Analysis of EFSA methodological needs for evidence use in scientific assessments

European Food Safety Authority

Abstract

The European Food Safety Authority (EFSA) PROMETHEUS (PROmoting METHods for Evidence Use in Scientific assessments) project aims at improving further the methods for ‘using’ (i.e. collecting, appraising and analysing) scientific evidence in EFSA assessments and increasing their consistency within the Authority. To date, the project has encompassed two main deliverables (both endorsed by the EFSA Scientific Committee): first, a scientific report (EFSA, 2015a), illustrating the principles for evidence use (impartiality, excellence in scientific assessments, transparency, openness and responsiveness) and describing a four-step approach (plan/carry out/verify/report) to fulfil those principles; second, this technical report on ‘EFSA methodological needs for evidence use’. These are any elements that can contribute to fulfil the principles and implement the four-step process for evidence use and include cross-cutting methodological documents applicable to all panels and units, training for staff and experts, instructions for applicants to integrate the existing regulatory frameworks, specialised repositories of data, IT needs, or more structured and harmonised approaches to outsourcing data collection, appraisal and syntheses. The methodological needs were defined by a working group of independent experts and EFSA staff, on the basis of a survey administered to EFSA panel members and scientific staff in the period from December 2015 to March 2016. This survey represented an important opportunity to take stock of views of the EFSA scientific community on the methodological needs for evidence use within the Authority. It provides input to the EFSA management and the Scientific Committee to identify appropriate follow-up actions. Overall, the analysis highlights the clear benefits to be gained from a cross-panel strategy. The diverse needs, intrinsic to the different panels’ remit will nevertheless have to be accommodated. The PROMETHEUS project also foresees a phase during which the implementation of the four-step approach is piloted in a series of EFSA case-studies. These case-studies may lead to the identification of further methodological needs.

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Keywords: data collection, evidence appraisal, evidence integration, uncertainty assessment, expert knowledge elicitation

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Summary

To develop the excellence of its scientific assessments, enhance their transparency and openness in line with best practice in the scientific community, in 2014, the European Food Safety Authority (EFSA) started the PROMETHEUS (PROmoting METHods for Evidence Use in Scientific assessments) project. This aims to improve the methods for ‘using’ (i.e. collecting, appraising and analysing) scientific evidence in EFSA scientific assessments and increasing consistency within the Authority. Methodological aspects related to the definition of the risk assessment process and domain-specific methodological issues are beyond the scope of PROMETHEUS. The project plays a key role in realising strategic objectives laid out in the EFSA Strategy 2016–2020 concerning the data collection/management and methods for scientific assessments and in achieving and maintaining an ISO 9001:2015 certification.

So far, the project has encompassed two main deliverables, both endorsed by the EFSA Scientific Committee (SC). The first was a scientific report (EFSA, 2015a) illustrating the principles for data collection, appraisal and synthesis (impartiality, excellence in scientific assessments, transparency, openness and responsiveness) and a four-step approach for evidence use (plan/carry out/verify/report), which helps to fulfil those principles. The implementation of this approach is pilot tested in a series of case-studies in different EFSA areas (e.g. EFSA-ANS, 2015b and EFSA-BIOHAZ, 2016c). The second deliverable is represented by this technical report on the analysis of the EFSA ‘methodological needs’ (i.e. any element that can contribute to fulfil the principles and implement the four-step process illustrated in the first PROMETHEUS deliverable). Methodological needs are represented by guidance on the process for evidence use (addressed by cross-cutting methodological documents for use by all EFSA scientific panels and units/teams), specific training for EFSA staff and experts, further instructions in the existing regulatory frameworks for applicants, specialised repositories of data, IT needs, or more structured approaches to outsourcing data collection, appraisal and syntheses.

The analysis of the EFSA methodological needs was undertaken by a working group (WG) of experts and EFSA staff from all panels and units/teams and by means of a survey of the EFSA panel members and scientific staff views in the period from December 2015 to March 2016. A total of 207 experts and 176 staff members were consulted. The analysis of the survey results was complemented by WG focussed study sessions. This report also documents on-going EFSA projects that cover some of the needs identified through the survey.

The survey was performed through a questionnaire that was administered in two rounds. The first round was at individual level, aiming to collect the personal views of the panel members and scientific staff. The response rate was 85% (175/207) and 63% (111/176), respectively. Then, the results of this first round of consultation were considered by each panel and unit to generate a collective answer for each panel and each unit/team to the questions. An exception to this was represented by the survey questions on the usefulness of some existing cross-cutting methodological documents, for which only the individual answers were considered. The process used to reach the collective view was carried out either via written procedure or through group discussion. When a group discussion could not be held, the panel and/or unit/team considered the most frequent responses as their joint answers to the questions. This step of the process lost detail from the initial round of consultation. However, it was decided to base the overarching analysis on the collective view of each group instead of the individual answers, aiming to simplify the definition of the possible follow-up actions addressing the needs identified through the survey.

The survey provides input for the EFSA management and the Scientific Committee on the methodological needs for evidence use as perceived at the time when the survey was conducted and

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for identifying their risks, benefits, desirable characteristics, mitigation actions and priority. It will also help to define follow-up actions to meet the needs. Overall, it highlights the clear benefits of a cross-panel strategy. Notwithstanding, it recognises a diversity of specific needs, intrinsic to the different panels’ remits, which will have to be addressed separately.

Specific conclusions and recommendations are summarised below using specific descriptive phrases that summarise the WG interpretation of the survey results, in a sort of decreasing priority scale, as follows: ‘clear need’, ‘useful to implement’ (but not a pressing need) and ‘no foreseen need’. The latter never occurred.

1. The following aspects were identified as clear needs:
   a. panel-specific training in uncertainty assessment (this type of training was especially favoured by EFSA staff) and technical support from specialists in uncertainty assessment;
   b. regular support by the EFSA Library to experts and staff to, for example, develop and implement literature searches, appraise searches done by others (e.g. applicants, contractors, authors of published reviews), etc., and better communication on the available Library services; if possible, direct access to EFSA Library subscriptions for experts and access without a Virtual Private Network (VPN) card for staff, to allow timely access to literature;
   c. further description, in the various EFSA regulatory frameworks, of the methods to be applied by the applicants for dealing with ‘already existing’ data (e.g. literature data and data from sources other than literature). This expressed need for more detailed advice included methods for analysing and integrating data and reporting aspects;
   d. manual for drafting the scientific part of the calls for tender for outsourcing data collection, appraisal and syntheses (it applies to EFSA staff only). As a further suggestion to strengthen the process for outsourcing data collection, appraisal, etc., the BIOHAZ team indicated that guidance on the evaluation of outsourced reports would be very useful;
   e. specialised training for EFSA staff in protocol development, literature search techniques, evidence appraisal and statistics;
   f. provision of external elicitors to support complex expert knowledge elicitation (EKE) processes and the identification of an EFSA contact person for elicitations. These needs were especially immediate for the respondents from the Risk Assessment and Scientific Assistance (RASA) department.

2. The following aspects were considered useful to implement:
   a. multi-panel training in uncertainty assessment;
   b. guidance document on ‘protocol development for scientific assessments’ (various units expressed the need for templates for protocols and for technical support to develop protocols);
   c. guidance document on ‘appraising literature searches’ and specialised support by EFSA staff in this area;
   d. guidance document on ‘methodology for integrating new evidence’;
   e. inventory of collections of data other than literature (e.g. databases such as Eurostat4); 
   f. plain language summary of EFSA scientific outputs, (especially favoured by panel members);
   g. specialised training for EFSA experts in protocol development, literature search techniques, evidence appraisal and statistics;
   h. additional training in EKE for experts and staff, best practices for EKE and mapping of European expertise.

4 http://ec.europa.eu/eurostat
3. Guidance on ‘evidence appraisal’ was deemed a clear need by the EFSA staff and useful to develop by the experts.

4. With regard to cross-cutting methodological documents on evidence use applicable to all panels and units/teams, the results of the survey support the view of the EFSA-SC in its scientific opinion ‘Guidance on the review, revision and development of EFSA’s cross-cutting guidance documents’ (EFSA-SC, 2015). In particular, the survey outlined the strong need for designing and executing an implementation plan whenever new guidance is developed. It was impossible to conclude on the usefulness of six existing cross-cutting methodological documents in EFSA, as a result of the limited number of respondents who indicated that the document had been used and thus answered the additional question on their usefulness. It is possible that these methodological documents have been used by some experienced staff or experts without this being general knowledge within a working group or panel, so there is uncertainty in this conclusion. The PROMETHEUS WG recommended that the relevance of these documents to the various EFSA areas (e.g. of the EFSA guidance on systematic review; EFSA, 2010a) and/or their level of obligation for the various actors involved (experts, staff, applicants and contractors) is further considered by the SC.

The main additional recommendations that have arisen from the survey concerning all EFSA cross-cutting methodological documents are:

a. greater flexibility of cross-cutting methodological documents;

b. consultation with panels before starting the development of a new cross-cutting methodological document or the update of an existing one;

c. reduction in number and merger of methodological documents, where possible;

d. panel-specific trainings in the implementation of these documents, with presentation of case-studies to illustrate the application of the methods;

e. technical support to facilitate their implementation.

Further recommendations on cross-cutting methodological documents, elaborated by the PROMETHEUS WG and complementary to those of the EFSA-SC, were classified in five main categories (i.e. a. related to the characteristics of the documents, b. related to the process for developing the documents, c. related to implementation and communication actions, d. related to follow-up actions and e. other specific recommendations):

a. the level of obligation (Unconditional/Conditional) of cross-cutting methodological documents should be defined not only for EFSA staff, experts and applicants, but also for contractors providing EFSA with preparatory work through outsourced projects; documents should be concise and contain an extended summary, as well as examples of how to use them and a clear indication of reporting aspects;

b. the process for developing documents should include tests with case-studies (with a representative from each panel and unit/team involved in the implementation of the case-studies) and an internal commenting phase should be instituted;

c. an implementation plan should be designed and executed for all intended users including applicants and contractors; if the intended users include applicants and/or contractors, there should be proper, timely and targeted communication to ensure implementation; a system should be in place to ensure that all available cross-cutting methodological documents are considered at the beginning of a scientific assessment and their use is documented throughout the process and in the final scientific output. In the case where relevant cross-cutting documents are not used, this should be explained and reported; EFSA staff should ensure consideration and implementation of cross-cutting

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7 See footnote 5
methodological documents; the presentation of cross-cutting methodological documents at panel and unit/team meetings should include explanation of their importance/relevance/applicability, intended users and level of obligation;

d. a programme should be in place to ensure new panel members are properly and continuously informed about existing methodological documents (coaching; ideally on a one to one basis); experiences on implementation of cross-cutting documents should be exchanged within the Authority and with member states, other relevant European Union (EU) agencies and the scientific community;

e. in addition to this, the WG noted the close relationship between 10 EFSA cross-cutting methodological documents either finalised, on-going or possibly to be developed and considered that the plans for communication and implementation of these documents should be carefully coordinated and include testing with case-studies (when applicable). The WG concluded that, after completion of the testing periods for the first PROMETHEUS deliverable and the three on-going SC guidance documents on Uncertainty assessment,\(^8\) Weight of evidence\(^9\) and Biological relevance,\(^10\) it should be considered whether it is beneficial to develop one individual roadmap document connecting the application of the four different documents.

5. Information was also collected on the priorities for each panel and unit/team for data collection to be added to the EFSA Scientific Data Warehouse (EFSA, 2015c\(^11\)).

6. Overall conclusions and considerations on training needs were that: in general, there is a perceived higher need for cross-cutting methodology training for staff than for experts; training should be complemented by technical and scientific support from specialists; the value to EFSA will increase the sooner the training is delivered in the panel cycle; and online training should be available.

7. Overall conclusions and considerations on measures for facilitating the implementation of structured EKE approaches in EFSA were that: in general, there is a higher perceived need for implementing EKE in the RASA department than the department on Regulated Products (REPRO). This may be because implementation started in RASA. Implementation should continue and be extended to all panels; support for decisions on the use of EKE has been requested. Implementation of uncertainty guidance is likely to increase the need for informal EKE (semi-formal), with need for related training; EFSA should promote sharing of best EKE practice within the Authority, with Member States and other EU agencies.

8. One additional aspect, identified by the PROMETHEUS WG after participating in the group discussions, was that improved performance of the current IT tools (e.g. the EFSA document management system) will benefit efficient working in many methodological areas.

This survey has presented a unique opportunity to take stock of the views of the EFSA scientific community (staff and panel members) relevant to the methodological needs of the Authority.

The survey also served to inform and update panel members and scientific staff on projects and tools available to support their scientific activities.

Further needs are expected to be identified as progress is made in the implementation of the case-studies testing the PROMETHEUS four-step approach and could complement the analysis illustrated in this report.

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\(^8\) Guidance on Uncertainty assessment: this guidance had been made available for public consultation at the time of the survey. Revised version of the guidance on Uncertainty assessment available online: https://www.efsa.europa.eu/sites/default/files/160321DraftGDUncertaintyInScientificAssessment.pdf


\(^11\) European Food Safety Authority, 2015c. The EFSA Data Warehouse access rules. EFSA supporting publication 2015:EN-768. 18 pp.
EFSA methodological needs for evidence use

Table of contents

Abstract..................................................................................................................................................1
Summary................................................................................................................................................3
1. Foreword...........................................................................................................................................8
1.1. Background of EFSA PROMETHEUS project..............................................................................8
1.2. Objectives and deliverables of EFSA PROMETHEUS project .......................................................8
2. Introduction.......................................................................................................................................10
2.1. Terms of reference.......................................................................................................................10
2.2. Interpretation of the terms of reference, methodology and content of this report ..................10
2.3. Relevance of PROMETHEUS to the 2016–2020 EFSA strategy and ISO 9001:2015 certification 11
3. Survey on the EFSA methodological needs for evidence use .......................................................11
3.1. Survey design and implementation.............................................................................................11
3.2. Interpretation of the survey results ............................................................................................13
4. Methodological needs identified through the survey ..................................................................14
4.1. EFSA cross-cutting methodological documents on evidence use .............................................14
4.1.1. Usefulness of existing EFSA cross-cutting methodological documents ......................................14
4.1.2. Need for measures to facilitate the implementation of the draft EFSA guidance on uncertainty assessment .................................................................................................................................19
4.1.3. Need for additional EFSA guidance documents on evidence use ...........................................21
4.1.4. General recommendations on cross-cutting methodological documents on evidence use ........28
4.2. Need for an inventory of collections of data other than literature .............................................30
4.3. Need for regular support by the EFSA Library ..........................................................................31
4.4. Need for further data collections in the context of the EFSA Scientific Data Warehouse ........31
4.5. Assessments of regulated products: need for further information on dossier preparation for applicants ................................................................................................................................................32
4.6. Need for a plain language summary in EFSA scientific outputs .................................................34
4.7. Methodological needs in the area of outsourcing data collection, appraisal, analyses and integrations ......................................................................................................................................................35
4.8. Need for training of experts and staff .........................................................................................36
4.9. Expert knowledge elicitation (EKE) ...........................................................................................38
4.9.1. Measures for facilitating the implementation of structured EKE approaches in EFSA ...........39
4.9.2. Training in EKE .......................................................................................................................41
4.10. Need for an interface supporting the lifecycle of EFSA scientific outputs ................................43
5. Concluding remarks ....................................................................................................................44
References..............................................................................................................................................46
Glossary and abbreviations ...............................................................................................................48
Appendix A – Data collections to be conducted and maintained in the EFSA Scientific Data Warehouse, as indicated through the survey........................................................................................................50
1. Foreword

1.1. Background of EFSA PROMETHEUS project

The European Food Safety Authority (EFSA) PROMETHEUS project (PROmoting METHods for Evidence Use in Scientific assessments) was initiated in 2014 to bring forward some of the objectives laid out in the EFSA 2012–2016 Science Strategy and 2014–2016 EFSA Single Programming Document.

The EFSA 2012–2016 Science Strategy set out the principles for further strengthening EFSA scientific work by identifying four key strategic objectives: (a) further development of the excellence of EFSA scientific advice; (b) optimisation of the use of risk assessment capacity in the European Union (EU); (c) development and harmonisation of methodologies and approaches to assess risks associated with the food chain; and (d) strengthening of the scientific basis for risk assessment and risk monitoring.

These objectives were outlined also in the 2014–2016 EFSA Single Programming Document, which emphasised the importance to the Authority of (a) ensuring that its advice is fit for purpose and perceived as useful to risk managers, (b) enhancing sustainability by improving its efficiency internally and by increasing cooperation with national food safety agencies, European bodies and international organisations and (c) increasing the trust of stakeholders and citizens, by continually enhancing openness and transparency in relation to both working processes and access to the scientific data used in its assessments as well as the steps and decisions taken in their evaluation.

According to the EFSA Strategy 2012–2016, essential elements for ensuring excellence of EFSA scientific advice are the evidence used and the methods available to address a given topic. This is also the trend in the wider scientific community, where harmonised and systematic methods for dealing with the evidence used in scientific assessments are being developed. A growing number of institutions (e.g. AHRQ, OAH/TNP, US-EPA, WHO) have started to implement assessment processes characterised by, for example, upfront development of protocols; clear rules to collect, validate, analyse and integrate evidence; and rigorous methods for documenting processes and results.

1.2. Objectives and deliverables of EFSA PROMETHEUS project

In this context, the PROMETHEUS project aims to improve further the methods for ‘using’ (i.e. collecting, appraising and analysing) scientific evidence in EFSA assessments, as well as increase the consistency of these methods across the various EFSA areas. Methodological aspects related to the definition of the risk assessment paradigm are already defined and beyond the scope of PROMETHEUS. Domain-specific methodological issues are also not covered in this project.

To achieve its objectives, to date, the PROMETHEUS project has addressed the following deliverables (both endorsed by the EFSA Scientific Committee; SC):

1. The scientific report on the ‘Principles and process for dealing with data and evidence’ (EFSA, 2015a), illustrating:
   - The principles for evidence use (impartiality, excellence in scientific assessments, transparency, openness and responsiveness), based on the EFSA core values;
   - How the process for evidence use is best conducted to fulfil those principles (i.e. by applying a four-step approach), which consists of: (1) planning the strategy (or ‘protocol’) for the collection of data and their appraisal and analysis in advance, before initiating any formal data collection. This includes tailoring the methodology for evidence use, to address the need for minimising bias and random error at the same time as delivering an efficient assessment that is fit-for-purpose; (2) carrying out the

14 Agency for Healthcare Research and Quality (Berkman et al., 2013)
15 Office of Health Assessment and Translation/National Toxicology Program (OAH/TNP, 2015)
assessment in line with the predefined strategy; (3) verifying compliance with the
plan; and (4) documenting and reporting the process, results and conclusions, and
ensuring accessibility of methods and data. A key point is the recording of any
deviations from the planned strategy.

The principles and process for evidence use defined in PROMETHEUS are applicable to all
types of EFSA scientific assessment. This includes assessments carried out by generating data
de novo, by using already existing data (e.g. data from literature) or by eliciting expert
knowledge and with any possible objective (e.g. efficacy, safety), scope (i.e. either full risk
assessments or parts of risk assessment) or actors involved (e.g. EFSA, applicants,
contractors).

2. The present technical report, illustrating the ‘EFSA methodological needs for evidence use in
scientific assessments’ as identified by a working group (WG) of experts and EFSA staff, on
the basis of a survey administered to EFSA panel members and scientific staff in the period
December from 2015 to March 2016.

The PROMETHEUS project includes a phase for piloting the implementation of the four-step approach
(plan/carry out/verify/report) in a series of case-studies in different EFSA areas and types of scientific
assessment. Some case-studies are already complete: the Scientific opinion on the risk assessment for peri-
and post-menopausal women taking food supplements containing isolated isoflavones (EFSA-ANS, 2015b) and the Scientific opinion on the evaluation of the safety and efficacy of Listex™ P100 for
reduction of pathogens on different ready-to-eat (RTE) food products (EFSA-BIOHAZ, 2016).
2. **Introduction**

2.1. **Terms of reference**

After publishing the first PROMETHEUS report on the ‘Principles and process for dealing with data and evidence’ (EFSA, 2015a), EFSA re-defined the overall scope of the second project deliverable, for which it identified two main objectives:

1. First, to identify the EFSA ‘methodological needs for evidence use’, along with their priority, risks, benefits, desirable characteristics and/or possible mitigation actions. Methodological needs are to be interpreted as any elements that can contribute to fulfil the principles and implement the four-step process (plan/carry out/verify/report) described in the first PROMETHEUS report, with regard to data collection, appraisal, analysis and integration. Examples of possible EFSA needs are cross-cutting methodological documents applicable to all panels and units, training for staff and experts, instructions for applicants to integrate the existing regulatory frameworks, and specialised repositories of data. The principles for evidence use are those of impartiality, excellence of scientific assessments, transparency and openness, and responsiveness. The latter refers to the extent to which the assessment is fit-for-purpose (i.e. answers the original question in a way that is understandable and usable for the requestor and in a timely manner). There follows the need to streamline and facilitate the activities of EFSA experts and staff. Specifically, such needs may include IT needs, or more structured and harmonised approaches to outsourcing data collections, appraisals and syntheses. The analysis of the EFSA methodological needs would be updated in 4 years’ time.

2. Second, to provide recommendations for implementing new methods or approaches in EFSA, thereby meeting any needs identified. It was expected that these recommendations would provide further input to on-going EFSA projects and would trigger the development of new ones.

The methodological framework described in the first PROMETHEUS report and the analysis of the EFSA needs illustrated in the second report would serve as the basis for ensuring that all EFSA projects and activities defining methodological approaches are consistent with commonly agreed principles and for enhancing harmonisation of methods across EFSA.

2.2. **Interpretation of the terms of reference, methodology and content of this report**

To carry out the analysis of the EFSA methodological needs, a working group was established composed of staff and experts from all EFSA units and panels and with thorough experience of EFSA work.

The WG decided to undertake the analysis by administering a survey to all EFSA panel members and scientific staff, with the aim of collecting their views on EFSA methodological needs based on their perception at the time when the survey was implemented (December 2015 to March 2016).

The WG considered that the survey would provide useful input for the EFSA management and the Scientific Committee on the methodological needs for evidence use and for identifying their risks, benefits, desirable characteristics, mitigation actions and priority. It will also help to define follow-up actions (thereby meeting the needs).

Therefore, this technical report illustrates the WG conclusions on the results of the survey on the EFSA methodological needs as perceived by the respondents and contains some preliminary considerations and recommendations on possible follow-up actions. The latter mainly relate to cross-cutting EFSA methodological documents for evidence use, applicable to all panels and scientific units (Section 4.1 and in particular Section 4.1.4) and on the part on regular support by the EFSA Library (Section 4.3).

The report also documents on-going EFSA projects that aim to cover some needs identified through the survey.

Further methodological needs may be identified through the continuing case-studies that implement the PROMETHEUS four-step approach and which were envisaged to complement the analysis illustrated in this report.
2.3. Relevance of PROMETHEUS to the 2016–2020 EFSA strategy and ISO 9001:2015 certification

EFSA recently launched a new overarching strategy for the period 2016–2020, which covers all aspects related to the Authority strategic planning and execution and sets five main strategic objectives that will enable it to progress in its main areas of work.

One of these objectives is to ‘Widen EFSA evidence base and optimise access to its data’, with a focus on fostering innovation and efficiency in the data collection and management process and on making data amenable to re-use. Another strategic objective (‘Prepare for future risk assessment challenges’) focuses, among other aspects, on identifying methodologies for evidence-based risk assessments. PROMETHEUS is a key project for achieving these strategic objectives and for promoting innovation in EFSA scientific assessments, as it defines and supports a common approach for data collection, appraisal and integration, which fosters the principles of impartiality, excellence in scientific assessments, transparency, openness and responsiveness.

The EFSA strategy also defines a long-term plan for development and review of guidance documents, to be implemented in collaboration with EU and international partners and in consultation with stakeholders, taking into account international developments in scientific assessments. In addition, the strategy foresees that EFSA becomes a hub for methodologies and tools used in risk assessment, implying all tools and methods used for EFSA scientific assessments to be built taking into consideration, as appropriate, existing international standards and to be made available online and easy to use. By contributing to identifying further needs in terms of guidance documents and of any other aspect strengthening the process for evidence use in EFSA, PROMETHEUS (deliverable 2) helps to accomplish this further operational objective.

In addition, in the context of achieving and maintaining an ISO 9001:2015 certification, the project plays a key role from two main viewpoints: first, the progressive implementation in EFSA scientific outputs’ workflow of the PROMETHEUS four-step approach (plan/carry out/verify/report) can serve as a framework for quality assurance; second, the analysis undertaken in deliverable 2 provides a picture of the methodological needs for evidence use in EFSA, as perceived by panel members and scientific staff. These methodological needs can be considered for implementing measures to improve further the process for evidence use in EFSA scientific assessments.

3. Survey on the EFSA methodological needs for evidence use

3.1. Survey design and implementation

The survey on the EFSA methodological needs for evidence use was administered to all EFSA panel members (207 experts) and scientific staff (176 staff) in the period from December 2015 to March 2016.

The survey was performed using a questionnaire. The latter was drafted by enquiring into the process for evidence use illustrated in the first PROMETHEUS report into a set of questions covering methodological needs pre-identified by the WG in consultation with all relevant EFSA areas (Figure 1; the detailed survey questions are illustrated in Section 4).

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18 Available online: https://www.efsa.europa.eu/it/corporate/pub/strategy2020
19 These did not include the EFSA Scientific Committee.
SURVEY QUESTIONS

PROTOCOL DEVELOPMENT
1. Question 1. Possible guidance on Protocol development for scientific assessments (non-regulated) and outsourced projects
2. Question 2. Other suggestions on Protocols for scientific assessments

DATA COLLECTION
4. Question 4. Possible guidance on appraising a literature search
5. Question 5. Existing EFSA Inventory of sources of evidence
6. Question 6. Possible inventory of sources of data
7. Question 7. EFSA Library
8. Question 8. Other suggestions on data collection

EFSA SCIENTIFIC DATA WAREHOUSE
9. Question 25. Need for additional data collections in the Data Warehouse

EVIDENCE APPRAISAL
10. Question 9. Possible guidance on the appraisal of already existing studies
11. Question 10. Other suggestions on evidence appraisal

EVIDENCE ANALYSIS AND INTEGRATION
12. Question 11. Existing EFSA opinion on Statistical significance and biological relevance
13. Question 12. Existing EFSA guidance on Systematic review
14. Question 13. Possible guidance on Methodology for integrating new evidence
15. Question 14. Other suggestions on evidence analysis and integration

UNCERTAINTY ANALYSIS
16. Question 15. Draft EFSA guidance on Uncertainty analysis

EXPERT KNOWLEDGE ELICITATION (EKE)
17. Question 16. Existing EFSA guidance on EKE
18. Question 17. Implementation of EKE in EFSA

ASSESSMENTS OF REGULATED PRODUCTS [restricted to panel members/staff dealing with applications only]
20. Question 18. Need for further information on dossier preparation for applicants
21. Question 19. Other suggestions for assessments of regulated product

OUTSOURCING DATA COLLECTIONS, APPRAISALS, ANALYSES AND INTEGRATIONS [restricted to staff only]
22. Question 20. Possible manual on drafting Technical specifications (scientific part) for outsourcing data collections etc.
23. Question 21. Other suggestions on outsourcing

REPORTING
24. Question 22. Existing EFSA guidance on Statistical reporting
25. Question 23. Plain language summary
26. Question 24. Other suggestions on reporting

TRAINING FOR STAFF AND EXPERTS
27. Question 26. Type of training
28. Question 27. Other suggestions on training for staff and experts

IT TOOLS
29. Question 28. EFSA INTERFACE

OTHER
30. Question 29. Additional suggestions [optional question]

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Figure 1. Outline of the questionnaire on EFSA methodological needs for evidence use (based on the process for evidence use illustrated in the scientific report ‘Principles and process for dealing with data and evidence’, EFSA 2015a)
The respondents were asked to indicate whether the potential needs suggested in the survey represented actual needs for their panel or unit/team or not and, if there was a perceived need, to specify whether each need would be a ‘nice to have’ or a ‘must have’. They were then asked to integrate the list of needs with any other element deemed necessary for the panel or unit to improve the process for evidence use. The respondents could also express their views on the usefulness of a series of existing EFSA cross-cutting methodological documents applicable to all panels and units covering the process for evidence use to some extent (Section 4.1.1).

The questionnaire was administered in two rounds: first, at the individual level, to collect the personal view of the panel members and scientific staff (the response rate was 85% – 175/207 and 63% – 111/176, respectively); then, the results of the first round of consultation were then considered by each panel and unit to generate a collective view of the group on the questions (with the exception of the questions on ‘existing EFSA methodological documents on evidence use’, for which only the individual answers were considered20). The process for reaching the collective view was either via written procedure or through group discussion. In some cases, when group discussion could not be held, the panel/unit decided to consider the most frequent responses as the final answers to the questions. It is acknowledged that this step of the process introduced some simplifications in the responses, thus losing the level of detail achieved in the initial round of consultation. However, despite this possible weakness, it was decided to base the analysis on the collective view of each group instead of the individual answers, aiming to ease the definition of possible follow-up actions addressing the needs identified through the survey.

3.2. Interpretation of the survey results

For the majority of the survey questions seeking to assess the need for specific elements supporting the process for evidence use, the WG conclusions were elaborated in the light of the following criteria:

- a. presence of a prevalent answer within the all-panels and within the all-units/teams answers;
- b. presence of answers within the all-units/teams and all-panels groups that clearly deviate from the prevalent answer and possible explanation, based on any additional responses and considerations by PROMETHEUS experts;
- c. comparison across all-units/teams and all-panels of distributions of results;
- d. consistency of results within each pair (panel/supporting-unit/team) and in particular detection of the discordance ‘Not needed’ versus ‘Must have’.

The conclusions were drawn considering the ‘majority/most prevalent’ answers for the following survey questions: on the completeness of the regulatory framework (Section 4.5), on outsourcing data collections, appraisals and integrations (Section 4.7), on training needs for staff and experts (Section 4.8), on needs in the field of expert knowledge in EFSA (Section 4.9) and on the interface supporting the lifecycle of EFSA scientific outputs (Section 4.10).

The WG members concluded, for each element described in the survey, on its need as perceived by the respondents at the time when the survey was administered and the conclusions were expressed as follows:

- No foreseen need for this element.
- Useful element to implement.
- Clear need for this element.

The WG conclusions on the survey questions aiming to assess the usefulness of existing general methodological documents were elaborated considering different aspects, which are illustrated in Section 4.1.

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20 As a result of the fact that, to express their view on the usefulness of those existing documents, the respondents had to be aware of the content of the documents and this was not possible for all members in a panel or unit.
4. Methodological needs identified through the survey

This section illustrates the WG conclusions on the survey results together with some preliminary considerations and recommendations on possible follow-up actions. On-going EFSA projects aiming to cover some of the needs identified through the survey are also reported.

4.1. EFSA cross-cutting methodological documents on evidence use

4.1.1. Usefulness of existing EFSA cross-cutting methodological documents

The questionnaire included a series of questions designed to assess the usefulness of six existing EFSA cross-cutting methodological documents on evidence use (Table 1).

These are the only survey questions for which, as described above, the individual answers were used for the analysis, and no collective views were sought from the panels and units.

These six cross-cutting methodological documents were selected because they are applicable to all EFSA panels and units and provide information to support the process for evidence use at different levels (from data collection to evidence integration) and in different ways. Panel-specific guidance documents or scientific opinions were not included in the survey because they are not applicable to all panels and/or do not necessarily cover the process for evidence use.

For four out of those six documents mentioned in the survey (a scientific opinion and three guidance documents), the EFSA Scientific Committee, in its scientific opinion ‘Guidance on the review, revision and development of EFSA cross-cutting guidance documents’ (EFSA SC, 2015), indicated the level of obligation for EFSA panels and applicants as either ‘Unconditional’ or ‘Conditional’ (Table 1), as follows:

- Unconditional (compulsory), with a requirement to follow.
- Conditional (not compulsory), with a requirement to follow if the recommended approach is chosen. Conformity is expected unless circumstances justify deviation from the guidance, which should be clearly justified and recorded in the text of the scientific assessments.

The level of obligation (i.e. compulsory/not compulsory to follow) for organisations contracted by EFSA to undertake scientific projects through tender procedures (e.g. outsourced data collection, appraisal and syntheses) was not specified in the SC guidance.

For each of the six documents, the questionnaire assessed, first, whether the respondents knew if the document had been used for producing their panel and/or unit/team outputs and, if so, whether it was useful. If the respondents indicated that usefulness was limited or absent, the questionnaire asked respondents to indicate the reasons.

The PROMETHEUS WG conclusions, additional considerations and recommendations on these survey questions are reported in Table 1. They are based both on the survey results and WG discussion and were drawn considering mainly the following points:

- Time of availability of the document.
- Respondents’ experience of EFSA (expressed in years at EFSA and number of EFSA meetings attended, respectively for staff and panel members).
- Presence of an implementation plan, including clear communication of the content, objectives and intended users of the surveyed document.
- Relevance and applicability of the document depending on the panel outputs.
- Relevance and applicability of the document depending on the respective tasks of staff and panel members.

When analysing the results by units/teams and panels separately, the level of conformity in the all-units/teams and all-panels groups was considered, as well as the comparison between each individual group and the respective group overall (all-panels or all-units group). In general, for all six
documents, the results show similar trends across units, aligned with all-units’ results and across panels, aligned with all-panels’ results.

For the question ‘Has the document ever been used for producing your panel/unit outputs?’, overall, the survey shows some inconsistency in the respondents’ awareness of the application of the six documents. For example, within the same group (e.g. same panel and/or unit), for all six documents, some respondents answered ‘Yes, it has been used for producing my panel/unit outputs’ and others ‘No, it has never been used’, in most cases. Among those who answered ‘Don’t know’, for all six documents, there is a positive correlation with less experience of EFSA. This is expected for panel members with experience of less than 21 EFSA meetings (i.e. at their first mandate, started in July 2015) and for staff working at EFSA for less than 2 years. For general documents available for 3 years or longer, the responses of panel members and staff with more experience of EFSA (i.e. panel members who participated in 21+ meetings and staff with ≥ 2 years in EFSA) may suggest a limited awareness of the document, implying the need for improved internal communication and implementation planning. In general, staff members show greater awareness than panel members, independently of the document, possibly as a result of the nature of their duties. Indeed, staff are more involved in the structured aspects of developing scientific outputs, where guidance documents are particularly useful. Panel members’ expertise and judgement are devoted to more conceptual aspects.

The usefulness of most of the documents could not be assessed because the number of respondents who indicated that the document had been used and thus answered the additional question on the usefulness was too limited. However, it is possible that these methodological documents have been used by some experienced staff or experts without this being general knowledge within a working group or panel, and so there is uncertainty relevant to this aspect. When participants answered that the documents had been used, overall, they also indicated that the documents were either useful or partially useful. ‘No’ answers were exceptions and ‘Don’t know’ were in the range 10–30% depending on the specific document. Staff members tended to value the documents’ usefulness more than panel members.
Table 1. Conclusions, additional considerations and recommendations on six EFSA cross-cutting methodological documents on evidence use, based on survey results and WG discussion

<table>
<thead>
<tr>
<th></th>
<th>Title of the document, intended users and level of obligation indicated by the European Food Safety Authority (EFSA) Scientific Committee (SC)21</th>
<th>Conclusions, additional considerations and recommendations based on survey results and group discussion</th>
</tr>
</thead>
</table>
| 1 | Technical manual for literature searches in food and feed safety (outsourced project, 201322) Intended users and level of obligation: not applicable (document not covered in EFSA-SC, 2015) | Conclusions and additional considerations:  
- Awareness of use: inconsistent results and limited awareness  
- The document was finalised in 2013, but it was not published on the contractor website until 2015. In addition, there was no communication and implementation plan for this project  
- The manual is relevant for and applicable in all EFSA areas where a literature search is to be designed and conducted. This applies to EFSA staff and scientific experts, applicants preparing dossiers and contractors  
- Difficult to conclude on actual usefulness, as a result of the limited number of respondents to this question  
Recommendations:  
- It should be made Conditional for all EFSA ‘stakeholders’: panels and staff, applicants and contractors  
- Implementation plan should be established and executed |
| 2 | Inventory of sources of scientific evidence relevant to EFSA risk assessments and information sessions on literature searching techniques (outsourced project, 201323) Intended users and level of obligation: not applicable (document not covered in EFSA-SC, 2015) | Conclusions and additional considerations:  
- Awareness of use: inconsistent results and limited awareness  
- The inventory was finalised in 2013. The communication and implementation plan was limited  
- The inventory is relevant for and applicable in all EFSA areas where a literature search is to be designed and conducted. This applies to EFSA staff and scientific experts, applicants preparing dossiers and contractors  
- Difficult to conclude on actual usefulness, as a result of the limited number of respondents to |

23 The inventory was made available on the contractor’s website in 2013 (http://www.metaxis.com/EFSAInventory/). See also EFSA supporting publication: Glanville et al., 2014 available online: http://www.efsa.europa.eu/en/supporting/pub/593e
| 3 | EFSA Scientific Committee opinion on Statistical significance and Biological relevance (EFSA-SC, 2011) | **Conclusions and additional considerations**:
- Awareness of use: inconsistent results and limited awareness
- The opinion has been available since 2011
- The opinion is relevant for and applicable to all EFSA areas and in 2015 it was defined by the SC as Unconditional (compulsory) for EFSA experts and staff, and applicants
- The opinion will be complemented by the SC guidance on Biological relevance

| **Recommendations**:
- Active dissemination should start, to increase awareness |
| Intended users and level of obligation: |
| - EFSA experts and staff: Unconditional |
| - Applicants: Unconditional |

| 4 | EFSA guidance on Application of systematic review methodology to food and feed safety assessments to support decision making (EFSA, 2010a) | **Conclusions and additional considerations**:
- Awareness of use: inconsistent results and limited awareness
- The guidance has been available since 2010
- In 2015 it was defined by the SC as Conditional (not compulsory) for EFSA experts and staff and not applicable to applicants. However, it is considered that the guidance is relevant and applicable to all cases when a literature review is conducted, including the case of applicants reviewing literature for a dossier and contractors conducting reviews through outsourced projects |
| **Recommendations**:
- Implementation plan should be established and executed
- It should be made Conditional also for applicants and contractors |
| Intended users and level of obligation: |
| - EFSA experts and staff: Conditional |
| - Applicants: not applicable |

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<table>
<thead>
<tr>
<th></th>
<th>Title of the document, intended users and level of obligation indicated by the European Food Safety Authority (EFSA) Scientific Committee (SC(^2))</th>
<th>Conclusions, additional considerations and recommendations based on survey results and group discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td><strong>EFSA guidance on Expert knowledge elicitation (EKE) in food and feed safety risk assessment (EFSA, 2014a)</strong>&lt;br&gt;Intended users and level of obligation:&lt;br&gt;• EFSA experts and staff: Conditional&lt;br&gt;• Applicants: not applicable</td>
<td><strong>Conclusions and additional considerations:</strong>&lt;br&gt;• Awareness of use: inconsistent results and limited awareness&lt;br&gt;• The guidance has been available since 2014&lt;br&gt;• In 2015, it was defined by the SC as Conditional (not compulsory) for EFSA experts and staff and not applicable to applicants&lt;br&gt;• The guidance is applicable in those cases where relevant and reliable data are limited&lt;br&gt;• An implementation plan was included in the guidance&lt;br&gt;<strong>Recommendations:</strong>&lt;br&gt;• The guidance should be applied in additional case-studies as examples for future application&lt;br&gt;• There should be further communication on the guidance mainly in panels from the department on Regulated Products (REPRO), clarifying the relevance to this field and its possible further implementation&lt;br&gt;• The implementation plan should continue&lt;br&gt;• Further EFSA-tailored training may help the application of the guidance (Section 4.9.2)&lt;br&gt;• When/if updating the guidance, the reasons for being only partially useful indicated by the survey respondents should be considered</td>
</tr>
<tr>
<td>6</td>
<td><strong>EFSA guidance on Statistical reporting (EFSA, 2014b)</strong>&lt;br&gt;Intended users and level of obligation:&lt;br&gt;• EFSA experts and staff: Unconditional&lt;br&gt;• Applicants: Unconditional</td>
<td><strong>Conclusions and additional considerations:</strong>&lt;br&gt;• Awareness of use: inconsistent results and limited awareness&lt;br&gt;• The guidance has been available since 2014&lt;br&gt;• The guidance is relevant and applicable in all EFSA areas and, in 2015, it was defined by the SC as Unconditional (compulsory) for EFSA experts and staff, and applicants&lt;br&gt;• Difficult to conclude on actual usefulness, as a result of the limited number of respondents to this question&lt;br&gt;<strong>Recommendations:</strong>&lt;br&gt;• Implementation plan should be established and executed&lt;br&gt;• It should be made Unconditional for contractors</td>
</tr>
</tbody>
</table>
4.1.2. Need for measures to facilitate the implementation of the draft EFSA guidance on uncertainty assessment

A questionnaire section sought to define measures to facilitate the implementation of the draft EFSA guidance on uncertainty assessment,\textsuperscript{25} which had been made available for public consultation at the time of the survey. This guidance is applicable to all types of EFSA scientific outputs (i.e. assessments of regulated products and more generic assessments) and for EFSA experts and staff.

Each panel and unit/team was asked to express their collective view (as ‘must have’, ‘nice to have’ or ‘not needed’) on the following possible measures to facilitate implementation:

1. Multi-panel training in uncertainty assessment.
3. Technical support by staff and experts from the uncertainty WG.

The respondents were also invited to indicate any further possible means to facilitate the implementation of the guidance, to evaluate whether these were a ‘must have’ or ‘nice to have’, and/or to add any other relevant comment.

The PROMETHEUS WG conclusions and considerations on each measure for facilitating the implementation of the draft guidance on Uncertainty assessment are summarised in Table 2. A clear need for panel-specific training in uncertainty assessment was expressed (especially in the view of the staff). Technical support to be given by staff and experts from the uncertainty WG was also indicated as a clear need.

\textsuperscript{25} Guidance on Uncertainty assessment: this guidance had been made available for public consultation at the time of the survey. Revised version of the guidance on Uncertainty assessment available online: https://www.efsa.europa.eu/sites/default/files/160321DraftGDUncertaintyInScientificAssessment.pdf


<table>
<thead>
<tr>
<th>Measure for facilitating the implementation of the draft European Food Safety Authority (EFSA) guidance on uncertainty assessment</th>
<th>Conclusions on the need for the measure as perceived by the respondents and additional considerations based on group discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Multipanel training in uncertainty assessment</td>
<td>It is considered a <strong>useful measure to implement</strong>, but <strong>not a pressing need</strong>. The respondents expressed a preference for panel-specific training (see below)</td>
</tr>
<tr>
<td></td>
<td>This type of training started in April 2016 (i.e. after the survey)</td>
</tr>
<tr>
<td></td>
<td>'Must have' indicated by: one unit (SCER)</td>
</tr>
<tr>
<td></td>
<td>'Nice to have' indicated by:</td>
</tr>
<tr>
<td></td>
<td>• Five panels (CONTAM, FEEDAP, GMO, NDA, PLH)</td>
</tr>
<tr>
<td></td>
<td>• Four units/teams (ANS, CEF, GMO, NUTRI)</td>
</tr>
<tr>
<td></td>
<td>'Not needed' indicated by:</td>
</tr>
<tr>
<td></td>
<td>• Five panels (AHAW, ANS, BIOHAZ, CEF, PPR)</td>
</tr>
<tr>
<td></td>
<td>• Six units/teams (AHAW, BIOHAZ, CONTAM, FEED, PLH, Pesticides)</td>
</tr>
<tr>
<td></td>
<td>These conclusions are reinforced by the similarity of all-units/teams and all-panels distributions of results and by the mild discordance in panel-unit/team pairs</td>
</tr>
<tr>
<td></td>
<td>The exceptional answer by the SCER unit ('Must have') could be a result of the overarching view of this unit, which sees this training as an opportunity for harmonisation of methods across panels</td>
</tr>
<tr>
<td>2 Panel-specific training in uncertainty assessment</td>
<td><strong>Clear need for this measure, especially according to staff</strong></td>
</tr>
<tr>
<td></td>
<td>'Must have' indicated by:</td>
</tr>
<tr>
<td></td>
<td>• Six panels (ANS, BIOHAZ, CEF, CONTAM, GMO, PPR)</td>
</tr>
<tr>
<td></td>
<td>• Eight units/teams (AHAW, BIOHAZ, CEF, CONTAM, FEED, GMO, NUTRI, PLH)</td>
</tr>
<tr>
<td></td>
<td>'Nice to have' indicated by:</td>
</tr>
<tr>
<td></td>
<td>• Four panels (AHAW, FEEDAP, NDA, PLH)</td>
</tr>
<tr>
<td></td>
<td>• Three units/teams (ANS, Pesticides, SCER)</td>
</tr>
<tr>
<td></td>
<td>'Not needed' indicated by: none</td>
</tr>
<tr>
<td></td>
<td>These conclusions are reinforced by the similarity of all-units/teams and all-panels distribution of results and by the mild misalignment of panel-unit/team pairs</td>
</tr>
</tbody>
</table>
Measure for facilitating the implementation of the draft European Food Safety Authority (EFSA) guidance on uncertainty assessment

<table>
<thead>
<tr>
<th>Measure</th>
<th>Conclusions on the need for the measure as perceived by the respondents and additional considerations based on group discussion</th>
</tr>
</thead>
</table>
| Panel-specific training should: | • consider the specificity of the relevant area (including the regulatory framework, if any)  
• include the presentation of specific relevant practical examples |
| Technical support by staff and experts from the uncertainty WG | Clear need for this measure. This type of support officially started in April 2016  
‘Must have’ indicated by:  
• Eight panels (ANS, BIOHAZ, CEF, CONTAM, FEEDAP, GMO, PLH, PPR)  
• Eight units/teams (AHAW, BIOHAZ, CONTAM, FEED, GMO, NUTRI, PLH, SCER)  
‘Nice to have’ indicated by:  
• Two panels (AHAW, NDA)  
• Three units/teams (ANS, CEF, Pesticides)  
‘Not needed’ indicated by: none |

These conclusions are reinforced by the similarity of all-units/teams and all-panels distribution of results, panel-unit/team alignment and by the additional comments to this survey question

4.1.3. Need for additional EFSA guidance documents on evidence use

Each EFSA panel and scientific unit/team was asked to express its view on the need, in the respective EFSA area, for four additional guidance documents supporting the process for evidence use, such as guidance on: Protocol development for scientific assessments; Appraising a literature search; Appraising ‘already existing’ studies (e.g. literature studies); and Methodology for integrating new evidence. The possible content, intended users and/or EFSA areas of application of these guidance documents as indicated in the questionnaire are illustrated in Table 3.

The need for each guidance document was expressed as ‘must have’, ‘nice to have’ or ‘not needed’ and, in case one of the first two options was chosen, the survey assessed the possible measures for facilitating the implementation of the guidance. These were summarised as follows:

- The guidance should be listed among the cross-cutting documents that all experts and staff should be informed of.
- At least one expert per panel and one staff per unit should be identified as ‘ambassador’ for the guidance, to ensure compliance.
- Other (in this case the panel/unit was asked to specify the measure for facilitating the implementation of the guidance).

26 The term ‘protocol’ was used to refer to the ‘strategy’ for scientific assessments, as defined in the first PROMETHEUS report (EFSA, 2015a). According the report, the protocol should be developed before initiating any formal data collection and include a clear definition of: (1) the objectives of the assessments; (2) the context of the assessment, all (sub)-questions that must be answered and how they combine in the overall assessment; (3) the evidence needs; and (4) the approach that will be applied or dealing with data and evidence. It includes tailoring the methodology to deliver an efficient assessment that is fit-for-purpose.
The respondents were also asked to add any comment with regard to these new proposed guidance documents.

The WG conclusions on the need for the guidance as perceived by the respondents are illustrated in Table 3. To draw conclusions on the need for guidance on ‘Protocol development’ and ‘Appraising existing studies’, the answers to the open questions on ‘additional suggestions on protocol development’ and ‘additional suggestions on evidence appraisal’ were also considered. Overall conclusions can be summarised as follows:

- Some EFSA units/teams expressed a stronger need for these additional cross-cutting guidance documents than the panels.
- The guidance on evidence appraisal seems to be the most in demand compared to the others.
- As for the measures for implementing each new guidance (if the guidance was indicated as needed), ‘listing the document among the cross-cutting documents that all experts and staff should be informed of’ was selected by the vast majority of the respondents for all four guidance documents, whereas the need for ambassadors was indicated by about half of the respondents (a bit higher for the guidance on protocol development). The PROMETHEUS WG also identified the need for establishing and executing an implementation plan if any of these guidance documents is developed by EFSA (Section 4.1.4).
### Table 3 Conclusions and additional considerations on the need for four new EFSA guidance documents

<table>
<thead>
<tr>
<th>Possible new European Food Safety Authority (EFSA) guidance</th>
<th>Content and/or presentation of guidance, as illustrated in the questionnaire</th>
<th>Intended users and/or EFSA area of application as specified in the questionnaire</th>
<th>Conclusions on the need for the guidance as perceived by the respondents</th>
</tr>
</thead>
</table>
| 1 Protocol development for scientific assessments          | The term ‘protocol’ for scientific assessments was used in the questionnaire to refer to the term ‘strategy’ as used in the first PROMETHEUS report EFSA, 2015a). This guidance would illustrate, for example:  
• the content of a protocol for a scientific assessment;  
• the process and method for developing a protocol (including dialogue with mandate requestors);  
• the expertise needed for developing a protocol;  
• how to document and report the process for developing a protocol along with specific template;  
• how to verify compliance between protocol and final output;  
• the opportunity of publishing protocols before initiating the assessment | • EFSA (staff and experts) conducting scientific assessments not in the field of regulated products  
• Contractors carrying out an outsourced project implying data collection, appraisal and synthesis (including literature reviews) | • Useful to develop this guidance, despite some heterogeneous view amongst the staff  
• Various units (including those answering ‘not needed’) expressed the need for templates for protocols and for technical support to develop protocols  
• Some respondents indicated the need for a catalogue of examples of protocols developed for dealing with specific mandates. These could be considered for new mandates  
• Although originally indicated in the survey as applicable only in the area on non-regulated assessments, the use of protocols is tested also for the evaluation of dossiers (e.g. the PROMETHEUS case-study EFSA-BIOHAZ, 2016)  
‘Must have’ indicated by:  
• Panels: none  
• 2 units/teams (CEF, CONTAM)  
‘Nice to have’ indicated by:  
• 9 panels (AHAW, ANS, BIOHAZ, CEF,
<table>
<thead>
<tr>
<th>Possible new European Food Safety Authority (EFSA) guidance</th>
<th>Content and/or presentation of guidance, as illustrated in the questionnaire</th>
<th>Intended users and/or EFSA area of application as specified in the questionnaire</th>
<th>Conclusions on the need for the guidance as perceived by the respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Appraising a literature search</td>
<td>In EFSA assessments, there is often the need for appraising literature searches carried out by others (e.g. applicants, contractors or available in published reviews). A 'literature search' is one of the initial steps of a literature review, when search strings are designed and implemented in relevant information sources (e.g. bibliographical databases). In addition to the technical manual for literature searches in food and feed safety (outsourced project, 2013(^{27})), EFSA recently published a Critical Appraisal Tool (CAT) for appraising an Extensive Literature Search (ELS) (EFSA, 2015b). The manual illustrates the features that must be considered for appraising a literature search (e.g. syntax, use of Boolean operators,</td>
<td>Not specified in the questionnaire</td>
<td>• Useful to develop this guidance, according to experts and units, despite some heterogeneous views amongst the staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Some additional comments expressed the need for <strong>specialised support by EFSA staff</strong> (Section 4.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>'Must have' indicated by:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Panels: none</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 3 units/teams (CEF, CONTAM, GMO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>'Nice to have' indicated by:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 10 panels (AHAW, ANS, BIOHAZ, CEF, CONTAM, FEEDAP, GMO, NDA, PLH, PPR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 7 units/teams (ANS, BIOHAZ, FEED, Nutri, PLH, Pesticides, SCER)</td>
</tr>
</tbody>
</table>

\(^{27}\) Available online: http://www.yhec.co.uk/portfolio-items/technical-manual-for-performing-electronic-literature-searches-in-food-and-feed-safety/
<table>
<thead>
<tr>
<th>Possible new European Food Safety Authority (EFSA) guidance</th>
<th>Content and/or presentation of guidance, as illustrated in the questionnaire</th>
<th>Intended users and/or EFSA area of application as specified in the questionnaire</th>
<th>Conclusions on the need for the guidance as perceived by the respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>sensitivity/precision, etc.)</td>
<td>Has the CAT does not contain detailed instructions on how to appraise each feature</td>
<td>EFSA staff and experts in all types of scientific assessments (i.e. regulated and not)</td>
<td>The Pesticides unit indicated that this new guidance should complement the existing guidance on literature review for pesticides (EFSA, 2010), trying to address its weaknesses</td>
</tr>
<tr>
<td>The new possible guidance would complete the CAT on ELS</td>
<td>• Applicants &lt;br&gt; • Contractors</td>
<td>• Useful to develop this guidance, according to experts</td>
<td>‘Not needed’ indicated by: &lt;br&gt; • Panels: none  &lt;br&gt; • 1 team (AHAW)</td>
</tr>
</tbody>
</table>

3 Appraising ‘already existing’ studies  

The term ‘already existing studies’ was used in the questionnaire to refer to studies available in the literature and studies whose data are published in an electronic database (e.g. Eurostat\[^{28}\] or European Chemicals Agency database on chemicals\[^{29}\]) They can have different origins:  
- included in dossiers submitted to EFSA for the assessment of a regulated product;  
- submitted to EFSA by other external parties (e.g. European Commission, Focal Points – Information Exchange Platform, etc.);  
- Applicants <br> • Contractors | • Clear need for this guidance according to staff | ‘Must have’ indicated by:  
- Panels: none |

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\[^{28}\] http://ec.europa.eu/eurostat/data/database  
\[^{29}\] http://echa.europa.eu/information-on-chemicals  
<table>
<thead>
<tr>
<th>Possible new European Food Safety Authority (EFSA) guidance</th>
<th>Content and/or presentation of guidance, as illustrated in the questionnaire</th>
<th>Intended users and/or EFSA area of application as specified in the questionnaire</th>
<th>Conclusions on the need for the guidance as perceived by the respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• collected by EFSA (experts, staff); • collected by awarded contractors via procurements/grants and submitted to EFSA. EFSA recently published a CAT for some study designs (EFSA, 2015b). However this document would require further development, in particular as regards to instructions for appraisal</td>
<td>• EFSA staff and experts in all types of outputs (generic/regulated) • Applicants • Contractors</td>
<td>• 5 units/teams (ANS, CEF, CONTAM, GMO, SCER) ‘Nice to have’ indicated by: • 10 panels (AHAW, ANS, BIOHAZ, CEF, CONTAM, FEEDAP, GMO, NDA, PLH, PPR) • 5 units/teams (BIOHAZ, FEED, Nutri, PLH, Pesticides) ‘Not needed’ indicated by: • Panels: none • 1 team (AHAW)</td>
<td>'New evidence', in the questionnaire meant evidence that becomes available when the scientific assessment is almost completed, before publication of the scientific output. The new possible guidance would illustrate, for example: the method for analysing the impact of new evidence on the results of the assessment (e.g. sensitivity analysis); how to document this impact</td>
</tr>
<tr>
<td>Possible new European Food Safety Authority (EFSA) guidance</td>
<td>Content and/or presentation of guidance, as illustrated in the questionnaire</td>
<td>Intended users and/or EFSA area of application as specified in the questionnaire</td>
<td>Conclusions on the need for the guidance as perceived by the respondents</td>
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<td></td>
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<td></td>
<td>Pesticides) These conclusions are suggested by some inconsistency between all-experts and all-staff results’ pattern and by the mild misalignment of panel-unit/team pairs. The PROMETHEUS WG noted that the EFSA-SC standing working group on guidance review started a ‘Reflection paper on motivations, criteria and procedures to update and re-open EFSA scientific assessments’ (provisional title), which will address these methodological aspects (on-going project, mandate number M-2016-0038, question number EFSA-Q-2016-00326, accessible via the EFSA Register of Questions database (<a href="http://www.efsa.europa.eu/en/request/requests.htm">http://www.efsa.europa.eu/en/request/requests.htm</a>)</td>
</tr>
</tbody>
</table>
4.1.4. **General recommendations on cross-cutting methodological documents on evidence use**

Cross-cutting methodological documents such as guidance covering specific aspects of the process for data collection, appraisal, analysis and integration contribute to promoting impartiality (by facilitating processes that are method-driven and not data-driven). They promote consistency across EFSA and with existing internationally recognised approaches, transparency, scientific excellence and efficiency. They also help to reduce subjectivity in the process for evidence use.

In its scientific opinion ‘Guidance on the review, revision and development of EFSA cross-cutting guidance documents’ (EFSA-SC, 2015), the EFSA Scientific Committee defined the intended users and level of obligation for twenty-three EFSA cross-cutting methodological documents published up to the end of 2014, and issued a series of conclusions and recommendations with regard to the implementation and process/periodicity for reviewing/updated cross-cutting guidance.

The results of the PROMETHEUS survey support the view of the EFSA-SC. Some further recommendations on cross-cutting methodological documents, based on the survey results and/or the view of the PROMETHEUS WG members, follow below.

**Recommendations based on the survey results:**

1. Cross-cutting methodological documents should not be prescriptive, but should allow flexibility in the choice of the methods, depending on the scientific assessment;
2. EFSA panels should be consulted before starting the development of a new guidance document or the update of an existing one;
3. The number of cross-cutting methodological documents should be reduced and the documents merged where possible;
4. Training on the implementation of these documents should be panel-specific and based on case-studies. Online training should be possible;
5. Technical support should be guaranteed to panels and units to facilitate the implementation of cross-cutting methodological documents;
6. The current practice of taking into consideration existing international standards/guidance when developing new documents should continue.

**Additional recommendations based on WG discussion:**

The additional recommendations based on the view of the PROMETHEUS WG are classified in five main categories: (a) related to the characteristics of the documents; (b) related to the process for developing the documents; (c) related to implementation and communication actions; (d) related to follow-up actions; and (e) Other specific recommendations.

**(a) Recommendations related to the characteristics of the documents:**

1. The level of obligation (Unconditional/Conditional) of cross-cutting methodological documents should be defined for EFSA contractors (and, accordingly, there should be a proper communication and implementation plan—see below);
2. Cross-cutting methodological documents should be as concise as possible and accompanied by an extended summary (which could be a standalone document) that helps to navigate the main document;
3. If available, they should contain examples of how to use them;

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31 Including answers to free-text questions.
4. They should include detailed indications of how to document and report the methodological aspects addressed and, if appropriate, by means of defined templates (e.g. how to report data collection, appraisal, etc.);

(b) Recommendations related to the process for developing the documents:

5. Before being finalised, cross-cutting methodological documents should be tested on case-studies, at least one from each panel. A representative from each panel and unit/team should be involved in the implementation of the case-studies;

6. A commenting phase should be allowed via internal communication;

(c) Recommendations related to implementation and communication actions:

7. An implementation plan should be designed and executed for each cross-cutting methodological document and for all intended users;

8. If the intended users include applicants and/or contractors, there should be proper, timely and targeted communication, to ensure implementation (e.g. for contractors, by providing clear instructions in the technical specifications of the calls for tender);

9. A system should be in place in EFSA to ensure that all available cross-cutting methodological documents are considered at the beginning of a scientific assessment and their use is documented throughout the process and in the scientific output. In cases where relevant cross-cutting documents are not used, this should be explained and reported;

10. EFSA staff should play a key role to ensure consideration and implementation of cross-cutting methodological documents;

11. The presentation of cross-cutting methodological documents at panel and unit/team meetings should include explanation of their importance/relevance/applicability, intended users and level of obligation;

(d) Recommendations related to follow-up actions:

12. EFSA staff and the Scientific Committee should ensure the revision and updating of cross-cutting methodological documents and establish a process to collect feedback and lessons learnt through their application. The WG noted that this is currently being covered by the EFSA quality management, with the development of standard operating procedures;

13. A consistent programme for coaching of new panel members on EFSA cross-cutting methodological documents should be in place. This would imply teaming up new appointees, ideally on a one to one basis, with more experienced expert/staff members who have detailed knowledge of the available documents, to ensure continuous source of information and personal advice about what is in place and how to access it;

14. EFSA should ensure exchange of experiences on implementation of cross-cutting documents within the Authority and with member states, other relevant EU agencies and the scientific community.

(e) Other specific recommendations:

The WG noted the close relation between ten EFSA documents either finalised, on-going or possibly to be developed (Box 1) and considered that the plans for communication and implementation of these documents should be carefully coordinated and include testing with case-studies (when applicable). The working group concluded that, after completion of the testing periods for the first PROMETHEUS scientific report on ‘Principles and process for dealing with data and evidence’ and the three on-going Scientific Committee guidance documents on Uncertainty assessment, Weight of evidence and Biological relevance (Box 1), it should be considered if it is beneficial to develop one individual roadmap document setting out how the four different documents should be implemented together, in a practical fashion in EFSA work.
Box 1. EFSA cross-cutting methodological documents deemed closely related by the PROMETHEUS WG

1. EFSA Scientific Committee guidance on Transparency in the scientific aspects of risk assessment (EFSA-SC, 2009)
2. EFSA scientific report on ‘Principles and process for dealing with data and evidence’ (EFSA, 2015a)
3. EFSA Scientific Committee opinion on Statistical Significance and Biological Relevance (EFSA-SC, 2011)
4. EFSA guidance on Application of systematic review methodology to food and feed safety assessments to support decision making (EFSA, 2010a)
5. EFSA guidance on Expert knowledge elicitation in Food and Feed Safety Risk Assessment (EFSA, 2014a)
6. EFSA guidance on Statistical reporting (EFSA, 2014b)
7. EFSA Scientific Committee guidance on Uncertainty assessment (on-going)
8. EFSA Scientific Committee guidance on Weight of Evidence (on-going)
9. EFSA Scientific Committee guidance on Biological Relevance (on-going)
10. Possible guidance on ‘Appraising existing studies’, completing the EFSA Critical Appraisal Tool already available (EFSA, 2015b) (the need for this guidance was assessed through the survey)

4.2. Need for an inventory of collections of data other than literature

The survey assessed, for each panel and scientific unit, the need for an inventory of collections of data other than literature (e.g. databases such as Eurostat) relevant to the various EFSA domains. In the questionnaire, it was specified that the inventory could be used by EFSA staff and experts in all types of scientific assessments (i.e. assessments of regulated products and more generic assessments), applicants and contractors. As with their responses to the other survey questions, each panel and unit expressed their need for this inventory as a ‘must have’, ‘nice to have’ or ‘not needed’, along with the related reasons and/or additional comments. The WG conclusions are illustrated in Box 2.

Box 2. Conclusions on the need for an inventory of collections of data other than literature

Useful to have the inventory, reinforced by the similarity of all-units/teams and all-panels distributions of results

‘Must have’ indicated by: 1 panels (PLH); 2 teams (BIOHAZ, PLH)

‘Nice to have’ indicated by: 9 panels (AHAW, ANS, BIOHAZ, CEF, CONTAM, FEEDAP, GMO, NDA, PPR); 8 units/teams (ANS, CEF, CONTAM, FEED, GMO, Nutri, Pesticides, SCER)

‘Not needed’ indicated by: panels: none; 1 team (AHAW)

32 Guidance on Uncertainty assessment: this guidance had been made available for public consultation at the time of the survey. Revised version of the guidance on Uncertainty assessment available online: https://www.efsa.europa.eu/sites/default/files/160321DraftGDUncertaintyInScientificAssessment.pdf
35 http://ec.europa.eu/eurostat
4.3. Need for regular support by the EFSA Library

One survey question designed to assess the need, also expressed as ‘*must have*’, ‘*nice to have*’, ‘*not needed*’, for regular support by the EFSA Library to WG experts and staff to e.g. develop and implement literature searches; appraise searches done by others (e.g. applicants, contractors, authors of published reviews), etc. The WG conclusions based on survey results and additional considerations are illustrated in Box 3.

**Box 3. Conclusions and additional considerations on the need for regular support by the EFSA Library**

**Conclusions on the need for regular support by the EFSA Library as perceived by the respondents and additional considerations**

**Clear need for regular support by the EFSA Library**, reinforced by similarity of all-units/teams and all-panels distributions of results (although the latter have a stronger opinion) and by the comments received in response to the survey question on ‘need for guidance on appraising literature searches’

‘*Must have*’ indicated by: 4 panels (AHAW, ANS, BIOHAZ, CONTAM); 9 units/teams (AHAW, ANS, BIOHAZ, CEF, CONTAM, FEED, GMO, PLH, Pesticides). ‘*Nice to have*’ indicated by: 6 panels (CEF, FEEDAP, GMO, NDA, PLH, PPR); 2 units (Nutri). ‘*Not needed*’ indicated by: none

The PROMETHEUS WG also highlighted the need for:

- Direct access to the EFSA Library for experts, in particular to the subscriptions to scientific journals. The WG agreed that this aspect may have other implications which would need to be assessed in consultation with the EFSA Legal and Regulatory Affairs Unit
- Access to Library subscriptions without a Virtual Private Network (VPN) card for staff
- Better communication on the available list of subscriptions and Library services. The PROMETHEUS WG noted that the EFSA Library has started to communicate on its resources, training opportunities and activities

4.4. Need for further data collections in the context of the EFSA Scientific Data Warehouse

Each panel and scientific unit was asked to indicate the need for performing and maintaining data collections through the Scientific Data Warehouse (S-DWH) project (EFSA, 2015c).

Through this project, EFSA currently performs and maintains the following data collections:

- dietary consumption (Comprehensive Food Consumption, EUMenu);
- chemical contaminants’ occurrence tested in laboratory studies;
- pesticides’ residues;
- food additives’ occurrence;
- zoonoses (prevalence, antimicrobial resistance, foodborne outbreaks, animal disease, animal population);
- chemical hazard (toxicological data on chemical substances, collected from EFSA opinions);
- compendium on botanicals.36

The data on chemical contaminants occurrence, pesticides’ residues, and food additives’ occurrence are collected in Standard Sample Description (SSD) format (EFSA, 2010b). Further data collections to be included in the S-DWH during 2016 are:

- Veterinary Medicinal Product residues (compliant with the Standard Sample Description ver. 2.0 format) (EFSA, 2013);

molecular typing data (compliant with the Standard Sample Description ver. 2.0 format) (EFSA, 2013); 
- food composition data.

The data collections indicated by the panels and units through the survey are reported in Appendix A.

### 4.5. Assessments of regulated products: need for further information on dossier preparation for applicants

In the field of regulated products at EFSA, applications may contain data generated *de novo* by the applicants and existing data that applicants extract from other sources (e.g. literature).

The first PROMETHEUS report (EFSA 2015a) outlines the importance for applicants to apply the 4-step process ‘plan-carry out-verify-report’ and highlights that the protocol for the assessment is already covered to varying degrees by the content of the legislative acts and technical documents\(^\text{37}\) (i.e. the ‘regulatory framework’), which typically define the data requirements and methods to be applied for dealing with those data.

The PROMETHEUS survey sought to collect the views of the panels and units/teams on the completeness of the various regulatory frameworks, with regard to the process for evidence use: i.e. assess the extent to which, in the various EFSA fields, the combination of legislative acts and complementary technical documents (EFSA and non-EFSA) is considered to provide sufficient detail on the data requirements and related methods for collecting, appraising, analysing and integrating such data.

This part of the questionnaire was restricted to the EFSA panels and scientific units dealing with regulated products: i.e. six panels and their supporting units/teams (ANS, BIOHAZ, CEF, FEEDAP, GMO and NDA) and the Pesticides unit. The PPR panel was not consulted on this aspect because it is not directly involved in dossier evaluation.

One survey question asked whether there is the need, in the regulatory framework, for further description of five main aspects related to the preparation of the dossiers. These are reported in Table 4, together with the PROMETHEUS WG conclusions and considerations. No further suggestions for this area were proposed through the additional open question present in the questionnaire.

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37 Technical documents can be EFSA and non-EFSA guidance or guidelines (e.g. OECD guidelines – http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm)
Table 4. Conclusions and additional considerations on the need for further information on dossier preparation for applicants

<table>
<thead>
<tr>
<th>Aspect for which further description may be needed in the regulatory framework, as illustrated in the questionnaire</th>
<th>Conclusions on the need for further description of the aspect, as perceived by the respondents and additional considerations based on group discussion</th>
</tr>
</thead>
</table>
| 1 Additional ‘data requirements’ (i.e. data and information that the applicant must provide to allow EFSA to carry out a complete assessment)  
‘Must have’ indicated by: 2 panels (BIOHAZ, FEEDAP); units/teams: none  
‘Nice to have’ indicated by: 2 panels (GMO, NDA); 1 team (BIOHAZ)  
‘Not needed’ indicated by: 2 panels (ANS, CEF); 6 teams/units (ANS, CEF, FEED, GMO, Nutri, Pesticides) | For the first two aspects, the survey results differed from area to area and could be considered at panel and unit/team level  
In some cases (ANS and CEF), nothing was highlighted for ‘data requirements’ by either the panels or the supporting team  
The varying answers of the FEEDAP panel and supporting FEED unit were explained by a different interpretation of the survey question. The panel wanted to highlight the frequent lack of compliance of the applicants with regard to the data requirements, rather than an incompleteness of the regulatory framework, resulting in the need for the panel to ask for additional information |
| 2 The methods that should be applied by the applicant for generating and reporting the data required to support the application. This would include all aspects that help to ensure the reliability of the studies conducted by the applicant: how to minimise bias and/or adjust for confounding in the specific study design; how to minimise risk of random error (e.g. power analysis or setting precision targets). Examples of aspects to consider: appropriate sampling size; number of replicates; appropriate test material; blinding; randomisation; dealing with missing data, etc.  
‘Must have’ indicated by: 3 panels (BIOHAZ, FEEDAP, NDA); Units/teams: none  
‘Nice to have’ indicated by: 1 panel (GMO); 5 units/teams (ANS, BIOHAZ, CEF, FEED, Nutri)  
‘Not needed’ indicated by: 2 panels (ANS, CEF); 2 units (GMO, Pesticides) | With regard to the last 3 aspects, there is a clear need for further description of them in the various EFSA regulatory frameworks, with the exception of the one related to plant protection products  
The Pesticides unit commented ‘However an update of the current guidance on how to conduct literature searches in the framework of the pesticides regulation is considered essential for addressing weaknesses on some aspects such as appraisal of literature |
| 3 The methods that should be applied by the applicant for retrieving, selecting and appraising literature studies (including reporting)  
‘Must have’ indicated by: 5 panels (ANS, BIOHAZ, CEF, FEEDAP, NDA); 3 units/teams (CEF, FEED, GMO)  
‘Nice to have’ indicated by: 1 panel (GMO); 3 units/teams (ANS, BIOHAZ, Nutri)  
‘Not needed’ indicated by: panels: none; 1 unit (Pesticides) | |

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38 In the questionnaire, the term ‘regulatory framework’ was used to refer to the combination of legislative acts and technical documents (EFSA and non-EFSA).
4.6. Need for a plain language summary in EFSA scientific outputs

One survey question asked each panel and unit/team on the need for a ‘plain language summary’ in their scientific outputs, describing the findings of an output in everyday language, understandable by a non-scientific audience. The PROMETHEUS WG conclusions on the survey results are reported in Box 4.

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<table>
<thead>
<tr>
<th>Aspect for which further description may be needed in the regulatory framework,(^{38}) as illustrated in the questionnaire</th>
<th>Conclusions on the need for further description of the aspect, as perceived by the respondents and additional considerations based on group discussion</th>
</tr>
</thead>
</table>
| 4 | The methods that should be applied by the applicant for extracting and validating data from sources other than literature (including reporting)  
'\textit{Must have}' indicated by: 4 panels (ANS, BIOHAZ, CEF, FEEDAP); 2 units/teams (CEF, GMO)  
'\textit{Nice to have}' indicated by: 2 panels (GMO, NDA); 4 units/teams (ANS, BIOHAZ, FEED, Nutri)  
'\textit{Not needed}' indicated by: Panels: none; 1 unit (Pesticides) |  
These results are aligned with those on the need for guidance on appraising ‘existing studies’ (e.g. literature studies), for which a clear need was indicated by the respondents. This guidance would be applicable to the applicants as well.  
Overall, the PROMETHEUS WG noted that various initiatives are being considered at panel level for updating and integrating existing guidance  
The methods for analysing and integrating data will be partially covered by the three SC guidance on Uncertainty assessment, Weight of evidence and Biological relevance (Box 1 above) |
| 5 | The methods that should be applied by the applicant for analysing and integrating all data (and reporting)  
'\textit{Must have}' indicated by: 5 panels (ANS, BIOHAZ, CEF, FEEDAP, NDA); units/teams: none  
'\textit{Nice to have}' indicated by: 1 panel (GMO); 6 units/teams (ANS, BIOHAZ, CEF, FEED, GMO, Nutri)  
'\textit{Not needed}' indicated by: panels: none; 1 unit (Pesticides) |
**Box 4. Conclusions on the need for a plain language summary**

### Conclusions on the need for a plain language summary as perceived by the respondents

**Useful to have a plain language summary of EFSA scientific outputs**, although the difference in the distribution of results between all-units/teams and all-panels reveals much stronger support from the panels

- *'Must have'* indicated by: 3 panels (AHAW, PLH, and PPR); units/teams: none. Reasons expressed by one panel for this being a must refer to the general need for special 'extension' approaches (e.g. video documentation, apps, or other outputs)

- *'Nice to have'* indicated by: 6 panels (ANS, BIOHAZ, CEF, CONTAM, GMO, NDA); 6 units/teams (ANS, CONTAM, GMO, Nutri, PLH, Pesticides)

- *'Not needed'* indicated by: 1 panel (FEEDAP); 5 units/teams (AHAW, BIOHAZ, CEF, FEED, and SCER). Reasons expressed by some units for this not being a need include: *'this is already covered by the communication activities that should translate scientific language into everyday language; EFSA outputs are per definition scientific and that may oversimplify the conclusions and recommendations; it should be answered at strategic and corporate level’*

The view of the PROMETHEUS WG is that it would be useful for some outputs but not all. The WG also noted that EFSA is currently investigating the value of the concepts of a plain language summary among the external stakeholders in order to make an informed decision in this respect.

### 4.7. Methodological needs in the area of outsourcing data collection, appraisal, analyses and integrations

EFSA is currently promoting a centralised process for outsourcing data collections, appraisal, analyses and integrations (including literature reviews) (e.g. by means of framework contracts or frameworks partnership agreements).

This survey section was restricted to EFSA scientific staff. It assessed the possible need for a manual for EFSA staff, for drafting the technical specifications (scientific part) of calls for tender on data collections, appraisals, analyses and integrations (including literature reviews), and it also asked for any further suggestions for strengthening the outsourcing process thereof.

As for the manual, in the survey, it was specified that, in line with all relevant EFSA guidance, it would illustrate the method that the contractor should apply for: collecting data (including controlled terminology and data dictionaries); appraising study reliability; validating data; analysing and integrating evidence; and reporting the entire process and results (along with defined templates). The manual would enhance the harmonisation of technical specifications (and in turn of outsourced deliverables) and, at the same time, allow flexibility depending on the topic.

The survey also asked whether the manual should be mandatory or if any other aspects would be required for facilitating its implementation.

The PROMETHEUS WG conclusions on the survey results are reported in Box 5.
Box 5. Conclusions on the need for a manual to assist drafting the technical specifications of calls for tender on data collections, appraisals, analyses and integrations

Conclusions on the need for a manual for drafting the technical specifications of calls for tender on data collections, appraisals, analyses and integrations, as perceived by the respondents

Clear need for this manual

Must have’ indicated by 3 units/teams (CEF, GMO, Pesticides)

‘Nice to have’ indicated by 6 units/teams (ANS, CONTAM, FEED, Nutri, PLH, SCER)

For 6/9 units/teams indicating that the manual is a ‘Must have’ or ‘Nice to have’ the manual should also be mandatory

‘Not needed’ indicated by 2 teams (AHAW, BIOHAZ)

As a further suggestion to strengthen the process for outsourcing data collections, appraisals, etc., the BIOHAZ team indicated that guidance on the evaluation of outsourced reports would be very useful.

4.8. Need for training of experts and staff

The survey assessed the possible need for training in the process for evidence use. In particular, the panels and units were asked to indicate the need for four possible types of training for staff and experts:

1. Training in development of protocols for scientific assessments (e.g. how to translate the terms of reference into clearly formulated questions; literature scoping to prepare an overview of the available evidence; how to define what data to collect and by what means);
2. Training in literature search techniques covering, such as how to design a search string; how to identify and search relevant information sources (e.g. bibliographical databases, grey literature search engines); and how to appraise a literature search done by others (e.g. by applicants, contractors or available in a published review);
3. Training in evidence appraisal (e.g. literature studies, databases);
4. Training in statistics (basic and advanced and including specific statistical methods; e.g. meta-analysis).

In the questionnaire, no details were given on the possible format (e.g. face-to-face or e-learning) or duration of training. The respondents were invited to provide further comments or suggestions.

The PROMETHEUS WG conclusions on the survey results are reported in Table 5. Overall conclusions and considerations were based on answers to open questions and consensus in group discussion:

- In general, there is a perceived higher need for training for staff than for experts. This could be a result of training in these horizontal methodological aspects being more important for EFSA staff in view of its role supporting experts in the panels and increasing the consistency of methods within EFSA.
- Training can provide information on the basic principles and their application and should be complemented by technical and scientific support by specialists on request of the panels.
- The value to EFSA will increase the sooner the training is delivered in the panel cycle.
- Online training should be available.

The PROMETHEUS WG noted that EFSA is currently considering implementing a Learning Management System (i.e. an online platform that will be used to deliver education courses or training programmes). It will help in organising the courses in terms of their creation, registration of participants and evaluation. It will also give a chance to the participants to interact with each other through a forum and to access the material and e-learning modules at any time and place.

39 See definition in footnote 24.
Table 5. Conclusions on the need for training for staff and experts

<table>
<thead>
<tr>
<th>Type of training and target audience as indicated in the questionnaire</th>
<th>Conclusions on the need for the training as perceived by the respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Protocol development for staff</td>
<td>Clear need for this training. Higher sense of need expressed by panel members compared to staff</td>
</tr>
<tr>
<td></td>
<td><em>Must have</em> indicated by: 5 panels (ANS, BIOHAZ, CEF, CONTAM, GMO); 3 units/teams (AHAW, CEF, Nutri)</td>
</tr>
<tr>
<td></td>
<td><em>Nice to have</em> indicated by: 4 panels (AHAW, NDA, PLH, PPR); 6 units/teams (ANS, CONTAM, FEED, PLH, Pesticides, SCER)</td>
</tr>
<tr>
<td></td>
<td><em>Not needed</em> indicated by: 1 panel (FEEDAP); 2 units/teams (BIOHAZ, GMO)</td>
</tr>
<tr>
<td><strong>2</strong> Protocol development for experts</td>
<td>General trend useful having this training</td>
</tr>
<tr>
<td></td>
<td><em>Must have</em> indicated by: Panels: none; 1 team (CEF)</td>
</tr>
<tr>
<td></td>
<td><em>Nice to have</em> indicated by: 9 panels (AHAW, ANS, BIOHAZ, CEF, CONTAM, GMO, NDA, PLH, PPR); 8 units/teams (AHAW, ANS, CONTAM, FEED, Nutri, PLH, Pesticides, SCER)</td>
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<tr>
<td></td>
<td><em>Not needed</em> indicated by: 1 panel (FEEDAP); 2 units/teams (BIOHAZ, GMO)</td>
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<tr>
<td><strong>3</strong> Literature search techniques for staff</td>
<td>Clear need for this training. Good agreement between panel members and staff</td>
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<tr>
<td></td>
<td><em>Must have</em> indicated by: 5 panels (ANS, BIOHAZ, CONTAM, FEEDAP, PPR); 6 units/teams (AHAW, BIOHAZ, CEF, CONTAM, GMO, PLH)</td>
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<td></td>
<td><em>Nice to have</em> indicated by: 5 panels (AHAW, CEF, GMO, NDA, PLH); 5 units/teams (ANS, FEED, Nutri, Pesticides, SCER)</td>
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<tr>
<td></td>
<td><em>Not needed</em> indicated by: none</td>
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<tr>
<td></td>
<td>This training will start in the second half of 2016</td>
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<tr>
<td><strong>4</strong> Literature search techniques for experts</td>
<td>Useful having this training. Good agreement between panel members and staff</td>
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<tr>
<td></td>
<td><em>Must have</em> indicated by: none</td>
</tr>
<tr>
<td></td>
<td><em>Nice to have</em> indicated by: all panels; 10 units/teams (ANS, BIOHAZ, CEF, CONTAM, FEED, GMO, Nutri, PLH, Pesticides, SCER)</td>
</tr>
<tr>
<td></td>
<td><em>Not needed</em> indicated by: Panels: none; 1 team (AHAW)</td>
</tr>
<tr>
<td></td>
<td>This training will start in the second half of 2016</td>
</tr>
<tr>
<td><strong>5</strong> Evidence appraisal for staff</td>
<td>Clear need for this training. Higher sense of need expressed by staff compared to panel members</td>
</tr>
<tr>
<td></td>
<td><em>Must have</em> indicated by: 2 panels (CONTAM, PPR); 7 units/teams (AHAW, BIOHAZ, CEF, CONTAM, GMO, Nutri, PLH)</td>
</tr>
<tr>
<td></td>
<td><em>Nice to have</em> indicated by: 8 panels (AHAW, ANS, BIOHAZ, CEF, FEEDAP, GMO, NDA, PLH); 4 units/teams (ANS, FEED, Pesticides, SCER)</td>
</tr>
<tr>
<td></td>
<td><em>Not needed</em> indicated by: none</td>
</tr>
<tr>
<td>Type of training and target audience as indicated in the questionnaire</td>
<td>Conclusions on the need for the training as perceived by the respondents</td>
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<tr>
<td>Training in some aspects of evidence appraisal will start in 2017</td>
<td></td>
</tr>
<tr>
<td>Evidence appraisal for experts</td>
<td>Useful having this training. Higher sense of need expressed by staff compared to panel members</td>
</tr>
<tr>
<td>'Must have' indicated by: 1 panel (NDA); 3 teams (CEF, CONTAM, PLH)</td>
<td></td>
</tr>
<tr>
<td>'Nice to have' indicated by: 9 panels (AHAW, ANS, BIOHAZ, CEF, CONTAM, FEEDAP, GMO, PLH, PPR); 8 units/teams (AHAW, ANS, BIOHAZ, FEED, GMO, Nutri, Pesticides, SCER)</td>
<td></td>
</tr>
<tr>
<td>'Not needed' indicated by: Panels: none; 1 team (AHAW)</td>
<td></td>
</tr>
<tr>
<td>Training in some aspects of evidence appraisal will start in 2017</td>
<td></td>
</tr>
<tr>
<td>Statistics for staff</td>
<td>Clear need for this training. Higher sense of need in staff compared to experts</td>
</tr>
<tr>
<td>'Must have' indicated by: 3 panels (ANS, CONTAM, FEEDAP); 5 units/teams (CONTAM, FEED, GMO, Nutri, PLH)</td>
<td></td>
</tr>
<tr>
<td>'Nice to have' indicated by: 7 panels (AHAW, BIOHAZ, CEF, GMO, NDA, PLH, PPR); 6 units/teams (AHAW, ANS, BIOHAZ, CEF, Pesticides, SCER)</td>
<td></td>
</tr>
<tr>
<td>'Not needed' indicated by: none</td>
<td></td>
</tr>
<tr>
<td>Training in statistics will start in 2017</td>
<td></td>
</tr>
<tr>
<td>Statistics for experts</td>
<td>Useful having this training</td>
</tr>
<tr>
<td>'Must have' indicated by: 1 panel (NDA); Units/teams: none</td>
<td></td>
</tr>
<tr>
<td>'Nice to have' indicated by: 9 panels (AHAW, ANS, BIOHAZ, CEF, CONTAM, FEEDAP, GMO, PLH, PPR); 10 units/teams (ANS, BIOHAZ, CEF, CONTAM, FEED, GMO, Nutri, PLH, Pesticides, SCER)</td>
<td></td>
</tr>
<tr>
<td>'Not needed' indicated by: Panels: none; 1 team (AHAW)</td>
<td></td>
</tr>
<tr>
<td>Training in statistics will start in 2017</td>
<td></td>
</tr>
</tbody>
</table>

### 4.9. Expert knowledge elicitation (EKE)

#### 4.9.1. Measures for facilitating the implementation of structured EKE approaches in EFSA

Each EFSA panel and scientific unit was asked to express its view on the possible measures for facilitating the implementation of structured EKE approaches in EFSA.

Possible measures pre-defined in the questionnaire were:

1. Additional training in EKE for experts and staff;
2. External elicitors to support complex EKE;
3. Implementing and harmonising best practices for EKE (e.g. knowledge network of EKE users of EFSA and other institutions; ‘steering committee’ with ambassadors from all EFSA units; regular EFSA meetings for exchange on specific problems; exchange platform; etc.).
4. EFSA contact person for elicitations to support WGs and perform elicitations when appropriate as in-house elicitor;

5. Mapping of European expertise (list of possible contacts for different areas in the food sector, when expertise from outside the WGs is needed).

The respondents were also asked to indicate any other actions to facilitate the implementation of structured EKE approaches in EFSA (and to express their priority as ‘must have’ or ‘nice to have’) and to add any other relevant comment.

The PROMETHEUS WG conclusions on the survey results and additional considerations are reported in Table 6.

Table 6. Conclusions on the need for measures for facilitating the implementation of structured EKE approaches in EFSA

<table>
<thead>
<tr>
<th>Measure for facilitating structured expert knowledge elicitation (EKE) approaches</th>
<th>Conclusions on the need for the measure as perceived by the respondents</th>
</tr>
</thead>
</table>
| 1 | Additional training in EKE for experts and staff | **General trend useful having additional training in EKE**  
Risk Assessment and Scientific Assistance (RASA) department:  
• ‘**Must have**’ indicated by: Panels: none; 2 units/teams (PLH, SCER)  
• ‘**Nice to have**’ indicated by: 4 panels (AHAW, BIOHAZ, CONTAM, PLH); 3 units/teams (AHAW, BIOHAZ, CONTAM)  
• ‘**Not needed**’ indicated by: none  
REPRO department:  
• ‘**Must have**’ indicated by: 1 panel (FEEDAP); 1 team (CEF)  
• ‘**Nice to have**’ indicated by: 4 panels (CEF, GMO, NDA, PPR); 4 units/teams (ANS, FEED, GMO, Nutri)  
• ‘**Not needed**’ indicated by: 1 panel (ANS); 1 unit (Pesticides)  
Further training in EKE is foreseen for the end on 2016/beginning of 2017 (see also next section) |
| 2 | External elicitors to support complex EKE | **Clear need for external elicitors according to RASA department panels/units. Useful for REPRO panels and units**  
RASA department:  
• ‘**Must have**’ indicated by: 1 panels (BIOHAZ); 3 units/teams (AHAW, BIOHAZ, SCER)  
• ‘**Nice to have**’ indicated by: 3 panels (AHAW, CONTAM, PLH); 1 team (PLH)  
• ‘**Not needed**’ indicated by: Panels: none; 1 team (CONTAM)  
REPRO department:  
• ‘**Must have**’ indicated by: Panels: none; 1 unit (GMO)  
• ‘**Nice to have**’ indicated by: 5 panels (CEF, FEEDAP, GMO, NDA, PPR); 4 units/teams (ANS, CEF, FEED, Nutri)  
• ‘**Not needed**’ indicated by: 1 panel (ANS); 1 unit |
<table>
<thead>
<tr>
<th>Measure for facilitating structured expert knowledge elicitation (EKE) approaches</th>
<th>Conclusions on the need for the measure as perceived by the respondents</th>
</tr>
</thead>
</table>
| (Pesticides) | **General trend useful implementing this measure**  
RASA department:  
- ‘Must have’ indicated by: none  
- ‘Nice to have’ indicated by: 4 panels (AHAW, BIOHAZ, CONTAM, PLH); 3 units/teams (AHAW, BIOHAZ, SCER)  
- ‘Not needed’ indicated by: Panels: none; 2 teams (CONTAM, PLH)  
REPRO department:  
- ‘Must have’ indicated by: 1 panel (FEEDAP); Units/teams: none  
- ‘Nice to have’ indicated by: 4 panels (CEF, GMO, NDA, PPR); 5 units/teams (ANS, CEF, FEED, GMO, Nutri)  
- ‘Not needed’ indicated by: 1 panel (ANS); 1 unit (Pesticides) |
| Implementing and harmonising best practices for EKE | **Clear need for an EFSA contact person on EKE both for RASA and REPRO departments panels and units (although higher sense of need in RASA department)**  
RASA department:  
- ‘Must have’ indicated by: 3 panels (AHAW, BIOHAZ, PLH); 3 units/teams (AHAW, BIOHAZ, SCER)  
- ‘Nice to have’ indicated by: 1 panel (CONTAM); 2 units/teams (CONTAM, PLH)  
- ‘Not needed’ indicated by: none  
REPRO department:  
- ‘Must have’ indicated by: 2 panels (CEF, FEEDAP); 1 team (CEF)  
- ‘Nice to have’ indicated by: 3 panels (GMO, NDA, PPR); 4 units/teams (ANS, FEED, GMO, Nutri)  
- ‘Not needed’ indicated by: 1 panel (ANS); 1 unit (Pesticides) |
| EFSA contact person | **Useful to implement this measure, although lower perceived need compared to other measures**  
RASA department:  
- ‘Must have’ indicated by: none  
- ‘Nice to have’ indicated by: 4 panels (AHAW, BIOHAZ, CONTAM, PLH); 3 units/teams (BIOHAZ, CONTAM, SCER)  
- ‘Not needed’ indicated by: Panels: none; 2 teams (AHAW, PLH)  
REPRO department:  
- ‘Must have’ indicated by: none  
- ‘Nice to have’ indicated by: 3 panels (GMO, NDA, PPR); 4 units/teams (ANS, FEED, GMO, Nutri)  
- ‘Not needed’ indicated by: 1 panel (ANS); 1 unit (Pesticides) |
| Mapping of European expertise | |
Measure for facilitating structured expert knowledge elicitation (EKE) approaches | Conclusions on the need for the measure as perceived by the respondents
---|---
| | ‘Must have’ indicated by: panels: none; 1 team (CEF)
| | ‘Nice to have’ indicated by: 5 panels (CEF, FEEDAP, GMO, NDA, PPR); 3 units/teams (ANS, FEED, Nutri)
| | ‘Not needed’ indicated by: 1 panel (ANS); 2 units (GMO, Pesticides)

Overall conclusions and considerations based on the answers to open questions and group discussion:

- Actual application of EKE has started in the EFSA Risk Assessment and Scientific Assistance department only. The EKE guidance was defined as not applicable to applicants (EFSA-SC, 2015). This might explain the overall greater perceived need to implement EKE in the RASA department, compared to the REPRO department.
- Implementation should continue and be extended to all panels.
- Support in decisions on the use of EKE (decision schemes, tools, and external support) is requested.
- Implementation of the uncertainty guidance is likely to increase the need for informal EKE (semi-formal), with need for related training.
- EFSA should ensure sharing of best EKE practice within the Authority, with member states and other EU agencies.

4.9.2. **Training in EKE**

This survey question was optional. The panels and units were asked to express their collective view on the need for training courses in expert knowledge elicitation for experts and staff. Four types of training, both for experts and staff, were proposed in the survey:

1. Probabilistic judgement, to enable performance and interpretation of standardised judgements based on probability distributions;
2. Steering an EKE, to permit their use in scientific risk assessments;
3. Acting as elicitor for EKE, to perform an elicitation with a group of experts and analyse the results;
4. Informal EKE within a working group, focussing on specific problems in performing an elicitation within an existing working group and/or under limited resources (mostly intended for WG chairs and staff).

The respondents were also invited to indicate any additional training needs in EKE, with related priority. The survey results are reported in Figure 2.
### Figure 2. Survey results on need for training in EKE for staff and experts and additional considerations

<table>
<thead>
<tr>
<th>panel/unit-team</th>
<th>Probabilistic judgement</th>
<th>Steering</th>
<th>Acting as elicitor</th>
<th>Informal EKE</th>
<th>Probabilistic judgement</th>
<th>Steering</th>
<th>Acting as elicitor</th>
<th>Informal EKE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RASA department</strong></td>
<td></td>
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<tr>
<td>AHAW panel</td>
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<tr>
<td>AHAW team</td>
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<tr>
<td>BIOHAZ panel</td>
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<tr>
<td>BIOHAZ team</td>
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<td>CONTAM panel</td>
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<tr>
<td><strong>REPRO department</strong></td>
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<tr>
<td>PPR panel</td>
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<tr>
<td>Pesticides</td>
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<td></td>
</tr>
<tr>
<td>ANS panel&lt;sup&gt;40&lt;/sup&gt;</td>
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<td>ANS team</td>
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<tr>
<td>CEF panel</td>
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<tr>
<td>CEF team</td>
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<td></td>
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<td>FEEDAP panel</td>
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<tr>
<td>NUTRI unit</td>
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</tr>
</tbody>
</table>

<sup>40</sup>This panel indicated that it would have preferred to answer 'Don't know'. However, the option 'don't know' was not included in the questionnaire administered during the second round of the survey (i.e. the one aiming at gathering the collective view of each panel and unit/team).
WG overall conclusions and considerations based on answers to open questions and group discussion:

- As for the previous questions on EKE, there is an overall higher perceived need in the RASA department for measures that will implement EKE in EFSA better compared to the REPRO department, and this may be a result of the actual application of EKE being started in the RASA department only;
- Panel-specific training was requested by some units;
- Training on steering an EKE, probabilistic judgements, acting as elicitor are currently planned and should be implemented as soon as possible.

Further training in EKE is foreseen.

### 4.10. Need for an interface supporting the lifecycle of EFSA scientific outputs

The survey investigated the need for a web-based interface in support of EFSA staff, experts and contractors during the entire lifecycle of a scientific output (non-application assessments; assessments of regulated products; and outsourced data collections, analyses and integrations).

In the questionnaire, it was clarified that the interface would support and facilitate the following fundamental aspects of the EFSA scientific work:

- The process for collecting data;
- The process for appraising and integrating data and evidence;
- The process for eliciting expert knowledge;
- The on-going writing of the output as the work progresses (before finalisation and transfer to Wiley, for publication).

In support of outsourced data collection, appraisal and syntheses, it was explained that the interface would facilitate:

- For EFSA staff: the drafting of the technical specifications (for outsourcing) by means of harmonised approaches and templates; the continuous monitoring during the development of the outsourced output; the archive of all data and information related to the outsourced output into EFSA repositories;
- For awarded contractors: the process for developing and reporting, in line with EFSA standards, of the outsourced output.

In addition, the interface would serve as a tool for centralising and facilitating the communication, retrieval and query of all methodological supports/tools available in EFSA.

The most relevant characteristics of the interface as defined with EFSA IT specialists and illustrated in the survey are summarised in Box 6.
Box 6. Most relevant characteristics of the proposed EFSA interface supporting the lifecycle of EFSA outputs, as described in the questionnaire

<table>
<thead>
<tr>
<th>The interface is expected to facilitate the scientific work by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Allowing easy-access, query and use of all data and information archived in: EFSA Scientific Data Warehouse; other types of EFSA repositories of data and information; non-EFSA bibliographical databases (this would be supported also by allowing the generation of search strings); other non-EFSA sources of data (e.g. Eurostat)</td>
</tr>
<tr>
<td>• Integrating the relevant EFSA and non-EFSA services and applications (e.g. EFSA document management system, EFSA risk assessment workflow, EndNote™, DistillerSR, statistical software such as R and SAS, etc.). Evidence appraisal would also be facilitated by means of standardised yet customisable Critical Appraisal Tools for different study designs</td>
</tr>
<tr>
<td>• Being web-based and allowing simultaneous work by different users (e.g. experts, staff or contractors, in case of outsourced projects), keeping track of the identity of the users; allowing versioning; allowing appropriate setting of confidentiality rules/data property and access rights, in function of the needs of the specific user group</td>
</tr>
<tr>
<td>• Being accessible without a VPN card; allowing optimisation of format depending on the support (e.g. tablet, smartphone, etc.) and extraction of Word/Excel/etc., files at any time</td>
</tr>
<tr>
<td>• Containing a forum for scientific discussion among users and providing tutorial for use (e.g. how to upload information, how to download, how to introduce customised queries) and online technical support</td>
</tr>
</tbody>
</table>

As in the other survey questions, the respondents were asked to express the need for the interface in terms of ‘must have’, ‘nice to have’, ‘not needed’ and to add any additional comments or suggestions.

The survey results show that overall it is considered useful to develop and implement the interface. Indeed, all answered ‘nice to have’, with the only exception of the FEEDAP panel (whose preference would have been the answer ‘don’t know’) and the Pesticides unit, which indicated ‘Not needed’ (highlighting the need for the current IT tools to work efficiently and that the fact that the on-going EFSA Matrix project for applications will cover the need for the interface).

However, the most important aspect, as identified by the PROMETHEUS WG after participating in the group discussions, was that the performance of the current IT tools (e.g. the EFSA document management system) is deemed unsatisfactory and would need improvement to facilitate the daily work of EFSA staff and panel members.

5. Concluding remarks

This survey represents an important opportunity to take stock of views of the EFSA scientific community (staff and panel members) on the Authority methodological needs for ‘evidence use’ (i.e. collection, appraisal and synthesis). These were defined as any elements that contribute to fulfil the principles and implement the four-step process (plan/carry out/verify/report) described in the first PROMETHEUS report on ‘Principles and process for dealing with data and evidence’. They include cross-cutting methodological documents applicable to all panels and units, training for staff and experts, instructions for applicants to integrate the existing regulatory frameworks, specialised repositories of data, IT needs, or more structured and harmonised approaches to outsourcing data collections, appraisals and syntheses. The usefulness of some existing cross-cutting guidance documents was also assessed.

The survey provides input for the EFSA management and the Scientific Committee on the methodological needs for evidence use as perceived at the time when the survey was implemented (December 2015-March 2016) and for identifying their risks, benefits, desirable characteristics,

41 The option ‘don’t know’ was not included in the questionnaire administered during the second round of the survey (i.e. the one aiming at gathering the collective view of each panel and unit/team).

42 Development of an electronic platform and processes for management of applications of regulated products
mitigation actions and priority and defining follow-up actions (thereby meeting the needs). Overall, it highlights a clear need for a comprehensive cross-panel strategy, at the same time as allowing a diversity of needs, intrinsic to the different panels’ remits, to be accommodated. Specific conclusions and recommendations are provided in the various sections and are summarised at the end of this section.

As an additional, valuable aspect, the survey served to inform and update EFSA panel members and scientific staff regarding projects and tools available for their scientific activities.

Further needs are expected to be identified as progress is made in the implementation of the case-studies testing the four-step approach described in the first PROMETHEUS deliverable and could complement the analysis illustrated in this report.

Summary conclusions and recommendations are reported in the section ‘Summary’ of this technical report.
References


EFSA (European Food Safety Authority), 2015b. Tools for critically appraising different study designs, systematic review and literature searches. EFSA supporting publication 2015:EN-836. 65 pp.

EFSA (European Food Safety Authority), 2015c. The EFSA Data Warehouse access rules. EFSA supporting publication 2015:EN-768. 18 pp.


### Glossary and abbreviations

**Glossary:**

*De novo* Latin expression meaning ‘from the beginning’, ‘afresh’, ‘anew’

*Panel of EFSA* Pool of independent scientific experts responsible for providing the scientific opinions within their own spheres of competence

*Versus* Latin word meaning ‘against’

**Abbreviations:**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHAW</td>
<td>EFSA panel and unit on Animal Health and Welfare</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
</tr>
<tr>
<td>ANS</td>
<td>EFSA panel and team on Food Additives and Nutrient Sources Added to Food</td>
</tr>
<tr>
<td>BIOHAZ</td>
<td>EFSA panel and team on Biological Hazards</td>
</tr>
<tr>
<td>CAT</td>
<td>Critical Appraisal Tool</td>
</tr>
<tr>
<td>CEF</td>
<td>EFSA panel and team on Food Contact Materials, Enzymes, Flavourings and Processing Aids</td>
</tr>
<tr>
<td>CONTAM</td>
<td>EFSA panel and team on Contaminants in the Food Chain</td>
</tr>
<tr>
<td>DCF</td>
<td>Data Collection Framework</td>
</tr>
<tr>
<td>EFSA</td>
<td>European Food Safety Authority</td>
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<tr>
<td>EKE</td>
<td>expert knowledge elicitation</td>
</tr>
<tr>
<td>ELS</td>
<td>Extensive Literature Search</td>
</tr>
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<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FEED</td>
<td>EFSA unit support the FEEDAP Panel</td>
</tr>
<tr>
<td>FEEDAP</td>
<td>EFSA panel on Additives and Products or Substances used in Animal Feed</td>
</tr>
<tr>
<td>GMO</td>
<td>EFSA panel and unit on Genetically Modified Organisms</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Lowest Observed Adverse Effect Level</td>
</tr>
<tr>
<td>MS</td>
<td>Member State</td>
</tr>
<tr>
<td>NDA</td>
<td>EFSA panel on Dietetic Products</td>
</tr>
<tr>
<td>NOAEL</td>
<td>No Observed Adverse Effect Level</td>
</tr>
<tr>
<td>NUTRI</td>
<td>EFSA unit supporting the NDA Panel</td>
</tr>
<tr>
<td>OHAT/NTP</td>
<td>Office of Health and Translation/National Toxicology Programme</td>
</tr>
<tr>
<td>PLH</td>
<td>EFSA panel and team on Plant Health</td>
</tr>
<tr>
<td>PPR</td>
<td>EFSA panel on Plant Protection Products and their Residues</td>
</tr>
<tr>
<td>PROMETHEUS</td>
<td>PROmoting METHods for Evidence Use in Scientific assessments</td>
</tr>
<tr>
<td>R</td>
<td>Software environment for statistical computing and graphics</td>
</tr>
<tr>
<td>RASA</td>
<td>EFSA department on Risk Assessment and Scientific Assistance</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<tr>
<td>REPRO</td>
<td>EFSA department on Regulated Products</td>
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<tr>
<td>RTE</td>
<td>ready-to-eat</td>
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<td>SAS</td>
<td>Statistical Analysis software</td>
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<td>Abbreviation</td>
<td>Description</td>
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</tr>
<tr>
<td>SC</td>
<td>EFSA Scientific Committee</td>
</tr>
<tr>
<td>S-DWH</td>
<td>Scientific Data Warehouse</td>
</tr>
<tr>
<td>SSD</td>
<td>Standard Sample Description</td>
</tr>
<tr>
<td>US-EPA</td>
<td>US (United States) Environmental Protection Agency</td>
</tr>
<tr>
<td>VPN</td>
<td>virtual private network</td>
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<tr>
<td>WG</td>
<td>Working group</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</tbody>
</table>
Appendix A – Data collections to be conducted and maintained in the EFSA Scientific Data Warehouse, as indicated through the survey

Table 7. Additional data collections for the Data Warehouse, indicated by AHAW panel and supporting team

<table>
<thead>
<tr>
<th>Panel/team</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHAW panel</td>
<td>Animal based measures for animal health and welfare</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Echinococcus multilocularis (continuing/annual data collection, now in DCF, should go into S-DWH)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Africa Swine Fever laboratory data collection (continuing/annual data collection, now in EFSA data collection framework – DCF, should go into S-DWH)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Geographical distribution and prevalence of vectors (continuing/annual data collection, now in DCF, should go into S-DWH)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>AHAW team</td>
<td>Data collection on animal based measures of welfare (same as proposal from panel above)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Efficacy of preventive and control measures of animals diseases</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Geographical distribution and prevalence of animal diseases (note: already in zoonoses)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Infection dynamics after experimental infection with disease agents affecting livestock and pets</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
### Table 8. Additional data collections for the Data Warehouse, indicated by ANS panel and supporting team

<table>
<thead>
<tr>
<th>Panel/team</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
</table>
| **ANS panel** | **Food composition**  
(note: inclusion in S-DWH already foreseen)  
**Data collection on specifications of regulated compounds, at least with information on impurities that may be present, especially those that are genotoxic or both genotoxic and carcinogenic**  
**Data collection on occurrence uses using the food labelling ingredients information with market share of food supply**  
**Food concentration data for all relevant regulated and no regulated compounds based on a same total diet survey food sampling strategy implemented by MS at European level**  
(note: database and data model already available to collect these data, there is an issue of data generation rather than data collection) | X         |              |
| **ANS team** | **Food supplements: information on their composition and more detailed consumption data**                                                                                                                                                                                                                                               |           | X            |

### Table 9. Additional data collections for the Data Warehouse, indicated by BIOHAZ panel and supporting team

<table>
<thead>
<tr>
<th>Panel/team</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BIOHAZ panel</strong></td>
<td><strong>Nothing was indicated</strong></td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>BIOHAZ team</strong></td>
<td><strong>The molecular typing data collection should be extended to be able to handle DNA sequence data and to provide linkage to external international data repositories</strong></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Table 10. Additional data collections for the Data Warehouse, indicated by CEF panel and supporting team

<table>
<thead>
<tr>
<th>Panel/team</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEF panel</td>
<td>Technical conversion factors/Raw agricultural commodity factors/Processing factors Standard recipe data (note: work is on-going on this conversion factors to be used for consumption data)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Extraction of No Observed Adverse Effect Level (NOAEL)/Lowest Observed Adverse Effect Level (LOAEL) data from e.g. flavouring opinions (note: covered in the chemical hazard database)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Food packaging usage statistics, storage statistics (time/temperatures) and migration data (e.g. the MATRIX project, the FACET tool) (Note: the first two are covered in the EFSA MATRIX project)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>CEF team</td>
<td>Food Ingredients and recipes</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Extension of database on evaluated substances in the EU member states, then in the US. Development of a pan-European database on chemical hazard and evaluation carried out by institutions including EFSA, the German Federal Institute for Risk Assessment (BfR), the US Food and Drug Administration (FDA), etc.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical data, e.g. hospital monitoring for food-related diseases, data on food allergenicity</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Molecular pathways database (e.g. Adverse outcome pathways)</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Table 11. Additional data collections for the Data Warehouse, indicated by CONTAM panel and supporting team

<table>
<thead>
<tr>
<th>Panel/team</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTAM panel</td>
<td>Feed consumption database for farmed livestock and companion animals in the EU</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>CONTAM team</td>
<td>/</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>
### Table 12. Additional data collections for the Data Warehouse, indicated by FEEDAP panel and supporting unit

<table>
<thead>
<tr>
<th>Panel/unit</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEEDAP panel/FEED unit</td>
<td>Feed composition</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>FEEDAP panel/FEED unit</td>
<td>Feed additives inventory with sales data in EU member states</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>FEEDAP panel/FEED unit</td>
<td>Data/assessments from European Chemicals Agency (ECHA), European Medicines Agency (EMA), Food and Drug Administration (FDA), Joint FAO/WHO Expert Committee on Food Additives (JECFA), CODEX Alimentarius</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>FEEDAP panel/FEED unit</td>
<td>An extension of chemical hazards: toxicological data from assessments performed outside EFSA on chemicals of EFSA interest (other EU authorities, MS authorities, non-EU authorities)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>FEED unit</td>
<td>Animal and feed production data</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

### Table 13. Additional data collections for the Data Warehouse, indicated by GMO panel and supporting unit

<table>
<thead>
<tr>
<th>Panel/unit</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMO panel</td>
<td>Compositional data of GMO and comparators</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO panel</td>
<td>Agronomic and phenotypic data of GMO and comparators</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO panel</td>
<td>Epidemiological data/publications of food/supplements/additives/pesticides/contaminants/etc. and incidence of disease</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO panel</td>
<td>Exposure data (consumer groups by region, age, gender, etc.). Food safety issues that arise across EU (e.g. BSE) (note: Consumption data are available. Having occurrence values from post marketing surveillance, exposure may be calculated. The Rapid Alert System for Food and Feed (RASFF) is not currently integrated with the EFSA data warehouse)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO unit</td>
<td>Compositional data of GMO and comparators</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO unit</td>
<td>Agronomic and phenotypic data of GMO and comparators</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO unit</td>
<td>Proteins (e.g. newly expressed in genetically modified plants)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO unit</td>
<td>Allergens</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO unit</td>
<td>Protein toxicology</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO unit</td>
<td>Information on imported genetically modified varieties</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>GMO unit</td>
<td>Reference variety data</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
### Table 14. Additional data collections for the Data Warehouse, indicated by NDA panel and supporting unit

<table>
<thead>
<tr>
<th>Panel/unit</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NDA panel</strong></td>
<td>Database on non-food components</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>A EU environmental database: i.e. an environmental exposure database to nutrients/contaminants through other sources (different from diet) at the European level</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Data about allergens and their occurrence in foods</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>NUTRI unit</strong></td>
<td>Data collection on food allergy in EU dietary surveys is needed for allergen risk assessment for labelling purposes</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

### Table 15. Additional data collections for the Data Warehouse, indicated by PLH panel and supporting team

<table>
<thead>
<tr>
<th>Panel/team</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PLH panel</strong></td>
<td>Comprehensive database of plant movement within the EU; e.g. the database on importations of plants for planting from Third Countries developed under the ISEFOR EU research project (Increasing sustainability of European forests: Modelling for security against invasive pests and pathogens under climate change)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Comprehensive database on plant quarantine pest outbreaks outside EU</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Early warning on new or incoming pests in the EU territory</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Distribution and incidence of plant pests and plant diseases in the EU (NUTS 1 spatial scale) (NUTS = Nomenclature of Territorial Units for Statistics)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Information on variation in crop husbandry agricultural/horticultural practices across Europe</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Detailed information on trade flows of plants and plant products at greater detail than currently provided by CN (Combined Nomenclature) codes/HS (Harmonized System) codes in Eurostat</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Database of all findings of plant diagnostic clinics in the EU (comparable to the National Plant Diagnostic Network in the USA)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>PLH team</strong></td>
<td>Geographical database including land use at the level of crop, land cover, vegetation, crop distribution, soil, water and other terrain distribution</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Cropping practices</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Pathways: import/export of plants for planting and of risky plant commodities not covered in detail by EUROSTAT (e.g. pallets)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Plant products processing and waste treatments</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Climatic/weather data</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
### Table 16. Additional data collections for the Data Warehouse, indicated by PPR panel and Pesticides unit

<table>
<thead>
<tr>
<th>Panel/unit</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PPR panel</strong></td>
<td>Real time Geographic Information System (GIS) maps of pesticides usage</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Health statistics on an EU wide basis</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Pesticides unit</strong></td>
<td>/</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

### Table 17. Additional data collections for the Data Warehouse, indicated by the SCER unit

<table>
<thead>
<tr>
<th>Panel/unit</th>
<th>Data collection</th>
<th>Must have</th>
<th>Nice to have</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SCER unit</strong></td>
<td>Database on plant pests</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Type of packaging in contact with food</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Data on wildlife species occurrence</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>population viability in agricultural areas (nice to have)</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>