A note on EFSA's ongoing efforts to increase transparency of uncertainty in scientific opinions

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This is a comment on Lofstedt and Bouder's paper, which explores the prospects of evidence based uncertainty analysis in Europe, focusing on the ongoing development on uncertainty analysis at the European Food Safety Authority (EFSA). We very much welcome a discussion on the need to develop better treatment and communication of uncertainty in risk analysis, as we believe that such discussion is long overdue. Lofstedt and Bouder raise many relevant points, in particular the call for evidence based uncertainty analysis. However, there is need to distinguish different types of communication in the discussion and facilitate - not diminish - the description and communication of uncertainty between risk assessors and decision makers. We find that EFSA has taken steps towards a novel approach to guide their scientific experts and risk assessors in uncertainty analysis based on a modern and scientific view on uncertainty.

Keywords: uncertainty; guidance; communication; subjective; EFSA

Introduction

In this short piece, we comment on Lofstedt and Bouder's paper (2017), which explores the prospect of evidence based uncertainty analysis in Europe, focusing on the ongoing development on uncertainty analysis at the European Food Safety Authority (EFSA). We very much welcome a discussion on the need to develop better treatment and communication of uncertainty in risk analysis, as we believe that such discussion is long overdue.

Similarily to Lofstedt and Bouder, we describe and refer to what is in a guidance for uncertainty analysis drafted by EFSA (2016). We emphasize that EFSA's guidance is just a draft, and does not yet represents EFSA's official view. For example, the draft guidance is still subject to trialing and internal testing, and might well change substantially after this process. The final version is not expected until the end of 2017 (https://www.efsa.europa.eu/en/press/news/160321).

Uncertainty analysis in flux

We agree with Lofstedt and Bouder that new approaches for uncertainty analysis are required to meet the challenges faced by today's decision makers. Because of the increasing scale as well as the increasing mathematical and social complexity of systems being studied, uncertainty analysis needs to embrace quality of knowledge,

subjective aspects of risk, decision context, and stakeholders. In addition, we welcome progress to ensure that, in practice, uncertainty analysis is built upon a proper scientific basis. Luckily, uncertainty analysis is already in flux.

The subjective dimension of probability (to represent uncertainty) can be traced back as far 1660 (Hacking 2006), and has been part of probability theory ever since its conception. In certain circles, during a major part of the 20th century, "subjective" became synonymous with "non-scientific" or "biased" (Cox 2006). Today, the swing is going in the other direction, and the subjective dimension of uncertainty (and risk) is being studied and acknowledged much more explicitly, in academic discussions (see e.g. Aven and Guikema 2011) as well as in applied fields such as medicine (Sox, Higgins, and Owens 2013; Fischhoff and Davis 2014).

In decision contexts, a conceptual and sound understanding of uncertainty is required to build a scientific approach to uncertainty analysis. This includes, for example, viewing uncertainty not just as an add-on, but as part of the description of risk, using uncertainty to support decisions, and acknowledging the subjective dimension of uncertainty where necessary.

Recently, the Society for Risk Analysis produced a paper discussing whether risk could be viewed as the assessor's uncertainty about events and consequences, given the background knowledge and its strength (Aven et al. 2015). Thus, there is an ongoing discussion on how to better account for differences in strength of knowledge bases used in risk assessment, and in general knowledge production to support decisions. Due to the complexity of the required analysis of risk, possible conflicts of interest, and values at stake, decisions on how to treat uncertainty must be reconsidered for every assessment problem, often in an iterative process.

An emphasis on the decision context is put forward by ISO (ISO 31000 (2009)/ISO Guide 73:2002) where risk is defined as the "effect of uncertainty on objectives". This view is quite different compared to the more traditional view that risk can be reduced to likelihoods and consequences (Kaplan and Garrick 1981) or properties of a complex system (Haimes 2009). It is being acknowledged that the way in which risk should be described depends on the (assessment) question asked.

Even though EFSA's draft guidance is not yet adopted by EFSA, we follow Lofstedt and Bouder and revisit how uncertainty is viewed in EFSA's draft from 2016. The draft considers uncertainty to be any type of limitation in available knowledge that affects the range and probability of possible answers to an assessment question (EFSA 2016 p. 20). By available knowledge, they mean knowledge (evidence, data, etc.) available to assessors at the time the assessment is conducted and within the time and resources agreed for the assessment (EFSA 2016 p. 20). Consequently, uncertainty is conditional on the knowledge that is relevant to the assessment and available to those conducting the assessment, at the time that the assessment is conducted, and also conditional on the assessors involved (EFSA 2016 p. 30). It is also clarified that there is no single "true" uncertainty (EFSA 2016 p. 30), which argues for evaluating an analysis of uncertainty based its logic rather than on its performance of outcomes in hindsight. To conclude, the view on uncertainty in the draft guidance is well motivated and in line with recent developments of uncertainty analysis.

Also, with such perspectives on risk and uncertainty, it becomes very difficult for uncertainty analysis to NOT be an integral part of risk assessment, which is one of the concerns raised by Lofstedt and Bouder. Different from Lofstedt and Bouder, we don't find that the draft guidance suggests uncertainty analysis as something that will be published along-side the scientific opinion. We'd like to emphasize that the "tools" offered in the draft guidance are not just a set of methods, but also includes:

- a conceptual framework for uncertainty,
- a range of different approaches for uncertainty analysis depending on the problem at hand and the resources available, and
- a support framework to make an informed choice about the methods to derive uncertainty in the output of the risk assessment.

In practice, new ideas on uncertainty are being picked up at a slow pace. An acceptance of subjective probability in an academic discourse does not mean that it is fully established in practice or in the teaching of future decision makers and risk assessors. In fact, we experience a large variation between scientific disciplines, fields of applications, and countries. Thus, widening the view on uncertainty and uncertainty analysis in scientific risk assessment will take time. We believe that EFSA's ongoing work is a step in the right direction.

"Evidence based" uncertainty analysis

We welcome Lofstedt and Bouder's initiative to raise the discussion on what is needed to develop an evidence based uncertainty analysis. Note that the term "evidence based uncertainty analysis" might be taken to mean two things:

(1) Uncertainty analysis should be based on evidence such as high quality data, well established mathematical models, unanimously agreed expert opinions, and so on.
(2) The procedures for the uncertainty analysis itself (i.e. how to treat and communicate uncertainty) should be based on the premise that there is evidence that these procedures work well.

The first sense will hopefully be obvious to readers. Lofstedt and Bouder are clearly concerned with evidence based uncertainty in the second sense, which is a lot less trivial. For example, what type of evidence is asked for? Also, it can be discussed if evidence based uncertainty communication is a better term, with the argument that analysis is motivated by the need to communicate and setting the limitations of what to communicate.

Evidence for the treatment of procedures for uncertainty analysis can take many forms, including:

(1) Logical arguments, mathematical soundness and consistency.
(2) Case studies (possibly comparative) on theoretical problems.
(3) Case studies (possibly comparative) on real world applications.

An important question to ask is whether we need evidence from case studies at all if we already have good logical arguments for a particular procedure in a specific situation.

For communication of uncertainty, matters become often really tricky, and we envisage the type of evidence produced by social scientists on the communication and perception of risk (such as White and Johnson 2010, and several of the references provided by Lofstedt and Bouder). There is an opportunity here to combine the scientific perspective on treatment and the social perspective on communication to create a new agenda for evidence based uncertainty analysis. We believe that this is exactly the opportunity identified in Lofstedt and Bouder's paper.

Structured procedures for using expert knowledge in risk assessment (e.g. formal and semi-formal expert knowledge elicitation) are good examples of situations where both scientific and social perspectives are combined. These procedures have a

strong theoretical basis, but are also designed to deal with cognitive biases and heuristics identified by social sciences (Tversky and Kahneman 1974; O'Hagan et al. 2006). Other good examples are studies of the effects of the assessor's choice of how to describe and communicate uncertainty. This choice can be based on evidence of what enables the public to learn and understand the message (Dieckmann et al. 2016). Finally, there is plenty of research on how to communicate uncertainty in a way that avoids unnecessary reactions from recipients resulting from the manner in which the communication is done. We strongly support Lofstedt and Bouder's advice to test risk messages before making them public, especially on socially sensitive matters.

With a broader view on uncertainty analysis, there are other sources of uncertainty to consider. For example, bias can result from the decisions taken by the risk assessors themselves, values (Vareman and Persson 2010) and (as identified by Lofstedt and Bouder) path-dependence, i.e. one tends to use the methods, models, theories that one already spent a lot of time on. Maxim and van der Sluijs (2011) identify this as a procedural source of uncertainty. Here, it would be useful to have evidence of the severity of such sources of biases (how common are they and should we worry about them?), and evidence on the effect of methods to reduce their impact on a risk assessment.

The role of uncertainty quantification

Lofstedt and Bouder write that "trying to develop new quantifications to capture uncertainties will be of limited interest because biases will be introduced to constrain or distort the analysis". Even though they not directly refer to what is in the draft guidance by EFSA, we would like to clarify the use of quantification therein. First, the draft guidance is not introducing any methods that are new: the methods included are all well established in the literature as well as in practice. Second, the draft guidance is promoting qualitative analysis as complement to quantitative ones, e.g. the NUSAP analysis (van der Sluijs et al. 2005; Fischhoff and Davis 2014) is included. The draft guidance is in fact very comprehensive and is quite novel as a guidance for uncertainty analysis, as it includes an extremely wide range of methods, along with support for what and when to use those methods.

Quantification is a scientific approach to describe the states of the world. However, we know that quantification of our uncertainty about unobserved or partially observable states of the world is challenged due to the epistemic and value laden nature of risk assessment, and that is why uncertainty analysis, reflecting the limits of our knowledge, is so important.

Understanding all flavors of quantification takes time and experience. Here, we would like to take the opportunity to explain how we perceive what the draft guidance is trying to achieve with respect to quantification.

First, there is a clarification of roles. Decision makers are responsible for resolving the impact of uncertainty on decisions, which requires weighing the scientific assessment against other considerations (EFSA 2016 p. 23). Risk assessors are responsible for characterizing uncertainty, which requires scientific expertise. These are seen as two conceptually distinct activities, but interaction between them is essential (EFSA 2016 p. 23). The draft guidance seeks to improve this interaction with regard to uncertainty analysis. First, they identify what the decision maker wants to know:

- What is the range of possible answers, and how probable are they?
- Is further investigation needed?

- What are the main sources of uncertainty affecting the outcome of the assessment?

Second, it sets requirements and preferred aims of an uncertainty analysis. It is necessary to characterise the combined uncertainty on the assessment questions, since this is what matters for decision making. In addition, the combined uncertainty on the output should be quantified, either by calculation or by expert judgment.

It is not necessary to characterise all uncertainties individually. The draft guidance recognises that assessors may be unable to quantify some sources of uncertainty. If so, they should identify and describe these.

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An iteration of an uncertainty analysis consists of four steps:

(1) Identify sources of uncertainty
(2) Assess individual sources of uncertainty
(3) Assess the combined impact of individual sources of uncertainty on uncertainty in the assessment output
(4) Assess the relative contribution of individual sources to uncertainty in assessment output

The draft guidance contain descriptions on what each method to assess uncertainty can do and cannot do, relative to the form of uncertainty that the method provides (qualitative or quantitative, ranges, intervals, or probability distributions) and which of the steps (1 to 4) are covered by a method (EFSA 2016 Table 7). In addition, the draft guidance provides an evaluation of the strengths and weaknesses of each method with respect to ten criteria (EFSA 2016 Table 6). This is an innovative and novel approach, since it encourages risk assessors (including scientific experts) to make an active and informed decision about the (combination of) methods to use for a specific uncertainty analysis, depending on the knowledge basis and type of problem, in accordance with requirements on the level of the uncertainty analysis.

Uncertainty transparency: about what and to whom?

Communicating uncertainty is about communicating what we know, and clarifying the limitations of our current knowledge. Lofstedt and Bouder are worried about the consequences of being transparent about uncertainty, i.e. what we know and don't know.

In this sometimes confusing discussion, there is a need to distinguish between analyzing uncertainty in risk assessment and communicating uncertainty in various contexts. In all circumstances, uncertainty must be described before there is anything to communicate. How uncertainty is described sets the limits of what is possible to communicate, not necessarily saying that everything must be communicated. Transparency of the process to analyze uncertainty is important for the perception and accountability in the uncertainty being communicated (Fischhoff and Davis 2014). Consequently, the draft guidance (EFSA 2016) provides a structured process for scientific panels to decide which methods to use for uncertainty analysis, with the purpose to increase transparency in the process. Assessors are asked to report identified sources of uncertainty, how uncertainty is expressed, the methods used, and the

combined uncertainty in output and influential sources of uncertainty (EFSA 2016 Table S.2).

In our view, subjectivity in scientific analysis is impossible to avoid. A more transparent uncertainty analysis will bring the subjective nature of scientific analysis much more to the forefront. That is exactly why it is important for us scientists to admit subjectivity whenever we must make a subjective assessment. Therefore, we welcome that the draft guidance also explicitly acknowledges this dimension of uncertainty.

In addition, there is a request to be transparent about knowledge itself. Lofstedt and Bouder compare being transparent about uncertainty to being transparent about data. In our view, there is a difference between making data publicly available and informing decision makers on the combined uncertainty in an assessment output. We think that this concern about transparency must be treated differently depending on the parties involved: is it about communication between the risk assessor and the decision maker, between the risk assessor and the public, or between the decision maker and the public?

Lofstedt and Bouder argue that being more open to analyze uncertainties may lead academics critical of the dominant risk analysis model to argue for policy not based on evidence and informed by risk. This is a valid concern, but not a valid argument to ignore uncertainty when assessing risks. For instance, we do not see the valid worry of more frequent applications of the precautionary principle as an argument to stop risk assessors (e.g. EFSA) from describing and communicating uncertainty to decision makers (e.g. DG SANTE). Even though being transparent about the limits of the scientific knowledge available to a decision maker might incur fear in the public, should a risk assessor be worried about communicating what they know, and the limits thereof, to the decision maker if in fact there really is a large degree of uncertainty? What would happen if a risk assessor would be accused of hiding uncertainty to decision makers? Most members of the public naturally favor being part of a society governed by decision makers who are certain, but are they really willing to accept that decision makers at the same time are denied information that could influence the decisions made, and thereby affect their own safety?

Lofstedt and Bouder (Lofstedt and Bouder 2017) are worried that an authority like EFSA might lose public trust by acknowledging uncertainty. Ignoring known sources of uncertainty to avoid losing trust is quite controversial, and seen as an immoral act by some. Public trust can be lost, but also gained, from being transparent about uncertainty (White and Johnson 2010).

In our view, the way forward is simply to become better in uncertainty analysis. Adequate training of scientific experts, risk assessors, decision makers and facilitators of knowledge production and communication is required, not only at EFSA, but in the larger community of scientists and practitioners. Before uncertainty analysis can be "evidence based", there a need to establish a scientific perspective on uncertainty analysis. EFSA have taken the initiative to provide a comprehensive "conceptual model" for uncertainty analysis. There is, to our knowledge, no previous guidance of uncertainty analysis taking this approach.

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