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From:	General Secretariat of the Council
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on mercury, and repealing Regulation (EC) No 1102/2008 - Comments from delegations

Delegations will find in the Annex comments on the abovementioned proposal received from BE, BG, DK, EL, HU, PL, and SE.

BELGIUM

Belgium would like to thank the Dutch Presidency for the compromise text proposal presented in doc. ST 7022/16. Belgium supports an as quick as possible adoption of this Regulation.

Belgium has the following comments addressing the Article 13 on Disposal of Mercury waste:

Belgium opposes to the provisions related to the Final disposal as they currently stand in the proposal. Besides, we see a contradiction in the proposal referring to (future) adoption of a delegated act (in reference to Minamata and Basle achievements) present under art 7.3. while not appearing under art 13 on Mercury waste. Please find our reasoning below, including our preferences for alternative proposal by Commission:

We consider that the current proposal contradicts the commitment of EU and its Member States in reference to the signature of the Minamata Convention. Indeed, as presented below, we request that the Mercury Guidelines under Basel are taken into accounts for defining the conditions for final storage. Therefore, we have a clear preference for drawing a reference to the Landfill directive and allow waste experts to take decision on the final storage conditions taking into consideration, in particular, further decision by Basel convention and/or the Minamata Convention in this respect. Alternatively, an Implementing act, based on the Committee presented under article 18 of the present proposal would represent an option.

History: When the conditions for the temporary storage were established under the current Regulation (Regulation (EC) No 1102/2008), Landfill directive decided that further investigation where needed regarding the permanent storage and more specifically in which chemical and physical form mercury should be stored permanently.

The present COM proposal implicitly allows storage of liquid mercury and, furthermore, allows the Member States to decide not to impose the existing conditions applicable to temporary storage for permanent storage purposes.

Storage solid or liquid? During the negotiations for the Minamata Convention, the EU and its member states called for strict conditions for the permanent storage of mercury. These should be drawn in close cooperation with the Basel Convention and be subject to the adoption by the Minamata Conferences of the Parties (COP).

During the last COP of the Basel Convention (2015), the EU agreed to the adoption of the technical guidelines on the environmentally sound treatment of mercury waste. Specifically mentioned in those guidelines state (section 186*) "Wastes Consisting of mercury or mercury compounds shouldering be stabilized and / or solidified before final disposal."

Stabilizing / solidifying of metallic mercury is a necessary and effective solution to drastically reduce the risk to the Environment: it should prevent that mercury is released into the environment should prevent that Mercury comes back on the market in metallic form. When a container of metallic mercury leaks, mercury spreads and direct negative effects can arise with it both in rock formation and salt mines given that security and stability is not certain. Furthermore, we consider that costs of continued control to prevent that mercury released into the environment can reach very high level, given the extensive period the monitoring should be applied.

Currently the Landfill Directive set out conditions for temporary storage therefore including a reference to the new Regulation to the Landfill Directive: Until there are no decision on the final storage, the storage should be considered temporary and the applicable provisions should remain valid.

Finally, it should be stressed that individual Member States should not decide whether and how to impose the defined the condition for storage, as incidents (liquid) mercury waste may have transboundary effects. The associated comitology process should take place based on an Implementing act so that participation is ensured from Member State and includes their expertise.

Belgium reserves the right to submit further comments.

BULGARIA

Having regard to the link between the Minamata Convention and the Basel Convention as regards the waste-related issues and given the fact that the *Technical guidelines on the environmentally sound management of wastes consisting of, containing or contaminated with mercury or mercury compounds*, adopted by BC COP 12, were being discussed in WPIEI Basel we recommend that the proposed mercury waste related articles of the proposed Regulation on mercury are consulted with WPIEI Basel.

Art. 2 Definitions, p. 3

We would like that the Commission once again clarifies the relation between the definitions of “mercury waste” as proposed in the regulation and “mercury wastes” as defined in the Minamata Convention.

In our understanding and as explained by COM during the meeting on 24.02.2016 for the purpose of the regulation “mercury waste” covers only the “metallic mercury (Hg, CAS RN 7439-97-6) that qualifies as waste in accordance with the definition laid down in the Waste Framework Directive” thus partially corresponding to the first part of Art. 11, point 2(a) of the Convention – “*mercury wastes means substances or objects (a) Consisting of mercury ...*”

In practice this means that the provisions of Art. 13 of the regulation would apply only to the “metallic mercury that qualifies as waste in accordance with the definition laid down in the Waste Framework Directive” while any other waste mercury compounds, wastes containing mercury and mercury compounds and wastes contaminated with mercury and mercury compounds shall be treated according to the general requirements for waste treatment laid down in the relevant waste legislation.

Art. 10 Dental amalgam

Bulgaria has a scrutiny reservation as regards the dental amalgam. This is in due respect to the significant importance of the issue at a national level. As expressed previously in our position, Bulgaria supports in principle the Commission’s approach in providing a transitional period for the implementation of the mandatory use of amalgam separators in dental practices. Nevertheless for Bulgaria the proposed transitional period of one year is insufficient in respect of introduction of amalgam separator on a national scale throughout the dental clinics and private practices. Almost all dental practices are micro enterprises and the investment in amalgam separators would be of a considerable financial burden for them. We do believe that this measure has to be adopted with the appropriate transitional period longer than the proposed one year long by the COM. We would like to hear the opinion of other MS affected.

As regarding the use of the encapsulated form of dental amalgam Bulgaria supports the proposed measure.

Art. 11 Mercury waste

Bulgaria supports the deletion of the reference to Commission Decision 2000/532/EC but sees the need of amending the first sentences as follows:

“The following shall be considered as mercury waste and disposed of without endangering human health or harming the environment”

The addition makes clear that the mercury listed in the points from (a) to (d) shall be considered “mercury waste” as defined in Art. 2, p. 3 of the regulation and shall be subject to the requirements of Art. 13.

If the leading sentence of Art. 11 is not amended we would have two separate articles in the regulation defining “mercury waste” without a clear indication that the mercury listed in Art. 11 shall be subject to the requirements of Art. 13 of the regulation.

Art. 13 Disposal of mercury waste

At this stage Bulgaria would like to maintain a scrutiny reservation on Art. 13. The following comments are preliminary:

1. Bulgaria is in favor of alignment of the requirements for permanent storage of “mercury wastes” in the regulation with the recommendations of the *Technical guidelines on the environmentally sound management of wastes consisting of, containing or contaminated with mercury or mercury compounds* that “wastes consisting of mercury or mercury compounds should be stabilized and/or solidified before final disposal and final disposal should be carried out in accordance with national and local laws and regulations.” (point 189).
2. As regards the temporary storage of mercury waste in above-ground facilities we would like to know why Recital 10 of Council Directive 2011/97/EU is not transposed to a legally-binding requirement. In our view strengthening of the requirements for temporary storage in above-ground facilities through the introduction of a time limit is necessary otherwise it represents a legal option for “permanent storage of mercury wastes in above-ground facilities”.

DENMARK

Denmark has the following comments regarding articles 10 and 13:

1) Article 10 Dental Amalgam

Denmark would like to see a more stringent requirement on the use of dental amalgam. We believe there are available alternatives on the market and that EU should move forward on this issue worldwide. The MC specifically prescribes a phase-down on the use of dental amalgam (MC Annex A, part II).

To that end we have the following text proposal:

Article 10 **Dental amalgam**

1. From 1 January 2019 onwards dental amalgam may not be used for dental care. shall only be used in an encapsulated form.
2. By way of derogation from paragraph 1 dental amalgam may be used in encapsulated form, only in:
 - a) permanat molars where an amalgam filling will outlast a plastic filling; and
 - i) only in cases limited to treatments with no possibility for desiccation,
 - ii) limited accessibility to the cavity,
 - iii) a particularly large cavity, or
 - iv) large distance to neighboring teeth or
 - b) in respect of specific medical needs when no other alternative are suited.
- 2.3. From 1 January 2019 onwards dental facilities shall be equipped with amalgam separators aimed at retaining and collecting amalgam particles. Those separators shall be maintained as required to ensure a high level of retention.
- 3.4. Capsules and amalgam separators complying with harmonised EN standards or with other national or international standards that ensure an equivalent level of quality and of level retention shall be presumed to satisfy the requirement set out under paragraphs 1 and 2.

2) Article 13 Disposal of mercury waste – permanent storage facilities

Denmark finds that the requirements for the permanent storage of mercury set forward in article 13 will pose a serious threat to human health and the environment since the requirements for permanent storage are proposed only to be in line with the requirements for temporary storage.

To that end we have the following text proposal:

Article 13
Disposal of mercury waste

1. By way of derogation from point (a) of Article 5(3) of Directive 1999/31/EC, mercury waste may be stored in one of the following ways:
 - a) temporarily stored for no longer than 5 years ~~more than one year~~ or permanently stored in salt mines that are adapted for the disposal of mercury, or in deep underground hard rock formations or in above ground facilities providing a level of safety and confinement equivalent to that of those salt mines;
 - b) temporarily stored for no longer than 5 years in above-ground facilities dedicated to and equipped for the temporary storage of mercury.
2. The specific requirements for the temporary storage of mercury waste, as laid down in Annexes I, II and III to Directive 1999/31/EC shall apply to the permanent storage facilities referred to in point (a) of paragraph 1 of this Article under the following conditions laid down in the following Annexes to that Directive:
 - a) Annex I, Section 8 (first, third and fifth indents) and Annex II to Directive 1999/31/EC shall apply;
 - b) Annex I, Section 8 (second, fourth and sixth indents) and Annex III, Section 6, to Directive 1999/31/EC shall only apply where deemed appropriate by the competent authorities of the Member States in charge of implementing that Directive.
3. Permanet storage of metallic mercury as referred to in paragraph 1, a, is only allowed after stabilisation and/or solidification of the mercury. The criteria for stabilisation and/or solidification shall be defined in Directive 1999/31/EC.
4. The Commission shall present a proposal as soon as possible and at the latest by 1 October 2017 for criterie as refered to in paragraph 3.

Rationale:

At the last Basel Convention COP (COP12) EU and its Member States agreed in the adoption of the revised BC guidelines on environmentally sound management of mercury waste. In this guideline it's stated in para 186 that" Before mercury wastes undergo final disposal according to the operations D5 and D12, they should be treated so as to meet the acceptance criteria of the disposal facilities (see section III, G, 2, (b) and (c) below). **Wastes consisting of mercury or mercury compounds should be stabilized and/or solidified before final disposal.**"

During the negotiations of the Minamata Convention the EU and its MS argued for strict requirements for the permanent disposal. The augmentation being that:

1. The stabilization / solidification of metallic mercury is effective to significantly reduce the risk of this mercury being released into the environment.
2. The stabilization / solidification of metallic mercury are an effective way to dramatically reduce the risk of that mercury being brought back into the market.

Denmark supports that this is the case and we do not find any argumentation in the impact assessment explaining why we should not request these requirements.

Technologies are available also within the EU. This is also an opportunity for EU-companies to expand in a new market.

We propose that the requirements to the permanent storage should be set out in directive 1999/31/EC and that we in the new EU Mercury regulation include a reference to this and that permanent storage is not to take place before criteria has been agreed– in line with the reference in the existing EU Mercury regulation.

Denmark has the following remarks to other articles:

3) Article 3 and 4. Import/export of mercury and mercury compounds and of mixtures listed in annex I.

According to the MC art.3.6(a) each party shall not allow the export of mercury except to a party that has provided the exporting party with its written consent, and only for the purpose of ...

We do not find that it is possible to make a comparison on export obligations between this regulation and the PIC regulation/RC provisions and as such we do not find that the explanation given so far answers the question Denmark has raised earlier on the procedure to be followed internally in the EU.

Under Minamata Convention we have a reporting obligation for each party. RC has no such obligation. And under the PIC regulation (649/2012/EC) the Agency (the European Chemicals Agency established under Regulation (EC) No 1907/2006) plays an important role – a role which will have to be played by the national authorities.

Question raised earlier:

If a MS imports mercury listed in annex I for a use allowed under the Convention and a use allowed under EU regulation from another EU member state the new EU Mercury regulation does not provide for a form (art. 6) to be filled in or a written consent.

In this case, we question if the MS, as party to the MC, can fulfil its obligations under the Convention in relation to requirements of written consent if the “notification procedure” and the written consent shall only be given to imports from countries outside the EU. Could the Commission clarify this?

And secondly, how shall a MS be able to fulfil their individual reporting obligations as each party shall report on imports of mercury?

- 4) Art. 4 - Support to the Swedish proposal to include an import ban on import of metallic mercury.
- 5) Art. 5 - Support to the Swedish proposal to include an export ban on all mercury added products which are banned under EU-law.
- 6) Article 8.3 and 8.4 Notification of new mercury-added products and manufacturing processes

In Article 8, § 4, the following changes should be made:

The Member States shall forward each notification received from an economic operator to the Commission. Upon notification by the Member State concerned, the Commission shall verify in particular whether it has been demonstrated that the new mercury-added product or new manufacturing process would provide significant environmental and health benefits and that no technically and economically feasible mercury-free alternatives providing such benefits are available.

Rationale: A “may”-provision could lead to an uneven application of the exemption from the general prohibition as set out in art. 8.1. Furthermore it will not give clarity to producers and manufactures and could be applied differently in each MS. We prefer “shall”, primarily from a harmonization perspective.

7) Article 15 - Reporting

Denmark still has some concerns to the possible extra burden which might be put on MS in regard to the questionnaire to be developed and adopted (art. 15.2).

We agree to the reporting obligation with regard to what is established under art. 21 in the MC and that the Union as well need to make a reporting based on the MS art. 21 reporting. However extra questionnaires could give a burden which we believe will not have any effect.

Denmark has a scrutiny reservation and a parliamentary reservation on the whole proposal.

GREECE

Concerning mercury amalgams for dental purposes, Greece has reservations **in Article 10.3** as already mentioned in the comments sent from delegations in the text 7011/16 on the 10th of March 2016. Greece strongly believes that **the relative standards EN** for the capsules as well as amalgam separators should be mentioned.

Rationale: There are ISO standards developed specifically for dental amalgam separators. These standards are designed to ensure that the separator removes at least 95% of waste mercury from the dental wastewater before discharge to sewer. Someone must be sure that the separator was tested using the official **EN-ISO 11143**. An ISO certified amalgam separator regularly maintained is a key to wastewater and dangerous waste compliance in dental offices. Also **ISO 24234:2015** specifies the requirements and tests methods for dental amalgam alloys that are suitable for preparation of dental amalgam together with the requirements and test methods for that dental amalgam and the requirements for packaging and making. **Purpose:** To enhance the safety of dentists and support staff and minimize the consequence that might result from the accidental damage to containers during shipping, to avoid the use and supply of non-capsulated mercury.

Why it is demanded? Because the equivalent level of the national or other standards should be proved with a specific standard, in cases of dispute in a court. In addition, this is the EU *acquis* in other legislations concerning, for example, chemicals as in **REACH** Regulation.

Examples:

In entry 3 of annex XVII of REACH:

<<Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).>>

Entry 50 of annex XVII of REACH:

The standard EN 16143:2013 (Petroleum products — Determination of content of Benzo(a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils — Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits referred to in the first subparagraph.

Greece is in favour of the rest of Article 10, meaning Articles 10.1 and 10.2. Greece supports a phase-down approach and opposes to the introduction of a ban on the use of amalgam.

Rationale: Dental amalgam continues to be a safe and effective restorative material which has advantages of ease of use and durability over some of the alternatives in a range of clinical situations. There is the risk that imposing a ban on amalgam will encourage Member States to avoid introducing or enforcing environmental controls including amalgam separators. It must not be forgotten that there remains a significant, reservoir of amalgam in the general population which will continue to need to be managed for many years to come both environmentally and clinically. The Minamata Convention sets out an integrated set of proposals to support a phase-down in use. From the perspective of environmental burden in the context of the Convention of Minamata, reduce the use of dental amalgam is desirable but not necessary complete ban, as available and affordable technology for the removal of mercury from waste water of dental practices exists.

HUNGARY

Hungary's comments regarding definitions, Chapter IV on storage and disposal of mercury waste and Art. 10 on dental amalgam:

1. We support the suggestion made by FI and UK that the expression of „mercury compounds” should be added to Article 2, para 3.
 2. We support the suggestion made by DE that „mercury sulphide” should be mentioned in Chapter IV.
 3. As to dental amalgam, we have identified several issues regarding the financial impacts of the proposal. We are preparing to provide a more detailed position at the next WPE meeting. In advance, we would like to emphasise the need for a longer preparatory period before the date of entry into force of the restrictions proposed, taking into account the different financial situations of Member States. We also propose considering other possible measures listed in Annex A Part II of the Convention instead of restricting the use of dental amalgam.
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POLAND

Article 10 (1)

No comments

Article 10 (2)

1. The scope of entities covered by the obligation to be equipped with separators

The obligation for dental facilities to be equipped with dental amalgam waste separators should be limited only to facilities where services related to the use of dental amalgam, or other dental services which generate waste containing mercury, are provided. For example, orthodontic, periodontic and prosthetic services not necessarily generate waste containing mercury, since potential procedures involving removal of multi-canal teeth filled with amalgam are performed in other specialized facilities (i.a. facilities which perform procedures under general anaesthesia). Amalgam is not used in facilities intended for youngest patients (children under 13), in which dental cavities are filled with composite materials which do not contain mercury. There is no justification for the obligation of equipping all dental facilities with amalgam waste separators and it would cause unnecessary additional costs for dental facilities where no waste containing mercury is produced. In order to clarify the scope of entities to which the obligation applies, it is proposed to apply a criterion related to the waste containing mercury generated during dental services. This is due to the fact that in Poland there is diversified scope of dental services provided in different facilities and at the same time it is difficult to determine facilities for which equipping with separators is not justified. However, according to national regulations, each dental facilities can be monitored and controlled. It should also be noted that in March this year a total of 17,526 dental facilities were registered in Poland, including 7,720 facilities which provide so-called guaranteed services, based on contracts with the National Health Fund (NFZ). It is estimated that dental amalgam may be used mostly for the purposes of free-of-charge guaranteed services. In private dental facilities amalgam is not used, however other services which cause the generation of waste containing mercury are provided. In the case of Poland, the cost of purchase and installation of the separator is no less than PLN 3,000 (approx. EUR 714), but the minimum price would usually be higher because of the need of replacing entire dental stations. The increase of costs related to the planned regulations may lead to the increase of dental service costs, which would be the cause of further reluctance to seek and continue dental treatment in less prosperous patients. Moreover, introducing the obligation of using separators in all dental facilities, irrespective of the actual needs, might be accused of providing particular support for companies producing such equipment.

Therefore, it is important that the new obligations regarding the use of separators apply to certain entities, which may actually cause the problem of mercury release into the environment, and that the obligations are introduced reasonably, without generating unnecessary expenses for other dental facilities. Moreover, regulations aimed at specified target group of entities should not cause general trend in dental service price growth, therefore they should not limit the access to dental services in middle-income UE societies.

2. Derogation solutions

The fulfilment of the obligation, which exceeds the existing European Union regulations, particularly by individual entities, requires a certain period of time for the adjustment actions to be taken. The EU Member States, including Poland, are willing to accomplish ambitious goals of environmental policy, nevertheless, the actions should be balanced and tailored to specific national conditions, especially since there are no regulations in this respect in the European Union and currently the Member States have many different approaches. For this reason it is proposed that the deadline for the implementation of the obligation is extended until 1st January 2022. The originally planned deadline of 1st January 2019 may prove to be too short to introduce the regulations and fulfil the obligation to install separators in individual dental facilities. Considering the average duration of the legislation process in Poland as well as the procedure for the conclusion of three-year agreements between the NFZ and the service providers (the agreements would specify the requirements, i.a. regarding the use of separators), the deadline for the fulfilment of the obligation under the provisions of Article 10 (2) in its current form is not viable. If the agreements between the NFZ and the dental facilities were signed in January 2018, the fulfilment of the obligation of equipping these facilities with separators as of 1st January 2019 would not be possible.

In the light of the above, Poland suggests the following wording of Article 10 (2) of the draft Regulation on mercury and repealing Regulation (EC) No. 1102/2008 of 22.10.2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury:

„[From 1 January 2022] onwards dental facilities, in which services generate dental amalgam waste, shall be equipped with amalgam separators aimed at retaining and collecting amalgam particles. Those separators shall be maintained as required to ensure a high level of retention.

SWEDEN

SWEDEN'S COMMENTS 6 APRIL 2016
(Notwithstanding possible future comments)

[...]

Chapter I **General provisions**

Article 1 **Subject matter**

This Regulation establishes measures and conditions concerning the trade, manufacture, use and interim storage of mercury, mercury compounds, mixtures, mercury-added products and the management of mercury waste **in order to ensure a high level of protection of human health and the environment from mercury. Where appropriate, Member States may apply stricter requirements than those laid down in this Regulation.**

(Comment: This principle should be reflected also in recitals.)

Rationale:

The aim of this Regulation is the protection of human health and the environment. In the field of environmental policy, Member States are, according to art.193 in TEUF, not prevented from applying stricter requirements. We want to ensure that member states states with stricter rules can keep them and we therefore want that this possibility of keeping such rules clearly expressed in the regulation, in order not to induce lower level of safety for environment or health.

Article 2 **Definitions**

For the purposes of this Regulation, the following definitions shall apply:

1. 'mercury' means metallic mercury (Hg, CAS RN 7439-97-6);
- 1a. **'mercury compounds' means any substance consisting of atoms of mercury and one or more atoms of other chemical elements that can be separated into different components only by chemical reactions;**
2. 'mercury-added product' means a product or product component that contains mercury and/or mercury compounds that were intentionally added;

3. 'mercury waste' means mercury **and metallic mercury waste converted to mercury sulphide (HgS)** that qualifies as waste, in accordance with Article 3(1), of Directive 2008/98/EC of the European Parliament and of the Council¹;

Rationale:

The definition of "mercury waste" should be extended to include "metallic mercury waste converted to mercury sulphide (HgS)", as this mercury sulphide also must be considered waste and disposed of accordingly. This change will induce changes in art. 11 and 13.

[...]

Chapter II

Trade and manufacturing restrictions concerning mercury, mercury compounds and mercury-added products

[...]

Article 4

Import restrictions

1. The import of mercury and of mixtures listed in **Part I of Annex I** for uses other than disposal as waste shall be prohibited.

~~By way of derogation from the first subparagraph, import for a use allowed in a Member State shall be allowed where the importing Member State concerned has granted its written consent to the import in any either of the following circumstances:~~

~~—— the exporting country is a Party to the Convention and the exported mercury is not from primary mercury mining as set out in Article 3(3) and (4), of that Convention; or~~

~~—— the exporting country not being a Party to the Convention has provided certification that the mercury is not from primary mercury mining and not from the chlor-alkali industry, and the importing Member State has granted its written consent to the import.~~

- ~~2. The import of mercury for use in artisanal and small-scale gold mining shall be prohibited.~~

¹ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312 of 22.11.2008, p. 3).

~~3. The national authority or authorities designated in accordance with Article 4 of Regulation (EU) No 649/2012 shall carry out the administrative functions resulting from the requirements laid down in paragraphs 1 and 2 of this Article.~~

Rationale:

Sweden prefers a general EU import prohibition of metallic mercury (option P1O2) in line with the opinion of a vast majority of stakeholders.

- Such a ban would send a strong message that use of mercury is not needed nor wanted.
- It creates less administrative burden and is easier to implement – better regulation.
- It gives incentives for an EU market of recycled mercury and thus more waste containing mercury will be collected and treated.
- As this will be a non-discriminatory measure designed to protect human health and the environment, it would be possible to defend under WTO-rules.
- There is no need to import mercury in the EU. As stated earlier, we believe that the demand for the use of mercury in the EU is highly overestimated in the I.A. The production of mercury containing lamps will most likely be substantially reduced in coming years. The mercury originating from recycling activities within the EU could meet the demand for dental amalgam. If amalgam separators in dental clinics would be more widely used across the EU and if there is a functioning EU market for recycled mercury there could be more than enough mercury to meet the demand.
- Lastly, the use of mercury in ASGM depends on the price of gold more than anything else. If the EU imports moderate amounts of mercury from Parties to the MC or not will probably only have a minor impact on consumption elsewhere.

Article 5

Export, import and manufacturing of mercury-added products

1. Without prejudice to stricter requirements set out in other applicable Union legislation, the export, import and the manufacturing in the Union of ~~the~~ mercury-added products ~~as set out in Annex H~~ shall be prohibited ~~from 1 January 2021~~~~from 1 January 2021 as from the dates indicated therein.~~

Rationale:

Sweden supports a complete export ban of all mercury-added products. As a minimum export of products that are currently not allowed on the EU-market should be prohibited.

According to the I.A., a stricter regulation of export of mercury-added products than in the MC would lead to economic losses, loss of jobs and increased global emissions of mercury. However, the only sector concerned is manufacture of certain lamps containing mercury. The only reference supporting this statement in the impact assessment is a personal communication with an interest organisation representative. We therefore consider the basis for this analysis to be far too weak. The economic effects of a ban are likely to be limited since the use of lamps containing mercury are expected to decrease anyway, mainly due to the increased use, and falling prices of LED-lamps (for references, see our previous comments). Furthermore, a majority of stakeholders expressed support for a general export ban on products banned within EU in the impact assessment (option P2O2).

2. The prohibition laid down in paragraph 1 shall not apply to the following mercury-added products:
 - products essential for civil protection and military uses;
 - products for research, calibration of instrumentation, for use as reference standard.

[...]

Chapter III

Restrictions on use and storage of mercury and mercury compounds

[...]

Article 10

Dental amalgam

The use of dental amalgam should be phased-out. In order to reach that goal, the following shall apply:

1. **From 1 January 2018, dentists shall offer alternatives to dental amalgam.**

Rationale:

This would be a measure that actually contributes to a phase-down of the use of amalgam, as required by the Convention (part II of annex A). The encapsulation and the installation of separators are merely risk management measures.

2. **From 1 January 2018~~9~~ onwards dental amalgam shall only be used in an encapsulated form.**

Rationale:

While we understand that some time may be needed for the installation of separators, we don't believe the same time is necessary to implement the switch to encapsulated dental amalgam since this product is already widely available on the market and a switch doesn't need any installation or investment.

32. **From 1 January 2019 onwards dental amalgam in any form may not be used for treatment of**
 - a) pregnant women,**
 - b) children under the age of...**

- 34. By way of derogation from paragraph 3, Member States may allow use of dental amalgam in respect of specific medical needs when no other alternatives are suitable.**

Rationale:

Sweden urges the EU and its MS to aim at a complete phase-out of mercury use in dental materials. A first step taken towards that end, which would allow us to comply with the MC-requirement of phasing down the use of dental amalgam, could be to prohibit the use of amalgam in vulnerable groups, such as children and pregnant women. Such a measure can be motivated by the following arguments:

- The Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR) was consulted by the Commission during its preparatory work. SCENIHR recommended that for primary teeth, and for pregnant patients, alternative materials to amalgam should be the first choice in its opinion from April 2015, as noted in the Commission's impact assessment (p.40)
- Dental amalgam is already in practice virtually phased-out for use in at least children in an important number of EU countries.

The clinical exemptions that are foreseen in a total ban could apply also to these vulnerable groups, which is foreseen through the proposed paragraph 4.

- 25.** From 1 January 2019 onwards dental facilities shall be equipped with amalgam separators aimed at retaining and collecting amalgam particles. Those separators shall be maintained as required to ensure a high level of retention.
- 36.** Capsules and amalgam separators complying with harmonised EN standards or with other national or international standards that ensure an equivalent level of quality and of level retention shall be presumed to satisfy the requirement set out under paragraphs 1 and 2.
- 7. Notwithstanding p. 1-5, Member States may further restrict, as they deem necessary, the use of dental amalgam.**

(Comment: This principle should be reflected also in recitals.)

Rationale:

In line with the aim of the Regulation, it should be made clear that the above are minimum requirements and that Member States are allowed to ban the use of dental amalgam altogether if they deem it appropriate.

Chapter IV

Storage and disposal of mercury waste

[...]

Article 13

Disposal of mercury waste

1. By way of derogation from point (a) of Article 5(3) of Directive 1999/31/EC, mercury waste may be stored in one of the following ways:
 - a) temporarily stored for more than one year or permanently stored in salt mines that are adapted for the disposal of mercury, or in deep underground hard rock formations providing a level of safety and confinement equivalent to that of those salt mines;
 - b) temporarily stored **for more than one year and for less than 5 years** in above-ground facilities dedicated to and equipped for the temporary storage of mercury.

Rationale:

A temporary storage should be temporary and an upper time-limit is therefore necessary.

2. The specific requirements for the temporary storage of mercury waste, as laid down in Annexes I, II and III to Directive 1999/31/EC shall apply to the permanent storage facilities referred to in point (a) of paragraph 1 of this Article under the following conditions laid down in the following Annexes to that Directive:
 - a) Annex I, Section 8 (first, third and fifth indents) and Annex II to Directive 1999/31/EC shall apply;
 - b) Annex I, Section 8 (second, fourth and sixth indents) and Annex III, Section 6, to Directive 1999/31/EC shall only apply where deemed appropriate by the competent authorities of the Member States in charge of implementing that Directive.
3. **Mercury waste shall be placed into storage in batches followed by the sealing and backfilling of the storage chamber, which shall not to be left open for longer than [x months].**

Rationale:

In order to avoid emissions from mercury that is stored permanently, it is important that the waste is put in batches and that the storage chamber is then sealed, backfilled and not kept open for longer than a certain number of months.

4. Without prejudice of paragraphs 2 and 3 of this article, metallic mercury that is permanently stored shall be transformed to mercury sulphide (HgS) through stabilization or solidification prior to its storage. It shall be stored only in licensed underground storage in salt mines or hard rock formations for which proof of long-term safety has been furnished in accordance with Annex A of Council Decision 2003/33/EC of 19 December 2002.

Rationale:

The requirements for the permanent storage of mercury set in art. 13 will pose a serious threat to human health and the environment since the requirements for permanent storage are not going beyond the requirements for temporary storage. In order to protect human health and the environment from mercury emissions, only solidified mercury should be disposed of in underground storage.

At the last Basel Convention COP (COP12), EU and its Member States agreed in the adoption of the revised BC guidelines on environmentally sound management of mercury waste. In this guideline it's stated in para 186 that "Before mercury wastes undergo final disposal according to the operations D5 and D12, they should be treated so as to meet the acceptance criteria of the disposal facilities (see section III, G, 2, (b) and (c) below). *"Wastes consisting of mercury or mercury compounds should be stabilized and/or solidified before final disposal."*

During the negotiations of the Minamata Convention the EU and its MS argued for strict requirements for the permanent disposal. The argumentation being that:

- The stabilization / solidification of metallic mercury is effective to significantly reduce the risk of this mercury being released into the environment.
- The stabilization / solidification of metallic mercury are an effective way to dramatically reduce the risk of that mercury being brought back into the market.
- Technologies are available and companies in the EU are just waiting to enter the market. We have information of activity in several member States, such as DE, ES and PL.

Sweden still believes that this is the case and we do not find any argumentation in the impact assessment explaining why we should not set out these requirements.

The requirements for permanent storage should be set out in directive 1999/31/EC and the new EU Mercury regulation should include a reference to this and that permanent storage is not to take place before criteria has been agreed– in line with the reference in the previous EU Mercury regulation.

Chapter V

Penalties, ~~and~~ reporting and review

[...]

Article 15 bis

Review

The Commission shall, no later than..., carry out a review of this Regulation *inter alia* in light of the development of the Minamata Convention and shall, if appropriate, make proposals relating to the development of the Convention.

Rationale:

We believe that it is necessary to introduce a review clause. This is common practice (See, for example, the review clause in Article 30 of the Ship recycling regulation (1257/2013)) and it might be necessary to adapt the regulation to the future developments of the Convention and of the EU-market.

[...]

Mercury-added products referred to in Article 5

Part A – Mercury-added products

Mercury-added products	Date after which the manufacture, import and export of the mercury-added product shall be prohibited
1. Batteries, except for button zinc silver oxide batteries with a mercury content $< 2\%$, button zinc air batteries with a mercury content $< 2\%$.	31.12.2020
2. Switches and relays, except very high accuracy capacitance and loss measurement bridges and high frequency radio frequency switches and relays in monitoring and control instruments with a maximum mercury content of 20 mg per bridge, switch or relay.	31.12.2020
3. Compact fluorescent lamps (CFLs) for general lighting purposes that are ≤ 30 watts with a mercury content exceeding 5 mg per lamp burner.	31.12.2020
4. The following linear fluorescent lamps (LFLs) for general lighting purposes: (a) Triband phosphor < 60 watts with a mercury content exceeding 5 mg per lamp; (b) Halophosphate phosphor ≤ 40 watts with a mercury content exceeding 10 mg per lamp.	31.12.2020

5. High-pressure mercury vapour lamps (HPMV) for general lighting purposes.	31.12.2020
6. The following mercury added cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for electronic displays: (a) short length (≤ 500 mm) with mercury content exceeding 3.5 mg per lamp; (b) medium length (> 500 mm and $\leq 1\,500$ mm) with mercury content exceeding 5 mg per lamp; (c) long length ($> 1\,500$ mm) with mercury content exceeding 13 mg per lamp.	31.12.2020
7. Cosmetics with mercury and mercury compounds, except those special cases included in Annex V entry 17 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council.	31.12.2020
8. Pesticides, biocides and topical antiseptics.	31.12.2020

<p>9. The following non-electronic measuring devices where no suitable mercury-free alternative is available:</p> <p>(a) barometers;</p> <p>(b) hygrometers;</p> <p>(c) manometers;</p> <p>(d) thermometers;</p> <p>(e) sphygmomanometers;</p> <p>This entry does not cover the following measuring devices:</p> <p>(a) non-electronic measuring devices installed in large-scale equipment or those used for high precision measurement where no suitable mercury-free alternative is available;</p> <p>(b) measuring devices more than 50 years old on 3 October 2007;</p> <p>(c) measuring devices, which are to be displayed in public exhibitions for cultural and historical purposes.</p>	<p>31.12.2020</p>
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Part B—Additional products excluded from the list in Part A of this Annex

~~Switches and relays, cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for electronic displays and measuring devices, when they are used to replace a component of a larger equipment and provided that no feasible mercury-free alternative for that component is available, in accordance with Directive 2000/53/EC of the European Parliament and of the Council² and Directive 2011/65/EU of the European Parliament and of the Council³.~~

Rationale:

This annex will not be need if art.5 is modified as proposed above.

Mercury-related requirements applicable to manufacturing processes

Part I: Prohibited use of mercury or mercury compounds in manufacturing processes

- a) **from 1 January 2018: chlor-alkali production**
- b) from 1 January 2019: acetaldehyde production
- c) from 1 January 2019: vinyl chloride monomer production

Rationale:

Even if the Commission Implementing Decision 2013/732/EU (IA, p. 14) concludes that the mercury cell technique cannot be considered BAT under any circumstances and hence will have to be phased out by the end of 2017 we believe it could, for sake of clarity, be good to include an end date for use of mercury in chlor-alkali production in Annex III.

[...]
