Annex 4: Analytical methods

INTRODUCTION

Due to the two distinct issues covered, the Impact Assessment is not based on a single methodology, but rather on a variety of qualitative and quantitative approaches that have been synthesised. Most Policy Options will likely induce various magnitudes of effects on operators, associated manufacturers, Member States’ Authorities, National Health Care Systems and the general public, which is very difficult to quantify at high accuracy levels at an overall EU level. The assumptions and methods used for the assessment of these impacts are described in the respective sections in Annex 7.

The following summary provides information on the analytical methods used.

1. OVERVIEW OF TASKS AND METHODS

The methods employed were developed according to the European Commission’s Better Regulation Guidelines and Toolbox, adapted based on the time available to complete the Impact Assessment support work and the report team’s wealth of practical experience in delivering Impact Assessments.

The Impact Assessment support work was structured around seven tasks, represented in Figure 1.

Figure 1: Overview of the tasks of the Impact Assessment support work

Each task was based on and/or followed the EC’s Better Regulation Guidelines and Toolbox. These tasks are described below:

- Task 1: Define and clarify the problem to be addressed
This task aimed at setting the scene by developing an overall problem definition as well as specific definitions for each of the three focus areas of this study (dental amalgam, mercury emissions from crematoria and mercury-added products).

- **Task 2: Construct the baseline scenario against which impacts of options will be assessed**
  The study considered how the status quo would likely evolve and based on that developed baseline scenarios, which form the basis for comparing the impacts of different policy options (developed, assessed and compared under tasks 3, 4 and 5).

- **Task 3: Develop policy options**
  Whilst the baseline was being defined, the study team engaged with the European Commission and stakeholders to develop a longlist of policy options that could address the problems identified, taking into account the problem drivers. As not all policy measures or actions were viable, the external expert team defined the screening criteria to shortlist the most relevant options.

- **Task 4: Assessment of impacts of identified options**
  A longlist of possible impacts was developed and screened. From these, impact categories were identified as likely to be significant for a more in-depth assessment. Across these impact categories, different types of costs and benefits were considered.

- **Task 5: Comparison of the options and concluding results**
  The evidence on impacts, costs and benefits was employed to compare policy measures and options and develop conclusions as to whether a given option would contribute to achieving set objectives and generate benefits that would likely outweigh costs.

- **Task 6: Stakeholder consultations (public and targeted)**
  Stakeholder engagement was a horizontal task and key to this support study, feeding into all of the aforementioned tasks. The consultation activities and data analysis carried out in this study included an open consultation, a targeted survey, workshops, focus groups and interviews.

- **Task 7: Additional targeted assessment**
  This task aimed at allowing the external expert team to provide ad-hoc additional targeted assessments depending on feedback received from the Regulatory Scrutiny Board and/or questions from the European Parliament of the Council. It also allows for continued support in additional discussions and/or negotiations with Member States and other stakeholders.

Multiple methods were employed across these tasks, which are presented in Table 1.
Table 1: Overview of the approach for the synthesis of evidence

<table>
<thead>
<tr>
<th>Element</th>
<th>Approach</th>
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<tbody>
<tr>
<td>Desk research</td>
<td>• Clearly set out what sources were used giving an indication of the reliability of the data sources and possible bias (for example, date of the report, geographical coverage, which stakeholder group commissioned/produced it, whether it was peer reviewed or not.)</td>
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<td></td>
<td>• Indicate what specific data gaps were there (e.g., lack of studies at the national level, or a lack of recent studies etc.) and the approach taken to fill them.</td>
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<td>Field research (survey, interviews and public consultation submissions)</td>
<td>• Indicate which stakeholders were asked about each topic and what research tools were used (interviews/surveys).</td>
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<td>• Report on the responses provided where relevant or cross-reference to the stakeholder consultation report.</td>
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<td></td>
<td>• Indicate which groups the responses came from and how representative the responses were (for surveys).</td>
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<td></td>
<td>• Reflect as to whether the input refers to facts, estimates or opinions and their relevance for the specific questions.</td>
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<td>• Indicate limitations such as low number of responses, low quality of responses, or views of some stakeholder groups not being well-represented.</td>
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<tr>
<td>Case studies</td>
<td>• Use a similar approach as for desk research presenting the relevant findings to illustrate impacts in a specific context (e.g., country, product, issue)</td>
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<td></td>
<td>• Identify the limitations (in terms of scope, ability to extract more general conclusions).</td>
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<tr>
<td>Technical Workshops / Focus groups</td>
<td>• Indicate which types of stakeholders participated</td>
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<td></td>
<td>• Report on the responses provided by stakeholder type</td>
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<td></td>
<td>• Indicate which groups the responses came from and how representative the responses were.</td>
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<td></td>
<td>• Reflect the level of agreement among different categories of stakeholders.</td>
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<td>Overall conclusions for impact assessment</td>
<td></td>
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<tr>
<td>Synthesis of evidence</td>
<td>• Set out clear conclusions for the specific impacts drawing together the evidence presented from the different assessment methods</td>
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<td></td>
<td>• Compare to what was anticipated in the baseline Reflect and comment on the balance and strength of evidence and conclusions (triangulation or cross-checking of conclusions from alternative sources)</td>
</tr>
<tr>
<td>Comment on level of certainty and robustness of conclusions</td>
<td>• Summarise the level of certainty of the conclusions based on the robustness of available evidence and taking into account the nature of the sources used.</td>
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<td>• Be clear on where conclusions are stemming from the stakeholder input and where they are stemming from the literature review. For example, conclusions based predominantly on the online stakeholder consultation that were not possible to triangulate (or at least cross-check) with other sources will need to</td>
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The **analysis of problems** followed the major steps advised in BR Guidelines Tool #14. For the **Intervention logic**, links between problem drivers and policy options were established.

The development of the **baseline and analysis of options**, including the development of baseline, was based on the principles set out in BR Guidelines Tool #17. In particular, an initial set of (sub)policy options were screened by using a set of criteria for determining which options to include or not as advised in BR Guidelines Tool #17.

A description and, where possible, quantification of the economic, social and environmental **impacts** of the short-listed options was performed, following BR Guidelines Tool # 19. The main direct impacts were quantified and monetised (for both the baseline and the policy options under consideration). Furthermore, indirect impacts were quantified, where possible, and if not then they were assessed qualitatively with a clear indication of their nature and likely magnitude. **Costs and benefits** identified according to the standard typology of costs (e.g., administrative, enforcement) and benefits (BR Guidelines Tool #58 and #59). The **assessment** was undertaken in line with the Better Regulation Guidelines and, in particular, Chapter 8 of the Toolbox (“Methods, models and costs and benefits”).

**Stakeholder consultation** followed the advice outlined in BR Guidelines Tools # 53 – # 56. In line with BR Guidelines Tool #54, **questionnaire surveys** were used to allow the stakeholders and the public to voice their opinions on the review of the Mercury Regulation. To avoid limitations of a questionnaire survey in terms of the focus on pre-defined answer options, open questions and follow-up **interviews** were designed. **Descriptive statistics** and MS Excel were used for the analysis of quantitative data. Visual aids were used for the presentation of quantitative data. For interpreting qualitative data **thematic analysis** was applied and supported by NVivo content analysis software.

### 2. DATA RESOURCES AND ANALYTICAL SUPPORT

Evidence utilised has been collected from literature (studies, reports, articles) to support the analyses in most of the tasks, especially in Tasks 1-5.

- Review of the core sources for this report, such as the recent Commission Review Report\(^1\), the Assessment of the feasibility to phase-out dental amalgam\(^2\) as well as the Commission’s Inception Impact Assessment and associated feedback.

- Carry out evidence mapping exercise to identify key needs and/or data gaps.

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\(^2\) Deloitte and Woods study (2020)
- Undertake a literature review through systematic web searches, coverage of a wide range of stakeholders’ sources and considering a diverse set of document types.

- Screening of literature to determine the types of information contained and the extent that the data is reliable and sound.

The output of this process is the evidence base that underpins the impact assessment.

3. **Consultations and field research**

a. **Open public consultation (OPC)**

The online OPC offered the opportunity for interested individuals from any type of stakeholder groups to give their opinion on the review of the Mercury Regulation. The OPC was launched on the Commission’s website.

b. **Targeted stakeholder engagement: online survey**

To gather more in-depth information from those stakeholders already possessing a good understanding of mercury and the associated problem areas addressed, a combination of targeted stakeholder consultation methods was used. A targeted online survey was utilised to gather the views of key groups of stakeholders, including Member States’ authorities, industry sector (individual companies or trade associations) or other types of organisations (e.g., environmental or civil society NGOs, research bodies, etc).

c. **Interviews**

Targeted telephone interviews to complement the online survey took place with representatives of regional and national competent authorities, industry associations, civil society, and other key stakeholders.

d. **Focus group**

A focus group discussion was held on mercury-added products to complement the online survey and interviews. Representatives of industry associations and the NGO community took part in the discussion. Attendance at the focus group was by invitation only.

e. **Stakeholder workshops**

Two workshops were held online.

4. **Robustness of the Evidence**

a. **Consultations**

The level of credibility varies with regard to each source of information that has been used for the assessment. In principle, sources of information that are based on measured or reported information are believed to be quite certain. However, even in these cases the

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3 [Mercury – review of EU law (europa.eu)]
robustness depends on the correct measuring and/or reporting of the parameter concerned. It is assumed that even if there are errors, these are not systematic.

In other cases, literature may draw itself on a lot of stakeholders opinion, or be based on a small sample or have other features that weaken its robustness.

Literature which originates from stakeholders with a particular vested interest are treated with greater caution. Such literature may selectively present information or present it in a certain manner to support an argument that the interested party may wish to pursue.

Stakeholder opinion presents similar risks to stakeholder-sourced literature. In their opinions, stakeholders may be seeking to manipulate the results to support their preferred outcome.

In the case of this assessment, one dentist association holds opposite views to researchers and NGOs, specifically on problem 1a (phase-out of the use of dental amalgam). In general, it opposes a short-term phase-out of the use of dental amalgam, pointing to the potential for problems in access to dental health care. Conversely, researchers and NGOs would like to see a complete phase-out of the use of dental amalgam in 2025.

b. Analytical methods

Dental amalgam

Uncertainties of the estimate

The quantification estimate bears some uncertainties, which are discussed below:

The use of the DMFT index to quantify the amount of caries in the European Union’s population: Indeed, this index is the Decayed, Missing, and filled Teeth index, meaning that not only filled teeth and teeth to treat are considered but also the missing teeth. This index is well correlated with the amount of treated caries for the population up until 40 to 50 years, when teeth removal starts to increase and outweigh cavity treatment. So, the model is expected to overestimate the total use of mercury per year.

Inconsistencies in historical data: The historical datasets used for extrapolation of the estimates are poorly collected. Most importantly, the time of recording age and the DMFT index is inconsistent. This reduces the power of forecasting. Moreover, we have extant data on DMFT per median age for every member state. Using the same to estimate a distribution across age intervals can lead to overestimation and/or high variance.

The model does not consider the replacement of failing filling material: Materials used for teeth filling when treating cavities does is not everlasting, so it needs sometimes to be replaced. The replacement was not considered due to too much uncertainty on the failure rate of the different materials as well as on the share of dental amalgam used to replace the failed materials. So, a small underestimation of the quantity of mercury used per year is expected.

The share of the dental amalgam used in tooth filling: These estimates for all Member States come from the 2012 BioIS report, and no better values could be found. Unfortunately, it cannot be said what type of deviation can be expected from this source of uncertainty.

The assumption under which the improvement of dental health in the EU follows the same trend in all Member States: Indeed, our assumption is that the evolution of dental health in different MS can be compared to Germany (for which a lot of data was available). It cannot be said what type of deviation from reality this model can cause, however, we expect it to be small.
It is believed that the overestimation due to the use of the DMFT index will compensate the underestimation due to the unconsidered replacement of failed filling material.

**Emissions from crematoria**

*Data gaps and uncertainties*

The assessment of impacts associated with measures addressing emissions from crematoria follows the same quantitative framework as used to establish baseline emissions. The uncertainties in quantification are set out in Annex 5. These include uncertainties and assumptions made in aspects including uptake of abatement technology across the EU in the baseline scenario, cremation rates across different Member States, and the use of dental amalgam across Europe. In quantifying emissions in the future baseline and measure scenarios, projections of key parameters have been made based on historical data and there are uncertainties associated with such forecasting.

Limited information could be obtained through the literature review and stakeholder consultation on the role of SMEs in the sector across Europe. It is assumed that SMEs will form at least part of the sector, especially in countries with a high number of small-capacity crematoria, but specific information upon which to base an assessment of the impacts on SMEs was not available. Further engagement with the industry through Member State surveys could provide further details which could inform a judgement on the impacts to SMEs.

**Mercury-added products**

*Data gaps and uncertainties*

For the estimation of impacts of policy measures, models were developed that allow quantitative statements on future export volumes, export values and mercury contents, at least for fluorescent lamps for general lighting purposes. The models and the associated assumptions and model parameters are described in the Annex 5. For most of the factors used, bandwidths describing the known or assumed uncertainties were used. Many of these factors and ranges were discussed with stakeholders or derived based on information from stakeholders. Some factors are based on assumptions in the absence of concrete data. These factors are discussed in detail and the range used is explained. Nevertheless, it cannot be ruled out that individual factors will turn out differently in the actual future development. For example, unforeseen political decisions in important importing countries can cause a significant drop in demand that exceeds the forecast range. Special effects, such as strong price increases for components, could make certain lamp types considerably more expensive and less attractive.

A quantitative assessment was only possible for fluorescent lamps and, with restrictions, for dental amalgam. For other lamp types as well as for other MAPs, the data material was missing. Based on the available information, however, it is assumed that fluorescent lamps have the highest export volume and dental amalgam the highest mercury content. These two products are thus the most important from an economic and environmental point of view. When a quantitative assessment of measures appeared too uncertain, either a qualitative assessment was made, or the magnitude of an effect was estimated.