

Dear members of the REACH committee,
Dear members of the Health and Environment Alliance (HEAL) and European Environmental Bureau (EEB),

The European Society for Tattoo and Pigment Research (ESTP) is an independent research society with ideal aims founded in 2013. ESTP amalgamates stakeholders from medical professionals, researchers, health authorities, tattooists and manufacturers – many of which are experts in this fields for many years dating back to the first European Council Resolution ReSAP(2003) on safety of tattooing. Hence, we are proud to unite decades of experience in tattoo complications and legislation processes. **Our society supports a European wide action to increase safety of tattooing. Today we are reaching out to stress our points on the current restriction proposal under REACH and to oppose misinformation currently introduced to the REACH committee by different parties.**

The current restriction involves over 4000 substances which is indeed unprecedented but also leads to many pitfalls since many substances are neither harmonized nor classified and thus not part of the annex IV of the CLP Regulation. We acknowledge the immense work of the ECHA and all involved parties but raise the point that a true risk assessment of this many substances would need by far more years and workforce than granted in this process which lead to many inconsistencies, over or under regulation in some parts and the loss of the possibility for a white list of chemicals for the next decades since chemicals can now not be regulated on national levels.

REACH is designed to safeguard handling of individual chemical substances and not directly for composite commercial products in common use. EU for this reason primarily attempted to regulate commercial ink stock products as consumer products. Tattoo pigments are nano- and micrometre sized physical particles of very low solubility, widely unknown biokinetics and fate in the body, however, constructed to remain intact as depos in the skin for decades. The toxicology out of the special formulation and application of tattoo inks is very, very little known. Application of REACH to such composite products apparently has not been practised before by EU, and the discussed regulation of tattoo inks is thus experimental and a first try ever. No nation in the world seems so have regulated tattoo ink products this way and so extensively, with so little scientific support. It is completely outside the scope of USA FDA regulation of inks and not suited to promote harmonization at a global scale. The tattoo ink marked in Europe is dominated by inks manufacture in USA.

The restriction instrument under REACH is solely applicable to ban unacceptable but known risks posed by chemicals. In contrast, even RAC admitted in its opinion on page 45 that the Annexes of the Cosmetics Directive (CPR) “[...] include[...] **substances restricted without traceable or recently revised opinions of the Scientific Committee on Consumer Safety (SCCS) or its predecessors**” - so no data on risks or hazards are available for these substances anymore.

Our recommendations are as follow:

- **Delete the derogation on volatile substances.** Volatiles, even gases such as CO₂, are solved to a certain extend in the liquid phase. In the last comment phase we raised this point using formaldehyde as an example, but this is of course the case for all volatiles. The derogation of volatiles is not scientifically sound.
- **Grant full derogation of Pigment Green 7 and Blue 15:3 until scientific proof of hazards.** To cite the RAC again, *“many of the pigments prohibited in hair colours were included in Annex II of the CPR on the basis of the cosmetic industry not providing relevant information to justify continued use in the hair dyes application.”*, which is why these two pigments were added to the list and are therefore subsequently prohibited for tattoo inks without scientific rationale. In contrast, Blue 15:3 is even on the positive lists for long term application in cosmetics without constraint in Annex IV of the CPR. Since no research data conducted under acceptable quality criteria exist that proof any hazard of these substances, the pigments do not fulfil the scope of a restriction under REACH for justified risks for consumers. The application of these pigments is essential to the industry without alternatives in performance and health risks (see our last comment to the RAC opinion at the ECHA website). **A ban of these pigments will in contrast to the scope of the restriction lead to a massive decrease of consumer health** since pigments without any previous assessment - not even for cosmetics - will be used as a replacement.
- **Grant the use of higher concentrations of irritants and corrosive substances upon reasonable justifications.** Most of these substances listed, e.g. acids, will only show these effects upon high concentrations. Acids and bases are naturally used to adjust the pH (even in *intravenous* medicine). Also, preservatives such as propionic acid which is approved by EEA and/or Switzerland for use in biocidal products **more favourable for the environment, human or animal health** is classified as irritant as pure chemical but is only used in a 2% non-irritant concentration. Whit the current REACH restriction for tattoo inks it would be limited to 0.1 or 0.01% and therefore ban such favourable preservatives. These concentration limits are hazard and not risk based in contrast to the scope of a restriction that should limit the risks to consumers. This approach of banning threshold endpoints such as corrosion and irritants with a strict limit is not scientifically sound and in contrast to risk assessment guidelines. It is therefore necessary to include a clause to the restriction that allows higher concentrations if risks to consumers are not present.
- **Establish a guideline to which exact tests and data are demanded for tattoo risk assessment.** We are aware that tests were proposed by different authorities. However, most of these tests are not applicable to pigments or take the special route of application into account. Thus, using non-OECD guideline tests would be necessary but the acceptance of authorities would remain unclear posing extreme economic risks to this small industry. If, especially for pigments the lack of data is raised again the demanded test for needed endpoints must be clarified.
- **We support the derogation of CMR by the inhalatory route.** It is by nature of pigments and other insoluble particles that are applied in massive amounts to induce such over-dose effects upon inhalation. We are pleased that a toxicologist with knowledge of particle-lung interactions obviously considered this in the dossier.
- **Demand or specifically allow full labelling of substances.** A CLP labelling compared to a full list of ingredients will decrease the consumer health and possibilities for treatment and prevention upon medical problems. Many problematic substances are not harmonized in their classification nor part of the CPR annexes and therefore may not be listed.

- **Include a clause allowing deletion of substances from the scope of this restriction upon scientifically justification.**

We appreciate effort of all participants in finding a final scientifically, economically and practically sound restriction, but we shall emphasize that a coming regulation must be truly sound and realistic. We fear the tattoo ink supplies will become chaotic and out of control despite good intentions behind a REACH regulation. **We strongly believe that a stand-alone legislation specifically on tattoo ink products is the only suitable measure able to comprise not only inks but all tattoo related risk factors including hygiene aspects, full labelling and European wide positive lists in the future.** Thus, the commission is encouraged to revisit the fundamental aspects of a REACH regulation of tattoo inks considering all the pros and cons and considering alternative regulatory instruments in particular some narrow or broad stand-alone solution with a sharp focus.

We have to the present communication attached the letter of concern and the detailed comments we submitted in the public hearing, for your convenient update.

We have submitted a request to the Commission to invite a representative from ESTP as external expert to coming REACH committee meetings in which the restriction of tattoo inks is discussed.

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On behalf of ESTP

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