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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	16 September 2019
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	Proposal for a COUNCIL DECISION on the position to be taken on behalf of the European Union at the third meeting of the Conference of the Parties to the Minamata Convention on Mercury as regards the adoption of a Decision on the phasing-out of dental amalgam and amending Annex A to this Convention

Delegations will find attached document COM(2019) 414 final.

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2019/0194 (NLE)

Proposal for a

COUNCIL DECISION

on the position to be taken on behalf of the European Union at the third meeting of the Conference of the Parties to the Minamata Convention on Mercury as regards the adoption of a Decision on the phasing-out of dental amalgam and amending Annex A to this Convention

EXPLANATORY MEMORANDUM

1. SUBJECT MATTER OF THE PROPOSAL

This proposal concerns the decision establishing the position to be taken, on the Union's behalf, at the third meeting of the Conference of the Parties to the Minamata Convention on Mercury in connection with the envisaged adoption of a Decision on the phasing-out of dental amalgam and amending Annex A to that Convention.

2. CONTEXT OF THE PROPOSAL

2.1. The Minamata Convention on Mercury

The Minamata Convention on Mercury ('the Agreement') is the main international legal framework aimed at protecting human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds to air, water and land.

It addresses the whole life-cycle of mercury, from primary mercury mining to mercury waste disposal, including the interim storage of mercury, mixtures of mercury with other substances, including alloys of mercury, with a mercury concentration of at least 95% per weight ('mercury mixtures'), and of six mercury compounds, including mercury (I) chloride, mercury (II) oxide, mercury (II) sulphate, mercury (II) nitrate, cinnabar and mercury sulphide, other than waste mercury. The Agreement entered into force on 16 August 2017. The European Union is a Party to the Agreement[1] as well as most Member States[2].

2.2. The Conference of the Parties

The Conference of the Parties to the Agreement ('COP') performs the functions assigned to it by the Agreement and, to that end, shall consider and undertake *inter alia* any additional action that may be required for the achievement of the objectives of the Agreement, including the adoption of relevant guidelines.

According to Article 28 of the Agreement and Decision MC-1/1 on Rules of Procedures adopted by the COP at its first meeting (24-29 September 2017), each Party has one vote. However, the Union, as a regional economic integration organisation, exercises its right to vote, on matters within its competence, with a number of votes equal to the number of its Member States that are Parties to the Agreement. The Union shall not exercise its right to vote if any of its Member States exercises its right to vote, and vice versa.

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1 Council Decision (EU) 2017/939 of 11 May 2017 on the conclusion on behalf of the European Union of the Minamata Convention on Mercury (OJ L 142, 2.6.2017, p. 4).

2 On 20 June 2019, twenty-three Member States had ratified the Minamata Convention on Mercury, i.e. Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovakia, Slovenia, Sweden and the United Kingdom.

2.3. The envisaged act of the Conference of the Parties

Based on information made available to Parties of the Agreement, the COP is expected to adopt on 25 November 2019, during its third meeting, a Decision regarding the phasing-out of dental amalgam and the amendment of Annex A to the Convention as a follow-up to a joined proposal made by six African countries which are Parties to the Agreement (Gabon, Chad, Guinea Bissau, Botswana, Senegal, Niger), in accordance with Articles 26 and 27 of the Agreement ('the envisaged act').

Part I of Annex A to the Agreement contains a list of mercury-added products (e.g. certain compact fluorescent lamps for general lighting purposes), the manufacturing, import and export of which is prohibited as from 2021, in accordance with Article 4(1) of this Agreement.

Part II of Annex A to the Agreement contains a list of nine measures on the phasing-down of the use of dental amalgam. In accordance with Article 4(1) and Part II Annex A to the Agreement, Parties must take at least two measures (e.g. to restrict the use of dental amalgam to its encapsulated form).

The objective of the envisaged act is to phase-out the use of dental amalgam. To do so, the envisaged act proposes to regulate the manufacture of and the international trade in dental amalgam in two steps. Firstly, it provides for the phasing-out, as from 2022, of the manufacture, import and export of dental amalgam when destined to be used for the treatment of deciduous teeth, as well as of teeth of children under the age of 15 and of pregnant and breastfeeding women. Secondly, it foresees to apply this prohibition as from 2025 to the manufacture, import and export of dental amalgam for all other uses, except where no mercury-free alternatives are available. In this respect, the envisaged act proposes to delete Part II of Annex A to the Agreement and to include dental amalgam in the list of mercury-added products referred to in Part I of Annex A to the Agreement.

3. POSITION TO BE TAKEN ON THE UNION'S BEHALF

The proposed position to be taken on the Union's behalf is to support, at the third meeting of the COP, the adoption of a Decision that is consistent with the EU *acquis.*

Article 10(2) of Regulation 2017/852/EU of the European Parliament and of the Council of 17 May 2017 on Mercury[3] ('Regulation 2017/852/EU') prohibits, as from 1 July 2018, the use of dental amalgam in the EU for the treatment of deciduous teeth, as well as of the teeth of children under the age of 15 and of pregnant and breastfeeding women.

Article 19 of Regulation 2017/852/EU foresees *inter alia* that the Commission will report to the European Parliament and to the Council, by 30 June 2020, on the feasibility of a phase-out in the EU of the use of dental amalgam in the long term, and preferably by 2030, whilst taking into account the Member States' national plans on the phasing down of the use of dental amalgam referred to in Article 10(3) and fully respecting their national competence for the organisation and delivery of health services and medical care. In light of this, the European Commission has launched in September 2018 an assessment on the feasibility of such a

[3] OJ L 137, 24.5.2017, p.1.

phasing-out in the EU by 2030. The study outcome will contain a technical assessment, including the analysis of above-mentioned national plans, which all Member States had to submit by 1 July 2019. This study will conclude in February 2020 and will inform the above-mentioned Commission's report due by end June 2020.

Hence, the EU *acquis* regulates the use dental amalgam but does not currently prevent its manufacture, import and export. In the future, consideration may be given to the option of widening the restrictions on use to include a ban on manufacture, import and export of dental amalgam depending *inter alia* on the outcome of the review of Regulation 2017/852/EU in accordance with Article 19.

Accordingly, at the third meeting of the Conference of the Parties to the Agreement, the EU can only support the adoption of a Decision that is consistent with the EU *acquis.* A Union position is needed as, once adopted, the Parties to the Agreement will have to implement the envisaged act.

4. LEGAL BASIS

4.1. Procedural legal basis

4.1.1. Principles

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for decisions establishing '*the positions to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement*.' The concept of '*acts having legal effects*' includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are '*capable of decisively influencing the content of the legislation adopted by the EU legislature*'[4].

4.1.2. Application to the present case

The COP is a body set up by an agreement, namely the Minamata Convention on Mercury.

The envisaged act, which the COP is called upon to adopt, constitutes an act having legal effects. The envisaged act has legal effects because Parties to the Agreement shall take measures to ensure that it is implemented and complied with.

The envisaged act does not supplement or amend the institutional framework of the Agreement. Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU.

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[4] Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI: EU:C:2014:2258, paragraphs 61 to 64.

4.2. Substantive legal basis

4.2.1. Principles

The substantive legal basis for a decision under Article 218(9) TFEU depends primarily on the objective and content of the envisaged act in respect of which a position is taken on the Union's behalf. If the envisaged act pursues two aims or has two components and if one of those aims or components is identifiable as the main one, whereas the other is merely incidental, the decision under Article 218(9) TFEU must be founded on a single substantive legal basis, namely that required by the main or predominant aim or component.

4.2.2. Application to the present case

The main objective and content of the envisaged act relate to environment. Therefore, the substantive legal basis of the proposed decision is Article 192(1) TFEU.

4.3. Conclusion

The legal basis of the proposed decision should be Article 192(1) TFEU, in conjunction with Article 218(9) TFEU.

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THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Minamata Convention on Mercury[5] ('the Agreement') was concluded by the Union by Council Decision (EU) 2017/939[6] and entered into force on 16 August 2017.

(2) Pursuant to Decision MC-1/1 on Rules of Procedures adopted by the Conference of the Parties to the Agreement at its first meeting, the Parties shall make every effort to reach agreement on all matters of substance by consensus.

(3) The Conference of the Parties to the Agreement, during its third meeting on 25-29 November 2019, is expected to adopt a Decision ('the proposed Decision') on the phasing-out of dental amalgam and amending Annex A to the Agreement.

(4) It is appropriate to establish the position to be taken on the Union's behalf in the Conference of the Parties to the Agreement, as this proposed Decision, if approved, will have legal effects since the Parties to the Agreement will have to take measures to implement it at national and/or regional levels.

(5) The proposed Decision foresees a prohibition as from 2022 on the manufacture, import and export of dental amalgam when used for treatment of deciduous teeth and of teeth of children under the age of fifteen and of pregnant and breastfeeding women. The proposed Decision envisages extending such prohibition, as from 2025, to the manufacture, import and export of dental amalgam for all other uses, except where no mercury-free alternatives are available. The proposed Decision provides for the

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5 Certified copy of the Minamata Convention on Mercury available at: https://treaties.un.org/doc/Treaties/2013/10/20131010%2011-16%20AM/CTC-XXVII-17.pdf

6 Council Decision (EU) 2017/939 of 11 May 2017 on the conclusion on behalf of the European Union of the Minamata Convention on Mercury (OJ L 142, 2.6.2017, p. 4).

amendment of Annex A to the Agreement as a means to implement those prohibitions in the Agreement.

(6) Article 10(2) of Regulation 2017/852/EU of the European Parliament and of the Council on Mercury[7] prohibits as from 1 July 2018 the use of dental amalgam in the Union for the treatment of deciduous teeth and of teeth of children under the age of fifteen and of pregnant and breastfeeding women; whereas Article 19 of that Regulation provides that the Commission will assess and report by 30 June 2020 to the European Parliament and to the Council on the feasibility of a phase-out in the Union of the use of dental amalgam in the long term, and preferably by 2030.

(7) The proposed Decision should accordingly only be supported as far as its elements on the phasing-out of the use of dental amalgam for the treatment of deciduous teeth and of teeth of children under the age of fifteen and of pregnant and breastfeeding women are concerned; whereas the Union should only support the adoption of a Decision by the Conference of the Parties to the Agreement that is consistent with the Union *acquis*.

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in the third meeting of the Conference of the Parties to the Agreement shall be to support the adoption of a Decision on the phasing-out of the use of dental amalgam that is consistent with the Union *acquis*.

Article 2

This Decision is addressed to the Commission.

Done at Brussels,

For the Council
The President

[7] Regulation 2017/852/EU of the European Parliament and of the Council of 17 May 2017 on Mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p.1).