

**REPLY FROM THE EUROPEAN UNION TO THE COMMENTS RECEIVED FROM CHINA
REGARDING NOTIFICATION**

G/TBT/N/EU/410

**DRAFT COMMISSION REGULATION 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**

The European Union (EU) would like to thank the Chinese authorities for their comments of 9 December 2016 on the "*Draft Commission Regulation 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*".

The Chinese authorities consider that the rationale behind the restriction introduced by the notified draft is unreasonable because the risk to human health, which the restriction is intended to address, derives from the misuse or deliberate ingestion of products containing methanol. The Chinese authorities observe that, on this basis, the manufacture, placing on the market and use of all industrial products that are capable of being misused or intentionally consumed are liable to being restricted.

The EU takes the view that the risks to human health or the environment that arise from the reasonably foreseeable misuse of substances may clearly be addressed by the REACH Regulation¹. This point was discussed and agreed upon with the EU Member States. In the present case, the ingestion of windscreen washing and defrosting fluids that contain methanol was reported as having caused severe poisoning in a number of Member States and it is difficult to argue that it is not reasonably foreseeable. In this regard the exposure to methanol present in windscreen washing fluids in a concentration above 0.6 % by weight presents a risk of death, severe ocular toxicity or other severe effects of methanol poisoning.

In October 2017 the Committee established under Article 133 of the REACH Regulation (known as the REACH Committee) gave a favourable opinion on the notified draft. The adopted restriction concerns methanol in windscreen washing fluids and defrosting fluids, but – in contrast to the notified draft - no longer concerns denatured alcohol. The Commission Regulation (EU) 2018/589 as regards methanol was published in the Official Journal of the European Union on 19 April 2018² and a corrigendum was published on 23 April 2018³.

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1423064258789&uri=CELEX:32006R1907>

² http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.099.01.0007.01.ENG&toc=OJ:L:2018:099:TOC

³ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.102.01.0099.01.ENG&toc=OJ:L:2018:102:TOC

The Chinese authorities also ask for a justification of the maximum concentration limit of 0.6% by weight. The initial restriction dossier submitted by Poland according to Article 69(4) of the REACH Regulation suggested a concentration limit of methanol of 3% by weight. However, the Committee for Risk Assessment (RAC) of the European Chemicals Agency considered that adverse effects including mortality could occur at methanol concentration values equal to or greater than 0.6% by weight. The RAC therefore considered a 0.6% methanol concentration to be protective against methanol-induced severe ocular toxicity and death. The RAC based its opinion on the calculation of the severe ocular toxicity as the point of departure (PoD) leading to a derived no effect level (DNEL) of 0.088 g/kg by weight, assuming a body weight of 60 kg and ingestion of 1 litre of methanol-containing product in 24 hours.

The EU would like to thank the Chinese authorities once again for providing comments on the notified draft and hopes that the response conveyed sufficient clarity on the issues raised.

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