Commission Regulation (EU) No 474/2014 of 8 May 2014 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 1,4-dichlorobenzene (Text with EEA relevance)

COMMISSION REGULATION (EU) No 474/2014

of 8 May 2014

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 1,4-dichlorobenzene

(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) A risk assessment on 1,4 dichlorobenzene (hereinafter 'DCB') was carried out by the French authorities in accordance with Council Regulation (EEC) No 793/93[(2)] on the evaluation and control of the risks of the existing substances appearing in the European Inventory of Existing Commercial Substances. The final report was published in 2004 on the European Chemicals Bureau website (EC, 2004)[(3)].

(2) In February 2008, the Commission communication[(4)] on the results of the risk evaluation and the risk reduction strategies for DCB was published in the *Official Journal of the European Union*. That communication recommended that, in order to limit the risk for consumers, marketing and use restrictions in Council Directive 76/769/EEC[(5)] should be considered for the use of DCB in air fresheners, moth repellents and toilet blocks. Restrictions on the use of DCB as a moth repellent, as recommended by that communication in 2008, are already covered by Commission Decision 2007/565/EC[(6)] (product type 19 — Repellents and attractants) and therefore restriction under Regulation (EC) No 1907/2006 is not necessary for that use.

(3) In November 2011, in accordance with Article 69(1) of that Regulation, the Commission requested the European Chemicals Agency (hereinafter 'the Agency') to prepare a restriction dossier for DCB conforming to the requirements of Annex XV to that Regulation (hereinafter 'the Annex XV dossier').

(4) In its request the Commission specifically asked the Agency to address the exposure of consumers at home and in public toilets, including the exposure of professionals attending or cleaning such toilets, taking into account the most recent and relevant information in scientific literature and the decline of the use of DCB in Europe. The report[7] commissioned by the Commission on the socioeconomic impacts of a restriction of DCB was also to be considered in this assessment.

(5) DCB is listed in part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[8] as a carcinogen in hazard category 2, as well as for its eye irritation properties and its high toxicity to aquatic organisms, with long lasting effects. It is estimated that approximately 800 tonnes per year of DCB are used in the Union, for the manufacturing of air fresheners and toilet deodoriser products, of which 10 % is destined for domestic uses and the rest for professional uses (essentially as deodorisers in public toilets).

(6) On 19 April 2012, the Agency submitted to its Committee for Risk Assessment (hereinafter 'RAC') and to its Committee for Socio-Economic Analysis (hereinafter 'SEAC') the Annex XV dossier. In that dossier[9], it was demonstrated that the placing on the market and use of DCB-based air fresheners and toilet blocks should be restricted for both domestic and professional uses as risks associated with them are not adequately controlled and the benefits arising from the restriction outweigh the costs. The dossier further demonstrated that action on a Union-wide basis is necessary.

(7) On 8 March 2013, RAC adopted by consensus its opinion on the restriction proposed in the Annex XV dossier. According to the RAC opinion, the restriction is the most appropriate Union-wide measure to address the identified risks posed by DCB used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas, both in terms of effectiveness and practicability. However, RAC proposed to modify the restriction for enforceability reasons, specifying a concentration limit of 1 % by weight for DCB in such products, thereby avoiding products containing DCB as an impurity being unduly affected. That concentration corresponds to the limit value which triggers classification of a mixture as a category 2 carcinogen under Regulation (EC) No 1272/2008.

(8) As indicated in the background document to the RAC opinion, reliable analytical methods to determine contents of DCB are available on the Union market.

(9) In its assessment, RAC considered that carcinogenicity (mitogen, threshold carcinogen) is the end-point of greatest relevance to the human health. Based on data on inhalation exposure to DCB vapours, RAC proposed to reduce the identified risk to consumers when they use air fresheners and toilet deodorisers, containing DCB, continuously at home. That scenario was considered to represent reasonable worst-case conditions of exposure. In addition, the RAC opinion stated that exposure of professional toilet attendants and cleaners needs to be reduced as risk has been identified where toilets are poorly ventilated.

(10) In analysing the scope of the restriction RAC considered the exposure of consumers to air fresheners and toilet deodorisers in households and in public toilets as well as of

professionals who work in public toilets, including toilet attendants and cleaners, but also other groups such as maintenance personnel. Consumers and professionals who visit and work in indoor areas (other than toilets) where air fresheners containing DCB are used were also considered. Other professional or industrial uses were not considered.

(11) On 5 June 2013, SEAC adopted by consensus its opinion on the restriction proposed in the Annex XV dossier. According to the SEAC opinion, the restriction, as modified by RAC and SEAC, is the most appropriate Union-wide measure to address the identified risks in terms of the proportionality of its socioeconomic benefits to its socioeconomic costs. Based on the RAC conclusion that exposures to DCB need to be reduced for domestic and professional users and some evidence that use of toilet blocks and air fresheners containing DCB will persist in the absence of any intervention, SEAC agreed that a restriction is an appropriate and an effective measure. Concerning proportionality of a restriction on domestic use, SEAC concluded that the measure is proportionate. Concerning the proportionality of a joint restriction on domestic and professional use, SEAC, taking account of the inferred health benefits and the scale of costs involved, concluded that the measure may not be considered to be disproportionate.

(12) The Forum for Exchange of Information on Enforcement was consulted during the restrictions process and their comments on the wording of the conditions of the restriction and on the transitional period were taken into consideration by RAC and SEAC.

(13) On 17 June 2013, the Agency submitted to the Commission the opinions of RAC and SEAC, based on which the Commission concludes that an unacceptable risk to human health arises from the placing on the market and use of DCB, as a substance or as a constituent of mixtures in a concentration equal to or greater than 1 % by weight, used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas. The Commission further considers that these risks need to be addressed on a Union-wide basis. The socioeconomic impacts of this restriction, including the availability of alternatives, have been taken into account.

(14) It is appropriate to provide for a period of 12 months after the entry into force of this Regulation within which stakeholders should take measures to comply with it, including for air fresheners and deodorisers that are already in the supply chain or in stock.

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

(16) 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*.