



Council of the
European Union

Brussels, 28 April 2016
(OR. en, fr)

**Interinstitutional File:
2016/0023 (COD)**

7684/16
ADD 2

LIMITE

ENV 204
COMER 35
MI 201
ONU 35
SAN 120
IND 63
CODEC 394

NOTE

From: General Secretariat of the Council
To: Delegations

No. Cion doc.: 5771/16 ENV 41 COMER 7 MI 55 ONU 8 SAN 38 IND 23 CODEC 118 -
COM(2016) 39 final

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 FR,
SI and SE.

FRANCE

20 April 2016

Dans le cadre des discussions actuelles au niveau européen relatives à la proposition de règlement mercure en objet, visant notamment de permettre à l'Union européenne de ratifier la Convention de Minamata, la Présidence néerlandaise a demandé aux Etats membres de lui fournir des commentaires sur l'article 10 relatif aux amalgames dentaires et sur le chapitre V relatif au stockage et l'élimination de déchets de mercure.

La présente note présente les commentaires des autorités françaises sur les amalgames dentaires en complément de la note envoyée précédemment relative au chapitre V (élimination de déchets de mercure). Elle ne préjuge pas d'éventuels commentaires supplémentaires qui pourraient être développés par la suite sur ces aspects ou sur les autres parties de ce projet de règlement.

Commentaires relatifs à l'article 10 sur les amalgames dentaires:

Les dispositions prévues par l'article 10 font déjà l'objet de mesures nationales :

- Obligation d'utiliser des amalgames sous forme encapsulée : cette mesure est en vigueur depuis 2001¹. Il convient néanmoins de préciser la formulation, pour lever toute ambiguïté :

« A partir du 1^{er} janvier 2019, les amalgames dentaires ne sont utilisés que sous forme de capsule prédosée »

Cette précision doit également être apportée au considérant 17.

En effet, le point 3 de l'article 10 prévoit que les capsules et séparateurs d'amalgames soient conformes aux normes EN harmonisées ou équivalentes. La norme EN ISO 13897² citée dans l'exposé des motifs prévoit deux classes de capsules, le type 1 (capsule de mélange prédosée) et le type 2 (capsule de mélange réutilisable). L'amalgame conditionné sous forme de capsule prédosée permet de réduire les émissions de vapeurs de mercure lors de la préparation de l'amalgame dentaire et de standardiser la quantité de mercure ajoutée à l'alliage, évitant ainsi tout risque de surdosage.

- Obligation d'installer des séparateurs d'amalgame dans les établissements de soins dentaires : cette mesure est pleinement entrée en vigueur depuis 2001, complétée des modalités d'élimination des déchets d'amalgame issus des cabinets dentaires³.

¹ Décision du 14 décembre 2000 relative à l'interdiction d'importation, de mise sur le marché et d'utilisation de certains amalgames dentaires, Afssaps

² Norme européenne EN ISO 13897, Art dentaire - Capsules pour amalgame - (ISO 1397:2003), mai 2004

³ Arrêté du 30 mars 1998 relatif à l'élimination des déchets d'amalgames issus des cabinets dentaires

En 2015, l'Agence nationale de sécurité du médicament et des produits de santé (ANSM) a actualisé son rapport de 2005 relatif au mercure dans les amalgames dentaires. Elle conclut que les arguments épidémiologiques existants dans la littérature concernant la possibilité de risques pour la santé associée au port d'amalgames dentaires apparaissent faibles⁴. L'ANSM développe des recommandations à destination des chirurgiens-dentistes afin de préciser les situations cliniques dans lesquelles l'amalgame peut être employé et en rappelle les précautions d'emploi. Les recommandations de l'ANSM de 2015 précisent que l'utilisation des amalgames dentaires est justifiée en particulier pour la restauration des dents permanentes postérieures en cas de prévalence carieuse élevée et de lésions multiples et étendues. Les pics d'exposition au mercure intervenant lors de la pose et de la dépose des amalgames, il est également recommandé d'éviter la dépose d'amalgame chez la femme enceinte ou allaitante, en laissant à l'appréciation du praticien la nécessité de la pose d'un amalgame par rapport à un autre matériau.

Le Comité scientifique sur les risques sanitaires émergents et nouvellement identifiés (SCENIHR) conclut également que les amalgames sont des matériaux sûrs, à ce jour associés à un faible taux d'effets indésirables locaux et à aucune maladie systémique, et que les données actuelles ne permettent pas d'empêcher leur utilisation. Concernant les personnels dentaires, quoique plus exposés que les patients, les études récentes n'indiquent pas qu'ils souffrent d'effets indésirables qui pourraient être attribués à l'exposition au mercure des amalgames dentaires⁵. De plus, le Comité scientifique pour les risques sanitaires et environnementaux (SCHER) concluait dans son rapport de 2014 que le risque d'effets graves pour la santé humaine était faible au regard de la contribution estimée de l'utilisation des amalgames dentaires à l'exposition indirecte au méthylmercure. Concernant l'environnement, les conclusions du SCHER sont qu'il est raisonnable de considérer que le risque écologique est faible⁶. Dans son avis du 29 avril 2015 le SCENIHR reconnaît qu'il y a besoin d'approfondir les recherches relatives notamment à l'évaluation de la neurotoxicité potentielle du mercure dans les amalgames dentaires.

Les autorités françaises ont réaffirmé récemment leur volonté auprès des professionnels de limiter le recours à l'amalgame dentaire aux seules situations justifiées et jugées sans alternatives, et de voir diminuer de façon significative leur utilisation dans le traitement de la carie dentaire. En particulier, l'utilisation de l'amalgame dans les dents de lait doit être réduite et n'est indiquée qu'en toute dernière intention, leur désolidarisation naturelle facilitant leur élimination directe dans l'environnement, en dehors de tout dispositif adapté.

Ces questions inquiètent la société civile et les ONG qui alertent régulièrement les autorités sur les risques liés à l'usage de ces amalgames.

Les expériences des pays qui ont établi des mesures d'interdictions, montrent qu'une transition progressive vers l'élimination des amalgames dentaires est techniquement et économiquement envisageable. En France, les ventes d'amalgames ont diminué de 38% entre 2007 et 2011, et le taux de restauration faite par l'amalgame est passé de 52% en 2003 à 25% en 2011, montrant que le recours à cette technologie diminue naturellement du fait de l'apparition d'alternatives et d'une préférence grandissante des patients pour de solutions plus esthétiques.

⁴ Le mercure des amalgames dentaires – actualisation des données, Agence nationale de sécurité du médicament et des produits de santé (ANSM), avril 2015

⁵ The safety of dental amalgam and alternative dental restoration materials for patients and users, SCENIHR, avril 2015

⁶ Opinion on the environmental risks and indirect health effects of mercury from dental amalgam (update 2014), SCHER, mars 2014

Enfin, il est important de noter que la Convention de Minamata précise que la liste des mesures qu'elle propose dans son annexe A sont des mesures à prendre par les Parties pour éliminer progressivement l'utilisation d'amalgames dentaires. Si la proposition de la Commission répond bien à la demande d'adopter des mesures, elle ne reprend pas cet objectif d'élimination progressive.

Les autorités françaises sont favorables aux dispositions de l'article 10 relatif aux amalgames dentaires en particulier la proposition de limiter l'utilisation des amalgames à leur forme encapsulée au 1er janvier 2019. Elles considèrent que ces dispositions permettent de réduire l'exposition humaine et environnementale au mercure liées à l'utilisation des amalgames.

Les autorités françaises estiment que ces dispositions doivent être considérées comme une première étape vers une élimination progressive des amalgames dentaires. A cet effet, la proposition devrait être complétée de dispositions interdisant à moyen terme l'usage de ces amalgames chez les enfants.

Les autorités françaises affirment leur volonté de voir leur utilisation réduite et restreinte aux situations justifiées et jugées sans alternative à l'utilisation des amalgames dentaires. A ce titre elles souhaitent que soit ajouté dans l'article 10, afin de répondre au mieux à l'approche de réduction progressive des amalgames dentaires défendue dans la Convention de Minamata, une disposition rappelant aux Etats membres d'encourager les professionnels de santé à réduire et à recourir de façon appropriée aux amalgames au mercure, en premier lieu pour les femmes enceintes.

Courtesy translation

The provisions established by article 10 are already implemented at national level:

- Obligation to use dental amalgam only in an encapsulated form: this measure is implemented since 2001¹. However it appears necessary to use a more specific wording, to remove any ambiguity:

"From 1 January 2019 onwards dental amalgam shall only be used in a pre-dosed capsule form"

This clarification should also be brought to recital 17.

As a matter of fact, article 10 para 3 provides that capsules and amalgam separators shall comply with harmonised EN standards or equivalent standards. Standard EN ISO 13897², mentioned in the explanatory statement, establishes two types of capsules, type 1 (pre-dosed capsules) and type 2 (reusable capsules).

The use of the pre-dosed capsule form allows to reduce mercury vapour during preparation of dental amalgam and to standardize the quantity of mercury added to the alloy, avoiding any overdose.

- Obligation to install amalgam separator in dental practices: this measure is fully in force since 2001, and complemented by provisions regarding amalgam waste disposal from dental practices³.

In 2015 the French National Agency for Medicines and Health Products Safety (ANSM) updated its 2005 report regarding mercury in dental amalgam. It concludes that the epidemiologic evidence existing in the literature regarding the possibility of health risks related to the use of dental amalgam are deemed low⁴. ANSM develops recommendations towards dental surgeons, to specify in which clinical situations amalgam can be used, and recalls the precautions for use. In its recommendation, ANSM specifies that the use of dental amalgam is justified for posterior teeth restoration in case of high prevalence of dental cavities and multiple and extensive lesions. Since peak exposures happen during placement or removal of amalgams, it is recommended to avoid amalgam removal on pregnant or breastfeeding women, and deciding upon the necessity to use amalgam instead of other material should be left to the practitioner.

¹ Decision of 14 December 2000 regarding the prohibition of import, placing on the market and use of dental amalgams, Afssaps

² Norme européenne EN ISO 13897, Art dentaire - Capsules pour amalgame - (ISO 1397:2003), mai 2004

³ Arrêté du 30 mars 1998 relatif à l'élimination des déchets d'amalgames issus des cabinets dentaires

⁴ Mercury in dental amalgam – of data, French National Medicines and Health Products Safety (ANSM), April 2015

The Scientific Committee on Emerging and Newly Identified Health Risks (*SCENIHR*) also concludes that amalgams are safe materials, to date, associated with a low amount of local adverse effects and no systemic disease, and that current data doesn't plead for banning their use. Regarding workers in dental practices, even if they are more exposed than patients, recent studies don't show that they suffer from any adverse effects that could be linked to mercury in dental amalgam exposures⁵. Furthermore the Scientific Committee on Health and Environmental Risks (*SCHER*) concluded in its 2014 report that the risk of serious impact on human health was low as regard to the estimated contribution of the use of dental amalgam to indirect exposure to methyl mercury. Regarding the environment, the *SCHER* concludes that it is sensible to consider that the ecological risk is low⁶. However in its opinion from April 29, 2015, the *SCENIHR* recognizes a need for further studies regarding especially potential neurotoxicity of mercury in dental amalgam.

The French authorities recently re-affirmed their will to limit the use of dental amalgam to the only situations where it is justified and where no alternatives are available, and also to see a significant decrease in their use for treating dental cavities. In particular, the use of amalgam have to be reduced for baby teeth and should only be used as a last resort, their natural disassociation eases their direct elimination in the environment outside of suitable waste system.

These are topics of concern for the civil society and NGOs who regularly alert the authorities regarding the risks associated with the use of dental amalgam.

The examples of countries that adopted bans show that a gradual shift toward dental amalgam elimination is technically and economically practicable. In France, sales of dental amalgam present a 38% decrease between 2007 and 2011 and the amount of restoration using amalgam went down from 52% in 2003 to 25% in 2011, showing that the use of this technology naturally decreases due to alternatives becoming more available and customer choices for more aesthetic solutions

To finish with, it is important to note that the Minamata convention states that the list of measures proposed in its annex A are measures to be taken by Parties to phase down the use of dental amalgam. If the Commission proposal answers the call to adopt some of these measures, it doesn't take up the phasing down goal.

The French authorities are in favour of the provisions proposed in article 10 regarding dental amalgam, especially the proposition to limit the use of dental amalgam to encapsulated form from the first of January 2019. They consider that these provisions provide a decrease in human and environmental exposures to mercury from dental amalgam uses.

The French authorities believe that these provisions shall be considered as a first step towards a phasing out of dental amalgam. The proposal should be complemented with mid-term provisions banning the use of amalgam for kids.

⁵ The safety of dental amalgam and alternative dental restoration materials for patients and users, *SCENIHR*, April 2015

⁶ Opinion on the environmental risks and indirect health effects of mercury from dental amalgam (update 2014), *SCHER*, mars 2014

The French authorities confirm their wish for the use of dental amalgam to be decreased and restricted to relevant situations for which no alternatives are available. In this respect, and to better comply with the phasing down approach of dental amalgam in the Minamata Convention, they ask for additional provisions in article 10 to recall Member States to encourage healthcare professionals to reduce and use dental amalgam only when appropriate, especially for pregnant women.

French comments to Presidency compromise text (7022/16)

Proposal for a
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on mercury, and repealing Regulation (EC) No 1102/2008**
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

FR comment: in order to help the Presidency in establishing a new proposal, as indicated at the WPE meeting on april 21, this document presents comments and amendment proposals that the French delegations presented orally during the WPE meetings and that complements the written comments sent by the French authorities. This document is for information of the Presidency and is without prejudice of further possible comments that FR could provide in the context of the work on this proposed regulation.

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) ~~and Article 207~~ thereof,

FR supports the choice of a sole environmental legal basis for this regulation following the rationale of the Council Legal Service

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

pm

HAVE ADOPTED THIS REGULATION:

1 OJ C , , p. .

2 OJ C , , p. .

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 anthropogenic emissions and releases.**

FR supports this addition aiming at reaffirming that the main objective of the regulation is to protect environment and health. FR suggests an addition at the end of the para inspired by the wording of the Minamata Convention.

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 mercury compounds that qualify as waste, in accordance with Article 3(1), of Directive 2008/98/EC of the European Parliament and of the Council³;
4. 'export' means any of the following:
 - a) the permanent or temporary export of a chemical meeting the conditions of Article 28(2) of the Treaty on the Functioning of the European Union;

FR is in favour of mentioning compounds as they can also qualify as waste in accordance with the waste directive

3 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).

- b) the re-export of a chemical not meeting the conditions of Article 28(2) of the Treaty on the Functioning of the European Union which is placed under a customs procedure other than the external Union transit procedure for movement of goods through the customs territory of the Union;
- 5. 'import' means the physical introduction into the customs territory of the Union of a chemical that is placed under a customs procedure other than the external Union transit procedure for movement of goods through the customs territory of the Union;
- 6. 'primary mercury mining' means mining in which the principal material sought is mercury;
- 6a. **'placing on the market' means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.**

Chapter II

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

Article 3 **Export restrictions**

1. The export of mercury and of the mercury compounds and of mixtures listed in Annex I shall be prohibited.

The first subparagraph shall not apply to the export of the mercury compounds listed in Annex I for laboratory-scale research.
2. The export of mixtures of mercury not listed in Annex I for the purposes of recovering the mercury shall be prohibited.

FR is in favor of mentioning all the compounds identified in the MC in Annex I and of applying the restrictions to the whole list.

This approach would be clearer and would help limit mercury trade more broadly. Please refer to comments in Annex I for more explanations.

Article 4
Import restrictions

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

FR is in favour of including the compounds under the import restrictions. We think this would help to limit the trade and use of mercury in general and send a stronger message. However any important current needs could still be covered using the derogation system proposed here.

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:

FR supports this change establishing the need for a written consent by the importing MS in any case.

- 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.~~

– FR would have preferred provisions to forbid import from a country that is not Party to the MC, but understands from the legal explanations given that such provision would not be compatible with the international trade agreements

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

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 II shall be prohibited ~~from 1 January 2021~~ **as from the dates indicated therein.**
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.

Article 6
Forms for Import and Export

The Commission shall adopt decisions, by means of implementing acts, to specify the forms to be used for the purpose of implementing Articles 3 and 4.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Chapter III
Restrictions on use and storage of mercury and mercury compounds

Article 7
Industrial activities

1. The use of mercury and mercury compounds in the manufacturing processes listed in Part I of Annex III is prohibited as from the dates indicated therein.
2. The use of mercury and mercury compounds in the manufacturing processes listed in Part II of Annex III shall only be allowed under the conditions set out therein.
3. Interim storage of mercury and **of the** mercury compounds, and of mixtures **listed in Annex I** shall be carried out in an environmentally sound manner.

The Commission shall be empowered to adopt delegated acts in accordance with Article 17 in order to set out requirements for environmentally sound interim storage of mercury and mercury compounds adopted by the Conference of the Parties to the Convention, where the Union has supported the Decision concerned **by means of a Council Decision adopted in accordance with Article 218(9) TFEU**.

FR sees no reason to avoid mentioning mixtures in this part of the regulations. Mixtures should also be carried out in an environmentally sound manner

Article 8

New mercury-added products and new manufacturing processes

1. The manufacture and placing on the market of mercury-added products not covered by any known use prior to 1 January 2018 shall be prohibited.
2. Manufacturing processes involving the use of mercury and/or mercury compounds that did not exist prior to 1 January 2018 shall be prohibited.

This paragraph shall not apply to processes manufacturing and/or using mercury-added products others than those falling under paragraph 1.

3. By way of derogation from paragraphs 1 and 2, where an economic operator intends to manufacture and/or place on the market a new mercury-added product or to operate a new manufacturing process, the operator shall notify the competent authorities of the Member State concerned and provide them, with the following:
 - a technical description of the product or process concerned;
 - an assessment of its environmental and health risks;
 - a detailed explanation of the manner in which such product or process must be manufactured, used and operated to ensure a high level of protection of the environment and of human health.
4. **The Member State concerned may forward to the Commission the notification received from the economic operator and may include its own assessment of the information provided therein.**

FR considers that the procedure established here should be clarified. In that para 4 it should be made clearer that the MS concerned could decide to proceed or not with the request. If the MS decides to proceed then it shall forward the request to the Commission and may include its assessment.

5. Upon **receipt of the notification forwarded** 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.

FR comment: This para also needs to be clarified. Different things should be added: The commission should forward the notification for information to MS. A verification of the information by the Commission doesn't appear to be enough, an evaluation of the information provided in the notification and possible other info should be carried out. The text should also explain a bit more how the Commission will assess this. Will the Commission ask for experts opinion? If so, which experts committee will be in charge?

The Commission shall adopt decisions, by means of implementing acts, in view of specifying whether the relevant new mercury-added product or new manufacturing process is allowed.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Article 9

Artisanal and small-scale gold mining

Member States on the territory of which more than insignificant artisanal and small-scale gold mining and processing activities **in which mercury amalgamation is used to extract gold from ore** shall:

- take steps to reduce, and where feasible eliminate, the use of mercury and mercury compounds in, and the emissions and releases to the environment of mercury from, such mining and processing;
- develop and implement a national plan in accordance with Annex IV.

Article 10

Dental amalgam

1. From 1 January 2019 onwards dental amalgam shall only be used in a pre-dosed capsule form.

FR comment : This change is necessary as different kinds of capsules exist. The text has to be specific to avoid problems of interpretation. This change is also to be made in recital 17.

FR considers that this proposal is appropriate as a first step towards the phasing out of dental amalgam. However provisions should be added to this text to forbid the use of amalgam for children as a mid-term objective and to ask MS to encourage dentists to limit their use of amalgam and to use it only when it's relevant, especially regarding pregnant women. For more detailed information please refer to the written comments sent by the French Authorities.

2. 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. 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.

Chapter IV

Storage and disposal of mercury waste

Article 11

Mercury waste

Without prejudice to Directive 2008/98/EC ~~Without prejudice to Commission Decision 2000/532/EC⁴~~, in particular the following shall be considered as waste and be disposed of without endangering human health or harming the environment :

The idea behind these amendments is to make clear that the list presented here doesn't exclude other sources of mercury to be considered as waste. The proposed wording is unclear and could be understood as a limitation of the definition provided in article 2

- a) mercury that is no longer used in the chlor-alkali industry;
- b) mercury generated from the cleaning of natural gas;
- c) mercury generated through non-ferrous mining and smelting operations;
- d) mercury extracted from cinnabar ore in the Union.

Article 12

Reporting on mercury waste from large sources

1. The companies operating within the industry sectors referred to in points (a), (b) and (c) of Article 11 shall send each year by 31 May to the competent authorities of the Member States concerned data related to the total amount of mercury waste stored in each installation and sent to individual temporary or permanent storage facilities as well as the location and contact details of those facilities.
2. The data referred to in paragraph 1 shall be expressed using the codes laid down in Regulation (EC) No 2150/2002 of the European Parliament and of the Council⁵.

~~4~~ ~~Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3).~~

5 Regulation (EC) No 2150/2002 of the European Parliament and of the Council of 25 November 2002 on waste statistics (OJ L 332, 9.12.2002, p.1).

3. The obligation established in paragraphs 1 and 2 shall cease to apply to **a company** ~~companies~~ operating chlor-alkali installations **after one the year after from the date that** all mercury cells **operated by the company** will have been decommissioned in accordance with Commission Implementing Decision 2013/732/EU⁶ and all mercury has been handed over to waste management facilities.

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;
 - c) *FR is against the possible permanent underground storage of liquid mercury and considers it's not an environmentally sound solution. Please refer to the written comments sent by the French Authorities for further explanations*
 - b) temporarily stored **for more than one year** 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.

- d) *FR is not convinced that the provisions established for temporary storage are robust enough to ensure a sound underground disposal of mercury. In particular elements related to the stability of the underground storage, its isolation from underground and surface waters, etc, should be detailed further. Please refer to the written comments sent for more detailed information.*

⁶ Commission implementing Decision 2013/732/EU of 9 December 2013 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for the production of chlor-alkali (OJ L 332, 11.12.2013, p. 34).

Chapter V

Penalties and reporting

Article 14

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are applied. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by [xxx] and shall notify it without delay of any subsequent amendment affecting them.

Article 15

Report

1. Member States shall prepare, update and publish online a report with the following information:
 - c) information concerning the implementation of this Regulation;
 - d) information needed for the fulfilment by the Union and by the Member States of its reporting obligation established under Article 21 of the Minamata Convention;
 - e) a summary of the information gathered in accordance with Article 12;
 - f) ~~a list of individual stocks of mercury when exceeding 50 metric tonnes, which are and located in on their territories:~~
 - e) **i) a list of individual stocks of mercury;**
 - f) **ii) a list of sites where mercury waste are accumulated;** and
 - g) where Member States are made aware, a list of sources of mercury supplying generating ~~annual stocks of mercury exceeding~~ **more than 10 metric tonnes of mercury per year.**

Member States shall inform the Commission of their report and of their updates within one month of their publication.

2. The Commission shall adopt appropriate questionnaires in order to specify the content, the information and the key performance indicators to be included in the report referred to in paragraph 1 as well as the format of this report and the timing of its publication and of its updates.

The questionnaires may also organise reporting in such a way as to enable the Union to provide the Secretariat of the Convention with a single report submitted on behalf of the Union and its Member States.

The Commission shall adopt decisions, by means of implementing acts, to provide a template for those questionnaires and to make an electronic reporting tool available to the Member States.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Chapter VI

Delegated and implementing powers

Article 16 **Amendment of Annexes**

The Commission shall be empowered to adopt delegated acts in accordance with Article 17 in order to amend Annexes I, II, III and IV to transpose Decisions adopted by the Conference of the Parties to the Convention, where the Union has supported the Decision concerned **by means of a Council Decision adopted in accordance with Article 218(9) TFEU**.

Article 17

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of powers referred to in Articles 7(3) and 16 shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.
3. The delegation of power referred to in Articles 7(3) and 16 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 3a. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of [date].**
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 7(3) and 16 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

Article 18

Committee procedure

1. For the adoption of forms for import and export under Article 6, of a decision under Article 8(4), and of questionnaires in accordance with Article 15(2) the Commission shall be assisted by a Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Chapter VII
Final provisions

Article 19

Repeal

Regulation (EC) No 1102/2008 is hereby repealed as from the date of application set out in **Article 20**.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 20
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1st January 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament

For the Council

The President

The President

ANNEX I

Mercury compounds and mixtures subject to Articles 3 and 4

FR comment: The Presidency proposal also includes article 7

Mercury compounds:

Mercury (I) chloride (Hg₂Cl₂, CAS RN 10112-91-1)

Mercury (II) oxide (HgO, CAS RN 21908-53-2)

Cinnabar ore

Mixtures:

Mixtures of mercury with other substances, including alloys of mercury, with a mercury concentration of at least 95 % weight by weight.

Mercury compounds:

Mercury sulphate (HgSO₄, CAS RN 7783-35-9)

Mercury nitrate (Hg(NO₃)₂, CAS RN 10045-94-0)

Mercury sulphide (HgS, CAS RN 1344-48-5)

FR comment: This proposal could make the provisions of the text difficult to read and bring confusion about what part of the annex applies to what article of the regulation. FR considers that a clearer and simpler approach should be retained. FR supports the proposal of the Presidency to add additional compounds to this Annex. However this addition shouldn't be standing as a separate part but should be included in the list already existing in the initial Commission proposal. In other words the provisions of article 3, 4 and 7 should apply to the whole list of compounds. The Commission explained that it limited the list to the compounds for which exportations happen nowadays. Adding the other compounds wouldn't have economic impacts if they are not subject to exports, but it would be useful to make sure that new development will not happen in the future regarding these other compounds. That would be coherent with the objective of limiting new activities and developments relying on mercury uses. Following the same objective, we believe that mercury compounds should also be covered by article 4. That would encourage to limit the use of mercury and its compounds to the necessary minimum (using the derogation process in that regard).

End of the text (form Annex II onwards) : no comments/amendment proposals from the French authorities

SLOVENIA

1. Export and manufacturing of mercury-added products (Article 5)

Slovenia believes that in order to demonstrate its commitment to the scope and purpose of the Minamata Convention, the EU should aim to exceed the minimum requirements of the convention, where possible. For many mercury-added products in the EU market, higher standards are already applied (e.g. in ROHS directive, EU Cosmetics regulation, REACH, etc.). It is therefore in our view not only logical, but also ethical that the EU implements the same standards for such mercury-added products exported from the EU to third countries.

Since these products would neither be allowed to be placed on the EU market nor exported there would obviously be no need for their production. Consequently, their production should be prohibited. Furthermore, these provisions would be much easier to control and enforce at the production sites than at the actual export.

In order to reflect this commitment we propose that a new paragraph is added to Article 5:

Article 5(3) NEW

3. Where stricter requirements are set out in other Union legislation regarding the placing on the market of mercury-added products, those requirements shall also apply to exports and manufacturing.

2. Reporting requirements (Article 15)

Slovenia believes that the article on reporting should not duplicate the reporting requirements of the Minamata convention and it should not introduce any additional administrative burden to the competent authorities by requiring any reporting beyond the requirements of the Convention. Should any additional information be necessary for the implementation of the Convention at the EU level, this information should be gathered by other means on a case-by-case basis.

We therefore propose that the existing text in Article 15 is replaced by the following:

ARTICLE 15

"The Commission shall adopt appropriate electronic questionnaire to specify the key performance indicators and other information related to the implementation of this Regulation and the Convention.

The information gathered should be limited to the information necessary for the implementation of this Regulation and should not duplicate the reporting obligations of the Member states under the Convention.

The Commission shall adopt decisions, by means of implementing acts, to provide a template for this questionnaire and to make an electronic reporting tool available to the Member States.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2)."

(Swedish comments already submitted on these parts of the regulation are also included below)

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on mercury, and repealing Regulation (EC) No 1102/2008

[...]

Chapter IV
Storage and disposal of mercury waste

Article 11
Sources of mercury waste

~~Without prejudice to Commission Decision 2000/532/EC[‡], 1. The~~ the following shall be considered as waste and be disposed of without endangering human health or harming the environment in accordance with Directive 2008/98/EC:

- a) mercury that is no longer used in the chlor-alkali industry;
- b) mercury generated from the cleaning of natural gas;
- c) mercury generated through non-ferrous mining and smelting operations;
- d) mercury extracted from cinnabar ore in the Union.

2. *The Commission shall be empowered to adopt, at the latest by 1 January 2019, delegated acts in accordance with Article 17 in order to set out thresholds for mercury levels in waste containing or contaminated with mercury or mercury compounds, and to adopt requirements for environmentally sound management of these waste streams.*

Rationale

New title - The title of this article should be modified for sake of clarity as it the current wording could be confusing in relation to other parts of the regulation, in particular art. 2 (3).

[‡] ~~Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3).~~

New para 2 - The Minamata Convention (MC) covers not only *mercury waste* but also waste *containing mercury or mercury compounds* and waste *contaminated with mercury or mercury compounds*. Swedish inventories of such wastes show that large amounts of wastes would fall into the latter category and that these wastes also contain a significant amount of mercury. In order to implement the MC in an appropriate manner, the EU legislation needs to give special attention also for these wastes. Whereas the mercury contaminated wastes with the lowest mercury contents, e.g. less than 0,1 % of mercury, could be managed within the framework of the available EU legislation (Waste framework directive, Acceptance criteria for wastes etc), it is judged necessary to study in further detail the appropriate management of wastes with mercury concentrations within the range 0,1 % to 99 %.

Mercury containing and contaminated waste exist in significant amounts and if stored in surface facilities may pose a significant threat to the environment. Mercury may evaporate from the stored waste and once in the atmosphere will be dispersed over large areas and contribute to increased background levels of mercury in the environment. In view of the pollution situation in Europe, it is desirable to decrease the input of mercury into the atmosphere and the aquatic environment by means of developing appropriate legislation for and management of mercury contaminated or containing wastes.

Mercury contaminated waste stored in surface facilities is vulnerable to fire incidents, erosion, flooding and “other acts of nature”.

Mercury contaminated or containing waste may, if mixed or brought in contact with other wastes containing organic carbon, transform to the very toxic substance methylmercury which may subsequently be released into the environment. This change will imply changes in art.17.

Mercury-related requirements applicable to manufacturing processes

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

- a) **from 10 October 2017: polyurethane using mercury containing catalysts**
- b) **from 1 January 2018: chlor-alkali production**
- c) from 1 January 2019: acetaldehyde production
- d) 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.

New (a) - We have heard of a new PUR-product produced that is not among the five covered by REACH (reg. 848/2012, entry 62). This shows us that the REACH entries can create a loophole that should be discussed and preferably be stopped. It could therefore be helpful to have an end-date for manufacturing of PUR in annex III of the regulation, which would also be desirable for the sake of clarity. MC annex B, part II, has similar measures for mercury containing catalysts in PUR-production as for the alcoholates.

Part II: Manufacturing processes subject to restrictions on use and releases of mercury and mercury compounds

Production of sodium or potassium methylate or ethylate

The production of sodium or potassium methylate or ethylate shall be **phased out as fast as possible and within 10 years of the entry into force of the Convention. Before that date, it shall be** carried out in accordance with the following requirements:

- No use of mercury from primary mining;
- Reduction of direct and indirect release of mercury and of mercury compounds into air, water and land in terms of per tonne of substances produced by 50% by 2020 as compared to 2010; and

- At the date of entry into force of this Regulation, the capacity of installations using mercury and mercury compounds for the production of sodium or potassium methylate or ethylate that were in operation before that date shall not be increased and no new installations shall be allowed.

Rationale

Regarding the alcoholates, it seems not all measures listed in MC annex B, part II, are included in the draft regulation, only two out of six are included. What is the reason for this? If we are to comply with the Convention, it is important to include the different items, and especially (i.) about phasing out the use of mercury *as fast as possible and within 10 years of the entry into force of the Convention.*
