Commission Regulation (EU) 2018/589 of 18 April 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards methanol (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/589

of 18 April 2018

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards methanol

(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 January 2015, Poland submitted to the European Chemicals Agency ('the Agency') a dossier[(2)] pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'), in order to initiate the restriction procedure set out in Articles 69 to 73 of that Regulation. The Annex XV dossier indicated that exposure to methanol in windscreen washing fluid and denatured alcohol poses a risk to human health and proposed to prohibit their placing on the market. The Annex XV dossier demonstrated that action on a Union-wide basis is necessary.

(2) The restriction proposed in the Annex XV dossier aims to reduce the incidence of severe methanol poisoning following consumption by chronic alcoholics and sporadically by non-alcoholics of windscreen washing fluids or denatured alcohol used as a cheap substitute for consumable alcohol. The restriction is also expected to prevent methanol poisoning following accidental ingestion of windscreen washing fluids and denatured alcohol, including poisonings in children. The Annex XV dossier and the public consultation reported cases of poisoning caused by ingestion of windscreen washing fluids in seven Member States and fatal cases in at least two Member States.

(3) On 4 December 2015, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion concluding that exposure to methanol present in windscreen washing fluids and in denatured alcohol in a concentration above 0,6 % by weight presents a risk of death, severe ocular toxicity or other severe effects of methanol poisoning. RAC further

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/589. (See end of Document for details)*

advised that the proposed restriction is the most appropriate Union-wide measure to address the risks identified, both in terms of effectiveness and practicability.

(4) On 11 March 2016, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion on the proposed restriction. As regards denatured alcohol, the lack of socioeconomic data in the Annex XV dossier and from the public consultation meant that SEAC could not evaluate the socioeconomic impact of its inclusion in the proposed restriction. Regarding windscreen washing fluids, SEAC considered that the proposed restriction is the most appropriate Union-wide measure to address the risks identified in terms of its socioeconomic benefits and socioeconomic costs. Overall, SEAC considered that divergences in national legislation across Member States could distort the internal market.

(5) The Agency's Forum for Exchange of Information on Enforcement was consulted during the restrictions process and its advice has been taken into account, notably to include in the proposed restriction fluids used to defrost windscreens.

(6) On 28 April 2016, the Agency submitted the opinions of the RAC and the SEAC to the Commission[(3)]. Based on those opinions, the Commission concluded that the presence of methanol in windscreen washing fluids and windscreen defrosters poses an unacceptable risk to human health which needs to be addressed on a Union-wide basis.

(7) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction, in particular to allow sales of stocks and to ensure adequate communication within the supply chain. The application of the restriction should therefore be deferred.

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

(9) 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/589. (See end of Document for details)*

Done at Brussels, 18 April 2018.

For the Commission

The President

Jean-Claude JUNCKER