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EXTERNAL SCIENTIFIC REPORT

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OC/EFSA/SCER/2014/02-Lot 1

“Specialised training courses on certain aspects of food safety risk assessment for members of EFSA’s Scientific Committee/Panels and their working groups, open to EFSA staff” –final report

Louise Wipfler, Theo Brock, Andy Hart, Lorraine Maltby, Peter Craig

Abstract

This final report evaluates the training courses delivered under the contract OC/EFSA/SCER/2014/02-Lot 1. Two types of specialised training courses were delivered: a training course addressing uncertainty in EFSA’s scientific assessments and a training course on Environmental Risk Assessment. Both trainings were evaluated as very good by the participants.

In addition to its primary aim of supporting the understanding and practical implementation of best risk assessment practices, the uncertainty training was used to obtain feedback on the draft guidance document. Therefore, only invited participants could follow the training and selection ensured that each unit was represented in the training. The training course now has to be updated in line with the final version of the guidance document.

One of the objectives of the training was to strengthen the dissemination of ERA guidance and modelling practises and to ensure the uptake of guidance on cross-cutting risk assessment approaches amongst members of EFSA’s Scientific Committee/Panels, their working groups and EFSA staff. This aim is partly achieved as participants of different backgrounds joined the trainings. It was noted however, that only a few panel member participated and participants with a background in pesticide risk assessment were over-represented as compared to the other work fields of EFSA.

Key words: Final report, Training course, Environmental Risk Assessment, Addressing uncertainty in EFSA’s scientific assessments.

Question number: EFSA-Q-2014-00892

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Summary

EFSA has recognized a need for advanced training of its Panel and Scientific Committee members and scientific staff to facilitate their understanding, uptake and use of the best risk assessment practices developed by EFSA. In addition there is a need to strengthen the cross-fertilisation of scientific discussion and support harmonization between the different scientific domains in EFSA.

Two types of specialised training courses were delivered within the project: a training course addressing uncertainty in EFSA's scientific assessments and a training course on Environmental Risk Assessment. Each course covered four blocks of four hours each. Over the period 2015-2017, a total of three training courses on addressing uncertainty in EFSA's scientific assessments were organised and six on Environmental Risk Assessment. The courses had 191 participants in total of which 83 participated in the course addressing uncertainty in EFSA's scientific assessments and 108 participated in the Environmental Risk Assessment course. In addition to Panel and Scientific Committee members, scientific staff, and members of selected EFSA networks could also attend the Environmental Risk Assessment courses.

The overall objective of the specialised training courses was (i) to support the understanding and practical implementation of best risk assessment practices amongst members of EFSA's Scientific Committee/Panels, their working groups and EFSA staff in particular on horizontal aspects of the risk assessment workflow, (ii) to strengthen the dissemination of Environmental Risk Assessment guidance and modelling practises and to ensure the uptake of guidance on cross-cutting risk assessment approaches already developed by EFSA amongst members of EFSA's Scientific Committee/Panels, their working groups and EFSA staff.

Both trainings were evaluated as very good by the participants. The uncertainty training was additionally used to obtain feedback on the recently published draft guidance document. Therefore, only invited participants could follow the training and selection ensured that each unit was represented in the training. The training course content and structure evolved rapidly over the three trainings. The training course now has to be updated in line with the final version of the guidance document.

The ERA training aimed to strengthen the dissemination of ERA guidance and modelling practises and to ensure the uptake of guidance on cross-cutting risk assessment approaches amongst members of EFSA's Scientific Committee/Panels, their working groups and EFSA staff. This aim is partly achieved as only a few panel member participated and participants with a background in pesticide risk assessment were over-represented as compared to the other work fields of EFSA.

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1. Introduction

1.1. Background as provided by EFSA

In line with their strategic goals, EFSA has set up specialised training courses for EFSA Scientific Committee/ Panel members in order to deepen knowledge on certain aspects of risk assessment that cut across the work of different panels. The aim is to offer a structured way to go through critical aspects of risk assessment performed in EFSA, in line with the EFSA guidance documents. Organising such courses involving the participation of members from different panels, as well as staff from different science units of EFSA and EFSA networks, will have the beneficial effect to cross-fertilise scientific debate and to foster harmonisation in the risk assessment across different scientific domains. These specialised courses are part of an induction package offered to new panel member. The specialised courses are structured around the body of best risk assessment practices and cross-cutting guidance that EFSA has developed over the past years, and is now being extended to include training courses on: (i) Environmental Risk Assessment, (ii) variability and uncertainty in risk assessment, (iii) benchmark dose approach, and (iv) computational toxicology modelling tools in food and feed risk assessment.

This contract/grant was awarded by EFSA to:

Contractor/Beneficiary:

- Alterra, institute with the legal entity DLO, part of Wageningen University and Research, the Netherlands, lead contractor
- The Food and Environment Research Agency (FERA), UK, contractor
- The University of Sheffield (TUoS), UK, contractor
- University of Durham, UK, subcontractor

Contract/Grant title: "Specialised training courses on certain aspects of food safety risk assessment for members of EFSA's Scientific Committee/Panels and their working groups, open to EFSA staff"

Contract/Grant number: OC/EFSA/SCER/2014/02- Lot 1: training courses on Environmental Risk Assessment and training courses on variability and uncertainty in risk assessment.

1.2. Objectives

The specific objective of the project was to provide EFSA with a number of specialised training courses. Two types of specialised training courses were delivered: a training course on Environmental Risk Assessment and a training course addressing uncertainty in EFSA's scientific assessment¹.

The overall objective of the specialised training courses was twofold:

- To support the understanding and practical implementation of best risk assessment practices amongst members of EFSA's Scientific Committee/Panels, their working groups and EFSA staff in particular on horizontal aspects of the risk assessment workflow such as (i) Environmental Risk Assessment and (ii) variability and uncertainty in risk assessment.
- To strengthen the dissemination of Environmental Risk Assessment guidance and modelling practises and to ensure the uptake of guidance on cross-cutting risk assessment approaches already

¹ The original title referred to in the contract was: 'Training course on variability and uncertainty'. In consultation with EFSA, the title was changes to 'Training courses addressing uncertainty in EFSA's scientific assessments' in order to better reflect the content of the training

developed by EFSA amongst members of EFSA's Scientific Committee/Panels, their working groups and EFSA staff.

The training courses were organised by a consortium led by Wageningen Environmental Research (Alterra) and included the partners FERA sciences limited and the University of Sheffield.

1.3. Set up

This document summarizes the activities and tasks carried out by Alterra in order to deliver the training sessions under this contract and evaluate the training courses. In Section 2 the training course on addressing uncertainty in EFSA's scientific assessments is discussed and in Section 3 the training course on Environmental Risk Assessment. Conclusions and recommendations for future training courses are provided in Section 4.

2. Training course Addressing uncertainty in EFSA's scientific assessments

2.1. General

This training course was organised on three occasions (i.e. 6 April – 8 April 2016, 26 April – 28 April 2016 and 26 May – 28 May 2016). Each course was delivered by tutors Andy Hart (Fera) and Peter Craig (Durham University)

The general objectives of this training course were:

- To enable the understanding and practical implementation of best risk assessment practices amongst Panel/Scientific Committee members and EFSA scientific staff, in particular the horizontal aspect of addressing variability and uncertainty in risk assessment.
- To strengthen the dissemination of guidance on addressing variability and uncertainty amongst Panel/Scientific Committee members and EFSA scientific staff, and promote and facilitate its uptake.
- To make a link between the theory and practice by including practical sessions with examples of variability and uncertainty from the work of EFSA.

Intended learning outcomes were:

By the end of the course, participants should be able to understand and describe:

- On the scientific information (refers here to (1) empirical evidence; (2) raw data; and (3) expert opinion) feeding into a risk assessment, what is variability and how can it be assessed using different descriptive and statistical techniques;
- On the scientific information feeding into a risk assessment, what is uncertainty and how can it be assessed using different descriptive and statistical techniques;
- On the risk assessment process, why should variability and uncertainty be separated in a risk assessment and how can this be done both in qualitative and quantitative risk assessments.

During the inception phase of the project an additional aim was added: to support the trial period of the new Guidance Document on Addressing uncertainty in EFSA's scientific assessments. Also it was decided to target the training more on uncertainty and less on variability. The new guidance document on uncertainty in EFSA's scientific assessments was published for public consultation shortly before the start of the training. The course tutors developed a training course based on the contents of this guidance document and the feedback of the participants was used as part of the trial period of the guidance document. In view of this, the contract was amended to allow for additional support by Peter Craig to the training development and delivery.

The course was divided into a series of sessions, with a mix of lectures, general practicals and case practicals. Some of the general practicals used an everyday example which, although not drawn from food safety, was considered relevant to all participants and avoided the need for specialist knowledge on other parts of EFSA's work. For the Case Practical, participants brought assessments being used by their Panel or Unit in the Trial Period of the Uncertainty Guidance.

The detailed program of the course is given in Appendix A, as the program developed over time, both the programs of the first training and the third training are given.

Approximately 10 days in advance of the training, participants were asked by email to inform the tutors which example they would bring from their Panel/Unit. Participants were recommended to: (1) read the Extended Summary of the draft Guidance before attending the course (<http://www.efsa.europa.eu/en/topics/topic/uncertainty>); (2) read Chapter 4 of the draft Guidance, and the parts of Chapter 5 of personal interest; (3) watch the video on the topic page on the EFSA website (<http://www.efsa.europa.eu/en/topics/topic/uncertainty>).

A website was launched to support the registration of Panel members. After launching the website but before the start of the first training, it was decided however that participation in this training was by invitation only. Each EFSA unit could propose a limited number of participants. Participants could be EFSA Panel members, members of the Scientific Committee and EFSA scientific staff. Each training course was open to 30 participants and places were filled up as much as possible. Detailed information on the number of participants participating in each course is given in Table 1. In total 83 participants followed the training, which was 92% of the number of reserved places, 48% of the participants were experts (Panel or Scientific Committee members), 52% of the participants were EFSA staff.

Table 1: Participation of EFSA experts and staff in the courses addressing uncertainty in EFSA's scientific assessments

| UNIT | Course 1 6-8/4/2016 | | Course 2 26-28/4/2016 | | Course 3 26-28/5/2016 | | Total |
|--------------|------------------------------------|-----------|------------------------------------|-----------|------------------------------------|-----------|-----------|
| | Panel / Scientific committee | Staff | Panel / Scientific committee | Staff | Panel / Scientific committee | Staff | |
| AHAW | 2 | 1 | | | 2 | 2 | 7 |
| ANS | 2 | 1 | | | | | 3 |
| BIOHAZ | 2 | 1 | | 1 | 3 | 4 | 11 |
| CEF | | | 2 | 2 | 2 | | 6 |
| CONTAM | 1 | 1 | 2 | 2 | 1 | 1 | 8 |
| FEEDAP | 2 | 1 | 1 | 2 | | | 6 |
| GMO | 1 | 2 | 3 | 4 | 3 | | 13 |
| NDA | 1 | 3 | 2 | 1 | | 1 | 8 |
| PLH | 2 | 2 | 2 | 3 | | 1 | 10 |
| PPR | 1 | | 1 | | | 2 | 4 |
| SCER | 2 | | | | | 2 | 4 |
| AMU | | | | 1 | | 2 | 3 |
| total | 16 | 12 | 13 | 16 | 11 | 15 | 83 |

Training material was handed out at the beginning of each course both in hard-copy as electronically. The training material included the course programme as well as the presentations and the practical exercises. It was updated and improved after each of the trainings and evaluations by participants were a valuable source of feedback for improvement of the course.

The participants received a course attendance certificate after the course that included the name of the participant, name of the course, dates of the course and names of the tutors.

The participants evaluated the training course by completing a questionnaire. The questionnaires were handed out on paper and left by each participant at the end of the training session. The template of the course questionnaire, which is shown in Appendix B, requested feedback on satisfaction related to the overall experience, curriculum and teaching and course administration and venue, and suggestions for improving the training.

2.2. Course evaluation and development

Average evaluation scores for the course were between 3.5-4.4 out of 5, where 1 is 'no satisfaction' to 5 'full satisfaction'. The answers given by the participants are summarized in Table 2. More detailed analysis is provided in appendix C. The tutors used the feedback to improve the training. After the first training this resulted in a shift in the content of the training i.e. more time was given to the practicals and the content of the lectures were reduced, while focussing more on the key issues. Less time was also given to the general example case. Also a larger room was reserved to allow for break-out groups to work in the same room. For reference, a detailed program of the training course 1 and 3 is given in Appendix A.

The evaluation score of the second training was higher than the first training. After the second training the lectures were reduced a bit further in favour of the practicals. Also more time for discussion was allowed for in the programme and the lectures on probabilistic methods were revised.

The third training course had slightly lower evaluation ratings. The tutors considered the material used in the third training to be good. However, further changes made in the third course did not fully work, leading to more discussions which, while useful, resulted in the loss of time for the practicals. This was reflected in the feedback by the participants, and can be resolved by further adjustments.

Table 2: Average score out of 5 of the consecutive trainings. The score ranged from 1 (no satisfaction) to 5 (full satisfaction).

| | Course 1 6-8/4/2016 | Course 2 26-28/4/2016 | Course 3 26-28/5/2016 |
|--------------------------------------|------------------------|--------------------------|--------------------------|
| Overall experience | 3.5 | 3.9 | 3.6 |
| Curriculum and teaching ² | 3.7 | 4.1 | 3.8 |
| Course administration and venue | 4.0 | 4.4 | 4.4 |

3. Training course on Environmental Risk Assessment

3.1. General

This training course was organised on six occasions (i.e. 30 September–2 October 2015, 23–25 November 2015, 11-13 April 2016, 19-21 September 2016, 20-22 March 2017 and 27-29 June 2017). All training were given by Theo Brock (Alterra), Lorraine Maltby (University of Sheffield) and Louise Wipfler (Alterra).

The Environmental Risk Assessment (ERA) training course aimed to explain the scientific background of how to conduct environmental risk assessments and focused on environmental risk assessment under the various legislation within EFSA's remit.

It further included:

- Exercises in problem formulation in order to better identify those aspects of the environment that need to be protected from harm. This is done according to the environmental protection

² Question 2.2 was not included in this score as the question had three instead of five possible answers

goals as set by EU legislation and the ecosystem services concept to derive specific protection goals.

- Exercises and lectures on motivations and criteria for the selection of (focal) non-target organisms for risk assessment
- Exercises and lectures on how to gather relevant and reliable evidence that can be used in the tiered approach and the application and use of statistics in the interpretation of results
- Exercises and lectures on how to conduct environmental exposure assessment
- Exercises and lectures on life stage analysis: How to investigate the effect of exposure patterns on sensitive life stages and on populations, while using appropriate modelling tools.
- Lectures on calibration and scientific validation of models and tools used.



The programme consisted of four sessions of four hours each. Practical sessions were planned after each lecture, except for Session 1 on day 1, which consisted of two lectures followed by one practical.

Each training could accommodate 25 participants and EFSA staff members, EFSA panel members and EFSA network members were invited to participate in the training. Potential participants could register via the website:

<http://www.wageningenur.nl/en/Research-Results/Projects-and-programmes/EFSA-training-courses.htm>

Detailed information on the number of participants joining each course is given in Table 3. In total 108 participants attended the training courses, which was 72% of the reserved places. After the first two trainings it was decided to address network members explicitly on the registration website, this resulted in an increased number of participants from the network of EFSA. The number of participants increased after the first training and stabilized around 20 people per training. Specifically people from the pesticide steering committee (network) and the Scientific Network for Risk Assessment in Plant Health showed the greatest interest. Although the aim was to equally divide the available places over the categories of participants, only 9% of the participants were experts (panel/ scientific committee), whereas 44 % of the participants were in the network of EFSA and 46 % of the participants were staff members.

Training material was handed out at each course both in hard-copy as electronically. The training material included practical information, the course programme as well as presentations and practical exercises. It was updated and improved after each course.

All participants received a course attendance certificate that included the following information: name of the participant, name of the course, dates of the course and names of the tutors.



Table 3: Participation of EFSA experts and staff in the training courses on Environmental Risk Assessment

| UNIT | Course 1 30/9-2/10/2015 | | | Course 2 23-25/11/2015 | | | Course 3 11-13/4/2016 | | |
|--------------|------------------------------|----------|----------|------------------------------|-----------|----------|------------------------------|----------|-----------|
| | Panel / Scientific committee | Staff | Network | Panel / Scientific committee | Staff | Network | Panel / Scientific committee | Staff | Network |
| AFSCO | | 1 | | | | | | 2 | |
| ANS | | | | | | | | | |
| APDESK | | 3 | | | 1 | | | | |
| CONTAM | | | | | | | | 1 | |
| DATA | | | | | 1 | | | | |
| FEEDAP | 1 | 4 | | | | | 1 | | |
| FIP | | | | | 3 | | | 1 | |
| GMO | | | | 1 | | | | | 2 |
| NDA | | | | | | | | | |
| PLH | | | | | 6 | | | | |
| PRAS | | 1 | 4 | 1 | 2 | | | | 10 |
| SCER | | | | | 2 | | | 1 | |
| other | | | | | | | | | |
| total | 1 | 9 | 4 | 2 | 15 | 0 | 1 | 5 | 12 |

| UNIT | Course 4 19-21/9/2016 | | | Course 5 20-22/3/2017 | | | Course 6 27-29/6/2017 | | | Total (all trainings) |
|--------------|------------------------------------|----------|-----------|------------------------------------|----------|----------|------------------------------------|----------|-----------|--------------------------|
| | Panel / Scientific committee | Staff | Network | Panel / Scientific committee | Staff | Network | Panel / Scientific committee | Staff | Network | |
| AFSCO | | | | | | | | | | 3 |
| ANS | 1 | | | | | | | | | 1 |
| APDESK | | | | | | | | | | 4 |
| CONTAM | | | | 1 | | | | | | 2 |
| DATA | | | | | | | | 2 | | 3 |
| FEEDAP | | | | | 1 | | | | | 7 |
| FIP | | | | 1 | 1 | | | | | 6 |
| GMO | 1 | | 1 | | 1 | 1 | | | | 7 |
| NDA | 1 | 1 | | | | | | | | 2 |
| PLH | | 1 | 3 | | | | | | | 10 |
| PRAS | | 4 | 7 | 1 | 1 | 8 | | 3 | 12 | 54 |
| SCER | | 1 | | | | | | 2 | | 6 |
| other | | 1 | | | | | | 2 | | 3 |
| total | 3 | 8 | 11 | 3 | 4 | 9 | 0 | 9 | 12 | 108 |

3.2. Course evaluation and development

At the end of each of the training courses the participants were asked to provide feedback via a questionnaire as well as in plenary. The questionnaires were handed out on paper and collected from each participant. The template of the course questionnaire is shown in Appendix E. Results of the evaluation forms are visualised in the figures of Appendix F.

The training courses were evaluated positively, with overall satisfaction with the course scoring between 3.9 to 4.7 out of 5 (Table 4). The feedback by the participants was appreciated and used to improve the training. After the first training the programme was adapted such that the lectures and the practicals alternated and the content was reduced. After the first training the satisfaction with the amount of lectures as compared to the amount of practicals increased. In Appendix D the program of the 1st and the 6th ERA training is given for reference.

After the second training a glossary was added to support the participants with less background in ERA. Also registrants were explicitly informed that the training was intended for participants with a certain background in ERA. This increased the number of participants that indicated that they had sufficient background to follow the course, although still some of the participants indicated that they had little or no background on ERA at all.

The training course had its focus on concepts useful for all environmental risk assessments conducted under the remit of EFSA and less so on practical day-to-day examples for a specific EFSA panel/unit. It was decided that this should be made clear to the participants in advance of the training. After the 3rd training course participants were explicitly informed on the focus of the training.

Network members were specifically asked to reflect on the relevance of the training for their daily work. The training course was very much appreciated. The ERA concepts presented enabled participants to better understand the evaluation process. However, training with specific practical examples in line with their day-to-day decision making would have been appreciated. Participants with a background in plant health experienced difficulty in following the concepts as they only partly reflect the daily assessment work in the plant health arena.

Table 4: Average score out of 5 of the consecutive trainings. The score ranged from 1 (no satisfaction) to 5 (full satisfaction).

| | Course 1 30/9- 2/10/2015 | Course 2 23- 25/11/2015 | Course 3 11- 13/4/2016 | Course 4 19- 21/9/2016 | Course 5 20- 22/3/2017 | Course 6 27- 29/6/2017 |
|------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| Overall experience (question 9) | 4.1 | 3.9 | 4.5 | 4.6 | 4.7 | 4.5 |

4. Conclusions and recommendations

4.1. General

In this section conclusions are drawn and recommendations are given regarding the content of the training courses, the requested background and previous knowledge and the requested facilities for the training course at EFSA. In addition, an outlook is given towards future trainings and how they could evolve.

4.2. Training course addressing uncertainty in EFSA's scientific assessments

In addition to its primary aim of supporting the understanding and practical implementation of best risk assessment practices, the uncertainty training was used to obtain feedback on the draft guidance document. Therefore, only invited participants could follow the training and selection ensured that each unit was represented in the training. As the guidance document was only recently made available for public consultation, the training on uncertainty evolved rapidly between the three trainings and is currently under revision as part of the trial period of the guidance document (outside the remit of this contract).

Recommendations related to the training course addressing uncertainty in EFSA's scientific assessments:

- To better respond to the different backgrounds of the participants, EFSA could consider to organise different versions of the training, for example, one for participants working on chemical risk assessment and another for the other areas of EFSA's work. Some participants requested panel-specific courses.
- There is a need to update the training in line with the final version of the guidance document, which will be published by the end of 2017.
- It is recommended to use a single version of the current expert elicitation example and develop extra expert elicitation training courses next to this training course.
- One of the key skills in uncertainty is probabilistic judgement. It is recommended to develop a specific training on this either in the form of a classic training or in the form of e.g. an e-learning module.
- EFSA might consider to develop short video trainings focussing on key aspects of uncertainty.
- After the 2nd Uncertainty training specific training logistics support started. Logistical support was given during preparation and delivery of the training. This was of great help to the coordinator and the tutors. It is recommended to continue this support.

Recommendations for the revised document (secondary aim of the training):

- Participants reported that the draft Guidance Document on addressing uncertainty in EFSA's scientific assessments is long, complicated and difficult to absorb. It would be helpful to write an additional simpler document.

4.3. Training course on Environmental Risk Assessment

One of the objectives of the training was to strengthen the dissemination of ERA guidance and modelling practises and to ensure the uptake of guidance on cross-cutting risk assessment approaches amongst members of EFSA's Scientific Committee/Panels, their working groups and EFSA staff. This aim is partly achieved as participants of different backgrounds joined the trainings. It was noted however, that only a few panel member participated. In addition, participants with a background in pesticide RA were over-represented as compared to the other work fields of EFSA.

This is the first training course for which network member of selected units were invited. The number of participants from the network was relatively high, especially from the pesticide arena. During the course of the project more people from the pesticide network joined the trainings, i.e. the percentage of participants with a pesticide-network background increased from 28% in the 1st course to 57% in the 6th course. This certainly identified a need for training of the member states registration authorities.

The training course was adapted after each training based on the feedback by the participants and the tutors' evaluation. The balance between the time dedicated to presentations and practical is now

optimal, although there are still some requests to dedicate more time to the practicals, also due to differences in background knowledge of participants.

It was noted that people with a background in plant health struggled with the fact that a large part of the tiered approach presented is not applied in their work.

Some of the participants asked to dedicate more time to risk assessment based on complex (semi) field experiments.

Especially network members requested for a follow up with more practical examples and cases.

Recommendations related to the training course on Environmental Risk Assessment:

- The aim of this training was on dissemination of current practices on ERA. We observed a need for a training that provides an outlook to the future ERA practices. Topics to be addressed could be: 1) landscape-level environmental risk assessment and risk mapping, 2) environmental scenarios and modelling approaches to address extrapolation in space and time, 3) specific training on exposure assessment, 4) new developments/ trends in ERA. Also topics like e.g. combination toxicity and mixture toxicity could be addressed. Instead of one training, a number of specialized trainings could be organised.
- A specialised ERA course to address the needs of specific units such as the Plant Health unit with respect to ERA is recommended. An alternative could be to organise a training in two stages; starting with a general introduction and then focussing on unit-specific topics is possible.
- More specialized guidance on higher tier options in new guidance documents could be addressed.
- As we observed a need for practical trainings on ERA by member states/ pesticide registration authorities, a road show along the different member states would be an alternative solution to solve this need.
- In future trainings it is recommended to ask for the background of the participant on the evaluation form (expert, staff, network, field of expertise). This would improve the understanding of the feedbacks.
- We discussed with EFSA the options for webinars or e-learning as part of future ERA training courses. The tutors support this, but also point out that plenary discussions and face-to-face meetings are essential for good learning outcomes.
- After the third ERA training, specific training logistics support started. Logistical support was given during preparation and delivery of the training. This was of great help to the coordinator and the tutors. It is recommended to continue this support.

Appendix A – Programme of the course addressing uncertainty in EFSA's scientific assessments

Training course 1:6-8 April 2016

TRAINING COURSE ON ADDRESSING UNCERTAINTY IN EFSA'S SCIENTIFIC ASSESSMENTS

Contract: OC/EFSA/SCER/2014/02

Tutors: Andy Hart (Fera) and Peter Craig (Durham University)

The course is divided into a series of sessions, each containing a Lecture, a General Practical and a Case Practical (except Sessions 8 and 11). The General Practicals will use an everyday example which, although not drawn from food safety, is relevant to all participants and avoids the need for specialist knowledge on other parts of EFSA's work. In the Case Practicals, participants will work on assessments being used by their Panel or Unit in the Trial Period of the Uncertainty Guidance.

PROVISIONAL TIMETABLE: 6-8 April 2016

MODULE I. 1400 – 1800. DAY 1

SESSION 1. Introduction

Learning objectives: Understand the need to address uncertainty. Understand EFSA framework. Learn how to express scientific uncertainty quantitatively by expert judgement.

- 14:00 LECTURE 1. Introduction - framework and basic concepts
- 14:30 GENERAL PRACTICAL 1. Making probability judgements
- 15:15 CASE PRACTICAL 1. Introductions: participants and trial period assessments
- 15:45 Break

SESSION 2. Assessments using standardised procedures

Learning objectives: Learn to identify standard assessments and standard components of assessments. Learn to identify non-standard uncertainties affecting a standard assessment and assess their combined impact.

- 16:15 LECTURE 2. Assessments using standardised procedures.
- 16:45 GENERAL PRACTICAL 2. Combined uncertainty for an assessment using a standardised procedure
- 17:30 CASE PRACTICAL 2. Identifying standard and non-standard procedures in your trial period assessment
- 18:00 MODULE ENDS

MODULE II. 0900 – 1300. DAY 2

SESSION 3. Planning case-specific assessments

Learning objectives: Learn to ensure questions for assessment are unambiguous, distinguish quantitative and categorical questions, when/how to break into sub-questions, and how to map out the assessment structure.

- 09:00 LECTURE 3. Planning case-specific assessments
- 09:30 GENERAL PRACTICAL 3. Assessment planning: general example
- 09:50 CASE PRACTICAL 3. Planning your trial period assessment
- 10:45 Break

SESSION 4. Identifying and prioritising uncertainties

Learning objectives: Learn to identify uncertainties in a case-specific assessment, prioritise which to assess individually, and perform 'minimal assessment'

- 11:15 LECTURE 4. Identifying and prioritising uncertainties
- 11:45 GENERAL PRACTICAL 4. Identifying and prioritising uncertainties in the general example
- 12:30 CASE PRACTICAL 4. Identifying and prioritising uncertainties in your trial period assessment
- 13:00 Lunch

Continued on next page

MODULE III. 1400 – 1800, DAY 2

SESSION 5. Qualitative methods for uncertainty analysis

Learning objectives: Understand and explain common qualitative methods and identify when they are useful.

- 14:00 LECTURE 5. Qualitative methods for uncertainty analysis
- 14:20 GENERAL PRACTICAL 5. Using a pedigree matrix and combining qualitative scales
- 14:40 CASE PRACTICAL 5. Using a pedigree matrix

SESSION 6. Quantitative methods for uncertainty analysis - deterministic

Learning objectives: Understand and explain deterministic assessment and identify when it is useful. Understand degree of conservatism and how to assess and adjust it.

- 14:50 LECTURE 6. Quantitative methods for uncertainty analysis - deterministic
- 15:15 GENERAL PRACTICAL 6. Combining conservative assumptions
- 15:30 CASE PRACTICAL 6. Considering deterministic approaches to your trial period assessment
- 15:50 Break

SESSION 7. Quantitative methods for uncertainty analysis - probabilistic

Learning objectives: Understand and explain principles of probabilistic methods and identify when they are useful.

- 16:20 LECTURE 7. Quantitative methods for uncertainty analysis - probabilistic
- 16:50 GENERAL PRACTICAL 7. Probabilistic treatment of the general example
- 17:40 CASE PRACTICAL 7. Considering probabilistic approaches to your trial period assessment
- 18:00 MODULE ENDS

MODULE IV. 0900 – 1300, DAY 3

SESSION 8. Choosing which methods to use

Learning objectives: Understand and apply the preliminary advice on this in draft Guidance.

- 09:00 LECTURE 8. Preliminary advice on choosing methods
- 09:15 CASE PRACTICAL 8. Preliminary consideration of methods for your trial period assessment

SESSION 9. Combined uncertainty and reporting the assessment

Learning objectives: Able to assess combined uncertainty for case-specific assessments, and document uncertainty analysis transparently.

- 09:45 LECTURE 9. Combined uncertainty and reporting the assessment
- 10:05 GENERAL PRACTICAL 9. Combined uncertainty for the general example
- 10:35 CASE PRACTICAL 9. Considering combined assessment for the trial period assessments
- 10:45 Break

SESSION 10. Influence, refinement and emergency assessments

Learning objectives: Understand and explain principles of influence and sensitivity analysis and how it guides refinement. Plan appropriate level of uncertainty analysis for an emergency situation.

- 11:15 LECTURE 10. Influence, refinement and emergency assessments
- 11:35 GENERAL PRACTICAL 10. Sensitivity analysis and refinement options for the general example
- 11:50 CASE PRACTICAL 10. What if your trial period assessment was an emergency request?

SESSION 11. Overall framework and interactions with decision-makers

Learning objectives: Recollect overall framework. Understand the role and timing of interactions with decision-makers. Review progress on trial period assessments and identify key obstacles and solutions for next steps.

- 12:00 LECTURE 11. Overall framework and interactions with decision-makers
- 12:15 CASE PRACTICAL 11. Next steps and decision-maker interactions for your trial period assessment
- 12:45 COURSE EVALUATION AND SUGGESTIONS FOR IMPROVEMENT
- 13:00 COURSE ENDS

Training course 3: 26-28 May 2017

TRAINING COURSE ON ADDRESSING UNCERTAINTY IN EFSA'S SCIENTIFIC ASSESSMENTS

Contract: OC/EFSA/SCER/2014/02

Tutors: Andy Hart (Fera) and Peter Craig (Durham University)

The course is divided into a series of Sessions, with a mix of Lectures and Practicals. Some General Practicals will use an everyday example which, although not drawn from food safety, is relevant to all participants and avoids the need for specialist knowledge on other parts of EFSA's work. For the Case Practicals, participants will bring assessments being used by their Panel or Unit in the Trial Period of the Uncertainty Guidance.

PROVISIONAL TIMETABLE: 24-26 May 2016

MODULE I. 1400 – 1800. DAY 1

SESSION 1. Introduction - framework, key concepts

Learning objectives: Understand the need to address uncertainty. Understand the basic EFSA framework and some key concepts. Understand and explain standard procedures for addressing uncertainty.

- 14:00 LECTURE 1. Introduction - framework and key concepts
14:55 LECTURE 2. Standardised procedures for addressing uncertainty
15:20 Break

SESSION 2. Planning the assessment

Learning objectives: Learn to ensure questions for assessment are unambiguous, distinguish quantitative and categorical questions, when/how to break into sub-questions, and how to map out the assessment structure. Understand and explain the difference between variability and uncertainty.

- 15:50 LECTURE 3. Planning the assessment
16:35 GENERAL PRACTICAL 1. Assessment planning: demonstration for a general example
17:00 CASE PRACTICAL 1. Planning your trial period assessment
18:00 MODULE ENDS

MODULE II. 0900 – 1300, DAY 2

SESSION 3. Identification and initial prioritisation of uncertainties

Learning objectives: Learn to identify uncertainties in an assessment and prioritise which to assess individually.

- 09:00 LECTURE 4. Identification and initial prioritisation of uncertainties
09:35 GENERAL PRACTICAL 2. Identifying and prioritising uncertainties in the general example - demonstration
09:45 CASE PRACTICAL 2. Identifying and prioritising uncertainties in your trial period assessment
10:35 Break

SESSION 4. Assessing combined uncertainty

Learning objectives: Able to understand, explain and conduct combined uncertainty assessments.

- 11:05 LECTURE 5. Assessing combined uncertainty
11:35 GENERAL PRACTICAL 3. Combined uncertainty - demonstration EFSA example
12:00 GENERAL PRACTICAL 4. Quantifying expert judgement
13:00 Lunch

MODULE III. 1400 – 1800, DAY 2

SESSION 5. Qualitative methods for uncertainty analysis

Learning objectives: Understand and explain common qualitative methods and identify when they are useful.

14:00 LECTURE 6. Qualitative methods for uncertainty analysis

14:35 CASE PRACTICAL 3. Using a pedigree matrix

SESSION 6. Quantitative methods for uncertainty analysis - deterministic

Learning objectives: Understand and explain deterministic assessment and identify when it is useful.

Understand degree of conservatism and how to assess and adjust it.

15:10 LECTURE 7. Quantitative methods for uncertainty analysis - deterministic

15:40 Break

16:10 GENERAL PRACTICAL 5. Combining conservative assumptions in the general example

SESSION 7. Quantitative methods for uncertainty analysis - probabilistic

Learning objectives: Understand and explain principles of probabilistic methods and identify when they are useful.

16:50 LECTURE 8a. Probabilistic methods for uncertainty analysis - initial considerations

17:10 LECTURE 8b. Probabilistic methods for uncertainty analysis - sources of probabilities

17:35 LECTURE 8c. Probabilistic methods for uncertainty analysis - quantifying uncertainty

18:00 MODULE ENDS

MODULE IV. 0900 – 1300, DAY 3

SESSION 7 (continued). Quantitative methods for uncertainty analysis - probabilistic

09:00 LECTURE 8d. Probabilistic methods for uncertainty analysis - quantifying uncertainty and variability

SESSION 8. Influence and sensitivity analysis

Learning objectives: Understand and explain principles of influence and sensitivity analysis.

09:45 LECTURE 9. Influence and sensitivity analysis

10:10 Break

SESSION 9. Choosing which methods to use

Learning objectives: Understand and apply the preliminary advice on method selection in the draft Guidance.

10:40 LECTURE 10. Preliminary advice on choosing methods for uncertainties to be assessed individually

11:10 CASE PRACTICAL 4. Preliminary consideration of method choice for your trial period assessment

SESSION 10. Overall framework and interactions with decision-makers

Learning objectives: Understand and explain options for refining assessments and principles and approaches for reporting. Understand the role and timing of interactions with decision-makers. Plan next steps for trial period assessments and identify key obstacles and solutions.

11:55 LECTURE 11. Refinement, reporting and communication

12:15 CASE PRACTICAL 5. Next steps and decision-maker interactions for your trial period assessment

12:50 COURSE EVALUATION AND SUGGESTIONS FOR IMPROVEMENT

13:00 COURSE ENDS

Appendix B – Template of the course questionnaire for the Uncertainty training course

EVALUATION FORM

Thank you for your participation in this training course. It would be very much appreciated if you could please complete the following questions with regards various aspects of the course.

Your comments and feedback are very important and valued. They ensure we are able to fully address any potential areas of concern promptly, and to help inform continuous improvement of the training.

Your responses are anonymous, unless you choose to indicate your name at the end of the form, and will be reviewed as each training course concludes to inform the refinement and development of future training in this topic area. Additionally, a summary of responses received across the complete programme of training will be included in the final evaluation report submitted to EFSA.

For each question, please circle the numerical rating or descriptive option that best fits your opinion. Specific comments, particularly to explain any low ranking ratings or to highlight aspects that you found of most value and which worked especially well, will help ensure we are able to apply learnings to future training.

In addition to completing this questionnaire, if you have a specific query and/or comments that you wish to discuss in person, please speak to a member of the training team at any point during the course.

PLEASE ALSO WRITE ANY DETAILED SUGGESTIONS FOR IMPROVEMENT ON THE COURSE HANDOUTS AND RETURN THEM TO THE TUTORS AT THE END OF THE COURSE.

Thank you for your time.

1 OVERALL EXPERIENCE

| | | |
|---|-----------------------------|-----------|
| 1.1 Did the course fully meet your expectations and requirements? | | |
| No, not at all 1 2 3 | Yes, completely 4 5 | Comments: |
| 1.2 Have you reached the intended learning outcomes of the course? | | |
| No, not at all 1 2 3 | Yes, completely 4 5 | Comments: |
| 1.3 Has the course facilitated your future work for EFSA? | | |
| No, not at all 1 2 3 | Yes, completely 4 5 | Comments: |

2 CURRICULUM AND TEACHING

| | | |
|---|-----------------------------|-----------|
| 2.1 Are you satisfied with the content of the course? | | |
| No, not at all 1 2 3 | Yes, completely 4 5 | Comments: |
| 2.2 Was the course material at the correct level for your needs? | | |
| Too basic Just right Too advanced | | Comments: |
| 2.3 Are you satisfied with the balance of practical sessions versus lectures? | | |
| No, not at all 1 2 3 | Yes, completely 4 5 | Comments: |
| 2.4 Was sufficient time allocated for discussions with fellow participants and tutors? | | |
| No, not at all 1 2 3 | Yes, completely 4 5 | Comments: |

| | | | | | |
|---|---|-----------------|---|---|-----------|
| 2.5 Are you satisfied with the teaching ability and the professional and technical competence of the tutors? | | | | | |
| No, not at all | | Yes, completely | | | Comments: |
| 1 | 2 | 3 | 4 | 5 | |
| 2.6 Which part/s of the course did you find most and/or least useful/instructive and why? | | | | | |
| Comments | | | | | |

3 COURSE ADMINISTRATION & VENUE

| | | | | | |
|--|---|-----------|---|---|-----------|
| 3.1 Did the overall organisation and administration associated with the course, prior to and during the training, meet your requirements? | | | | | |
| No, not at all completely | | Yes, | | | Comments: |
| 1 | 2 | 3 | 4 | 5 | |
| 3.2 Did the venue and training facility provided meet your requirements? | | | | | |
| No, not at all completely | | Yes, | | | Comments: |
| 1 | 2 | 3 | 4 | 5 | |
| 3.3 How relevant and user friendly were the training materials/hand outs? | | | | | |
| Very poor | | Very good | | | Comments |
| 1 | 2 | 3 | 4 | 5 | |

ANY ADDITIONAL COMMENTS

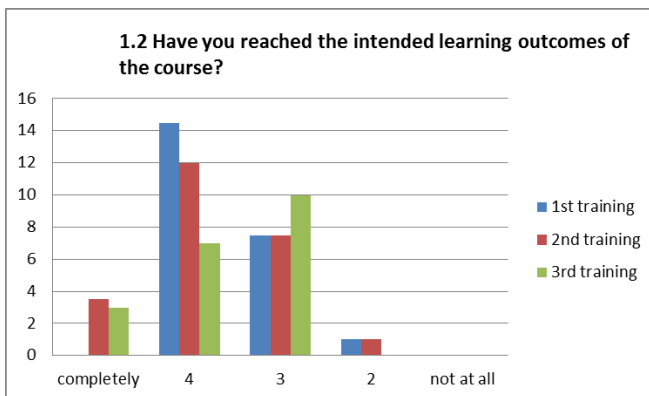
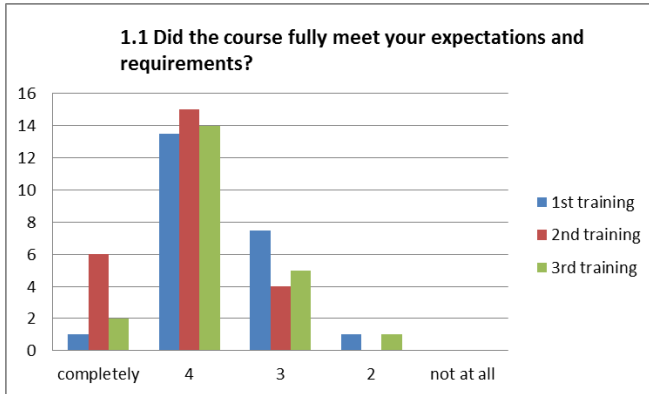
Please add any other comments that you have or suggestions on how the course and/or administration/ organisation could be improved.

THANK YOU FOR COMPLETING THE QUESTIONNAIRE.

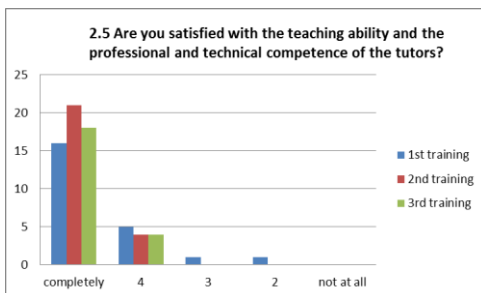
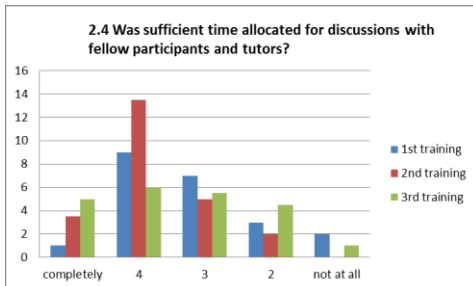
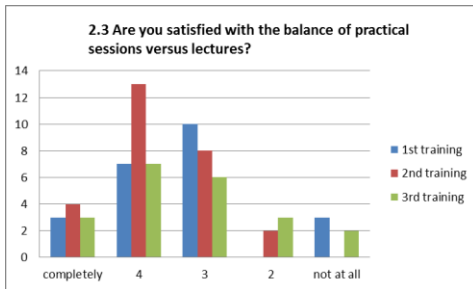
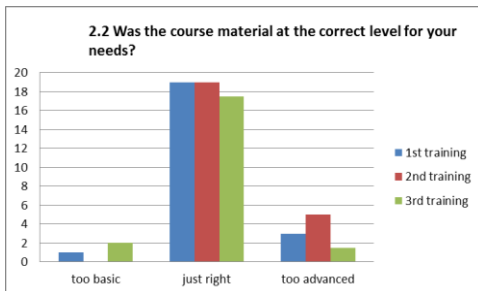
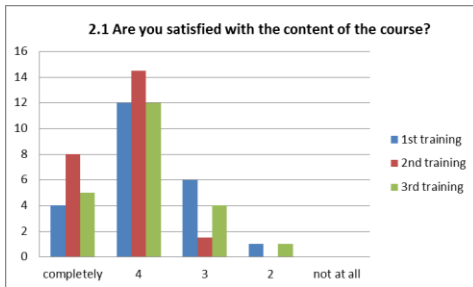
Appendix C – Figures evaluation by participants training course addressing uncertainty in EFSA’s scientific assessments

Results presented in number of participants.

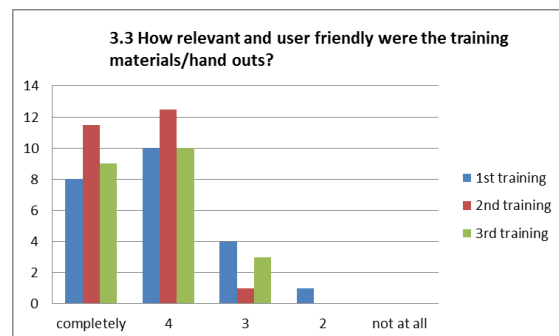
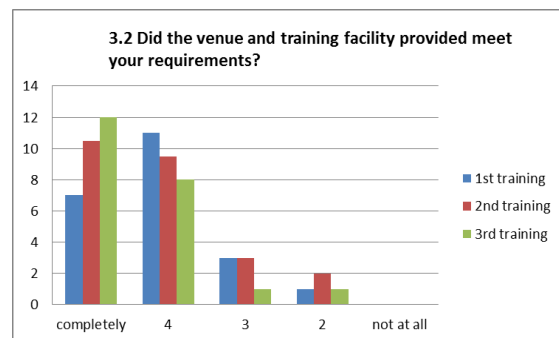
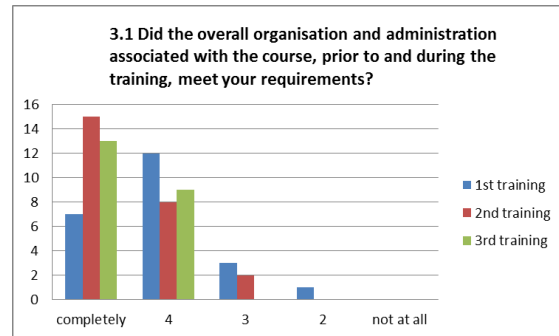
Overall experience:



Curriculum and Teaching:



Course administration and Venue:



Appendix D – Training program of the ERA training course

Training program of training course 1: 30 September 2015 – 2 October 2015

PROGRAM day 1: 30 September 2015

SESSION I

| | |
|-------|--|
| 13.30 | Arrival and registration at EFSA ³ |
| 14.00 | Opening of the training Welcome, objectives and learning outcomes, logistics <i>Louise Wipfler</i> |
| 14.15 | Lecture 1-1: Introduction to ERA <i>Theo Brock</i> |
| 15.15 | Break |
| 15.45 | Lecture 1-2: Problem formulation step for ERA & introduction to the practical <i>Theo Brock & Lorraine Maltby</i> |
| 16.45 | Practical 1: Exercise and discussions in groups Example ERA issues, learn to understand the differences in role and perspective between e.g. risk managers and risk assessors <i>Theo Brock & Lorraine Maltby</i> |
| 17.35 | Practical 1: Round table discussion Example ERA issues, learn to understand the differences in role and perspective between e.g. risk managers and risk assessors <i>Theo Brock & Lorraine Maltby</i> |
| 18.00 | Closure of day 1 |

³ Address EFSA:
Via Carlo Magno, 1A
43126 Parma, Italy

PROGRAM day 2: 1 October 2015

SESSION II

- 9.00 **Lecture 2-1: Introduction to Exposure in ERA**
Louise Wipfler
- 9.45 **Lecture 2-2: tiered approach and exposure scenarios**
Louise Wipfler
- 10.30 Break
- 11.00 **Lecture 2-3: Exposure models and experimental determination of
chemical properties** *Louise Wipfler*
- 11.45 **Practical 2: Exercise and discussions in groups**
Application of exposure concepts and exposure scenario derivation
Louise Wipfler & Theo Brock
- 12.35 **Practical 2: Round table discussion**
Application of exposure concepts and exposure scenario derivation
Louise Wipfler & Theo Brock
- 13.00 Lunch break

SESSION III

- 14.00 **Lecture 3-1: Selection of non-target test organisms and test approaches**
Theo Brock
- 14.45 **Lecture 3-2: Laboratory tests**
Lorraine Maltby
- 15.30 Break
- 16.00 **Lecture 3-3: Higher Tier Approaches**
Theo Brock / Lorraine Maltby
- 16.45 **Practical 3: Exercise and discussions in groups**
Using an existing case and data for different tiers
Theo Brock & Lorraine Maltby
- 17.35 **Practical 3: Round table discussion**
Using an existing case and data for different tiers
Theo Brock & Lorraine Maltby
- 18.00 Closure of day 2

PROGRAM day 3: 2 October 2015

SESSION IV

- 9.00 **Lecture 4-1: Life stage analysis and addressing ERA on the appropriate spatial-temporal scale**
I: What does this mean and why is it important?
Lorraine Maltby
- 10.05 Break
- 10.35 **Lecture 4-2: Life stage analysis and addressing ERA on the appropriate spatial-temporal scale**
II: What approaches are available and what are their limitations?
Lorraine Maltby
- 11.40 **Practical 4: exercise and discussions in groups**
Using an existing case and data for different tiers
Theo Brock & Lorraine Maltby
- 12.20 **Practical 4: round table discussion**
Using an existing case and data for different tiers
Theo Brock & Lorraine Maltby
- 12.45 Course evaluation and feedback
- 13.00 Closure of the training course

Training program of training course 1: 27-29 June 2017

PROGRAM day 1: 27 June 2017

SESSION I

| | |
|-------|--|
| 13.00 | Arrival and registration at EFSA |
| 13.30 | Opening of the training Welcome, objectives and learning outcomes, logistics <i>Louise Wipfler</i> |
| 13.45 | Lecture 1-1: Introduction to ERA <i>Theo Brock</i> |
| 14.30 | Introduction of participants |
| 14.45 | Lecture 1-2: Problem formulation step for ERA & introduction to the practical <i>Theo Brock & Lorraine Maltby</i> |
| 15.45 | Break |
| 16.15 | Practical 1: Introduction, exercise and discussions in groups Example ERA issues, learn to understand the differences in role and perspective between risk managers and risk assessors <i>Theo Brock & Lorraine Maltby</i> |
| 17.15 | Practical 1: Round table discussion, including feedback from the tutors Example ERA issues, learn to understand the differences in role and perspective between e.g. risk managers and risk assessors <i>Lorraine Maltby & Theo Brock</i> |
| 18.00 | Closure of day 1 |

PROGRAM day 2: 28 June 2017

SESSION II

- 9.00 **Lecture 2-1: Introduction to Exposure in ERA, tiered approach**
Louise Wipfler
- 10.00 **Practical 2a: Exercise and discussions in groups**
Application of exposure concepts and exposure scenario derivation
Louise Wipfler & Theo Brock
- 10.30 Break
- 11.00 **Lecture 2-2: Exposure scenarios, exposure models and experimental determination of chemical properties**
Louise Wipfler
- 12.00 **Practical 2b: Exercise and discussions in groups**
Application of exposure concepts and exposure scenario derivation
Louise Wipfler & Theo Brock
- 12.20 **Plenary discussion of exercises**
- 13.00 Lunch break

SESSION III

- 14.00 **Lecture 3-1: Tier-1 and Tier-2 effect assessment**
Lorraine Maltby & Theo Brock
- 15.00 **Practical 3a: Exercise and discussions**
Using an existing case and data for different tiers
Lorraine Maltby & Theo Brock
- 15.30 Break
- 16.00 **Lecture 3-2: Tier-3 effect assessment and calibration of lower tiers**
Theo Brock & Lorraine Maltby
- 17.00 **Practical 3b: Exercise and discussions**
Using an existing case and data for different tiers
Theo Brock & Lorraine Maltby
- 17:40 **Plenary discussion of exercises**
- 18.00 Closure of day 2

PROGRAM day 3: 29 June 2017

SESSION IV

| | |
|-------|--|
| 9.00 | Lecture 4-1: Life stage analysis and addressing ERA on the appropriate spatial-temporal scale I: What does this mean and why is it important? <i>Lorraine Maltby & Theo Brock</i> |
| 10.00 | Practical 4: exercise and discussions in groups <i>Lorraine Maltby & Theo Brock</i> |
| 10.45 | Break |
| 11.15 | Lecture 4-2: Life stage analysis and addressing ERA on the appropriate spatial-temporal scale II: What approaches are available and what are their limitations? <i>Lorraine Maltby & Theo Brock</i> |
| 12.15 | Outlook discussions <i>Theo Brock & Lorraine Maltby</i> |
| 12.45 | Course evaluation and feedback |
| 13.00 | Closure of the training course |

Appendix E – Template of the questionnaire of the ERA training course

Dear participant, we appreciate your feedback on the ERA training course. Therefore we would like to ask you to answer the questions listed below:

| Question | Score | | | | |
|---|-----------|------|------------|----------------|------------|
| | 5 | 4 | 3 | 2 | 1 |
| 1. Are you satisfied with the content of the course? | very much | much | just right | little | not at all |
| 2. Are you satisfied with the amount of lectures and the amount of | very much | much | just right | little | not at all |
| 3. Did you have sufficient background knowledge to follow the course? | very much | much | reasonable | little | not at all |
| 4. Was sufficient time allocated for discussions with fellow participants | very good | good | adequate | quite adequate | inadequate |
| 5. Are you satisfied with the teaching ability and professional | very good | good | adequate | quite adequate | inadequate |
| 6. Are you satisfied with the practical organisation of the course including application procedure, information | very good | good | adequate | quite adequate | inadequate |
| 7. How relevant and user friendly was the training material? | very good | good | adequate | quite adequate | inadequate |
| 8. Has the course facilitated your future work for EFSA? | very much | much | just right | little | not at all |
| 9. Overall, are you satisfied with the course? | very much | much | just right | little | not at all |

Feel free to add comments in the box below if you think this is appropriate:

--comments--

Appendix F – Figures evaluation by participants training course on Environmental Risk Assessment

Results presented in % of participants.

