

Proposed European restriction on tattoo inks and permanent make-up: HEAL and EEB's updated analysis



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On 7th April 2020, the European Commission notified the World Trade Organization about its draft regulation amending Annex XVII to REACH in a view to restrict hazardous chemicals in tattoo inks or permanent make-up (PMU) [1]. This proposal is listed in the discussion points of the next REACH committee meeting, which is scheduled on 13th May 2020 [2].

The Health and Environment Alliance (HEAL) and the European Environment Bureau (EEB) acknowledge that significant work has been invested by the European Chemical Agency (ECHA), Member States (and in particular Denmark, Italy, Norway, Germany - the dossier submitters – with the assistance of Germany) and the Commission in order to solidly build up this restriction, since the discussion started in 2017.

We welcome the final proposal, which answers several of the concerns that our organisations have raised [3] throughout the process and strikes a good compromise towards overall enhanced safety of the tattoo inks and permanent make-up put on the European market.

We highlight that the restriction is a positive illustration of ECHA's and the Commission's efforts to address and regulate large groups of chemicals, for which there is direct human exposure leading to well-founded short- and long-term health concerns. We look forward to further initiatives to address entire groups of chemicals, be it by family or use types.

DETAILED ASSESSMENT

We particularly welcome:

- ➔ ● **The removal of the problematic derogations for a number of inks and the time-limited (24 months) derogations for pigment blue 15:3 and green 7.**
- ➔ ● **The proposed dynamic link with both the Cosmetics Product Regulation (CPR) and the Regulation on Classification, Labelling and Packaging (CLP), as recommended by ECHA's Risk Assessment Committee; with a clear acknowledgement that *"the need to ensure a high level of protection of human health takes precedence over considerations related to technical and economic feasibility of alternatives as regards substances used in tattoo inks"* in order to justify the approach taken [4]. This will also greatly contribute to ensuring consistency between protection levels offered by the various regulations.**

We acknowledge progress on:

- ➔ **The proposed concentration limits for certain substances**
 - Early in the process, our organisations raised concerns that any harmonisation of concentration limits for certain substances used in tattoo inks and permanent make-up (PMU) should be based on the highest levels of protection for human health, by following the guidelines included in the existing Council of Europe resolution (ResAP, 2008).
 - We acknowledge that the final draft has improved compared to earlier versions and has harmonised some concentrations with those proposed in the ResAP towards higher protection (for example, barium [5]).
 - We however regret that the opportunity to align the concentrations for other substances was missed – for instance, zinc [6], copper [7] or lead [8].

➔ Labelling

- We acknowledge the practical approach taken through the establishment of a mandatory label to describe the intended use of all tattoo inks and PMU (*“Mixture for use in tattoos or permanent make-up”*), which will provide general guidance for tattoo artists and professionals in their supplying.
- When going to the details of the proposed labelling scheme, we regret that the option of *“a list of substances added during the process of formulation and present in the mixture for use for tattooing purposes”* [9] was favoured over our demand for labelling all substances present and suspected to be present in the mixtures.
- We stress that labelling will only serve the purpose of rightly informing tattoo professionals and receivers, if properly enforced. Moreover, while we welcome the regulation inclusion of a

requirement for professionals using the mixtures to inform the person undergoing the use about the information on the label and/or instructions of use, we also stress that proper enforcement will remain difficult to check in practice (especially considering the fact that the tattooing business is mostly made up of independent entrepreneurs and very small enterprises). In this regard, proactive communication and awareness-raising from national authorities towards professionals and consumers will be of utmost importance.

➔ Mixture toxicity

- We acknowledge the efforts made by RAC to account for mixture effects of reprotoxic substances through the use of an assessment factor. We expect that such an approach is followed in the future when assessing the impacts of mixtures of chemicals and that it also develops to reflect on the impacts of mixtures of non-threshold chemicals.

We regret the missed opportunities to:

➔ Address risks for professionals arising from inhalation

- Professionals have been considered out of the scope of this restriction, while we consider they are exposed to the substances used for tattooing and permanent make-up (PMU) on a chronic basis through their occupation.
- While we acknowledge that the primary channel of exposure for those receiving tattoo inks and PMU is through dermal and/or intradermal exposure, and that accounting for and addressing exposure through the inhalation route is more complex, we regret that the significant work invested to develop this particular broad and complex restriction was not seized as an opportunity to go one step further and make it truly comprehensive.

➔ Address risks arising of exposure to endocrine disrupting chemicals (EDCs)

- Although most of the EDCs used in tattoo inks and PMU are covered by the reprotoxic classification, we consider that the proposal should explicitly include the restriction of ED substances in order to avoid regrettable substitution.

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REFERENCES

1. Draft Commission Regulation 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 substances in tattoo inks or permanent make-up, 7th April 2020. Available from : https://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country_ID=EU&num=709&dspLang=en&basdatedeb=01/04/2020&basdatefin=21/04/2020&baspays=&basnotifnum=&basnotifnum2=&bastypepays=ANY&baskeywords=
2. REACH committee meeting, 13th May 2020, Agenda item 6, “for discussion” https://ec.europa.eu/transparency/regcomitology/index.cfm?do=Search.getPDF&ds_id=66988&version=1&AttLang=en&db_number=1&docType=AGENDA
3. HEAL and EEB, “Proposed European restriction on tattoo inks and permanent make-up: HEAL and EEB’s final assessment”, September 2019: <https://www.env-health.org/wp-content/uploads/2019/09/September-2019-HEAL-EEB-assessment-on-proposed-EU-restriction-on-tattoo-inks-format-web.pdf>
4. Commission regulation, paragraphs (30) and (31), p.7
5. The level was lowered to 0,05% in the final proposal. See annex to the Commission regulation, p.6
6. The Commission regulation proposes 0,2% compared to 0,005% in the ReSAP. See annex to the Commission regulation, p.6
7. The Commission regulation proposes 0,025% compared to an earlier 0,05% but this is still higher than the RESAP proposal of 0,0025%. See annex to the Commission regulation, p.6
8. The Commission regulation proposes 0,00007% compared to 0,0002% in the ReSAP. See annex to the Commission regulation, p.6
9. Commission regulation. Paragraph (35). p.8