



EUROPEAN
COMMISSION

Brussels, **XXX**
[...](2017) **XXX** draft

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

of **XXX**

**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) .../...

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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/EC¹, and in particular Article 68(1) thereof,

Whereas:

- (1) On 16 January 2015, Poland submitted to the European Chemicals Agency ('the Agency') a dossier² 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 advised that a restriction is the most appropriate Union-wide measure to address the risks identified, both in terms of effectiveness and practicability.

¹ OJ L 396, 30.12.2006, p 1.

² <https://echa.europa.eu/documents/10162/78b0f856-3751-434b-b6bc-6d33cd630c85>

- (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 socio-economic data in the Annex XV dossier and from the public consultation meant that SEAC could not evaluate the socio-economic impact of its inclusion in the proposed restriction and did not support the inclusion of denatured alcohol in the scope of the restriction. Regarding windscreen washing fluids, SEAC considered that a restriction is an appropriate Union-wide measure to address the risks identified in terms of its socio-economic benefits and socio-economic costs, whilst not excluding that other measures or initiatives may be equally or more effective. Overall, SEAC considered that divergence 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 Commission³. Based on those opinions, the Commission concluded that the presence of methanol in windscreen washing and defrosting fluids poses an unacceptable risk to human health which needs to be addressed on a Union-wide basis.
- (7) In keeping with the principle of proportionality, the risk to human health presented by accidental ingestion of such fluids should be addressed through the obligatory introduction of an additive that would deter ingestion. The risk to human health presented by the deliberate ingestion of such fluids by chronic alcoholics is unlikely to be addressed by the introduction of an additive but it would not be proportionate to extrapolate the incidence of such behaviour in a small number of Member States to the whole of the Union. Accordingly, in keeping with the principle of subsidiarity, Member States should be permitted to take other measures at national level to address this risk, appropriate to their own societal and cultural circumstances.
- (8) 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.
- (9) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (10) 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.

³ <https://echa.europa.eu/documents/10162/2b3f6422-ab4d-4b85-9642-ebe225070858>

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER