EUROPEAN
COMMISSION

Brussels, XXX
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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 1-methyl-2-pyrrolidone

(Text with EEA relevance)

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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 1-methyl-2-pyrrolidone

(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) On 9 August 2013, the Netherlands submitted to the European Chemicals Agency ('the Agency') a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'[2]), proposing to restrict 1-methyl-2-pyrrolidone (NMP). The Annex XV dossier demonstrated that action on a Union-wide basis was necessary to address risks to the health of workers exposed to NMP.

(2) The Netherlands based its hazard assessment of NMP on the effects of the substance on several human health endpoints. Developmental toxicity was considered the most critical of those endpoints and was used to determine a level (the derived no-effect level or 'DNEL') above which workers should not be exposed to NMP by inhalation.

(3) Regulation (EC) No 1272/2008 of the European Parliament and of the Council[3] provides that, where NMP is present in mixtures in a concentration of 0,3 % or higher, they are to be classified as toxic for reproduction, category 1B. The restriction should apply in relation to such mixtures, as well as to the substance on its own.

(4) On 5 June 2014, the Agency's Risk Assessment Committee (RAC) adopted its opinion, confirming that developmental toxicity was the most critical health endpoint. RAC considered, however, that a different assessment factor from that used by The Netherlands should be applied to calculate the DNEL for NMP. This resulted in a level twice as high as that proposed by The Netherlands for exposure of workers to NMP

1 OJ L 396, 30.12.2006, p 1.

2 https://echa.europa.eu/documents/10162/ee4c88a9-d26f-4872-98fd-fb41646cc9e1

3 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 and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L353, 31.12.2008, p.1).

via the inhalation route. RAC also calculated a DNEL for exposure of workers to NMP via the dermal route, which had not been proposed by The Netherlands.

(5) RAC confirmed that overall exposure to NMP above those two DNELs poses a risk to the health of workers and that the proposed restriction, based on those two DNELs, is the most appropriate Union-wide measure to reduce that risk in terms of its effectiveness.

(6) On 25 November 2014, the Agency's Socio-Economic Assessment Committee (SEAC) adopted its opinion, concluding that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to reduce the risk to the health of workers arising from NMP in terms of its socio-economic benefits and socio-economic costs.

(7) SEAC recommended a five year general deferral of application of the restriction, in line with the period proposed in the Annex XV dossier, to allow stakeholders to take the necessary compliance measures. SEAC considered that a longer deferral period might be appropriate for the wire coating sector, which was identified by The Netherlands as the sector on which the proposed restriction could have the greatest impact in relation to costs.

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

(9) On 9 December 2014, the Agency submitted the opinions of RAC and SEAC[4] to the Commission.

(10) On becoming aware of a discrepancy between the DNEL for exposure to NMP via the inhalation route proposed by RAC in its opinion and the indicative occupational exposure limit for NMP established under Council Directive 98/24/EC[5] following a scientific opinion of the Scientific Committee on Occupational Exposure Limits for chemical substances (SCOEL), the Commission asked RAC and SCOEL to work together to resolve the issue in accordance with Article 95(3) of Regulation (EC) No 1907/2006. As a result of this, on 30 November 2016 RAC proposed a modified DNEL for exposure of workers to NMP via the inhalation route.

(11) Based on the opinions of RAC and SEAC, the Commission considers that there is an unacceptable risk to the health of workers during the manufacture and use of NMP which needs to be addressed on a Union-wide basis. A restriction establishing DNELs for exposure of workers to NMP via both the inhalation and the dermal routes is the most appropriate Union-wide measure to address that risk. Such a restriction would be more appropriate than the indicative occupational exposure limit for NMP established under Directive 98/24/EC for the following reasons: the overall risk characterisation ratio is based on quantified DNELs for inhalation and dermal exposure to NMP; the harmonisation of the chemical safety report in the registration dossier via harmonised DNELs can only be established under Regulation (EC) No 1907/2006; downstream users will have the same time period as manufacturers and importers to put in place the appropriate risk management measures and operational conditions in order to

[4] http://echa.europa.eu/documents/10162/9ce0977b-3540-4de0-af6d-16ad6e78ff20

[5] 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.)

ensure that exposure of workers to NMP is below the two DNELs; the safety data sheets will include those DNELs in the appropriate specific sections.

(12) Therefore, the proposed restriction is the most appropriate Union-wide measure to address the risk to the health of workers from exposure to NMP.

(13) DNELs are to be applied when conducting the chemical safety assessment of a substance under Regulation (EC) No 1907/2006 in order to help determine the measures that need to be taken to manage the risk presented by the substance in particular exposure scenarios. Where manufacturers, importers or downstream users intend to place NMP as a substance on the market on its own or in mixtures in a certain concentration, that assessment should be made available to users of the substance by means of chemical safety reports and safety data sheets. Manufacturers and downstream users should ensure that the DNELs are complied with when the substance is manufactured or used, on its own or in a mixture.

(14) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction, particularly in the wire coating sector, where the costs of implementing the restriction will be particularly high. Therefore, taking into account the SEAC recommendation, the application of the restriction should be deferred. The deferral period should have regard to the delay in the restriction process due to the collaboration between RAC and SCOEL.

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

(16) 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.

Done at Brussels,

For the Commission
The President
Jean-Claude Juncker