NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** EUROPEAN UNION**If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** European Commission**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** European Commission,EU-TBT Enquiry Point,Fax: +(32) 2 299 80 43,E-mail: grow-eu-tbt@ec.europa.euWebsite: <http://ec.europa.eu/growth/tools-databases/tbt/en/> |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** *N,N*-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP) |
| **5.** | **Title, number of pages and language(s) of the notified document:** 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); (5 page(s), in English), (3 page(s), in English) |
| **6.** | **Description of content:** This draft Regulation relates to new entries of Annex XVII to REACH Regulation (EC) No 1907/2006.The draft Commission Regulation proposes a restriction for placing *N,N*-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP) on the market in concentrations higher than 0.3%, unless the registration dossiers and the safety data sheet are updated with the new DNEL values, and manufacturers and downstream users ensure the protection of workers by keeping their exposure below those values.Application of the restriction is deferred for 18 months for all industrial sectors and for 48 months for the man-made fibres sector, to give industry sufficient time to comply. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The occupational exposure to *DMAC* above the following Derived No-Effect Levels (DNEL), 13 mg/m3 for long-term exposure by inhalation and 1.8 mg/kg bw/day for long-term dermal exposure, poses a risk to the health of workers due to its reprotoxic properties.The occupational exposure to *NEP* above the following Derived No-Effect Levels (DNEL), 4.0 mg/m3 for long-term exposure by inhalation and 2.4 mg/kg bw/day for long-term dermal exposure., poses a risk to the health of workers due to its reprotoxic properties.The aim of the restriction is to appropriately address the risks resulting from inhalation and dermal exposure to DMAC and NEP.The transitional period (18 months) before the application of the proposed restriction will allow stakeholders sufficient time to comply with the proposed restriction. For DMAC in the Man-made Fibres sector a transitional period of 48 months is proposed; Protection of human health or safety |
| **8.** | **Relevant documents:** * Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation): <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1423064258789&uri=CELEX:32006R1907>
* The opinions of the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC): <https://echa.europa.eu/documents/10162/847134de-5d46-355d-bbf0-650fd9f59f78>
* Further background information is available at: <https://echa.europa.eu/documents/10162/75a0c497-69e0-1c74-689d-667bd49e47b9>
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| **9.** | **Proposed date of adoption:** First quarter of 2025**Proposed date of entry into force:** 20 days from publication in the Official Journal of the EU. Application of the restriction would be deferred for 18 months after entry into force, for DMAC the man-made fibres sector, the restriction is deferred for 48 months, to give industry sufficient time to comply. |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** European Commission,EU-TBT Enquiry Point,Fax: + (32) 2 299 80 43,E-mail: grow-eu-tbt@ec.europa.euThe text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/><https://members.wto.org/crnattachments/2024/TBT/EEC/24_04902_00_e.pdf><https://members.wto.org/crnattachments/2024/TBT/EEC/24_04902_01_e.pdf> |