Council of the European Union

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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	15 November 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	[…](2024) XXX draft - D 100643/2 ANNEX
Subject:	ANNEX to the COMMISSION REGULATION (EU) …/… amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP)

Delegations will find attached document […](2024) XXX draft - D 100643/2 ANNEX.

Encl.: […](2024) XXX draft - D 100643/2 ANNEX

EUROPEAN
COMMISSION

Brussels, XXX
D100643/02
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ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) …/…

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP)

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entries are added:

'...[*OP please insert the next consecutive number*]. *N*,*N*-dimethylacetamide (DMAC) CAS No 127-19-5 EC No 204-826-4	1. Shall not be placed on the market as a substance on its own, as a constituent of other substances, or in mixtures in a concentration equal to or greater than 0,3 % after …[*OP, please insert the date: 18 months after the entry into force of this Regulation*] unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, derived no-effect levels (DNELs) relating to exposure of workers of 13 mg/m^3 for long-term exposure by inhalation and 1,8 mg/kg bw/day for long-term dermal exposure. 2. Shall not be manufactured, or used, as a substance on its own, as a constituent of other substances, or in mixtures in a concentration equal to or greater than 0,3 % after… [*OP, please insert the date: 18 months after the entry into force of this Regulation*] unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1. 3. By way of derogation from paragraphs 1 and 2, the obligations laid down therein shall apply from …[*OP, please insert the date: 48 months after the entry into force of this Regulation*] in relation to placing on the market for use, or use, as a solvent in the production of man-made fibres.
...[*OP please insert the next consecutive number*]. 1-ethylpyrrolidin-2-one (NEP) CAS No 2687-91-4 EC No 220-250-6	1. Shall not be placed on the market as a substance on its own, as a constituent of other substances, or in mixtures in a concentration equal to or greater than 0,3 % after …[*OP, please insert the date: 18 months after the entry into force of this Regulation*] unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, derived no-effect levels (DNELs) relating to exposure of workers of 4,0 mg/m^3 for long-term exposure by inhalation and 2,4 mg/kg bw/day for long-term dermal exposure. 2. Shall not be manufactured, or used, as a substance on its own, as a constituent of other substances, or in

	mixtures in a concentration equal to or greater than 0,3 % after [*OP, please insert the date: 18 months after the entry into force of this Regulation*] unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1.’.