



ESTP
RESEARCH

European Society of Tattoo and Pigment Research

ESTP Secretariat

c/o CAP Partner

Nordre Fasanvej 113, 2.

DK-2000 Frederiksberg

Denmark

www.estp-research.org

president@estp-research.org

08.02.2023

Subject: Petition No 0712/2022 and proposed improvement for restrictions under REACH

Dear Member of the European Parliament, dear Members of the Petition Committee,

I am writing to you today on behalf of the board of the Society of Tattoo and Pigment Research (ESTP). The goal of the ESTP is to advance the safety of tattoo and permanent make-up inks through scientific exchange on all aspects in the field. Therefore, we engaged in the commenting of the currently discussed REACH restriction process for these products. Since 2003, members of our board have repeatedly acted as scientific experts for the European Commission in many tattoo-related matters.

We are very thankful for your work, time and effort as an MEP and to all members of the EU Committee on Petitions.

Members of our board and society alerted **the problem and scientific inaccuracy of banning pigment Blue 15 and Green 7 already half a decade ago. We, as scientists and society got involved during the two commenting procedures to RAC and SEAC (Risk and Socio Economic Assessment Committee), but were also directly interviewed in 2017 by ECHA** at one of our conferences, who compiled the restriction as ordered by the EC.

We here want to address three specific points:

1. The ban of these pigments is scientifically not sound

We as natural scientists, epidemiologists and physicians strongly agree that we should aim to protect consumers and the environment from dangerous chemicals. However, the ban of pigment Blue 15:3 derives from a complex way of citation and misinterpretation of the Cosmetics Regulation within the REACH restriction. For these two pigments, **no data exist that give any indication of high concern to human health, which** is also acknowledged by national authorities (<https://www.bfr.bund.de/cm/349/tattoo-inks-risk-assessment-for-pigment-blue-15-3-and-pigment-green-7.pdf>). The principle of a **restriction within REACH only allows banning hazardous chemicals, which was violated here.** In the RAC opinion concerning this restriction, on page 45 it is stated that the Annexes of the Cosmetics Regulation “[...] include[.] substances restricted without traceable or recently revised opinions of the Scientific Committee on Consumer Safety (SCCS) or its predecessors”.

We invite you to also seek legal advice in this matter. The solution to the current ban, as emphasized by the EC in a webinar in March 2022 and other occurrences, requires proof that these two pigments are not harmful to health. This requirement implies an authorization before using these two pigments for tattooing. This is only foreseen for so-called “substances of very high concern” under the REACH law and does not apply here. These requirements are also not applying to any other pigment or ingredient used in these inks currently. Furthermore, providing these data is difficult as the ECHA and other authorities do not disclose which data they would accept to proof safety and current standard methods can often not be used for pigments. Hence, **it is currently not possible to provide proof for any pigment to declare it as “save” to fulfill the EC requirements for changing the ban.**

2. The process of drafting and reviewing restrictions under REACH should be improved

We agree that public hearings are key to strengthen our democracy. The way they are carried out is, however, a limited democratic process since there is no possibility to reply to the ECHA comments. This can already be necessary if specific points raised in the stakeholder comments were by accident not answered or misunderstood.

3. A scientific committee is needed for external dossiers within the REACH regulation

There is currently no official way for science, industry and NGOs to submit data to improve the restriction under REACH. As comparison: For cosmetics, the SCCS accepts and reviews scientific dossiers and prepares recommendations to improve the Cosmetics Regulation.

The danger that comes with **this missing module in the REACH law** is that it **produces a high pressure on national governments, MEPs and the EC from lobbyists.** This is, since only they are able to mandate the ECHA to compile a new dossier to change restrictions under REACH. For example, **we would have very much preferred to be able to address our concerns and data to a scientific committee today.** At the moment, however, our only option is to **ask for your support as MEP in order to obtain a decision via the parliament.** In our view, establishment of an official committee with a transparent system of reviewing new data is urgently necessary to strengthen the democracy in the chemical law making.

We are aware, that the task the ECHA has been given by the EC with restricting over 4000 substances at once was almost unmanageable. This makes it all the more important for the EU to show that the will for improvement exists. Especially since about 10-20% of people in the EU are tattooed and therefore affected by this restriction.

In our opinion, the ban of Pigment Green 7 and Blue 15:3 needs to be deleted from the restriction for scientific and legal reasons and to avoid substitution with potentially harmful pigments. A postponed transition time until methods are defined to identify save pigments in general would be another option.

On behalf of the ESTP board

Sincerely,

Ines Schreiber

ESTP president