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Subject: **COMMISSION REGULATION (EU) No .../.. of XXX** amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") as regards phenylmercury compounds

Delegations will find attached Commission document D018571/03.

Encl.: D018571/03



EUROPEAN COMMISSION

Brussels, XXX
D018571/03
[...] (2011) XXX draft

COMMISSION REGULATION (EU) No .../..

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") as regards phenylmercury compounds

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

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amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") as regards phenylmercury compounds

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 68(1) thereof,

Whereas:

- (1) In its Communication to the Council and the European Parliament on a Community Strategy Concerning Mercury² the Commission outlined that it is necessary to reduce mercury levels in the environment and human exposure and proposed as objectives, among others, the reduction of entry into circulation of mercury in society, by cutting supply and demand, the reduction of mercury emissions and the protection against mercury emissions. That Communication was reviewed in 2010³.
- (2) The Council has reaffirmed several times its commitment to the overall objective of protecting human health and the environment from the release of mercury and its compounds by minimising and, where feasible, ultimately eliminating global anthropogenic mercury releases to air, water and land. In this context, the Council underlined that mercury-added products, where viable alternatives exist, should be phased out as rapidly and as completely as possible, with the ultimate goal that all

¹ OJ L 396, 30.12.2006, p 1.

² COM (2005) 20 final.

³ COM(2010) 723 final.

mercury-added products should be phased-out, taking into due account technical and economic circumstances and the needs for scientific research and development⁴.

- (3) Mercury and its compounds are highly toxic to humans, ecosystems and wildlife. High doses can be fatal to humans, but even relatively low doses can have serious adverse neurodevelopmental impacts and have also been linked with possible harmful effects on the cardiovascular, immune and reproductive systems. Mercury is considered as a global persistent pollutant, circulating between air, water, sediments, soil and biota in various forms and can change in the environment into methylmercury, its most toxic form.
- (4) Regulation (EC) No 1907/2006 provides that, if a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall prepare a dossier after notifying that intention to the European Chemicals Agency (hereinafter 'the Agency').
- (5) Pursuant to Decision of the EEA Joint Committee No 25/2008 of 14 March 2008 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement⁵, Regulation (EC) No 1907/2006 was incorporated into the Agreement on the European Economic Area.
- (6) Norway has prepared a dossier concerning five phenylmercury compounds, namely phenylmercury acetate, phenylmercury propionate, phenylmercury 2-ethylhexanoate, phenylmercury octanoate and phenylmercury neodecanoate, which demonstrates that action on a Union-wide basis is necessary to address the risk to human health and the environment posed by the manufacture, use and placing on the market of those substances, on their own, in mixtures and articles. That dossier was submitted to the Agency in order to initiate the restriction process.
- (7) The five phenylmercury compounds are known to be used especially as catalysts in polyurethane systems used for coatings, adhesives, sealants and elastomer applications. The mercury catalysts are incorporated into the polymer structure and remain in the final article from which mercury or phenylmercury compounds are not released intentionally. Other phenylmercury compounds are not known to be used as catalysts in polyurethane systems and therefore they were not included in the assessment performed in the dossier.
- (8) The life-cycle of the phenylmercury compounds leads to a significant release of mercury to the environment and adds to the overall emissions of mercury. In particular, the phenylmercury compounds are degraded in the environment and give degradation products, including methylmercury, with equivalent level of concern to persistent, bioaccumulative and toxic substances (PBTs). The interconversion of metabolites of phenylmercury compounds allows for long range transport properties. Therefore as transformation/degradation products with PBT-properties are being generated, the phenylmercury compounds themselves must be treated like PBT-

⁴ Council Conclusions of 15 March 2011 "Review of the Community Strategy Concerning Mercury", of 4 December 2008 "Addressing global mercury challenges" and of 24 June 2005 "On the Community Strategy Concerning Mercury".

⁵ OJ L 182, 10.7.2008, p. 11.

substances with regard to emission and exposure control. To this end, the exposures and emissions to humans and the environment should be minimized as much as possible.

- (9) The main exposure to humans via the environment may be through food, in which the phenylmercury compounds degradation products, including methylmercury, may be found. Methylmercury biomagnifies especially in the aquatic food chain, making human population and wildlife with a high intake of fish and seafood particularly vulnerable. Methylmercury readily passes both the placental barrier and the blood-brain barrier, inhibiting potential mental development even before birth, making the exposure of women of child-bearing age and children of greatest concern.
- (10) On 10 June 2011, the Committee for Risk Assessment of the Agency (RAC) adopted its opinion on the proposed restriction, taking into account its effectiveness in reducing the risks to human health and the environment. Moreover, RAC identified that other organomercury compounds might be used as catalysts in the polymer production. However, these substances were not included in the assessment performed in the dossier.
- (11) On 15 September 2011 the Committee for Socio-economic Analysis of the Agency adopted its opinion on the proposed restriction, taking into account its effectiveness in addressing the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs.
- (12) The Agency has submitted to the Commission the opinions of the Committees for Risk Assessment and Socio-economic Analysis.
- (13) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take the measures that may be required to comply with the measures set out in this Regulation.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

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 [insert date - 5 years after entry into force of this Regulation]

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

Done at Brussels,

*For the Commission
The President*

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry 62 is added:

<p>"62.</p> <p>(a) Phenylmercury acetate EC No.: 200-532-5 CAS No.: 62-38-4</p> <p>(b) Phenylmercury propionate EC No.: 203-094-3 CAS No.: 103-27-5</p> <p>(c) Phenylmercury 2-ethylhexanoate EC No.: 236-326-7 CAS No.: 13302-00-6</p> <p>(d) Phenylmercury octanoate EC No.: - CAS No.: 13864-38-5</p> <p>(e) Phenylmercury neodecanoate EC No.: 247-783-7 CAS No.: 26545-49-3</p>	<p>1. Shall not be manufactured, placed on the market or used as substances or in mixtures after [insert date - 5 years after entry into force of this Regulation] if the concentration of mercury in the mixtures is equal to or greater than 0,01% by weight.</p> <p>2. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after [insert date - 5 years after entry into force of this Regulation] if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01% by weight .</p>
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