



## EFSA cross cutting Working Group on Uncertainty

### Minutes of the 2<sup>nd</sup> cross cutting WG on Uncertainty (WGU)

**Teleconference, 3 April 2019 (9.30-12.45)**

**(Agreed on 08 April 2019)**

#### **Working Group Members:**

- **Panel and external experts:**

Dominique Bicout, Julio Alvarez, Peter Craig, Andrew David Hart, Konstantinos Koutsoumanis, Maarten Nauta, Giuseppe Ru,

- **EFSA:**

SCER unit: Caroline Merten

AMU unit: Federica Barrucci, Laura Martino and Fulvio Barizzone



## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received by Laura Ciccolallo from EFSA AMU unit.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. Additional interests were declared by Andy Hart orally at the beginning of this meeting. No conflict was identified.

## **4. Monitoring implementation of uncertainty Guidance document**

The WG discussed and reviewed a template to capture the information to report on each mandate in which the uncertainty guidance document has been implemented. The template contains information on the different methodologies used to characterise the individual uncertainties and the overall uncertainty. The template will be filled out by either the WG chair or scientific coordinator before a mandate's outputs will undergo public consultation and when the output will be adopted as final for publication. The aim of this information is to serve as a repository for illustrative examples on how uncertainty analysis has been assessed within the implementation of the new EFSA guidance document on uncertainty<sup>2</sup>.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/5123>



## 5. Ad hoc support requests on ongoing & new mandates in 2019

The WG discussed two ad hoc requests to support the implementation of the uncertainty GD in the following mandates:

- Mandate on Scientific opinion on dietary references values (DRVs) for sodium (EFSA-Q-2011-01224): The WG discussed how the overall uncertainty was characterised for that mandate. The opinion was published for public consultation on 5 April 2019.
- Mandate on Scientific opinion providing an update and review of control options for *Campylobacter* in broilers at primary production (EFSA-Q-2018-00676): The WG discussed the general plan on how to address uncertainty in relation to the different control options.

## 6. Support on panel tailored training materials

- Biological hazard (BIOHAZ) tailored training: The training took place 5- 6 March 2019. The WG discussed the feedback from the plenary discussion on the break out and required follow ups. The case studies developed for this specific training will need to be revised to serve best as illustrative examples for the BIOHAZ panel and working group experts.
- Animal Health and Animal Welfare (AHAW): The WG was informed about the finalisation of the case study and subsequent discussion of it and the checklist at the AHAW Panel plenary on 21 March 2019.

The WG agreed to use the same version of the checklist (version3.1) in both panels (AHAW and BIOHAZ) in the future when implementing the guidance document in the respective working groups. It was agreed that the checklist is a working document. The current version is shown in annex 1. It was also agreed that potential updates to the checklist would be discussed at the regular WG meetings.

The WG agreed to discuss at their next meeting an agenda item on the communication aspects on how to report best on uncertainty based on the recommendations for risk assessors from the recent EFSA guidance document on how to communicate on uncertainty<sup>3</sup>.

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<sup>3</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/5520>



Further support from the WG will be needed in the second and third trimester 2019 to develop case studies for tailored panel training materials for the panel on contaminant hazards.

## **7. Any Other Business**

The agenda item on Integration of scientific assessment process into the uncertainty check list was postponed to the next WG meeting due to time constraints.

The dates for the remaining WG meetings in 2019 are the following:

- 3rd meeting cross cutting WG uncertainty: (1day physical meeting) – 24 June
- 4th meeting cross cutting WG uncertainty: (TC: 4 hours) - 3 October
- 5th meeting cross cutting WG uncertainty: (TC: 4 hours) – 10 December



## ANNEX 1: CHECKLIST FOR APPLYING EFSA'S UNCERTAINTY GUIDANCE IN A CASE-SPECIFIC ASSESSMENT – Version 3.1

**Note:** iteration of some steps may be required.  
Guidance.

\*GDn.n: see section n.n of the EFSA Uncertainty

### A. When Interpreting the Terms of Reference (ToRs) for the assessment (except for open questions)

1. **Check the ToR questions are well-defined. If not, make a well-defined interpretation, consulting with the Panel and/or requestor if needed.** A *well-defined question or conclusion* (GD10\*) refers to an outcome or quantity that could (in principle) be observed or measured without ambiguity in the real world, or obtained from a defined scientific procedure. Check each word has a defined meaning and that the population, region & time period of interest are specified. For a *variable* quantity, specify which statistic(s) and/or quantile(s) are required. Also define the question the assessment will actually answer, if it differs from that posed by the ToR, so that this can be taken into account when assessing overall uncertainty in step C5.

### B. When planning the data and methodologies for the assessment

1. **Consider the data and methodologies you plan to use in the assessment and identify any major uncertainties associated with them.** See next page #1 for types of uncertainties to look out for (GD7).

2. **Decide whether it would be beneficial to quantify any of these uncertainties within the assessment calculations or procedure, rather than later when assessing overall uncertainty.** If the former, decide how to express (GD11,12) and combine (GD13-15) these uncertainties and integrate this into the planning and implementation of your assessment. Seek specialist support if needed.

3. **Consider including sensitivity or influence analysis in your uncertainty analysis (UA), to help when prioritising uncertainties and/or when assessing overall uncertainty** (GD8).

4. **Make a plan for the assessment & UA** and seek feedback from the Panel if appropriate. **Include meeting time for assessing overall uncertainty** (C5 below).

### C. When carrying out the assessment and uncertainty analysis

1. **Be alert for additional sources of uncertainty and add them to your list.** See next page #1 (GD7).

2. **If the assessment involves calculations, review the preliminary results and consider again whether it would be beneficial to quantify any (more) uncertainties within the calculations (GD4.2-4.4) or subject them to sensitivity analysis** (GD8). If so, integrate this into a revised plan for the remaining steps of your assessment & UA.

3. **When developing draft conclusions on the ToRs, ensure they are well-defined** (see A1 above for explanation). When a conclusion *directly* answers a ToR that is already well-defined, this should be sufficient.

4. **Review all uncertainties which were not yet quantified and list or tabulate them concisely, ordered or grouped in a way that will be helpful for readers. Decide whether to quantify some of them separately (individually or in groups) before assessing overall uncertainty.** It may be easier to make separate judgements for uncertainties affecting different parts of the assessment (GD9), or separate uncertainties affecting model inputs from those about how model outputs relate to real outcomes. If you do this, decide how you will express the contribution of each group (GD11,12) and whether to combine them by calculation or expert judgement (GD13-15).

5. **Quantify the overall uncertainty of each conclusion.** If there are many conclusions, prioritise those where the uncertainty will have most impact on decision-making, if this is known; otherwise, prioritise those conclusions that address the ToRs most directly and/or are more uncertain. If no uncertainties were quantified in earlier steps, assess the combined impact on each conclusion of all the identified uncertainties by expert judgement



(GD4.1, Figure 6, steps C-E). If any uncertainties were quantified in earlier steps, take the results of that into account together with all the other uncertainties you have identified, either by expert judgement (GD16.16.1) or by a combination of expert judgement and calculation (GD16.2). **Use a formal or semi-formal expert knowledge elicitation procedure for the judgements required to quantify overall uncertainty.** For options and basic procedure, see next page #2.

**□ D. When reporting the assessment and its conclusions**

- **1. Report the methods and results of the uncertainty analysis in the same way as other parts of the assessment**, making sure they can be easily found by readers of the Opinion or Report (GD17).
- **2. Report each conclusion with your quantitative expression of its overall uncertainty**, making clear this involves expert judgement. **Report also the rationale for the assessment of uncertainty with the conclusion and/or in the body of the Report or Opinion. Highlight any sources of uncertainty you were unable to include in the quantitative expression, and state what assumptions were made about them (GD17). If unable to quantify any uncertainties, report that the probability of the conclusion is unknown.** If legislation or risk managers require firm conclusions, define the level of certainty required for these and report only conclusions for which this level is met (GD17 #5).

**SUPPORTING INFORMATION (#1) Types of uncertainties to look for in an assessment (GD 7)**

The Uncertainty Guidance offers the following table of general types of uncertainties. Use the table to help *identify* uncertainties; it is not necessary to classify them. Over time, EFSA Panels are encouraged to develop lists of specific types of uncertainties which they commonly encounter in their work. Lists provided by other methodologies (e.g. EFSA’s framework for evidence based scientific assessments, GRADE, etc.) should be used where relevant (GD7.2).

Uncertainties associated with data	Uncertainties associated with assessment methodologies
1. Ambiguity	1. Ambiguity
2. Accuracy and precision of the measures	2. Excluded factors
3. Sampling uncertainty	3. Distributional assumptions
4. Missing data within studies	4. Use of fixed values
5. Missing studies	5. Relationship between parts of the assessment
6. Assumptions about inputs	6. Evidence for the structure of the assessment
7. Statistical estimates	7. Uncertainties relating to the process for evidence from literature
8. Extrapolation uncertainty (i.e. limitations in external validity)	8. Expert judgement
9. Other uncertainties (including uncertainty due to conflicting evidence)	9. Calibration or validation with independent data
	10. Dependency between sources of uncertainty
	11. Other uncertainties

**SUPPORTING INFORMATION (#2) Basic principles for quantifying overall uncertainty by expert judgement**

The Guidance uses probability judgements to quantify overall uncertainty about whether a conclusion is correct, and about estimated quantities. The Guidance recommends that these judgements should be obtained by formal or semi-formal ‘expert knowledge elicitation’ (EKE) methods, (GD12.6). Formal EKE methods are described in EFSA’s 2014 Guidance on EKE and require weeks to months to implement. Semi-formal EKE can be done within a single Working Group (WG) meeting and should follow the steps below, to support good quality judgements and guard against biases (request advice/support from EFSA AMU or Standing WG on Uncertainty if needed):

- Ensure each conclusion or estimate to be considered is expressed in well-defined terms (see A1 in Checklist).
- Decide which WG members will participate and invite additional experts (e.g. from Panel) if appropriate.
- Identify a suitable form for expressing overall uncertainty: a probability distribution (GD12.1) or probability bounds (GD12.2) for an estimate; a probability (GD12.1), approximate probability (GD12.2) or the approximate probability scale (GD12.3, see Table below) for a conclusion, or for an estimate falling in a specified range.



- Plan the agenda for the elicitation session, allowing at least 2 hours per judgement and including appropriate elements to guard against bias (e.g. eliciting plausible limits before central estimates; ask for advice if needed).
- Add 1 hour for training in probability judgements unless all participants are already familiar with it.
- Identify a suitable person who is not making judgements to facilitate: their job is to keep to time and ensure a balanced discussion based on evidence and reasoning. Identify a second person to take detailed notes.
- In the meeting, after training (if needed), for each conclusion or estimate in turn:
  - Have a summary of the evidence and uncertainties to hand (e.g. from the draft opinion or report)
  - Each participant makes their own judgement(s) privately, taking account of the evidence and uncertainties
  - Display the individual judgements together, discuss reasons for differences, and discuss whether higher or lower judgements could be plausible (to guard against over-confidence)
  - Facilitated discussion to elicit a consensus judgement: what a rational impartial observer would judge, having seen the evidence, uncertainties and individual judgements and heard the discussion
  - It is essential to elicit also the group’s rationale for the consensus judgement.
  - If there are any uncertainties which the experts cannot include in their quantitative judgements, agree and record what assumptions will be made about them
  - Record the *consensus judgement*, the *consensus rationale* for that judgement, and *which experts contributed*
  - If individual judgements and discussion are recorded, do not attribute them to the individuals involved.

**Approximate probability scale recommended for harmonised use in EFSA, where appropriate (GD12.3):**

Probability term	Subjective probability range	Additional options	
Almost certain	99-100%	More likely than not: >50%	Unable to give any probability: range is 0-100%
Extremely likely	95-99%		
Very likely	90-95%		
Likely	66-90%		
About as likely as not	33-66%		Report as ‘inconclusive’, ‘cannot conclude’, or ‘unknown’
Unlikely	10-33%		
Very unlikely	5-10%		
Extremely unlikely	1-5%		
Almost impossible	0-1%		

## EFSA cross cutting Working Group on Uncertainty

### Minutes of the cross cutting WG on Uncertainty (WGU)

**Teleconference, 23 November 2018(9.30-12.30)**

**(Agreed on 29 November 2018)**

#### **Working Group Members:**

- **Panel and external experts:**

Dominique Bicout, Peter Craig, Andrew David Hart, Konstantinos Koutsoumanis, Maarten Nauta, Giuseppe Ru, Salomon Sand, Wopke van der Werf, Heather Wallace

- **EFSA:**

SCER unit: Caroline Merten

AMU Unit: Laura Ciccolallo, Laura Martino, Olaf Mosbach, Federica Barrucci

## **1. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Julio Alvarez and Barizzone Fulvio (AMU unit).

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## **4. Terms of references of cross cutting WG uncertainty**

EFSA has developed a harmonised approach to assessing and taking account of uncertainties in food safety, and animal and plant health. This approach aims at increasing the transparency of the resulting scientific advice and make it more robust for decision-making. The EFSA Scientific Committee (SC) guidance on Uncertainty in EFSA's scientific assessments offers a diverse toolbox of scientific methods and technical tools for uncertainty analysis (published in January 2018)<sup>2</sup>. It is sufficiently flexible to be implemented in such diverse areas as plant pests, microbiological hazards and chemical substances. A separate opinion has been published separately describing in detail the principles and methods supporting the concise Guidance Document<sup>3</sup>.

The long-term goal is that the new guidance on uncertainty will be an integral step in all EFSA's scientific assessments. EFSA will implement the approach in two stages. In general scientific areas, the guidance will apply from autumn 2018 after the renewal of the Authority's scientific panels. In regulated products areas such as pesticides, food additives or food contact materials it will be phased in later on, in light of the experience gained in the 'non-regulated' areas.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/5123>

<sup>3</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/5122>

To support the implementation of the above-mentioned EFSA SC Guidance document, EFSA has established a cross-cutting EFSA Working Group on uncertainty (cross-cutting WG uncertainty).

**Terms of reference:**

The objective of the cross-cutting WG uncertainty is to support EFSA panels and units and, in particular, those from the Risk Assessment and Scientific Assistance (RASA) department in implementing the EFSA guidance on uncertainty by:

- (i) Providing scientific advice and support to ad hoc requests on how to apply the uncertainty guidance document across the various EFSA opinions, guidance documents, technical and scientific reports ;
- (ii) Providing scientific advice and support to the development of panel tailor made training materials;
- (iii) Ensuring a sustainable capacity building across the panels on uncertainty analysis;

The chairmanship of the cross-cutting WG uncertainty remains within the SCER unit.

The composition of the cross cutting Working Group is available on the EFSA website.

The WG discussed and agreed on the terms of references and working process of the cross cutting WG.

**5. Monitoring implementation of uncertainty GD**

The WG agreed to develop a template to capture in which upcoming EFSA opinions the uncertainty GD has been implemented and how. This information will be published next year in the EFSA knowledge junction<sup>4</sup>.

**6. Ad hoc support requests on ongoing & new mandates in 2018**

The WG discussed two new ad hoc requests to support the implementation of the uncertainty GD in the following mandates:

- Mandate on Scientific opinion on dietary references values (DRVs) for sodium (EFSA-Q-2011-01224): The WG discussed a template to record in a structured way the uncertainties identified on the evidence and on the methods used for the scientific assessment.

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<sup>4</sup> <https://zenodo.org/communities/efsa-kj?page=1&size=20>

- Mandate on Scientific opinion providing an update and review of control options for *Campylobacter* in broilers at primary production (EFSA-Q-2018-00676): The WG for this mandate will meet for the first time in early December.

## **7. Support on panel tailored training materials**

The WG discussed the next steps in facilitating the implementation of the uncertainty analysis in the Animal Health and Animal Welfare panel: checklists on what to consider at the different steps of the risk assessments process to integrate uncertainty analysis will be developed.

Further support from the WG will be needed:

- in the first trimester of 2019 to develop case studies for tailored panel training materials for the panel on biological hazards;
- in the second trimester 2019 to develop case studies for tailored panel training materials for the panel on contaminant hazards;

## **8. Any Other Business**

3 teleconferences and one physical meeting will be organized in 2019. The dates will be fixed in early January 2019.