Upstream meeting RSB – ENV
Impact Assessment for the Revision of the Mercury Regulation
11 January 2022

The purpose of RSB upstream meetings is for report authors and Board members to discuss informally questions concerning how to prepare the best possible report on the issue at hand. Board members give their advice in a personal capacity and advice is not binding for the subsequent Board meeting.

List of participants:

ENV: Veronica MANFREDI, [redacted], [redacted], [redacted]
[redacted], [redacted], [redacted]

RSB: Veronica GAFFEY, [redacted], [redacted], [redacted]
[redacted], [redacted], [redacted]

SG: [redacted] (A2), [redacted] (D2), [redacted] (D2)

JRC: [redacted]

DG ENV provided an overview of the ongoing work on the impact assessment for the revision of the Mercury Regulation. In particular, ENV underlined specific assessment challenges related to the three areas that the revision will focus on:

- Dental amalgam – limited information available on mercury-free alternatives and differences across the EU in terms of health and insurance systems;
- Crematoria – challenges related to the evidence base and the subsidiarity aspect (as this falls within the remit of Member States);
- Mercury-added products – the large variety of products and the impacts on global markets of possible EU measures.

Points raised in the discussion

- Board members stressed the importance of using the available evidence and expertise to produce a report that is accessible to non-experts and that can inform policy makers. To this end, it will be important to explain clearly how the initiative links to relevant international commitments. The report should also be clear about why we are acting now and what exactly is in scope (e.g. when it comes to the mercury-added products), as well as any link to related initiatives (e.g. Sustainable Products Initiative).
- Board members underscored the need to be as explicit as possible on the scale of the problem. Given the identified data challenges, it will be important to find some way (for
example, case studies, examples from particular countries, emission levels, output, sales and export estimates, number of affected EU producers) to show at least the order of magnitude of the issues. The report should also show whether the identified problem affects certain Member States more than others and would therefore potentially require longer time for a phase out. On this, it should be clarified whether a total ban is envisaged and feasible. The problem analysis should differentiate problem drivers from external factors. Problem drivers should be within the scope of the initiative. For example, a lack of dental hygiene is probably an external factor, not a problem driver.

- The **baseline** should show how the problem will evolve without the initiative, especially given that the substitution of dental amalgam seems to be happening anyway. This should include information, if possible, on whether some Member States are moving more rapidly to phase out mercury in dental amalgam.

- When presenting the **options**, the report should be clear on their content and feasibility (both technical and practical implementation). The subsidiarity dimension will be crucial in the analysis to ensure that sufficiently flexible solutions are identified, corresponding to the kinds of challenges that different Member States may face.

- All relevant **impacts** need to be identified for the different stakeholder categories affected (especially businesses and citizens) clearly showing ‘winners’ and ‘losers’. There will likely be impacts on revenues for businesses and on price for citizens as patients or customers. The cost pass through will therefore be an important element to consider. Costs and benefits should be quantified to the extent possible, also considering ‘one-in, one-out’.

- The Board highlighted the importance of the **impact on third countries and competitiveness**. It will be important to show whether and if so, how the EU intends to encourage third countries to impose similar restrictions. The report should also explain whether EU measures would apply to third country competitors and, in turn, how EU businesses would be expected to collect used products from third countries. The report should clarify how the extended producer responsibility would work in practice, including the potential link to the upcoming Sustainable Products Initiative. It should thoroughly assess the impacts on international competitiveness of EU business.

**JRC comments**

JRC made the following comments in view of future monitoring and evaluation.

1. How to measure success. The Inception Impact Assessment (IIA) states that the “initiative aims at further restricting the use of mercury in products, including dental amalgam, at EU level”, and in particular to:

   a) phase-out dental amalgam used in the EU and address mercury emission from crematoria;
   
   b) prohibit the manufacture and export of certain mercury-added products (MAPs), fostering the production and export of alternative materials.
It would be important to define indicators or measures of success overall and for each of these specific objectives. This is relevant both to compare merits of options in the impact assessment (IA), as well as for the planning of future monitoring and evaluation.

2. Measuring success on the phase-out, point (a). The residual use of mercury-based amalgam in the EU is going to impact certain dental businesses and low income households, depending mainly on the reimbursement policies in Member States. A final set of outcomes in on emissions and the environment.

- Concerning businesses: what data sources are foreseen to contain information on residual use of mercury-based amalgam? Are they going to come from residual trade of mercury-based amalgam within the EU (a trade approach), or is it foreseen to identify the sub-sector of dental practices going to be affected (sectorial approach)? Are surveys of dental practice foreseen to monitor the residual use of it or is the supply chain of mercury-based amalgam going to be monitored? The latter appears a less costly option to a survey of dental practices.

    A proper plan to obtain hard field data on the implementation of the phase out appears to be needed. A territorial dimension of the phase out is probably going to be important, as the residual use of mercury-based products may be concentrated in specific areas of the EU.

- Concerning households: is there a plan to monitor impacts on households both in terms of costs and in terms of health-related outcomes? Is there a plan to exploit data on dental costs in existing surveys of household expenditure? Are other administrative data sources (tax records) being considered? In terms of unit costs, social and private social insurance data could be used to estimate the expected reduction of the price wedge between mercury-based and mercury-free dental material. Is this foreseen?

    Emissions: how are mercury emissions originating from preparation and removal of dental amalgam, disposal, waste, human cremation and burial going to be monitored? Are specific policy interventions foreseen to reduce this practice? What data sources are foreseen on this?

3. Measuring success on point (b), the ban to manufacture and export mercury-added products (MAPs) and the plan to fostering alternative materials. It is expected that these measures will impact R&D investment and trade of alternative materials. Measuring success may involve a combination of the following areas.

- R&D: one could count the number of studies on new mercury-free dental materials that could replace dental amalgam entirely. If this is foreseen, it would help to ask a special identifier to be inserted in the acknowledgements of these studies, as this would help to trace these studies in research databases later. Is this foreseen?

- How is increasing investments and expenditure in R&D for mercury-free dental materials going to be identified within existing sources of data?

- How are prices of mercury-free dental materials going to be monitored? Are specific identifiers going to be introduced for this purpose?

- Increasing market share for safe alternatives to mercury-added products manufacturers. How is this going to be monitored?

- How can the data on these outcomes be collected more systematically for the future?

4. Joint monitoring and evaluation plan. The monitoring and evaluation of this initiative could have synergies with monitoring and evaluation of other chemical products. The administrative cost for a joint monitoring and evaluation plan with some of these other
initiatives may imply synergies and cost-savings. Enough information should however be collected to distinguish the specific contribution of the present initiative. A side effect of a joint monitoring and evaluation plan would be to see how different related initiatives are working, reinforcing each other or otherwise.

would be happy to discuss and give further input if useful.

It also shared the following piece of information, in case modelling is used in this IA:

Models used in support to Commission Impact Assessments (IA) should be made available in MIDAS, the Modelling Inventory of the Commission, at the time of publication of the IA report. If there is a plan to use simulation models, please contact the Competence Centre on Modelling at EU-MIDAS@ec.europa.eu to insert in MIDAS the description of the model as well as of its contribution to the IA. Models already used on behalf of the Commission are already included in the system; in this case, the information can be easily retrieved and updated if needed. Please note that the model descriptions included in MIDAS allow to easily generate the information required for Annex 4 of the IA report.