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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

laying down rules for the application of Regulation (EC) No 1907/2006 as regards applications for authorisation and review reports for the uses of substances in the production of legacy spare parts and in the repair of articles and complex products no longer produced and amending Regulation (EC) No 340/2008

(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/EC¹, and in particular Article 74(1) and 132 thereof,

Whereas:

- (1) Article 56(1) of Regulation (EC) No 1907/2006 sets out an authorisation requirement for the placing on the market and the use of substances of very high concern listed in Annex XIV to that Regulation. The compliance with that requirement, in certain cases, constitutes a significant administrative burden for undertakings. In its Communication of 18 June 2014 “Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook”² the Commission announced that it was considering simplifying the authorisation process in some specific cases. Simplifying the applications for continued use of substances of very high concern in the production of legacy spare parts was identified as one of the actions in the Commission Communication of 5 March 2018 “Commission General Report on the operation of REACH and review of certain elements”³.
- (2) The Commission Communication of 2 December 2015 “Closing the loop – An EU action plan for the Circular Economy”⁴ describes that the extension of the lifetime of products by way of repair helps avoid wastage. The Council conclusions of 20 June 2016 on that action plan⁵ invite the Commission to investigate what initiatives can be taken at Union level in the interest of extending the lifetime of products, in particular by promoting the availability of spare parts.

¹ OJ L 396, 30.12.2006, p. 1

² COM(2014) 368 final

³ COM(2018) 116 final

⁴ COM(2015) 614 final

⁵ Closing the loop - An EU action plan for the Circular Economy - Council conclusions of 20 June 2016, ST 10518 2016 INIT.

- (3) In order to avoid the premature obsolescence of articles or complex products⁶ that are no longer produced after the sunset dates referred to in Annex XIV to Regulation (EC) No 1907/2006, spare parts as well as substances and mixtures that are necessary for the repair of such articles or complex products need to continue to be made available on the market and used. If a substance listed in Annex XIV to Regulation (EC) No 1907/2006 has been used to produce such articles or complex products and, if after the sunset date the spare part cannot be produced or the product cannot be repaired without the use of that substance, the requirements as regards the content of the application for authorisation and of the review report of an authorisation for such uses should be clarified in order to simplify such applications for authorisation.
- (4) As regards the analysis of alternatives referred to in Article 62(4)(e) of Regulation (EC) No 1907/2006, providing justification demonstrating that the article or complex product is no longer produced after the sunset date, that it cannot function as intended without the spare part and that such spare part cannot be produced without the substance, or that the article or complex product cannot be repaired otherwise than by using the substance, should be considered sufficient to conclude on the lack of suitable alternatives. As the use of the substance in the production of such spare parts or repair of such articles or complex products will gradually decrease since its intended use is for a product that is no longer produced, while the substitution costs for research and development, testing, qualification, and industrialisation of possible alternatives for such uses are likely to be high in view of the expected decreasing trend, such provision is deemed justified.
- (5) Similarly, the justification demonstrating that the article or complex product is no longer produced after the sunset date, that it cannot function as intended without the spare part and that such spare part cannot be produced without the substance, or that the article or complex product cannot be repaired otherwise than by using the substance should be considered sufficient in order to demonstrate the socio-economic benefits of the use of the substance in the socio-economic analysis referred to in point (a) of Article 62(5) of Regulation (EC) No 1907/2006. The non-availability of spare parts or the impossibility to repair articles or complex products no longer produced without that substance would lead to the premature obsolescence of those articles or complex products before the end of their lifetime use and therefore to their premature disposal, likely causing high costs to operators, consumers or society. Moreover, the number of uses and quantities of the substance used for such spare parts are expected to decrease, leading to a diminishing impact on human health and the environment associated with the exposure to or emission of the substance used. It is therefore appropriate that contents of the socio-economic analysis referred to in point (a) of Article 62(5) of Regulation (EC) No 1907/2006 be provided by the applicant in a succinct form. This is without prejudice to the consideration of the risk posed by the use of the substance to human health or the environment and to the need for the applicant to demonstrate that socio-economic benefits outweigh that risk.
- (6) The clarification of the content of applications for authorisation for the use of a substance in the production of spare parts for repair or in the repair of articles and complex products no longer produced should result in a reduction of the workload for

⁶ 'Complex products' as described in the judgment of the Court of Justice of 10 September 2015, *Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB)*, C-106/14, ECLI:EU:C:2015:576, paragraphs 48-54.

the European Chemicals Agency ('the Agency') in assessing applications for authorisation in those specific cases. The fees levied for such applications should be proportionate to the expected workload of the Agency in such cases and, hence, be reduced when compared to the fee levied for the applications for other uses. For the same reasons, the charges applicable to the review of authorisations granted for those uses should be reduced by the same proportion.

- (7) Commission Regulation (EC) No 340/2008⁷ should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

This Regulation implements Articles 61(1), 62(4)(e) and 62(5)(a) of Regulation (EC) No 1907/2006 as regards applications for authorisation and review reports for any of the following uses of a substance, on its own or in a mixture, listed in Annex XIV to that Regulation

- (a) the production of spare parts as articles or as complex products for the repair of articles or complex products, the production of which ceased or will have ceased before the sunset date for that substance specified in Annex XIV, where that substance was used in the production of those articles or complex products and these cannot function as intended without that spare part and the spare part cannot be produced without that substance ('production of legacy spare parts');
- (b) the repair of articles or complex products, the production of which ceased or will have ceased before the sunset date for that substance specified in Annex XIV, where that substance was used in the production of those articles or complex products and they cannot be repaired otherwise than by using that substance ('repair of articles or complex products no longer produced').

Article 2

1. An application for authorisation pursuant to Article 62 of Regulation (EC) No 1907/2006 for the use of a substance in the production of legacy spare parts or in the repair of articles or complex products no longer produced shall be considered to comply with point (e) of Article 62(4) of that Regulation when it includes the following:
 - (a) a description and analysis of the function of the substance, and
 - (b) a justification demonstrating that the conditions set out in points (a) or (b) of Article 1 of this Regulation as appropriate have been fulfilled.
2. An application for authorisation pursuant to Article 62 of Regulation (EC) No 1907/2006 for the use of a substance in the production of legacy spare parts or in

⁷ Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107 17.4.2008, p. 6).

the repair of articles or complex products no longer produced shall be considered to comply with point (a) of Article 62(5) when it includes the following:

- (a) a succinct description of the human health or environmental impacts in accordance with the information provided in the chemical safety report;
 - (b) a succinct description of the socio-economic benefits of the use applied for, including a justification demonstrating that the conditions set out in points (a) or (b) of Article 1 of this Regulation as appropriate have been fulfilled;
 - (c) a conclusion based on a comparison of the risks and benefits of the use of the substance applied for, as described in points (a) and (b) of this paragraph.
3. Where the application for authorisation is submitted for the use of a substance in the production of legacy spare parts or in the repair of articles or complex products no longer produced, information referred to in paragraphs 1 and 2 of this Article, together with any third party contributions on possible alternatives submitted in accordance with Article 64(2) of Regulation (EC) No 1907/2006, shall suffice for the purpose of assessing the socio-economic factors and the suitability of the alternatives associated with the use of the substance.
 4. Paragraphs 1, 2 and 3 of this Article shall apply *mutatis mutandis* to review reports submitted pursuant to Article 61(1) of Regulation (EC) No 1907/2006 concerning an authorisation granted for the use of a substance in the production of legacy spare parts or in the repair of articles or complex products no longer produced.
 5. By [*insert date - 14 days after date of entry into force*] the European Chemicals Agency ('the Agency') shall make publicly available specific formats for the analysis of alternatives and the socio-economic analysis to be used in applications for authorisation for uses of substances in the production of legacy spare parts or in the repair of articles or complex products no longer produced as well as in review reports concerning an authorisation granted for such uses, submitted in accordance with this Regulation, reflecting the elements referred to in paragraphs 1 and 2.

Article 3

Regulation (EC) No 340/2008 is amended as follows:

- (1) In Article 8(2), the following subparagraph is added after the fifth subparagraph:

'The Agency shall levy a reduced fee as set out in point 2 of Annex VI to this Regulation for applications for authorisation for uses of substances in the production of legacy spare parts for the repair of articles or complex products no longer produced as described in point (a) of Article 1 of Commission Implementing Regulation ...⁺ and in the repair of articles or complex products no longer produced as described in point (b) of Article 1 of that Regulation, submitted in accordance with that Implementing Regulation.

* Commission Implementing Regulation .../... of ... on ... (OJ ...).'

⁺ OJ Please insert in the text the number of this Implementing Regulation and insert the number, date, title and OJ reference of this Implementing Regulation in the footnote.

- (2) In Article 9(2), the following subparagraph is inserted after the fourth subparagraph:
‘The Agency shall levy a reduced charge as set out in point 2 of Annex VII to this Regulation for applications for authorisation for uses of substances in the production of legacy spare parts for the repair of articles or complex products no longer produced as described in point (a) of Article 1 of Implementing Regulation ...+ and in the repair of articles or complex products no longer produced as described in point (b) of Article 1 of that Regulation, submitted in accordance with that Implementing Regulation’.
- (3) Annexes VI and VII are replaced by the text as set out in the Annex to this Regulation.

Article 4

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
Ursula VON DER LEYEN