

Fact sheet for timely and efficient consideration of uncertainties

The start of the work on the uncertainty analysis often occurs towards the end of the work on the Restriction Report. However, usually, analysts experience regrets of not having considered uncertainties earlier in the process of writing the report. This is because there tends to be a lack of time in the final work stages and the need to revisit and reassess some elements of seemingly completed sections of the Restriction Report suggests inefficiencies in the overall workflow. To support timely and efficient consideration of uncertainties, a factsheet with an overview of the steps in uncertainty analysis and recommendations for tasks to complete during the work on the respective chapters of the Restriction Report is provided. The steps and tasks described in the following refer to the corresponding main document “Guiding principles for uncertainty analysis in Annex XV Restriction Reports – a proposal based on EFSA’s guidance material”. More detailed information can be found in this document.

Step 1 – Identify uncertainties

Task 1.1: Systematically examine every part of the Restriction Report for uncertainties, including inputs to the assessment and methodologies used in the assessment (e.g. statistical methods, calculations or models, reasoning or expert judgement).

This can already be done while working on each section of the Restriction Report and should entail checking the used data, assumptions and methodologies for examples of uncertainties (see table below).

Table 1. Non-exhaustive collection of examples of uncertainties¹.

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

When screening for uncertainties, it may be of help to think about what the assessment in the Restriction Report would look like with complete knowledge (i.e. in the absence of uncertain elements). Note that it is not the goal of the screening to find uncertainty in all inputs or selected approaches to the assessment (applying the mindset “nothing is certain”). The selection of a list of relevant uncertainties is linked to the (realistic) expectation that the decision maker would have towards the outcome of the scientific assessment and the elements that the decision maker would be interested to be informed about before using the results of the Restriction Report.

¹ See: <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2018.5122> – Page 44ff.

Task 1.2: Present and describe identified uncertainties.

Whenever an uncertainty is spotted during the work on the main parts of the Restriction Report, a brief description of uncertainties can directly be documented in the following table (to be inserted in the section for uncertainty analysis).

Table 2. Identified uncertainties in the assessment

Section of the Restriction Report	Identified uncertainties		Source of uncertainty	
	No.	Description of the uncertainty	Assessment input	Assessment methodology
[Section 1.4, Baseline]	1	[..., e.g.: Quantity of Product X placed on the EU market is unknown and difficult to approximate.]	[X]	
	2	[..., e.g.: The calculation of the cost of lost jobs lacks required information about the real gross wages of dismissed employees. A variety of different positions within a company are affected.]		[X]
[...]	[...]	[...]	[X]	[X]

Task 1.3: Check if some of the identified uncertainties are standard uncertainties

Any standard uncertainties that are explicitly or implicitly addressed by the provisions of a standardised procedure/assessment element, i.e. that should have been assessed when the standardised procedure was established, can be set aside (lower priority).

Step 2 – Prioritise uncertainties

Task 2.1: Analyse sensitivities of intermediate results (e.g. of the output of a model used for calculation) to the uncertain elements, i.e. to the possible range of inputs and/or methodological choices that were reported as identified uncertainties.

For each identified uncertainty, it is important to show the consequence of using other possible inputs and/or methodological choices than those used in the main part of the Restriction Report. This step can already be prepared while working on the different sections of the Restriction Report by documenting the following information (e.g. in an excel file).

1. The range of values or choices that are considered possible (e.g. best case, worst case, mean, median, other relevant possibilities)
2. Repeated calculations under consideration of the full range of different possible inputs and/or methodological choices, and
3. Comparison of the differences in the intermediate results of the relevant models.

Task 2.2: Analyse the influence of uncertainties on the results and conclusions of the Restriction Report.

Influence analysis builds on the performed sensitivity analysis by reviewing the pathways and thresholds for different inputs and/or methodological choices in the assessment to affect other parts of the assessment and ultimately the overall results and conclusions of the Restriction Report (not only the intermediate output variables). While working on the Restriction Report information on the cascade of effects that could start with a variation in an uncertain value or choice can already be documented. This includes:

1. Describing the cascade of effects triggered by a change in an uncertain element,
2. Measuring the impacts of assuming the best- and worst-case scenarios for each uncertainty on the results and conclusions of the Restriction Report (e.g. break even points), and
3. Performing a collective best-case and worst-case analysis demonstrating the change in the results and conclusions of the Restriction Report when all uncertain elements are set equal to their respective best-case assumptions and when set equal to their respective worst-case assumptions.

The last step helps to gain a better understanding of the collective impact of the identified uncertainties on the assessment results and corresponding conclusions of the Restriction Report, i.e. the robustness of the end results.

Task 2.3: Prioritise the identified uncertainties by ranking them according to the relative contribution of each source of uncertainty to the uncertainty of the Restriction Report as a whole (using a combination of the magnitude of uncertainty shown by sensitivity analysis and the impact on the results of the assessment shown by influence analysis).

For example, the following ranking may be used:

- **Priority 1:** Uncertainties of largest magnitude and highest potential impact on the result of the Restriction Report
- **Priority 2:** Uncertainties of comparatively small magnitude but comparatively high potential impact on the result of the Restriction Report
- **Priority 3:** Uncertainties of comparatively large magnitude but comparatively low potential impact on the result of the Restriction Report
- **Priority 4:** Uncertainties of smallest magnitude and lowest potential impact on the result of the Restriction Report

The remaining steps can be performed when the more formal work on the uncertainty analysis starts, i.e. when the main analysis has been completed.

Step 3 – Grouping of uncertainties

Task 3.1: Take a moment to consider how to group uncertainties (creating parts of the uncertainty analysis) and how to later combine the findings of the analysis in each part to characterise overall uncertainty.

Task 3.2: Divide the uncertainty analysis into an appropriate number of parts and communicate the structure.

Step 4 – Estimate probabilities of the effects of uncertainties

Task 4.1: Decide how to express uncertainty about the elements that have potential to change the conclusions of the Restriction Report (i.e. how to express the likely hood of variation in the uncertain element to change the conclusion of the Restriction Report).

Task 4.2: Evaluate each uncertainty by assigning a probability judgement to the different possible outcomes for an uncertain element (i.e. the range of possible answers or values) or, alternatively, by utilising appropriate qualitative techniques.

Step 5 – Combine uncertainties to characterise overall uncertainty

Task 5.1: Decide how to combine quantified uncertainty to arrive at a quantitative characterisation of overall uncertainty.

Task 5.2: Combine all quantified uncertainties (i.e. probabilities) to characterise overall uncertainty about the results and conclusions of the Restriction Report.

Task 5.3: Take account of the contribution of any additional uncertainties.

Task 5.4: Check for any unquantified uncertainties and, if applicable, describe them qualitatively.

Task 5.5: Evaluate whether the result of the uncertainty analysis is sufficient for decision making.