

Call for evidence: Tattoo inks and permanent make-up

Background note

Objective

The European Commission has requested ECHA assess whether there is a need to restrict certain substances used in tattoo inks and permanent make-up (PMU). ECHA, in cooperation with the competent authorities of Denmark, Germany, Italy, and Norway, will analyse the risks to human health, the availability of alternatives and socio-economic impacts of a possible restriction on EU-wide basis. The starting point for this assessment are:

- substances restricted in the Cosmetic Products Regulation (EC) N° 1223/2009,
- substances with harmonised classification as carcinogenic, mutagenic and toxic to reproduction (CMR) or as sensitisers in Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation),
- other substances in the Council of Europe's Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up,¹ as well as
- any other substances in tattoo or PMU inks identified that may present risks to human health.

The objective of this call is to gather information from relevant stakeholders for the preparation of an Annex XV restriction dossier on tattoo inks and PMU. Information needed includes substances used in tattoo inks and PMU, tonnages, release and exposure, costs of tattoo inks, PMU and tattooing services, issues related to enforceability and alternatives (their hazard and risk profile, technical characteristics (e.g. are they effective replacements for the restricted substances) and costs).

This call targets companies (manufacturers, importers, distributors, retailers) and professional users of tattoo inks and PMU, trade associations, environmental organisations Member State Authorities and any other members of the public holding relevant information. We have asked some specific questions on certain issues of particular interest to us.

This call ends on 23 November 2016.

For any clarifications on completing the questionnaire, please contact Evgenia Stoyanova at: restriction-survey@echa.europa.eu

Background

Tattoos and PMU have increasing popularity. In 2003, the Council of Europe (CoE) published a resolution on requirements and criteria for the safety of tattoos and permanent make-up and the European Commission launched a research project to gather and scrutinise all available information for considering the need for a coordinated initiative on tattoo and PMU inks at EU level. In the following years, the CoE published a revised version of their resolution, updating the negative list of substances (ResAP(2008)1) and a number of member states introduced national measures incorporating CoE's recommendations.

1

The work of the European Commission is summarised in three main publications on the Safety of tattoos and permanent make-up:

- *Compilation of information on legislative framework and analytical methods:* http://publications.jrc.ec.europa.eu/repository/bitstream/JRC94760/wp1_tr_publications.pdf
- *State of play and trends in tattoo practices:* <https://ec.europa.eu/jrc/en/publication/safety-tattoos-and-permanent-make-up-state-play-and-trends-tattoo-practices>
- *Final report:* <https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/safety-tattoos-and-permanent-make-up-final-report>

If the work of ECHA and partner Member States demonstrates that action on EU-wide basis is necessary, a restriction dossier will be submitted will initiate the restriction process (possibly in July 2017).

Specific questions

ECHA is looking to gather additional and more detailed information than the information gathered to date in the reports quoted above. The information relevant for the development of an Annex XV restriction dossier, include: substances included in the scope; information on hazard, exposure and release; analytical methods and other information relevant for enforcement; socio-economic information, such as information on alternatives (availability, technical and economic characteristics), impacts on stakeholders, etc.

Any relevant information is welcome. ECHA would like to also draw your attention to the following specific topics:

1. *Could you please provide information on tattoo inks and PMU that do not contain the substances in the scope of the assessment (i.e., Cosmetic Products Regulation, ResAP(2008)1, CMRs, or sensitisers)? I.e., information on their risk, technical characteristics, average price, availability on the EU market (tonnages produced, imported, exported by the EU), quality in comparison to existing inks on the EU market, colours (pigments) covered. Would there be any pigments that would not be available if the substances in the scope are banned?*
2. *Would a restriction on using specific substances in tattoo inks and PMU have an impact (positive or negative) on your business (as a manufacturer, distributor, importer, SME, professional tattoo artist, etc.)? What would be the impact on consumers? What concentration limit would be acceptable to limit the negative impacts of a potential restriction e.g. to take into account impurities in tattoo ink ingredients? Please be as specific as possible and provide quantitative information.*
3. *Do you have information regarding the limit of quantification that can be achieved by surveillance laboratories? E.g., for substances listed in Table 3 of ResAP(2008)1, for substances listed on Table 1 of ResAP(2008)1, using GC-MS(SIG01-ND428) of the Dutch Food and Consumer Product Safety Authority, or for polycyclic aromatic hydrocarbons (PAH) restricted under entry #50 of REACH Annex XVII.*
4. *Do you have information on any adverse health effects or reaction (skin irritation, allergy) as a result of application of tattoos or PMU that can be directly attributed to the substances in the tattoo ink or PMU? Please be as specific as possible and provide supportive information or documentation.*

5. *What has been the experience with existing (national or regional) regulations on tattoo inks? Are there difficulties complying with existing restrictions?*
6. *Do you have any information on the number of tattoo sessions provided in your country (or provided by your business) per year? What is the average price per tattoo/PMU session? How large of a tattoo could be made within one tattoo session, i.e., a typical tattoo size or the largest that could be made assuming a typical tattoo session is between 1.5 and 2 hours?*