

European Society of Tattoo and Pigment Research (ESTP), [www.ESTPresearch.org](http://www.ESTPresearch.org)

## **Letter of concern from ESTP to the Commission of the European Union**

*Re. European Union regulation of tattoo ink stock products as chemicals und REACH, proposal of the chemical agency ECHA forwarded for the final decision of the European Commission*

### **POSITION STATEMENT OF ESTP FOR THE ATTENTION OF THE EUROPEAN COMMISSION**

ESTP is deeply concerned about several aspects of the proposal. With this letter we express our strong warning about the proposal, which is foreseen to result in a chaotic future in the tattoo ink supplies in Europe with a high risk of illegal activities that cannot be controlled. The proposal is deficient in content and scope, and unrealistic to implement and maintain particularly in the present situation of a weakened Europe challenged by national fragmentations.

In the opinion of ESTP, regulation of tattoo ink safety is very special and on its own. It cannot fit into existing EU regulatory systems and directives. The tattoo industry is a huge and unprepared business not ready for complicated regulation. Tattoo inks are not cosmetics, not pharmaceuticals, not ordinary consumer products, and certainly not individual and pure chemicals as REACH is primarily designed for.

**ESTP finds that regulation of tattoo ink products under REACH is not logic, not rational, not sufficiently argued, not possible to implement, and not possible to follow and control by the ink industry and the national authorities having the police function. Safety of tattoo inks go far beyond the narrow scope of REACH. Other critical issues determining tattoo ink safety in practical use needs to be included as exemplified by sterility and microbial product contamination representing a measurable major threat to the health of customers.**

**ESTP foresee that REACH applied to tattoo inks, not possible for the business to follow in practice, bares a major risk of criminalization of the whole sector since the pressure from tattoo customers and tattooists is strong and will remain, with tattoo inks bought over the internet from non-European manufacturers, who already are branded and dominating the market.**

**Tattoo inks need its own regulatory standard made specifically for tattoo inks, and ESTP adjures the Commission starts a regulatory process from scratch which then comprises all important issues of tattooing beyond chemicals.**

ESTP in June 2018 and in February 2019 responded to public hearings on the ECHA/REACH proposal. The two comments are attached. The ESTP responses include 17 comments from different stakeholders with a synopsis and a conclusion, argued from specific comments to the ECHA draft proposal. Essential points of the ESTP critique are summarized as follows

- No EU- wide positive lists will be possible in future with REACH
- No full declaration of ingredients can be demanded

- Not a hazard-based restriction (which is the scope of REACH) since linked substances in cosmetic regulation are not necessarily been added to the annexes due to data on hazards (but the lack of submitted safety data)
- No or very limited knowledge about the dermal release of chemical substance from pigment particles and metals in inks and the immediate and long-term exposure of tattooed individuals; needed for each of the ingredients in inks to estimate potential toxicological risks and decide threshold levels. Tattooing is single injection and not directly comparable to the bulk of toxicological studies based on high dose and chronic exposures.
- Major problem with chemical analysis of the about 4000 chemicals included in the proposal; lacking standards for analysis, lacking reference chemical standards for many substances needed to establish precise and reproducible methods, etc.
- At least derogations of pigments Blue 15 and Green 7 (C.I. 74160, C.I.74260) must be implemented
- Limits for skin irritants are too low, eye irritant and eye damaging are no skin related endpoints
- Link to biocide regulation with in-can-products does not exhibit adequate safety for tattoo inks and prohibits use of safe biocides known from cosmetics
- Clinical endpoint: No solution of the commonest health problems seen in tattooed persons namely bacterial infections, allergies from various colors, granuloma and sarcoidosis from carbon black, photosensitivity, neurosensitivity with pain, etc.
- Missing knowledge: despite the huge number of tattooed people no epidemiological studies are available to estimate the long-term risks of tattoo inks.
- Medical observations and publications from hospitals and clinics have, however, until now not depicted cancers as a special risk associated with tattoos. No known fatal case proven caused by tattoo ink is found in the medical literature.
- Cancer prevention: nevertheless, tattoo inks should not contain CMR substances according to respective maximum permissible values.
- Manufacturers of ink in Europe and in other countries have no or very little insight and hardly no facility for chemical analysis, and they are widely unprepared. Authorities responsible for REACH control also are widely unprepared and not equipped properly.
- Tattooists will not be capable to check their use of inks versus the REACH proposal and estimate if an ink they use on a customer is legal or not. Labelling remains uncertain.
- Economy: New inks accordant with REACH will foreseeably be expensive as compared to existing marked prices, and not competitive. The burden of REACH may close tattoo ink industries in Europe, or make them move outside EU (maybe to UK depending on the Brexit). Authorities will need big funding even to practice minimum surveillance.

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*On behalf of ESTP*

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