EUROPEAN
COMMISSION

Brussels, XXX
[…](2019) 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 lead and its compounds

(Text with EEA relevance)

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(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/EC[1], and in particular Article 68(1) thereof,

Whereas:

(1) On 16 December 2016, the European Chemicals Agency ('the Agency') submitted, at the request of the Commission, a dossier[2] pursuant to Article 69(1) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'), demonstrating that releases of lead from articles produced from polymers or copolymers of vinyl chloride (PVC) containing lead stabilisers, during their life-cycle, contribute directly and indirectly to human exposure to lead. The dossier proposed to ban the use of lead and lead compounds in articles produced from PVC. Moreover, it proposed that PVC articles containing a concentration of lead equal or greater than 0.1% of the PVC material should not be placed on the market. A number of derogations to this restriction, inter alia for recovered PVC material, were also contained in the proposal.

(2) Lead is a toxic substance which affects the development of the nervous system, produces chronic kidney disease and has adverse effects on blood pressure. Although no threshold for neurodevelopmental effects in children and for renal effects has been established, according to the European Food Safety Agency the current human exposure to lead from food and other sources still exceeds the tolerable exposure levels and leads to adverse neurodevelopmental effects in children[3].

(3) Lead stabilisers in PVC articles allow the PVC to endure longer fabrication (heating) time and protect it against photo-degradation. Industry in the Union voluntarily phased out the use of lead stabilisers in PVC and reported that that process was successfully

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1 OJ L 396, 30.12.2006, p. 1.

2 https://echa.europa.eu/documents/10162/e70aee23-157b-b2a4-2cae-c42a1278072c (report); https://echa.europa.eu/documents/10162/cc1c37a8-22f9-7a7a-cb33-5c29edba7094 (annex)

3 EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Lead in Food. EFSA Journal 2010; 8(4):1570.

completed in 2015[4]. PVC articles containing lead, especially construction products, have long service lives, remaining in use for periods exceeding several decades, after which they become waste upon disposal and may undergo recycling, potentially re-introducing lead into products via the recovered PVC material. Given the phase-out of lead stabilisers in the Union, the Agency calculated that 90 % of the estimated total emissions of lead from PVC articles in the Union in the year 2016 was attributable to imported PVC articles.

(4) Considering that lead compounds cannot stabilise PVC in an effective way at concentrations below approximately 0,5 % by weight, the concentration limit of 0,1 % proposed by the Agency should ensure that the intentional addition of lead compounds as stabilisers during PVC compounding can no longer occur in the Union.

(5) Except for certain lead-containing pigments, which are subject to authorisation under REACH and specifically exempted under the proposed restriction, no other lead compounds than stabilisers are used in PVC. To facilitate the enforcement of the proposed restriction, it is therefore appropriate to extend the scope of the restriction to all lead and lead compounds, thereby making it unnecessary to determine the specific identity and function of the lead compounds present in the PVC material. On 5 December 2017, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion[5], concluding that the restriction proposed by the Agency is the most appropriate Union-wide measure to address the identified risks posed by lead compounds present as stabilisers in PVC articles in terms of effectiveness in reducing such risks, practicality and monitorability. The RAC proposed modified derogations from the restriction in relation to certain articles containing recovered PVC.

(6) On 15 March 2018, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion in which it concluded that the restriction proposed by the Agency, as modified by both the RAC and the SEAC, was the most appropriate Union-wide measure to address the identified risk, in terms of its socioeconomic benefits and socioeconomic costs. The SEAC reached that conclusion based on best available evidence, taking into account the properties of lead as a non-threshold toxic substance and its impact on human health and the affordability of the costs associated with the proposed restriction. Consideration was also given to the fact that there are suitable alternatives widely available and already used by supply chains in the Union, the cost-effectiveness of the restriction as well as the result of the break-even analysis.

(7) The RAC agreed to include a derogation for recovered PVC articles and proposed that higher lead content limits for rigid and flexible PVC recyclate should be established, respectively, at 2 % and 1 % by weight. That proposal takes account of the estimation that the alternative to recycling such articles, i.e. disposal of PVC waste via landfilling and incineration, would increase emissions to the environment and not reduce risk. The different limits proposed take into account the current estimated average lead content of rigid and flexible PVC, the expected impact on recycling volumes and the fact that the release of lead from flexible PVC is known to be higher compared to rigid PVC.

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4 VinylPlus progress report of 2017, p. 14; see https://vinylplus.eu/uploads/downloads/VinylPlus_Progress_Report_2017.pdf.

5 https://echa.europa.eu/documents/10162/86b00b9e-2852-d8d4-5fd7-be1e747ad7fa (compiled RAC and SEAC opinion).

(8) The SEAC agreed with the Agency that considering the projected evolution of the concentration of lead in recovered PVC, that concentration will decrease sufficiently by 2035 – 2040 to allow articles made from recovered PVC to comply with the proposed general lead concentration limit of 0,1 %. Therefore, the derogation for articles made from recovered PVC should apply for 15 years. The SEAC further agreed that, in order to account for the uncertainty with respect to the future trends regarding the amount of post-consumer PVC waste going to recycling and its lead content, that period of application should be reassessed within 10 years.

(9) It is expected that encapsulation techniques will allow limiting releases of lead from recovered flexible PVC present in certain types of articles such as traffic management articles and waterproofing membranes, by enclosing the lead entirely within a layer of newly produced PVC or other suitable material. Such techniques are not yet readily available and their implementation will require additional time and capital investment from economic operators. It is therefore appropriate to lay down a transitional period. During this period of 6 years certain articles containing recovered flexible PVC do not need to be coated, if they are to be covered by the derogation from the 0,1% general maximum lead content restriction for PVC in those articles. After the transitional period, that derogation should only apply to the recovered flexible PVC contained in those articles if it is completely enclosed by an outer layer of newly produced PVC or other suitable material.

(10) The proposed derogation for recovered PVC aims to achieve an appropriate balance between the overall long-term benefits from circular use of those materials and the overall long-term health concerns relating to that material.

(11) A derogation is appropriate for PVC-silica separators in lead batteries in view of the low risks and the lack of suitable alternatives. According to information submitted by producers of those PVC separators suitable alternatives will be available in approximately 10 years.

(12) The Agency's Forum for Exchange of Information on Enforcement was consulted on the proposed restriction and its opinion was taken into account, resulting in a modified description of the scope and of the derogations from the proposed restriction.

(13) The RAC and the Agency agreed that the uses of lead compounds other than as stabilisers should be covered by the proposed restriction and to provide for a specific derogation for the lead pigments "lead sulfochromate yellow" and "lead chromate molybdate sulfate red" from the restriction. Those pigments are currently subject to an existing application for authorisation under Regulation (EC) No 1907/2006 and are the only lead compounds known to be used in PVC for a purpose other than stabilisation. In June 2018 the Agency published its intention to submit a restriction dossier relating to the risks stemming from the use of the two lead pigments pursuant to Article 69(2) of Regulation (EC) No 1907/2006. The Commission will re-examine the applicability of the derogation for those lead pigments following the outcome of that restriction process.

(14) For reasons of consistency, a derogation should be laid down for articles already covered by Union legislation regulating lead content in PVC.

(15) Considering that for enforcement purposes it is essential to be able to distinguish articles that contain recovered PVC from those that do not, a requirement to mark all articles covered by the derogation for articles containing recovered PVC should be introduced.

(16) Considering the difficulties to determine if PVC material in articles, especially imported articles, is of recovered origin, suppliers of articles benefitting from derogations associated to their content in recovered PVC should be able to prove the recovered origin of the material by presenting documentary evidence. In the Union, several schemes are available to recyclers to support claims on the traceability of recovered PVC[6]. Given the lack of suitable practical means for enforcement authorities to verify recovery claims associated to recovered PVC in imported articles, such claims should be substantiated via independent third party certification.

(17) Economic operators should be granted a period of 24 months in order to be able to adapt to the new requirements, dispose of their stock and communicate relevant information on the restriction within their supply chains. Furthermore, the restriction should not apply to articles already placed on the market before the end of that period as that would give rise to considerable enforcement difficulties.

(18) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(19) 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*.

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

Done at Brussels,

For the Commission
The President
Jean-Claude Juncker

[6] Examples of such schemes are the Recovinyl audit framework and the EuCertPlast certification for plastic recyclers. In addition, several other certification schemes are available in some Member States, all of which are based on requirements in EN 15343:2007 "Plastics recycling traceability and assessment of conformity and recycled content".