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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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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 *N,N*-dimethylformamide

Delegations will find attached document [...] (2021) XXX draft - D 070424/04.

Encl.: [...] (2021) XXX draft - D 070424/04



Brussels, **XXX**
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[...](2021) **XXX** draft

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 *N,N*-dimethylformamide

(Text with EEA relevance)

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 *N,N*-dimethylformamide

(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/EC¹, and in particular Article 68(1) thereof,

Whereas:

- (1) *N,N*-dimethylformamide is an aprotic medium polar organic solvent classified as toxic to reproduction 1B, acute toxicant 4 (inhalation and dermal route) and as an eye irritant 2 in accordance with Regulation (EC) No 1272/2008². *N,N*-dimethylformamide is a high production volume substance used in many industrial settings and professional activities across Europe.
- (2) On 5 October 2018, Italy (hereinafter ‘the dossier submitter’) submitted to the European Chemicals Agency (‘the Agency’) a dossier³ 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 and proposed to restrict the industrial and professional use, as well as the placing on the market of *N,N*-dimethylformamide on its own or in mixtures.
- (3) The dossier submitter based its hazard assessment of *N,N*-dimethylformamide on the systemic effects of the substance on several endpoints. This resulted in a long-term inhalation derived no-effect level (‘DNEL’) and a long-term dermal DNEL based on animal data on decreased body weights, clinical chemistry changes and liver injury.

¹ OJ L 396, 30.12.2006, p. 1.

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).

³ <https://echa.europa.eu/documents/10162/d3feb838-3c17-bcf9-db88-92b83f5a43fc>

- (4) On 20 September 2019, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion⁴ 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 *N,N*-dimethylformamide in terms of its effectiveness in reducing the risk, its practicality and monitorability.
- (5) As the dossier submitter's assessment considered several contributing scenarios for *N,N*-dimethylformamide containing substances at low concentrations, RAC proposed to clarify the wording of the scope by including the presence of the substance, regardless of whether *N,N*-dimethylformamide is a constituent, a main constituent, an impurity or a stabiliser.
- (6) The dossier submitter proposed a long-term inhalation DNEL of 3,2 mg/m³ based on hepatic effects in animals. However, RAC recommended a long-term inhalation DNEL of 6 mg/m³ based on a combination of human data and animal data, taking into account liver toxicity and developmental toxicity, respectively.
- (7) For the long-term dermal DNEL, RAC recommended a DNEL based on a dermal study rather than making a route-to-route extrapolation from an oral 28-day study as proposed by the dossier submitter. Therefore, RAC proposed to use the value of 1,1 mg/kg/day as the long-term dermal DNEL.
- (8) On 5 December 2019, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion⁵, 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 *N,N*-dimethylformamide, taking into account its socio-economic benefits and costs. SEAC recommended a 24-month deferral of application of the restriction for all sectors, in line with the Annex XV dossier, to provide sufficient time to stakeholders to fully implement the restriction requirements.
- (9) The Forum for Exchange of Information on Enforcement was consulted on the proposed restriction and its recommendations have been taken into account.
- (10) On 1 April 2020, the Agency submitted the opinions of RAC and SEAC to the Commission. The said opinions confirmed that the risk to the health of workers in all occupational settings during the manufacture and use of *N,N*-dimethylformamide is not adequately controlled.
- (11) Taking into account the Annex XV dossier and the RAC and SEAC opinions, the Commission considers that there is an unacceptable risk to workers arising from exposure to *N,N*-dimethylformamide above specific DNEL values and that the proposed restriction establishing a DNEL for exposure of workers to *N,N*-dimethylformamide via both the inhalation and the dermal routes is the most appropriate Union-wide measure to address that risk.
- (12) 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 DNELs for inhalation and dermal exposure to *N,N*-

⁴ <https://echa.europa.eu/documents/10162/44ad5cd9-1143-0072-0550-5860846ffbb4>

⁵ <https://echa.europa.eu/documents/10162/b6644298-54a4-052a-9bbc-6824966d151e> (compiled version of final RAC and SEAC opinions)

dimethylformamide; 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.

- (13) Stakeholders should be allowed sufficient time to comply with the proposed restriction, and downstream users, in particular, should have the same time period as manufacturers and importers to implement the appropriate risk management measures and operational conditions in order to ensure that exposure of workers to *N,N*-dimethylformamide is below the DNELs. The Commission therefore considers, in line with the Annex XV dossier and the opinion of SEAC, that the application of the restriction should be deferred for 24 months.
- (14) It is expected that, to comply with the DNELs for exposure of workers to *N,N*-dimethylformamide, the polyurethane coatings and membranes and the synthetic fibre manufacturing sectors will require more time. Therefore, longer transitional periods are suggested for the polyurethane coatings and membranes sector, where *N,N*-dimethylformamide is used as a solvent in direct or transfer polyurethane coating processes on textiles and paper material or in the production of polyurethane membranes (36 months) and, for the synthetic fibre manufacturing, where *N,N*-dimethylformamide is used as a solvent in the dry and wet spinning processes of synthetic fibres (48 months).
- (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 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