EUROPEAN
COMMISSION

Brussels, XXX
[…](2024) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

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)

(Text with EEA relevance)

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(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) *N,N*-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP) are dipolar aprotic solvents. DMAC is listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008[2] as toxic to reproduction category 1B based on developmental toxicity and as acute toxic category 4. NEP is listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as toxic to reproduction category 1B based on developmental toxicity.

(2) DMAC and NEP are used in industrial settings and by professionals as solvents in the formulation of mixtures, for example in agrochemicals, pharmaceuticals and fine chemicals. DMAC is also used as a solvent in coatings and is extensively used in the production of man-made fibres and films and during the production of polyamide-imide enamels (varnishes) used for electrical wire insulation. NEP is applied in cleaning agents and as a binder and a release agent. NEP is also used in oil field drilling and production operation processes, in functional fluids, in polymer processing, in water treatment, as an excipient in agrochemicals and in road and construction applications. Both substances are used as a laboratory agent.

(3) On 22 April 2022, the Netherlands ('the dossier submitter') submitted to the European Chemicals Agency ('the Agency') a dossier[3] pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'), in order to initiate the restriction process set out in Articles 69 to 73 of that Regulation. The Annex XV dossier demonstrated that action on a Union-wide basis was necessary, beyond measures already in place, to address risks to the health of workers exposed to DMAC and NEP and proposed to

[1] OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 199/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008 p.1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

[3] https://echa.europa.eu/documents/10162/a3b07a9a-1144-9507-69a0-ebfed72b1baa

restrict the manufacture, use, as well as the placing on the market, of DMAC and NEP on their own, as constituents of other substances or in mixtures.

(4) The dossier submitter based its hazard assessment of DMAC and NEP on the systemic effects of the substances on several endpoints. In the dossier, it derived a long-term inhalation derived no-effect level ('DNEL') and a long-term dermal DNEL based on occupational human and animal studies on developmental toxicity, clinical chemistry changes and liver weight and function for both DMAC and NEP. For NEP, the dossier submitter also derived a DNEL for acute exposure by inhalation.

(5) On 13 March 2023, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion[4] confirming that there is a risk to human health that is not adequately controlled for several industrial and professional uses of DMAC and NEP and concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks arising from exposure to DMAC and NEP in terms of its effectiveness in reducing the risk, its practicality and monitorability.

(6) For DMAC, the dossier submitter proposed a long-term inhalation DNEL of 13 mg/m^3 based on animal data on developmental toxicity. RAC agreed with that assessment and with the proposed DNEL.

(7) For the long-term dermal DNEL of DMAC, RAC did not agree with the dossier submitter in proposing a long-term dermal DNEL based on increased relative liver weight in rats. RAC however recommended a long-term dermal DNEL of 1,8 mg/kg bw/day derived from animal data on oral prenatal developmental toxicity study in rats.

(8) For NEP, RAC agreed with dossier submitter and recommended a long-term inhalation DNEL of 4,0 mg/m^3 based on an oral 90-day toxicity study. For NEP, RAC did not agree with the dossier submitter in proposing to set a DNEL for acute local inhalation. RAC proposed not to give any separate acute local DNEL, among others, because the long-term inhalation DNEL value of 4,0 mg/m^3 is considered sufficient to prevent local respiratory tract effects in continuous repeated NEP exposure.

(9) For the long-term dermal DNEL of NEP, RAC agreed with dossier submitter proposing a long term dermal DNEL derived on the basis of animal liver toxicity data observed in a 90-day oral toxicity study. Therefore, RAC proposed to use the value of 2,4 mg/kg bw/day as the long-term dermal DNEL.

(10) There is an indicative occupational exposure limit (OEL) of 36 mg/m^3 for DMAC established at Union level in accordance with Commission Directive 2000/39/EC[5], which became a binding OEL under Directive (EU) 2022/431 of the European Parliament and of the Council[6]. RAC concluded that the limit, developed in 1994[7], is outdated and higher than the DNELs proposed by RAC. There is no binding OEL for NEP.

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4 https://echa.europa.eu/documents/10162/bbd1ed1e-7da9-4e16-0a2c-0b3c41dce3b2

5 Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 142, 16.6.2000, p. 47, ELI: http://data.europa.eu/eli/dir/2000/39/oj).

6 Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 88, 16.3.2022, p. 1, ELI: http://data.europa.eu/eli/dir/2022/431/oj).

7 Recommendation of the Scientific Expert Group on Occupational Exposure Limits for N,N-Dimethylacetamide (https://echa.europa.eu/documents/10162/35144386/034_n-n-dimethylacetamide_oel_en.pdf/35b1e94b-4df2-e989-cefb-09d491f5217d?t=1691407222861)

(11) On 9 June 2023, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion[8], concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the risk to the health of workers arising from DMAC and NEP, taking into account its socio-economic benefits and costs.

(12) SEAC recommended an 18-month deferral of application of the restriction, in line with the Annex XV dossier, to provide sufficient time to stakeholders to fully implement the restriction requirements. SEAC further recommended a longer transitional period for DMAC in the sector of man-made fibres production (48 months) in order to allow for a gradual implementation of more appropriate, but also more costly risk reduction technologies, mainly local exhaust ventilation to address inhalation exposure.

(13) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1), point (f), of Regulation (EC) No 1907/2006, was consulted on the proposed restriction and its recommendations have been taken into account.

(14) On 31 August 2023, the Agency submitted the opinions of RAC and SEAC to the Commission. The opinions confirmed that there is a risk to the health of workers in the manufacture and use of DMAC and NEP, which is not adequately controlled.

(15) Taking into account the Annex XV dossier, demonstrating the need for Union-wide action beyond measures already in place, and the RAC and SEAC opinions, the Commission considers that there is an unacceptable risk to worker's health arising from remaining exposure to DMAC and NEP and that the proposed restriction establishing long-term DNELs for exposure of workers to DMAC and NEP via both the inhalation and the dermal routes is the most appropriate Union-wide measure to address that risk. In particular, the Commission considers that the proposed restriction, as modified by RAC and SEAC, is appropriate for the following reasons: the overall risk characterisation ratio is based on quantified long-term DNELs for inhalation and dermal exposure to DMAC and NEP; the harmonisation of chemical safety reports in the registration dossiers via harmonised DNELs can only be achieved under Regulation (EC) No 1907/2006; the safety data sheets will include those DNELs in the appropriate specific sections.

(16) Stakeholders should be allowed sufficient time to comply with the restriction and ensure that exposure of workers to DMAC and NEP is below the DNELs. The Commission therefore considers that the application of the restriction should be deferred in line with the SEAC opinion.

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

[8] https://echa.europa.eu/documents/10162/847134de-5d46-355d-bbf0-650fd9f59f78

(18) This Regulation applies without prejudice of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[9], 92/85/EEC[10], 94/33/EC[11] and 98/24/EC[12] and Directive 2004/37/EC[13].

(19) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) 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.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen

9 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

10 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

11 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

12 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

13 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50, ELI: http://data.europa.eu/eli/dir/2004/37/oj).