UK REACH – restriction proposals 002 - Call for evidence: substances in tattoo inks and permanent make-up (PMU)

Comments of the ESTP, Submitted 02. November 2022

Page 2 - Non-confidential comments

Add comment (restricted to 1000 characters)	In brief, the ESTP supports a stand-alone legislation for tattoo & PMU inks referring to the CEN - EN 17169:2020 in terms of hygiene and without a link to the Cosmetic Directive or Biocidal Product Regulation. Concerning the Commission Regulation (EU) 2020/2081 (REACH) for tattoo & PMU ink, it should only include substances were risks have been proven. In the Risk Assessment Committee opinion concerning this restriction, on page 45 it is stated that the Annexes of the Cosmetics Directive *"[..] include[.] substances restricted without traceable or recently revised opinions of the Scientific Committee on Consumer Safety (SCCS) or its predecessors*". Thus, a link to the Cosmetics Directive is not justifiable. The REACH system does not allow the industry to improve the regulation by providing data or risk assessments for certain chemicals as it is common practice with the Cosmetics Directive with a clear defined path. Hence, if REACH is entering into force, there is no direct possibility to submit data for its improvement in terms of substances covered or given limits even if new data are available.

Page 3 - Existing regulations and standards that apply to the use and safety of tattoo inks and PMU

Are you aware of any regulations or industry driven standards/initiatives which aim to ensure the safety of tattoo inks or PMU? We are particularly keen to understand regulations and standards that apply to the ingredients that	YES

are used to make tattoo inks and PMU.	
If you answered 'yes', please expand	- CEN - EN 17169:2020 Tattooing - Safe and hygienic practice - Regulations based on ResAP(2008)1 in 7 European Countries & Switzerland (no ban of pigment Blue 15 in Switzerland) - Queensland, Australia (currently on the way to make their stand-alone legislation on tattoo inks) - Biocidal Products Directive (BPR) - EU REACH Restriction for substances in tattoo inks or permanent make-up (Commission Regulation (EU) 2020/2081) - Norway Positive list for Preservatives in Tattoo Inks
To what extent do you agree or disagree with the following statement: "In my experience, these regulations and standards are easy to understand and comply with". Please state the reasons for your response.	Strongly disagree
Please provide more information below	- The CEN hygiene standard was developed together with tattoo artists. It is easy to follow. - The Queensland draft on tattoo regulations is a stand-alone regulation, therefore easy to follow. - EU Biocidal Product Directive also applies to tattoo & PMU ink and product type 6 was assigned. This was not based on a rationale decision making. The biocides in this type are in no way appointed to or assessed for skin contact but e.g. for wall paints or similar where skin contact should be avoided by any means. It is unknown at the moment what this means since none were registered for use in tattoo inks. Preservatives need to be regulated by a positive list (e.g. like introduced Norway or Switzerland) in a stand-alone regulation for tattoo inks. These are partly adapted from the Cosmetics Directive for leave-on cosmetics. Hence, biocides in tattoo inks within the BPR is not easy to understand and tattoo inks can and should not comply with the BPR type 6. - Contrary to the opinion of SEAC, The EU REACH Restriction for substances in tattoo inks or permanent make-up is not easy to comply with. REACH limits have been set for several thousand of substances hitherto not regulated. First measurements show that limits for acetaldehyde, formaldehyde, diethanolamine, benzoic acid, isopropyl alcohol, phenoxyethanol are not met by contemporary inks and that this will certainly be the case for many more. Limits for these and other substances should be re-assessed in terms of toxicology & technical achievability and should replace the unspecific group derived limits for these components

	(as was done in this REACH restriction for aromatic amines). - In detail, some limits are below the technical achievable level and not justified by proper risk assessment. The potency of chemicals within the same toxicological endpoint are not integrated. This applies to carcinogens and most obvious to corrosive or irritant substances. A substance that is corrosive as pure chemical has a threshold at which limit it is neither corrosive nor irritant. A generic limit as given in REACH is not scientifically sound. In the current REACH version, it would now be possible to use 11% of methanol but 2-propanol is completely banned. Some carcinogens, such as PAA or PAH were addressed by specific limits, others were not. - REACH does not allow for a change of these limits driven by manufacturers or distributors even if a more detailed assessment or new data would be available at a later time point. - The exposure scenario within REACH is not representing a realistic tattooed area (CURRENT scenario: full body & fully colored, not taking shadings into account). A realistic scenario, covering the 90th percentile of the tattooed area in people, should be addressed (cf. data of average tattooed skin area/tattoo size from https://onlinelibrary.wiley.com/doi/full/10.1111/j.1600-0536.2007.01301.x). This fact results in limits that are not easy to comply with.
Before today, were you aware that the EU is introducing a restriction on the use of certain substances in tattoo ink and PMU?	YES
To what extent do you agree/disagree with the following statement: "The EU action has had an impact on the availability of tattoo inks or PMU, or pigments that may be used in tattoo inks or PMU"	Strongly agree
What impact on availability do you think the EU action has had on tattoo inks or PMU, or pigments that may be used in tattoo inks or PMU?	Significantly less available than before
Please provide more information below (if necessary)	**General remark:** The restriction in only entering into force in January 2022, the questions should therefore be stated in future tense. - Currently, many popular inks are sold out due to panic buying in fear of the upcoming regulation and the reduced availability of these color shades. It is yet unclear how many colors & brands will be available

	from January 2022 being sold as compliant to the REACH restriction since only one brand is already selling inks stating their compliance but only offers black and white tattoo inks. - Availability of inks that are truly compliant (not just claimed by the manufacturer) will be close to zero (currently, ~ 40% according to Swiss market surveillance according to the current ReSAP(2008)1 based legislation before REACH)
In your best estimate, what proportion of tattoo ink and PMU on the GB market is already compliant with the EU restriction? (Add comment (restricted to 1000 characters)	We have no direct information present specific to UK but it is likely that the situation is the same as in continental Europe: About 100% of the inks would be taken from the market if REACH is directly applied to inks sold at the moment (Source: World Conference on Tattoo and Pigment Research 2021, Amsterdam, Market Monitoring results). Although some known problems with colorants and impurities may be solved until the start of the restriction, most others are not due to technically NOT achievable limits for certain newly restricted impurities. In addition, the problem with the technically unreplaceable pigments (Pigment Blue 15, Pigment Green 7) will make most blue or green inks or inks including these pigments for color shading non-compliant. If the regulation is set up in a way that the industry cannot comply with it no matter how much is changed, there will be work arounds and the regulation will fail its actual goal: To make inks safer through safer ingredients.
Non-confidential attachment If needed, attach additional non-confidential information below. The Agency may publish the contents of this attachment – please ensure it contains no confidential information (this should be included in a separate confidential attachment if necessary – please see below).	Attach the REACH technical comment
Confidential version attachment If needed, attach confidential information below. This should include justification(s) for keeping information confidential.	Evtl. WCTP2021 talk from Urs Hauri Sharing was granted by the author for this and personal use, not for publication in the internet. Copy right must be warranted Norway Positive list for Preservatives in Tattoo Inks (man konnte nur 1 hochladen)

Page 4- Availability of alternatives, their hazards and risks and technical and economic feasibility

Considering the types of substances that we expect will be in scope of this assessment (see the background document for more information about the types of substances that we will be assessing). Could you please provide the following information on tattoo inks and PMU that you think will not contain these types of substances: To the best of your knowledge, are you aware of any health risks associated with inks and PMU that you think will NOT contain these types of substances?	YES
Please provide details about these ink or PMU products and the health risks you think may be associated with these products (if you have supporting evidence about these health risks please provide this. Links to submit attachments are available at the end of this call for evidence).	Blue inks with non-phthalocyanine pigments are available & may pose health risks
What information do you have on the quality and technical characteristics of these inks and PMU? For example, are they less effective/vibrant than the inks or PMU that you currently use, might you need to use greater quantities to achieve the same effect? Add comment (restricted to 1000 characters)	- increased health risks (and less toxicological data overall) of blue pigments & their limitations in durability & color strength are summarized in the non-confidential attachment under "Existing regulations and standards that apply to the use and safety of tattoo inks and PMU"
Please provide information, if any, that you may have on the extent to which these substances migrate away from the site of injection and the potential for these substances to break down within the body? Add comment (restricted to 1000 characters)	- all pigments migrate within the body to a certain but unknown degree- hence migration cannot be a criteria in terms of risk assessment - no metabolism was ever reported on these phthalocyanine pigments and their break down is chemically less likely then those of azo-pigments. For risk of metabolisation and degradatio of blue substitutes please see the attached file.
Please provide information, if any, that you may have on the average prices for these inks and PMU? Add comment (restricted to 1000 characters)	No comment
How does the cost of these inks and PMU compare with the products that you currently use? Add comment (restricted to 1000 characters)	No comment
What is the availability of these inks and PMU on the GB market (tonnages produced, imported and exported by GB)? Add comment (restricted to 1000 characters)	No comment

Are there any other technical or economic feasibility issues associated with these alternatives? Add comment (restricted to 1000 characters)	See above
What timescales/phase-in (if any) would be necessary in order to switch to an alternative? Add comment (restricted to 1000 characters)	If the health protection of the consumer is the key goal of a regulation, the main question should be if a yet un-tested alternative with a little structural alteration of a banned substance is leading to an increased safety or not? If no harm can be related to substances due to a lack of data or lack of risk assessment including potency (pigments or other CLP substances)- why force the industry to use other substances where neither hazard data nor risk assessment are present. E.g., Pigment Blue 15 & Green 7 have a relatively low toxicity (see attached file, opinion of the German Federal Institute for Risk Assessment). The current REACH restriction will force the industry to use other pigments with unknown risks and less safety data.
Are you aware of any pigments that are used in tattoo inks or PMU that are within scope of the assessment for which a suitable alternative is NOT available? Yes No If you selected yes, please specify which pigments	YES Pigment Blue 15, Green 7
To what extent do you agree/disagree with following statement: "I would be more likely to formulate my own ink/PMU as a result of the restrictions on certain substances"? Please give reasons for your answer.	Agree Although we are only a research association, we are in contact with tattoo artists. We already came to notice that during conventions or similar, courses for mixing the inks from pigments are well frequented by tattooists. Since mixing is not that easy, the proportion of artists that would do so is yet unknown and might only be a minority. Despite the legal aspect, the safety will certainly decrease tremendously if this practice increases since the tattoo artists are neither chemists, nor toxicologists and have no possibility to control the quality of the raw ingredients they would use for such mixtures. We therefore strongly oppose such self-mixed inks.
Non-confidential attachment If needed, attach additional non-confidential information below. The Agency may publish the contents of this attachment – please ensure it contains no	- opinion of the German Federal Institute for Risk Assessment, Blue & Green

confidential information (this should be included in a separate confidential attachment if necessary – please see below).	
Confidential version attachment If needed, attach confidential information below. This should include justification(s) for keeping information confidential.	

Page 5 - Impact on industry and professionals

What, if any, impact (positive or negative) do you think a restriction on using specific substances in tattoo inks and PMU would have on your business? Please provide further details on the type of business you are (manufacturer, distributor, importer, tattoo artist, PMU practitioner) and whether this is a small business, employing between 10 and 49 full-time employees, or a micro business, employing between one and 9 employees). Add comment (restricted to 1000 characters)	NGO dedicated to Research & Tattoo Safety, ~ 150 international members (www.estpresearch.org) Positive: EU & UK wide uniform measures were the positive starting point for a common legislation to facilitate easier trading of tattoo & PMU inks across Europe. Including the CLP harmonized substances is in general a most welcome idea. Negative: - The arbitrary limits that are not scientifically justified to the CLP harmonized substances and other substances in the table now listed with the REACH restriction - ban of pigments without scientific proof of their harmfulness - Suppliers, tattoo artists and ink manufacturers will be forced to quit business or move into a grey/illegal area
If a restriction on the manufacture and use of tattoo and PMU inks were introduced, what, if any, substitution costs would you incur? Please provide as detailed a breakdown of annual costs as possible. Add comment (restricted to 1000 characters)	No comment
What would be the cost impact on consumers following a potential restriction on the use of certain hazardous substances in tattoo ink and PMU? Add comment (restricted to 1000 characters)	- although costs for side effects with tattoos must officially paid in privat (not health care insurance), it is common practice to add a false ICD No. - Cost impact: With an estimated annual tattoo incidence of 1% (670,000) in the UK, a conservative estimation of 1% (6,700) side effects & increase to 2% (13,400) after REACH due to tattooist who start buying the now “illegal” inks online (e.g. dark web) and/or homemade inks: 6,700 (additional patients) *500 £ (acute medical treatment cost of 2 visits at a dermatologist), this would sum up to additional costs of 3.35 Mio £ per year in just acute treatment,

	disregarding additional cost for chronic problems, medication and potential increase in tattoo incidence.
f you are a manufacturer, formulator, distributor or importer, is your business a small or micro business (SMB)? Add comment (restricted to 1000 characters)	No comment
What is the proportion of tattoo and PMU ink manufacturers, formulators, distributors and importers in GB that are SMBs? Add comment (restricted to 1000 characters)	Across Western Countries, the incidence of tattooed individuals is about 20% (for certain age groups around 40%). A workable legislation should not only be driven by economical losses in terms of trade reduction or closing of SMBs. Tattooing is a part of culture for a large part of the population which should be reason enough to devote time and effort to implement a scientifically sound legislation.
What difference would it make to you in terms of impacts if such a restriction was introduced over a longer time scale e.g. 5 years instead of 2 years? Add comment (restricted to 1000 characters)	- the manufactures would have time to adjust to the new limits for some substances covered, e.g. by changing their raw material or ingredients. Since the quality of a durable ink can only be estimated *in vivo* (durability, healing, color strength), the time period to test this adds to the mere change of ingredients. - some other pigments & substances named above will not be replaceable in any time frame given and should therefore be deleted from the restriction (pigments) or technical achievable limits should be defined
What difficulties, if any, do you expect if the concentration limits that have been adopted by the EU for substances in tattoo inks and PMU are also adopted in GB? Add comment (restricted to 1000 characters)	See above, some limits cannot be met- some not at the moment, others may be not at all. Given the thousands of newly restricted substances, analytical methods to test their compliance are mostly lacking. At presence, especially with polyaromatic hydrocarbons (PAH) or pigment quantification, methods are not defined or available, respectively. The manufacturer can therefore not test the products for their compliance with Resap(2008)1 and soon REACH, and a market surveillance laboratory might use another method giving higher values. In contrast, either suppliers will end their business since they have the responsibility upon selling non-compliant inks or we generate a cat-and-mouse game where the market surveillance will take a certain ink batch number from the market but the brand will continue to sell the product. If the supply of inks gets limited, the artist will find other ways to continue their art & business, eventually decreasing the safety for the costumer. Others might stop their business.
What information, if any, do you have on any adverse health effects or reactions (e.g. skin irritation, allergy) as a result of application of tattoos or PMU that can be directly attributed to the	We have no proof that the substances within the scope of this regulation will provide a solution to the following side effects occurring with tattoos or PMU that are directly related to the content of the ink: - Allergy (Culprit allergens are not yet identified)

substances in the tattoo ink or PMU? Please be as specific as possible and provide supportive information or documentation. (Links to submit attachments are available at the end of this call for evidence) Add comment (restricted to 1000 characters)	- Granuloma, Sarcoidosis / Uveitis (Cause of this side effect is not yet identified) - Infections (not integrated into the REACH restriction) - Scars and other bad tattoo outcomes due to lay tattoo artists (professional training is still not implemented unlike hairdressers). It has to be noted, that potential systemic health effects of tattoo inks (e.g. certain types of cancer) have not been sufficiently evaluated yet and thus can neither be proven nor excluded. Epidemiological studies are underway but results cannot be expected soon. Some already proposed to equate tattooing & tobacco & alcohol in terms of warning signs addressing the unsolved risks instead of regulations that are not fully scientifically sound.
What information, if any, do you have about the possible migration of substances in tattoo inks and PMU away from the site of injection and potential for substances to break down within the body? Add comment (restricted to 1000 characters)	By law of physico-chemical properties of the soluble ingredients, they will be distributed throughout the body. The exact exposure is yet unknown but new results can be expected within the next year. A portion of all pigments and particles will be distributed within the body (as reported by many observations)- however, it is yet unknown if the deposition in lymph nodes or likely other organs has any health effect due to a lack of studies. Break-down of azo-pigments by sunlight is commonly reported by scientist (cf. PubMed or https://estpresearch.org/index.php?id=9386 (not up to date))
Non-confidential attachment If needed, attach additional non-confidential information below. The Agency may publish the contents of this attachment – please ensure it contains no confidential information (this should be included in a separate confidential attachment if necessary – please see below).	https://onlinelibrary.wiley.com/doi/10.1111/cod.12271 https://onlinelibrary.wiley.com/doi/abs/10.1111/ddg.14530 van der Bent SAS, Rauwerdink D, Oyen EMM, Maijer KI, Rustemeyer T, Wolkerstorfer A. Complications of tattoos and permanent makeup: overview and analysis of 308 cases. J Cosmet Dermatol. 2021;00:1– 12. https://onlinelibrary.wiley.com/doi/full/10.1111/jocd.14498 Identification of pigments related to allergic tattoo reactions in 104 human skin biopsies: https://onlinelibrary.wiley.com/doi/epdf/10.1111/cod.13423 Maijer, K.I. van der Bent, S.A.S. Vercoutere, W. & Rustemeyer, T. Granulomatous **Tattoo reaction with Associated Uveitis successfully treated with methotrexate.** Journal of the European Academy of Dermatology and Venereology 32(9):e338-e339 (2018). Laux, P., Traulau, T., Tentschert, T., Blume, A., Al Dahouk, S., Bäumler, W., Bernstein, E., Bocca, B., Alimonti, A., Colebrook, H., De Cuyper, C., Dähne, L., Hauri, U., Howard, P., Janssen,

	P., Katz, L., Klitzman, B., Kluger, N., Krutak, L., Platzek, T., Scott-Lang, V., Serup, J., Teubner, W., Schreiver, I., Wilkniß, E. & Luch, A. **A medical-toxicological view of tattooing.** The Lancet 387:395-402 (2016). Serup, J., Sepehri, M. & Hutton Carlsen, K. **Classification of Tattoo Complications in a Hospital Material of 493 Adverse Events.** Dermatology, 232:668-678 (2016). Sepehri, M., Hutton Carlsen, K. & Serup, J. **Papulo-Nodular Reactions in Black Tattoos as Markers of Sarcoidosis: Study of 92 Tattoo Reactions from a Hospital Material.** Dermatology, 232:679-686 (2016).
Confidential version attachment If needed, attach confidential information below. This should include justification(s) for keeping information confidential.	

Page 6 - Number of tattoo sessions and PMU procedures, professionals working as tattoo artists and carrying out PMU procedures, manufacturers and volume of inks and PMU.

What information, if any, do you have on the number of tattoo artists and PMU practitioners in GB (both registered/licenced and unregistered/unlicensed)? You do not need to identify specific premises in your response. Links to submit attachments or confidential information are provided at the end of this call for evidence. Add comment (restricted to 1000 characters)	No comment
What information, if any, do you have on the number of tattoo sessions performed in GB (or performed by your business) per year, we assume that a typical tattoo session lasts between 1.5 and 2 hours? Add comment (restricted to 1000 characters)	No comment
What information, if any, do you have on the number of PMU procedures performed in GB (or by your business) per year? Add comment (restricted to 1000 characters)	No comment
How much time would a typical PMU procedure take to carry out? Add comment (restricted to 1000 characters)	No comment
If you work as a tattoo artist or provide PMU services, where do you purchase your ink or PMU? Add comment (restricted to 1000 characters)	No comment

What information, if any, do you have on the number of tattoo ink and PMU manufacturers in GB? Of these, how many do you think manufacture either tattoo ink or PMU but not both? Add comment (restricted to 1000 characters)	No comment
What is the volume of tattoo ink manufactured in GB and what is the annual sales/turnover? Add comment (restricted to 1000 characters)	No comment
If you are a manufacturer/formulator of ink or PMU or you blend your own inks or PMU, what factors do you take into consideration when deciding which ingredients to purchase? Add comment (restricted to 1000 characters)	No comment
If you are a manufacturer/formulator of ink or PMU or you blend your own inks or PMU, how important is cost over quality when determining which ingredients to purchase? Please provide any further details in the space below.	No comment
If you are a manufacturer/formulator of ink or PMU or you blend your own inks or PMU, do you consider the purity of pigments when deciding which pigments to purchase? Add comment (restricted to 1000 characters)	No comment
What information, if any, do you have on the number of tattoo ink and PMU importers/exporters to and from GB? Of these, how many import or export either tattoo ink or PMU but not both? Add comment (restricted to 1000 characters)	No comment
If you are a manufacturer/distributor/importer, what would you say is the volume of tattoo ink and PMU you import to GB annually? A link to submit confidential information is available at the end of this call for evidence. Add comment (restricted to 1000 characters)	No comment
Attachments	No attachments

Page 7 - Costs

What is the average total cost (including supplies, rent, labour, overhead) incurred per tattoo/PMU procedure by the tattoo artist/PMU practitioner? If possible, please specify what proportion of this average total cost is accounted for by the cost of tattoo ink or PMU. Add comment (restricted to 1000 characters)	No comment
What is the average price you charge to customers per tattoo or PMU procedure? Add comment (restricted to 1000 characters)	No comment

How much do prices of tattoos and PMU procedures vary according to geographic region within GB? Add comment (restricted to 1000 characters)	No comment
If you are an importer or manufacturer of tattoo/PMU ink, what is the annual average bulk sale price per litre? Add comment (restricted to 1000 characters)	No comment
Attachments	No attachment