on the likelihood of such a worst-case scenario in Europe and on its relevance especially for pesticides only classified for repeated toxicity.

2.2 Topic II: Methods of uncertainty analysis

2.2.1 Uncertainty assessment in *Campylobacter* spp. source attribution models: some qualitative approaches

Adrian I. Ardelean[1,2,3], Paolo Calistri[2], Armando Giovannini[2], Daniela Morelli[2], Guido Di Donato[2], Francesca Dall'Acqua[2], Antonio Maitino[2], Francesca Cito[2], Maria Luisa Danzetta[2], Daria Di Sabatino[2], Simona Iannetti[2], Valentina Zenobio[2]

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Introduction
The continuous improvement of microbiological risk assessment (MRA) and the development of sophisticated source attribution models, incorporating genomic sub-typing data, are introducing new sources of uncertainties, often difficult to properly evaluate. It has been already postulated by Donald H. Rumsfeld in 2002 "The silent diagnosis" that underlined that there are two types of unknowns: known unknowns, and unknown unknowns. This study has the purpose to define some methodologies designated to assess the sources of uncertainties in source attribution models used in *Campylobacter* MRA. The present assessment is linked to EFSA EU FORA fellowship programme cohort 2018–2019.

Methods
For the purpose of identifying and mitigating both unknowns was considered some methodologies as failure mode effect analysis (FMEA), fault tree analysis (FTA), and, at the same time was tested EFSA and other approaches. Before starting the assessment, the entire workflow has been designed, and the quality indicators (QIs) have been defined. The following stages were defined: pre-preanalytical, preanalytical, analytical, postanalytical and post-postanalytical. Also, the actors were defined for each stage.

Results
The FMEA and FTA methodologies can be useful the MRA. However, there are some limitations because a deep and exhaustive approach is time and resource consuming. Alternatively, by involving more participants, a standardised approach might enhance in time the MRA through using FMEA and FTA. The quality indicators (QIs) are very useful for total process monitoring and a mutual standardisation of them will lead to obtaining benefits. Discussion
Combining different qualitative methodologies in the MRA, such FMEA, and FTA, and using QIs applied to all processes, can lead to enhancing the consistency of the evaluation and can be a useful approach for uncertainty mitigation. Through standard definitions and weighting of all processes, a real-time methodology can be developed for risk assessment and for applying more advanced methodologies in the future, such as the one based on the artificial neural network system.

2.2.2 A general framework to weigh evidence and deal with uncertainty in expert panel risk assessments

Sandrine Fraize-Frontier, Chris Roth

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Transparency in risk assessment has been increasingly challenged these last decades. Driven by growing public concern, diverse regulators and/or internationally recognised health and safety agencies have recently increased efforts to reassert the need to improve risk assessment so as to provide the most pertinent information for decision-making needs. This has led to elaborating methodological recommendations to ensure that risk assessments draw the most relevant conclusion from the available scientific data and address uncertainty in the most complete and systematic way. The French agency for food, environmental and occupational health and safety (Anses), for example, has developed a general methodological framework for weighing evidence and analysing uncertainty, based on an extensive and critical review of literature. Three critical points were addressed in this work: a harmonised approach to document and assess the weight of evidence in hazard identification, a classification of uncertainty sources and a harmonised approach to analyse uncertainty in all steps of the risk assessment process. The present work concerns the next step of the process, that is how to implement the proposed general methodological framework in all of Anses' daily risk assessment work. The importance of considering the decision-making context as well as the practical time-resource constraints of the assessment right from the planning stage is stressed in the implementation approach. As such an iterative fit-for-purpose approach was developed, flexible enough to ensure that the level of analysis is suited to needs of the assessment.

2.2.3 Comparing Bayesian and fuzzy logic approaches for modelling uncertainty

Katja Ickstadt, Swetlana Herbrandt
TU Dortmund University, Germany

Realistic modelling of uncertainties in engineering models requires appropriate uncertainty models. Here, probabilistic approaches play an important role. Uncertainties are often categorised into aleatoric ones, i.e., uncertainties associated with natural variability in parameters or processes, and epistemic ones, i.e., uncertainties due to limited data or lack of knowledge. Suitable probabilistic approaches comprise Bayesian modelling, where uncertainty is reflected in the prior distribution of random variables and propagated through the model to quantify corresponding posterior uncertainties, as well as models using fuzzy based random variables, where the formulation of suitable membership functions leads to fuzzy intervals. In this contribution we compare the Bayesian and the fuzzy approach towards uncertainty modelling in a soil and earth structure application. The comparison may then be used to combine both approaches for formulating suitable polymorphic uncertainty models in the presence of aleatoric and epistemic variables. The work is supported by the DFG Priority Programme SPP 1886 on Polymorphic Uncertainty Modelling for the Numerical Design of Structures.

2.2.4 Risk assessment of benzo[*a*]pyrene in heat-processed meat in Denmark: A probabilistic approach

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Background
Consumption of meat prepared by barbecuing is associated with risk of cancer due to formation of carcinogenic compounds including benzo[*a*]pyrene (BaP). Assessment of a population's risk of disease and people's individual probability of disease given specific consumer attributes may direct food safety strategies to where impact on public health is largest. The aim of this study was to propose a model that estimates the risk of cancer caused by exposure to BaP from barbecued meat in Denmark, and to estimate the probability of developing cancer in subgroups of the population given different barbecuing frequencies and the attending uncertainty.

Methods
We developed probabilistic models applying two-dimensional Monte Carlo simulation to take into account the variation in exposure given age and sex and in the individuals' sensitivity to develop cancer after exposure to BaP, and the uncertainty in the dose response model. We used the Danish dietary consumption survey, monitoring data of chemical concentrations, data on consumer behaviour of frequency of barbecuing, and animal dose response data.

Findings
We estimated an average extra lifetime risk of cancer due to BaP from barbecued meat of 6.8 * 10^-5 in the Danish population with a large 95 % uncertainty interval (2.6 * 10^-7– 7.0 * 10^-4). The impact per barbecuing event on the risk of cancer for men and women of low body weight was higher compared to higher bodyweight. However, the difference due to sex and bodyweight between subgroups are dwarfed by the uncertainty.

Interpretation
This study proposes a model that can be applied to other substances and routes of exposure, and allows for deriving the change in risk following a specific change in behaviour. In the future, the presented methodology can serve as a valuable tool for risk management, addressing the variation in exposure and the uncertainty, and allowing for the formulation of behaviour advice targeted to specific sub-groups in the population.

2.2.5 Quantifying uncertainty with structured expert judgment

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Expert judgement may be required to inform a range of tasks under uncertainty, including model development, estimates of probabilities and quantities, and to inform prioritisation tasks. We consider the elicitation and aggregation of expert judgements related to uncertain events and quantities. For quantitative estimates, a common approach is to elicit a point estimate. However, there are strong theoretical and practical arguments to say that the proper representation of experts' knowledge about uncertain quantities is through probability distributions. Repeated evidence also indicates that these judgements should be elicited from multiple experts. However, challenges arise when the model requires a single probability distribution, which means that the various judgements must be aggregated. This aggregation can be done by the experts themselves, through a process of interaction that is designed to encourage consensus (behavioural aggregation). Alternatively, it may be done externally, by applying an aggregation formula (mathematical aggregation). We will present and motivate a third (combined) way of aggregation which combines the IDEA protocol for structured expert judgement with the mathematical aggregation scheme of the Classical Model (CM) (i.e. the weighted linear combination of judgements, where weights are calculated based on experts' prior performance on similar tasks).

2.2.6 A global sensitivity analysis for mathematical models to predict in vitro toxicity for a regulatory context

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Mathematical models are often used in the regulatory context in the field of toxicology and pharmacology. Inherent to the quantitative approach is the presence of uncertainties in input data, in assumptions, in values and meaning of outputs, and hence in the quality of the information conveyed to the high stake policy-making/decision process. There is a need for some methodological approach to make sure mathematical models are fit for purpose. Uncertainty analysis (UA) and sensitivity analysis (SA) are well established methodologies for the quality assurance of models employed in evidence-based policy. UA aims at quantifying the uncertainty in the model output, to know the uncertainty on the presumed impact of a policy option. Once this uncertainty is quantified, SA moves back to the inputs quantifying the portion of output variability due to each input. A variance-based Global Sensitivity Analysis (GSA) has been conducted on the Virtual Cell Based Assay (VCBA), in order to establish the impact of input factors (both user-defined and model related) on the model output uncertainty. The VCBA is a mathematical model that describes the fate and partition of the chemical(s) in an in vitro system, allowing estimation of free concentrations which is of great interest when extrapolating from in vitro data. A GSA on the VCBA was never conducted before. Caffeine was used and four outputs have been investigated: free, intracellular, headspace and medium concentrations. The analyses provide information about both ‘factor prioritisation’ (identification of inputs with high individual contribution to model variance) and ‘factor fixing’ (identification of variables that can be fixed because of irrelevant total effect on output variance). The unique results obtained by the UASA tools help in model simplification, grant enhanced credibility to the model, and can contribute to improve the development and the acceptance of these kinetic models in the regulatory context.

2.2.7 Uncertainty in exposure assessments: A case study for illustrating the respective uncertainty guidelines of EFSA and BfR

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Since uncertainty analysis is an integral part of risk assessment, the European Food Safety Authority (EFSA) and the German Federal Institute for Risk Assessment (BfR) have developed uncertainty guidelines. We report here from a comparison study of both guidelines in the framework of an EFSA-BfR joint project (https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1472). In general, both documents share the same overall philosophy, but they differ in the scope of the guidelines and weight of the importance of qualitative and quantitative description of uncertainties. To illustrate the different approaches, the following case study was chosen: Uncertainty analysis of an exposure assessment regarding aluminium in cocoa and chocolate. The BfR guideline was mainly employed to identify sources of uncertainties, while the EFSA guidance document, building on the results of the BfR uncertainty analysis, was applied to handle the quantification of these uncertainties. After the occurring uncertainties were identified (using question lists from the BfR guideline), a simple sensitivity analysis was carried out to prioritise them. The results allowed to choose a plan on how to proceed with the quantitative uncertainty analysis, including which uncertainties needed to be assessed individually and which collectively as well as the decision which uncertainties could be handled by a mathematical model and which needed to be determined by an expert knowledge elicitation (EKE). After the outcomes of these parts were derived, they were combined and the remaining uncertainties including newly arising model uncertainties were quantified using an overall EKE. As a result, it could be shown that both guidelines complement each other very well. Moreover, the case study illustrates typical challenges arising with the quantification of uncertainty and ways to deal with them.

2.2.8 Managing food consumption data uncertainty via cluster analysis

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Objective
Uncertainties linked to dietary exposure assessment are unavoidable because of precision and accuracy of data regarding chemical occurrence in food and food consumption data. Armenia implements dietary exposure assessment starting from 2012 for which the required consumption data has long been provided by National Statistical Service (NSS) responsible for food insecurity assessment. The objective of this work was to compare and understand the role of uncertainties in poultry consumption data using national and private data.

Methods
Poultry consumption was determined with food frequency questionnaire (FFQ). To get a normal distribution of consumption values, K-means cluster analysis method was applied. This method is effective especially for the analysis of dietary patterns in a large population using food frequency questionnaires. The study also compared the poultry consumption data provided by NSS based on household approach.

Results
As a result of K-means cluster analysis, four clusters were identified and risk assessment was conducted for each cluster. According to these clusters, 70 % of the participants consume 42 g/day of poultry meat. Approximately 16 % consume 129 g/day, 13 % consume 193 g/day and only 2 % of participants consume 374 g poultry meat per day. While, according to NSS the average poultry consumption is 45 g/day for the whole population.

Conclusion
The application of cluster analysis has been effective in reducing the level of uncertainty in two aspects. First, it reduced the uncertainty with potential to cause over/under estimation of exposure as it includes separation of consumption amounts and reveals homogeneous groups of consumers. Second, cluster analysis enabled target oriented risk communication possibility as it better informs people in which consumption group they belong. Therefore, in order to manage uncertainties, cluster analysis method has to be applied when food insecurity assessment data is used for food safety assessment.

2.3 Topic III: Communication of uncertainties

2.3.1 The importance of target group-oriented risk communication for Aflatoxin B1 (case study in Armenia)

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Aflatoxin B1 (AFB1) is the most frequently detected mycotoxin, which is classified as a human carcinogen. The level and frequency of AFB1 exposure depend not only on the implemented practices through the food chain but also on the dietary habits of target consumers. In Armenia the results of the previous investigations have indicated that AFB1 risk through consumption of cereal crops (rice, buckwheat, maize, and wheat) did not exceed the toxicological reference value. It should be stressed that in that case risk communication was intended for the whole studied population, without taking into consideration certain groups of consumers. In contrast, this research aimed to use target group-oriented risk communication about the potential health risks associated with the consumption of cereal crops in Armenia. In the frame of this study, the target groups of consumers were identified. The statistical analyses showed that among the other studied groups, the diabetic consumers have the highest intake of buckwheat. Moreover, the results of dietary exposure assessment pointed out that only for this target group of consumers the daily intake of AFB1 exceeded the toxicological reference value. Hence the intake of AFB1 via buckwheat consumption poses potential health risks to diabetic consumers. Therefore there is a need to inform people more effectively about the potential health risks associated with the consumption of buckwheat. The main findings of the research allow us to conclude that there is an urgent need for risk communication which will be oriented more towards target groups to eliminate the uncertainties.

2.3.2 Challenges in risk communications: How should scientific institutions deal with scientific uncertainty?

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How should public scientific institutions, especially in times of crisis, deal with scientific uncertainty? Using examples from the work of the German Federal Institute for Risk Assessment (BfR), some of the challenges associated with the communication of risks are presented. The communication of risks not only involves the conveyance of substantiated knowledge but also how to deal with what is not known and how to communicate uncertainty. A clear understanding of how risks are perceived and what factors influence risk perception are indispensable for adequate risk communication. To obtain information on how the public or specific social groups assess an issue, the BfR studies the risk perception and risk behaviour of different target groups. The results can be used to design risk communication processes effectively – including the communication of uncertainty. Consumers expect easy-to-follow tips and clear information that are helpful to them in their everyday life. For this reason, the BfR always begins its scientific opinions with a summary that includes concrete recommendations, written in language that the general public can understand. In addition, a risk profile has been developed which summarises the key points of the opinions in the form of a graph, thereby visualising the described risk. The information includes the validity of the data which is one aspect of uncertainty. Different types of risks require different approaches to risk communication. Emergency food safety events require a rapid response, while enduring food safety problems require ongoing communication with target audiences and stakeholders, including consumers. Especially in times of crisis or crisis-type events, open, transparent and active risk communication is imperative. With the help of some concrete examples (e.g. fipronil in eggs, glyphosate in breastmilk, aluminium in food and antiperspirants, arsenic in rice, EHEC) different approaches and risk communication guidelines are presented.

2.3.3 Communication of uncertainty propagation in pesticides biodegradation networks

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Reactive transport models are crucial tools to predict pesticides dynamics in the environment. Few current models allow to fully account for nonlinear feedbacks between pesticides and soil biogeochemical processes, fluid flow and transport of dissolved chemicals. Parametric and model uncertainty increase with model complexity; typical approaches for conducting uncertainty analyses make use of sensitivity analyses, which rely on metrics that can quantify the impact of a given parameter on a model output. Porta *et al.* (2018a) applied moment based sensitivity metrics (Dell'Oca *et al.*, 2017) to identify key parameters and biological processes driving atrazine biodegradation in agricultural soil. The analysis relies on the model proposed in la Cecilia and Maggi (2017), which encompasses 75 biokinetic parameters. Later, those new metrics were used to quantify the implications of uncertain soil hydraulic parameters on the biodegradation and dispersion of glyphosate and its metabolite AMPA (Porta *et al.*, 2018b).

In this communication, we start from our earlier results to numerically show to what extent the uncertainty in hydrological/hydraulic and biogeochemical input parameters can affect pesticide concentrations in the environment in the long term. The choice of meaningful indicators and a clear, open, and transparent communication of potential concerning outcomes is pivotal for allowing risk assessors and managers and policy makers to make informed choices, and will also contribute to build trust and understanding amongst stakeholders. For this reason, we will address different metrics and visualisation techniques of uncertainty quantification and sensitivity analysis studies applied to pesticides biodegradation. Our proposed tools address key concerns of target audiences, and at the same time, allow each stakeholder to quickly and correctly interpret the implications of data uncertainty in pesticides fate in the environment.

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Acknowledgements
The authors acknowledge the Sydney Informatics Hub and the University of Sydney's high performance computing cluster Artemis for providing the high performance computing resources that have contributed to the research results presented. G.M. Porta and M. Riva acknowledge funding from MIUR (Italian ministry of Education, University and Research, Water JPI, WaterWorks 2014, Project: WE-NEED- Water NEEDs, availability, quality and sustainability). The authors were supported by the Sydney Research Excellence Initiative (SREI "EnviroSphere") of the University of Sydney. F. Maggi was also supported by the Sydney Research Accelerator Fellowship (SOAR) by The University of Sydney.

2.3.4 Antimicrobial resistance in livestock farming: Italian veterinarians' perceptions and information needs

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The improper use of antimicrobials in both human and veterinary medicine is considered among the major causes of the insurgence and diffusion of resistant microorganisms, with serious consequence for both public and animal health. The promotion of the responsible and prudent use of antimicrobials in the veterinary sector is crucial to preserve their efficacy and to reduce the spread of resistant bacteria from livestock animal to human through foods. Veterinarians are the key figure in this process as they are responsible for the prescriptions of antimicrobials to farm animals. The analysis of veterinarians' opinions regarding antimicrobials resistance (AMR) and the level of attention in the prescription of antibiotics is essential to enhance effective actions of prevention and control. The present study is aimed at raising veterinarians' awareness of AMR issues in livestock farming and their consciousness of the interconnection between animal and human health.

A survey was conducted in Italy in 2017. The questionnaire was administered through the CAWI (Computer Assisted Web Interviewing) method to veterinarians who work in Italian livestock farms. Data collected were analysed through both quantitative statistics and qualitative techniques.

A total of 789 veterinarians participated in the survey. Results allowed mapping respondents' perceptions and information needs on AMR risks and its impact on food safety issues. The results highlighted the presence of contrasting opinions and sceptical attitudes. Comparison among veterinarians working in different breeding sectors (pigs, cattle, poultry, rabbits…) was performed and differences in the levels of risk perception and in prescribing behaviours were observed.

Starting from these data a training intervention for veterinarians was designed with the aim to clarify controversial issues, shape a consistent and scientifically grounded knowledge and strengthen the efforts of veterinarians to make a responsible use of antimicrobials.

2.3.5 Transparency and consistency of uncertainty factors for occupational exposure limits

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Uncertainty factors (UFs) are commonly used to communicate a combined estimate of uncertainty and variability when setting limit values for chemicals. Here, we investigate the transparency and consistency of UFs applied by the European Commission's Scientific Committee on Occupational Exposure Limits (SCOEL) in their recommendations for occupational exposure limits (OELs). We extracted explicitly stated UFs (EUFs), the point of departure (PoD) and PoD-study details from 128 SCOEL recommendations. In 63 of these (49 %), no EUF was given; we then calculated an implicit safety margin (ISM) by dividing the stated PoD by the OEL. For the 65 EUFs 1 to 3 aspects of uncertainty were qualitatively described (e.g. absence of a No-Observed Adverse Effect Concentration or a poorly reported key study). However, quantitative distinction between multiple aspects was only performed in 3 out of 31 cases. The magnitude of UFs EUFs and ISMs combined followed both expected and unexpected patterns. As expected, the UFs were generally lower for OELs based on human data and No-Observed Adverse Effect Concentrations compared to animal data ($p<.0001$) and Lowest Observed Adverse Effect Concentrations ($p=.04$), respectively. However, no differences were seen in UFs for repeated dose studies of different durations, nor for OELs based on local compared to systemic effects ($p=.09$). Interestingly, EUFs were, on average, 1.8 times higher than ISMs ($p<.0001$). For OEL recommendations based on animal data and systemic effects ($n=31$), we used the APROBA (v1.00 employing default parameters) tool for semi-probabilistic uncertainty analysis to quantify the coverage, i.e. the per cent confidence in the OELs for a population incidence goal of 1 %. The coverage ranged from 13.4 % to 95 % (median 44 %). We conclude that transparency was unsatisfactory and that consistency can improve. We recommend limit-setters to employ an articulate framework for identifying and communicating different aspects of uncertainties.

2.3.6 EFSA guidance on communication of uncertainty in scientific assessments

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Risk communication is a core task for EFSA and effective communication of uncertainties to partners, stakeholders and the general public is considered vital to this role. While developing guidance on uncertainty analysis in its scientific assessments, EFSA determined to develop practical guidance for risk communicators on how to communicate the results of uncertainty analysis to different audiences. The resulting guidance document guides communicators on how to communicate the various expressions of uncertainty described in EFSA's 'Guidance on uncertainty analysis in scientific assessments'. It also contains specific guidance for assessors on how best to report the various expressions of uncertainty to support effective communication. It provides a template for identifying expressions of uncertainty in scientific assessments and locating the specific guidance for each expression. The guidance is structured by three broadly defined categories of target audience: 'entry', 'informed' and 'technical' levels. Communicators should use the guidance for entry and informed audiences, assessors should use the guidance for the technical level. The structured guidance and best practice advice was formulated using evidence from the scientific literature, grey literature and two EFSA research studies, with expertise in social sciences and practical application to examples of EFSA's assessments. Where evidence was incomplete or missing, judgement and reasoning were used. Limitations of the evidence sources inform the recommendations for further research on uncertainty communication.

2.4 Topic IV: Accounting for uncertainty in decision making

2.4.1 Identifying uncertainties in read-across and (Q)SAR for toxicity data gap filling

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In silico models for toxicity prediction rely on a number of inputs including the toxicological activity of the compounds modelled and their physico-chemical and structural properties as well as the statistical or other technical applied. Models vary from the use of grouping allowing for read-across to quantitative structure-activity relationships (QSARs). Such models have been increasingly used for regulatory purposes and their use is likely to increase in the future. A key element for regulatory use is the assessment of the uncertainty of the in silico approach in order to determine the confidence of a prediction. This study aimed to develop means of describing the uncertainty of read-across and QSAR models – these being the most commonly applied for regulatory purposes – with the aim of deriving a (semi-quantitative) assessment identifying areas of the model where further data or information may increase confidence. Due to the different approaches in read-across and QSARs, the definition of uncertainty was performed separately for these types of models. For read-across an all encompassing approach was derived based around their intended use and case-specific issues, the hypothesis and justification of similarity and the data to be read across. For QSARs a number of criteria for the assessment of uncertainty has been derived around the data used, the description of the model and its application. The assessment of uncertainties by these methods has been shown to illustrate the aspects of both grouping and read-across approaches and QSAR models that will require further data to improve confidence in their use. Case studies on examples of read-across approaches and published QSARs demonstrate how the definition of uncertainties identified deficiencies which could be addressed with New Approach Methodology data to increase the confidence in the use of the model.

2.4.2 Food origin as an uncertainty in dietary exposure assessment

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Introduction
The EU-FORA fellowship programme gives the possibility for international cooperation as VKM (Norwegian Scientific Committee for Food and Environment) in Norway and BfR (German Federal Institute for Risk Assessment) in Germany participate in the 2018/2019 programme. The project launched in this cooperation is concerned about origin as source of uncertainty in dietary exposure assessment. Fish as a food is supplied from different catching areas. Since fish contains various contaminants, and relations between catching area and contaminant concentration already are observed in different studies, fish is chosen as example.

Methods
Norwegian and German data on contaminant concentrations are considered for selected fish species. Contaminant concentrations are grouped by catching areas of fish to identify if different contamination levels exist for different areas.

Results
Differences in available fish from various catching areas between Norway and Germany are evaluated. This project will investigate how, and to what extent, uncertainty can be introduced to dietary exposure assessment if fish origin influences contaminant concentrations significantly, but where origin-related grouping is not considered in the exposure estimate.

Discussion
The origin-related grouping of contaminant concentrations in fish using catching areas could be used as a basis for a refined exposure assessment referring to both the Norwegian and the German situation. Previous investigations on agricultural products show influences of origin grouping on dietary exposure, which could be also relevant for fish from different catching areas. This is of special importance if European risk assessments are carried out combining concentration data recorded in several countries without taking origin into account.

2.4.3 Calculation automates the decision: socio-technical perspectives of strong belief in simulation technology for nuclear emergency in Japan

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It is a widespread notion that quantitative calculation of technological risk should help better our decisions concerning risk management and emergency response for nuclear utilisation. However, sometimes it is believed more than to “help” the decision, but to “automate” it. After the Fukushima nuclear accident in 2011, it has been criticised that the Japanese nuclear community was overdependent on such a belief, while neglected to establish the capacity and institutional framework to utilise it in an appropriate manner. Our qualitative study revealed that this kind of belief is still alive, although a lot of efforts to overcome it. We have witnessed highly polarised and stereotyped disputes: probabilistic risk assessments (PRA), or the System for Prediction of Environmental Emergency Dose Information (SPEEDI) are deemed either totally useful, or utterly useless. The imaginaries held by relevant stakeholders on methods of risk quantification and its consequences are contested, but at the same time partly unanimous. To analyse the mechanism which persistently reproduces the “Calculation Automates the Decision” belief, we conducted a study on the policy process centering on those simulation techniques. We recently published a paper on the SPEEDI case, in which the authors discussed the negative implications of this situation, such as the obstruction of practical, effective implementation of such technologies. In this paper, to deepen our insights on the socio-technical interactions in that dysfunctional process, we should like to explore the history centering on PRA technique and SPEEDI technology, in which the notion had been evolved and institutionalised since early 1980s. Socio-political interactions among relevant actors, technical concepts, legal frameworks and social atmosphere will be critically analysed, to identify the key factors which encouraged the very particular evolution process of institutional psychological overdependence on the belief.

2.4.4 Categorisation of uncertainties in dietary exposure assessment Case study of Armenia

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The in depth understating of the exposure assessment is crucial for balancing costs and benefits of risk mitigation measures. Dietary exposure assessment uncertainties related to the insufficiency of data on chemical occurrence in food and amounts consumed are unavoidable. The categorisation and mapping of uncertainty sources is a milestone for decision makers to allocate finances and manage resources efficiently. It has been only a year since the topic of risk assessment methodology in compliance with international requirements is included in priority objectives of Armenia's government. Hence, the mapping of uncertainties is an effective tool for elaboration of feasible strategy.

The uncertainty sources shall be categorised in three major groups of importance (high – H; medium – M; low – L). The categorisation criteria were based on level of influence. The investigated uncertainty sources include the following areas: sampling, concentration data, measurement, added use levels instead of actual chemical concentration, handling of non-detects, processing factors, extrapolation, imprecise language, bodyweight, food consumption data and coding. The results of investigation indicated that the issues of high priority are concentration and consumption data uncertainties. Concentration data can be obtained from national monitoring programmes. However, monitoring programmes include only few areas and are limited to animal origin products (fish, honey). According to the consumption data, significant contributors in diet are grains and grain based products, fruits and vegetables, which are not included in state monitoring programmes. Another issue of high priority is that food consumption data collection method is not individual based. Even though all the mentioned sources of uncertainties are present in Armenia, the significance of uncertainty issues included in high importance group outweighs the significance of all the other issues.

2.4.5 Consideration about uncertainty in the practices of intergovernmental and national elaboration of pesticide residues limits in foods

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Uncertainty as supplementary tools to the risk assessment and risk management in issues of food safety draws increasingly attention of the publics and different stakeholders. But there are gaps between theory and practice, what are confusing the correct understanding of risk analysis at all. Difficulties during decision making exist always by laying down the thresholds for Maximum Residue Limits of pesticide residues (MRLs) in foods, for example, and by application of MRLs in monitoring, and enforcement as well. It is to be firmly believed, despite so many unknowns, that the dialectic process on uncertainty for risk analysis in the field of food safety could result a convincing solution.

The Codex Committee on Pesticide Residues (CCPR), and such as China National Committee on Pesticide Residue Limits hire the similar procedure of establishment of MRLs in foods. The data came from sponsors (normally the manufacture of pesticides, in specific cases from member governments or observers). Risk assessment is driven by an expert group, namely JMPR for CCPR, and a group trusted by the national authorities. The policies for risk assessment on pesticide residues are but decided by CCPR or the National Committee on Pesticide Residue Limits in case of Chinese procedure, what are based on the logics of pesticide toxicology, residue chemistry, food consumption, and representative agricultural practices worldwide or in the country.

MRLs are numerical standards derived from the combination of above mentioned data. Different models are used for this purpose, mainly deterministic and probabilistic models in methodology. First goal of MRLs is to ensure food safety, i.e. every MRL must not bring unacceptable dietary risk to consumers. The second goal of MRLs is monitoring if the production of the food commodities are under good agricultural practices, and enforcement to eliminate the possible exposure in trade. Under these circumstances, lacking on quality and quantity of the data, compromises must be taken. Estimation of an uncertainty of the assessment became necessary. At the same time, an acceptance of uncertainty of the decision making was very much expected. Normally, the overall recommendation is based on the 95th percentage to cover the population. But the pre-condition of this assumption often neglected or failed at all.

Seeking for solution for the estimation of more precise uncertainty in risk analysis of pesticide residues, new knowledges, appropriate models, feedback from monitoring practices, especially qualified data are under consideration. Ways for combination of basic factors for risk analysis in pesticide residue evaluation, and decision making will make the important sector of food safety more reliable and responsible.

2.4.6 Data gap filling with ECOSAR and the validity check of the tool application for K-REACH compliance for environmental risk assessment

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US EPA/OPPT developed ECOSAR (Ecological Structure Activity Relationships) model and still updates it for hazard and risk assessment on hazardous chemicals under the TSCA (Toxic Substances Control Act). It is a QSAR (quantitative structure-activity relationship) model estimating eco-toxicity and used for estimating data for hazard and risk assessment of a chemicals where limited data are available. The model utilises classes of chemicals according to their structures as well as the mechanisms of toxic action. As a screening tool of toxicity, it could be used at other chemical regulations such as EU REACH or K-REACH (South Korea). We used the latest version of ECOSAR (v2.0) to estimate toxicities of three major aquatic species (fish, daphnia, algae) where few or no experimental data are available. The data estimated were used for the development of Species Sensitivity Distribution (SSD) of 20 hazardous organic chemicals listed on the Chemicals Requiring Preparation for Accidents in South Korea law (Chemicals Control Act) and additional 15 chemicals showing specific mechanism of action. Before the full application of ECOSAR, however, we tested the model whether it shows good estimation capacity in regulatory perspective with newly accumulated toxicity data in ECOTOX database. Data were collected at ECOTOX database, excluded old data, and used for species mean toxicity value with standard deviation. The performance of ECOSAR was evaluated by comparing model output value with experimental data, where we focused on the appearance point by considering real data range of 1, 2, and 3 standard deviations (SDs). Estimates shall be under mean value (-1SD, -2SD, and -3SD) of collected data (data from ECOTOX database) if it shall be more meaningful in regulatory perspective. In contrast, estimates shall be placed in between ± 1SD if it shall be accurate in scientific perspective. As a result, estimates of fish toxicity of 18 chemicals are appropriate for chemicals management under K-REACH. Among those 18 chemicals, 4 chemicals were highly conservative (placed in between -2SD, -3SD or outlier) but these values were not appropriate the estimation of exact value in scientific perspective. The other 5 chemicals from 18 chemicals were moderately conservative (data were placed in between -1SD and -2SD range). The remaining 9 chemicals were placed in between mean and -1SD range (slightly conservative). Those 9 organic chemicals are Neutral organics (3), Phenols (2), Halides (3), and Anilines (1). As a conclusion, ECOSAR may not appropriate for 5 (data were placed in between -1SD and -2SD range) or 4 (placed in between -2SD, -3SD or outlier) organic chemicals, which was located far lower range from the mean value calculated with real data collected from ECOTOX database. In addition, 16 among 35 chemicals were located in between ± 1SD range, meaning that ECOSAR are predictive of toxicity appropriately for 46 % of target chemicals in this study.

2.4.7 Using hypothesis test frameworks for handling uncertainty in allocating surveillance resources

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Allocating border surveillance resources to detect invasive pests, diseases, and pathogens on exposure pathways requires a trade-off between (i) the need to detect as many contaminated items as possible and (ii) the need to acquire knowledge about contamination rates, reducing uncertainty. We develop a model and an algorithm that provide guidance for the allocation of inspection resources across multiple dynamic entry pathways in cases where not every item can be inspected. The model applies a null hypothesis that the contamination rate of a pathway is above a specified level: a risk cutoff. Pathways with estimated risk above the cutoff are fully inspected, and those with estimated risk below the cutoff level are monitored at a rate that would detect a change of the risk to being above the cutoff level with high probability. We base our decision on the estimated 95 % upper confidence limit for the contamination rate. We demonstrate via simulations and a data set that focusing inspection resources on specific pathways can result in substantially more effective intervention, and that the reduction in overall effectiveness of monitoring low-risk pathways need not be substantial. Use of the model demands the selection of the risk cutoff, and this limit can be set according to projected consequences.

2.4.8 Impact of analytical uncertainty on withdrawal period determination in edible tissues

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The treatment of food-producing animals with veterinary medicinal products (VMPs) can result in the occurrence of residues in foodstuff (e.g. meat, eggs, milk and honey). As the consumption of such food commodities may pose a potential risk to consumer health, so-called maximum residue limits (MRLs) are established before the marketing authorisation to ensure consumer safety. Furthermore, it is necessary to derive a withdrawal period (WP) representing the time period between the last administration of the VMP and the earliest possible production of foodstuffs (e.g. slaughter).

The WP is calculated based on the residue depletion profile, using a linear regression technique. The uncertainty originating from the biological variability is taken into account by requesting the statistical estimate of the upper 95th percentile of the residues in the treated population to be below the MRL with 95 % confidence [1]. Other uncertainty contributions, such as the analytical measurement uncertainty have so far been less addressed. Relevant guidelines [1] recommend correction of data for systematic measurement errors. However, more comprehensive concepts to estimate the measurement uncertainty are usually not taken into account.

To investigate the potential impact of measurement uncertainty contributions (e.g. analytical accuracy and precision) on the WP, a set of real life residue depletion data was artificially changed using different assumptions for normal distributions of accuracy and precision rates, covering the acceptable limits for these analytical parameters, as specified in relevant guidelines [2]. Both accuracy and precision of the chemical analysis had a noticeable effect on the overall WP. The exercise illustrated that due consideration of different sources of measurement uncertainty may improve the robustness and quality of regulatory decisions.

[1] EMEA/CVMP/036/95 (final, currently in force) and EMA/CVMP/SWP/735325/2012 (draft revision)
[2] EMA/CVMP/VICH/463202/2009

2.4.9 Data uncertainties in risk assessment of fruits and vegetables in Armenia arising from seasonality and consumption variability

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Background:
The method of sample collection and dietary pattern investigation shall be well suited to the type of dietary exposure assessment. Current approaches regarding state monitoring of fruits and vegetables in Armenia do not take into consideration the seasonal variability. Traditionally, the monitoring of plant origin food is carried out only in the summer season when the locally produced fruits and vegetables are available. For the first time, a study was carried out among Armenians to analyse how fruit and vegetable consumption patterns change throughout the year.

Methods:
From 2017–2018 a semi-quantitative, 12 item food frequency questionnaire (FFQ) was developed and used to assess the fruit and vegetable consumption among Yerevan population for each season. A total of 1310 people took part in the survey.

Results:
The results indicated that the fruit and vegetable consumption patterns of Armenians change significantly with season. Not only the amounts of foods consumed change but also the assortment, type and origin of fruits and vegetables change. In winter people consume greenhouse vegetables and imported citrus fruits, while in summer they consume predominantly field grown ones. This is important for the chemical occurrence. The risk of trace elements is emphasised in summer due to soil contamination of several regions, while the risk of pesticides is emphasised in winter due to the significant share of imported foods in Armenians' diet. Also, the changes in consumption are highly correlated with price changes of fruits and vegetables.

Conclusion:
The uncertainty associated with food seasonality and consumption pattern variability leads to a biased exposure estimate. To reduce the uncertainty in exposure assessment, it is necessary to carry out the sampling of fruits and vegetables in all four seasons. Moreover, decision makers shall take into consideration these uncertainties for the effectiveness of the programme and include information about seasonality and source.

2.4.10 Uncertainty in the context of safety of agrochemicals

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Plant protection products (PPPs) undergo a strict regulatory safety assessment based on extensive robust data requirements and principles before authorisation; the conclusions provide a solid basis for decision making. Elements of uncertainty exist for many of our decisions. It is important to balance uncertainty (what we do not know) with certainty (what we know) to identify where uncertainty truly matters and to prioritise areas of concern. Assuming every thinkable adversity must be fully assessed at decision making is unrealistic and unnecessary. We would not drive cars, take medicines, fly planes etc. if all uncertainty had to be addressed before deciding to act. There is a trend to unrealistic and excessive precaution on PPPs, considering only potential hazard without the likelihood and amount of exposure. This responds to and exacerbates public fear stemming from perception of no control and assumption that any exposure is bad. The public is poorly informed about the exhaustive safety investigation and their actually very low exposure to PPPs as shown in food residue monitoring. Epidemiology consistently shows that humans occupationally exposed to agrochemicals (production and use) on average live longer and healthier than the general public, indicating existing uncertainty is unlikely relevant to public health. Innovation constantly develops solutions tailored and more efficiently delivered to specific targets, reducing exposure and having less potential adverse effects. Despite these facts, public fear of plant protection products is driving extremes in regulatory decisions because of over-emphasising perceived uncertainties. Result is that important agricultural innovation will not be available for European farmers to maintain competitiveness and improve safety at their workplace, favouring reliance on existing products. This presentation highlights the strength and robustness of available data that is routinely used to characterise actual relevant uncertainty.

2.5 Topic V: Dialogues on uncertainty in an open society

2.5.1 Legal regulation of plant genome edited by directed mutagenesis techniques and, in particular, CRISPR/Cas9: New genetically modified organisms?

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On the 25th of July 2018, the Court of Justice of the European Union has issued its decision in Case 528/16 and confirmed that organisms developed by directed mutagenesis techniques are GMOs within the meaning of Directive 2001/18 and are regulated under this Directive. Considered as a significant milestone in the interpretation of Directive 2001/18, this decision clarifies its scope and more precisely, the ambit, the rationale and the effects of the exemption enshrined in its Article 3 and Annex IB. In fact, since only the term 'mutagenesis' is mentioned in the exemption, the question is whether this exemption encompasses any kind of mutagenesis including those which were unknown at the time of the adoption of Directive 2001/18 or only the random mutagenesis technique. While the significant differences between random and directed mutagenesis are highlighted, plants modified genetically by directed mutagenesis are considered as GMOs since they meet the conditions set up in Directive 2001/18. In addition, organisms obtained by directed mutagenesis do not fall within the scope of the exemption and this, irrespective of whether the directed mutagenesis involves the insertion of recombinant DNA into the genome or only its use anytime in the genetic modification process without necessarily being inserted. Indeed, all organisms obtained by directed mutagenesis techniques should be regulated and, consequently, be subject to the case-by-case environmental risk assessment, the traceability and the mandatory food labelling before being placed on the EU market or released into the environment. Otherwise, the absence of regulation for certain organisms developed by directed mutagenesis may generate significant risks both for human health and the environment, lead to a legal circumvention of Directive 2001/18 and is likely to undermine the confidence of the European consumers who will be unable to know how their foodstuff is produced given that they massively reject GM products.

2.5.2 Risk calculators and risk perception

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Based on mathematical models of infectious diseases, we want to provide risk assessment functionality to potential users via responsive website (free of charge, open licensed) for both individuals and professionals in Poland. We have created risk calculators for human diseases such as sexual transmitted infections (http://interdisciplinaryresearch.eu/index.php/ankieta) as well as hospital infections (http://platforma.sirsz.pl/ankieta/zak/) for clients and patients and we are currently developing ASFV (African Swine Fever Virus) arrival time estimator for farmers (http://interdisciplinaryresearch.eu/index.php/asf). The results of calculations are presented 'real-time' to interested users in percentage of chance (or time) as well as with a meaningful description. End user fills the form to obtain risk assessment and can test different settings to learn the overall risk. Questions have been chosen by literature review and database analysis and translated into quantitative and qualitative variables. The algorithms process data from questionnaires by applying mathematical modelling: i) to assess risk of acquiring hospital infection during child delivery, tree logistic regression is applied; ii) to assess risk of sexually transmitted infections during sexual intercourse (currently only for HIV), Bayesian inference is used; iii) to estimate most likely arrival times of ASFV and most likely introduction paths to disease free area, quasi-gravity propagation model is proposed. We have already compared in a pilot study the actual risk (according to our algorithms) against risk perception both in professionals and a patient cohort in a child delivery case. Unexpectedly, there was no difference in the average standard error (absolute difference between actual risk and perception of the risk in %) between both cohorts. However, variance of the standard error was significantly lower in professionals than in the patient cohort, because patients had tendency to over/under estimate risk in much larger extend. Concluding, the idea is to give some functionality of epidemiological intelligence (already developed for stakeholders) to farmers or patients as an educational tool, must be carefully implemented. On one hand, user receives risk assessment from interactive web application with additional description about modifiable risk factors and can benefit from evidence based knowledge and recent guidelines. On the other hand, such a tool can objectivise the relation patient – doctor/farmer – veterinarian and in some circumstances can even harm a user.

2.5.3 "Scientisizing" how safe is safe enough: A critical analysis of nuclear safety goals in Japan

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No matter how much we try to mobilise the best available knowledge of nuclear safety, there are always uncertainty, ambiguity and ignorance around its risk management. We can never eliminate completely the risks where nuclear accidents seriously affect public health and welfare. These conditions make it necessary for society to address the problem of "how safe is safe enough" if we are willing to continue utilising nuclear energy. Some countries such as US and UK try to tackle this issue by setting "safety goals" or categorising tolerable/ acceptable risk region through intensive deliberation process among experts and public. Although efforts have been made to establish nuclear safety goals also in Japan, its spirit and philosophy have not deeply digested even among nuclear professionals. The author's recent qualitative study has revealed that before 2011 the draft safety goals in Japan had been functioned as an explanation tool for emphasising an assertion that "nuclear power plants had already been safe enough" contrary to their original role as improving continuously industrial and regulatory practice of risk assessment and management. In this paper, the author will deepen consideration of the socio-political context of nuclear safety goals through analysing critically the post-Fukushima regulatory actions and relevant discourses, particularly focusing on the relevant actors' "scientism" and a lack of public dialogue on risk and uncertainty even though "how safe is safe enough" is evidently a trans-scientific issue which inevitably entails value judgment.

3 Workshop abstracts

3.1 Topic II: Methods of uncertainty analysis

3.1.1 Quantifying uncertainty with structured expert judgement

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Expert judgement may be required to inform a range of tasks under uncertainty, including, model development, estimates of probabilities and quantities, and to inform prioritisation tasks. In this workshop we concentrate on the elicitation and aggregation of expert judgements related to uncertain events and quantities. For quantitative estimates, a common approach is to elicit a point estimate. However, there are strong theoretical and practical arguments to say that the proper representation of experts' knowledge about uncertain quantities is through probability distributions.

Repeated evidence also indicates that these judgements should be elicited from multiple experts. However, challenges arise when the model requires a single probability distribution, which means that the various judgements must be aggregated. This aggregation can be done by the experts themselves, through a process of interaction that is designed to encourage consensus (behavioural aggregation). Alternatively, it may be done externally, by applying an aggregation formula (mathematical aggregation). We will present and motivate a third (combined) way of aggregation which combines the IDEA protocol for structured expert judgement with the mathematical aggregation scheme of the Classical Model (CM) (i.e. the weighted linear combination of judgements, where weights are calculated based on experts' prior performance on similar tasks).

At the end of this workshop participants will be familiar with both the IDEA and the CM protocols. They will benefit from a series of hands on exercises, lecture style explanations, a list of relevant literature, and relevant contacts in the field. The work-shop is aimed at professionals, academics, policymakers, regulators, and (MSc, PhD) students who are, or will soon be involved in decision problems or risk analysis modelling with scarce resources, and insufficient data.

3.1.2 Quantification and communication of epistemic uncertainty by precise and bounded probability

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In this workshop, we will discuss the benefits and disadvantages of two alternative expressions for epistemic uncertainty: precise probability and bounds on probability, including verbal encapsulations that encode uncertainty. The quantification will be demonstrated using open-source code for the R programming environment. We will then compare expressions from these two approaches and discuss them in light of research and principles of risk analysis. The workshop will also present research from risk communication literature and an overview of experiments comparing the success in communicating epistemic uncertainty by bounds or precise probability. The question we would like to answer is, when and why to use bounds or not? The workshop will explain and focus on the difference between aleatory and epistemic uncertainty. It will address two problems drawn from existing EFSA opinions, one with medium and one with weak background knowledge.

The target audience for this workshop are scientific experts, experts on uncertainty analysis and communicators.

3.2 Topic IV: Accounting for uncertainty in decision making

3.2.1 Accounting for uncertainty in data-poor scenarios: case studies on risk analysis in food safety

Alberto Mantovani
Istituto Superiore di Sanità, Italy

Background:
Uncertainty analysis is an essential component and a main challenge for risk assessment, with many examples provided by EFSA activities. A specific area of concern is provided by data-poor scenarios that, nevertheless, call for timely, and even fast, decision making.

Such scenarios may include:

- Risk analysis in countries where data collection still present gaps, yet, public health and/or regulatory decisions have to be taken.
- Emergencies when risk assessors are requested to provide fast advice with limited information available.
- Emerging issues leading risk assessors and risk managers to deal with data-poor scenarios

Goals:
The workshop will exploit a set of case studies in order to derive lessons and to discuss a possible set of recommendations on how to account for uncertainties in risk analysis when dealing with data-poor scenarios.

Format:
The workshop will start at 10.30 and end at 17.00. After a short introduction by the presenter, four case studies will be presented (30 minutes each).

A guided discussion will follow on lessons from the case studies; active contributions by participants will be elicited. The final round-up will identify a possible set of recommendations.

Contents:
The four case studies will be presented by

- Alberto Mantovani, Istituto Superiore di Sanità, Italy (risk assessment of data-poor issues: solvents, thorium)
- Elizabeta Micovic, Administration for Food Safety, Slovenia (risk management/ communication in emergencies: natural substances, biocides)
- Rusudan Tsiklauri, Saba Kobakhidze, National Food Authority, Georgia (assessing food monitoring data in Georgia)
- Olaf Mosbach-Schulz, EFSA (emerging issues in plant health as a model)

The guided discussion will pivot on the lessons learnt from the case studies, including how to frame questions, categorise uncertainties and communication between risk assessors and risk managers/policy makers.

Target audience:
Risk assessors and risk managers from EU and EU-acceding/neighbouring countries.

3.3 Topic V: Dialogues on uncertainty in an open society

3.3.1 Let's play at giving uncertainty a protagonist role in science stories! – A Dubitarte workshop making use of ludo-pedagogy

Catherine Leclercq[1], Laura Martino[2], Giorgia Nicolo'[1], Anthony Smith[2], Domagoj Vrbos[2]

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Opening the door to uncertainty, to the unknown or little known, often induces fear and may lead actors in the scientific risk assessment area to conceal or minimise uncertainty. A researcher may be afraid to reduce his/her credibility when acknowledging that uncertainty in his/her findings is high. A policy maker may fear that his/her decisions will be questioned if all the uncertainty they are based on is revealed. A journalist or a knowledge broker may feel that, by communicating uncertainty, he/she will not be able to give clear answers to lay people.

The first goal of this workshop is to allow participants to question themselves on the deeper meaning and implications of uncertainty and trust and on their own intellectual honesty and critical mind. The second goal is to enhance their awareness and their ability to deal with uncertainty in risk analysis.

The workshop consists of a series of collective games developed by the presenters using the ludo-pedagogy methodology (for more information see www.dubitarte.com). Participants experience their contact with the unknown in an unusual way. After ice-breaker activities, participants are invited to play games where "uncertainty" takes the form of objects or characters that they either just imagine based on a description, or see, or even touch. Participants experience playing different roles (risk assessor, risk manager, risk communicator) and having different attitudes towards "uncertainty" with the use of case studies. They also experience manipulating "uncertainty". These games are followed by a group discussion on the implications of different strategies to deal with uncertainty in the area of risk/benefit analysis. The workshop ends with the reading of a literary passage with music background. Participants are invited to a cold-set restitution by filling out a questionnaire after the workshop.

This workshop is targeted at scientists, risk assessors, policy makers and communicators.

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