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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. Cion doc.:	5561 + ADD 1
Subject:	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 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and TDFAs – decision not to oppose adoption

1. Regulation (EC) No 1907/2006 provides for the prohibition of placing on the market of a substance which poses a risk to human health or the environment that is not adequately controlled and needs to be addressed.
2. On 20 April 2016, the Kingdom of Denmark submitted to the European Chemicals Agency a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006, in order to initiate the restrictions process as set out in Articles 69 to 73 of that Regulation (the ‘Annex XV dossier’). The Annex XV dossier indicated that exposure to (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (those derivatives are referred to as TDFAs) combined with organic solvents in spray products causes serious acute lung injury and therefore poses a risk to human health. Accordingly, it

was proposed to prohibit the placing on the market of those mixtures in spray products for supply to the general public. Denmark concluded that the Annex XV dossier demonstrated that action on a Union-wide basis is necessary

3. Based on the opinions of RAC and SEAC¹, the Commission proposed to prohibit the placing on the market for supply to the general public of spray products containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and/or TDFAs combined with organic solvents includes making them available to the general public.
4. Therefore, in accordance with Article 5a(2) of Council Decision 1999/468/EC², the Committee established under Regulation (EC) No 1907/2006 was consulted on 11 December 2018. It voted in favour of the above draft Regulation.
5. Consequently, the Commission submitted the above draft Regulation to the Council on 16 January 2019, in accordance with Article 5a(3)(a) of Council Decision 1999/468/EC.
6. Under the regulatory procedure with scrutiny, the Council, acting by qualified majority, may oppose the Commission's adoption of the draft Commission Regulations on the grounds that the draft measures presented by the Commission:
 - exceed the implementing powers provided for in the basic instrument, or
 - are not compatible with the aim or the content of the basic instrument, or
 - do not respect the principles of subsidiarity or proportionality.
7. The delegations were asked on 1 February 2019 to indicate their possible opposition to the draft Regulation before 7 September 2018. No delegation raised any of the above-mentioned grounds for opposition.
8. The Permanent Representatives Committee is therefore invited to recommend to the Council to confirm, as an "A" item of its agenda, that it is not opposed to the draft Regulation in subject.

¹ <https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/13918/term>

² Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23), as amended by Decision 2006/512/EC (JO L 200, 22.7.2006, p. 11).
