

Letter to the European Ombudsman

Legal uncertainties of the current REACH Restriction on tattoo ink and permanent make-up

06. November, 2020

Dear Ms Emily O'Reilly,

We, the European Society of Tattoo and Pigment Research, were founded in 2013 with the aim to advance safety of the tattooing practice and ink ingredients. We promote research in this field to understand the relation of ink ingredients and side effects of tattoos. Our board comprises dermatologists, researchers specialized in toxicology, chemistry and other related field that add up to decades of knowledge on tattoo side effects and ingredients.

Soon, the amendment of Annex XVII to Regulation (EC) No 1907/2006 (*REACH regulation*) that include substances in tattoo inks or permanent make-up will enter into force. We intensively commented on the initial draft in the public consultation phases and reached out to members of ECHA and the European Commission afterwards, but main issues that are pointed out in the following were not or insufficiently addressed:

1. Legal issue of reference to Regulation (EC) No 1223/2009 (*Cosmetic Products Regulation, CPR*)

The **current amendment of Annex XVII to Regulation (EC) No 1907/2006** – Restriction on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (*REACH restriction*) – for tattoo inks and permanent make-up comprises over 4500 substances.

Chapter 2, article 68 of the REACH regulation states that Annex XVII shall be amended “***When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances [...]***”. The REACH restriction on tattoo inks and permanent make-up refers to substances with harmonised classification and labelling (Annex VI Regulation (EU) No 2018/1480, *CLP*) which were scientifically reviewed for their hazardous properties (>4000 substances). However, there is also a reference to the Cosmetic Products Regulation (EC) No 1223/2009 (*CPR*).

The ECHA and European Commission until now, owe the proof of hazard properties and the toxicological risk for the substances listed in the CPR which is a prerequisite to include them into Annex XVII of the REACH Regulation, as stated above. Especially a proof of hazards of pigments cannot be found in most cases, e.g. pigment blue 15:3 and green 7 (C.I. 74160 & C.I.74260). Even **ECHA stated** in their proposal for restriction, version 1.2, 2017 (P.54: <https://echa.europa.eu/documents/10162/6f739150-39db-7e2c-d07d-caf8fb81d153>):

“Furthermore, both Pigment Green 7 and Blue 15:3 are phthalocyanines, which are insoluble in water and stable in most solutions. As shown in Appendix B.9, risk for these substances cannot be demonstrated with the currently available information. Therefore, a derogation is also proposed for Pigment Green 7.”

These two pigments are of major importance for tattooing. However, the absence of available hazard data also accounts for other pigments and substances listed in the CPR and have not been provided by the ECHA. Partly, this is due to the complicated and decade-long compilation of the CPR these data are either lost, or have never existed, as the case for pigments in Annex II of the CPR. Also, the Risk Assessment Committee (RAC) of ECHA stated in its opinion on page 45 that the Annexes of the 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. In later discussions with member states and the EC some data suggested potential risks of pigment blue 15 and green 7 that did not fulfil any criteria of scientific conduct that ECHA would demand for hazard assessment under REACH and are therefore void.

In contrast, the discussion of inclusion or exclusion of these pigments developed in the direction of demanding safety data from the manufacturers. This may appear sound but would fall under Annex XIV *Authorisation* of the REACH Regulation. The European Commission, in contrast, requested a REACH Restriction to be the future legislative measure for tattoo inks and permanent make-up. The demand of safety data is a **reversal of evidence** and **outside of the scope of Annex XVII of the REACH restriction**.

2. Unsound concentration limits of substances

We support the ban and restriction of substances that have been proven to be a hazard to human health and pose a risk during tattooing or permanent make-up procedures (e.g. harmonised substances). However, the concentration thresholds given for the substances are “one limit for all”. However, Paracelsus taught us “only the dose makes the poison” which is different for each single substance.

In Annex XV, II. Content of dossiers, 3. Dossiers for restriction proposal under the heading ‘Information on hazard and risk’ of the REACH regulation it is written:

“The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I [...].”

*“The objectives of the human health hazard assessment shall be to determine the classification of **a substance** in accordance with Regulation (EC) No 1272/2008; and to **derive levels of exposure to the substance above which humans should not be exposed.**” (Annex I, 1.0.1, REACH Regulation)*

The exposure based health hazard (risk) assessment has only been conducted for a limited amount of substances in the scope of the REACH restriction on tattoo inks and permanent make-up although data for (semi)quantitative risk assessment for more substances exist.

Qualitative assessment has been carried out for substances that may/can cause skin irritation/corrosion, eye damage/eye irritation, sensitisation, and mutagenicity/carcinogenicity. The general justification of ECHA was that **“these are non-threshold substances [and] it cannot be excluded that risks to consumers can occur”** (see link to proposal for restriction, version 1.2, 2017).

For substances with harmonised classification as eye irritant/damaging and skin irritant/corrosive substances, **ECHA proposed a practical concentration** to discourage intentional use. However, for these

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substances **reliable thresholds exist** or can be determined which do to not pose the risk of irritation or corrosion which was also not denied by the Risk Assessment Committee RAC.

A very understandable, yet not valid explanation for this lack of accurate risk estimation is the huge amount of substances that fall within this restriction (>4500 substances). Yet, we cannot except that a time limit leads to unjustified substance limits.

Also, there is yet no common guideline on how to conduct a risk assessment for intradermal application. In the **(semi)quantitative risk assessment** conducted by ECHA a **full coverage of the whole body with tattoo ink without any shadowing was used** as exposure scenario. To the best of our knowledge, no such human being exist. Since this would need multiple tattoo sessions and hence lead to a repeated exposure, limits based on a daily intake were used. We strongly oppose the use of limits based on the daily intake since >80% of all tattoos are less than 900 cm³ (3 sessions according to ECHA calculations) and > 50% of all tattoos are one or less than the 300 cm² surface area tattooed per day used by the ECHA for their calculations. Here, a safe but meaningful risk estimation has to be conducted.

3. Previous contacts to resolve the matter with the institutions in question

The first statement of ESTP concerning the REACH restriction for tattoo ink and permanent make-up was made during the first public consultation phase in 2018 where we also raised concern on concentrations thresholds and the fact that the proposed regulation is not risk based in terms of the exposure scenario of tattooing. The answer of ECHA to our statement *“The ECHA proposal is hazard based, not risk based”* was:

“All substance groups have been subject to a risk assessment according to Annex I of REACH and the relevant ECHA guidance, either qualitative or quantitative, that takes into account that these substances have been introduced into the dermis (in one or several tattooing session) and are available to exert their effects.”

In the second consultation phase (2019), we submitted a dossier that included more data and scientific citations to clarify our points. Here, we clearly stated our doubt on the legitimacy to refer to the Cosmetic Product Regulation when there are no data available (see No. 1 in this letter).

The answer: *“You state it is ‘questionable if the Annexes II and IV can be legally included into a REACH restriction dossier’ as for the substances covered in the Annexes II and IV which are only linked to the restriction without scientific justification based on hazards and risks. As this concerns the hazard and risk discussion in RACs remit **SEAC will not reply to it.**”*

We are especially disappointed that both answers to the public consultation reveal that our statements are not taken serious if not ignored.

Details of the documents can be found here: <https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e180dff62a>

Lastly, we saw the need to compile an “ESTP Open letter to the European Commission” which was send on October 24th 2019 with our comments from the public hearing attached to the REACH committee of the

European Commission, responsible for the tattoo and permanent make-up restriction under REACH. We did not receive any response to this.

In summary, we would like the ombudsman to support:

- **that the European Commission conducts a legal review of the legitimacy of this regulation in terms of the reference to the Cosmetic Products Regulation since the scientific proof of the hazards and risks of these substances is not provided**
- **that legal reviews may be conducted on a standard basis with an integrated statement in the procedure**
- **a realistic risk assessment based on average tattoo size and single exposure scenarios**
- **an understandable statement of the European Commission or ECHA how risk based concentration calculations for each substance can be submitted to amend the concentration thresholds of the restriction. The statement should include to whom this can be submitted and if this can be done by us and other stakeholders.**

We are grateful that the importance of tattoo safety was addressed on a European wide bases. The safety assessment of this intra-dermal application is a completely new field and does not yet allow to declare any substance as completely safe for this application. Hence, the European Commission decided to implement a restriction to ban at least substances known to have a negative impact on human health. We do promote the implementation of a law that promotes safety, but oppose restricting the use of substances with no proven hazards that may be replaced by other substances with completely unknown risks.

Nowadays, where the trust in governance institutions on EU level seems to be questioned from a wide base of European citizens, adding up with reduced trust in science and reason, we would wish that a legislation that attracts that much public attention and that can be based on science and reason due to the tradition of risk assessment in the EU for decades, follows this expectation. According to the final report of the EU Joint Research Centre more than 60 million people are tattooed in the EU-28. Hence, with an increasing rate of tattooing many people and tattoo artists will be affected from this legislative measure.

If you have any questions or need clarification of the points we raised here you can contact us anytime.

On behalf of the ESTP



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