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

of 3.5.2023

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament
and of the Council as regards lead and its compounds in PVC**

(Text with EEA relevance)

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amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards lead and its compounds in PVC

(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) On 16 December 2016, the European Chemicals Agency ('the Agency') submitted, at the request of the Commission, a dossier² 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 Agency suggested in the Annex XV dossier to restrict the placing on the market or use of lead in articles produced from PVC if the concentration of lead is equal to or greater than 0,1 % by weight of the PVC material. Considering that lead compounds cannot stabilise PVC in an effective way at concentrations below approximately 0,5 % by weight, the concentration limit proposed should ensure that the intentional addition of lead compounds as stabilisers during PVC compounding can no longer occur in the Union. The Agency also included in the Annex XV dossier a number of derogations to this suggested restriction, notably for PVC articles containing recovered PVC. 'Recovered' is used in line with the definition of 'material recovery' in Article 3, point 15a, of Directive 2008/98/EC of the European Parliament and of the Council³.
- (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

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 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 22.11.2008, p. 3).

exposure to lead from food and other sources still exceeds the tolerable exposure levels and leads to adverse neurodevelopmental effects in children⁴.

- (3) Lead stabilisers increase the thermal stability of PVC during compounding and article production. They also protect PVC against photo-degradation. Industry in the Union voluntarily phased out the use of lead stabilisers in PVC compounding and PVC articles and reported that that process was successfully completed in 2015⁵. 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. The Annex XV dossier showed 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, due to the phase-out of lead stabilisers in the Union.
- (4) To facilitate the enforcement of the proposed restriction, it is appropriate to restrict any lead present in PVC regardless of its intended function.
- (5) On 5 December 2017, the Agency's Committee for Risk Assessment ('RAC') adopted its final opinion⁶, 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.
- (6) RAC proposed to ban the use of any concentration of lead in PVC articles. RAC also agreed with the Agency that a derogation should be laid down for PVC articles containing recovered PVC. RAC however proposed that higher lead content limits for certain PVC articles containing recovered rigid and flexible PVC should be established, respectively, at 2 % and 1 % by weight. That proposal took account of the estimation that the alternative to recycling such articles, i.e. disposal of PVC waste via landfilling and incineration, would increase the emissions to the environment and not reduce the risk. The different limits proposed took into account the estimated average lead content of rigid and flexible PVC waste in 2013, the expected impact on recycling volumes and the fact that the release of lead from flexible PVC is known to be higher compared to the one from rigid PVC. Due account was taken of the fact that some articles have a high content of recovered PVC that may reach 100 % by weight of the PVC in the final article.
- (7) On 15 March 2018, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its final opinion⁷ in which it concluded that the restriction proposed by the Agency, as modified by both RAC and SEAC, was the most appropriate Union-wide measure to address the identified risk, in terms of its socioeconomic benefits and socioeconomic costs. 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. SEAC considered that there are suitable alternatives widely

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

⁵ VinylPlus progress report of 2017, p. 14; see

https://vinylplus.eu/uploads/downloads/VinylPlus_Progress_Report_2017.pdf.

⁶ <https://echa.europa.eu/documents/10162/86b00b9e-2852-d8d4-5fd7-be1e747ad7fa>.

⁷ <https://echa.europa.eu/documents/10162/86b00b9e-2852-d8d4-5fd7-be1e747ad7fa>.

available and already used in the Union. It also considered the cost-effectiveness of the restriction. Finally, it concluded that even limited human health impacts in terms of intelligence quotient loss, would be sufficient to break even with the costs of the restriction.

- (8) SEAC agreed with the proposal in the Annex XV dossier that, considering the projected evolution of the concentration of lead in recovered PVC, that concentration would decrease sufficiently by 2035 - 2040 to allow PVC articles containing recovered PVC to comply with the proposed general lead concentration limit of 0,1 %. Therefore, the derogation for certain PVC articles containing recovered PVC should apply for 15 years from the entry into force of the restriction. SEAC further agreed that, in order to account for the uncertainty with respect to the future trends regarding the amount of PVC waste going to recycling and its lead content, that period of application should be reassessed within 10 years from the entry into force of the restriction. In line with the aim of the 2015 EU Action Plan for the Circular Economy⁸ to promote non-toxic material cycles and preserve the high level of protection for human health and the environment, the Commission considered that that period of application should be reassessed within 7,5 years from the entry into force of the restriction.
- (9) 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.
- (10) On 26 April 2018, the Agency submitted the final opinions of RAC and SEAC to the Commission.
- (11) Taking into account the Annex XV dossier and the opinions of RAC and SEAC, and considering that there is an unacceptable risk to human health from lead in PVC articles, the Commission proposed a draft Commission regulation restricting the use of any concentration of lead and its compounds in PVC articles and the placing on the market of lead and its compounds in PVC articles in a concentration equal to or greater than 0,1 % by weight of the PVC material ("the draft regulation"). The draft regulation received a favourable opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006 on 20 November 2019.
- (12) In accordance with the regulatory procedure with scrutiny referred to in Article 133(4) of Regulation (EC) No 1907/2006, a resolution objecting to the draft regulation was adopted by the European Parliament plenary on 12 February 2020⁹. Consequently, the draft regulation was not adopted by the Commission.
- (13) In its resolution, the Parliament asked the Commission to remove the derogations for recovered PVC, as it would lead to the carry-over of lead into new products. The Parliament also requested the removal of the derogation for the two lead pigments subject to the authorisation regime under REACH. Furthermore, the Commission was asked to delete the proposed marking requirements for PVC articles containing

⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Closing The Loop - An EU Action Plan for the Circular Economy. COM/2015/0614 final.

⁹ European Parliament resolution of 12 February 2020 on the draft Commission regulation 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 (OJ C 294, 23.7.2021, p. 2).

recovered PVC as it considered it misleading and not reflecting that recovered PVC contains higher amounts of lead than newly produced PVC. Finally, the Parliament asked the Commission to reduce the proposed transitional period for when the provisions of the regulation shall apply.

- (14) The Commission has carefully assessed the resolution of the Parliament and acknowledges the need to address certain concerns. In addition, it considers that there is still an unacceptable risk to human health from lead in PVC articles, which needs to be addressed on a Union-wide basis. Against this background, the Commission decided to amend some of the provisions of the draft regulation to reflect the arguments brought forward by the Parliament and take into account relevant new data received from the Agency and stakeholders.
- (15) In particular, the Commission considers that clean recycling technologies which allow the removal of legacy substances of concern, including lead, from PVC waste should be encouraged. Current recycling technologies, however, can reduce but not completely eliminate legacy substances. It is therefore necessary to set a concentration limit of 0,1 % of lead by weight not only for the placing on the market but also the use of lead and its compounds in PVC, in order to allow both the placing on the market of articles containing less than 0,1 % of lead by weight of the PVC material and the continued use in articles of PVC material containing lead below that limit, such as PVC material recovered through chemical recycling or solvent dissolution and containing very small amounts of lead.
- (16) As a means of limiting the carryover of lead in new products, the derogation for PVC articles containing recovered flexible PVC should be removed from the draft regulation. However, economic operators should be granted a 24-month period to adapt to the new requirements.
- (17) However, a derogation for certain PVC articles containing recovered rigid PVC should be laid down to achieve an appropriate balance between the overall long-term benefits from the circular use of those materials and the overall long-term health concerns relating to that recovered material. Following industry reports that the average lead concentration in recovered rigid PVC is below 1,5 % due to routine mixing of pre- and post-consumer waste, the allowed lead concentration limit in recovered rigid PVC should be reduced from 2 % to 1,5 % by weight. To prevent the possible leaching of lead and the formation of lead-containing dust, recovered rigid PVC in derogated articles should be entirely enclosed within a layer of newly produced PVC, recovered PVC or other suitable material that contains less than 0,1 % of lead by weight, unless the derogated article is inaccessible during normal use. In addition, the Commission agrees with the Parliament that the benefits to health protection to be achieved with the restriction should be pursued faster. Consequently, the duration of the derogation should be decreased from 15 to 10 years. A review of the derogation should take place at the latest 5 years after the entry into force of the restriction. The review should include verifying trends regarding lead concentration in recovered PVC, the availability of adequate decontamination techniques and the socio-economic impact of removing the derogation, considering the risk to human health and to the environment.
- (18) To limit the presence of lead from recovered rigid PVC to certain known articles, rigid PVC recovered from profiles and sheets in buildings and civil engineering works and containing more than 0,1 % of lead by weight of the PVC should only be used to produce new PVC profiles and sheets for the same applications. In combination with appropriate marking obligations, this should ensure the identification of lead-

containing products and facilitate future decontamination activities. It should also promote a separate collection and recycling of PVC pipes (currently rarely recycled), as pipe producers who currently use PVC recovered from profiles and sheets to produce new pipes will need to replace it with an alternative PVC source. However, in order to allow economic operators sufficient time to put in place dedicated PVC waste collection and recycling, re-organise their supply chains and, where needed, procure recovered PVC from other origin than profiles and sheets, this obligation should apply after 36 months from the entry into force of this Regulation.

- (19) For enforcement purposes and to ensure that professionals and consumers are adequately informed of possible risks, PVC articles containing recovered rigid PVC should be marked if they contain lead in a concentration equal or greater than 0,1 % by weight of the PVC material. This should also facilitate the separate collection of lead-containing waste.
- (20) Considering the difficulties to determine if PVC in articles is of recovered origin, suppliers of PVC 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 certification schemes, all of which are based on technical specifications in EN 15343:2007¹⁰, are available to recyclers to support claims on the traceability of recovered PVC. 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.
- (21) The specific derogation previously proposed for the lead pigments "lead sulfochromate yellow" and "lead chromate molybdate sulfate red" should be removed from the draft regulation. In view of recent case law¹¹ and the Agency's intention to submit a restriction dossier pursuant to Article 69(2) of Regulation (EC) No 1907/2006 related to the risks stemming from the use of those two lead pigments, the Commission considers that that derogation has become unnecessary.
- (22) In view of the low risks and the lack of suitable alternatives, a derogation for PVC-silica separators in lead batteries should be set out for a period of 10 years from the entry into force of this Regulation, after which suitable alternatives are expected to be available.
- (23) To avoid double regulation, a derogation should be laid down for articles already covered by Regulation (EC) No 1907/2006 or other Union legislation regulating lead content in PVC.
- (24) As industry in the Union has not been using lead stabilisers in PVC since 2015, a period of 18 months is considered sufficient for most economic operators 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 PVC articles already placed on the market before the end of that period, as that would give rise to considerable enforcement difficulties.
- (25) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

¹⁰ Standard EN 15343:2007 on Plastics - Recycled Plastics - Plastics recycling traceability and assessment of conformity and recycled content, approved by the European Committee for Standardization on 2 November 2007.

¹¹ *European Commission v Kingdom of Sweden*, Case C-389/19 P, ECLI:EU:C:2021:131.

(26) 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, 3.5.2023

For the Commission
The President
Ursula VON DER LEYEN