Commission Regulation (EU) 2015/326 of 2 March 2015 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 polycyclic aromatic hydrocarbons and phthalates (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/326

of 2 March 2015

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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 131 thereof,

Whereas:

(1) Annex XVII to Regulation (EC) No 1907/2006 contains, amongst others, the restrictions previously laid down in Council Directive 76/769/EEC[(2)].

(2) Directive 2005/69/EC of the European Parliament and of the Council[(3)] prohibited the placing on the market and use of extender oils for the production of tyres or parts of tyres if they contain more than 1 mg/kg of benzo(a)pyrene (BaP), or more than 10 mg/kg of the sum of the eight listed polycyclic aromatic hydrocarbons (PAHs). That restriction is currently laid down in paragraph 1 of column 2 of entry 50 of Annex XVII to Regulation (EC) No 1907/2006.

(3) At the time of adoption of that restriction, there were no harmonised test methods available to determine the specific concentration of the eight listed PAHs in extender oils. Therefore, the analytical method IP 346:1998[(4)], used by the petroleum industry to determine the concentration of polycyclic aromatic compounds (PCA), is referred to in that restriction as an indirect method to determine compliance with the limits specified for BaP and the sum of all listed PAHs.

(4) The analytical method IP 346:1998 is not specific to the eight listed PAHs. Furthermore, it is well established that this method is limited in its scope to unused lubricating base oils, free of asphaltene fractions and having not more than 5 % of their components

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/326. (See end of Document for details)*

with a boiling point below 300 °C. For samples not meeting those requirements, that method may be unsuitable.

(5) As called for in Directive 2005/69/EC, on 3 July 2007 the Commission issued a mandate to the European Committee for Standardisation (CEN) for the development of a more specific method.

(6) The new standard method has been adopted and published by CEN as EN 16143:2013 (Petroleum products — Determination of content of Benzo(a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils — Procedure using double LC cleaning and GC/MS analysis).

(7) The Commission considers that, given that this new standard provides a specific analytical method to analyse the relevant PAHs in extender oils and overcomes the shortcomings of the previous method, it is appropriate to replace the citation of method IP 346:1998 by the new standard EN 16143:2013 as the reference method to determine compliance of extender oils with the restriction in paragraph 1 of column 2 of entry 50 of Annex XVII to Regulation (EC) No 1907/2006.

(8) An informal consultation carried out with Member States and representatives of relevant stakeholder associations indicated that, for extender oils, there is in general a good correlation between the results of method IP 346:1998 and gas-chromatographic analytical methods, which follow the same principle as the new CEN method, to measure individual carcinogenic PAHs. Economic operators have indicated that the replacement of IP 346:1998 by the new CEN method is not expected to have impacts on the compliance of extender oils. However, the new analytical method is reported to be more complex and costly to perform than IP 346:1998.

(9) A transitional period of eighteen months should be granted whereby both the old and the new analytical methods could be used alternatively for determining compliance with that restriction. This transitional period should allow laboratories to set up and obtain the necessary experience in the operation of the new analytical method. It should also facilitate determining compliance of extender oils placed on the market already before the entry into force of this Regulation.

(10) The Commission has completed its re-evaluation of the measures of entry 51 of Annex XVII to Regulation (EC) No 1907/2006 regarding the substances bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP), in accordance with paragraph 3 of that entry. This re-evaluation was launched on 4 September 2009 by the Commission's request to the European Chemicals Agency (ECHA) to review the available new scientific information and to evaluate whether there is evidence that would justify a re-examination of the existing restriction. In providing the information to the Commission in March 2010, ECHA pointed out that an assessment of the relevant REACH registration dossiers should be considered. Therefore, the Commission asked ECHA to proceed as suggested. However, in April 2011, the Kingdom of Denmark initiated the restrictions process regarding the presence of those phthalates in articles for indoor use and articles that may come into direct contact with the skin or mucous membranes, in which, amongst other things, the registration dossiers were considered. As communicated on 9 August 2014[(5)], at the

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end of the restriction process, the Commission did not propose an amendment to Annex XVII to Regulation (EC) No 1907/2006. Furthermore, by means of Commission Regulation (EU) No 143/2011[(6)], the Commission included those phthalates in Annex XIV to Regulation (EC) No 1907/2006. Consequently, pursuant to Article 69(2) of that Regulation, ECHA has the obligation to consider after the 'sunset date' whether the use of those phthalates in articles poses a risk to human health or the environment that is not adequately controlled. Therefore, no further review of the measures for this restriction of those phthalates was considered necessary and it is therefore appropriate to delete that paragraph from that entry.

(11) In January 2014, the Commission completed its re-evaluation of the measures of entry 52 of Annex XVII to Regulation (EC) No 1907/2006 regarding the substances di-'isononyl' phthalate (DINP), di-'isodecyl' phthalate (DIDP) and di-n-octyl phthalate (DNOP), in accordance with paragraph 3 of that entry. This re-evaluation was launched on 4 September 2009 by the Commission's request to ECHA to review the available new scientific information and to evaluate whether there is evidence that would justify a re-examination of the existing restriction. The available information was subsequently complemented by the information from the registration dossiers received by the 2010 registration deadline. ECHA then submitted its draft review report to its Committee for Risk Assessment (RAC) for a detailed evaluation. RAC adopted its opinion in March 2013 and the final ECHA review report was provided to the Commission in August 2013. Based on the ECHA report the Commission decided not to propose any amendment to the provisions of entry 52 of Annex XVII, and to consider the re-evaluation in accordance with paragraph 3 of that entry as completed. The Commission's conclusions on the re-evaluation have been made publicly available[(7)]. It is therefore appropriate to delete paragraph 3 from that entry.

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

(13) 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.