

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



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For millions of Europeans, a tattoo can be a means of self-expression. It may also, however, represent a direct source of exposure to a complex cocktail of chemicals. It is estimated that the number of tattooed people in Europe more than doubled between 2003 and 2014 (EEA 31), from about 30 to 60 million [1].

No EU-wide regulation currently exists to protect tattoo recipients from hazards found in tattoo inks. The Council of Europe (CoE) has twice passed nonbinding resolutions, most recently ResAP (2008), providing guidelines for chemical safety of tattoo inks. To date, seven Member States – France, Belgium, Germany, the Netherlands, Spain, Slovenia and Sweden - have incorporated these guidelines into national regulations. In 2017, the European Chemicals Agency (ECHA), along with Denmark, Italy and Norway, proposed two REACH restriction options for substances in tattoo inks [2]. After a public consultation period, a revised set of proposals was developed in a combined opinion issued by ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), and published in June 2019 [3].

The Health and Environment Alliance (HEAL) and the European Environmental Bureau (EEB) support the proposal for an EU-wide restriction on tattoo inks, building on existing national legislations and based on the highest standards of protection of human health. In this brief note, we provide feedback on the revised proposal, which will now be taken up for development into a legal proposal by the Commission before being discussed for final agreement with Member States. We also highlight some important systemic problems with the restriction process.

TATTOO INKS

Tattoo inks represent a challenge that is far more complex than the typical restriction.

- ① Exposure to tattoo inks is widespread in the European population – 12% of Europeans are estimated to be tattooed, including teenagers, according to the EU Joint Research Centre (JRC) [4].
- ② More than 4,000 chemicals are covered by the proposed restriction (although many have not been detected in tattoo inks) [5].
- ③ Tattoo inks consist of complex chemical mixtures. A typical ink can include preservatives, viscosity regulators, solvents, an astringent, and water, along with up to six pigments [6].
- ④ Inks represent clear and deliberate exposure (intra-dermal) and can be assumed to be 100% bioavailable. The intra-dermal route may also bypass some of the body's detoxification and metabolic pathways. Since intra-dermal exposure is atypical for most compounds, there is very little data available on health impacts of this route.
- ⑤ Many inks include known hazardous substances. One report found that "about 51% of the tattoo inks on the Swedish market contained forbidden substances or too high levels of contaminants" [7]. In countries that have established national regulations on tattoo inks, an estimated 30-50% of inks are not compliant with national regulations [8].
- ⑥ Pigments in inks are known to travel from the tattoo site and through the body (e.g. to the lymph system and the liver) [9].
- ⑦ The observed migration of inks to other organs raises the possibility of long-term systemic effects like cancer or reproductive toxicity, which are by their nature much more difficult to study than acute, localized effects. The revised opinion does not attempt to quantify or monetise these poorly-understood outcomes, but notes their high (potential) costs [10]. In our opinion, this highlights the need for a precautionary approach to address systemic toxicity.

THE REVISED PROPOSAL

The original (2017) restriction proposal included two restriction options, RO1 and RO2. RO2 was widely dismissed by commenters as providing far too little protection, and we will not discuss it further. Although RO1 is somewhat stronger, many commenters echoed Belgium's opinion that it "lacks of ambition and should be subject to supplemental provisions" [11]. The 2019 revision of RO1 improves on that proposal in a number of important ways [12].

DEROGATIONS. The 2017 proposal listed 21 derogations for specific inks without an identified alternative. The revised proposal brings these down to two derogations (Pigment Green 7 and Pigment Blue 15:3).

CONCENTRATION LIMITS have been amended and harmonised. One major concern about the 2017 proposal was that it was in some places less protective than the ResAP guidelines, raising the possibility that EU-wide regulation would weaken existing laws in some Member States. For example, Belgium highlighted impurities which are controlled at a stricter level in its national (ResAP-based) legislation than in the proposed restriction [13]. Many of these concentration limits have been clarified and aligned in the revised proposal. However, in other cases, including zinc and barium, the proposal still appears to be weaker than existing regulations [14] and we urge the Commission and Member States to upgrade these limits in a health-protective way.

LINK WITH COSMETIC PRODUCT REGULATION (CPR) and CLASSIFICATION, LABELING AND PACKAGING REGULATION (CLP).

We support RAC's proposal for a dynamic link with both CPR and CLP, which we believe is the most effective way to ensure the highest level of consistency between protection levels offered by the various regulations. While SEAC acknowledges that a dynamic link "would ensure immediate benefits for human health as new information on hazard and risk becomes available" [15], its arguments in favour of a static link are mainly based on socio-economic considerations that would weaken the restriction's benefits for health [16]. In this regard, we urge the European Commission and Member States to follow RAC's advice and establish a dynamic link with both CPR and CLP regulations.

PROBLEMS WITH THE REVISED PROPOSAL

Despite the improvements described above, several flaws in the proposed restriction have not been addressed. The Commission must now address these gaps as it considers the revised proposal.

DEROGATIONS. The revised proposal derogates two pigments, Green 7 and Blue 15:3, for two years after the restriction's entry into force. However, it provides no justification for the choice or derogation period, merely referring to these as "essential colourants in tattoo inks" [17], "necessary for the tattoo industry to cover this spectrum of colours" [18], and in the case of Blue 15:3 because "other blue pigments are lacking in brilliance" and further arguments to substantiate the timeframe of the derogation request were also not provided during discussions of the restriction in ECHA committees [19]. RAC's opinion is that "the uncertainties related to their hazard profile and fate... are too great to allow reliable risk assessment" [20], but each of these pigments is prohibited for use in hair dyes by the Cosmetic Product Regulation (CPR). Therefore, we call on the European Commission and Member States not to grant these derogations.

PRESERVATIVES. Tattoo inks typically include one or more preservatives, but these may fall into regulatory gaps. Because tattoo inks do not fall under the CPR, their preservatives are implicitly covered by the Biocides Product Regulation (BPR), and thus are omitted from the scope of the proposed restriction [21]. Yet preservatives may include a wide range of substances of varying hazard potential,

including formaldehyde (a known skin sensitizer and carcinogen) [22]. These substances may be restricted under a separate BPR process, but the failure to include them specifically in the tattoo inks restriction introduces a potentially dangerous loophole. One approach, suggested during public consultation, was that ECHA could establish a positive list of acceptable substances, which would provide useful guidance to formulators. This is also the approach recommended in ReSAP (2008): "The competent authorities should continuously take steps towards establishing an exhaustive positive list of safe substances with a view to replacing negative lists of harmful substances" [23]. SEAC has failed to take this option onboard [24]. We call on the European Commission and Member States to support the establishing of a positive list of acceptable substances.

WORKER PROTECTION. Tattoo artists and permanent make-up applicators are specifically excluded from the scope of the restriction, evidently with the understanding that the proposal is designed to cover intradermal exposure specifically. This exclusion of risks to tattoo artists is arbitrary and without justification, and no attempt is made to estimate their risks. As in many other professions, tattoo artists are very highly exposed (although primarily through the inhalation, not intradermal, route). Given the amount of time and data going into the proposed restriction, we believe that not including workers' protection in the scope of the restriction is a missed opportunity for health protection and we call on the European Commission and Member States to include it.

INHALATION ROUTE OF EXPOSURE. The proposal excludes substances identified as CMR by inhalation only. The people most at risk from this exposure route are the tattoo artists,

who have already been excluded from the scope; thus, the exclusion of workers and of inhalation-only hazards together seem intended to narrow the scope of the restriction. Yet no justification for these exclusions is provided, and no attempts are made to estimate risks of either tattoo recipients or artists via inhalation.

Moreover, excluding inhalation-only hazards is viable only if we assume that these hazards are irrelevant to intradermal exposures. We remain of the opinion that all routes of exposure supporting a substance classification – including intradermal and inhalation – should be taken into account, a view supported by several Member States including France and Belgium [25]. We therefore urge the Commission and Member States to include all classified CMR in the scope of this restriction, whatever the route of exposure.

REPROTOXIC SUBSTANCES. As stressed in previously submitted comments, we find the treatment of reprotoxic substances with endocrine disrupting properties worrisome. In our view the proposal's assertion that reprotoxic substances "traditionally... have been assumed to have an individual threshold level below which no adverse effect is expected" [26] is not supported by evidence.

In fact, a footnote in the restriction proposal annex provides a different assessment: "There are discussions whether endocrine disrupting substances act via a threshold mechanism or not" [27]. There is no clear consensus in the literature for this threshold assumption [28]. We are particularly concerned about assuming a threshold for endocrine disrupting chemicals (EDCs) like phthalates (four of which are assessed as reprotoxic substances in the proposal). EDCs can have an effect at extraordinarily low concentrations, but whether they have a true toxicologic threshold is very unclear. A 2013 review commissioned by KEMI found evidence on both sides of this question [29], whereas a recent report from the Danish Centre on endocrine disruptors recommended "a non-threshold approach as default to address specific uncertainties related to assessment of ED when deriving reference doses for EDs" [30].

RAC's opinion acknowledges that applying a threshold assumption to reprotoxic substances "will indicate a minimum level of risk where the concern may be higher if there was no threshold due to any ED effects" [31]. Therefore, if the threshold assumption for EDCs is likely to underestimate the risk, we are of the opinion that treating EDCs as non-threshold substances would provide a more appropriate approach. Rather than trying to quantify a "safe" level of an EDC, the non-threshold approach would require that known reprotoxic EDCs should never be knowingly added to tattoo inks.

Finally, in setting a group DNEL for reprotoxic substances, the proposal explicitly identifies the most sensitive endpoint—for tributyltin (TBT) — as an "outlier" and excludes it from the analysis. TBT is one of the best-studied

environmentally relevant EDCs, and should in this case serve as a model. Omitting the most potent reprotoxic substance artificially raises the permissible threshold for the entire group of substances. This almost certainly leads to an underestimate of the risk from TBT and it may underestimate the risks of other members of this group.

COMBINED EXPOSURE/MIXTURES. A typical tattoo ink comprises a mixture of many chemicals, including preservatives, astringents, viscosity regulators, solvents and several pigments [32]. Yet the proposed restriction only partially addresses the problems of mixture effects, by proposing the same approach for both threshold and non-threshold chemicals (in particular EDCs).

In the case of threshold substances, we acknowledge RAC's effort to address combined exposures through the application of an assessment factor [33].

However, we are not satisfied with the use of assessment factors when it comes to mixtures of non-threshold chemicals, in particular endocrine disruptors. Well-understood receptor theory, backed by substantial laboratory data, indicates that combinations of EDCs can cause additive effects even when each is below its apparent threshold [34]. Applying a threshold assumption to individual EDCs almost completely ignores the additive and inhibitory effects by which most endocrine-active compounds have effects. Although we acknowledge RAC's efforts to account for mixture effects for non-threshold chemicals, we therefore remain of the opinion that the use of assessment factors for non-threshold chemicals such as EDCs is neither well justified nor adequately health protective.

LABELING. The revised proposal requires the labelling of tattoo inks, including all substances that are covered by the proposed restriction as well as all substances classified for human health under the CLP regulation, whether or not they are covered by the proposed restriction. Strong labelling requirements are critical for tattoo inks, particularly given the large number of potentially sensitising substances that may be present. Moreover, since tattooists are independent artists and are not likely to have expertise in toxicology, clear labelling of the ink may be the only way to communicate any residual risk to them and the consumer.

Unfortunately, the revised proposal weakens the labelling language somewhat. It requires label only of substances "used in the tattoo ink" (focusing on intentionally added substances), as opposed to the stronger language of the original proposal requiring labelling for all substances "present in the tattoo ink", and also removes the original obligation to label restricted substances present even below the permissible limit. We are of the opinion that labels should cover all substances "known or suspected to be present in" ink formulations, including those substances not intentionally added but that might be co-occurring, and restricted substances in any concentration.

BROADER ISSUES IN THE RESTRICTION PROCESS

In addition to the above issues, the current restriction proposal demonstrates a number of problems with the ECHA committees' approach to the restriction process.

DEROGATIONS. This restriction proposal continues a longstanding pattern where the committees appear willing to accept derogations proposed by industry at face value, whether or not properly supported by evidence. The fact that the number of proposed derogations declined to only two in the revision is evidence that the initially retained derogations were not necessary or were avoidable. Valid justification is still missing for the two remaining derogations, beyond the claim that they are "essential colourants" [35]. Such derogations for hazardous substances claimed to be essential substances will hinder the development of new, less hazardous, alternatives. Derogations like these will also allow these chemicals to be injected under the skin of people, including teenagers, for the rest of their life.

EXCLUSIONS, as pointed out before with derogations, do not appear properly justified. The decision to exclude tattoo

artists from the scope, without even performing a proper risk assessment, is a significant omission. Similarly, the decision to exclude inhalation-only hazards is poorly justified, and no attempt is made to estimate risks for either tattoo recipients or artists via inhalation. As stated in the response of the Belgian Competent Authority to the public consultation, "we cannot simply dismiss relevant information without a full analysis of all available data". Although these assumptions simplify the restriction proposal, they go against the careful precautionary process described by REACH.

The **ANALYSIS OF AVAILABILITY OF ALTERNATIVES** (as required by REACH chapter 2, article 68) is insufficient and echoes other similar deficiencies highlighted in the context of the implementation of the authorisation process. ECHA's SEAC seems to rely heavily on industry's ideas of what is "essential" or substitutable. Independent attention must be given to identification of possible alternatives. Moreover, especially in the case of this specific proposal, an analysis of availability of alternatives should also include the option of no-use (in which an ink is restricted without a viable alternative), based on an honest discussion of what is an essential need for society rather than an essential use according to a manufacturer.

RECOMMENDATIONS

The revised opinion describes many areas of uncertainty in many technical details as well as in the assessment of social costs. Considering the number and magnitude of these uncertainties, **we strongly urge the Commission to use a precautionary approach when developing a proposal for the restriction.** This will particularly be true when considering reproductive toxicity; the vast unknowns associated with the intradermal route of exposure; unknown and unquantifiable systemic toxicity; likely mixture effects; and the wide range of substances that are known or may be identified in tattoo inks.

Therefore, **we call on the European Commission to address the following issues and gaps as it considers the revised proposal:**

- ① **Develop the restriction in a way that builds on existing national legislations and guarantees the highest standards of protection of human health,** including:
 - Not granting derogations for pigments Green 7 and Blue 15:3, which are not properly justified;
 - Ensuring that proposed concentration limits are harmonized towards the highest levels of protection and including preservatives in the scope of the restriction (through a positive list of acceptable substances);
 - Bringing workers' protection and exposure via inhalation in the scope of the restriction;
 - Explicitly considering reprotoxic substances – including endocrine disruptors – as non-threshold substances, in particular in the context of the mixture effects involved;
 - Supporting RAC's proposal for a dynamic link with both the cosmetics product regulation and the regulation on classification, labelling and packaging for consistency between the protection levels offered by the various regulations;
 - Strengthening the labelling requirements so that all substances "known or suspected to be present in" ink formulations are effectively covered.
- ② **Include a review clause in the proposal,** so that the restriction can be amended in a health-protective way, as soon as

new scientific evidence is released on the impacts of tattoo inks for human health – especially as regards long-term impacts.

In the context of the implementation of the action plan based on the REACH review, we also call on the Commission to consider overhauling the restriction process in a way that addresses some of the issues listed in the context of this restriction but valid for others, namely the sometimes unjustified granting of derogations or exclusions, the current inadequacy of the analysis of available alternatives, and the overall respect of the precautionary principle.

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